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Original Article

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Perception of Front-line workers on Covid 19 Vaccination: The Effects, Side effects and Acceptance

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Abstract

Background: In 2021 only very few COVID-19 vaccines were anticipated in India**.** There is lag in vaccination drive & scanty literature on perception of front-line workers on COVID-19 vaccination. The study was planned to get an insight into vaccination effects, side effects & acceptance.

Methods: A cross-sectional study was conducted among front-line workers in a tertiary healthcare institute from March - May 2021 through an online google survey form. The data of the study was collected & analysed using percentage.

Results: 84% were 21 to 30 years of age, 51% were male. Almost 90.4% had taken 2 doses of vaccination, majority had Covaxin (91.5%). 10.6% & 26.5% delayed taking 1st jab & 2nd jab, attributed to fear of side effects, unavailability, tested positive for covid-19. Around 61.7% experienced side effects & majority had myalgia, injection site pain. Most of them perceived it effective in terms of less severity of disease after vaccination. Other prophylactic measures included (95.7%) covid precautions, (40.4%) Ivermectin, (25.5%) immune boosters & (18%) home remedies, 75.5% perceived vaccination as best way to tackle pandemic, whereas 23% stated natural immunity is better. 68% vouched for given opportunity to choose their vaccine, 47.9% preferred government setup.

Conclusion: All perceived it effective with minimal side effects. Although initially doubtful later showed full acceptance towards vaccines. Based on evidence study recommends administrative strengthening, provision of opportunity to choose vaccines, capacity building of vaccinators & vaccine awareness.

Key words: covid 19 vaccination, perception, side effects.

Introduction

Covid 19 disease originated from Wuhan, Hubei province, China in December 2019[1]. It spread throughout the planet as a pandemic, infecting all the countries on the planet. The ICTV (International Committee on Taxonomy of Viruses) declared "Severe Acute Respiratory Syndrome Coronavirus 2" (SARS-COV-2) as the name of the new virus on February 11th 2020[2]. World Health Organization reported "COVID-19" as the name of this new disease on 11 February 2020[2]. In India, it affected every nook

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and corner of the country, in India the first case was recorded on 30th January 2020 in the state of Kerala [3].The incubation period varies from 2 to 14 days, the symptoms include fever or chills, cough, shortness of breath and difficulty in breathing, loss of smell or taste, and in severe cases leads to death[4]. So, the death rate kept on increasing throughout the globe. A few drugs like Hydroxychloroquine and Remdesivir have been used as a desperate measure to fight COVID – 19, but we need is a drug or vaccine that will protect against the COVID – 19 Disease. Many researchers were trying throughout the world to find the prevention and treatment of this disease, the promising results were shown up by the Vaccines. Vaccines are very productive tool that can cover the public health. On the global landscape many Vaccines were being under development, in India currently, we are using two vaccines, Covaxin and Covishield.

Covisheild

Manufactured by Serum Institute of India, Pune in Collaboration with Astra Zeneca. It is a viral vector based recombinant vaccine known by the specific name chAdox-1n Cov-19 (corona virus-19 type). It is a Single Recombinant Monovalent Type Vaccine. Given to the age group > 18 years, in 2 doses (0.5ml each) in the interval of 4 weeks apart, given through intramuscular and the preferred site is deltoid muscle[5].This vaccine got its approval on 1st January 2021 to use in India, from Central Drugs and Standard Committee (CDSCO)[6].

Covaxin:

Manufactured by Bharath biotech international ltd., in collaboration with the Indian Council of Medical Research (ICMR) and National Institute of Virology (NIV) Pune. Covaxin has been developed indigenously by Bharath Biotech, India. It is a Whole virion inactivated SARS-COV-2 vaccine represented by BB152. The strain used is NIV-2020-770, and the strength used for vaccine preparation in India is 6mcg per 0.5 ml dose[5]. Covaxin got its emergency use certificate on January 3rd 2021[6].

India started its largest vaccinationdrive on January 16th 2021 for 30 lakhs healthcare workers and front line workers [7]. The data regarding the people who are getting vaccinated, are entered in the CO-WIN database.

Objective:

- To evaluate the perception of frontline workers towards covid 19 vaccination.
- To access the after effect following the vaccination.
- To provide evidence-based recommendation.

Materials and Methodology

Study design: A cross-sectional study was conducted among the frontline workers, working in a tertiary care center in Srikakulam district, Andhra Pradesh.

Study period: March 2021 – May 2021.

Sampling method: Complete enumeration.

Sample size: 94

Study tool: Online google survey form having questions with sociodemographic details including age, gender, occupation, perception towards vaccine as multiple-choice questions, and open-ended questions.

Inclusion criteria:

- All medical frontline workers who have taken COVID-19 Vaccination.
- All participants who filled the survey forms.

Exclusion criteria:

- All medical frontline workers who did not respond to the survey.
- All participants who filled the survey form incompletely.

Statistical analysis:

The data were collected and entered in the Microsoft excel sheet and analysis was done in the form of frequency and percentage, to describe the study population and their perception towards Covid 19 vaccination.

Results

In our study, 84% of study participants belong to the age group of 21 – 30 years and 31-45 years was 16%. Majority of participants were males (51%) and 49% were females. Among the study participants 91.5% had taken the Covaxin and 8.5% had taken

the Covishield. Among the study participants, 90.4% had taken two doses of Covid 19 vaccination. Among the participants 35.1% were infected by Covid 19 disease before taking 1st dose of vaccination, 13% were infected between the 2 doses and 18% were infected after 2nd dose of vaccination. Around 33% of participants were not infected by Covid 19 disease before and after the vaccination.Among the study participants 75% perceived that if they take vaccination, they will be protected from the covid 19 infection and 22.9% of the participants perceived that once infected with covid 19 will provide them lifelong immunity and 2.1% of the participants perceived that both the infection and the vaccination will give them the protection. Among the study participants, 68% vouched for giving the option to choose between the vaccines. Majority of the participants, 47.9% felt government setup is the best place to get vaccinated where as 28.7% stated community setup and 23.4% stated private setup to get vaccinated. Majority of the participants, 62.7% preferred intramuscular route of administration of vaccine, 31.9% preferred nasal route and 5.3% preferred oral route of administration of the vaccine. Majority of the participants (81.1%) were observed for 30 minutes after vaccination and 13.2% were observed for 1 hour after vaccination to see for any side effects.

Table 1: Covid 19 vaccination side effects

Variables	Frequency	Percentage
Reason for taking Covid 19 vaccination.		
Protective against the covid 19 infection	71	75.5%
Peer pressure	23	24.5%
Awareness of side effects before taking the Covid 19 vaccination.		
Yes	89	94.6%
No	5	5.4%
Experienced side effects post vaccination.		
Yes	58	61.7%
No	36	38.3%
Delay in taking the Covid 19 vaccination.		
1stdose	10	10.6%
2nddose	25	26.5%
Reason for delay in taking the vaccination.		
Fear of side effects	23	24.4%
Unavailability of vaccine	10	10.6%
Tested positive for Covid 19	14	14.8%
Type of side effects experienced post vaccination.		
Myalgia	61	64.8%
Injection site pain	47	50%
Headache	42	44.6%
Tiredness	33	35.1%
Fever, nausea & irritability	32	34%
Vaccination side effects need to be managed by medication.		
Yes	20	21.2%
No	74	78.8%

Table 2: Perception of Covid 19 vaccination

Variables	Frequency	Percentage
Perception of participants about Covid vaccine efficacy. (Got covid 19 disease after vaccination).		
Effective	64	68%
Vaccination decreases the severity of the infection.	17	18%
Vaccination decreases mortality.	13	14%
Other prophylactic measures followed other than covid 19 vaccination.		
Covid precautions	90	95.7%
Ivermectin	38	40.4%
Immune boosters	24	25.5%
Home remedies	17	18%
Vaccination is the best method to tackle the pandemic.		
Yes	71	75.5%
No	21	22.3%
Maybe	2	2.2%
Natural immunity is better than Covid 19 vaccination.		
Yes	22	23.4%
No	55	58.6%
Maybe	17	18%

Discussion

As the fear of covid 19 disease was creating panic among the population, the introduction of vaccination has given a mixed response. In our study, we analysed the perception of the covid 19 vaccination among frontline workers, so that it provides an evidence-based data among the population and encourage them to get vaccinated.

From our study we found that 75.5% showed positive attitude towards vaccination that it will protect them from the COVID 19 disease. Our findings were similar with the studies done by USA which showed 70%[8] of vaccine acceptance, and in UK showed 86%[9] of vaccine acceptance.

We found that 75% of the participants has positive attitude towards the vaccine that it will protect them from the infection and 24.4% had the fear of side effect after taking the vaccine, 23.4% preferred natural immunity is better than the covid 19 vaccine. Which was similar to the study done by Danabal KGM et al., in Tamil Nadu India found that 50% of the population showed positive attitude toward vaccine, 14.5% preferred natural immunity and 24.6% hesitated not to take vaccine because of the fear of side effects of the vaccine and 32.6% preferred to take the vaccine for its effectiveness[10].

In a study done by Kishore J et al., found that 70.4% of the participants were showing the acceptance to get vaccinated and 55.6% of the participants wanted injectable form of vaccine and 44.3% wanted oral route of administration of the vaccine[11]. Which was similar to our study with 75% of vaccine acceptance and 62.7% of participants preferred the intramuscular route of administration and 31.9% preferred nasal route.

A study done by Jayadevan R et al., found that 65.9% of participants reported at least one side effect after taking covid 19 vaccine. The side effects reported were 45% of tiredness followed by myalgia (44%), fever (34%), headache (28%), and pain at injection site (27%). And 27% needed medication to relieve the symptoms. Which was similar to our study 61.7% of participants experienced side effect post vaccination. Majority of the participants experienced myalgia (64.8%), injection site pain (50%), headache (44.6%), tiredness (35%) and fever (34%) and 21.2% of the participants needed medication to get relief from the symptoms [12].

We analysed from our study the advantage of vaccination is:

- Provides individual immunity,
- Decreases the severity of the disease,
- Herd immunity and protection to others.

Disadvantages of vaccination is:

- Not 100% effective,
- Side effects like myalgia, injection site pain and fever.

Suggestions for vaccinators:

- Giving opportunity to choose in between the vaccines,
- Tackling the misinformation regarding the vaccines,
- Creating the awareness about the vaccination,
- Availability of the vaccines.

Conclusion

Our result displays all the participants perceived the vaccine with minimal side effects. Although initially there was a doubt about the vaccine but later showed full acceptance toward the vaccines. Based on the evidence the study recommends administrative strengthening, provision of opportunity to choose vaccines, capacity building of vaccinators and vaccine awareness.

Ethical Clearance: Taken from the Institutional Ethical Committee

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Original Study

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Study of Intrathecal Clonidine to Magnesium Sulfate as Adjuvants to Hyperbaric Bupivacaine in Subarachnoid Block in Tertiary Care Centre

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Abstract

Background: Spinal anaesthesia is the most preferred regional anaesthesia technique as it is easy to perform, economical and produces rapid onset of anaesthesia and complete muscle relaxation. The aim of intrathecal local anaesthetic is to provide adequate sensory and motor block necessary for all infra umbilical surgeries.

Aims and Objectives: The aim of the study is to compare the Onset and Duration of Sensory Block; Onset and Duration of Motor Block and other factors in two groups i.e., Hyperbaric Bupivacaine 0.5% with Clonidine 30µg &Hyperbaric Bupivacaine 0.5% with Magnesium sulphate 50 mg when given intrathecally.

Materials and Methods: A Comparative three group randomized clinical study with 90 patients with 30 patients in Group C (Clonidine), 30 patients in Group M (Magnesium) and 30 patients in Group N (Normal saline) to study the onset of motor and sensory block, changes in hemodynamics and side effects.

Results: Our study has demonstrated that Intrathecal clonidine (30 mcg) prolonged post-operative analgesia along with earlier onset and prolonged duration of sensory and motor blockade compared to both magnesium (50 mg) and control.Intrathecal magnesium (50 mg) also increased the analgesic duration compared to control but it was associated with delayed onset of both sensory and motor blockade compared to both clonidine and control.

Conclusion: Clonidine can be a good alternative adjuvant with 0.5% hyperbaric bupivacaine when compared to others like fentanyl, magnesium, midazolam, ketamine etc. as it provides early onset of sensory and motor blockade and also prolonged duration of post-operative analgesia.

Keywords: Spinal Anesthesia, Bupivacaine, Adjuvants, Clonidine, Magnesium Sulphate.

Introduction

Spinal anaesthesia is the most preferred regional anaesthesia technique as it is easy to perform, economical and produces rapid onset of anaesthesia and complete muscle relaxation. The aim of intrathecal local anaesthetic is to provide adequate sensory and motor block necessary for all infra umbilical surgeries.

Hyperbaric bupivacaine is the most commonly used intrathecal local anaesthetic. Various adjuvants have been added to Bupivacaine hydrochloride to shorten the onset of block and prolong the duration of block.

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Intrathecal clonidine potentiates post-operative analgesia by hyperpolarizing A delta and C fibers in the substantiagelatinosa of the spinal cord. Low-dose clonidine has good analgesic efficacy with a low incidence of adverse effects.[1]

Magnesium prevents the development of central sensitization of pain by antagonistic action on N-methyl-D-aspartate receptors in the spinal cord. Therefore, the present study was performed to compare clonidine and magnesium sulfate in their efficacy as adjuvants to subarachnoid block.[2,3]

Materials and Methods

Study Design: The present study was a comparative randomized clinical study.

Study Setting: The present study was conducted at Mallareddy Institute Of Medical Sciences and Hospital, Quthbullapur, Hyderabad.

Study Period: This study was conducted over a period of one year i.e; from August 2021 to August 2022.

Sample Size: 90 ASA Grade I and Grade II patients scheduled for major surgeries were included in the study.

Procedure

Patients shifted to Operating table, Baseline vitals were recorded. IV access was obtained on the forearm with No. 18G IV cannula and all patients were preloaded with 15ml/Kg, Ringer's Lactate, 15 mins before the surgery. Patients were randomly allocated into groups.

Under strict asepsis, using 23G Quincke-Babcock spinal needle,lumbar puncture was performed at L3-L4 space.

Group C received 3ml of 0.5% hyperbaric bupivacaine with 30 mcg Clonidine, Group M received 3ml of 0.5% hyperbaric bupivacaine with 1ml (50 mg) Magnesium sulphate and Group N received 3ml of 0.5% hyperbaric bupivacaine with 1ml Normal Saline.

Intraoperatively pulse rate, non-invasive blood pressure, electrocardiogram, SpO2 were also recorded, every 5 minutes for the first 50 minutes, every 10 minutes till the end of surgery.

Time of onset of sensory block was noted using pin prick method, time of onset of motor block was noted.

Motor block was assessed with Modified Bromage scale

Statistical Analysis : The statistical analysis between the various parameters in the two groups was done using the statistical package for the social sciences (SPSS) software version 25. The qualitative variables like incidence of complications (documented on a yes or no basis) were summarized as frequencies and percentages. The qualitative variables were compared between three groups using chi square test. The data was labelled statistically significant if the p value calculated to be less than 0.05, insignificant if the p value calculated to be more than 0.05 and highly significant if the p value calculated to be less than 0.001.

Results

Table No. 1: Distribution of study groups by Onset of Sensory Block

Onset of sensory block (in minutes)	Group N (n=30)	Group C (n=30)	Group M (n=30)	P value
Mean	6.22	3.90	7.68	<0.001, S
Standard deviation	0.48	0.07	0.15	

Table No. 2: Distribution of study groups by Onset of Motor Block

Onset of Motor Block (in minutes)	Group N (n=30)	Group C n=30)	Group M n=30)	P value
Mean	6.93	4.06	9.48	<0.001, S
Standard deviation	.50	.34	.76	

In the present study,a statistically significant difference was seen between the Mean Onset of motor Block between the three groups.

Table No. 3: Distribution of study groups by Duration of Sensory Blockade

Duration of Sensory Block ade (in minutes)	Group N (n=30)	Group C n=30)	Group M n=30)	P value
Mean	135.23	331.53	233.17	0.000,S
Standard deviation	9.85	22.46	27.55	

In the present study,a statistically significant difference was seen between the Mean Duration of sensory block ade between the three groups.

Table No. 4: Distribution of study groups by Duration of Motor Blockade

Duration of Motor Block ade (in minutes)	Group N (n=30)	Group C n=30)	Group M n=30)	P value
Mean	119.63	309.83	211.70	0.000,S
Standard deviation	7.98	21.37	25.83	

In the present study, a statistically significant difference was seen between the Mean Duration of Motor Blockade between the three groups.

Table No. 5: Distribution of study groups by Post-Operative Visual analogue scale

Post-operative VAS	Group N (n=30) Median (IQR)	Group C (n=30) Median (IQR)	Group M (n=30) Median (IQR)	P value
VASat1 hour	1(1-1)	1(1-1)	1 (1-1)	0.000,S
VASat2 hour	1(2-1)	1(1-1)	1(1-1)	0.000,S
VASat3 hour	3(3-3)	1(1-1)	1(2-1)	0.000,S
VASat4 hour	2(2-2)	1(1.25–1)	2(3-2)	0.000,S
VASat5 hour	3(4-2)	2(2-2)	3(3-3)	0.000,S
VASat6 hour	3(4-2)	3(3-3)	2(3-2)	0.000,S
VASat12hour	4(4-4)	2.5(3-2)	4(4-3)	0.000,S
VASat24hour	5(5-5)	3 (3.25-3)	4(4-4)	0.000,S

In the present study, a statistically significant difference was seen between the post –operative Visual Analogue Scale scores between the groups.

Discussion

Spinal anesthesia is a simple technique that provides a deep and fast surgical block and complete muscle relaxation through injection of small doses of local anesthetic solutions in subarachnoid space. It provides excellent operating conditions for surgeries below umbilicus.

The aim of intrathecal local anesthetic is to provide adequate sensory and motor block necessary for all lower abdominal and lower limb surgeries. Spinal anesthesia using Bupivacaine heavy 0.5% is one of the most frequently used techniques for lower abdominal and lower limb surgeries. Various adjuvants have been added to bupivacaine to shorten the onset of block and prolong the duration of block.

Traditionally, clonidine has been in use as an antihypertensive agent since the late 1960. Its primary effect is sympatholysis and it reduces peripheral no repinephrine release by stimulation of the prejunctional inhibitory α2-adrenoceptors. Clonidine

is a selective partial agonist of α2 – adreno receptors (α2 : α1 = 220:1). It is known to increase both sensory and motor block of local anaesthetics. The analgesic effect following its intrathecal administration is mediated through activation of postsynaptic α2 receptors in substantiage latinosa of the spinal cord, and it works by blocking the conduction of C and A delta fibers, increase of potassium conductance in isolated neurons in vitro and intensifying conduction block of local anesthetics.[4]

Magnesium is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist that blocks ion channels in a voltage dependent fashion. It is a suitable choice for intrathecal and peripheral nerve site administration. Newer methods of prolonging the duration of subarachnoid block and reducing post-operative analgesic requirements are of special interest in major surgical procedures for good peri-operative analgesia.[5]

Therefore, the present study was performed to compare clonidine and magnesium in their efficacy as adjuvants to spinal anaesthesia.

A) Onset of sensory block:

In the present study onset of sensory block was achieved in 3.90 minutes in Group C, in 7.68 minutes in Group M and in 6.22 minutes in Group N, with a P value of less than 0.001 which is statistically significant.

In a study conducted by Mamta Khandelwal et al.[6], onset of sensory block was achieved in 4 minutes in Clonidine (30mcg) group, in 7.1 minutes in Magnesium sulfate (50mg) group and in 6 minutes in Normal saline group. Similar results were seen in our study also. In a study conducted by Beigom et al.[7], onset of sensory block was achieved in 5.86 minutes with Magnesium sulfate (50mg) and 1.46 minutes with Fentanyl (25mcg).

It is evident from the above studies that Clonidine shortened the time to onset of sensory block and Magnesium sulfate delayed the onset of sensory block.

B) Duration of sensory block

In the present study duration of sensory block was 331.53 minutes in Group C, 233.17 minutes in Group M and 135.23 minutes in Group N, with a P value of less than 0.001 which is statistically significant. In a study conducted by Mamta Khandelwal et al., duration of sensory block was 166.5 minutes with Clonidine (30mcg), 123 minutes with Magnesium sulfate (50mg) and 94 minutes with Normal saline. In Sarika Katiyar, Chhavi Dwivediet al.[8], study the duration of sensory block was significantly longer 374.37 minutes with Fentanyl 25 mcg compared to Magnesium sulfate 100 mg 328.13 minutes.

C) Onset of motor block to Bromage 3:

In the present study the time to onset of motor block was 4.06 minutes with Group C, 9.48 minutes with Group M and 6.93 minutes with Group N, with a P value of less than 0.01 which is statistically significant. In a study conducted by Mamta Khandelwal et al., time to onset of motor block was 4 minutes with Clonidine 30 mcg, 8.5 minutes with Magnesium sulfate 50 mg and 6.7 minutes with Normal saline. Similar results were seen in our study also. In Beigom et al., study the onset of motor block with Magnesium sulfate 50mg was 8.1 minutes compared to 2.46 minutes with fentanyl group. It is evident from above studies that Magnesium sulfate delays the onset of motor block compared to Clonidine.

D) Duration of motor block:

In the present study the duration of motor block was 309.83 minutes in Group C, 211.70 minutes in Group M, 119.63 minutes in Group N, with a P value of less than 0.01 which is statistically significant.

In a study conducted by Mamta Khandelwal et al., duration of motor block was 218 minutes with Clonidine, 138 with Magnesium sulfate and 116 minutes with Normal saline. Similar results were seen in our study also.

In Beigom et al., study the duration of motor block with Magnesium sulfate 50mg was 118 minutes as compared to 171 minutes in Fentanyl group.

It is evident from above studies that Clonidine prolongs the duration of motor block compared to Magnesium sulfate.

E) Post Operative VAS Scores

In the present study lower VAS scores at 1, 2

,3 ,4, 5, 6, 12, 24 hours were observed in Group C with P value less than 0.001 which is statistically significant.

In a study conducted by MamtaKhandelwal et al., Among the three groups, VAS was significantly different (P < 0.001) from 30 min to 120 min whereas Group Normal saline showed significantly (P < 0.05) higher values of VAS compared to other two groups. The patients of Group Magnesium sulfate showed a significantly (P < 0.05) higher level of VAS compared to Group Clonidine at 60 min, 90 min and 120 min.

Conclusion

Clonidine can be a good alternative adjuvant with 0.5% hyperbaric bupivacaine when compared to others like fentanyl, magnesium, midazolam, ketamine etc. as it provides early onset of sensory and motor blockade and also prolonged duration of post-operative analgesia.

Conflict Of Interest: Nil

Source Of Funding: Self

Ethical Clearance: Ethical Clearance was obtained from the Institutional Ethics Committee prior to the commencement of the study.

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Avascular Necrosis of HIP After Active Covid-19 Infection

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Abstract

Background and objectives: The exact course of SARS -2(COVID-19) and its complications on multiorgan system are complex and still under studies. Musculoskeletal system has also been affected post covid in various forms. This study was taken up to analyse the effects of covid-19 disease on the hip bone and join tissue.

Materials and Methods: Retrospective analysis of ten patients was done who had been hospitalised with covid-19 infection and later complained of hip pain. They underwent MR imaging and were found to have degenerative changes characterizing with avascular necrosis (AVN) of head of femur .One of them had history of previous surgery of femur with PFN, doin well but developed AVN after covid.

Results: Observation of this group showed a clear correlation among the history of COVID-19 disease in the patients, moderately severe symptoms, high levels of IgG antibodies, and the time of occurrence of joint changes. No other risk factors for AVN or auto-immune or degenerative diseases were found in the study group. The group of patients responded well to empirical treatment with anti-inflammatory drugs ans supportive therapy, which subsided acute inflammatory symptoms and pain in the joints.

Conclusions: It is concluded that there have been obvious musculoskeletal complications in covid patients including AVN which could be attributed to the high use steroids and microembolism leading to bone necrosis. Hence more studies and long follow-up is suggested.

Keywords: avascular necrosis bone, osteonecrosis, SARS-CoV-2 infections, corticosteroids

Introduction

The coronavirus 2 (SARS-CoV-2) (COVID-19) pandemic has stimulated an unprecedented response by the global scientific community to better understand the disease. However, many questions about SARS-CoV-2 remain unanswered. Various hypotheses have been formulated in regard to its pathogenetic mechanisms and treatment [1]. A plethora of reports on the long-term consequences of the infection, which also include the musculoskeletal system, have been published [2].

Systemic inflammation may play a role in the physiology of bone and joint tissue in COVID-19 patients. Cytokines that are induced by COVID-19 include CXCL10, IL-17, and TNF-alpha. They are responsible for reducing the proliferation and differentiation of osteoblasts.

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Corticosteroids administered to most patients treated for COVID-19 in hospital also have an adverse effect on bone tissue [3,4].

In addition, single nucleotide polymorphisms in various genes encode for proinflammatory proteins, such as IL-1b, IL-6 and IL-8, which may affect biological activity and contribute to hypercoagulability in COVID-19 patients, thereby increasing the risk of bone necrosis [5]. The combination of hypercoagulability, leukocyte aggregation and vasculitis can impair blood flow in the blood vessels of the bone and contribute to the development of bone necrosis [5].

Material and Methods

After clearance from institutional review board of the institution, a retrospective analysis of a case series was taken up to study effects of covid-19 infectionon hip bone and tissues. Study group included the patients hospitalised at Hind institute of Medical sciences (HIMS), Sitapur during active covid disease from 2020-2022 and those who complained of hip disorders, selection was made based on inclusion and exclusion criteria.

Inclusion criteria: PCR indicating positive COVID-19 infection and joint pain during the course of the disease and follow up.

Exclusion criteria: prior injury to the affected joint, prior treatment with steroids, and patients with autoimmunity.

The study included a group of ten patients who developed pain and dysfunction around hip joint, were diagnosed as avascular bone necrosis in COVID-19 on MR images [6].

The criterion for classifying the severity of COVID-19 infection was defined according to a 4-point scale: mild, moderate, severe and critical(Table 1) [7]

Table 1: Characteristics of patients.

Patient No.	Age	Sex	Chronic Diseases	Severity of COVID-19	COVID-19 Therapy/Steroids
1	62	M	DM	severe	no
2	56	M	DM	mild	no
3	57	F	no	severe	yes
4	70	F	no	moderate	no
5	43	F	Hypertension	moderate	yes
6	54	M	Depression	moderate	yes
7	66	F	no	moderate	no
8	39	F	no	severe	yes
9	68	F	no	mild	no
10	24	M	no	moderate	no
mean SD	58.8 11.3				

The examined group of patients had not previously received any treatment for diseases of the musculoskeletal system (e.g., steroids), did not suffer from significant injuries or did not suffer from significant joint pain.

All the patients had a mean IgG and IgM COVID-19 antibody titer corresponding to the typical course of COVID-19 infection. Basic immunohistochemical tests were performed in all patients to rule out autoimmune diseases. HLA-B27 was negative in all patients. The examination of the synovial fluid in all patients revealed changes in the characteristics of aseptic arthritis.

The MRI consisted of (fat suppressed)-T2, pre- and postgadolinium T1-weighted imaging.

The MR images demonstrated bone lesions characteristic of AVN:

- T1 FSE: the initial specific findings are areas of low signal representing edema, which can be bordered by a hyperintense line, which represents blood products;

- T2 FR FSE: This may show a second hyperintense inner line between normal marrow and ischemic marrow. This appearance is highly specific for AVN of the hip and is known as the "double line sign".

Avascular bone necrosis was described using the Steinberg classification. The described changes also included subchondral infarctions with the involvement of articular cartilage (grade III) [8].

Statistical Analysis

Statistical analyses and data processing were performed using SAS/STAT version 14.3 (SAS Institute, Cary, North Carolina, USA) to determine the association between various comorbidities, ICU stay, mortality, and the orthopedic manifestations of COVID-19 patients. The frequencies of cohort demographics and descriptive statistics were calculated and analyzed using Pearson's chi squared test, the likelihood ratio, and the NPAR1WAY procedure (ANOVA) as appropriate. The critical value for significance was set at <0.05 for all statistical tests.

Results

The mean age of the patients was 61 years with six women and four men were included. Out of ten, 6 were right and 4 were left sided.

The course of infection was mild in three patients, moderate in five and severe in two patients. Four patients were treated with steroid therapy (6mg/day dexaven).

Clinical signs and symptoms of musculoskeletal occurred 7 to 22 days from onset of infection (mean 14 days) and appeared 5–10 days (mean 6 days) after the resolution of acute respiratory symptoms and elevated body temperature.

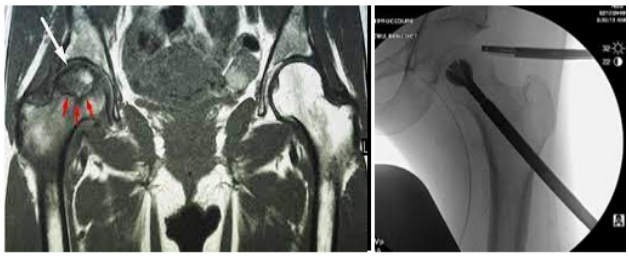
Patients were initially treated conservatively: non-steroidal anti-inflammatory drugs (NSAIDs), intra-articular steroid injections and therapeutic aspiration of the synovial fluid were implemented. There was no significant improvement.

Steroid therapy in mild doses was supplemented with an oral dose of dexamethasone 2 × 8 mg daily for a period of 2 weeks.

Finally, 3 out of 10 persons required arthroplasty and showed a good clinical outcome. Four patients underwent core-decompression surgery and improved One patient had chronic pain in the affected joint and is currently being treated conservatively; destruction of the joint surface was not shown in the control tests. In the remaining six people, there was no deviation in the control test follow up (Table 2).

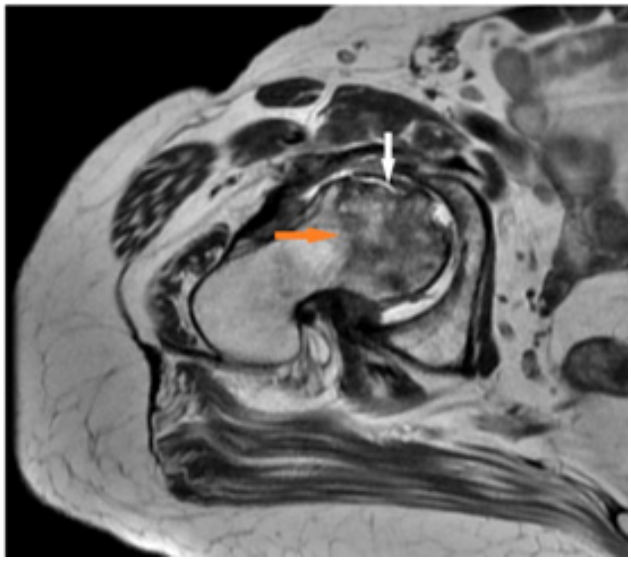
Table 2: Characteristics of joint lesions in patients with COVID-19.

No.	Joint	Time of Onset of Joint Symptoms from the Beginning of Infection	decompression	Steinberg Scale	Follow-Up (Months)	VAS Pain Initially	Pain Follow Up VAS
1	Hip	11		4	10	8	2
2	Hip	10	Decompression	2	9	9	0
3	Hip	11	Decompression	2	7	6	0
4	Hip	7	Decompression	4	7	8	0
5	hip	21		2	8	7	1
6	Hip	17		3	10	8	0
7	Hip	14		2	8	8	1
8	Hip	14	Decompression	2	5	8	1
9	Hip	22		2	5	7	0
10	Hip	17		4	4	8	0
mean		14		3	7	8	0,5



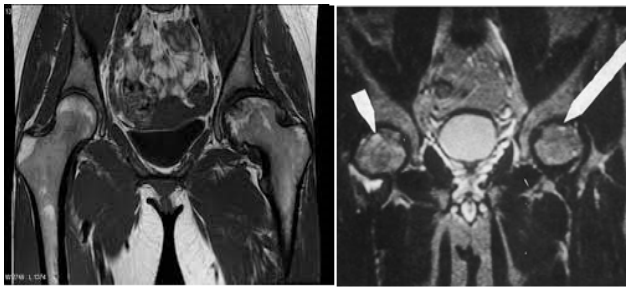
Case 1 (Patient No. 5)

Figure 1: A control magnetic resonance imaging was performed, which did not reveal any significant deviations from the norm



Case 2 (Patient No. 1)

Figure 2: Aseptic necrosis of the femoral head was visualized with the destruction of the articular surface and deformation of the femoral head



Case 3 (Patient No. 7)

Aseptic necrosis of the femoral head was visualized with the destruction of the articular surface and deformation of the femoral head

Figure 3: deformation of the femoral head figure: after HBOT

Discussion

Complications following COVID-19 infection are the focus of numerous clinical trials. Pathological changes following COVID-19 infection have also been described in the locomotor system. In our study, the formation of changes within the hip, with a background of AVN, was observed among the group of patients.

A similar etiology of vascular and embolic changes over the course of COVID-19 infection has also been described in organs outside of the respiratory system, such as multiorgan failure, acute cardiac injury, cerebrovascular diseases, acute kidney injury, liver dysfunction, and venous thrombosis [9,10,11,12,13,14]. Undoubtedly, exacerbation of underlying diseases by SARS-CoV-2 infection also tends to worsen bone metabolism [15,16].

ACE2 deficiency, caused by viral invasion, can lead to bone matrix degradation [16]. Given that coronaviruses cause pneumonia and infection of the upper respiratory tract via ACE2 receptors in ATII cells, ACE2-dependent effects on bone tissue should also be noted. ACE2 is a potential factor that regulates bone biology during COVID-19 infection [17,18].

Bone complications from infections or treatments are likely to emerge in the next few months, similar to the SARS outbreak in 2002–2003. At that time, reports of joint pain, decreased bone mineral density (BMD), and necrosis of femurs and tibias could only be partially explained by high-dose steroid treatment [19]. Another in vitro study showed that the specific SARS-CoV protein, 3a/X1, directly promotes osteoclastogenesis, thereby accelerating osteoclast differentiation from monocyte/macrophage precursors and increasing the expression of the NF-kB ligand receptor activator (RANKL) and inflammatory cytokines, such as TNF-α, which indirectly promote osteoclastogenesis [20,21].

This study observed people with symptoms of AVN after a history of COVID-19 without steroid therapy. The first symptoms appeared on average 14 days (range 7–22 days) after infection. Probably in our patient group, steroid therapy did not directly influence the development of AVN. One study reported that symptoms of AVN appeared 58 days (range 45–67 days) after infection with COVID-19.

However, the risk of AVN after steroid therapy ranges from 6 months to 1 year. There is a lack of consensus about the dose and duration of corticosteroid treatment as a risk factor for developing AVN. One prospective study found that the risk of AVN increases significantly with the dose of >20 mg/day [22]. Our patients used 6 mg/day. COVID-19 disease appears to be an independent risk factor for AVN and possibly accelerates the risk of AVN after a history of COVID-19 treated with steroid therapy.

In the case of COVID-19, corticosteroids were primarily considered as a way to contain this "cytokine storm" and its aftermath: ARDS, disseminated intravascular coagulation, and shock. This usually occurs within the first 8–15 days of infection [23]. Treatment with steroids is attempted, especially at the onset of dyspnea, or even earlier, to prevent the progression of the "cytokine storm" [21]. The anti-inflammatory properties of corticosteroids reduce systemic inflammation and exudates in the lung tissues, and prevent further diffuse alveolar damage, there by improving hypoxia and minimizing the risk of respiratory failure. Most of the studies on the use of corticosteroids to treat COVID-19 have shown variable results, but this is mainly due to a marked heterogeneity in the research methodology.

In the examined group of patients, no risk of bone changes in relation to the general condition of the patient and the severity of the course of COVID-19 disease was observed. For four patients of our observed group, the occurrence of AVN, with the consequent destruction of the articular surface and permanent changes (joint damage), was observed. These patients were treated with core decompression in relation to their hip joints. In the remaining seven patients, complete remission of the changes was observed after the steroid drugs, without permanent sequelae. However, the long-term consequences of bone changes over the course of COVID-19 are not known, as our observation period did not exceed several months.

AVN is a known complication after steroid treatment of severe COVID-19 infections or in long COVID-19 infections [24,25]. We described 10 cases who suffered from AVN shortly after a COVID-19 infection without prior steroid treatment. Apparently, COVID-19 infection alone may represent a risk factor for developing AVN. On average, AVN begins 2 weeks after COVID-19 onset in contrast to long COVID-19 late-onset AVN [20]. However it may vary.

The following differential diagnoses should be considered in an individual with signs or symptoms suggestive of COVID-19-related AVN: bursitis or tendinitis, chondral damage or loose bodies, stress fracture, labral tear, muscle strain, neoplasm, psoriatic arthritis, rheumatoid arthritis, septic arthritis, Paget's disease, piriformis syndrome, sacroiliac dysfunction, and radiculopathy [26].

Conclusion

SAR-CoV-2 can affect bones presenting with symptoms 2–3 weeks after infection. This may resolve with medical management or result in end stage AVN that may responds well to core decompression or hip arthroplasty. After effects of covid-19 infection over this human body are complex including musculoskeletal system. Further, long term studies are suggested to have a better understanding of the disease.

Informed Consent: written informed consent was taken from patients.

Ethical Approval: ethical committee approval was taken from the institutional committee of ethics.

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Original article

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A Study on Maternal Near Miss: The Submerged Iceberg, in a Tertiary Care Hospital of Central India

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Abstract

Background: Maternal near miss is defined as "a woman who nearly died but survived a complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy". It shows the quality of obstetric care of any country or society.

Objective: To estimate the proportion of severe maternal morbidity /near miss and its maternal characteristic and perinatal outcomes in tertiary care hospital of central India.

Methods: The present study was carried out at department of obstetrics and Gynecology at Sultania Zanana hospital (SZH) Bhopal for 6 months. A validated semi-structured questionnaire was used to collect the information regarding social demographic profile, ANC history and chief complaints was taken from the relatives i.e. either mother in law or husband. Subsequent information was taken from the mother as she got well and finally got discharge.

Results: majority of the mothers belonged to the age group 18-25% i.e. 58.73%.Around 55.5% of the near miss mothers belonged to rural background. maternal near miss ratio 10.16 / 1000 live birth,the ratio of maternal death to maternal near miss event was 1: 2.17. Hemorrhage and hypertension are the leading causes with 47.61 % and 28.57% respectively. Preterm birth and still birth were more common in maternal near miss cases as compared to general obstetric admission.

Conclusion: Achieving sustainable development goal for maternal mortality is still a far cry. As there is a huge gap of near miss cases to maternal death ratio of present study and ratios of developed countries.

Key Words: Maternal near miss, Mother, Preterm, Still birth, Rural.

Introduction

Every year worldwide, it is estimated that more than 300,000 mothers die from preventable causes during pregnancy, birth, and the postnatal period—approximately 830 women every day[1].From 2000 to 2017, the global maternal mortality ratio declined by 38 per cent – from 342 deaths to 211 deaths per 100,000 live births, according to UN inter-agency estimates. This translates into an average annual rate

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of reduction of 2.9 per cent. While substantive, this is less than half the 6.4 per cent annual rate needed to achieve the Sustainable Development global goal of 70 maternal deaths per 100,000 live births[2].

Maternal mortality ratio (MMR) in India has shown an appreciable decline from 398/100000 live births in the year 1997-1998 to 301/100000 live births in the year 2001-2003. Maternal mortality ratio (MMR) further reduces to 130/100,000 live births (LB) in 2014-2016. Couple of States such as Kerala and Maharashtra have lowered MMR to as low as 46 and 61, respectively, and achieved the MDG goal for 2015 (100/1 lakh live births)[3].

Maternal mortality is also being used as a sentinel event to assess the quality of a health care system in any country or society. The analysis of maternal deaths has been the criteria of choice for evaluating women's health and quality of obstetric care. But pregnant women's health status is not reflected by mortality indicators alone. Hence the concept of severe acute maternal morbidity (SAMM) is apt for the present health providing system. Severe acute maternal morbidity (SAMM), also known as 'near miss', has been defined by Mantel et al. The concept of maternal near miss is superior over maternal death in drawing attention to surviving women's reproductive health and lives[4].

In 2009, WHO has come up with clinical, laboratory, and management criteria for the Identification of Maternal near miss cases. According to the WHO, MNM is defined as "a woman who nearly died but survived a complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy"[1]. This study tries to estimate the proportion of severe maternal morbidity /near miss and its maternal characteristic and perinatal outcomes in tertiary care hospital of central India.

Material and Methods

It was a hospital based cross sectional studyinitiated from January 2015 to June 2015. The present study was carried out on seriously ill pregnant mothers from their admission to till they discharge. The present study was carried out at department of obstetrics and Gynecology at Sultania Zanana hospital (SZH) Bhopal. It's a tertiary care regional referral hospital. SZH receives inflow of patients from the Raisen, sehore and vidisha district. All seriously ill women pregnant women admitted during Ante partum, intra-partum or post partum period in the labour room of obstetrics department of SZH were included in the study.All patients or their relative who are not willing to give interview or participate in the study were excluded. Patient's or relative interview was taken after 2days of admission to ensure survival after critical condition of patient. WHO near miss criteria was used to select the pregnant mother as our study subject. A validated semi-structured questionnaire was used to collect the information regarding social demographic profile, ANC history and chief complaints was taken from the relatives i.e. either mother in law or husband. Subsequent information was taken from the mother as she got well and finally got discharge. Data was collected and entered in MS excel 2007. Coding and analysis was done using epi info software. Generation of descriptive statistics was done, for association between independent and dependent variable chi-square test was used. Ethical clearance for study was taken from Institutional Ethics committee. Informed consent from the participants was taken.Anonymity and confidentiality of data was assured to the participants.

Results

A total of 63 maternal near miss was identified using WHO criteria. Total live birth was 6198

And still birth recorded was 286. This gives the maternal near miss ratio 10.16 / 1000 live birth. Maternal near miss rate for hospital per 1000 obstetric admissions was 6.97 per 1000 obstetric admissions. the ratio of maternal death to maternal near miss event was 1: 2.17 as shown in table.1.

Table 2. Shows the distribution of maternal factors in near miss mothers. Among 63 maternal near miss cases around 7 (11.1%) mothers got married at the age below 18yrs and 20 (31.74%) near miss mothers got pregnant at the age of 18-20 years. 30.15% Maternal near miss mothers belongs to primi gravida and the multi gravid constitute 69.85% of the near miss cases. It is Important to note that the prim gravida and multigravida women who has 3 or

more gravid constitute 80.95% of the total near miss cases.About 17.46% of maternal near miss cases had not received any Antenatal care visit while 82.54% had at least one Antenatal visits. In figure.1. near miss mothers were categorized by final diagnosis with respect to hemorrhage, hypertension, sepsis, dystocia and Anemia and other medical disorders were considered as causes contributing to maternal near miss. Hemorrhage and hypertension are the leading causes with 47.61% and 28.57% respectively

Table 3. shows the outcomes of maternal near miss mothers. On comparing the mode of deliveries among the near miss and general obstetric admission (none near miss) we find the chi-square value of 0.342 with 1 degree of freedom and p value of 0.552. Which is statistically not significant. While on comparing the live birth and still birth among the near misses and general obstetric admission (none near miss) we get the P value of less than 0.0001 which is considered as extremely significant. On the other hand, while looking for association between term and preterm condition in near miss and general obstetric admission (none near miss)we get the chi square value of 13.22 with the 1 degree of freedom and p value of less than .0001 which is statistically highly significant.

Table 1: Indicators used to describe maternal events in hospital settings

Indicators	Rate & Ratio	(95 % CI)
Absolute number of near miss cases	63	-
Maternal near miss rate per 1000 obstetric admission	6.97	(5.45-8.93)
Maternal mortality rate per 1000 obstetric admission	3.20	(2.55-5.67)
Maternal near miss ratio per 1000 live births	10.16	(7.95-12.98)
Maternal mortality ratio per 1,000 live births.	4.67	(3.26-6.71)
Ratio of maternal near miss event to maternal death	2.17:1	-

Total no. of Obstetric Admission - 9030

Total no. of Live Births - 6198

Total no. of Still Births - 286

Table 2: Distribution of maternal factors in near miss mothers.

s. no	Maternal Factors	No. of Near miss	Percentage
1.	**Age at the time of marriage**		
	<18 yrs.	7	11.11
	≥18 yrs.	56	88.89
2.	**Age at first pregnancy**		
	18-20	20	31.74
	>20	43	68.26
3.	**No. of Antenatal Checkups**		
	0	11	17.46
	1	1	1.58
	2	4	6.35
	3	15	23.81
	≥4	32	50.80
4.	**Timing of first ANC visit**		
	1st Trimester	31	59.62
	2nd Trimester	17	32.69
	3rd trimester	04	7.69
5.	**No. of Gravida**		
	1	19	30.15
	2	12	19.05
	3	17	26.98
	≥4	15	23.82
6.	**Gestational Age at admission**		
	1-12	6	9.52
	13-28	4	6.34
	>28	43	68.27
	Postnatal	10	15.87
	Total	63	100

Table 3: Maternal outcome of near miss mothers.

Outcomes	Near miss (%) [severe acute maternal morbidity]	None near miss (%) [General obstetric admissions]	Chi-square value	P value
Mode of delivery *			$\chi 2$ =0.342 df=1	0.58
Normal Vaginal	34 (69.38)	4140(64.34)		
Caesarean Section	15(30.61)	2294(35.65)		
Delivery outcome#			$\chi 2$= 161.3 df=1	<0.001
Live Birth	32(58.18)	6198(95.58)		
Still Birth	23(41.81)	286(4.42)		
Pregnancy duration			$\chi 2$=13.228 df=1	<0.001
Term	41(70.68)	5630(87.50)		
Preterm	17(29.32)	804(12.50)		

* 9 – emergency laparotomy, 5 – pregnancy continued. # 3 – abortions, 5- Pregnancy continued.

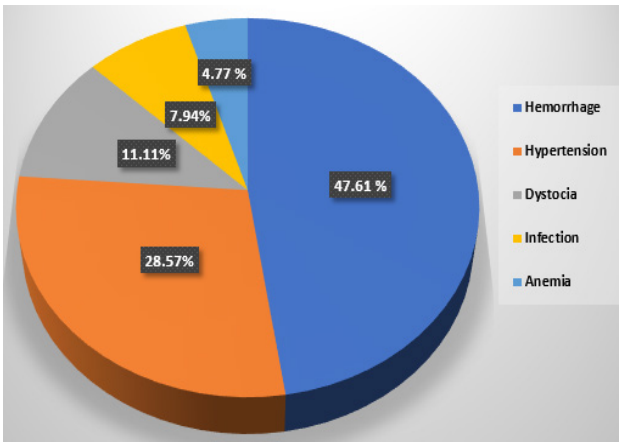

Figure.1. Diagnosis of Maternal near miss events.

Discussion

The maternal near miss ratio was 10.16/1000 live births, which was lower than Roopa PS et al who had reported ratio of 17.8/1000 live births [5]. Previous studies from developing countries show range anywhere between 15–40/1000 live births [6-8]. near miss events to maternal deaths ratio was **2.17:1.** Which means every 2 to 3 life threating conditions there was one maternal death in the facility. low ratio indicates a poor obstetric care in the facility. while previous studies from our country shows range from **3-8: 1** [9-10]. Higher ratios indicate better obstetric care. Syrian study showed a ratio of 60: 1 and study done in Nepal showed a ratio of 7.2: 1 [11-12]. Whereas there is still a long way to go if we compare near miss to death ratio with western countries [7]. In present study 58 percent of the near miss was below 25 years of age. This finding was in line with the results of studies done by Roopa et al in Karnataka, India & by Almeria et al in Syria which shows similar ageof the near miss mother[12,13]. A study done by Rathod et al at Aurangabad, at tertiary referral center of rural India shows a mean age of 23.63 in near miss [14]. Previous studies show a significant association between rural residence and near miss event [15-17]as in our study too, majority of cases were from rural areas. It may be relatable to the fact that most of the near-miss cases get delayed in reaching and receiving adequate care.

In present study half of the maternal near miss cases were those who had less than 4 ANC visits during Antenatal period. In agreement to our findings study from Ethiopia stats that Mothers who did not have antenatal follow-ups were more likely to experience near-misses [18,19]. In present study there has been a rise in hypertensive cases which makes it second most common cause for near miss events. Hemorrhage is still a most common cause of maternal near miss and maternal deaths in our study. In the study done by Shrestha et al in Nepal most common cause was Pregnancy induced hypertension while Bakshi et alin North India and Gupta D et alreported many severe PPH cases as cause for maternal near miss [20-22]. Findings in our study reveals that higher Still birth is associated with the maternal near miss events. The result was consistent with studies conducted elsewhere that tried to investigate the risk of still birth among maternal near miss cases[23-26]. Association of Pre term birth as an outcome to near miss event was also found to be significant. Similar

finding was reported by Oliveira Jr et al where the odds of preterm delivery in near miss cases was higher [27].

Conclusion

Achieving sustainable development goal for maternal mortality is still a far cry. As there is a huge gap of near miss cases to maternal death ratio of present study and ratios of developed countries. Through maternal near miss cases we can develop a system through which we can identify health system failures or priorities in maternal health. Because a mother surviving a fatal maternal morbidity can give more information than a maternal death. It has the advantage of events still being rare enough not to overload clinicians and data capturing personnel within a facility. MNM cases occur more often as compared to maternal deaths and have similar pathways that can directly give information about the strengths and weaknesses of the system that need to be overcome during the process of providing healthcare. Strengthening the available health system in rural parts of the country with a focus on maternity service is also a crucial step to avert serious maternal complications.

Conflict of interest: None

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Original article

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Prevalence of Alcohol use among the Indian Population and its Impact on Public Health

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Abstract

In the discussion on substance abuse alcohol is reported as one of the most commonly used substances. The public health perspective states alcohol is a major player not only leading to disability but also death and disease. The article aims to provide an insight into the overall understanding of the effect of alcohol consumption on the peoples' lives in India. It also describes the burden of alcohol consumption and its consequences. This article is based on secondary data, the secondary data are collected from different source such NFHS, published research papers and reports.

Keywords: Alcohol consumption, alcohol-related consequences, morbidity, mortality, risk factors, social-economic and cultural factors

Introduction

Alcohol, especially its hazardous use has been notorious for being one of the leading risk factors resulting not only in non-communicable diseases (NCDs) but also related to mental health, injuries and violence [13]. It must also be kept in mind that alcohol and tobacco are preventable health risk behaviours [10]. Hence, while alcohol use causes considerable health loss and is an important public health concern with effective interventions and regulations its negative health impact can be controlled or even reduced.

Celebrating an event, festival and joyful activities have been associated with drinking alcohol. Even after work many associate relaxation and peacefulness with drinking alcohol[4]. According to World Health Organisation (WHO,2014), the overall

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per capita intake of alcohol is 6.2L of alcohol per year by individuals above 15 years of age which equals almost 13.5 g of pure alcohol per day. One of the main risk factors for premature mortality and disability is consumption of alcohol, which is also leading to almost 3 million deaths per year globally. Harmful alcohol use is responsible for 7.1% (males) and 2.2% (females), which contributes to around 5.1% of the global disease burden [3].

Alcohol has been said to have an adverse impact on nearly 13 out of the 17 Sustainable Development Goals (SDGs) and directly impacting many health-related targets within the SDGs ranging from infectious diseases (HIV, hepatitis, TB), to NCDs, maternal and child health, etc. (WHO, 2020).There have been fair amount of deaths recorded as a result of alcohol-related incidents and a total of 3.7% of deaths (2.1 million deaths per year) and 4.4% of the disease are because of alcohol consumption. There has been an increase in consumption of alcohol over the past 10 years, of which, most is occurring in the developing countries [13]. Estimates by WHO (2018) indicate that the total adult alcohol per capita consumption (APC) in India has rapidly increased from 2.3 litres in 2000 to 5.5 litres in 2018 and have been forecasted to increase till 2025.

In the aftermath of COVID-19, it is all the more important, to highlight the interplay between substance, society and health. Due to COVID-19, many individuals found themselves confined in their homes with limited avenues of support from the outside. It has also been reported that while epidemics may not influence all forms of crimes, domestic violence as a form of violent crime is said to increase substantially during such events [1]. There is a plethora of literature that documents the relationship between alcoholism, domestic violence and their interplay impacting upon an individuals' mental health and wellbeing. It has been acknowledged that women disproportionately bear the health and psychological burdens of violence and domestic violence which most often occurs in a safe space i.e. their homes and the perpetrator is usually a person they trust[20]. Therefore, alcoholism is not only a health problem but also a social problem.

Alcohol consumption: Indian scenario

India used to be one of those countries which had lowest consumers of alcohol but now there are about 14 million people who are alcohol dependent and require help. As per the National Family Health Survey(NFHS)-4, 29.2% men and 1.2% women, whereas in NFHS -5, 18.8% men and 1.3% women consume alcohol. After comparing the trends from NFHS-4 and 5, it is evident that there is a gradual decrease in this practice [3]. While NFHS findings indicate a decreasing trend, WHO's report on Status on Alcohol Use and Health at Global level (2018) indicates a 38 per cent increase in APC among those aged ≥15 years in India from 2010-2017.

A recent trend of consuming alcohol has been observed with drinking patterns varying amongst different socio-cultural practices in developing countries like India. One of the major changes in the trend which has been observed is people have started consuming alcohol at younger ages. According to studies conducted by Alcohol and Drugs Information Centre India, a non-governmental organization (NGO) in Kerala, there has been an increase from 2% to more than 14% in the drinking population aged under 21 years and in the past two decades the average age of initiation has reduced from 19 years to 13 years.The introduction of flavoured alcoholic drinks has increased its consumption by attracting new consumers who were previously non-drinkers (OECD, 2021).

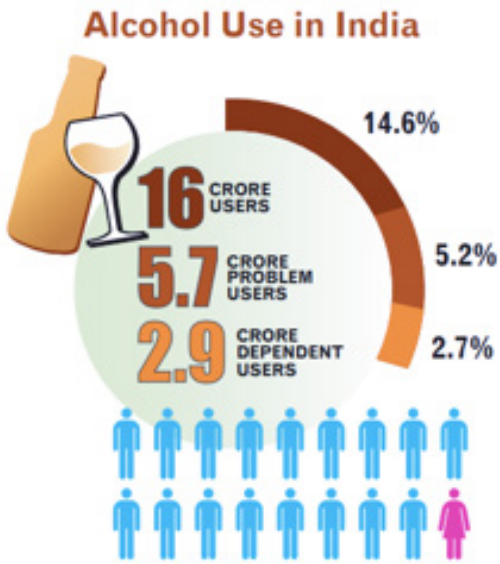


Fig 1: Prevalence of Alcohol Use in India

Source: National Survey on Extent and Pattern of Substance Use in India (2019), Ministry of Social Justice and Empowerment, Government of India

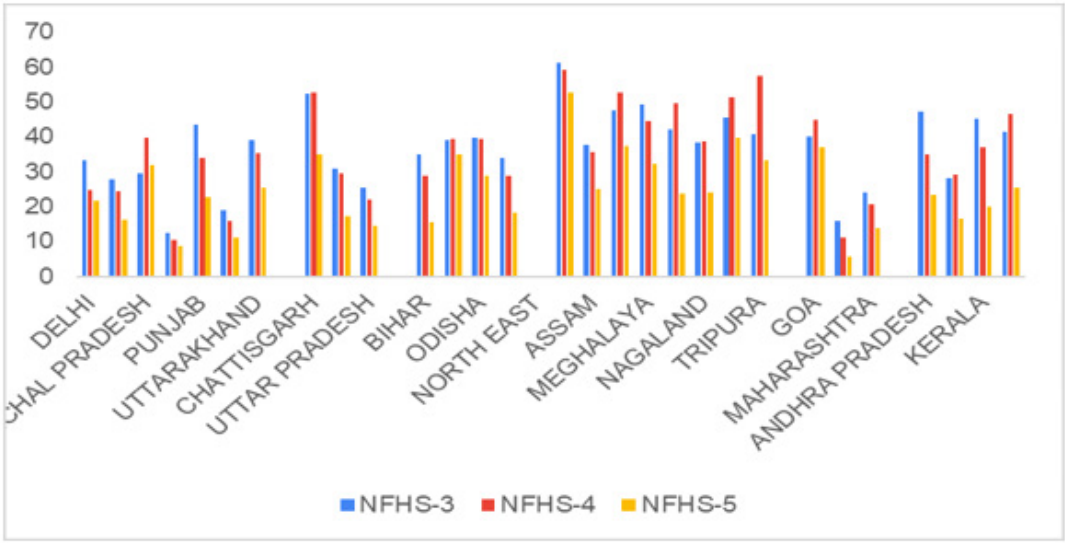
Alcohol consumption states wise in India-NFHS

According to a report on magnitude of substance use in India (2019) the states with the highest prevalence of alcohol use are Chhattisgarh, Tripura, Punjab, Arunachal Pradesh and Goa [7]. As per the NFHS-5 report 15.5% men above 15 years of age consume alcohol in Bihar which is a dry state (complete prohibition on the consumption of alcohol). Between NFHS-3 and NFHS-4, there was a considerable decrease in current alcohol use among men and women. In NFHS-5, there was a decrease in the proportion of men reporting alcohol usage in all but one state (Himachal Pradesh). In 12 states, the proportion of women reporting alcohol usage has decreased, while in three states it has increased (NFHS-3 to NFHS-5[3].

Prevalence of alcohol consumption among men

It may be seen from graph 1 that males in the northeast states consumed greater quantity of alcohol than rest of India. Among the states Arunachal Pradesh men consumed the most alcohol (53%) followed by Telangana(43%), Sikkim (40%) Manipur (37%), Goa (36%), and Jharkhand and Chhattisgarh each state shows (35%) alcohol consumption. Our findings are in line with other studies indicating that consumption of alcohol has regional variations and that alcohol use is most prevalent in the North-East, Chhattisgarh, Telangana, Himachal Pradesh, Punjab and Jharkhand [18].

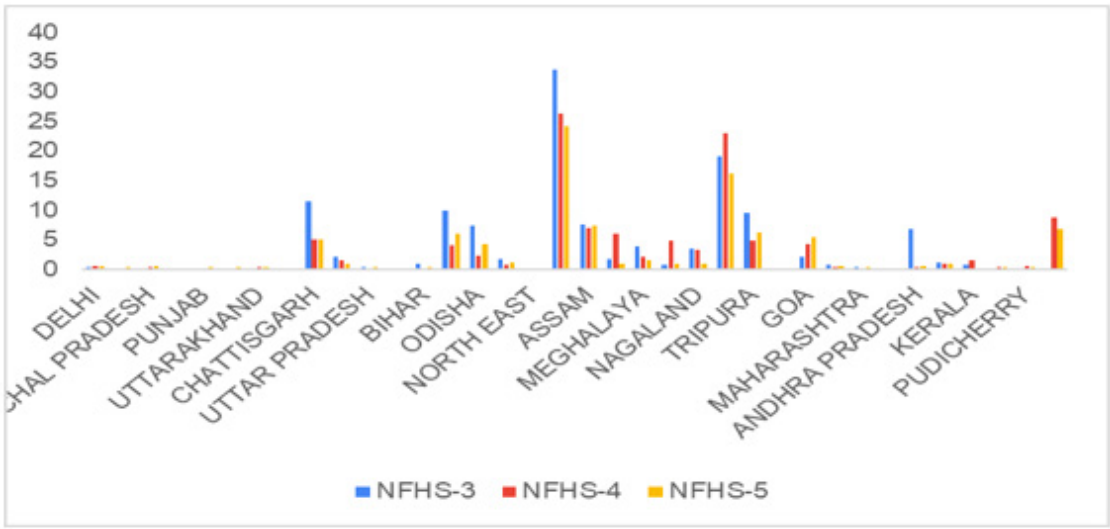
If we look at gender differences, while comparing NFHS-3 and NFHS-4 data there has been a decrease in alcohol consumption among men and same has been the case in NFHS-5 which could be attributed tounder reporting and/or alcohol sale restrictions due to COVID-19 and subsequent lockdown.



Graph-1: Men aged 15 and above who use alcohol by states in India (%)

Prevalence of alcohol consumption among women

The graph 2 shows that north east states women were consuming more alcohol than women from the other regions of the country. Among the states women from Arunachal Pradesh consumed highest alcohol (24%) followed by Sikkim (7%), Telangana (7%) Chhattisgarh (6%) and Tripura (6%) each state showing (35%) alcohol consumption. Compared to NFHS-3, NFHS-4 alcohol consumption by women has decreased in NFHS-5 due to covid-19 restriction and under reported the data. In India Goa one of the state is shown (5%) the alcohol consumption increasing in NFHS-5.



Graph-2: Women aged 15 and above who use alcohol by states in India (%)

Domestic violence

Literature suggests [16] alcohol use and violence may be considered as risk factors for poor mental health among women. Studies reveal that partner alcohol problems pose diverse health threats for women that go beyond the well-documented association with domestic violence. It was reported that women whose partners had alcohol problems were more likely to experience victimization, injury, mood disorders, anxiety disorders, and being in fair or poor health than women whose partners did not have alcohol problems. They are also said to experience more life stressors and have lower mental/psychological quality of life scores[5].

NFHS-3 (2005-6) has indicated that the experience of spousal physical or sexual violence varies with level of the husband's alcohol consumption. 69% of women whose husbands got drunk often had experienced spousal violence, as compared with 30% of women whose husbands did not drink alcohol. But over a period of a decade, this spousal violence has increased due to the easy proximity of drinks. NFHS-4 (2015-16) has indicated that the experience of spousal physical or sexual violence varies with levels of the husband's alcohol consumption. 71% of women whose husbands got drunk often had experienced spousal physical or sexual violence, compared with 22% of women whose husbands did not drink alcohol. Alcohol is said to be the culprit in up to 50% of the cases of sexual assault.

Family conflict arises

If consumed in excess, alcohol can affect all areas of a person's life, as well as the lives of their family and friends. It has been indicated that alcohol misuse may result in broken families, crimes, economic instability in family, etc.[6] including strained relations with their family members especially their spouse and children[21].Conversely, family support, bonding, and parental monitoring is associated with lower alcohol use [22]and social networks and social support also have protective effects[23].

Economic loss

The economic impact of alcohol consumption plays a major role in families belonging to the lower socio-economic strata. In fact, alcohol use not only causes personal economic losses but also costs the country's economy including having an impact on the developmental trajectory. WHO's Global Status Report on Alcohol and Health (2018) mentions that an increase in alcohol consumption in poorer societies or in lower-income segments of populations can even be detrimental in the achievement of the SDGs. Alcohol consumption would increase the societal burden of alcohol, inclusive of health system cost, out of pocket expenditure and productivity losses amounting to INR 121,364 billion (US$ 1867 billion). Even after adjusting for tax receipts from sale of alcohol, alcohol poses a net economic loss of INR 97,895 billion (US$ 1506 billion). This causes an average loss of 1.45% of the gross domestic product (GDP) per year to

the Indian economy [7]. In a study done by Girish et al. (2010)[4]. It was found that alcohol-dependent persons spent more money than they earned, they were forced to take loans to spend for their expenses related to alcohol consumption, on an average, 12.2 working days were lost to the habit and around 60% of the families were financially supported by the income from other family members.

Public health issue

Alcohol related accidents & injuries

One of the major reasons for road traffic accidents is alcohol intake as it impacts driving ability. A study was conducted by the National Institute of Mental Health and Neurosciences (NIMHANS) in 12 major hospitals of Bangalore city, and it revealed that nearly 28% of injuries were noted due to road traffic accidents under the influence of alcohol. Another study done by Gururaj (2003) revealed that alcohol abuse was reported in over 20% of traumatic brain injuries.

According to the data released by the National Crime Records Bureau (NCRB) 2020, Chennai in particular, recorded the highest number of drunk driving deaths in the country. Also in one of the studies conducted by [9] alcohol-dependent individuals with road traffic accidents showed high-risk behaviour most frequently.

Non communicable diseases

According to WHO (2018), alcohol consumption is found to be in association with more than 200 disease and injury conditions. Globally, 3 million deaths every year are noted from harmful use of alcohol (World Health Organization, 2020), which represent 5.3% of all deaths. Alcohol intake causes death and disability relatively early in life. In the age group 20–39 years approximately 13.5 % of the total deaths are alcohol-attributable. A causal relationship was found between harmful use of alcohol and a range of mental and behavioural disorders as noted also with other noncommunicable conditions and injuries.

Bagnardi et al. (2015), noted that heavy alcohol intake strongly increased the risk of cancers of the pharynx, oral cavity, oesophagus and larynx. Also, for both the genders, four drinks per day has increased risk for oral and esophageal cancers by approximately three-fold and rectal cancers by 1.5 fold[23].

Alcohol with eight other factors accounts for 61% of loss of healthy life years from cardiovascular diseases (CVDs) and 61% of cardiovascular deaths. It is related to many cardiovascular outcomes, including hypertensive disease, haemorrhagic stroke, and atrial fibrillation. Continuous heavy alcohol use has been associated with adverse cardiovascular outcomes. It has also been observed that average drinking in a limited quantity serves as a protective effect on ischaemic diseases, whereas when this drinking style changes to heavy drinking causes severe cardiovascular diseases [24].

Alcohol is associated with various kinds of liver disease, with fatty liver, alcoholic hepatitis and cirrhosis being the most common. The relationship is so strong that in an International Classification of Diseases (ICD) several subcategories of liver disease were given the prefix of alcoholic, e.g. alcoholic liver cirrhosis. The likelihood of developing liver disease is a function of both the duration and the amount of heavy drinking.

Eashwar et al. (2020), outlined several. medical complications that are said to occur as a result of alcohol-use including gastrointestinal (GI) complications, neurological disorders, alcohol related death, psychological stress and reduced quality of life. Regularly consuming alcohol can directly disrupt the lining of the stomach leading to acute gastritis. According to a study [8], it is seen that those who are chronic drinkers suffer from avascular necrosis of the femoral head and reduced bone density[17]. According to research, 17.6% of psychiatric emergencies in an Indian general hospital were noted due to alcohol consumption. Researchers have found that alcohol takes a psychological and physiological toll on the body and alcohol was itself the reason to cause stress on the body's physiological balance[4].

A study done in Chennai [25], noted that suicide rates were much higher among alcohol users as compared to those who do not take alcohol, and nearly (32%) aged 15–54 years men reported consuming alcohol with 9.4% of them were classified as 'alcohol dependent'. A major concern of suicidal attempts was observed which was found to be more common in those with depression amongst both men (6.6%) and women (7.9%). Level of depression was noted to be more prevalent in females compared to males.

Discussion

While public health has been improving with the advent of improved medical and technological development, we continue to be in the midst of an epidemiological transition. There has been reduction in mortality due to communicable diseases but this has also been followed by emerging NCDs. Today, once again we are fighting against NCDs while also dealing with re-emergence of infectious diseases. With COVID-19 not only India but the world has been dealing with an undying virulent disease despite having developed multiple vaccines. (OECD, 2021) In lower-middle-income countries, it is found that global alcohol consumption is increasing and it is likely that the impact of alcohol on inequalities will worsen in the future.

Keeping the above discussion in mind our paper has tried to explore the burden of alcohol-use on not only health but also attempted to suggest interlinkages and subsequent impacts on socio-economic standards,physical health and wellbeing due to domestic violence, economic losses, increasing stressors etc.

It should be noted that there are various policies which are concerned with the consumption and production of alcohol. In India, alcohol is a state subject and hence, states have full control over their alcohol related excise duties, legislation, legal drinking age, production and sale. As per the Indian Constitution state list of item number 51, "alcohol for human consumption", deals with the rules by which the business of liquor in the state is governed. Along with this, Article 47 that drafts the message of raising the level of nutrition, standard of living and improving health. It also takes responsibility to make sure the drinks and drugs which are injurious or detrimental to health are prohibited.

The Government of India has taken numerous initiatives to tackle the growing threat faced due to alcohol by formulating the various alcohol control policies such as The Motor Vehicle Act (1988) to prevent drunk driving and introducing the Minimum Legal Drinking Age(MLDA). According to the National Crime Record Bureau (NCRB, it has been recorded that around 2% of the total road traffic accidents are because of drunk driving. Law has been made against drinking and driving. States can independently take decisions in view of stopping the loss of health and property which leads to various catastrophic conditions.

Conclusion

It is clearly evident from the preceding discussion that there are many aspects to alcohol and its misuse. Talking about the ground level situation of the country in respect to consumption of alcohol, we observe that there are rules, there are policies formed to control and disseminate as well as the hazardous consequences which happen due to excessive alcohol consumption. But question is the whether the policies and rules which have been put into effect for the benefit of society have been able to make a difference?

There has been increasing liberalization in alcohol availability and its production, except for a few states, which have promulgated prohibition. However, prohibition has more or less failed to curb or reduce alcohol-related problems and even leading to the increase in illicit liquor trade[16].

Hence, it can be said from the above discussion that there exists an urgent need to monitor, develop regulations and awareness campaigns related to harmful use of alcohol and its subsequent possible impacts on various other indicators. We not only require sustained enforcement of programmes and policies but also an enhancement of alcohol related programs and policies for the near future in order to protect our country's future population health and development.

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Ethical clearance: Nil

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Original Article

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Prevalence of Hearing loss in Diabetes Mellitus Patients of Jharkhand Population

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Abstract

Background: Hearing loss in Diabetic patients is global problem WHO report has a suggestion that 50% of hearing loss in Diabetic patients is preventable. Hence various grades of hearing loss has to be evaluated

Method: 250 hearing loss patients,aged between 20 to 50 years were studied by pure tone audiometry, by audiometry degree, type and configuration of hearingwas assessed. General examination was done by otoscopy followed by pure tone audiometry in which manual audiometry was used.

Results: 123 (49.2%) had moderate loss, 89 (35.6%) moderate severe, 38 (15.2%) severe hearing loss, Associated clinical manifestation were 86 (34.4%) had parasthesia, 60 (24%) had skin disease, 50 (20%) had visual problems, 54 (21.6%) had lack of sleep.

Conclusion: In this pragmatic study it is concluded that there is strong correlation between Diabetes mellitus and hearing threshold levels especially at higher frequencies. Long duration and uncontrolled diabetes has more implications over hearing threshold. This study will help the ENT surgeon to diagnose the severity of hearing loss and treat efficiently to avoid morbidity mortality and social withdrawl.

Keywords: Audiometry, Otoscopy, Hyperglycaemia, HbsA1c, Jharkhand

Introduction

Aroteus coined the term diabetes meaning "Spihon" to explain the "liquefaction of the flash and bones into urine". He described diabetes in the following way. Diabetes is a wonderful affection, not very frequent among men, being melting down of the flesh and limbs into urine[(1)]. In the course of a cold and humid nature, as in dropsy. The course is the common one namely kidney and the bladder, for the patients never stop making water, but the flow is incessant as if from the opening of aqueducts. Later word Mellitus (honey sweet) added by Thomas Willis after realising the sweetness of urine in 1675[(2)(3)].

Diabetes related complications are coronary artery disease, peripheral vascular disease neuropathy, retinopathy, nephropathy etc. As per WHO report 5% of the world population (360 millions) of type-II DM are suffering with hearing loss[(4)]. Moreover there is a suggestion from WHO report that half of the hearing loss diabetic patients are preventable[(5)].

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But hearing loss in diabetes has not received as much attention and more research needs to be done in this area. Hence attempt was made to evaluate the facts and figures of hearings loss in Diabetes patients.

Material and Method

250 adult patients aged between 20 to 50 years diabetic patients having hearing loss problems regularly visiting to ENT department of PhuloJhano Medical College Dumka Jharkhand-814110 were studied.

Inclusive Criteria: Patients with hearing loss known type-II Diabetes Mellitus diagnosed as per the national Diabetes data group and World Health Organisation (WHO) diagnostic criteria. Random Blood Sugar level >200gm/dl, Fasting plasma glucose level>126mg/dl, Two hours plasma glucose >200 mg/dl, During glucose tolerance test HbsA1C was carried out to know the onset of DM. Age group above 20 years were selected for study.

Exclusion Criteria: Patients having history of noise damage, middle ear hearing loss, and history of cognitive function disability. Patients with Meiners disease or labyrinthitis were excluded from study.

Method: Two methods were used for hearing assessment of ear examination (1) General ear examination (2) Pure tone audiometry,by audiometry degree, type and configuration of hearing loss otoscopy was usedfor general ear examination. This was followed by tone audiometry in which manual audiometry was used. The instrument was made to deliver the pure tone of different variable frequency and various intensity using ear phones. Assessment was done at 1000 Hz, 2000 Hz, 4000 Hz, 8000 Hz, 500 HZ and 250 Hz in the similar order. The intensity was varied for each of the frequency and patients were instructed to signal when he/she hears any sound, both air borne and bone conduction testing was done in every patients. The results were classified as mild (20 to 30 dB), moderate (31 to 60 dB), moderates severe (61 to 70 dB), severe (71 to 90 dB) and profound (>91 dB).

Duration of study was January-2021 to September-2022.

Statistical analysis: The grades of hearing loss and associated clinical manifestation were classified with percentage. The statistical analysis was carried out SPSS software. The Ratio of male and female was 2:1.

Observation and Results

Table-1: Classification based on hearing threshold

Decibels – 20-30 is mild, 30-60 moderate, 61-70 moderately severe, 71-90 severe, >90 is profound.

Table-2: Distribution of hearing loss in diabetic patients – 123 (49.2%) moderate, 89 (35.6%) moderate severe, 38 (15.2%) severe.

Table-3: Associated Clinical manifestations in type-DM patients with hearing loss – 86 (34.4%) parasthesia, 60 (24%) Skin Disease, 50 (20%) Visual Problem, 54 (21.6%) Lack of sleep.

Table 1: Classification based on the hearing threshold

Sl. No	Decibels	Degree of hearing loss
1	20-30	Mild
2	31-60	Moderate
3	61-70	Moderately severe
4	71-90	Severe
5	>91	Profound
6	No hearing	Total complete deafness

Table 2: Distribution of patients having hearing loss in Diabetes

Sl. No	Particular	No. of patients (250)	Percentage (%)
1	Moderate	123	49.2
2	Moderate severe	89	35.6
3	Severe	38	15.2

Table 3: The associated clinical manifestation in hearing loss in Diabetes Mellitus

Sl. No	Clinical Manifestation	No. of Patients (250)	Percentage (%)
1	Parasthesia	86	34.4
2	Skin Disease	60	24
3	Visual Problem	50	20
4	Lack of sleep	54	21.6

Discussion

Present study of prevalence of hearing loss in Diabetes mellitus patients of Jharkhand Population – 123 (49.2%) had moderate hearing loss, 89 (35.6%) had moderate severe, 38 (15.2%) had severe hearing loss (Table-1). The associated clinical manifestations were 86 (34.4%) had parasthesia, 60 (24%) had skin disease, 50 (20%) had visual problems, 54 (21.6%) had lack of sleep (Table-3). These findings are more or less in agreement with previous studies [6][7][8].

Hearing loss in DM patients is due to involvement of micro vascular insufficiency of the cochlea like sclerosis of internal auditory artery thickened vessel walls of stria vascularise and basilar membrane, damage to the outer sheath of cochlear nerve and atrophy of spinal ganglion [9]. It is reported that there is a significant correlation between hearing loss and hyperglycaemia. The hearing impairment is sensorineural type because there was hearing loss. Moreover age factor is also confounding factor but DM is alone responsible for loss of hearing in young and adults patients.

It was also reported that out of 45 patients, 10 patients had hearing loss problems [10]. In such patients renal and urinary tract infections complications were also observed [11].

In type-II DM patients due to hyperglycaemia there will be more viscosity in the flow of blood which leads to ischemia, infarction to the respective organs of the body but in present loss of hearing is due to ischemia, infarction to cochlear apparatus which was macro and micro vascular supply.

Summary and Conclusion

Present study of hearing loss in the type-II DM patients of Jharkhand population. It is mandatory to every clinician to explain the consequences and risk factors of DM. If any onset of hearing loss, detailed history of cranial nervous system, ear examination has to be done along with related blood examination. The present study demands further genetic, hormonal, nutritional, environmental, immunological, patho-physiological studies because; diabetes being a hormonal disease quantum of release of hormone, duration of release is yet to be known.

Limitation of Study – Owing to tertiary location of research centre, small number of patients and lack of latest techniques we have limited findings and results.

This research paper was approved by Ethical Committeeof PhuloJhano Medical College Dumka Jharkhand

Conflict of Interest: No

Funding: No

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Original Research

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Association of Antenatal Corticosteroid use with Hypoglycaemia and Hyperbilirubinemia in Preterm Neonates Admitted in a Tertiary Hospital of Kolkata: A Longitudinal Study

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Abstract

Background: Timely use of antenatal corticosteroids in a mother of preterm labour decreases the rates of perinatal death, respiratory distress syndrome, intra-ventricular hemorrhage, necrotizing enterocolitis in the new borns. However it is reported to have a causative role in neonatal hypoglycemia and hyperbilirubinemia. So the present study attempts to determine the association between the use of antenatal corticosteroids with hypoglycaemiaand hyperbilirubinemia in newborns with less than 35 weeks of gestational age.

Methods: A prospective observational study was conducted during a time period of 24 months from January 2020 to December 2021 in a tertiary care hospital of Kolkata on 99 preterm neonates of less than 35 weeks of gestational age. Antenatal history of corticosteroid use, neonatal glucose level and bilirubin level were measured among others. Data were analyzed using MS-EXCEL.

Results: Majority of neonates' mothers (71.7%) had received antenatal corticosteroids. Only 4.0% of the cases had hypoglycaemia at birth. But there was no cases of hypoglycaemia at 12 hour and 24 hour after birth. In 58.6% of the cases bilirubin level was in the phototherapy range and double surface photo therapy was required. In 14.1% of the cases double volume exchange transfusion was required.

Conclusion: Antenatal corticosteroid administration is not associated with neonatal hypoglycaemia but it is significantly related to neonatal hyperbilirubinemia.

Key word: corticosteroid, preterm, hypoglycaemia, hyperbilirubinemia

Introduction

Preterm birth is the leading cause of perinatal morbidity and mortality. The incidenceof preterm birth in India is 7-9%,[1] and the rates are constantly rising. Preterm birth and its complications are the leading cause of perinatal mortality.[2] Preterm neonate is defined as a neonate born before

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37 weeks of gestation irrespective of the birth weight.

Timely use of antenatal corticosteroids in a mother reports with preterm labourbefore 34 weeks of gestation has the following clinical impacts in newborns who receive good supportive care by decreasing the rates of perinatal death (31%), respiratory distress syndrome (34%), intra-ventricular hemorrhage (46%), necrotizing enterocolitis (54%) and intensive care admissions.[3]Administration of antenatal corticosteroids to mothers at high risk for preterm birth has been shown to markedly improve neonatal outcomes, beginning with the landmark study by Liggins and Howie in 1972.[4]

In contrast to the beneficial effects for the fetus, maternal corticosteroids administration can result in a time limited period of maternal hyperglycemia.[5] The mechanism for this corticosteroid induced hyperglycemia is due to increased hepatic gluconeogenesis, elevated plasma glucagon levels and decreased utilization of peripheral glucose, via transport and receptormodifications.[6] Many neonates are born within days of antenatal corticosteroid administration and are thus exposed to this period of maternal hyperglycemia acutely before delivery. The 1952 Pederson hypothesis that maternal hyperglycemia leads to a state of fetal hyperinsulinemia and subsequent neonatal hypoglycemia and this may have relevance in the setting of short course antenatal corticosteroid administration.[7]WHO defines neonatal hypoglycemia as blood glucose level less than 45 mg/dl. Among ELBW infants, hypoglycaemiaoccurs more frequently in SGA neonates. Hypoglycaemiais the commonest metabolic disorder of neonates. If not detected in time, it can lead to considerable morbidity and mortality and both symptomatic and asymptomatic hypoglycemia can lead to long term neurological sequelae[8]

Similarly Corticosteroid use can also lead to hyperbilibubinaemia in children. it is observed that those exposed to antenatal dexamethasone had higher levels of serum unconjugated bilirubin for the first week after birth compared to non exposed population and their high level of hyperbilirubinemia requiring treatment[9]. Pathological hyperbilirubinemia in neonates can occur due to various reasons in newborn babies and is important because bilirubin is neurotoxic in neonates and even healthy babies can sometime sustain irrveversible brain damage. If hyperbilirubinemia is not managed promptly, adverse consequences include the classic manifestations of kernicterus, isolated auditory impairment or subtle, processing disturbances can occur[10].

So the present study attempts to determine the relation between the use of antenatal corticosteroids with neonatal hypoglycaemiaand hyperbilirubinemia in newborns with gestational age less than 35 weeks.

Materials and Methodology

A prospective Observational Study was conducted in neonatal Care Unit (SNCU & NICU) Department of Paediatric Medicine R.G.Kar Medical College & Hospital, Kolkata from January 2020 to December 2021. 99 preterm babies with Gestational Age less than 35 weeks were included in the study. Among those babies with presence of lethal congenital anomalies or severe perinatal asphyxia were excluded.

For dependent variable of hypoglycaemia 12 hourly CBG monitoring was done. For hyperbillirubinemia, transcutaneous Bilirubin (prior to phototherapy) & total Serum Bilirubin (after 24 hours of phototherapy) were measured. Maternal factors like age, sex, gestational age, mothers' blood group, gravida & parity, mothers' diabetic status, whether antenatal corticosteroids received or not were considered as independent variable. Whether the baby has received double surface phototherapy (DSBT) or double volume exchange transfusion (DVET) was also taken into account. Calculated sample size was 90 (ref) which was further increased by 10% to compensate non response rate and exclusion criteria. Data were collected using case sheets, clinical examination and laboratory investigation findings about the above mentioned parameters. Data were compiled and analysed using MS_Excel and 'R' statistical package.

Mothers/care givers were informed about the study objectives and written informed consent was

signed by them. In case of illiterate mothers finger print of write thumb was taken in presence of a witness. Approval was taken for institutional ethics committee of R.G.kar Medical College, Kolkata (Registration number: ECR/322/Inst/WB/2013; memo no. RKC/173)

Result

Out of 99, 53.54% neonates were male and 46.46% of them were females. 37 (37.37%) out of 99 neonates had birth weight between 1 to 1.499 kg, which is very low and the remaining 62 neonates had low birth weight of 1.5 to 2.499 kgs. The mean birth weight of the neonates is 1.6 kgs with standard deviation of 0.3 kgs. No neonates were found to be extremely preterm. The distribution of neonates among very preterm, moderate preterm and late preterm were found to be 33, 36 and 30 neonates respectively. The lowest gestational age is 28 weeks and the highest is 34 weeks. The mean gestational age is 32.2 and median is 33 weeks.

38 neonates' mothers took 1 dose and 40 neonates' mothers took 2 dose of Antenatal Corticosteroid (ACS). The "Appearance, Pulse, Grimace, Activity, and Respiration" score (APGAR score) of about 25% neonates was less than 7 which meant that 1/4th of the neonates faced difficulty in tolerating the birthing process and needed medical attention. The mean APGAR score is 7.6 and median is 8.

We see that about 95.96% of the neonates had normal capillary blood glucose level at birth and only 4.04% of the neonates had hypoglycaemia with mean CBG level of 70.7 mg/dl. The lowest CBG level of neonates at birth was 28 mg/dl and highest was 118 mg/dl. Whereas after 12 hrs of birth no neonate had hypoglycaemia and all of them had normal CBG level. Again 24 hours after birth it was seen that the CBG level of 1 neonate decreased to <45 mg/dl and the rest 98 out of 99 neonates had normal CBG level with mean CBG level of 63.7 mg/dl. With time, the mean and the median capillary blood glucose level could be seen decreasing among the neonates. The lower range on one hand increases after 12 hours of birth than at birth on the other hand the upper range decreases. After 24 hours of birth the upper range further decreases and the lower range is also seen to be decreasing than that after 12 hrs.Prior to phototherapy 41 (41.41%) neonates had hyperbilirubinaemia as per transcutaneous Bilirubin measurement (TCB). All 41 of those neonates required double surface phototherapy (DSPT)whereas 14 (14.14%) out of 99 of the neonates required double volume exchange transfusion(DVET).

When comparison of number of ACS doses received by the neonates' mothers and CBG level at 0 hour, after 12 hours, and after 24 hours, transcutaneous bilirubin level, double surface phototherapy requirement and double volume exchange transfusion requirement done it was found that 50% of the mothers received 1 dose of antenatal corticosteroid and 50% of them received 2 doses of ACS when neonates had capillary blood glucose level at birth <45 mg/dl. No cases of hypoglycemia were found after 12 hours of birth. 1 case of hypoglycemia was found after 24 hours of birth and the mother received 2 doses of ACS in this case.

7.3% of the mothers whose neonate had hyperbilirubinemia and required DSPT did not receive any dose of antenatal corticosteroids. 46.3% of the mothers received 1 dose of antenatal corticosteroid and 46.3% of them received 2 doses of ACS when neonates had hyperbilirubinemia. On the other hand 14.3% of the mothers whose neonate required double volume exchange transfusion did not receive any dose of antenatal corticosteroids. 35.7% of the mothers received 1 dose of antenatal corticosteroid and 50% of them received 2 doses of ACS when neonates required double volume exchange transfusion.

Table 1: Number of corticosteroid doses received by the mothers and CBG level at 0 hour, after 12 hours, and after 24 hours, Transcutaneous Bilirubin level, DSPT and DVET requirement. (n=99)

Number (%)		0 dose	1 dose	2 doses	Total
		Number (%)	Number (%)	Number (%)	
0 hr CBG	Hypoglycaemia	0(0)	2(50)	2(50)	4(100)
	Normal	21(22.1)	36(37.9)	38(40)	95(100)
12 hr CBG	Hypoglycaemia	0(0)	0(0)	0(0)	0(100)
	Normal	21(21.2)	38(38.4)	40(40.4)	99(100)
24 hr CBG	Hypoglycaemia	0(0)	0(0)	1(100)	1(100)
	Normal	21(21.4)	38(38.8)	39(39.8)	98(100)
Average TCB level	Hyperbilirubinemia	3(7.3)	19(46.3)	19(46.3)	41(100)
	Normal	18(31)	19(32.8)	21(36.2)	58(100)
DSPT Requirement	Yes	3(7.3)	19(46.3)	19(46.3)	41(100)
	No	18(31)	19(32.8)	21(36.2)	58(100)
DVET Requirement	Yes	2(14.3)	5(35.7)	7(50)	14(100)
	No	19(22.4)	33(38.8)	33(38.8)	85(100)

Discussion

In this study, an association between antenatal treatment with corticosteroids and neonatal hypoglycemia and hyperbilirubinemia is established. Though the association between corticosteroid treatment and hypoglycaemia in neonates is not significant, it is found to be significant between neonatal hyperbillirubinaemia and corticosteroid use.

Previous studies by Spencer G Kuper et al.[11] on 2017 and John Ryan G et al.[12] on 2018 had not found any significant association between antenatal corticosteroids and neonatal hypoglycaemia.

However studies by Roy Zigron et al. on 2017, NurunUstun et al. on 2020, Olivia Jansen et al. on 2021[13-15] shows the significant association between antenatal cortico steroids and neonatal hypoglycaemia.In the present study 71.7% of mothers had received antenatal cortico steroids and only 4% neonates had hypoglycaemia which is considered as insignificant with p value=0.27.

A study by EyalKrispin et al[16] on 2018 shows no significant association between antenatal corticosteroids and neonatal hyperbilirubinemia. On the other hand, studies by Kate E Petit etal[17]On 2013 shows significant association between antenatal cortico steroids and neonatal hyperbilirubinemia. Present study showed a significant association between antenatal corticosteroids and neonatal hyperbilirubinemia (p value= 0.017) which requires further treatment in the form of DSPT and DVET.

The advent of routine corticosteroid administration to mothers at high risk for impending preterm delivery was an incredible milestone in the field of obstetrics. Since the sentinel study by Liggins and Howie in 1972,[4] many studies have been conducted to identify the short and long term neonatal effects of antenatal corticosteroids. However neonatal metabolic derangements after maternal betamethasone administration have only been evaluated in small trials. In 1979, a study reported on 23 preterm infants exposed to antenatal betamethasone and 52 control preterm infants and showed that there was no difference in the rates of hypoglycaemia or the mean glucose level at 2-8 hr of age [18]

Though this study shows significant association of hyperbilirubinemia with dexamethasone-exposure, these results are not at all intended to discount the substantial improvement in perinatal morbidity and mortality associated with antenatal corticosteroids. So instead of curtailing antenatal corticosteroid use there should be more emphasis and preparedness to combat possible hyperbilirubinaemia in case of dexamethasone exposure in antenatal period.

Conclusion

Antenatal corticosteroid administration is not significantly associated with neonatal hypoglycaemia but it is significantly associated with neonatal hyperbilirubinemia .

Conflict of Interest: Nil

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Original Article

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Knowledge and Attitude towards Palliative Care among Nursing Students in Imphal West

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Abstract

Context: Palliative care increases comfort by lessening pain, controlling symptoms and lessening stress for the patient and family.Having adequate knowledge with proper attitude and practice among nurses is crucial to establish a good palliative care service.

Aims: Hence the study has been contemplated which aims at identifying the level of knowledge and attitude of nursing students.

Methods: A self-administered questionnaire containing a validated instrument 'Palliative care quiz for nursing (PCQN) was use. A stratified two-stage cluster sampling design with a probability proportionate to size was used. Data was collected from 430 students and entered in IBM SPSS version 21. Results were summarised using descriptive statistics. Chi-square test was used to see the significant difference between proportions.

Results: Knowledge was inadequate in 60.2% of the nursing students while 82.1% showed favourable attitude. There was significant association between academic year and knowledge for BSc nursing and FHW/ANM students. Knowledge was significantly associated with training received and attitude

Conclusion: Knowledge was inadequate in three-fifth of the nursing students while majority of them more than four-fifth showed favourable attitude. There was significant association between academic year and knowledge for BSc nursing and FHW/ANM students.Knowledge was significantly associated with training received and attitude.

Keywords: Palliative care,Nursing students,Knowledge, Attitude,

Introduction

WHO defines palliative care as an approach that improves the quality of life of patients and their families facing the problem associated with life threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.[1] Palliative care can be provided across multiple settings including in hospitals, at home, as part of community palliative care programmes and in skilled nursing facilities. Interdisciplinary palliative care teams work with people and their

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families to clarify goals of care and provide symptom management, psycho-social, and spiritual support.[2] Palliative care increases comfort by lessening pain, controlling symptoms and lessening stress for the patient and family and should not be delayed when it is indicated.[3] As disease progresses, continuity of care becomes increasingly important, coordination between services is required and information must be transferred promptly between professionals in the community, in hospitals and in hospices.[4] Palliative care provides relief from pain and other distressing symptoms and will enhance quality of life and may also positively influence the course of illness.[5]

Having adequate knowledge with proper attitude and practice among nurses is crucial to establish a good palliative care service. Even though there are studies on palliative care knowledge in different population and settings in India, only few have been conducted among nursing students. With this background the present study has been contemplated which aims at identifying the level of knowledge and attitude of nursing students .

Methods

Study Design: Cross-sectional study

Study Setting:

Nursing colleges in Imphal West district, Manipur. Total number of students studying in these nine nursing colleges was one thousand forty.

Study Population:

Students of Bachelor of Science (BSc) in Nursing, General Nursing and Midwifery (GNM) and Female Health Worker/Auxillary Nursing Midwifery (FHW/ANM) nursing colleges of Imphal West district.

Exclusion Criteria:

- Those who were absent during data collection
- Those who refused to participate

Sample Size:

Sample size was calculated based on the formula:

$N= 4PQ/L^2$

Taking a prevalence of adequate knowledge on palliative care among nursing students as 20.5% [KarkadaS et al[6]], 5% absolute allowable error at 95% confidence interval,. design effect of 1.5 and estimating a non-response rate of 10%, final sample size was 430.

Sampling Design:

A stratified two stage cluster sampling design was used to select a representative sample..There were nine nursing colleges in Imphal West district, Manipur. The colleges were stratified based on the different nursing courses namely - (1) GNM colleges (2) BSc nursing colleges and (3) FHW/ANM colleges. Twenty nine percent of the students from GNM colleges, fifty percent from BSc nursing colleges and twenty one percent from FHW/ANM with almost equal representation from all academic years were selected by simple random sampling based on probability proportionate to size using computer generated random numbers.

Study Variables

Outcome variable

1. Knowledge of palliative care
2. Attitude towards palliative care

Independent variable

1. Age ,Sex, type of course- B.Sc. nursing, academic year, experience in caring for terminally ill,training in palliative care

Study Tool:

A self-administered, pretested questionnaire was used for data collection which consist of three sections.

Part A: Background characteristics

Part B: Statements to assess knowledge of palliative care using validated instrument 'Palliative care quiz for nursing' (PCQN). PCQN is a 20 item questionnaire with three subscales including: **(1)** philosophy and principles of palliative care **(2)** management of pain and symptoms and **(3)** psychosocial and spiritual care Each item has the choices of "true", "false", and "I do not know". The internal consistency of the questionnaire was 0. 78 as

measured using Kuder Richardson formula 20 (KR-20).[7]

Part C: Ten statements to assess the attitude of the participants by using a five point-Likert scale

Operational Definition:

Knowledge scoring

The knowledge item answers were scored as one for correct and zero for wrong or do not know responses. The score ranged from 0-20 and the mean obtainable score was 10. Participants were said to have adequate knowledge when they scored more than the mean obtainable score of 10.

Attitude scoring

Each attitude statement was given a scale of 1-5 against their option (strongly disagree/disagree/uncertain/agree/strongly agree).

Favourable attitude: Score ≥ 35 (70% of maximum obtainable score)

Unfavourable attitude: Score < 35

Data Collection

A written permission was sought from the nursing college principals prior to the initiation of the study. The participants were approached in their respective colleges. Data was collected using the questionnaire.

Data Analysis

Data were entered in IBM SPSS version 21 and was summarized using descriptive statistics like mean, standard deviation and percentages. Chi-square test and Independent *t* test was used. A p value of less than 0.05 was considered significant.

Results

Out of the total 430 students, there were 125 GNM students, 215 BSc Nursing and 90 FHW/ANM students. Mean age of the participants was 20.10 ± 1.57 years with minimum age of 18 years and maximum age of 25 years.. Majority of participants were females (98.6%). Only 28.6% of participants had experience in caring for terminally ill. Only 21.4% of the participants had received training in palliative care..It was found that knowledge was inadequate in three-fifth (60.2%) of the nursing students .There was significant association between academic year and knowledge for BSc nursing students and FHW/ANM students which suggested that knowledge increased with academic year.

Table 1: Association between academic year and knowledge for different types of courses

A. GNM

Academic year	Knowledge of palliative care		p-value
	Adequate n (%)	Inadequate n (%)	
1st year	8 (23.5)	26 (76.5)	0.175
2nd year	15 (33.3)	30 (66.7)	
3rd year	20 (43.5)	26 (56.5)	

B. Bsc Nursing

Academic year	Knowledge of palliative care		p-value
	Adequate n (%)	Inadequate n (%)	
1st year	9 (18.8)	39 (81.3)	< 0.001
2nd year	5 (8.9)	51 (91.1)	
3rd year	35 (62.5)	21(37.5)	
4th year	43 (78.2)	12 (21.8)	

C. FHW/ANM

Academic year	Knowledge of palliative care		p-value
	Adequate n (%)	Inadequate n (%)	
First	13 (27.1)	35 (72.9)	**0.007**
Second	23 (54.8)	19 (45.2)	

There was significant association of training received in palliative care with knowledge(Table 2),. There was no significant association of knowledge with gender, age or experience in caring for terminally ill.

Table 2: Association between any training received in palliative care and knowledge

Any training received in palliative care	Knowledge of palliative care		p-value
	Adequate n (%)	Inadequate n (%)	
Yes	63(68.5)	29 (31.5)	< 0.001
No	108 (32)	230 (68)	

Majority of them (82.1%) showed favourable attitude towards palliative care.There was significant association of attitude with experience in caring for terminally(Table 3). Association of knowledge and attitude was also found to be significant(Table 4).

Table 3: Association between experience in caring for terminally ill and attitude towards palliative care

Experience in caring for terminally ill	Attitude towards palliative care		p-value
	Favourable n (%)	Unfavourable n (%)	
Yes	109 (88.6)	14 (11.4)	0.026
No	244 (79.5)	63 (20.5)	

Table 4: Association between knowledge and attitude towards palliative care

Attitude	Knowledge of palliative care		p-value
	Adequate n (%)	Inadequate n (%)	
Favourable	164 (46.5)	189 (53.5)	< 0.001
Unfavourable	7 (9.1)	70 (90.9)	

Discussion

In the present study majority of the participants were females (98.6%) and was found to be comparable to the study by KarkadaS et al[5] conducted among nursing students in Karnataka where 92% were females. The study addressed overall palliative care knowledge of nursing students. More than half of the participants (60.2%) had inadequate knowledge regarding palliative care. Studies conducted by KarkadaS et al[6], Mukemo et al[9] and Kassa H et al[10] found a higher proportion of participants (79.5%, 70.5% and 70% respectively) with inadequate knowledge regarding palliative care.The mean knowledge score in this study was 8.6± 2.85 while a study by Aboshaiqah AE[8] in Saudi Arabia reported a lower mean score of 5.23 while Brajtmanet al[11] found a higher mean knowledge score of 12 among Canadian nursing students.There was significant association between academic year and knowledge of palliative care for BSc nursing students (χ^2= 74.589, p<0.001) and FHW/ANM students (χ^2=7.150,p<0.007). This can also be supported from the fact that palliative care knowledge of nursing students steadily increase as they progress through their nursing education course. It was in line with the findings of Al Qadire et al[12] where knowledge increased with academic year. There was significant association of knowledge with training received in palliative care (χ^2= 40.278, p<0.001) which was comparable to the findings of the study by Aboshaiqah A[8] among nursing students in Saudi Arabia.

In the present study, 82% of participants showed favourable attitude towards palliative care. KarkadaS et al[6] reported a higher rate of 92% while only 59% of the nurses showed a favourable attitude in the study by Mukemo et al.[9] Students who had previous experience in care for terminally ill had favourable attitude towards palliative care (χ^2=4.989, p<0.0261). Association of knowledge and attitude regarding palliative care was also found to be significant (χ^2=36.850, p<0.001) thus showing that better knowledge and possessing a positive attitude go hand in hand.

Conclusion

The present study found that six out of every ten nursing students did not have adequate knowledge of palliative care. The students scored the lowest on palliative care knowledge subscale of management of pain and symptoms. Majority, that is eight in ten, however, had positive attitude towards palliative care. Experience in care for terminally ill persons favours positive attitude among the students. Knowledge and attitude towards palliative care were found to be significantly associated. Training received on palliative care and academic year were found to be significantly associated with knowledge. The need of a structured approach and an integrated curriculum involving principles of palliative care to improve the efficiency of undergraduate nursing education should be emphasized. A comprehensive education covering the basic principles of palliative care and pain and symptom management need to be validated and emphasised through various methods like theoretical teachings, practical training and workshops.

Conflict Of Interest: Nil

Source Of Funding: Self

Ethical Clearance

Ethical approval was obtained from the Research Ethics Board, RIMS, Imphal (NoA/206/REB-

Comm(SP)/RIMS//) before beginning of the study. Informed written consent was obtained from the respondents.

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Original Research Article

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Chemotherapy Induced Eosinophilia and its Significance among the Cancer Patients Treated at a Tertiary Care Teaching Hospital, West Bengal

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Abstract

Background: Cancer is a major burden and threat to global society. It is one of the leading causes of death in both developed and developing countries. The main modalities used for its treatment include surgery, radiation, chemotherapy, immunotherapy, and hormones.

Materials & Methods: The current study was performed to find incidence of chemotherapy induced eosinopillia in patients with different cancers who were receiving standard chemotherapy regimens (minimum two cycles and maximum six to eight cycles). Total leucocyte count, absolute eosinophil count and differential leucocyte count was done just before starting of chemotherapy. Differential leucocyte count (DLC) was reported after 1st cycle of chemotherapy agents, before last dose of chemotherapy, after 6 weeks of completion of chemotherapy, and after six month of completion of chemotherapy to see the changes on eosinophil counts.

Results: Most commonly used anticancer agents were 5 FU 61 (61%), doxorubicin 43 (43%), cyclophosphomide 53 (53%), cisplatin 10 (10%), paclitaxel 20 (20%), carboplatin 25 (25%), gemcitabine 11 (11%), oxaliplatin 14 (14%) and capecitabine 11 (11%). The pre-CT eosinophil count had a mean of 3.41 (range, 2 to 4) and post-CT after 1st dose had a mean of 5.06 (range, 3 to 8) ($p < 0.0001$). The pre-CT eosinophil count had a mean of 3.41 (range, 2 to 4) and post-CT after 6 months of chemotherapy had a mean of 6.85 (range, 5 to 8) ($p < 0.0001$). Increased eosinophil count after 1st dose and 6 months completion of chemotherapy was highly significant from baseline values ($P < 0.0001$).

Conclusion: Study has generated a hypothesis that administration of many anticancer agents may increase eosinophil count or peripheral eosinophilia. Additional large scale prospective studies must be performed to confirm our results.

Keywords: Cancer chemotherapy, chemotherapy induced eosinophilia, drug reaction with eosinophilia and systemic symptoms (DRESS), West Bengal

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Introduction

Eosinophils are predominantly tissue dwelling cells and express a specific chemo-attractant receptor and respond to a specific chemokine, eotaxin. They are moderately effective as a phagocyte for bacteria, yeast and protozoa but less effective than neutrophils.[1] The major function of eosinophil as a cytotoxic cell is against helminthic infections. Eosinophils can kill a wide variety of helminthic worms especially in their larval stages, by depositing cationic proteins on the surface of the parasite.[2] Conventionally eosinophils have been considered as an end-stage cells involved in host protection against parasites. Numerous lines of evidence however have now changed this perspective by showing that eosinophils are pleiotropic multifunctional leukocytes involved in initiation and propagation of diverse inflammatory responses, as well as modulators of innate and adaptive immunity.[1]

As a key player of the immune system eosinophils play an important role in combating parasitic infections in vertebrates and potentially cancer cells. Eosinophils secreted chemokines and other cellular mediators participate in immunomodulation and tissue remodeling. Study published in the Journal of Clinical Oncology examined the relationship between eosinophils in peripheral blood and the incidence of colorectal cancer.[3] The researchers found that a higher number of peripheral blood eosinophils were associated with a reduced risk of dying from colorectal cancer, especially in patients who never smoked and in males.[4]

Chemotherapy has dramatically changed the outcome of cancer patients. Despite this success, word of caution regarding toxicities of antineoplastic drugs deserves highlighting. It is vital to recognize these toxicities. Drug hypersensitivity should always be considered as a cause for unexplained eosinophilia. The list of agents is extensive and includes dietary supplements and herbal remedies.[5] The clinical manifestations associated with drug-induced eosinophilia range from asymptomatic to life-threatening.[5] Rarely a drug reaction with eosinophilia and systemic symptoms (DRESS syndrome) occurs 3-6 weeks after the introduction of a new drug. This syndrome is characterised by a triad of a skin eruption, fever and internal organ involvement (lung, liver, kidneys, lymph nodes or heart).[6, 7] Drug-induced vasculitis and eosinophilia is also reported, manifesting with purpura, arthralgia and myalgia with possible kidney and lung involvement.[8]

The approach to the identifying the cause of marked, persistent eosinophilia after cancer chemotherapy is a challenging problem. Excluding many causes of marked peripheral blood eosinophiliais required for making the diagnosis of cancer chemotherapy induced eosinophilia.

We hypothesized that drug-induced blood eosinophilia, probably underreported, could be a biological sign of hypersensitivity reaction, and could also predict severe delayed visceral hypersensitivity reactions. Keeping this in view, the present study will be undertaken to find out the incidence of chemotherapy induced eosinophilia, impact on absolute eosinophil count before and after cancer chemotherapy and the causality assessment for estimating the strength of relationship between drug(s) exposure and occurrence of eosinophilia inpatients admitted in Bankura Sammilani Medical College and Hospital.

Materials & Methods

A hospital OPD based prospective observational study was done Dec 2018– Nov 2019 in the Department of Chemotherapy and Department of Pathology. Approx 100 or more cases of cancer patients under cancer chemotherapy on day care basis were collected by simple random sampling procedure. There was variation in the inflow of cancer patients in Chemotherapy OPD at Bankura Sammilani Medical College and hospital. Moreover only day care basis cancer chemotherapy had been provided to cancer patients. So we had fixed 100 patients for logistic reasons.

Inclusion Criteria: The study was aimed to conduct among the patients who are seeking treatment in the chemotherapy department and on day care basis cancer chemotherapy with those who understood the purpose of the study and are ready to provide information regarding their health status and those who signed an informed consent document. Patient who have no prior eosinphilia during treatment seeking or have no prior hematological

malignanicies or have no blood dyscrasis or parasitic infestations will be included.

Exclusion criteria:

1. Under 18 years of age
2. Contraindication to cancer chemotherapy etc.
3. Patient who have prior eosinphilia during treatment seeking or have prior hematological malignanicies or have blood dyscrasis or parasitic infestations
4. Any condition resulting in severe learning disability (e.g. brain injury) or
5. Those unable to comprehend for other reasons will be excluded from the study.

The current study was performed to find incidence of chemotherapy induced eosinopillia in patients with different cancers who were receiving standard chemotherapy regimens (minimum two cycles and maximum six to eight cycles). Blood samples were collected aseptically from each of the 100 patients' pre cancer chemotherapy and after each chemotherapy cycle. Total leucocyte count, absolute eosinophil count and differential leucocyte count was done just before starting of chemotherapy. Differential leucocyte count (DLC) was reported after 1st cycle of chemotherapy agents, before last dose of chemotherapy, after 6 weeks of completion of chemotherapy, and after six month of completion of chemotherapy to see the changes on eosinophil counts. Absolute eosinophil count was also done after completion of cancer chemotherapy. Initially, all patients should have a full blood count performed and a blood film examined. This is to verify the eosinophil count because hypogranular eosinophils may not be counted accurately by automated counters. In patients who are otherwise well with mild to moderate eosinophilia between 0.5 and 1.5x 10^9/l, further testing may not be indicated. Patients with systemic symptoms or those with persistent eosinophilia (at least 1.5x 10^9/l), with or without suspected organ damage, should be considered for additional testing for primary and secondary causes of eosinophilia and for evaluation of organ damage.

Data was compiled in MS Excel, and then was presented as descriptive statistics mean and standard deviation. The statistical analysis was performed using SPSS version 19.0. Analysis of demographic data was done by Chi-square test and a "p-value" of less than 0.05-which was considered statistically significant.

Results

The study was conducted under the purview of Bankura Sammilani Medical College and hospital, a tertiary care hospital in Bankura District, West Bengal in the Department of Chemotherapy and Department of Pathology. About 100 or more cases of cancer patients under cancer chemotherapy on day care basis were collected by simple random sampling procedure.

Table 1: Distribution of different cancer patients under chemotherapy [n=100]

Type of malignancy or cancer	Number of cases	Percentage
CA Breast	40	40%
CA Lung	09	9%
CA Colon	05	5%
CA Gallbladder	07	7%
CA Testis	05	5%
CA Cervix	02	2%
CA Ovary	05	5%
CA Stomach	04	4%
CA Rectum	02	2%
CA Rt. Supraglottic mass	03	3%
CA prostate	02	2%
CA Penis	1	1%
Multiple Myeloma	2	2%
Miscellaneous malignancy	13	13%
Total	100	100%

There were 100 cancer patient's records reviewed at the tertiary care hospital pre and post cancer chemotherapy (CT). Among them 37 (37%) were males and 63 (63%) were females. Mean age of the participants was 49.86 (13.90). Minimum age was 16 and maximum was noted 76 years. Majority of patients fell in the age group of 35-64 years. Male to female ratio was 0.59:1. Cancer breast (40%) was leading site of cancer among participants for chemotherapy followed by cancer lungs (9%), cancer gallbaldder (7%), and cancer colon, cancer testis, cancer ovary (5%)[Table 1].

Table 2: Pattern of anticancer therapies used [n=100]

Anticancer agents	Number of pts prescribed (%)
Injection 5 FU	61 (61%)
Injection Doxorubicin	43 (43%)
Injection Cyclophosphomide	53 (53%)
Injection Cisplatin	10 (10%)
Injection Etoposide	6 (6%)
Injection Bleomycin	6 (6%)
Injection Paclitaxel	20 (20%)
Injection Carboplatin	25 (25%)
Injection Docetaxel	2 (2%)
Injection Gemcitabine	11 (11%)
Injection Oxaliplatin	14 (14%)
Tab. Capecitabine	11 (11%)
Injection Rituximab	2 (2%)
Injection Bendamustine	1 (1%)
Injection Actinomycin D	1 (1%)
Injection Methotrexate	1 (1%)
Injection Epirubicin	3 (3%)
Injection Iminodecan	1 (1%)
Tab. Thalidomide	2 (2%)
Injection Bevacizumab	2 (2%)
Injection Zoledronate	1 (1%)
Injection Leuprolide	1 (1%)
Tab Bicalutamide	1 (1%)
Injectable formulations	20
Tablets or syrup or suspension	03

Most commonly used anticancer agents were 5 FU 61 (61%), doxorubicin 43 (43%), cyclophosphomide 53 (53%), cisplatin 10 (10%), paclitaxel 20 (20%), carboplatin 25 (25%), gemcitabine 11 (11%), oxaliplatin 14 (14%) and capecitabine 11 (11%). Majority cases injectable preparations were administered. Only in 3 patients oral formulations of anticancer agents were administered Majority of the cancer patients had received 3-drugs regimen 75% followed by 2-drugs regimen 13% and 4-drugs regimen 11% [Table 2].

Table 3: TLC values before and after cancer chemotherapy

	TLC before chemotherapy [/cmm]	TLC after chemotherapy [/cmm]
Number of values	100	100
Minimum	6000	3000
25% Percentile	7225	3800
Median	8200	4200
75% Percentile	9175	4700
Maximum	10000	7200
Mean	8172	4311*
Std. Deviation	1096	721.4
Std. Error	109.6	72.14
Lower 95% CI	7954	4168
Upper 95% CI	8390	4454

The blood cell data was evaluated before and after the chemotherapy (CT). The pre-CT leukocyte count had a mean of 8172/uL (range, 6000/uL to 10000/uL) and post-CT leukocyte count had a mean of 4311/uL (range, 3000/uL to 7200/uL) ($p < 0.0001$) (Table 3). There was reduction in the total leukocyte count after completion of cancer chemotherapy ($p < 0.0001$). *P value and statistical significance: the two-tailed P value is less than 0.0001 when compared before and after chemotherapy. By conventional criteria, this difference is considered to be extremely statistically significant. Confidence interval: the mean of Group One minus Group Two equals 3861.000 95% confidence interval of this difference: from 3602.249 to 4119.751 Intermediate values used in calculations: t = 29.4259, df = 198, standard error of difference = 131.211

Table 4: AEC values before and after cancer chemotherapy

	AEC after chemotherapy	AEC before chemotherapy
Number of values	100	100
Minimum	120	126
25% Percentile	190.5	240
Median	218	283
75% Percentile	240	336
Maximum	336	396
Mean	220.02	279.8*
Std. Deviation	43.05	72.19
Std. Error	4.305	7.219
Lower 95% CI	211.5	265.4
Upper 95% CI	228.6	294.1

The blood cell data was evaluated before and after the CT. The pre-CT absolute eosinophil count (AEC) had a mean of 220.02 (range, 120 to 336) and post-CT AEC had a mean of 279.8 (range, 126 to 396)

(p <0.0001) [Table 4]. There was significant increase in the AEC after chemotherapy from baseline level (p <0.0001). P value and statistical significance: The two-tailed P value is less than 0.0001.

Table 5: Eosinophil count before, after 1st chemo dose and after cancer chemotherapy

	Eosinophil before chemo	Eosinophil after 1st dose chemo	Eosinophil after 6 months chemo
Number of values	100	100	100
Minimum	2	3	5
25% Percentile	3	5	6
Median	4	5	7
75% Percentile	4	5	7
Maximum	4	8	8
Mean	3.41	5.06*	6.85**
Std. Deviation	0.8177	0.9516	0.7437
Std. Error	0.08177	0.09516	0.07437
Lower 95% CI	3.248	4.871	6.702
Upper 95% CI	3.572	5.249	6.998

The pre-CT eosinophil count had a mean of 3.41 (range, 2 to 4) and post-CT after 1st dose had a mean of 5.06 (range, 3 to 8) (p <0.0001)*. The pre-CT eosinophil count had a mean of 3.41 (range, 2 to 4) and post-CT after 6 months of chemotherapy had a mean of 6.85 (range, 5 to 8) (p <0.0001)**. Increased eosinophil count after 1st dose and 6 months completion of chemotherapy was highly significant from baseline values (P < 0.0001) [Table 5].

Difference	1.650
Standard error	0.125
95% CI	1.4026 to 1.8974
t-statistic	13.151
DF	198
Significance level	P < 0.0001*
Difference	3.440
Standard error	0.111
95% CI	3.2220 to 3.6580
t-statistic	31.122
DF	198
Significance level	P < 0.0001**

Discussion

In the present study there were 100 cancer patient's records reviewed at the tertiary care hospital pre and post cancer chemotherapy (CT). Among them 37 (37%) were males and 63 (63%) were females. Mean age of the participants was 49.86 (13.90). Minimum age was 16 and maximum was noted 76 years. Majority of patients fell in the age group of 35-64 years. Male to female ratio was 0.59:1. Cancer breast (40%) was leading site of cancer among participants for chemotherapy followed by cancer lungs (9%), cancer gallbaldder (7%), and cancer colon, cancer testis, cancer ovary (5%). There were 4% cases gastric cancers, 3% cases right supraglotic malignant masses, and 2% cases multiple myeloma. About 13% cases there were miscellaneous malignancy like cancer cheek, follicular lymphoma, molar pregnancy, tongue cancer, carcinoma of head pancreas etc.

In Mathew M et al study[9], most of the patients were in the age group of 45–60 years (47%); this was in correspondence with the study carried out by Catic et al.[10], where 48% of patients were in the age group of 45–60 years. However, contradictory findings were also observed in a study conducted by Onwusah and Korubo[11] where 19.6% patients were in the age group of 61–70 years. Out of 230 patients, 51.7% were females and 48.3% were males. The study carried out by Manichavasagam et al. reported that females (54.57%) were predominant than the males (45.42%).[12] The present study is in concurrence with the reference study.

The pre-CT eosinophil count had a mean of 3.41 (range, 2 to 4) and post-CT after 1st dose had a mean of 5.06 (range, 3 to 8) (p <0.0001). The pre-CT eosinophil count had a mean of 3.41 (range, 2 to 4) and post-CT after 6 months of chemotherapy had a mean of 6.85 (range, 5 to 8) (p <0.0001). Increased eosinophil count after 1st dose and 6 months completion of chemotherapy was highly significant from baseline values (P < 0.0001).

To the best of our knowledge, circulating eosinophil counts have been reported by two studies in the literature of breast tumors. Gunduz and colleagues observed a survival benefit for patients with lower baseline eosinophil counts in a cohort of 62 HER2+ breast cancers treated with adjuvant trastuzumab.[13]

Conversely, Ownby and colleagues described a positive association between high baseline eosinophil counts and lower recurrence rates (2-year DFS rate, 21 ± 2% vs 34 ± 8%, $p < 0.02$) in 419 patients of all subtypes.[14] Better known is the impact of peripheral eosinophil count in melanoma patients treated with immunotherapy. Associations linking both high baseline eosinophil counts and increased counts during treatment, with both improved treatment response and increased survival rates, were observed.[15-17] Additionally, one report of an immunotherapy-induced increase in eosinophil count was published for lung cancer patients, but no efficacy data were presented.[18] In Onesti CE et al study, we observed a decrease in circulating lymphocyte numbers after primary treatment without significant variation at relapse. No significant impact on survival for post-surgery RLC was detected. Conversely, we observed an increase in circulating eosinophil number after surgery and a significant reduction at relapse.[19]

C.S. Spina et al study[19] hypothesized that granulocytes, including neutrophils and eosinophils, influence the immunologic response to chemoradiation therapy (CRT) and patient outcomes. Kaplan-Meier analysis demonstrated that patients with a persistently increased eosinophil count (> 150 cells/uL) 3 months after CRT lived 45% longer than patients with lower (or < 59 days confirmed that increased steroid use correlated a 35% decrease in overall survival (639 (CI 513-759) vs. 988 (856-1121) days, p<0.01), independent of initial performance status. Study demonstrates that treatment-induced increase in eosinophil count is the strongest hematologic predictor of overall survival in newly diagnosed GBM. Eosinophil count may serve as a proxy for immunologic response to therapy and thus yield more prognostic insight than ALC.[20]

Conclusion

Most of the patients were prescribed with a 3-drugs regimen anticancer drug. Most commonly used anticancer agents were 5 FU 61 (61%), doxorubicin 43 (43%), cyclophosphomide 53 (53%), cisplatin 10 (10%), paclitaxel 20 (20%), carboplatin 25 (25%), gemcitabine 11 (11%), oxaliplatin 14 (14%) and capecitabine 11 (11%). There was significant increase in the AEC after chemotherapy from baseline level (p <0.0001).

We have extensively searched published scientific documents to find out similar kind of study and to correlate. But we didn't find any of the published articles similar or identical to our study. Our study has generated a hypothesis that administration of many anticancer agents may increase eosinophil count or peripheral eosinophilia. Additional large scale prospective studies must be performed to confirm our results and to understand the mechanism by which anticancer agents increase eosinophil count which may have affect on the patient prognosis, with the goal of exploiting this natural anticancer mechanism to personalize patient treatment.

Conflict of interest: None

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Ethical Clearance: The study proposal along with other relevant documents was approved by the institutional ethical committee.

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Orbital Arteriovenous Malformations (AVM): A Review

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Abstract

Orbital arteriovenous malformations (AVM) are identified by abnormal high-flow connections between the veins and the arteries, which are often supplied by the branches of internal and external carotid arteries, also with a nidus of cellular stroma distributed between the vessels. Orbital arteriovenous malformations are rare among all congenital malformations. Pain, glaucoma, optic nerve ischemia and compression and retinal ischemia are some of the causes of enlarging orbital AVMs. Because of the rare nature of these lesions, they are usually misdiagnosed and treated improperly. For the diagnosis of such orbital AVMs, angiography becomes an essential tool. The primary method of diagnosing orbital AV malformations are non-invasive cross-sectional imaging and catheter angiography. Treatment for the same includes reducing the blood flow to the arteriovenous malformation (AVM) via preoperative embolization. And surgical resection. Complete excision is challenging because of the increased risk of involvement of the ophthalmic artery which can cause vision loss, preoperative embolization is difficult in some patients. An effective way of treating arteriovenous malformation is ethanol sclerotherapy. Diagnosing and managing Orbital AV malformations is important as these are rare and can cause permanent vision loss.

Keywords: Arteriovenous Malformations, AVMs, AFVs, infraorbital, periocular, orbital, diagnosing, lesions.

Introduction

There is a school of thought that infraorbital arteriovenous malformations (AVMs) congenital in origin may lead to major morbiditiessuch as abnormal visual development, cosmetic disfigurement, or chronic pain. Vascular malformations of the orbit have less frequent occurrence and appear to be complex and varied.[1] AVMs are an outcome of smooth muscle cell insufficiency during vein development,which often has an impact on proper functioning.Irrespective of when these lesions occur that is either at birth or later in life, they tend to increase in size as the patient grows; the symptoms associated with these lesions seem to intensify in their magnitude during hormonally active times such as growth spurts, puberty and pregnancy.

The site and location of AVMs can vary from in the orbit or the periorbital region or both. They

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have complex anatomical features concerning their clinical features and treatment. Despite beginning to manifest in early adulthood, they start developing early in the vicinity of an underlying constitutional MA differentiation of the vascular bed.[2-4] In cases of symptomatic orbital AVMs,the key featuresinclude an increase in the size of the ocular contents, periocular swelling, pulsation or bruit, proptosis, episcleral blockage, elevated intraocular pressure (IOP), pain, amblyopia, decreased extraocular movement and double vision.[4] Infraorbital AVMsare usually characterized by high flow shunts located in the anterior orbit thereby leading tobulging of the eyes, arterialise conjunctival vessels, chemosis, and periocular oedema, and were responsive to treatment modalities like intravascular embolization or surgery, or a combination of both approaches.[4]

There is significant functional morbidity, cosmetic disfigurement, and high-output cardiac failure caused by arteriovenous malformations (AVM) due to the high flow vascular anomalies and its hemodynamically active nature. Orbital AVMs being rare, require a multidisciplinary approach for diagnosis and management which is guaranteed by proper clinical examination and neuroimaging, thereby providing not only a satisfactory functional outcome but also a great cosmetic result.[5]

Clinical Features

Some common clinical signs are exophthalmos, mostly with pulsation and thrill; episcleral and conjunctivalvascular congestion; secondary glaucoma; and to different extents in the late stage, movement restrictionassociated accompanied diplopia and sometimes functional loss. When there is the involvement of orbit, arteriovenous malformations (AVMs) may present primary orbital signs, which include proptosis, chemosis, and dystopia; Secondary signs manifest as problems relatedto optic nerve function and morbidity in relation to orbital venous congestion.patients commonly show signs of periocular pain, proptosis, ptosis, periocular inflammation and swelling, decreased visual acuity, double vision, discolouration, tinnitus, and high-output cardiac failure. Due to thrombosis and intralesional haemorrhage, Orbital AVM can cause a sudden mass effect. Examination reveals dilated corkscrew vessels, pulsation, bruit, compressibility, and increased IOP. Clinically it becomes difficult to differentiate AVMs from other vascular anomalies such as carotico cavernous fistula, orbital arteriovenous fistula and cerebral AVMs with drainage into the orbital veins.[6-10] There are cases where orbital AVMs appear to be asymptomatic.

Diagnosis

In case of any suspected orbital vascular anomalies, Orbital AVM becomes an important Differential Diagnosis. Since orbital AVM require a multidisciplinary approach often including an interventional radiologist, diagnosis and management of such malformations become a challenge. It is very important to differentiate congenital vascular malformations from CHI as both present with different pathological findings and has varied treatment modalities. The diagnosis can be confirmed by imaging characteristics and histopathological findings. Angiographic study often reveals similar characteristics of Orbital AVMs and AFVs, hence demonstration of nidus becomes essential in confirming AVMs, which is not present in AFVs. Upon Valsalva manoeuvre, the orbital varix increases in size, hence it becomes important in differentiating it from orbital AVMs.Diagnosis of an AVM can be made by different imaging modalities such as dynamic arterial and Valsalva-augmented venous phase, multidetector CT angiography (DP-MDCTA), dynamic MRI, and magnetic resonance angiography.[10] The gold standard for diagnosis AVMs is DSA, which is a selective angiography technique mapping the feeder which involves the injection of contrast directly into one of its feeder vessels and digital image acquisition.[11] It not only helps in mapping the feeder vessels but also the draining veins. AVMstendto harbour new feeder vessels and they exponentially increase in size and extent of involvement. A very crucial radiographic technique to diagnose and define the exact site and extent of the lesion and assist in treatment planning is MRI with gadolinium contrast.

Management

As we have discussed earlier that proper Diagnosis and management of periorbital AVM pose a challenge and require a multidisciplinary approach the primary aim of the treatment planhappens to be

reducing the intensity of the symptoms, providing functional stabilityas well as improving aesthetics. It is very important to assess and evaluatethe risk-benefit ratio on a case-by-case basis before any interventional management of orbital AVMs. Before the management, one of the essential elements is understanding and considering the natural history of such lesions alongwith the risks of neuroradiologic and surgical interventions. Management of Orbital AVMS may be needed when the patient complains of persistent and progressive discomfort and visual disturbance. The intervention comprises stepwise observation, embolization, and surgical excision or combined pre-operative embolization and surgical excision and primarily depends on patient-specific features. [12-15] One of the main concerns in the management of AVMs happens to be the anatomical location of such AVMS as it is closely related to the central retinal artery.perioperative haemorrhage is the main of poor outcomes and it is because of its vascular nature. Current management depends on hemodynamic characteristics, vascular anatomy, and the location of lesions of AVM.

As the vascular convolutions are also supplied by the ophthalmic artery, the therapeutic plans which are normally applied for vascular deformities including surgical excision or embolization should be carried out with care in the orbit. For the embolization of brain AVMs, a non-adhesive embolic liquid agent named Squid is used. The composition of squid is ethylene-vinyl alcohol copolymer along with suspended micronized tantalum powder helpful in radiopacity and solvent namely dimethyl sulfoxide. The recommended treatment for patients with VM with minimum or no symptoms is conservative management. If surgical excision is not an option then ES is usually recommended in extensive facial VM with periorbital involvement. If sclerotherapy is not possible due to the location, Surgery can be done to debulk excessive orbital or periorbital VM or as a supplement to sclerotherapy.

Ethanol causes hypertonic dehydration of cells, protein denaturation, thrombosis, and vessel occlusion thus acting as a sclerosant.This in turn produces swelling via an intense inflammatory response.Tissue necrosis, nerve damage, pain, swelling, deep vein thrombosis, renal injury, and cardiopulmonary failure are some of the complications of ES. Nonsurgical management can include the use of various sclerosants,sodium morhuate, picibanil (OK-432), doxycycline, bleomycin, ethanol, onyx, sodium tetradecyl sulfate, acetic acid, and hypertonic saline. The sclerosant is usually chosen depending on the personal experience of the interventional radiologist of the multidisciplinary team which is involved. The response to sclerotherapy is usually better in lesions with large macrocysts. For treating this disease endovascular therapy and radiosurgery have become essential supplements. If endovascular entry to the feeding vessels can be done by negatingthe normal vessels at any major risk, it can be used for lower-grade AVMs too. Endovascular embolization is not a form of definite treatment. If endovascular therapy is used alone then the rate of total occlusion is approximated to be 10%.[12-15] There is also unknown durability of occlusion with this setting. In contrast, stereotactic radiosurgery gives an angiographic and clinical cure for many lesions.

Conclusion

Orbital AV malformations are usually difficult to detect because of their rare nature;therefore, diagnosis becomes a challenge for the clinician. But with the recent advancements and developments, diagnosing and managing the condition has become quite easy.It is quite challenging and requires an interdisciplinary team of expert physicians for a proper diagnosis and treatment. Forthe successful management of any AVMs, clinical features must be carefully analysed, and therapeutic options must be thoroughly evaluated. Diagnosing and managing Orbital AV malformations is important as these are rare and can cause permanent vision loss.

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Original Article

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A Thematic Analysis on an Exploration of Concerns of Cancer Patients and their Caregivers in the Context of the COVID-19 Pandemic

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Abstract

Background: COVID-19, a pandemic prevalent for a long time presents a multistep crisis;the first stage is an acute health crisis, followed by a healthcare recovery crisis in the second stage and a socio-economic crisis in an indefinite period. The study explores the challenges and specific concerns among patients diagnosed with cancer and their caregivers during the pandemic.

Materials and Method: Qualitative research employs specific research methods such as in-depth interviews, content analysis, observation methods, and life histories or biographies to examine people's experiences in detail. In the present study, a semi-structured questionnaire was developed and interviews were conductedto understand the experiences of cancer patients andtheir caregivers with health care and their daily challenges during the pandemic. A Non-random sampling method, involving males and females, within the age group of 18 to 65 years, and their primary care providers from the Regional Cancer Centre and other cancer hospitals are followed. Semi-structured interview responses were collected from cancer patients and their caregivers., illustrative quotes were summarised and key themes from the interviews were extracted.

Results and analysis: 9 Key themes with 20 subthemes were extracted in the content analysis. Difficulty having access to medical care, fear of infection transmission, lack of social support, loss of income source, drastic lifestyle changes, uncertainty about disease cure, and apprehension about the future,which result in cumulative disease burdenhave been frequently reported in the study.

Conclusion: The current research is relevant in describing the experiences and perspectives of cancer patients and their caregivers, throwing light on the psychosocial issues and challenges during the pandemic situation, thus emphasizing the need for developing a supportive psychosocial intervention.

Keywords: Psychosocial issues, Health care challenges during pandemic, Cancer, and Corona, Psychosocial intervention

Introduction

The pandemic-coronavirus disease (COVID-19) profoundly affected all aspects of life, such as health care, family dynamics, finance, social life, and the surrounding environment. The research

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explored the challenges during a pandemic crisis and closely examined the difficulties faced by patients diagnosed with chronic diseases like cancer who may need long-term medication and regular health assessment.[1,2]The lockdown has hindered the delivery of specialized medical services, drugs, and other healthcare needs to these patients.[3,4] While it disruptedthe lives of all in many ways, patients with chronic health problems and those who needed regular healthcare checks or procedures were the most affected. The caregivers of such patients also have to withstand the impact owing to the uncertainties and outcomes.

A study on the impact of COVID-19 on cancer patients (Zhang et al., 2020) found that 28.6% of study patients contracted the coronavirus due to nosocomial infection while hospitalized for their cancer treatment. This article describes cancer treatment given within 14 days of the COVID-19 diagnosis was reported as a risk factor for developing medical complications such as acute respiratory distress syndrome (28.6%), septic shock (3%), and acute myocardial infection (3.6%).[5] Thus, knowing the challenges and dilemmas,Tsamakis et al., 2020emphasized the screening for COVID infection and strict infection control measures in oncology units.[6] Self-isolation and quarantine are the first strategies recommended worldwide to slow down the spread of pandemics, but the restrictions also impose deliberate social isolation.[7] With little support, caregivers faced serious challenges in caring for their loved ones struggling with chronic diseases like cancer during the pandemic period (Shankar et al., 2020).[8]

The rationale of the study:

Chronic diseases like cancer present challenges in accessing medical care for ongoing treatment regimens like chemotherapy, radiation, or surgical procedures during the pandemic. Any delay in medical procedures could lead to disease progression, resulting in complications and a cumulative disease burden. On the other hand, a caregiver's dilemma is having to attend to their medical and other day-to-day needs without any social support to add to their woes. An attempt is made to explore the impact of the pandemic on cancer patients and caregivers in the present study.

Objectives of the Research

The present study focuses on the COVID-19 Pandemic, discussing psychosocial issues and challenges faced by patients diagnosed with cancer and their primary caregivers.The objectives of the research are:

1. To investigate cancer patients' difficulties and psychosocial issues during the COVID-19 pandemic phase.
2. To study caregivers' challenges and coping strategies during the pandemic period

Materials and Methods

One-on-one interviews were conducted with 18 cancer patients and their caregivers to capture in-depth information about their experiences and challenges during the prevailing pandemic period. An attempt was made to understand the psychosocial factors that play a significant role in providing quality care to cancer patients. This study also explores caregivers' challenges in coping with the prevailing pandemic situation.

Participant recruitment for qualitative interviews

A total of 36 participants, including 18 patients and their caregivers, both male, and female, within the age group of 18 to 65 years, from the Regional cancer center were recruited for the present study. Interviews facilitated by a semi-structured interview guide, lasting approximately 20–30 minutes were conducted for both groups (cancer patients and caregivers) and field notes and their responses were recorded.

Questionnaire Development

Interaction with health care providers, including doctors, nurses, and social workers, and the researcher's own experience as a medical professional attending to queries and concerns from cancer patients and their families helped to develop a semi-structured interview questionnaire. A total of twenty-four questions were included and when the tool was administered to 3 cancer patients along with their caregivers, whatever questions were not properly understood were reframed. Wherever necessary, spontaneous secondary and relevant questions were asked for better exploration. There are no positive

or negative answers andtherefore, no marks were allotted. Instead, all the participant's responses to the questions were carefully noted.

Collection of Data

Interviews were conducted by the researchers during the pandemic period. Participants were informed about the purposes and format of the interview as well as their rights, and informed consent was obtained. Socio-demographic and health questions included were direct and closed-ended, whereas open-ended questions were asked to explore their challenges and experiences during the pandemic period. The impact of the pandemic on health care, personal aspects (physical, emotional, and social), lifestyle changes, crisis if any, and their coping methods were noted. Any other factors that are important and have an impact on their lives were also included in the study.

Analysis of Data

The characteristics of the participants were summarized. The interview transcripts were reviewed and given numbers to maintain patient confidentiality and ensure transcript completeness and accuracy. The data underwent "thematic analysis" following a prescribed coding framework involving the extraction and review of excerpts, with new codes added as themes and concepts emerged from the data. Key themes and sub-themes related to patient experiences and caregivers' challenges during the pandemic were summarised and illustrative interview quotes were used to support the key findings identified from the interview transcripts.

Results

Sample characteristics: qualitative interviews

Interviews were conducted with 18 cancer patients from the regional cancer center and private hospitals along with their caregivers. There are 10 female and 8 male cancer patients in the given sample. The majority of participants in the caregiver's group were female, with the formal education of tenth or twelfth grade only, from a lower or middle socioeconomic status, and rural (12) as well as urban (6) areas. The mean participant age of cancer patients is 46 years old, and that of caregivers is 58 years old. Despite common responses by the participants, there were differences found in symptoms, contributors, coping, and progression of illness among cancer patients and their caregivers.

The transcribed data (semi-structured interview) was segmented, and responses were carefully analyzed and coded into sub-themes (20) and themes (9). Below are the illustrative quotes that describethe Interview participant's experiences and verbal responses on the impact of COVID- 19.

Key themes (Subthemes)are derived from the Illustrative Quotes. Here, (P) refers to cancer patients and (C) refers to Caregivers.

1. Healthcare needs & availability

(Access to medical information, Access to treatment, and Availability of drugs & healthcare resources during the pandemic)

(P) 'I have no idea when I will have my next treatment.

(P) 'It was miserable and I couldn't tolerate the pain and wanted to go to the hospital,' said a patient.

(C) 'We were trying to connect to the hospital several times, but they didn't answer.

(C) 'Where would we get medicine from during lockdown? Medicines for pain (morphine) are not available outside.

(C) "Buses or other transport were not available to travel to the hospital," remarked a caregiver.

2. Fear of infection

(Fear of corona infection, Expressed anxiety/ worry, Distress)

(P) One lung cancer patient anticipated the risks. I think all the treatment will go to waste if I get infected with the coronavirus. It may lead to serious complications and I may infect others too.

(P) Another participant commented, "If not for COVID, cancer would kill me."

(C) A lady expressed her fear of infection to her son as he is undergoing chemotherapy for cancer at a private hospital. She said, "What if he gets a Corona from the hospital itself?" I am tense and don't know what is right and what could go wrong at any time.

(C) "My parents are very old and there is always a risk of infection transmission to them."

(C) Another caregiver was anxious and upset about hospitals' not taking enough precautions and allowing the mixing of staff from the COVID Ward to the Oncology Block. "The hospital having a COVID block in the nearby premises is a threat to my family," he said.

3. Social challenges

(Lack of social interaction, reported lack of social support)

(P) "Sitting alone all day without even seeing someone and having nothing to do is very frustrating", a young cancer patient responded.

(C) 'I can't even get my parents home for some support due to the pandemic situation.'

(C) Due to the pandemic, even my helper is not coming and I can't seek any relative's help. I am so tired and left with no time for myself".

(C) 'Having no help from anywhere during a pandemic is tough', said a caregiver.

4. Financial challenges"

(Loss of business /income source/Loss of job)

(P) "I have applied for long-term leave and have had no salary for the past 4 months, said a cancer patient who is undergoing radiation treatment".

(C) A caregiver said, 'owing to a pandemic, our Kirana shop is closed and my elder son gets only half his salary.'

(C) 'We are left with very little money having no daily wage work and worried about my wife's treatment for breast cancer, a caregiver expressed.

5. Work-life balance"

(Challenges of working from home, online classes for children, managing office work and domestic chores)

(C) A caregiver expressed her woes that 'working from home and managing things at home is a double challenge'.

(C) 'Attending children having online classes and me working from home and taking care of my husband diagnosed with Prostate cancer is somewhat difficult.

6. Lifestyle disruption

(Procurement of Items,Lifestyle changes, Absence of Leisure activity)

(P) One cancer patient expressed his difficulty, 'I can't go out to buy any essentials even from nearby shops.

(P) Another patient said, 'I can't go out with my friends for my regular walks. I am always sitting at home.

(C) "There is no leisure activity when you work from home and it's like full-time work", remarked a caregiver.

7. Difficulty in adaptation to pandemic protocols

(Using face mask &sanitizer)

(P) One elderly patient diagnosed with lung cancer expressed anguish over the pandemic situation. He said 'I feel suffocated using masks all the time and even seeing others in masks makes me feel anxious.'

(C) "It is difficult to wear a mask and sanitize premises now and then".

8. Strategies of management

(Dealing with the changes and adjustment, self-care regime)

(P) 'I take precautionary steps such as using a mask, sanitizer very often and strictly avoids public places which are very crowded' as told by a breast cancer patient.

(C) A caregiver expressed, 'We regularly do self-care practices like yoga and breathing exercises. Also, we eat a nutritious diet and herbal supplements to boost our immunity.'

9. Fear of uncertainty

(Uncertainty & dilemma about the future)

(P) A lung cancer patient asked, 'What's more deadly Cancer or Corona? When will it get in control?'

(C) Caregiver expressed their concern, 'I have no idea whether the situation will improve or worsen with time?'

Apart from these responses, two of the patients

reported that they had received a phone call from a private Cancer Hospital and there was no delay in their scheduled chemotherapy session. "My treatment went smoothly, and the hospital had taken screening as well as proper safety measures." "Our medical records were sanitized and the premises were disinfected," said a caregiver.

Key themes that emerged in the study are health care needs and availability, fear of infection, social & financial challenges,work-life imbalance, lifestyle disruption,difficulty in adapting to covid protocols,strategies of management, and fear of uncertainty.

Figure 1. Themes from the Interview participant's responses (N=18)

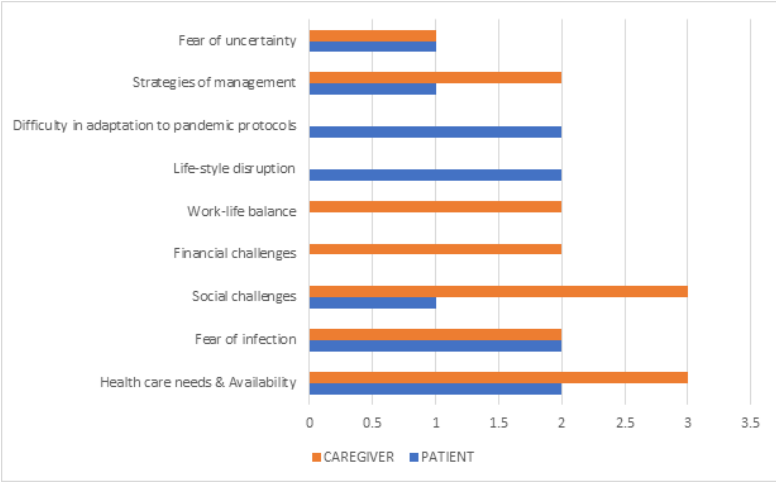

Figure 1: Represents nine key themesthat emerged in the study (comparing the verbal quotes from cancer patients and caregivers).

Discussion

The present study provided valuable insight into patients' and caregivers' perspectives on dealing with the dual challenges of cancer and corona. Healthcare needs, availability, and lack of social support are the most commonly reported symptoms by 6 cancer patients and their caregivers (33.3%). Difficulties in transport, procurement of medicines, and delays in treatment are the main difficulties reported by 10 caregivers, most of whom are located in remote or rural areas (55%). On the other hand, 6 patients reported having symptoms of pain and fatigue (33%), 2 patients reported disruption in lifestyle (11%), as well as difficulties adhering to COVID protocols (11%). Fear of infection, as well as fear of uncertainty, is expressed by 2 cancer patients and 3 caregivers (14%). Lack of social support and loss of an income source is burdensome, creating anxiety and deep worry, majorly reported by 6 caregivers (33%) in the present study.

Research provides supportive evidence that the potential mental health effects of COVID-19 might be associated with the primary effects of epidemic disease outbreaks as well as secondary effects of economic recessions and depression, loneliness, quarantine, and social isolation.[9-11]During the pandemic, the World Health Organization and most governments strongly advised people to stay at home and be safe. As a result, a large proportion of the population who lived alone had mental health concerns during this period. Prolonged periods of domestic confinement can lead to an increased prevalence of post-traumatic stress disorder, loneliness, boredom, and anger during and after quarantine.[12] Research(Matias, Dominski,& Marks, 2020) largely supports and rationalizes human needs in COVID-19 isolation. [13]Williams, Morelli, Ong, & Zaki,2018, describes in their study that being connected with others fulfilled self-affiliation, thus helping people to regulate their emotions, cope with stress and remain resilient.[14] It is evident that during the lockdown, unmet self-protection needs may cause systematic frustration of a deep-seated need to ensure the protection of self and family. It may induce fear, anxiety, and distress, and is also associated with insomnia, irritability,

and aggression. A sense of loss experienced in society due to the loss of direct social contact in multiple forms, such as loved ones, employment, education opportunities, social support, relaxation, and recreation, is reported.[15-16] The present study describes the challenges of having no social support and the psycho-social impact of Corona on cancer patients and their families.

Working in a lockdown phase during a pandemic from home had its challenges, according to research (Kumar, Kumar, Aggarwal, &Yeap, 2021)on COVID-19-induced work stress, job performance, distress, and life satisfaction.[17] Ashforth, Kreiner, & Fugate, 2000 explain in their study thatemployees who worked from home, shared household responsibilities, and switched from one role to another while being distracted by thoughts, emotions, or demands associated with another role be extremely frustrating.[18] According to the responses of the caregivers, this appears to be primarily a concern (Table 1). In the present study, caregivers majorly reported complaints of working from home, facing challenges sharing household responsibilities, family obligations, and work commitments, and missing work-life balance during the lockdown phase of COVID-19. Role overload, family distraction, changes in lifestyle choices, and occupational discomfort were significant predictors of distress during the lockdown. Life satisfaction has been reduced due to a significant increase in distress levels and lowered job performance. Pfefferbaum& North, 2020 reported in their study thatit is important to monitor vulnerability such as pre-existing physical or psychological conditions for medical evaluation, and supportive intervention such as psychoeducation and cognitive behavioral techniques to enhance coping is emphasized.[19]

Conclusion

Research studies suggest that interventions include online psychological support and psychological first-aid, imparting education through Telepsychology. This also explains that interventions based on technological tools and programs to mitigate the effects of the pandemic are the 'new normal. [20]Telemedicine emerging as the new perspective of well-being to address the several psycho-social concerns of patients and caregivers,[21-22] and psychosocial interventions designed to meet the needs of the patients and caregivers need to be focused.[23] Practical approaches such as educating people and creating awareness about the current pandemic situation, creating access to medical care and psychological support, and information from reliable sources are emphasized in the study.

Conflicts of Interest: There are no conflicts reported for the study and the research is not funded by any source.

The study fulfills the ethical guidelines and has taken permission from the parent institution and hospital authorities. Necessary information was provided and informed consent was given to the participants.

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Original Article

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Study of Pulmonary Function Tests in Rheumatoid Arthritis Patients and to Establish Correlation between Pulmonary Function and Disease Activity of Rheumatoid Arthritis in Eastern India

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Abstract

Background: Pulmonary involvement is one of the most common extra-articular manifestation of rheumatoid arthritis (RA) and the second common cause of death due to infection. Pulmonary function tests are widely used to provide objective measure of lung function for detecting and quantifying pulmonary impairments.

Material & Methods: This study was hospital based cross sectional nonintervention study. About 100 patients of rheumatoid arthritis have been selected from Rheumatology Clinic (OPD) of R. G. Kar Medical College and Hospital according to the ACR/EULAR diagnostic criteria, 2010. All patients were undergone for Hb% estimation, ESR determination, estimation of serum RA-factor, C-reactive protein and ACPA. Disease Activity of RA had determined by DAS-28 calculator. All cases and controls are undergone lung function test by means of electronic spirometer in the Department of Physiology of the same institute.

Results: In our study 82% cases were female and 18% cases were males. In our study we got significant changes in lung function of the RA patients. FVC, FEV1, PEFR and FEF 25-75% etc. were significantly deteriorated, (p-value<0.0001). About 44% cases showed evidence of restrictive type of pulmonary function abnormality, it was significant (p-value<0.05) whereas only 2% cases show evidence of obstructive type of abnormality, which was not significant (p-value>0.05). There was definite correlation between disease duration and disease activity with abnormal pulmonary function, (p-value<0.0001).

Conclusion: Therefore from the summary of this study, we can understand that lung function parameters can be used to stratify abnormalities in a clinically useful manner and lung function tests can be used as indicator of

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disease activity of rheumatoid arthritis. So all patients of RA should undergo PFTs to detect abnormality and by this way we can reduce morbidity and mortality of RA patients due to subclinical or overt pulmonary dysfunction.

Keywords: Rheumatoid arthritis (RA), DAS-28 disease activity score, pulmonary function test (PFT), rheumatoid factor, C-reactive protein, Anti-citrullinated protein antibody (ACPA)

Introduction

Rheumatoid arthritis (RA) is most common inflammatory arthritis affecting 1% of general population.[1] R A is a chronic multisystem disease of unknown etiology.[2, 3] Although there are a variety of systemic manifestations[4], the characteristic feature of established R A is persistent inflammatory synovitis, usually involving peripheral joints in a symmetric distribution. The potential of the synovial of the synovial inflammation to cause cartilage damage and bone erosion and subsequent change in joint integrity is the hallmark of the disease. Despite its destructive potential, the course of R A can be quite variable. Some patients may experience only a mild oligoarticular illness of brief duration with minimum joint damage, but most will have a relentless progressive polyarthritis with marked functional impairment.[4, 5]

The disease is more common in females as compared to males (female: male ratio is 3:1). The prevalence increases with age, and sex differences diminish in the older age group. The onset is most frequent during the fourth and fifth decades of life, with 80% of all patients developing the disease between the ages of 35 and 50. The clinical manifestations of rheumatoid disease are highly variable, but joint symptoms usually predominate.

Although acute presentations may occur, the onset of articular signs of inflammation is usually Insidious, with prodormal symptoms of vague periarticular pain or stiffness. The characteristic presentation of rheumatoid arthritis is pain, swelling and stiffness of involved joints. Joint involvement is usually symmetrical. Symmetric swelling of multiple joints with tenderness and pain is characteristic for RA.[5] The extra-articular manifestations in patients of RA include haematological abnormalities, vasculitis, pulmonary, cardiac and ophthalmic complications.[6]

Little is known regarding the development of these extra-articular manifestations. An abnormal autoimmune response, genetic factors, some environmental or biological factors, such as viral infection or hormonal changes is known to be trigger of RA. Pleuro-pulmonary involvements followed by its manifestations are one of the most common extra-articular manifestation of RA and second cause of death by infection. Interstitial lung disease is the most common and serious form of the lung involvement in RA. Radiographic change like fibrosis and physiological changes such as restriction or decreased diffusing capacity on pulmonary function test may occur in RA.[7-9] Though RA produces restrictive type of lung disease but recent studies show that RA can produce obstructive type of pulmonary disease also.[10] Different previous studies in cases of RA show that abnormal pulmonary function.

Besides this, other manifestations are pulmonary fibrosis, pleurisy and pleural effusion. There are very few Indian studies documenting respiratory system involvement in RA. Therefore the present study undertaken to evaluate pulmonary function test abnormalities in diagnosed cases of RA and correlation between lung function with disease activity of RA.

Aims & Objectives

Pulmonary involvement is one of the most common extra-articular manifestation of RA and the second common cause of death due to infection. Pulmonary function tests are widely used to provide objective measure of lung function for detecting a quantifying pulmonary impairment. This study was conducted to see pulmonary function tests in diagnosed rheumatoid arthritis cases, compare it with age sex matched apparently healthy control, and to see any correlation between lung function parameters and the disease activity.

Materials & Methods

Study area: Study was conducted at Department of Physiology, RG KAR Medical College and Hospital Kolkata, Rheumatology Clinic, Department of Medicine, RG KAR Medical College and Hospital, Kolkata.

Study population (Inclusion Criteria): Both male and female (age not less than 20 years and not more than 65 years, as the incidence of RA usually occurs at this age group) were suffering from Rheumatoid Arthritis based on ACR/EULAR Classification criteria (2010) are included for this study. All patients were RA-Factor positive.

Exclusion Criteria:

Patient with no history or evidence of existing cardio-pulmonary disease, non-smoker; no history of occupational exposure to any dust particle; no dyspnoea within the limits imposed by the arthritis, history of pulmonary tuberculosis, HIV+ve, cases or any history of chest infection, no gross anemia and treatment with corticosteroid were excluded.

Sample size: 100 Subjects, diagnosed cases of rheumatoid arthritis based on ACR/EULAR classification criteria (2010)[11] and serological tests were selected

Sample design: All diagnosed cases of rheumatoid arthritis was based on ACR/EULAR classification criteria (2010)[11] and serological tests. Cases were compared with normal healthy subjects (control). A control was selected from the relatives of patients, hospital staffs and students.

Study design: It was a comparative study between cases and controls. Both study groups was assessed by age, sex, history, physical examination and biochemical, serological test and pulmonary function tests. Parameters studied were as follows:

Clinical parameters: To fulfill ACR/EULAR classification criteria (2010) for rheumatoid arthritis (11)

Target population (who should be tested?): Patients who were

- Had more than 1 joint with definite clinical synovitis (swelling) and more than 6 weeks duration
- With the synovitis not better explained by another disease.

Classification criteria for RA (score based algorithm: add score of categories A– D; a score of ≥ 6/10 is needed for classification of patient as having definite RA).[11]

A. Joint Involvement Score	
1 large joint	0
2-10 large joint	1
1-3 small joint (with or without involvement of large joint)	2
4-10 small joint (with or without involvement of large joint)	3
>10 joint (at least 1 small joint)	5
B. Serology (at least 1 test result is needed for classification)	
0 Negative RF or negative ACPA	
2 Low-positive RF or low – positive ACPA	
3 High–positive RF or high – positive ACPA (RF: Rheumatoid Factor, ACPA: Anti – citrullinated protein antibody)	
Negative value: IU values ≤ upper limit of normal (ULN)	
Low – positive value: IU values higher than ULN but ≤ 3 times the ULN for the laboratory and assay.	
High – positive value: Refers to IU values that one >3 times the ULN for the laboratory and assay.	
C. Acute – phase reactants (at least 1 test result is needed for classification) Score	
Normal CRP and normal ESR	0
Abnormal CRP or abnormal ESR	1
D. Duration of symptom Score	
< 6 weeks	0
≥6 weeks	1

Biochemical parameters:

Serological test – detection of Rheumatoid factor, C-reactive protein (CRP), ACPA: Anti – citrullinated protein antibody, Erythrocyte sedimentation rate (ESR), Hemoglobin concentration (Hb %)

Pulmonary function test parameter

Different lung volumes and capacities[12]:

Forced Vital Capacity (FVC), forced expiratory volume in 1st second (FEV1), FEV1/FVC ratio, peak expiratory flow rate (PEFR) and forced mid expiratory flow (FEF25-75%). Clinical assessment of disease activities (activity of synovitis) depends on the degree of tenderness and swelling of joint. Disease activity was calculated by Disease Activity Score (DAS–28) with help of DAS Calculator.[13] The research proposal was approved by the ethical committee of the institution first. Proper informed consent in convenient language was taken first from the participating patients.

Spirometry Procedure: spirometry done to both cases and controls, in the Deptt. of Physiology by the following procedure: Patients were provided with proper information about the procedure of spirometry. Patients were asked to breathe into a mouthpiece that was connected to spirometer which records air-flow and time duration. Patients should inhale and exhale forcefully, when patient's nostrils are closed by the help of nose-clips. Airflow was recorded as forced and sustained expiration followed by forced and sustained inspiration. Three efforts, which were less than 5% variability between each other, were selected and the best efforts were used for interpretation. Routinely, only expiratory flow may be recorded before and after administration of the bronchodilators; two puffs of salbutamol (100 mcg/ puff).

Spirometric measurements: represented in two forms, absolute value & graphic forms. Absolute values: a) FVC: total vol. of air is expired with maximum effort after forceful inspiration in lit.

b) FEV1: volume of air expired in 1st sec. in lit.

c) FEV1/FVC: the ratio between FEV1 & FVC

d) PFER: the maximum air-flow during the 1st 10 sec. of expiration in lit./sec.

e) FEF 25-75%: the maximum expiratory flow rate in mid portion of expiration, in lit./sec.

Interpretation of spirometric data:

All the lung function parameters i.e. FVC, FEV1, FEV1/FVC, FEF 25-75%, PFER, are read as normal or abnormal when compared to their predicted values. Predicted values vary as per as age, sex, weight and height of the patient or subject. Value above 80% of the predicted are usually considered as normal healthy individual.

Results

All statistical results have done by EPI – Info Stat Calc. Program developed by CDC Atlanta U.S.A. For the purpose of study, both cases (i.e. rheumatoid arthritis) and controls are grouped in two ways. Criteria of the grouping were as follows:

1. Age (each included into 5 groups--- 20 to 29 yrs, 30 to 39 yrs, 40 to 49 yrs, 50 to 59 yrs, and ≥ 60 yrs)
2. Sex (each included into 2 groups------ Female and Male

Determination of pulmonary function test parameters (FVC, FEV1, FEV1/FVC, PFER and FEF 25-75%) was done in both cases and controls. Determination of rheumatoid factor, C-reactive protein, ACPA and disease activity of Rheumatoid Arthritis was done in cases only.

Table 1: Demographic and clinical characteristics between cases and controls

Age group	Case (n=100)	Control (n=100)
20-29 yrs	18	24
30-39 yrs	37	26
40-49 yrs	33	24
50-59 yrs	12	26
≥60 yrs	0	0
Female	82	63
Male	18	37
FVC% Predicted (normal)	55	97
FVC% Predicted (abnormal)	45	3
FEV1% Predicted value(normal)	55	74
FEV1% Predicted value(abnormal)	45	26
PEFR% Pred. value (normal)	48	75
PEFR% Pred. value (abnormal)	52	25
FEF 25-75% Pred.(normal)	21	41
FEF 25-75% Pred.(abnormal)	79	59

Table 1 shows age distribution, number of female and male among cases and controls. In this study 82% cases were female and 18% cases are male. About 63% controls female and 37% were male. FVC% predicted values of 55% cases are normal and 45% cases are abnormal. FVC% Predicted values of 97% controls are normal and 3% controls are abnormal. This is statistically significant, p value<0.0001. FEV1% Predicted value, which is normal in 55% cases and abnormal in 45% cases.FEV1% Predicted value normal in 74% controls and abnormal in 26% controls. This is statistically significant, p value<0.0001. FEV1/ FVC% Predicted values are normal in both 100% cases and controls. This is statistically not significant, p value >0.05. Table 1 shows PEFR% predicted values are normal in 48% of cases and abnormal in 52% of cases. PEFR% predicted values are normal in 75% of controls and abnormal in 25% of controls. This values are statistically significant, p value<0.0001. Table 1 shows the FEF 25-75% Predicted values are normal in 21% cases and abnormal in 79% of cases. FEF 25-75% Predicted values are normal in 41% of controls and abnormal in 59% of controls. The values are statistically significant, p value <0.0001.

Table 2: Levels of Rheumatoid Factor, ACPA and C-RP level of blood among cases

Rheumatoid Factor	Case (n=100)	% of Case
Low Positive	62	62
High Positive	38	38
ACPA level of blood		
Normal	17	17
Low Positive	55	55
High Positive	28	28
C-RP level		
Positive	67	67
Negative	33	33

Table 2 shows that 62% cases are RA-Factor low positive and 38% cases are high positive. The ACPA level of blood in 17% cases were normal, 55% cases low-positive and in 28% cases high-positive. It also shows that 67% cases are C-RP level of blood positive and 33% cases are C-RP level negative.

Table 3: Showing the distribution of disease duration and ACR/EULAR score of RA cases

Disease Duration	Cases(n=100)	% of cases
1-2 yrs.	17	17
3-4 yrs.	60	60
>4 yrs.	23	23
ACR/EULAR Score		
Normal (1-6)	4	4
Active disease (7-10)	96	96

Table 3 shows in 17% cases duration of RA 1-2 yrs, in 60% cases duration of RA 3-4 yrs, and in 23% cases duration of RA more than 4 yrs. It also shows that 96% of cases have definite RA disease and 4% cases not have definite RA disease as per as ACR/ EULAR classification criteria of RA, 2010.

Table 4: Showing the distribution of DAS-28 disease activity category among cases

DAS -28 disease activity	Case (n=100)	% of Case
Inactive	0	0
Moderate disease activity	33	33
High disease activity	67	67

Table 4 shows, 33% cases have moderate disease activity and 67% cases have high disease activity as per as DAS-28 disease activity score of RA.

Table 5: Showing association between rheumatoid arthritis and abnormal lung function status (case vs/ control)

Variables	Case (n=100)	Control (n=100)	OR &CI at 95%	P value
FEF 25-75%	79	59	OR=2.6;CI:1.3-5.1	0.002
FEF 25-75%	45	55	OR=12.8; CI:4.9-38.6	<0.00001
PEFR% Pred.	52	25	OR=3.2; CI:1.7-6.2	<0.00001
FVC% Pred.	45	3	OR=26.4; CI:7.8-137.1	<0.00001

*OR: Odds Ratio; CI: Confidence Limit

Table 5 shows association between the subjects (cases vs. controls) and their lung function test parameters. There is significant correlation between the lung function test parameters (FVC, FEV1, PEFR, FEF-75%) between cases vs controls. In cases of controls the lung function parameters are normal but, in cases, the same are abnormal. In each case p value < 0.05, that is significant. The only lung function parameter FEV1/FVC ratio, is not significant in this study as all cases and controls exhibit normal FEV1/FVC ratio, as shown in table 5.

Discussion

Rheumatoid Arthritis is a chronic inflammatory disease that leads to chronic pain, high rates of disability and unemployment.[6-9] Furthermore, the lifespan of RA patients is shortened by approximately 10 years [6-9]; and standardized mortality ratios for RA range from 1.28 to 3[2]. Respiratory causes, are a significant contributor to excess mortality in patients with RA ranking as the second major cause of death in this patient population.[14] While the treatment of rheumatoid articular disease has greatly improved in recent years, as measured by disease activity and quality of life instruments, these benefits have not extended to RA-associated lung disease. A number of pulmonary manifestations are associated with RA. The most common is interstitial lung disease (ILD) which leads to pulmonary fibrosis (PF) during which the lung parenchyma is involved.[15]

Interstitial lung disease (ILD) is not only the most common but also the most serious form of lung involvement in RA. Radiographic changes such as fibrosis, and physiological changes such as restriction or decreased diffusing capacity on pulmonary function testing, may precede symptoms by years; however, once clinically apparent, ILD is associated with significant mortality.[16] The reported prevalence of subclinical and symptomatic (clinically evident) ILD in RA varies depending on the method of detection and ranges between 1 and 58%.[17-21]

Recently, attention has been drawn to the higher prevalence or chronic obstructive pulmonary disease (COPD) in patients with RA. COPD has been reported to occur more frequently in patients with RA than in general population even after adjusting for smoking, and is believed to have a more pronounced impact on survival compared to COPD in patients without RA.[22] Thus, both restrictive (ILD) and obstructive lung disease produce clinically important effects in patients with RA. However, their diagnosis is often delayed as the early signs and symptoms may be indolent, non-specific and masked by reduced physical activity due to articular disease.[23]

In normal spirometry, FVC, FEV^1, and FEV^1 -to-FVC ratio are above the lower limit of normal. The lower limit of normal is defined as the result of the mean predicted value (based on the patient's sex, age, and height) minus 1.64 times the standard error of the estimate from the population study on which the reference equation is based. If the lower limit of normal is not available, the FVC and FEV^1 should be greater than or equal to 80% of predicted, and the FEV^1-to-FVC ratio should be no more than 8-9 absolute percentage points below the predicted ratio. The ATS has recommended the use of lower limits of normal instead of the 80% of predicted for setting the threshold that defines abnormal test results.[24]

Normal values are based upon subjects' age, sex, height and weight. Normal results are expressed as a percentage. A value is usually considered abnormal if it is less than 80% of the predicted value. A case report by Kawamura et al reported an incident of rheumatoid lung disease, in which lung involvement preceded arthritis.[25]

This study is limited to the patients with confirmed and diagnosed Rheumatoid Arthritis by RA-Factor positive(either low-positive or high-positive) and ACR/EULAR criteria 2010, with active disease, and all the patients in this study are free from respiratory signs and symptoms including all exclusive criteria. All cases and controls have undergone to their hemoglobin and ESR determination followed by lung function test. For cases only some relevant serological tests (serum RA-Factor, C-RP, ACPA etc.) have undertaken for this study. Disease activity has determined by DAS-28 calculator. In our study all cases are categorized under active disease, either moderate or high active disease. Lung function tests are different from other medical tests in that many of them require patients to participate actively and vigorously. Since some patients would have been unable to perform the tests.

In our study all patients are under age group from 20 yrs to 60 yrs. Table 1 showing different age group of patients. Onset is most frequent between the ages of 40 and 50. In our study 37 patients are under (30-39 yrs) and 33 patients under (40-49 yrs) age group. It is widely accepted that rheumatoid arthritis is one of many chronic inflammatory diseases, which is predominant in females. This is also reflected in this study, where the female to male ratio is 5:1 (approx). Table 1 shows sex distribution of the study population. This finding probably reflects the out patient population.

From analyzing the data obtained from disease activity parameters and pulmonary function tests in this cross sectional study of 100 active rheumatoid patients of Eastern India (82 female and 18 males), the results demonstrated a definite correlation between FVC% pred., FEV1% pred., PEFR% pred., FEF25-75% pred. with hemoglobin level (gm/%), p-value <0.0001 and an inverse relationship observed with ESR level and disease duration, p-value <0.0001. That is as the disease progresses, ESR level becomes high and hemoglobin level and lung function parameters deteriorate. There is also a clear correlation between FVC and hemoglobin % (p<0.0001) and inverse relation with ESR level and disease duration (p<0.0001). When comparing this study to a study by Saravanan et al[26], which demonstrated a clear correlation between FEV1 and the hemoglobin % (p value≈0.01) and borderline inverse relationship between FEV1 and ESR (p=0.05).

A study by Pelucchi A et al[27], confirmed that lung function in patients with juvenile arthritis are related to the clinical subtypes of the disease and the disease activity. In our study we also get strong association between lung function parameters and disease activity of RA as shown in table 5.

The exact mechanism for the development of airway obstruction in RA is unknown, however it is possible that the mucosal edema secondary to pre-existing airway inflammation may lead to bronchial narrowing and hence cause airway obstruction.[28] The measurement of respiratory volumes and capacities is an essential tool for determining how well the lung is functioning.[29] In this present study we get strong association between the deterioration of lung function parameters and RA cases, who are RA-Factor positive. Table 5 showing there is an association of lung function status between case and control. This is significant because most of the lung function parameter significantly deteriorate in RA cases, whereas controls are healthy, p-value<0.0001. Table 5 is showing abnormal lung function between RA-Factor high-positive and RA-Factor low-positive patients. In both cases lung function deteriorates. FVC% pred. and FEV1% Pred. are significant (p-value<0.0001) and this correlate with other studies.[30]

Vergnenegre et al recently reported a significant relationship between forced expiratory flow (FEF 25-75%), duration of articular disease, FEV1/FVC and also a parallel evolution of pulmonary exacerbation and flares of articular disease in some patients.[31] Furthermore, a study by Donagh et al[32] reported that pulmonary function is often impaired in a pattern similar to that of advanced interstitial lung disease in RA. While a study by Cannon et al[33] reported that disease modifying anti-rheumatic drugs have observed to cause interstitial lung disease. In this study we get restrictive type of pulmonary function abnormality in 44% cases, it is significant (p-value<0.05) and obstructive type of pulmonary function abnormality in 2% cases, that is not significant (p-value>0.05).

Limitations

In case of RA patients, both restrictive and obstructive type of pulmonary abnormalities can occur, but in this study we get restrictive type of abnormality significantly. This is due to the poor study population. Only PFTs can't determine the early stages of interstitial lung disease in RA patients. For this, more valuable investigation (DLco, HRCT,)[34] is necessary to detect early stage of pulmonary pathology.

Conclusion

It was observed that rheumatoid arthritis is more common in female than males. In our study 82% cases were female and 18% cases were males. Female to male ratio was 5:1 (approximately). In our study we got significant changes in lung function of the RA patients. FVC, FEV1, PEFR and FEF 25-75% etc. were significantly deteriorated, (p-value<0.0001).

About 44% cases showed evidence of restrictive type of pulmonary function abnormality, it was significant (p-value<0.05) whereas only 2% cases show evidence of obstructive type of abnormality, which was not significant (p-value>0.05). There was definite correlation between PFT change and Hb% whereas inverse relationship between PFT change and ESR level, (p-value<0.0001). There was definite correlation between disease duration and disease activity with abnormal pulmonary function, (p-value<0.0001).

Therefore from the summary of this study, we can understand that lung function parameters can be used to stratify abnormalities in a clinically useful manner and lung function tests can be used as indicator of disease activity of Rheumatoid Arthritis. So all patients of RA should undergo PFTs to detect abnormality and by this way we can reduce morbidity and mortality of RA patients due to subclinical or overt pulmonary dysfunction.

Conflict of Interest: None

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Original Article

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Study of Testosterone Levels in type-II Diabetes Mellitus Patients in North Karnataka Population

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Abstract

Background: Type-II DM is a major health problem globally. There are various complications related to diabetes mellitus, among them low testosterone levels in men is very obvious, health problem which affects the reproduction and sexual life.

Method: 250 type-II DM patients at different age groups were studied and compared with 150 controlled groups. The clinical investigation included- FBS, PPBS, Blood urea, S. creatinine, HBA^1C, lipid profile, Urine for albumin creatinine ratio, S. testosterone was estimated by using chemiluminescence immune assay and HbA^1c by HPLC.

Results: BMI in type-II DM group was 25.83 (±2.33) and controlled group was 24.8 (±3.22). Mean HBA^1C in type-II DM group was 8.81 (±1.93) and 4.80 (±0.402) in controlled group. S. testosterone level was 119.11 (±86.45) in type-II DM group and 402 (± 171.52) in controlled group.

Conclusion: This study revealed that higher sugar level is inversely proportion to lower testosterone levels. It will be a guide to physician, endocrinologist to treat such patients efficiently to elevate the testosterone levels.

Keywords: Chemiluminescence immune assay, HPLC, HbA1C, Metabolic syndrome.

Introduction

Low serum testosteronelevel hasbeen reported in men with type-2 diabetes mellitus [(1)]. Inverse relationship between the serum testosterone level and cardiovascular risk factors such as obesity, Hypertension, dyslipidemia and insulin resistance have been shown[(2)]. Recent studies have shown that low S. testosterone level is strongly associated with metabolic syndrome (MES) in men who belong to different ethnic groups. Low S.testosterone level is also related to adverse clinical outcomes including cardio-vascular diseases (CVD) and premature mortality[(3)].

The patients with type-II DM have sexual dysfunction, unexplained weight loss, weakness or mobility limitation. Hence interventional trials examining the effects of testosterone replacement on clinical outcomes have been carried out in men with symptomatic androgen deficiency[(4)]. The exact cause of decreased S. testosterone level in patients with type-II DM is not clear. Hence attempt was made to evaluate the various aetiologies related to low S. testosterone in type-II DM patients with different age groups.

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Material and Method

250 adult males between 30-50 years with known Diabetes Mellitusregularly visiting to the department of General Medicine,Faculty of Medical Sciences, Khaja Bandanawaz University,Kalaburagi -585104, Karnataka were studied.

Inclusive Criteria: Type-II DM patients irrespective of duration of diabetes currently on oral hypoglycaemic drugs or insulin.

Exclusion Criteria: Patients with age less than 30 years with type-II DM and patients on medications such ascorticosteroids, testosterone, thyroid supplements and chronickidney disease, cirrhosis of liver and immune-compromised patients were excludedfrom the study.

Method

Detailed history, occupation, clinical examination and investigation included CBC, Fasting and Post-parandial blood sugar, Blood urea, Serum Creatinine, HBA^1C, Lipid profile, Urine for albumin creatinine ratio. Diabetes mellitus was defined by ADA guide lines[5]. Serum testosterone levels (Morning sample were estimated using chemiluminescence immunoassay). Low testosterone was defined as serum testosterone level < 241 mg/dl and the prevalence of its deficiencies was calculated. Estimation of HbA^1C(4.2-6.2%) was performed by High performance liquid chromatography (HPLC).

The duration of study was from January-2021 to December-2021.

Statistical analysis: Various parameters in type-II DM patients were studied and compared with controlled group. The statistical analysis was carried out using SPSS software.

Observation and Results

Table 1: Clinical manifestation in type-II DM patients. The mean value of age was 55.26 (±11.16), BMI was 25.83 (± 2.33), P-Y was 8.92 (± 13.76), Mean HBA^1C was 8.81 (± 1.93), Mean Cholesterol 186.02 (± 72.30), Mean HDL 51.38 (± 11.25). Mean LDL 112.25 (± 49.02). Mean serum creatinine 2.4 (± 2.42), Mean Albumin creatinine ratio -2082 (± 4590), Mean serum testosterone 119.11 (± 86.45)

Table 2: Comparison clinical manifestation type-II DM patients with controlled group.

Mean value Age of type-II DM group was 55.26 (± 11.1) and 38.78 (± 7.82) in controlled group. Mean value of MI was 25.83 (± 2.33) in type-II DM group, 24.89 (± 3.22) in controlled group, Mean HBA^1C 8.81 (± 1.93) in type-II DM group and 4.80 (± 0.402) in controlled group, serum testosterone 119.11 (± 86.45) in type-II DM group, 402 (± 171.52) in controlled group.

Table 3: Distribution of type-II DM patients accounting to duration 60 (± 24%) were > 6 years, 89 (± 35.6%) were between 6-10 years, 68 (±27.2%) were between 11 to 15 years and 33 (±13.2%) > 16 years.

Table 1: Clinical Manifestations in diabetic patients

(Total No. of patients: 250)

Manifestations	Mean ±SD
Age	55.26 (± 11.16)
BMI	25.83 (± 2.33)
P-Y	8.92 (± 13.76)
Mean HBA^1C	8.81 (± 1.93)
Mean cholesterol	186.02 (± 72.30)
Mean HDL	51.38 (± 11.25)
Mean LDL	112.25 (± 49.02)
Mean serum creatinine	2.4 (± 2.42)
Mean Albumin creatinine Ratio	2082 (± 4590)
Mean serum testosterone	119.11 (± 86.45)

High Mean HBA^1C and least level of serum testosterone was observed P-Y pack year (year of smoking multiplied by average number of packs or fractions)

Table 2: **Comparison of clinical Manifestations in type-II DM patients with controlled group**

Parameters	II DM patients (250)	Controlled group (150)
Age	55.20 (± 11.16)	38.78 (± 7.82)
BMI	25.83 (± 2.33)	24.89 (± 3.22)
Mean HBA^1C	8.81 (± 1.93)	4.80 (± 0.402)
Serum testosterone	119.11 (± 86.45)	402 (± 171.52)

Lowest serum testosterone observed in type-II DM patients

Table 3: Distribution of type-II DM patients according to duration of disease

Duration of years	No of patients (250)	Percentage
> 6 years	60	24
6-10 years	89	35.6
11-15 years	68	27.2
> 16 years	33	13.2

Highest duration of DM patients were observed between 6-10 years and least duration were > 16 years

Discussion

The current study looked at testosterone levels in type II DM patients in the Karnataka population. The mean value of age was 55.26 (± 11.1%) in type-II DM group, 38.78 (± 7.8%) in controlled group, BMI 25.8 (± 2.3%) in type-II DM, 24.89 (± 3.2%) in controlled group, Mean HBA^{1}C 8.84 (± 1.93) in type-II DM, 4.80 (± 0.40%) in controlled. Serum testosterone 119.1 (± 86.4%) in type-II DM and 402 (± 171.5%) in controlled group (Table-2). Moreover elevated mean cholesterol 186.02 (± 72.3), Mean LDL 51.38 (± 11.2), Mean S. creatinine 2.4 (± 2.47%), Mean Albumin creatinine ratio 2082 (± 4590) was observed in type-II DM patients (Table-1). Distribution of type-II DM patients accounting to duration 60 (± 24%) were > 6 years, 89 (± 35.6%) were between 6-10 years, 68 (±27.2%) were between 11 to 15 years and 33 (±13.2%) > 16 years(Table-3). These findings are more or less in agreement with previous studies[6][7][8].

Defining the lower limit of normal for S. testosterone level poses a challenge for physicians. The adverse clinical outcomes occur in type-II DM is not known [9]. Testosterone in men is synthesized and secreted into circulation almost exclusively bythe leydig cells of the testes. It is mostly bound to plasma proteins. S. testosterone is composed of 0.5 to 3% of free testosterone – unbound to plasma proteins, 30-44% sex hormone binding globulin (SHBG) – bound testosterone and 54-60% albumin bound testosterone [10]. Moreover variations in S. testosterone metabolism are associated with environmental and / or genetic factors[11].

It is experimented in lower animals (mouse) that, testosterone therapy increase the muscle mass and reduce the fat mass both of which were expected to decrease insulin resistance. It is also observed in mice that, testosterone regulated skeletal muscle genes involved in glucose metabolism that led to decreased systemic insulin resistance[12].

It can be hypothesized that, low S. testosterone level could contribute to development of obesity and type-II DM through changes in body composition. In obese men, the peripheral conversion from testosterone to oestrogen could attenuate the amplitude of luteinizing hormone pulses and centrally inhibit testosterone production. Moreover leptin and adipokine has shown to be inversely correlated with serum testosterone level in men.

Low testosterone level can be perpetuated through defects in the (HPG) axis. Hence type-II DM patients had hypogonatropic hypo-gonadism. Aging is also well known to result in a decline of sex hormone level and is likely a combination of testosterone and pituitary hypothalamic defects. In elderly men, there is reduced testicular response to gonado-trophins with suppressed and altered pulsatility of the hypothalamic pulse generation.

Low testosterone is commonly associated with high prevalence of metabolic risk factors including insulin resistance, hypertension, dyslipidemia and obesity (particularly central adiposity), CVD and type-II DM, because testosterone has been shown to dilate coronary vessels in animals and men, suggesting that it might be an important regulator of vasculature compliance and modifier of blood pressure.

Summary and Conclusion

Present study of serum testosterone level in type-II DM patientscauses insulin resistance, Obesity and vascular dysfunction and inflammation. As there is high prevalence of type-II DM across the world. Further the genetic, hormonal, nutritional, pharmacological study is required to clarify whether low testosterone is merely a reflection of poor cardio-vascular risk factors control or is really causing adverse clinical outcomes.

Limitation of study: Owing to tertiary location of research centre, small numbers of patients and lack of latest techniques,we have limited findings and results.

This research paper was approved by Ethical committee ofFaculty of Medical Sciences, Khaja Bandanawaz University, Kalaburagi – 585104, Karnataka.

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Original Article

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Stress and Coping in Post Covid Sequelae in Indian Patients

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Abstract

Post-acute sequelae of COVID-19 (PASC) or more commonly known as Long COVID-19, is the term given to persistent symptoms 12 weeks from the initial presentation of COVID-19 infection. Several multi-organ symptoms have been reported by patients. Some common symptoms include headaches, fatigue, memory impairment and mental health complications such as anxiety and depression. People with previous psychiatric diagnosis are at greater risk of developing longer mental health implications from persistent COVID-19 symptoms. Additionally, healthcare workers are at increased risk of being long haulers leading to burnout and exhaustion. The objective of this article is to provide comprehensive evidence from existing literature on various symptoms reported by patients experiencing Long COVID-19 and the rate of occurrence of such symptoms in different populations. A long-term disease surveillance is required to further understand the persistent symptoms or the long-term impact of this infection.

Keywords: COVID-19, long-haulers, long COVID-19, multi-organ, mental health.

Introduction

The pathogen responsible for the COVID-19 pandemic is severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Like the previous coronavirus, SARS-CoV-1, this novel coronavirus can result in severe lower respiratory tract infection, often complicated by acute respiratory distress syndrome (ARDS)[1]. SARS-CoV-2, however, can also present with a broader variability in clinical syndromes and severity. Some of the most common symptoms of mild to moderate infection are cough, fever, and fatigue, where cough and fever are the most predominant. SARS-CoV-2 infection can also present with diarrhea, rhinorrhea, sore throat, myalgia, sinus congestion, loss of sense of smell or taste, muscle aches, and headaches[1]. However, approximately 40-45% of patients are asymptomatic during the duration of the infection, but they can transmit the virus to others for an extended period of time[2]. The main symptoms of COVID-19 infection usually appear within 2 to 14 days post-exposure. Duration of symptoms varies per individual, but most people recover by two weeks while some take longer to recover from COVID-19.

Overview of symptoms

Post-acute sequelae of COVID-19 is a wide term that includes a diverse variety of physical and psychiatric problems persisting weeks or months after COVID-19 infection. These need to be addressed more frequently so that they can be treated with evidence-based guidelines. The most prevalent consequences in

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post COVID-19 period are fatigue, early exhaustion, stress, brain fog (memory and attention deficit), palpitations, and dyspnea. There are several other symptoms reported which are less common but affect the social and personal life of COVID-19 recovered patients in various ways. Some of these problems include psychiatric issues, for example, depression, anxiety, disturbed sleep patterns, mood changes and headache, life-threatening cardiovascular problems (tachycardia, chest pain, venous thromboembolism, stress cardiomyopathy), gastrointestinal disturbances including stress-induced anosmia and ageusia, cough, myalgias and arthralgias limiting daily activities, dermatological symptoms like skin rashes or hair loss creating cosmetic concerns and hormonal responses like diabetic ketoacidosis in diabetic patients, or thyroiditis etc. These multisystem effects can sometimes prove hazardous for patients in post COVID-19 period. They may survive through COVID-19 infection, but post-acute sequelae of COVID-19 can be life-threatening for them.

Definition and Classification

Several terminologies have been used to define sequelae of COVID-19, including Post-acute COVID-19 syndromes[19], Long COVID-19[4,20], and Chronic COVID-19 Syndromes[20]. Al-Jahdhami et al. used the terms including Post-acute COVID-19 syndromes and Long COVID-19 interchangeably[9]. National Institute of Health Care and Excellence (NICE) guidelines classify acute COVID-19 (symptoms for up to 4 weeks), ongoing symptomatic COVID-19 (from 4 to 12 weeks), and post COVID-19 (more than 12 weeks)[21]. Venkatesan's commentary of NICE guidelines also uses the terms interchangeably and defines them as an "ongoing symptomatic COVID-19 for people who still have symptoms between 4 and 12 weeks after the start of acute symptoms"; and post COVID-19 syndrome for people who still have symptoms for more than 12 weeks after the start of acute symptoms[22]. Greenhalgh et al. define post-acute COVID-19 as extending beyond three weeks from the onset of first symptoms and chronic COVID-19 symptoms extending beyond 12 weeks[10]. Nalbandian et al. define post-acute COVID-19 syndrome as persistent symptoms or long-term complications of SARS-CoV-2 infection more than four weeks from the onset of symptoms[19]. Datta et al. proposed that the acute infection of COVID-19 lasts two weeks, followed by Post-Acute Hyperinflammatory Illness and, lastly, Late COVID-19 sequelae after four weeks[23]. Fernández-de-las-Peñas et al. classified the symptoms in 4 phases: Transition Phase (up to 4–5 weeks); Phase 1: Acute post COVID-19 symptoms (5th -12th week); Phase 2: Long post COVID-19 symptoms (12th -24th week); Phase 3: Persistent post COVID-19 symptoms (symptoms lasting more than 24 weeks)[24].

Mental health implication

In addition to the debilitating physical symptoms of COVID-19 infection, the prolonged sequelae of events in people with PASC/ Long-COVID-19 has resulted in various psychiatric issues, including depression, sleep difficulties, mild to severe anxiety, PTSD, phobias, avoidant behavior, obsessive compulsive symptoms, and in rare cases, dementia in the elderly population. People with prior history of psychiatric illness are at greater risk for mental health implications[19]. Alcohol and other substance use have reportedly increased in long haulers as a coping strategy from stress caused by the long period of illness and other psychosocial causes. In a meta-analysis, the post COVID-19 psychiatric symptoms reported were depressed mood, insomnia, anxiety, irritability, memory impairment, fatigue, delirium, agitation, and altered level of consciousness. The prevalence of post-traumatic stress disorder was reported to be 32.2%, depression 14.9%, and anxiety disorders 14.8%[50]. Rossi Ferrario et al. reported the most common post COVID-19 psychological issues were acute stress disorders (18.6%), anxious and demoralization symptoms (26.7%), depression (10.5%), and troublesome grief (8.1%)[51].Loneliness, economic losses/loss of job, and increased responsibility towards children and other family members due to closure of daycares/schools/ workplace and general lack of social support during these tough times further exacerbate these adverse mental health effects[52].

Neuro-psychiatric symptoms

The long-term complication in people who suffered early neurological symptoms due to COVID-19 infection such as stroke, are disabilities requiring rehabilitation. However, the most

commonly reported neurologic symptoms include headache, vertigo, loss or lack of taste and smell, memory impairment, and inability to concentrate (brain fog). The most unusual, reported symptom is called "brain fog'', which was reported as a long-term symptom of COVID-19 by the Centre of Disease Control and Prevention (CDC). Clinically known as dysexecutive syndrome, it is defined as a state of confusion and mental sluggishness. It often presents after recovery as a persistent cognitive sluggishness. Graham et al. published a prospective study of 100 patients at NeuroCOVID-19 clinic of Northwestern Memorial Hospital, Chicago. The most common neurological symptom reported by patients (81%) was a non- specific cognitive issue mentioned as "brain fog"[55]. According to pathologists at Johns Hopkins University in Baltimore and Brigham and Women's Hospital in Boston, "large bone marrow cells called megakaryocytes may be responsible for this presentation[56,57]. These megakaryocytes migrate to the brain triggered by activity of SARS-COV-2. They block blood flow through capillaries in the cerebral cortex and lead to a state of focal neurological impairment. Stefano et al. proposed that SARS-CoV-2 can damage the mitochondrial energy metabolism and it results from integration of the viral genome into the host cell mitochondrial matrix. Mitochondrial dysfunction with a pro- inflammatory response contributes to neuronal dysfunction and results in "brain fog"[58].

Conclusions

Given the recent emergence of the incidences of Long COVID-19 symptoms, it is unclear how long it can take for the symptoms to completely resolve. A long-term disease surveillance is required to understand the persistent symptoms or the long-term impact of this infection. However, some researchers have suggested holistic and evidence-based guidelines for the management of symptoms of long haulers. Providing additional support through long-term follow ups and disseminating resources on self-management are warranted.

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Original Research Article

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Comparison of Bupivacaine (0.5%) and Bupivacaine (0.5%) with Dexmedetomide for Spinal Anesthesia in Lower Abdominal and Pelvic Surgery

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Abstract

Background: Dexmedetomiodine has also been used intrathecally to enhance the duration of motor and sensory blockade produced by hyperbaric bupivacaine. By increasing the dose of intrathecal dose of intrathecal dexmedetomidine it has been found that there is a significant increase in duration of motor and sensory blockade produced by intrathecal hyperbaric bupivacaine. Purpose of this study was to evaluate whether addition of dexmedetomidine changes the characteristics of bupivacaine 0.5% analgesia and other effects when injected intrathecally.

Materials & Methods: This prospective, double-blind, randomized, controlled study was conducted in 100 patients of ASA PS I-II, aged between 20-60 yrs, of either sex, scheduled for elective lower abdominal and pelvic surgery were chosen and divided into two groups. Patients were randomly allocated to receive intrathecally either 3ml of 0.5% hyperbaric bupivacaine plus 1ml normal saline (group X) or 3ml of 0.5% hyperbaric bupivacaine plus dexmedetomidine 4 μg in 1 ml (group Y). The time taken to achieve peak sensory (T10 dermatome) and motor blockade (Bromage score 3), duration of block, recovery characteristics and hemodynamic changes were recorded. Any adverse symptoms like nausea, vomiting, shivering, pruritis, and sedation etc were noted.

Results: The mean time of sensory block to reach T10 dermatome was 5.56±1.23 minutes in Group Y, 6.48±1.18 minutes in Group X.The mean time to reach Bromage 3 scale was 8.94±1.62 minutes in Group Y and 11.88±1.42 minutes in Group X. The regression time to Bromage 0 was 291.7±30.2 minutes for Group Y and 144.8 ±10.5 minutes for Group X. Onset and regression of sensory and motor block were highly significant ($p<0.0001$). The mean time for 2 segment regression was 111.1±14.96 for group Y and 89.2±9.11 for group X ($p<0.0001$).

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Conclusion: The onset of sensory and motor blockade was shortened by dose of dexmedetomidine. The duration of sensory and motor block was also prolonged. Therefore it can be concluded that dexmedetomidine has effect on sensory and motor block when used as an adjuvant to bupivacaine in spinal anaesthesia.

Keywords: Spinal anesthesia, lower abdominal surgery, pelvic surgery, bupivacaine, dexmedetomide, motor and sensory blockade

Introduction

Among regional anaesthesia, spinal anaesthesia is most frequently used technique. Subarachnoid block provides adequate anaesthesia for patients undergoing spinal anaesthesia.[1] Patients undergoing infraumbilical surgery under spinal anaesthesia with hyperbaric bupivacaine alone occasionally experienced varying degree of intraoperative pain and discomfort in spite of apparently adequate level of sensory block. This requires treatment by supplementation of subarachnoid with intravenous opioids or sometimes by administration of general anaesthesia. Various studies have shown that intrathecal opioids used alone or as an adjunct to intrathecal local anaesthetics block afferent nociceptive stimuli at the level of dorsal root axon and the spinal cord by the mechanism distinct from local anaesthetics.[2, 3]

Neuroaxial opioids have some adverse effects like pruritis, nausea and vomiting, urinary retention and depression of ventilation. So other adjuvants like tramadol, a partial opioid agonist (weak μ agonist) and midazolam a benzodiazepine are also tried in this respect but these are not devoid of adverse effects.[4] The main reason for using adjuvant in subarachnoid block is to achieve a prolongation of duration of analgesia which may be beneficial in intraoperative as well as post operative period. Adjuvants potentiate the action of local anaesthetics and allow a decrease in the required dose.[5]

Many clinical studies have been carried out using intrathecal alpha-2 agonist like clonidine, dexmedetomidine as adjuvants to local anaesthetics. [6-8] They potentiate the effect of local anaesthetics and decrease the dose requirement to achieve optimal surgical anaesthesia.[9, 10] Dexmedetomidine is an α-2 agonist that is more selective to the α-2 receptor than other agonists like cloniodine. Previously it has been used for intravenous sedation. It has a significant opioid sparing effect and it also decreases inhalational anaesthetic requirement in general anaesthesia.[11] Dexmedetomiodine has also been used intrathecally to enhance the duration of motor and sensory blockade produced by hyperbaric bupivacaine. By increasing the dose of intrathecal dose of intrathecal dexmedetomidine it has been found that there is a significant increase in duration of motor and sensory blockade produced by intrathecal hyperbaric bupivacaine.[12]

Purpose of this study was to evaluate whether addition of dexmedetomidine changes the characteristics of bupivacaine 0.5% analgesia and other effects when injected intrathecally.

Materials and Methods

Patients of age group 20-60 yrs with ASA physical status I & II, either sex undergoing elective lower abdominal and pelvic surgery under spinal anaesthesia at General Surgical, Orthopedic, Gynae operation theatre, Post anesthetic care unit, M. G. M. Medical College, Kishanganj, Bihar were included for the prospective randomised double blind comparative study.

Exclusion Criteria

- Patient refusal to study
- Contraindication to subarachnoid block
- ASA PS III & IV
- Known sensitivity to study drugs
- Major cardiovascular, respiratory, renal or hepatic disease
- Metabolic and/ endocrine disease
- Patients using alpha-2 adrenergic antagonists, calcium channel blockers, ACE inhibitors, beta adrenergic blockers
- Patients noted to have dysrhythmia on ECG
- Patient body weight more than 120kg or height less than 150 cm

Total patients were 100.They was randomly allocated in two groups. Group X (n=50) received 0.5% hyperbaric bupivacaine 3ml plus 1ml normal

saline, (vol=4ml). Group Y (n=50) received 0.5% hyperbaric bupivacaine 3ml plus Dexmedetomidine 4 μg in 1ml normal saline (vol=4ml).

Comparison between the groups was done in the following manner.

A. Onset time of sensory blockade (time to reach t 10 dermatome level)

B. Maximum level of analgesia

C. Time to achieve maximum level of analgesia

D. Time to achieve maximum motor blockade

E. Duration of analgesia is assessed by two segment sensory regression

F. Time to regress analgesia upto level S1

G. Time for motor regression is assessed by recovery of motor power

H. Hemodynamic changes as changes in changes in pulse rate and blood pressure every five minutes after starting of spinal anaesthesia

I. Any other associated effects or side effect like sedation, nausea, vomiting etc.

Study tools were NIBP, SpO^2 and pulse oximetry

Written informed consent was taken from all patients prior to including them in the study during pre-anaesthetic check up. Airway assessment and appropriate haematological and radiological investigations was done for each patient. The patients were randomly allocated into two groups, namely Group X and Group Y. All patients will receive tab diazepam (0.2mg/kg) orally night before operation. After proper aseptic precaution spinal subarachnoid block was performed in the sitting position at L3-L4 or L4-L5 intervertebral space through a midline approach by a 25G quincke type spinal needle. Following subarachnoid block the patients received 2 litres/min oxygen via bi-nasal cannula. The patients was continuously monitored– SpO^2, NIBP, and ECG.

The sensory and motor blockade was assessed intra-operatively at 2 minutes interval till satisfactory height and depth of block suitable for the surgical procedure was attained and thereafter every 15 minutes till the end of surgery. The level of sensory blockade was assessed by pin-prick sensation using a blunt 25-gauge needle along mid clavicular line bilaterally. The motor blockade level was assessed by Bromage scale: Bromage 0, the patient is able to move hip,knees and ankle; Bromage 1, the patient is unable to move the hip but able to move the knee and ankle; Bromage 2, the patient is unable to move the hip and knees,but able to move ankle; and Bromage 3, the patient is unable to move hip, knees, and ankle.

The time to reach T10 dermatome, the dermatome level (peak sensory level), a two dermatome regression and regression to S1 dermatome was recorded. The time to reach Bromage 3 and regression to bromage 0 was also being recorded. All durations was calculated considering the time of intrathecal injection as time zero. A patient with partial or complete failure of spinal anaesthesia was excluded from the study. The mean arterial pressure (MAP), heart rate (HR), pulse oximetry was recorded every 5 minutes after starting of spinal anaesthesia. The level of sedation was assessed intraoperatively and post-operatively every 15 minutes using Ramsay score: 0-alert; 1-ocassionally drowsy but easy to arouse; 2- frequently drowsy but easy to arouse; 3-somnolent and difficult to arouse.[13]

Numerical parameters were compared between the groups by one way ANOVA if normally distributed or by or by Kruskall-Wallis ANOVA if otherwise. Comparison over time within a group would be done by repeated measure ANOVA or its non parametric counterpart Friedman's ANOVA. Categorical variables were compared between groups by Chi-square test or Fisher's exact.

Results

Study shows that there was no statistical significant difference between the groups in terms of the demographic characteristics of the patients namely age, sex, body weight, and ASA status. Hence these two groups are comparable from these aspects.

Table 1: ASA grade, inter space and peak SB wise distribution of cases in group X and group Y

ASA grade	Group X	Group Y	Total
I	48	48	96
II	2	2	4
Inter space			
L3 – L4	9	15	24
L4 – L5	41	35	76
Peak SB			
T6	22	18	40
T8	20	25	45
T10	8	7	15
Total	50	50	100

Table 2: Comparison of onset and peak time of sensory blockade; maximum and maximum time of motor blockade; duration by 2 segment regression and regression to level S1 and Bromage 0 in group X and group Y

Sensory blockade	Group X (n=50)		Group Y (n=50)		Z Value	P Value
	Mean	SD	Mean	SD		
Onset time (min)	6.48	1.18	5.56	1.23	3.82	<0.0001
Peak time (min)	10.56	2.1	8.12	1.36	6.9	<0.0001
Motor blockade						
Maximum	3	0	3	0	0	>0.05
Max time (min)	11.88	1.42	8.94	1.62	9.65	<0.0001
2 Segment regression						
Duration (min)	89.2	9.11	111.1	14.96	8.84	<0.0001
Regression to level S1 and Bromage 0						
Level S1 (min)	190.4	12.89	344.1	29.08	34.17	<0.0001
Bromage 0 (min)	144.8	10.5	291.7	30.2	32.49	<0.0001

Tables 2 showS the peak sensory block, onset time to reach T10 sensory, and Bromage 3 motor block and regression time to reach sensory S1 segment level and Bromage 0 motor scale were recorded. The mean time of sensory block to reach T10 dermatome was 5.56±1.23 minutes in Group Y, 6.48±1.18 minutes in Group X. The mean time to reach Bromage 3 scale was 8.94±1.62 minutes in Group Y and 11.88±1.42 minutes in Group X. The regression time to Bromage 0 was 291.7±30.2 minutes for Group Y and 144.8 ±10.5 minutes for Group X. Onset and regression of sensory and motor block were highly significant ($p<0.0001$). The mean time for 2 segment regression was 111.1±14.96 for group Y and 89.2±9.11 for group X ($p<0.0001$).

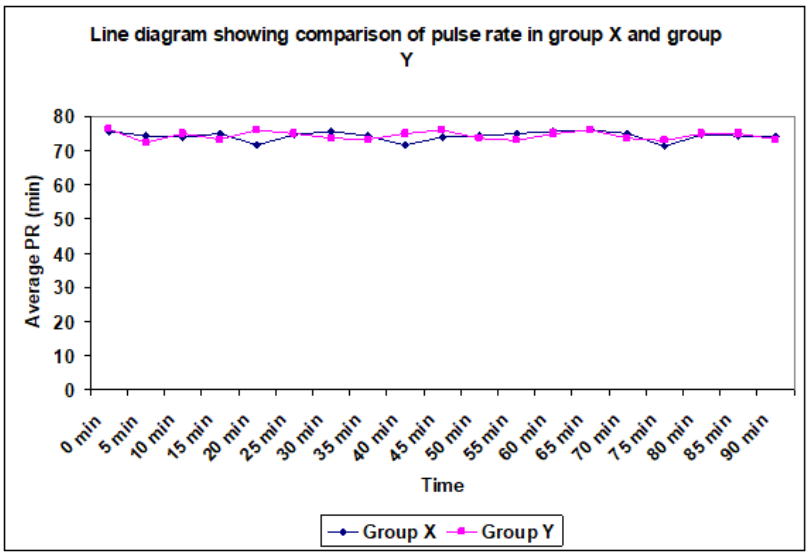

Figure 1: Comparison of pulse rate in group X and group Y

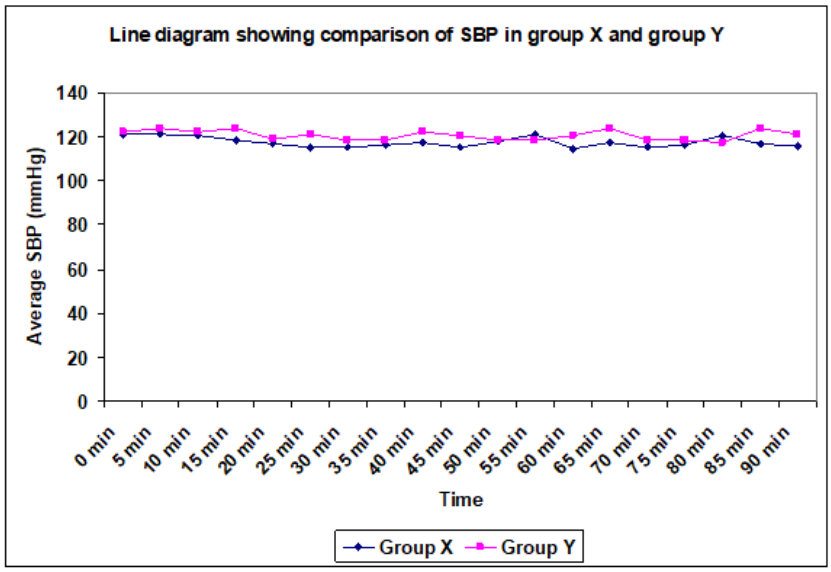

Figure 2: Comparison of Systolic Blood Pressure in group X and group Y

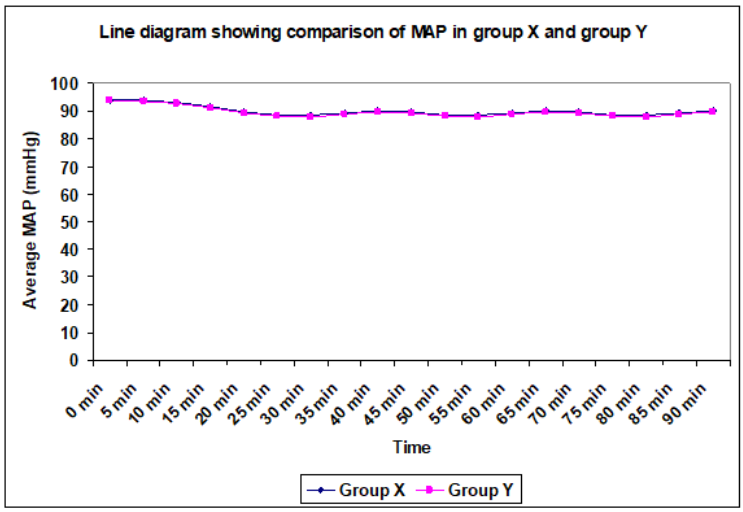

Figure 3: Comparison of Mean Arterial Pressure in group X and group Y

Table 3: Comparison of SPO^2 in group X and group Y

SPO^2 at	Group X (n=50)		Group Y (n=50)		Z Value	P Value
	Mean	SD	Mean	SD		
0 min	100	0	100	0	0	>0.05
5 min	100	0	100	0	0	>0.05
10 min	100	0	100	0	0	>0.05
15 min	100	0	100	0	0	>0.05
20 min	100	0	100	0	0	>0.05
25 min	100	0	100	0	0	>0.05
30 min	100	0	100	0	0	>0.05
35 min	100	0	100	0	0	>0.05
40 min	100	0	100	0	0	>0.05
45 min	100	0	100	0	0	>0.05
50 min	100	0	100	0	0	>0.05
55 min	100	0	100	0	0	>0.05
60 min	100	0	100	0	0	>0.05
65 min	100	0	100	0	0	>0.05
70 min	100	0	100	0	0	>0.05
75 min	100	0	100	0	0	>0.05
80 min	100	0	100	0	0	>0.05
85 min	100	0	100	0	0	>0.05
90 min	100	0	100	0	0	>0.05

Figures [1-3] show comparison of systolic, diastolic and mean blood pressure between groups at different time intervals. There was no significant differences between the groups. Table 3 shows peripheral oxygen saturation in all the groups are comparable. No patients required oxygen supplementation intraoperatively or in the PACU as SpO^2 values were greater than 98%.

Table 4: Comparison of side effects in group X and group Y

Side effects	Group X (n=50)	Group Y (n=50)	P Value
Sedation	0	11 (22)	<0.0001
Bradycardia	0	0	-
Dry Mouth	0	0	-
Anxiety	0	0	-
Dizziness	0	0	-
Pruritis	0	0	-
Hypotension	0	0	-
Restless	0	0	-
Urinary Ret	0	5 (10)	<0.05
Nausea Vomiting	0	0	-

Discussion

Spinal anaesthesia with hyperbaric bupivacaine is a widely accepted anaesthetic technique for infraumbilical and lower extremity surgical procedures. It reduces postoperative pulmonary and thrombotic complications.[2, 3] It also provides good quality early-post-operative analgesia and an overall reduction in postoperative morbidity and mortality.[2] Intrathecal opioid administration has been demonstrated to provide effective postoperative analgesia after a variety of surgical procedure,abeit at a cost of an increased risk of respiratory depression.[3]

Stimulation of α^2 receptors in locus cereleus terminates propagation of pain in descending medull- ospinal non adrenergic pathway. This results in termination of the propagation of pain signal leading to analgesia. At the spinal cord,stimulation of α^2 receptors at the substancia gelatinosa of the dorsal horn leading to inhibition of the firing nociceptive neurons and inhibition of release of substance of substance P. The spinal mechanism is the principal mechanism for the analgesic action of dexmedetomidine.[14]

Antonio Mauro Viera compared clonidine and dexmedetomidine and administered epidurally for post cholecystectomy analgesia and sedation. The dose of dexmedetomidine used was 2 mcg/kg.[15] Fukushima K et al administered 2 mcg/kg epidural dxmedetomidine for post-operative analgesia in humans without any reports of neurological defecits.[16] Maroof et al used dexmedetomidine, approximately 1.5 mcg/kg to decrease the incidence of post-operative shivering without any reports of neurological defecits.[17] In our patients, the three hour questionnarie showed that intrathecal dexmedetomidine preservative free, at dose of 5 mcg & 10 mcg was not associated with any new onset of back, buttocks or leg pain or weakness.

Studies using a combination of intrathecal of intrathecal dexmedetomidine and local anaesthetics are few. It was Kanazi et al in 2006 who first administered dexmedetomidine intrathecally. He administered dexmedetomidine 3 mcg or clonidine 30 mcg as adjuvants to spinal anaesthesia with bupivacaine in patients undergoing TURP. Intrathecal dose of dexmedetomidine selected was based on previous animal studies.[7,11] A dose of 1:10 ratio between intrathecal dexmedetomidine and clonidine produced similar effect in animal models. Kanazi showed that in humans, too dexmedetomidine (3 mcg) & clonidine (30 mcg) have an equipotent effect.[7] Patients receiving dexmedetomidine & clonidine have significant shorter onset of motor block and significantly longer sensory & motor regression time than control. Hemodynamic stability was maintained and lack of sedation was noted in both the study groups. Mahmud M Al Mustafa in 2009 added incremental doses of intrathecal dexmedetomidine (5 mcg,10 mcg) to isobaric 0.5% bupivacaine for urological procedures. He found that dexmedetomidine hasten the onset of sensory and motor blockade and prolong them significantly when used with bupivacaine in spinal anaesthesia in dose dependent manner.[8]

From the current study it has been found that the addition of dexmedetomidine to intrathecal bupivacaine significantly shorten the onset time to reach T10 sensory level and Bromage 3 motor block. Likewise the regression time to reach sensory S1 and Bromage 0 were significantly prolonged. The 2 segment regression were also prolonged. These results are comparable to those obtained by other authors using intrathecal dexmedetomidine. Use dexmedetomidine resulted in a significant shortening of onset and prolonged regression time of sensory and motor block. The dose dependent effect of intrathecal dexmedetomidine on sensory and motor block was also noted by Mustafa, Hala,Yektas.[8]

The present study shows comparison of mean pulse rate for different stages between groups. No therapeutic intervention was required in any of these groups as there was no significant hemodynamic deterioration. These findings are in agreement with the observations of Mustafa et al.[8] In his study the dose of 5mcg and 10mcg of intrathecally dexmedetomidine added to 12.5mg of bupivacaine compared with bupivacaine alone did not cause a significant decrease in blood pressure and heart rate intraoperatively or in the PACU. Similarly, Kanazi et al noted that addition of dexmedetomidine or clonidine to bupivacaine did not cause a significant decrease in the blood pressure intra-operatively or post-operatively.[7] Intrathecal local anesthetics block the sympathetic outflow and reduce the blood pressure. The sympathetic block is usually near-maximal with the doses used for spinal anesthesia. The addition of a low dose of α^2-agonist to a high dose of local anesthetics does not further affect the near-maximal sympatholysis.

The present study shows comparison of systolic ,diastolic and mean blood pressure between groups at different time intervals. There was no significant differences between the groups. It also shows peripheral oxygen saturation in all the groups are comparable No patients required oxygen supplementation intraoperatively or in the PACU as SpO^2 values were greater than 98%. It shows the sedation scores and incidence of urinary retention in the 1st postoperative hours of patients belonging to the groups.The level of sedation scores were in the range of 0-1. In this study they were not premedicated with any benzodiazepene group of drugs. These findings agree with the observations of Mustafa and Kanazi[7, 8],who noted similar lack of sedation. Intrathecally administered α^2-agonists have a dose-dependent sedative effect. The doses of clonidine and dexmedetomidine selected in this study were at the lower end of the dosing spectrum. This explains

the lack of sedative effects between the study groups. Hala studied the effect of higher doses of dexmedetomidine (10 & 15 mcg) added to intrathecal bupivacaine or anterior cruciate ligament surgery. Expectedly, higher dose of dexmedetomidine was associated with higher sedation scores and lower post operative analgesic requirements.[18]

Conclusion

The two groups were similar in respect to demographic parameters ($p>0.05$ in each case). The onset of sensory and motor blockade was shortened by dose of dexmedetomidine. The duration of sensory and motor block was also prolonged. Therefore it can be concluded that dexmedetomidine has effect on sensory and motor block when used as an adjuvant to bupivacaine in spinal anaesthesia. There was no significant difference in incidence of side effects between the two groups studied. Two segment sensory regressions were significantly delayed in patients receiving dexmedetomidine.

Conflict of interest: None

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Ethical Clearance: Approved by the institutional ethical committee, M. G. M. Medical College and L.S.K. Hospital, Kishanganj, Bihar

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Original Research Article

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Dissociation of Implant following Hemi Replacement Arthroplasty in an Osteoporotic Male Patient: A Case Report

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Abstract

Hip fracture is a major health concern in elderly people. Thc standard line of management is hip arthroplasty classified whether it is intracapsular or extracapsular. Hemi arthroplasty is the preferred surgery in geriatric population as less mobility and the large diameter of the femur head reduces the chances of dislocation. There are 4 surgical techniques for Hemi -arthroplasty: anterior (Smith-Peterson), anterolateral (Watson. lones), lateral (Hardinge or Liverpool) and posterior (moore). Common complications of hip replacement include infection, fracture, dislocation, venous thrombosis, nerve palsy, chronic pain and implant failure. ln literature: there are very few reported cases of Dissociation of the Implant in hemi arthroplasty. We hereby present a case report on dissociation of prosthesis which was timely recognised and treated adequately. The cemented bipolar prosthesis used can also lead to dissociation of the implant components and thereby the need for open reduction. Identification of the difference between dislocation of head and dissociation of the prosthetic componcnts is vital for favourable patient prognosis.

Key words: hemi arthroplasty, implant failure, dislocation.

Introduction

The standard protocol of management in elderly population for end stage hip diseases and unstable femur fracture is bipolar hemiarthroplasty. Availability of different sizes of head and neck in bipolar implant enables the treating surgeon to select appropriate prosthesis taking into consideration the age of the patient and desired range of motion. However there are severe but few complications associated with bipolar implant like dislocation, dissociation of the prosthesis etc.[1] For hip dislocations, patients are generally treated by close reduction techniques. Whereas dissociation of the prosthesis necessitates the need for open reduction. Timely recognition and differentiation between dislocation and dissociation of the prosthesis is very crucial for management and better outcome of the patient.

Case Report

A 70 year old male, presented to orthopaedics OPD with with right hip pain, swelling and restricted mobility following slip and fall on the ground

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1 day back in may, 2018. He underwent clinical and radiological examinations in which he was diagnosed as fracture neck of femur of right hip secondary to age related osteoporosis following trivial trauma as shown in figure 1a.

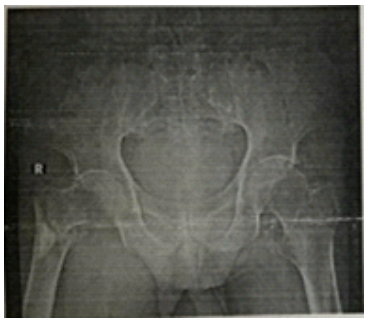

Figure 1a: X-ray pelvis AP view showing right sided neck of femur fracture.

Considering the age of the patient, he was operated for hemi replacement arthroplasty by posterior approach for which cemented bipolar prosthesis was used. Postoperatively on 5th day, when he went back to his home he sustained a trivial fall after which he felt sudden severe pain at operated side which aggravated on movements, non radiating in nature for which patient came back to hospital and underwent clinical and radiological investigations. On examination, there was swelling in the hip region with no open wound, scar or dilated veins. On palpation there was tenderness over the right scarpas area with bitrochanteric compression test positive. There was no neurological signs or symptoms. Plain radiograph revealed a completely dissociated acetabular component of the prosthesis lying near the neck of the stem.

The patient underwent revision surgery of the hip and dissociated bipolar prosthetic part was removed and after trial appropriate size of the cup and stem were selected and hip was reduced in its anatomical position as depicted in figure 1 b.

Figure 1 b: Intraoperative image showing dissociated bipolar implant.

Following this revision surgery the patient has been followed up for 1 year and he is asymptomatic with favorable outcome. figure 1 c shows post operative X-ray of pelvis with prosthetic implant in situ.

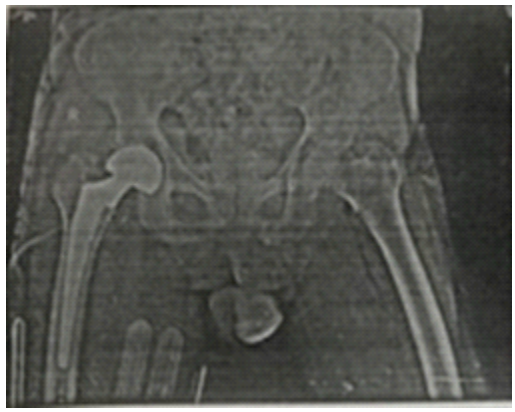

Figure 1 c: postoperative xray showing prosthetic implant in situ

Discussion

Over decades, hip hemiarthroplasty has been used successfully to manage end stage hip disorders and fracture of femur neck. Unipolar prosthesis were used initially but due to several disadvantages like recurrent dislocation. decreased range of mobility, more wear and friction of the acetabulua component of prosthesis superseded by bipolar prosthesis.. Dislocation of the prosthesis is a known complication after primary hemiarthroplasty and has been reported but dissociation of the implant is very rarely encountered causing significant permanent disability. There is 2.6% incidence of dislocation reported by Barneset al. in hips treated with bipolar hemiarthroplasty[2]

Here the most probable cause for this dissociation seem to be a weak bipolar bond between acetabulaum and femoral component if the implant or mechanically stressfull placement of the implant.[3]

The advantages of cemented prosthesis are improved post operative outcome and low rates of implant-related complications like dislocation, dissociation or peri-prosthetic femoral fracture[4].

Conclusion

Early diagnosis of this rare complication by orthopedic surgeons and its timely management by

open reduction and revision surgery plays a crucial role in decreasing morbidity of the patient and its successful outcome[5]. Postoperative radiographic examination should be kept routinely as a part of treatment protocol with patients who have undergone bipolar hemiarthroplasty.

Informed Consent: written informed consent was taken from patients.

Ethical Approval: ethical committee approval was taken from the institutional committee of ethics.

Source of Funding: funding source was self.

Conflict of Interest: there was no conflict of interest.

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Retrospective and prospective study **https://doi.org/10.37506/ijphrd.v14i3.19364**

Immunohistochemical Expression of p16 and CDK4 in Soft Tissue Tumors

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Abstract

Background: The large majority of soft tissue tumours are benign.Malignantmesenchymal neoplasms amount to less than 1% of the overall human burden of malignant tumours but they are life threatening and may pose a significant diagnostic and therapeutic challenge since there are more than 50 histological subtypes of STS, which are often associated with unique clinical, prognostic and therapeutic features.

Methods: The study was undertaken in department of Pathology, King George's Medical University, Lucknow. The Study Design was Retrospective and prospective study carried over a period of one year from September 2018 to august 2019 including 70 cases.

Results: Most common diagnosis of malignant cases was Synovial saroma (21.4%) followed by Leiomyosarcoma (19.0%) and Undifferentiated pleomorphic sarcoma & Fibromyxoid sarcoma (11.9% each). Less common diagnosis were Ewing's sarcoma, Liposarcoma and Rhabdomyosarcoma (9.5% each), 1 (2.4%) case each was diagnosed as Chondrosarcoma, MPNST and Myxoid liposarcoma.

Conclusions: Genetic alterations involving the 12q13-15 chromosomal region are common in musculoskeletal sarcomas, and many bone and soft-tissue malignant tumors showed amplification of various genes located in this region**.**

Keywords: synovial sarcoma;ewing's sarcoma; histopathological

Introduction

The large majority of soft tissue tumours are benign.Malignantmesenchymal neoplasms amount to less than 1% of the overall human burden of malignant tumours but they are life threatening and may pose a significant diagnostic and therapeutic challenge since there are more than 50 histological subtypes of STS, which are often associated with unique clinical, prognostic and therapeutic features.[1]

The aetiology of most benign and malignant soft tissue tumours is unknown. In rare cases, genetic and environmental factors, irradiation, viral infections and immune deficiency have been foundassociated with the development of usually malignant soft tissue tumours.[2] However, the large majority of soft tissue sarcomas seem to arise de novo, without an apparent causative factor. In this study we analyse the expression of CDK4 and p16 in the various

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lineages of soft tissue sarcoma and their role in differentiating atypical lipomatoustumor/WDL from benign lipomas.[3]

Material and Methods

The study was undertaken in department of Pathology, King George's Medical University, Lucknow. The Study Design was Retrospective and prospective study carried over a period of one year from September 2018 to august 2019 including 70 cases with

Inclusion Criteria: Histologically diagnosed cases of soft tissue tumors.

Exclusion Criteria: Inadequate biopsy tissue for immunohistochemistry.

Results

The present study was conducted in the Department of Pathology in collaboration of Departments of Surgical Oncology and Orthopedics, King George's Medical University, Lucknow to study the immunohistochemical expression of p16 and CDK4 markers in various lineages of soft tissue sarcomas. In the present study, 70 histologically diagnosed cases of soft tissue tumors fulfilling the inclusion criteria were enrolled in the study.

Age of patients enrolled in the study ranged from 1 to 97 years, mean age was found to be 34.98±19.96 years. Most common age groups were 31-40 years (20.0%) followed by 11-20 years and 41-50 years (18.6% each).

Out of 70 patients enrolled, majority were males (61.4%) and rest 38.6% were females.

Most common site of swelling were lower extremity (34.3%) followed by head and neck (22.9%) and Upper extremity (11.4%) while less common sites of swelling were Back and Trunk (8.6% each) and Pelvic and Retroperitoneum (7.1% each).

Majority of the patients presented with pain (61.4%) and showed progression of swelling (84.3%).

Duration of symptoms in majority of the patients was >6 months (77.1%).

Minimum size of tumour was 1 cm while maximum size was 18 cms. Mean size of tumour was 7.09±4.52 cms. Only 5 (7.1%) cases had tumour size >15 cm, 12.9% had tumour size 11-15 cm, 34.3% had tumour size 6-10 cm and rest 45.7% had tumour size ≤5 cm.

Excisional biopsy was done for majority of the cases (80.0%) and for rest of the cases Incisional biopsy was done (20.0%).

Out of 70 cases enrolled in the study, 42 (60.0%) were histopathologically found to be malignant, 20 (28.6%) as benign and rest 6 (11.4%) as intermediate.

Out of 20 cases histopathologically found to be benign, Lipoma was the most common diagnosis (25.0%) followed by Angiomyolipoma, Benign fibromyxoid neoplasm, Calcifying fibrous tumour and Fibroma (15.0% each), 1 (5.0%) case each was diagnosed as Dermatofibroma, hemangioma and myxoma.

Most common diagnosis of malignant cases was Synovial saroma (21.4%) followed by Leiomyosarcoma (19.0%) and Undifferentiated pleomorphic sarcoma & Fibromyxoid sarcoma (11.9% each). Less common diagnosis were Ewing's sarcoma, Liposarcoma and Rhabdomyosarcoma (9.5% each), 1 (2.4%) case each was diagnosed as Chondrosarcoma, MPNST and Myxoid liposarcoma.

Among histopathologically intermediate cases most common diagnosis was DFSP (62.5%) followed by Well differentiated liposarcoma (25.0%) and Low grade myofibroblastic sarcoma (12.5%).

Age of histologically benign cases ranged between 9 to 56 years of age, mean age was 29.55±15.37 years. Difference in age of benign cases with different diagnosis was not found to be significant statistically.

Range of age of histopathologically malignant cases was 1 to 97 years, mean age of these cases was 36.58±22.56 years. Age of 1 case each of Chondrosarcoma, MPNST and Myxoid liposarcoma was 40, 16 and 74 years respectively. Minimum mean age was observed for cases diagnosed as Rhabdomyosarcoma (1.88±0.85 years) followed by Ewing's sarcoma (12.25±6.29 years) while mean age was maximum for cases diagnosed as myxoid liposarcoma (74.00±0.00 yrs) followed by Undifferentiated pleomorphic sarcoma (61.60±25.58 years). Difference in mean age of malignant cases

with different diagnosis was found to be significant statistically.

Age of histopathologically intermediate cases ranged between 23 to 64 years, mean age was 40.13±13.27 years. Minimum mean age was observed for cases diagnosed as low grade myofibroblastic sarcoma (27.00±0.00 yrs) followed by DFSP (36.60±9.76 years) while maximum age was observed for cases diagnosed as Well differentiated liposarcoma (55.50±12.02 years). Difference in age of intermediate cases with different diagnosis was not found to be significant statistically.

Among benign cases majority were males (70.0%) and rest were females. Male preponderance was found for all the above diagnosis except for Dermatofibroma (33.3% males only). Difference in gender of benign cases with different diagnosis was not found to be significant statistically.

Out of 42 malignant cases 23 (54.8%) were male and rest were females. Male preponderance was seen for cases diagnosed as Chondrosarcoma, MPNST (100.0% each), Lipo sarcoma (75.0%) and synovial sarcoma (66.7%). Ewing's sarcoma and Leiomyosarcoma were present in equal proportion of males and females. Female preponderance was seen for cases diagnosed as Myxoid liposarcoma (100.0%), Fibromyxoid sarcoma (80.0^), Rhabdomyosarcoma (75.0%). Difference in gender of malignant cases with different diagnosis was not found to be significant statistically.

Out of 8 histopathologically intermediate cases 6 (75.0%) were males. Male preponderance was observed for cases diagnosed as DFSP (80.0%) and low grade myofibroblastic sarcoma (100.0%) while male:female ratio was similar cases diagnosed as Well differentiated liposarcoma. Difference in gender of histopathologically diagnosed intermediate cases with above diagnosis was not found to be significant statistically.

Positive p16 expression was observed in majority of the cases (51.4%) while negative p16 expression was observed for 44.3% cases and rest were found to be focal positive (4.3%).

Negative CDK4 expression was observed in majority of the cases (81.4%) while positive CDK4 expression was observed for 10.0% cases and rest were found to be focal positive (8.6%).

Both p16 & CDK4 positive expression was observed in only 12.9% cases, 38.3% had both negative expression and rest 48.6% cases had positive expression either for p16 or CDK4.

Negative p16 expression was observed among higher proportion of Benign as compared to malignant and intermediate cases (75.0% vs. 31.0% & 37.5%) while positive p16 expression was observed among higher proportion of malignant as compared to Benign & intermediate cases (66.7% vs. 20.0% & 50.0%) while focal positive expression was observed in higher proportion of Intermediate as compared to Benign & Malignant cases (12.5% vs. 5.0% & 2.4%). This difference was found to be significant statistically.

Negative CDK4 expression was observed among higher proportion of Benign as compared to malignant and intermediate cases (90.0% vs. 78.6% & 75.0%) while positive CDK4 expression was observed among higher proportion of Intermediate as compared to Benign & malignant cases (25.0% vs. 5.0% & 9.5%) while focal positive expression was observed in higher proportion of malignant cases as compared to Benign & Intermediate cases (11.9% vs. 5.0% & 0.0%). This difference was not found to be significant statistically significant.

Both p16 & CDK4 negative expression was observed among higher proportion of Benign as compared to malignant and intermediate cases (65.0% vs. 26.2% & 37.5%) while among higher proportion of malignant as compared to Benign & intermediate cases had either positive expression (57.1% vs. 35.0% & 37.5%), positive expression was observed among higher proportion of Intermediate as compared to benign and malignant (25.0% vs. 0.0% & 16.7%). This difference was not found to be significant statistically significant.

Out of 45 diagnosed cases of Sarcoma, majority had FNLCC Grade 3 (62.2%), only 11.1% were Grade 2 and rest 26.7% were Grade 1 cases.

TNM Staging was done for 31 cases. Majority of the cases were pT1 and pT2 (67.7%), only 12.9% cases were pT4 and rest 19.4% were pT3 stage.

An increment in p16 negative expression with increase in FNLCC Grade was observed (8.3%, 20.0% & 39.3%) while p16 positive expression was found to be higher in Grade 1 as compared to Grade 2 and Grade 3 (83.3% vs. 60.0% & 60.7%). Association of p16 expression with FNLCC grade was not found to be significant statistically.

Association of p16 expression with TNM staging was not found to be significant statistically.

A decline in CDK4 negative expression with increase in FNLCC Grade was observed (83.3%, 80.0% & 71.4%) while CDK4 positive expression was found to be higher in Grade 2 as compared to Grade 1 and Grade 3 (20.0% vs. 16.7% & 10.7%). Association of CDK4 expression with FNLCC Grade was not found to be significant statistically.

Association of CDK4 expression with TNM staging was also not found to be significant statistically.

For adipocytic tumors, majority of the benign tumours had negative expression of p16 (6/8; 75%) and CDK4 (8/8; 100%) while majority of malignant and intermediate tumours had positive p16 (7/7; 100%) and CDK4 (6/7; 85.7%) expression. These differences were found to be significant statistically (p16; χ^2=8.750; p=0.003; CDK4; χ^2=11.429; p=0.001).

Discussion

In present time apart from clinical and histomorphological picture there are many techniques to differentiate soft tissue tumors specially sarcomas. These techniques are immunohistochemistry, cytogenetics and molecular genetics. Immunohistochemistry is used to identify the differentiation of tumor cells in a particular section.Immunohistochemistry also plays a major role in soft tissue tumor classification, diagnosis, treatment and prognosis.

Genetic alterations involving the 12q13-15 chromosomal region are common in musculoskeletal sarcomas, and many bone and soft-tissue malignant tumors showed amplification of various genes located in this region[10].

p16 is a tumor suppressor gene and it is an important cell cycle regulator. It inhibits cell cycle at G1-S checkpoint by binding to cyclin-dependent kinases 4/6 and prevent inactivation of the Rb protein. p16may be mutated or deleted in many cancers[22,33-36].

Conclusion

Genetic alterations involving the 12q13-15 chromosomal region are common in musculoskeletal sarcomas, and many bone and soft-tissue malignant tumors showed amplification of various genes located in this region.

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Source of funding: Self

Conflict of Interest: Nil

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Original Research

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Effect of Oxidative Stress on Fetus Outcome in Hypothyroidism Associated Pregnancy in a Tertiary Care Hospital in Eastern Region of India

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Abstract

Introduction: Oxidative stress occurs due to the imbalance between reactive oxygen species generation & antioxidant defense which is more in pregnancy in comparison to normal population & it is also further augmented in hypothyroidism which is often detrimental for the fetus.We try to find the oxidative stress and its effect on mother and baby in the pregnant hypothyroid women.

Materials & Methods: we compared the total oxidative stress (TOS) by modified free oxygen radical test in 250 pregnant women (out of which 78 were hypothyroid & 172 euthyroid) compare the same in 250 non pregnant women from antenatal & G&O OPD of NRS Medical College, Kolkata. fT4 & TSH were estimated by ELISA method using standardized kit. Fetal outcome was measured in terms of birth asphyxia, neonatal hypothyroidism, low birth weight & early neonatal sepsis.

Result: Significantly higher levels of TOS ($p<0.001$) has been found in hypothyroid pregnant population than euthyroid. One way ANOVA test done between nonpregnant, pregnant euthyroid & pregnant hypothyroid population, came statistically significant ($F=410.4$ & $p<0.05$). posthoc ANOVA shows significant difference with each other between all the 3 groups. Significanltly increased levels of neonatal hypothyroidism, birth asphyxia & low birth weight has been found with babies of hypothyroid mothers.

Discussion: oxidative stress has been proved here to be augmented in pregnancy which is further worsen in hypothyroidism causing poor fetal outcome.

Keywords: oxidative stress, hypothyroidism, pregnancy, birth asphyxia.

Introduction

The thyroid dysfunction is the second most common endocrinal disorder complicating pregnancy throughout the world after diabetes.[1] In pre-existent undiagnosed hypothyroid cases, pregnancy worsen the load of disease, even can turn fatal if remains untreated.[2] Hypothyroidism in pregnancy affect

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intelligence quotient (IQ) and neuropsychological development of fetus adversely.[3]

The term oxidative stress refers to the imbalance between generation of reactive oxygen species (ROS) and the ability of antioxidant defence mechanisms. [4-5]. They oxidize fats, proteins, and DNA and thus can cause a cytostatic effect on the cell, damage cell membranes, and activate the apoptotic pathway.[6].

During pregnancy, increase in basic metabolism and "consumption" of oxygen and the use of fatty acids as the primary source of energy for most maternal retro-placental tissues lead to increased production of hydrogen peroxide [7-8]. Studies have shown that there is increased oxidative stress in pregnant women with hypothyroidism but effect on fetal outcome is not established properly.[9]

Objectives: So we design the study to compare the total oxidative stress in hypothyroid pregnant women along with its effect over the fetal outcome

Materials and Methods

The study was done at NRS Medical College & Hospital, Kolkata, West Bengal, in the Department of Biochemistry, from April 2020 to march 2021.

Ethical permission: permitted by institutional ethics committee of NRS medical college.

After exclusion a total of 250 pregnant women attending antenatal OPD were included as case alongwith 250 age matched non pregnant women as control. Out 250 pregnant women 78 were detected to have hypothyroidism & the rest 172 were euthyriod.

Serum fT4 & TSH was measured by ELISA method using standardized kit for all the collected samplesTotal oxidative stress (TOS) was measured from serum by Modified FORT test, standardized in our laboratory using N, N-dimethylp-phenylenediaminesulphate as chromogen[19-20]. The test is based on the ability of transition metals, such as iron, to catalyse the breakdown of hydroperoxides into derivative radicals, which are then preferentially trapped by the buffered chromogen (N, N-dimethyl-pphenylenediamine-sulphate) and develop a coloured product which can be colorimetrically measured. [10-11]Standardization and assay of total oxidative stress (TOS): Standard curve was prepared using different dilutions of hydrogen peroxide (H^2O^2) (in milli-mole per liter) at 505nm

Fetal outcome were measured in terms of thyroid hormonal status of the baby at birth (fT4 & TSH), birth asphyxia (APGAR score) & birth weight.

Result

Results shows there is a significant increase in oxidative stress in pregnancy which is further aggravated by hypo-thyroid status. Fetus outcome along with fetal hypothyroid status is also directly correlated with maternal thyroid status.

Table 1: Demographic and Biochemical characteristics of the study

	Non pregnant (n=250) (mean± SD)	Pregnant (n=250)	T value	P value
TOS (mmol/L – equivalent of H^2O^2)	31.09± 3.1	65.9± 2.9	134.5	<0.001
fT4 (ng/dl)	0.97± 1.3	0.5± 1.6	3.33	<0.0013
TSH (mU/L)	2.7± 1.9	5.1±2.4	16.8	<0.001

Table 2: One way ANOVA & post hoc ANOVA test (Tukey HSD) for TOS in 3 groups (non pregnant, pregnant euthyroid & pregnant hypothyroid)

	Mean square	F value	significance
Between group	28923.3	410.04	0.000
Within group	3068.35		

Table 3: Post hoc (Tukey HSD) for TOS in 3 groups

Pairwise comparison	Mean values	Mean differences	Q value	P value
T1:T2	M1: 31.09 M2: 53.39	22.29	20.37	0.000
T1:T3	M1: 31.09 M3: 77.02	46.02	42.05	0.000
T2:T3	M2:53.39 M3:77.02	23.73	21.68	0.000

Table 4: The fetal outcomes were measured at the time of delivery of both euthyroid & hypothyroid mothers

	Hypothyroid mother	Euthyroid mother
Baby TSH (mU/L) (mean±SD)	14.13±8.18	9.3±6.14
Baby fT4 (nd/dl) (mean±SD)	1.08±0.37	1.17±0.31

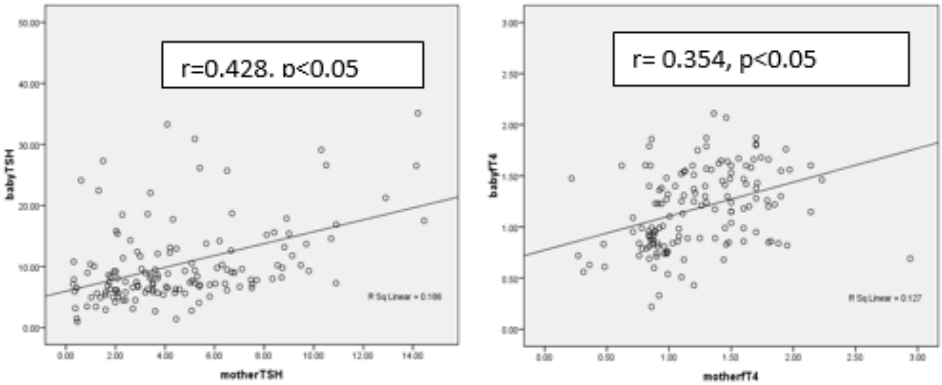

Fig 1: Correlation curves of thyroid status of mother & baby

Table 5: APGAR score at 5 minute of birth& lowbirth weight in hypothyroid & euthyroid mother

	Hypothyroid mother	Euthyroid mother	Odds ratio	P value
APGAR score (<5 at 5 min)	42%	5%	14.25	<0.05
Birth weight (<2.5 kg)	38%	24%	2.37	<0.05

Discussion

In this study there is significantly increased level of TOS & TSH level in pregnant population than the non-pregnant. [table 1] similar finding has been found in the study of P. Santulli et al.[12]

In thyroid dysfunction there is chance of more production of ROS and decreased glutathione can increase the oxidative stress also. [13-14]

Correlation of thyroid hormonal status of the mother and the baby shows statistically significant positive correlation between maternal and baby TSH levels with correlation coefficient (r value) is +0.428 and p value is <0.05. The fT4 levels of mothers and the babies were also significantly positively correlated with correlation coefficient (r value) is +0.354 and p value is <0.05.

In the study of Kris Poppe et al in 2003 the deficiency of maternal thyroid hormones may increase the chance of insufficient placental transfer of thyroid hormones which in turn increases the chances of congenital hypothyroidism. [15]

The incidence of adverse fetal outcome was found to be statistically significant in hypothyroid state for the Low birth weight(<2.5 kg) [odd ratio 2.37, p value= 0.026]similar finding has been found in the study of Leuang AS et al[16]&Low APGAR score [odd ratio 14.25, p value < 0.0001] Similar finding has been found in the study of La Franchi AS et al.[17]

Changes in maternal thyroid function during pregnancy result from a combination of increased metabolic demands, increased serum TBG concentrations, stimulation of the TSH receptor by human chorionic gonadotropin (hCG) [18].Moreover, modified iodine metabolism can also has its effect in pregnant hypothyroid status.Studies done on pregnancy complicated with hypothyroidism have confirmed that the reactive oxygen species are working efficiently along with reducing the levels of oxidants, e.g., vitamin E or C. A significantly lower antioxidant effect of trolox—a substance derived from vitamin E on lipid peroxidation processes in the placenta of women suffering from hypothyroidism—has been proven. [19].This increased oxidative stress effect the mother and fetus oucome by damaging various organs.Oxidative stress causes abnormalities in the structure of DNA that can lead to early miscarriages, preeclampsia, fetal growth restriction, fetal abnormalities, and birth defects [20-21].

Summary: Our study has brought forth a baseline idea of increase oxidative stress in pregnancy which is further augmented in hypothyroidism. It also shows that if it is diagnosed late in pregnancy or remain undiagnosed causes grave prognosis to the baby.

Limitations: The sample size is not large enough. long term followup of the new born was not possible in the study.

Conflict of interest: There is no conflict of interest

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Original Research

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Comparison of Endoscopic Versus Conventional Septoplasty in Jharkhand Population

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Abstract

Background: Although there are many techniques for septoplasty to cure nasal obstruction. Nasal endoscope is very useful tool to visualise posterior part of septum and perform the surgery more precisely, with less complication as compare to conventional method.

Method: Out of 90 (Ninety) patients having DNS associated with epistaxis,chronic rhino sinusitis, snoring were studied 45 were treated with Endoscopic septoplastyand 45 with conventional septoplasty pros and cons of both tools and techniques were noted.

Results: Post-surgical complications were least in Endoscopic surgery as compare to conventional septoplasty – 0% bleeding in Endoscopy and 2 (4.44%) in conventional, 7 (15.5%) DNS recurrence in conventional and 3 (6.66%) in endoscopic, 3 (6.6%) Epistaxis and crusting in conventional and 1 (2.2%) in Endoscopy and 0% crusting in Endoscopy.

Conclusion: It is concluded that Endoscopic septoplasty is quite safer due to better illumination which enables to identify the pathology of septum precisely and realignment of the cartilages for better results.

Keywords: Endoscopy, Conventional, Septoplasty, DNS, Rhino sinusitis

Introduction

Nasal obstruction is the most common complaint in rhino-logic practice and deviated Nasal septum (DNS) is the most common cause of nasal obstruction. A significantly deviated nasal septum has been implicated in epistaxis, sinusitis, obstructive sleep apnoea and headache attributed to contract points with structures of the lateral nasal well [(1)].

Surgical corrections of deviated nasal septum has been performed by a variety of technique of which submucosresection andseptoplasty procedures of surgical correction of nasal septum play a prime role in management of patients of nasal obstruction[(2)]. After the invention of nasal endoscopes tremendous changes have evolved in the field of septal surgery. Nowadays endoscopes are being used in performing septal surgery so as to allow in performing endoscopic sinus surgery where it is termed as Endoscopic .It is a surgical procedure that corrects the deformity of the nasal septum [(3)].

The ideal surgical procedure or corrections of Nasal septum should satisfy the following

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criteria (a) Should relieve the nasal obstruction (b) should be conservative (c) should not produce iatrogenic deformity (d) should not compromise osteometalcomplex (e) must have scope for revision surgery if require later [4]. The traditional surgeries of the nasal septum improve the nasal airways but do not fulfil the above mentioned criteria in most instances,because it has multiple reasons such as poor visualisation relative in accessibility, poor illumination[5] difficulty in evaluation of exact pathology, need for nasal packing unnecessary manipulation resection and over exposure of septal frame work reducing the scope for revision surgery.

Hence attempt was made to compare and evaluate the advantages and disadvantages in post surgical complications.

Material and Method

90 (Ninety) patients visited to Department of ENT, PhuloJhano Medical college Dumka Jharkhand-814110 were studied.

Inclusive Criteria: Adult patients aged between 18 to 50 years having symptoms of Deviated Nasal septum (DNS) obstruction, chronic rhino sinusitis, complication like Epistaxis headache snoring were selected for study.

Exclusion Criteria: Children below 8 years and adults above 80 years. The patients having externaldeviated nasal septum, acute rhinitis or allergic rhinitis, vasomotor rhinitis. The patient's previously undergone surgery of DNS. Immune compromised patients were excluded from study.

Method: All the patients were informed about the technique and written consent was taken from every patient before surgery premedication'swere given to the patients. 45 patients were selected for conventional septoplasly and 45 patients for endoscopic septoplasty technique

After infiltration with 2% xylocaine with adrenaline into columella and septum under head light incision (Hemitrans fixation incision) was made at coudal border. The muco-perichondrial and periosteal flaps were elevated up to perpendicular plate of ethmoid bone. The osseo-cartilagenous junction was dislocated A 0.5 cm of the anterior margin of perpendicular plate of ethmoid was removedwith LUC'S forceps. An inferior cartilaginous strip of 0.5cm was removed if necessary. The incision was closed using chronic catgut (3-0) and nasal packing was done technique for Endoscopic surgery. The procedure was performed under local or general anaesthesia. The septum was injected 2% xylocaine in 1:20,0000epinephrines on the convex side of the most deviated part of septum using rigid 4mm endoscope. Hemi Trans fixation incision was made Incision was needed to expose the most deviated part. A sub-muco-perichondrial flap was raised using a suctionelevator under direct visualisation with endoscope underlying bone was removed. The flap was re-positioned back after the suction clearance and edges of incision were just made to lie closely without the need of the suture. The nasal cavity was packed with Vaseline nasal packs.

Intra-operatively following parameters were noted (a) Duration of surgery (b) Blood loss during surgery (c) Associated turbinate procedure.

Nasal package was done for all cases in both groups (techniques) with Vaseline Nasal packs and IV th generation antibiotics started.

The patients of both groups were discharged with one week of antibiotics and analgesics. Decongestant nasal drops till next visit (follow up), post-operatively 2^{nd}, 4^{th} and 8^{th} weeks follow up were done and following points were noted on diagnostic nasal endoscopy (a) persistence of anterior / posterior deviation or spur (b) Formation of synechiae or spur (c) persistence of pathology Turbinates (d) presence of discharge in middle meatus (e) clod spatula test (f) Any change in external appearance.

Duration of study was January-2021 to August-2022.

Statistical analysis: Clinical manifestations, post-operative complications in both groups were classified with percentage. The statistical analysis was carried out in SPSS software. The ratio of male and female was 2:1.

Observation and Results

Table-1: Comparison of clinical manifestation is conventional septoplasty and endoscopic

septoplasty13 DNS in conventional, 11 (24.4%) Endoscopic,11(24.4%)leftDNSinconventional,9(20%) in Endoscopic, 8 (17.7%) spurin conventional and 5 (5.55%) in Endoscopic. Hypertrophied IT 10 (22.2%) in conventional and 15 in Endoscopic,polypoid MT in 2 (2.22%) concha ullosa, 2 (2.22%) Nasal discharge observed Endoscopic septoplasty 3 (6.66%) Nasal discharge in conventionalseptoplasty

Table 2: comparative study of post-operative complication

- Bleeding 0% in Endoscopic, 2 (4.4%) in conventional
- Synechie 1case in Endoscopic, 2 (4.4%) in conventional
- DNS 3 (6.66%) in Endoscopic, 7 (15.5%) in conventional
- Epistaxis 1 (2.22%) in Endoscopic and 3 (6.66%) in conventional
- Crusting 3 (6.66%) only in conventional

Table 1: Comparison of clinical manifestation in both conventional septoplasty and Endoscopic septoplasty

Sl. No.	Clinical Manifestation	Conventional (45)		Endoscopic (45)		Total	Percentage (%)
		No	%	No	%		
1	Right DNS	13	28.5	11	24.4	24	26.6
2	Left DNS	11	24.4	9	20	20	22.2
3	Spur	8	17.7	5	11.1	13	14.4
4	Hypertrophied IT	10	22	15	33.3	25	27.7
5	Polypoid MT	0	--	2	2.22	2	2.22
6	Concha Bullusa	0	--	1	1.11	1	1.11
7	Discharge	3	6.66	2	2.22	5	5.55

Table 2: Comparison of post-operative complication in both conventional and Endoscopic septoplasty

Sl. No.	Endoscopic Septoplasty (45)	Percentage (%)	Conventional septoplasty (45)	Percentage (%)
1	Bleeding	0	Bleeding	2 (4.44%)
2	Synechie	1 (2.22%)	Synechie	2 (4.44%)
3	DNS	3 (3.33%)	DNS	7 (15.5%)
4	Epistaxis	1 (2.22%)	Epistaxis	3 (6.66%)
5	Crusting	0	Crusting	3 (6.66%)

Discussion

Present comparative study of Endoscopic versus conventional septoplasty in Jharkhand Population. Right DNS were 13 (28.8%) in conventional, 11 (24.4%) in Endoscopic, 11 (24.4%) left DNS in conventional, 9 (20%) in Endoscopic spur, 8 (17.7%) in conventional, 5 (11.1%) in Endoscopic, Hypertrophied IT 10 (22.2%) in conventional, 15 (33.3%) in Endoscopic polypoid MT, 2 (2.22%) in Endoscopic, 1 (1.11%) concha Bullosa, 2 (2.22%) nasal discharge was observation Endoscopic septoplasty procedure (Table-1). Comparative study of post-operative complications in both septopastic surgeries were Bleeding was 0% in endoscopic and 2 (4.44%) conventional, Synechie 1 (22%) in endoscopic, 2 (4.44%) in conventional, Recurrence of DNS 3 (6.66%) in Endoscopic, 7 (15.5%) conventional, Epistaxis was 1 (2.22%) in Endoscopic, 3 (6.66%) in conventional, Crusting was 0% in Endoscopic 3 (6.66%) in conventional (Table-2). These findings are more or less in agreement with previous studies[6][7][8].

With the introduction of endoscopes in other branches of surgery, there have been attempts at its utilization in septal surgery. Endoscopic septoplasty

is an attractive, alternative to traditional head light approach for septoplasty.

It is noted that, conventional septoplasty has six phases (a) gaining access to septum (b) correction of pathology (c) removing pathology (d) shaping removed cartilage and bone (e) reconstruction of septum (f) stabilizing the septum [9]. Endoscopic septoplasty is not primarily meant for relieving nasal obstruction but mostly it is performed to gain access to surgical site as in cases of FESS (Functional Endoscopic sinus surgeries) in revision surgeries and also in cases with isolated septal spurs. Complex deformities need corrections by conventional approach so also, the caudal deflections.

Significantly higher rate of persistence of symptoms were found with conventional septoplasty in the present study. It was also noted in previous studies [10].

Under Endoscopy technique one could identify the bleeding points and reduce the incidences of haemorrhage. In the case of isolated spur it was easier to avoid mucosal tears [11].

Summary and Conclusion

In the present study it is concluded that, invention of endoscopic septoplasty is a major event in the history of septal surgery. It helps in dealing with posterior deviations and isolated spurs. It gives better illumination and precise vision of the anatomy of Nasal and thus helps in proper planning of the surgery. Endoscopic septoplasty is performed with minimal incision and least manipulation. This resulted in minimal damage to the tissues, minimal removal of septum and hence precise reconstruction. So the stability of the septum is not compromised. Mucosal tears are avoided and hence synechaeformation. But the present study demands further, genetic, nutritional, environmental, patho-physiological studies because exact pathogenesis of Deviation of Nasal septum is still unclear.

Limitation of study: Due to tertiary location of research centre small number of patients, lack of latest techniques, we have limited findings and results.

This research work was approved by Ethical committee of PhuloJhani Medical College Dumka Jharkhand-814110.

Conflict of Interest: No

Funding: No

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Original Article

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To Detect the Adulteration of Raw Milk by Color Test in the Laboratory as to Safe Guard the Human Health

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Abstract

Background: Milk is important part of diet due to its nutritive values. It is recommended for population of every age group.Milk is required for the growth and maintenance of health. When consumers buy milk they have a right toassume that milk will be pure and unadulterated. It is the duty of the milk vendors to provide unadulterated milk to the consumers. Adulteration is the act of addition of substances to a product that makes it unfit for human consumption. These additives are used to make the product cheaper and increase its amount.[1]

Material and Method: A prospective study was conducted by Central Research Laboratory of Muzaffarnagar Medical College, to find out the adulteration of raw buffalo milk sampleobtained from rural areas around Muzaffarnagar Medical College,by color test methodology. The Institutional ethical committee permission was taken.100 samples were collected from 30 different villages around Muzaffarnagar Medical College. The raw milk sample was analyzed for physical appearance, pH, quality,dilution and presence of adulterant by color test.

Result: It was observed that out of 100 samples, 85% samples were white and 15% samples were slightly yellow. The pH of the raw milk samples ranged from 6.5-7.0. The Methylene Blue Reduction Test (MBRT) showed 10samples of raw milk were of poor quality, 15 raw milk samples were fair quality, 45 raw milk samples were good quality and 30 raw milk samples were of very good quality.

Result: In our study water and table sugar were the common adulterants and Benzoic acid was present in traces. So it was concluded that the raw buffalo milk obtained from the near by rural area around Muzaffarnagar Medical College was comparatively of good quality. The common adulterants obtained from raw milk of buffalo were water and table sugar. These malpractices by local dairy owner should be checked to ensure good quality of milk to the consumers.

Keywords: Adulteration, Adulterants, Raw Milk, Color Test, Benzoic acid.

Introduction

Milk provides nutrition to all age group of human and animal population. It contains essential nutrients like, lactose and fat that gives energy, calcium and minerals that helps in bone growth. It provides body building proteins and vitamins needed for the development of humans[2]. The buffalo and Cow

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milk are consumed but have slight difference in their constituents [3]

S. no	Constituent of milk	Buffalo milk (%)	Cowmilk (%)
1.	Water	84.2	86.6
2.	Fat	6.6	4.6
3.	Protein	3.9	3.4
4.	Lactose	5.2	4.9

India is world's largest milk producer, with 22% of global production, followed by the United States of America, China, Pakistan and Brazil[4]. InIndiarural populationis more than the urban population andlarge amount of milk is sold by local vendors. It is important to check the adulteration of milk.

Adulteration includes the addition of chemicals and also accidental contamination during the process of collection, storage and transportation. Adulterated milk has adverse effect on health because of toxic nature of additional compounds .[1]The most common adulterants are:

- Water
- Starch
- Detergent
- Benzoic acid
- Table sugar
- Ammonium sulfate

It has been observed that the adulteration of milk is one of the commonpracticesthat the dairysector of India is facing. We conducted this study to find out the adulteration of raw buffalo milk sold by local vendors aroundMuzaffarnagar Medical College.

According to the national survey on milk adulteration conducted by FSSAI (India) in 2011, water was the common adulterant followed by detergent in the milk. [5] Inspite of the laws governing quality and sales of milk in India for many years the adulteration of milk has not been checked.

Materials and Methods

A prospective study was conducted by Central Research Laboratory of Muzaffarnagar Medical College, to find out the adulteration of raw buffalo milk sample obtained from rural areas around Muzaffarnagar Medical College by color test methodology. The Institutional ethical committee permission was taken. The duration of the study was six months. 100 raw buffalo milk samples were collected from 30 different villages around Muzaffarnagar Medical College.The samples were collected in 100ml clean sterilized bottles and were transported to laboratory without any delay. All possible precautions were taken to avoid external contamination during the time of sample collection.

The raw buffalo milk samples obtained from nearby villageswere analyzed for physical appearance, dilution, quality and presence of adulterants.

Impurities in milk were detected by carrying out chemical color test according to the protocol given by Food Safety and Standards Authority of India[6].

The various methods used in laboratory to detect the milk adulteration were as follows-

Detection of Table Sugar in milk:

1. Pour 10 ml of milk into the test tube .Labeled the test tube as table sugar color test. By pipette add concentrated HCI into the test tube.
2. Do the test in fume hood. Now shake the test tube gently so that the milk gets precipitated, weight 100 milligram of resorcinol and add this to the precipitated milk then shakes the test tube well.
3. Color of the milk solution changes to light brown now place the test tube with the test tube holder in a water bath at 100^0 Celsius for 5 minute.
4. The color milk solution turns red which shows the presence of table sugar, if the color remains the same it denotes absence of table sugar in milk.

Detection of Starch

1. Pour 5ml of milk in a test tube labeled it as starch color test. Place the test tube in a water bath at 100^0 Celsius using a test tube holder, after 5 minutes remove the tube from water bath.
2. Allow the tube to cool and then by the help of dropper add 2-3 drops of Iodine solution to the test tube and shake it well.
3. If the color of the milk solution turns yellow,

it indicates the absence of starch, if the milk turns dark blue color indicating the presence of starch in the milk.

Detection of Benzoic acid and Salicylic acid:

1. Pour 5 ml of milk from the beaker into the test tube labeled acid, add 5 drops of concentrated sulfuric acid into the milk and shake the test tube gently.
2. This should be done in the fume hood. With the help of dropper add 0.5%ferric chloride solution drop by drop and mix it well, buff color indicates the presence of Benzoic acid, if it turns violet color it shows the presence of Salicylic acid in the milk.

Detection of Soap:

1. Pour 10 ml of milk into a test tube.Labeled the test tube as soap color test Add 10 ml hot water to the milk, add 1 to 2 drops of phenolphthalein indicator into the test tube and mix it gently.
2. If the color turns pink it indicates the presence of soap in the milk.

Detection of Formalin in milk:

1. Pour 2 ml of milk into test tube andlabeled it as formalin. Add 2 ml of 90% sulfuric acid gently and then add ferric chloride with the help of glass pipette.
2. A purple violet ring is formed at the junction indicating the presence of formalin in the milk.

Detection of Ammonium Sulfate in milk:

1. Pour 5ml of milk into the test tube, labeled it as Ammonium sulfate. Now add 2.5ml of 2% NaOH solution, 2.5ml of 2% Sodium hypochlorite and 2.5ml of 5% Phenol solution.
2. Keep the test tube in a water bath at 100^0 Celsius for 20 seconds. If the color of the milkturns deep blue then it indicates the presence of Ammonium sulfate.

Detection of Microorganisms in milk (MBRT):

1. Pour 10 ml of milk in a test tube labeled it as Methylene Blue reduction test. Add 8 to 10 drops of Methylene Blue into the test tube and mix the contents well and incubate it for 30 minutes or more till the raw milk is decolorized up to 5mm from the surface.
2. The tube shall be observed for half an hour and then hourly thereafter. Record the time for complete decolorization of raw milk.

Grading of methylene blue reduction time[7]

Methylene blue reduction time	Grade
• ½ hour	Poor
• 1-2 hours	Fair
• 3-4 hours	Good
• 5 hours and above	Very Good

Result

The 85% of raw milk samples were white in appearance and 15% were slightly yellowish. The pH of the milk samples ranged from 6.5 to 7.0 (Table 1). The Methylene Blue Reduction Test (MBRT) showed that, 30 milk samples were of very good quality, 45 milk samples of good quality, 15 milk samples of fair quality whereas 10 milk samples were of poor quality. Adulterant found in the milk samples shown in Table 2.

Table 1: Physical properties of milk

S. No	Location (Muzaffarnagar)	Colour	Avg. pH
1.	Mansurpur (4 samples)	2 samples- white 1 sample-slightly yellow	6.5
2.	Bopara (4 samples)	All samples- white	6.7
3.	Johar (3 samples)	All samples- white	6.5
4.	Begrajpur (4 samples)	3 samples-white 2 sample-slightly yellow	6.8
5.	Khatauli (3 samples)	All samples-white	6.7
6.	Purbaliyan (2 samples)	All samples- white	6.6

Continue...

7.	Rampuri (3 samples)	2 samples- white 1 sample – slightly yellow	6.8
8.	Sabudin (5 samples)	4 samples- white 1 sample-yellow	6.6
9.	Jaroda (3 samples)	2 samples-white 1 samples-slightly yellow	6.5
10.	Sikhara (3 samples)	All samples- white	6.8
11	Santa (5 samples)	4 samples- white 1 sample- slightly yellow	6.5
12	Moghpur (3 samples)	All samples white	6.6
13	Dudhapadi (3 samples)	All samples white	6.9
14	Bhatoda (3 samples)	All samples white	6.7
15	Bhadarpur (4 samples)	3 samples- white 1 sample- slightly yellow	6.6
16	Nirana (2 samples)	All samples- slightly yellow	7.0
17	Rasulpur (3 samples)	All samples- white	6.9
18	Mulhadi (4 samples)	All samples- white	6.7
19	Nara (3 samples)	2 samples-white 1 sample-slightly yellow	6.5
20	Bilaspur (3 samples)	All samples- white	6.6
21	Chitoda (4 samples)	All samples- white	6.8
22	Dalatpur (3 samples)	2 samples- white 1 sample- slightly yellow	6.4
23	Agmatgardh (3 samples)	All samples- white	6.9
24	fempur (4 samples)	3 samples - white 1 sample- slightly yellow	6.6
25	Manawarpur (2 samples)	All samples- white	7.0
26	Bhikky (3 samples)	All samples- white	6.6
27	Bihari (5 samples)	3 samples- white 2 samples- slightly yellow	6.5
28	Tisang (3 samples)	All samples- white	6.8
29	Campus (2 samples)	All samples- white	6.9
30	Bhatodi (4 samples)	All samples- white	6.6

Table 2: Detection of adulterants in raw milk samples

S. no	Adulterants	Test	Samples Positive
1	Water	Slide test	77
2	Table sugar	Resorcinol test	20
3	Benzoic acid	Benzoic acid test	3 (traces)
4	Salicylic acid	Salicylic acid test	0
5	Ammonium sulfate	Ammonium Sulfate test	0
6	Soap	Soap test	0
7	Formalin	Formalin test	0
8	Starch	Iodine test	0

Discussion

Milk is reported as the most preferred food for humans as it has all nutrients in balanced proportion. The adulteration of milk is very common problem now a daysposing heavy toll to human health.

In the current study out of 100 samples, 85% sample were white in color and 15% slightly yellow in colorthese findings approve with the report of Judkins and Mack 8, who reported that normal milk is slightly yellow incolor due to presence of fat and casein and presence of small amount of coloring matter. The difference in color may be due to difference in buffalo fodder consumption or the breed of buffalo or fat and solid content of the milk[9]. The pH of the milk in our study ranged from 6.5 to 7.0 which coincides with study given by Shrishti and Rakesh 2013.[5] In our study, we graded 100 samples of raw buffalo milk by doing the methylene blue test. Out of 100 samples 75 samples were of good and very good quality, 15 samples were of fair quality and 10 samples were of poor quality while in Shrishti and Rakesh 2013 study 15 samples were of poor quality, 73 samples of fair quality and 12 samples were of good and very good quality. Our study also revealed that water is the most common adulterant in raw milk (77%) which coincides with Grace et al 2009.[10] Water is commonly added to increase the quantity of milk but it also reduces the nutritional value of milk. If the water added to the milk is contaminated then it increases the health risk to the consumer.[11] In our study table sugar was found as adulterant in 20 samples of raw buffalo milk. The table sugar may be added to increase the weight and used to mimic the natural sweetness of the milk.[12] Benzoic acid was found as an adulterant in 3 samples of raw milk but benzoic acid was in negligible amount. This may be added to increase the shelf life of milk.

Conclusion

High nutritional value of milk has made the milk as one of the important component of the diet for adults and children. From our study we conclude that the raw milk provided at the rural areas around Muzaffarnagar Medical Collegeis of good quality. The poor quality of milk was mainlydue to adulteration of water, table sugar and traces of benzoic acid. Adulteration of milk is becoming common practice due to exploding population and increase in demand of milk and dairy products. Water is added to the milk to increase the quantity and if water is contaminated it decreases the quality of milk and impose hazard to the consumers. The local milk vendors sometimes add table sugar to balance the sweetness of raw milk which can be dangerous for diabetics.The addition of preservatives like benzoic acid and salicylic acid in small amount may be due to increases in the shelf life of milk.

In a developing nation like India where milk plays an important role in health this study would bring more awareness to public about adulteration of the milk.

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Original Research Article

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Impact of Diabetes Mellitus on Spectrum of Presentation of Tuberculosis

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Abstract

Introduction: Increased occurrence of tuberculosis in diabetic population is known since long time. Tuberculosis (TB) remains one of the world's deadliest communicable diseases and India currently bears the highest burden of tuberculosis in the World. Diabetes mellitus (DM) is becoming the epidemic of the 21st century with India having the second largest diabetic populationglobally. This emphasizes the importance of investigating the association of tuberculosis and diabetes mellitus.

Aim: To evaluate clinic-radiological presentations of tuberculosis (pulmonary and extra pulmonary) in diabetic patients compared to non-diabetic patients.

Materials and Methods: Patients with active tuberculosis with and without diabetes mellitus were enrolled and the two groups were matched for age, sex, addiction habits, history of contact with tuberculosis and previous treatment for tuberculosis. Spectrums of tubercular involvement in both the groups were studied including severity of the disease. A symptom score comprising major TB related symptoms and a composite severity score utilizing clinical, radiological, and microbiological parameters were used to compare TB severity between the two groups.

Results: Patients with TB with DM were found to have male preponderance (70%), higher BMI, increased chance of having isolated lower lobe lesion (8%), multilobar lesion (42%) and cavitary lesion (20%), significantly higher TB symptom score and TB severity score compared to patients with TB without DM. The TB severity score has significant correlation with level of HbA^{1c} at presentation.

Conclusion: Presence of coexistent diabetes along with tuberculosis results in increased severity of tuberculosis and its severity has direct correlation with poor glycemic status at presentation.

Key words: Tuberculosis, Diabetes mellitus, clinic-radiological presentations, TB Symptom Score, TB Severity Score

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Introduction

Tuberculosis is at least as old as mankind and mycobacteria are believed to be amongst the oldest bacteria on earth. Tuberculosis (TB) is an infectious disease caused by various strains of mycobacteria, especially Mycobacterium tuberculosis and usually attacks the lung. It remains to be a major cause of morbidity and mortality throughout the World. Though there is a sharp drop in notification of newly diagnosed TB cases in 2020 compared to 2019, an estimated 9.9 million people fell ill with TB and 1.5 million died from the disease in 2020. Out of these, India accounted for 26% of the disease burden.[1]

Diabetes mellitus refers to a heterogeneous group of diseases characterized by chronic hyperglycemia due to absolute or relative deficiency of insulin affecting metabolism of carbohydrate, protein, and fat. Diabetes is fast gaining the status of a potential epidemic in India. The International Diabetes Federation (IDF) estimates the total number of diabetic adults to be around 74.2 million in India in 2021 and this is further set to raise to about 125 million by the year 2045. India is currently at the second place worldwide, next to China in this regard.[2] Several retrospective[3, 4] and prospective[5] studies has shown that patients with diabetes mellitus has higher risk of developing tuberculosis and vice versa.

Uncontrolled diabetes increases the risk of developing TB, thus increasing prevalence of diabetesleads to great challenge for control of tuberculosis. A study has shown that the countries with increase in prevalence of diabetes also had a significant burden of tuberculosis.[7] The association between diabetes and tuberculosis has been seen by several studies, and was found that people with diabetes are around 2.5 times more likely to develop tuberculosis.[8]

So the primary objective of the study is to find out the impact of diabetic epidemic on spectrum of presentation of tuberculosis in a tertiary health care center in view of huge socio-economic burden of both the diseases in present scenario.

Materials and Methods

A prospective tertiary healthcare based study over 1.5 years was done in OPD and IPD of Department of Respiratory Medicine, Institute of Post Graduate Medical Education and Research, Kolkata, West Bengal. About 50 patients of active tuberculosis (both pulmonary and extra-pulmonary) with known diabetes or found to have diabetes on initial screening (as per ADA guideline) were enrolled as cases and 50 patients having active tuberculosis without diabetes are enrolled as control group after matching age, sex, personal habits and history of contact with tuberculosis and antitubercular drugs intake. Patients with HIV infection, taking systemic steroids for >2 weeks in last 6 months, chronic kidney disease (stage G3b and above) and having malignancy were excluded from the study. Detailed history, clinical examination and radiological studies and other relevant investigations were done for all patients to assess the spectrum of the disease.

Severity of tuberculosis has been defined in two ways:

TB Symptom Score:

In order to estimate TB disease severity in our study population, we have used a modified version of a previously published symptom score by Alisjahbana et al[9]. In this scoring system, one point was given for the presence of each major TB-related symptom (cough, hemoptysis, dyspnea, fever, chest pain, weight loss, night sweats). The total score can range from zero (no symptoms) to 7 (all symptoms). In this context, patients presenting with a score value ≥4 were classified as having severe TB.

TB Severity Score:

We also built a TB Severity Score based on the composite score built by Leonardo Gil-Santana et al[10]. The scoring system is as follows:

- Cough, hemoptysis, dyspnea, fever, weight loss, chest pain, night sweat= 1 point each, total 7 points
- ECOG score = 0 to 5 points
- Multilobar lesion in chest radiograph= 1 point
- Presence of cavity in chest radiograph = 1 point
- Presence of AFB in sputum or FNAC/ Biopsy= 1 point
- Presence of disseminated TB= 1 point

Total score can range from 0 to 16. Patients with score ≤8 are defined to have mild disease and patients having score >8 are defined to have severe disease.

Results

This study included 50 patients with a diagnosis of active tuberculosis who has either previous history of diabetes or subsequently diagnosed as diabetics on screening and 50 patients with active tuberculosis without having diabetes to serve as control group. Both groups are matched for their age, sex, addiction habits, history of contact with tuberculosis and previous treatment for tuberculosis.

After analysing the initial presentation of the two groups,the mean BMI of the patients of TB-DM group is found to be 23.44±2.31 Kg/m^2 and it is significantly higher than patients of tuberculosis without having DM (p=0.04).Higher ECOG score (≥3) was found among TB with DM patients as compared to TB without DM patients (48% vs. 22%, p=0.004) and proportion of patients having pulmonary tuberculosis is significantly higher in TB-DM group compared to non-DM group (60% vs. 32%, p=0.005) [Table 1]. Presence of symptoms also varies between the two groups. Proportion of patients with cough (90% vs. 64%), dyspnea (64% vs. 24%), chest pain (64% vs. 24%) and weight loss (62% vs. 40%) was significantly higher for patients with DM than that of without DM (p<0.05) [Table 2].

Significantly higher proportion of patients of DM group has TB Symptom Score ≥4 compared to that of Non-DM group and The risk of having TB symptom score≥4 i.e. severe TB was 4.51 times more among TB patients with DM as compared to TB patients without DM and the risk was significant [OR-4.51 (1.88, 10.78); p=0.0004] (Table 2).

While looking at the pattern of involvement in chest radiograph, proportion of patients with isolated lower lobe lesion (8% vs. 0%), multi lobar lesion (42% vs. 14%) and presence of cavity (20% vs. 8%) is significantly higher for patients with DM than that of without DM (p<0.05) [Table 3]. Though there was no significant association between sputum microscopy for AFB at presentation and two groups (p=0.06), but proportion of patients with higher positive value (≥2+) for sputum microscopy for AFB at presentation is higher for the patients with DM compared to non-DM group (36% vs. 16%) [Table 4].

The mean of TB Severity Score in patients with DM is significantly higher than the patients of tuberculosis without having DM (7.78±2.45 vs. 5.34±2.90, t^{98} =4.54, p<0.00001). More patients in DM group presented with severe disease (score≥8) compared to non-DM group (44% vs. 12%, p=0.0004) [Table 5]. Correlation between TB Severity Score and level of HbA^{1c} at presentation was significant for the patients with DM (r=0.62, p<0.0001). So, with the increase in HbA^{1c} at presentation for DM patients, the severity of tuberculosis also increases [Table 6].

Table 1: Comparison between initial presenting features

Initial Presentation		TB with DM (n=50)	TB without DM (n=50)	p value
BMI (Mean)		23.46±2.33	22.04±1.66	0.04
ECOG Score	<3	26(52%)	39(78%)	0.006
	≥3	24(48%)	11(22%)	
Site of TB	PTB	30(60%)	16(32%)	0.005
	EPTB	15(30%)	31(62%)	
	Disseminated TB	5(10%)	3(6%)	

Table 2: Difference between presenting symptoms and comparison between TB symptom scores

Presence of symptoms	Patients with DM (n=50)	Patients without DM (n=50)	p-value
Cough	45 (90.0%)	32 (64.0%)	<0.0001
Hemoptysis	13 (26.0%)	7 (14.0%)	0.26

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Presence of symptoms	Patients with DM (n=50)	Patients without DM (n=50)	p-value
Dyspnea	32 (64.0%)	12 (24.0%)	<0.0001
Fever	39 (78.0%)	44 (88.0%)	0.06
Chest pain	32 (64.0%)	12 (24.0%)	<0.0001
Weight loss	31 (62.0%)	20 (40.0%)	0.0019
Night sweats	22 (44.0%)	21 (42.0%)	0.77
TB Symptom Score			
Score ≥4	39	22	0.0004
Score <4	11	28	

Table 3: Pattern of involvement of chest radiographs

Chest Radiograph	Patients with DM (n=50)	Patients without DM (n=50)	p-value
Isolated upper lobe lesion	6 (12.0%)	8 (16.0%)	0.41
Isolated lower lobe lesion	4 (8.0%)	0 (0.0%)	0.004
Multi lobar lesion	21 (42.0%)	7 (14.0%)	<0.001
Presence of cavity	10 (20.0%)	4 (8.0%)	0.0147
Pneumothorax	1 (2.0%)	0 (0.0%)	0.15
Pleural Effusion	16 (32.0%)	14 (28.0%)	0.54
Hydropneumothorax	2 (4.0%)	1 (2.0%)	0.41

Table 4: Sputum microscopy at presentation

Sputum microscopy for AFB	Patients with DM (n=50)	Patients without DM (n=50)	p value
Negative	23	36	0.06
Scanty	3	3	
1+	6	3	
2+	7	5	
3+	11	3	

Table 5: Distribution of TB severity score

Severity of TB	Patients with DM (n=50)	Patients without DM (n=50)	p value
Mild (score ≤8)	28	44	<0.00001
Severe (score>8)	22	6	
Mean±S.D.	7.78±2.45	5.34±2.90	

Table 6: Correlation between TB severity score and HbA^{1c} at presentation

Patients	Pearson Correlation Coefficient (r)	p value
Overall (DM and Non-DM)	0.19	0.06
With DM	0.62	<0.0001
Without DM	0.16	0.26

Discussion

It is widely believed that diabetic patients are more susceptible to different types of infections, especially tubercular infection which is one of the biggest public health problems in India. As the diabetic patients become immunocompromised, infections become more severe compared to non-diabetic patients. There are some predisposing factors for increased susceptibility to infections among diabetic patients like Interference to normal functions of respiratory epithelium and ciliary motility, increased risk of aspiration due to decreased esophageal motility and gastroparesis due to autonomic neuropathy, Alterations in host defense, Pulmonary microangiopathy and Co-existent morbidity.[11]

In our study, we found a strong correlation between tuberculosis and diabetes mellitus and patients with coexistent tuberculosis and diabetes mellitus often have more symptoms of tuberculosis and more severe form of the disease. We have matched the two groups in our study in terms of age, sex, addiction habits, history of contact with tuberculosis and previous treatment for tuberculosis to rule out the confounding factors related to the spectrum of presentation of tuberculosis. We found that patients with tuberculosis and diabetes have more BMI, higher ECOG score and increased chances of having pulmonary tuberculosis. Alisjahbana *et al.* have reported a significantly higher median BMI in TB-DM patients when compared tuberculosis patients without diabetes.[9] Thus the relation between obesity and diabetes holds true even in presence of a chronic debilitating disease like tuberculosis. They have also reported a significantly lower Karnofsky Score (≤80%) in TB-DM patients when compared to non-diabetic TB patients (45.7% vs 29.4%). Due to more severe form of tuberculosis, diabetic patients with tuberculosis often have poorer performance status which in turn affects the treatment outcome of such patients. In a study done by India Diabetes Mellitus – Tuberculosis Study Group in 2012 found that, among 226 new TB patients having DM, 173 (76%) have PTB and 52(24%) have EPTB.[12] Another study done by V Nissapatorn et al. in Malaysia[13] showed that 90.5% has PTB, 4.5% has EPTB and 5% has disseminated TB in patients belong to TB with DM group compared to 79% with PTB, 13% with EPTB and 8% with disseminated TB among non-DM TB cases. Our study also corroborates with these findings.

Cough, dyspnea, chest pain and weight losses are found to be significantly associated with patients of tuberculosis with diabetes group compared to non-diabetic group. Alisjahbana *et al.* have found that patients with TB who had DM presented with more symptoms and after adjustment for possible confoundingfactors, DM remained associated with a symptom score >4 (adjusted OR, 2.90; p=.001).[9]

Leonardo Gil-Santana et al did a retrospective study in Brazil and found that symptoms that are classically associated with TB (cough, night sweats, hemoptysis, and malaise) were more frequent in TB-DM patients. They did a clinical scoring and composite scoring to assess the severity of the disease presentation and TB-DM patients showed higher values in both the scoring systems.[10] In our study also, we found that mean severity score is significantly higher in TB-DM group and significantly more patients are presenting with severe disease compared to non-DM group.

C Pérez-Guzmán et al found that they had a decreased frequency of upper (17% vs 56%) and an increased frequency of lower (19% vs 7%) and combined upper and lower (64% vs 36%) lung field lesions. More TB-DM patients developed cavitations (82% vs 59%), more often in the lower lung fields (29% vs 3%).[14] Singla et al observed that isolated lower lung field lesions were significantly more common in diabetic than in non-diabetic patients (23.5% vs 2.4%).[15] In one of the largest series, Aktogu et al. found a higher rate of lower lung field lesions among diabetics as compared with non-diabetics (11% and 5.3%, respectively).[16] Few studies found that cavitary lesions are more common in TB-DM group, especially cavitary nodular lesions.[17] Some have suggested this difference is seen more in uncontrolled DM cases ($HbA^{1c} \geq 7$).[18, 19] We have also found that patients with tuberculosis with diabetes have increased chances of having isolated lower lobe lesion, multilobar lesions and cavitary lesions.

With regards to the rate of positive sputum smears at the time of diagnosis, conflicting results have been seen. Although some researchers showed no association between diabetes mellitus and

patients' bacteriology results[20], some authors also reported a higher frequency of negative sputum smears among TB DM cases[9] while others found DM as an independent risk factor for numerous acid-fast bacilli on the sputum smear examination[15, 21] and such conflicting results might be due to the extent of immunosuppression caused by diabetes, status of glycemic control and presence of underlying cavitations.[22] We found no significant association between diabetes and sputum smear status at presentation.

Status of glycemic control also directly related to the severity of the disease as we found in this study.TB Severity Score and level of HbA^{1c} at presentation are found to be significantly associated for the patients in TB-DM group. Thus, increased level of HbA^{1c} at presentation is associated with increased severity of tuberculosis.

Conclusion

It can be concluded that tuberculosis patients having diabetes mellitus has poorer clinic-radiological presentation and more severe tubercular disease compared to the tuberculosis patients without having diabetes mellitus and the severity has direct correlation with poor glycemic status at presentation. Improved understanding of the bidirectional relationship is necessary for proper planning to reduce the dual burden of diabetes and tuberculosis.

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Original Article

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Study of Facial Index in both sexes of Northern Maharashtra

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Abstract

Background: Face is an entity that helps to distinguish one person from another. It also signifies distinction between races, ethnic groups, Sexes and even members of same family. Hence it has anthropological, anatomical and medico legal importance.

Method: 60 adult males and 60 adults females aged between 18 to 35 were studied with spreading calliper, Facial Index was measured from Nasion to Gnathion, Zygion to zygion

Results: The male facial Index was 90.5 (± 0.5) and female was 87.2 (± 0.3) ($p<0.001$) p value was highly significant. The present Facial Index was classified anthropologically under Lepto proscopic facial Index.

Conclusion: Present Facial Index of Maharashtra Population is useful to anthropologist, anatomist and medico legal export to differentiate Maharashtra population from other racial or ethnic groups of India and abroad because morpho-metric values of mesodermalderivatives are un-certain.

Keywords: Spreading calliper, Sliding calliper, laptoproscopic, Anthropological, Medico-legal

Introduction

Study of facial Index has always has always has an interesting topic for anatomist, plastic surgeons, oral and maxillo facial surgeon and artist. Physical anthropologist have been measuring the skull for years and obtained the results enabled them to trace the relationship between the races as they believe that, the form of skull remain the same in each race and different facial index [(1)], the indices express the ratio of landmarks of an individual facial index is measurement related to the morpho-metric study of skull [(2)], moreover age, sex, geographical representation can be studied from facial index [(3)] [(4).] In addition to this congenital, post traumatic facial disfigures can be rectified by the maxillofacial surgeon with the help of regional facial Index. Hence attempt was made to study the facial Index in both sexes of adults in Maharashtra to know the difference between genders and compare with North Indian and Abroad Facial indices.

Material and Methods

60 adults males and 60 females healthy volunteers aged between18 to 35years visited to ACPM Medical college hospital Dhule-424002 (Maharashtra) were studied.

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Inclusive Criteria: Healthy, robust having ideal body mass Index were selected for study.

Exclusion Criteria: The volunteers having apparent physical deformities were excluded from study.

Methods

$$\text{Facial Index} \quad \frac{\text{Facial height}}{\text{Breath of zygomatic arch}} \times 100$$

1. Facial measurement were as under
2. Nasion = point at the nasal root intersected by mid sagital plane Nasal root is the depression of the nose but at the naso frontal suture which can be felt by slightly probing the root of the nose
3. Gnathion – It is the lowest point on the lower margin of lower jaw intersected by the mid-sagital plane. This point can be palpated on the lower jaw slightly another to chin
4. Zygion –It is the most laterally placed point on zygomatic arch
5. Total Facial Height –It measure the straight distance between Nasion to Gnathion (measured by sliding caliper)
6. Breath of Bizygomatic Arch –It measure straight distance between two zygon (measured by spreading caliper).

Duration of study Feburary-2021 to March-2022

Statistical analysis: Facial Index of both Male and female was compared with t test value and noted. The statistical analysis was carried out in SPSS software.

Observation and Results

Table 1: Comparative study of Facial in both sexes Facial 90.5 (± 0.5) was male index, 87.2 (± 0.3) was female facial Index, t test was 4.38 and p<0.001 (p value was highly significant)

Table 2: As per the anthropological classification of Facial Index. The present values of facial Index were classified under Leptoproscopic Facial Index (males 88 to 92.9 and Females 85 to 89.9).

Table 3: The present study of Facial Index was compared with previous studies of different ethnic groups of India and abroad.

Table 1. Comparative study of Facial Index in both sexes

Male-60, Female-60

Sl. No	Particulars	Male Facial Index	Female Facial Index	p value
1	Mean Value	90.5	87.2	P<0.01
2	SD	0.5	0.3	
3	t test	43.8		

Male Facial Index in more in malesthan female facial Index and p value is highly significant (P<0.01)

Table 2. Classification of Facial Index

Sl. No	Facial Type	Male	Female
1	Hyper Euryproscopic	78.9	76.9
2	Euryproscopic	79 to 83.9	77 to 80.9
3	Meso Proscopic	84 to 87.9	81 to 84.9
4	Leptoproscopic	88 to 92.9	85 to 89.9
5	Hyperlepto-proscopic	93	90 -

The present study of Northern Maharashtra has male facial Index was 90.5 (SD ±0.5) and female 87.2 (SD±0.3) belong to leptoproscopic

Table 3. Present study of Facial Index in both sexes is compared with previous studies

Sl. No	Author & Year	Ethnic Groups	Male Facial Index	Female Facial Index
1	Mahesh Kumar -2013	Hariyanvi	84.84	68.09
2	Zohre abatabae- 2010	Yazd	108.3	106.9
3	Agron Rexhepi-2008	Kosov	91.38	90.27
4	Vaishali Shetti -2011	a)North Indian b) Malaysian	87.19 87.71	86.75 85.72
5	Venkateshwar Rao 2018	South Indian	91.5	88.1
6	Present Study	Maharashtra	90.5	87.2

Present study findings were more or less in agreement with previous studies.

Discussion

Present study of Facial Index in both sexes of northern Maharashtra. Male facial Index Mean values was 90.5 (± 0.5) female facial Index was 87.2 (± 0.3), t test was 43.8 and $p<0.001$ (P value was highly significant) (Table-1). As per the anthropological classification of Facial Index the present finding are under leptoproscopic Facial Index (88 to 92.9 in males, 85 to 89 females (Table-2). These findings are more or less in agreement with previous studies [(5)(6)(7).]

The study of sexual dimorphism is an important concern for the forensic anthropologist as it is a key to individual identification; Assessing sexual dimorphism eliminates approximately half of the population from further consideration in cases of missing persons or unknown identity. Many morphological differences are sex is specific. The specificity is due to genetic factors, nutritional growth and habitat [(8)]. This difference leads to ethnic determination.

In North Indian and Punjab population has mesoproscopic facial Index this variation is due to migration of Iran population to India[(9)] and west Bengal population has euryscopic type of facial Index and Andaman Nicobar population has hypereuryproscopic type of facial Index [(10)]. These variations in the facial Index represents various ethnic origins migrated to India.

Summary and Conclusion

The present study of Facial Index in both sexes of adults Maharashtra population which has leptoproscopic Facial Index. This Index is of great importance in medico legal, anthropological and oral maxillofacial surgeon, anatomist but this study demands further genetic, anthropological, nutritional study because as bony skull is mesodermal origin and bone is most plastic tissue which adopts with environmental, nutritional status.

Limitation of Study: Due to tertiary location of research centre, small number of patients, lack of latest techniques, we have limited findings and results.

This research paper was approved by Ethical committee of ACPM Medical College hospital Dhule-424002 (Maharashtra)

Conflict of Interest: No

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Retrospective and Prospective Cross-sectional Study

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Analysis of Programmed Death- Ligand 1 Expression in Urothelial Carcinoma

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Abstract

Background: Urothelial bladder cancer is a disease of significant morbidity and mortality. It is ninth most common malignancy worldwide. It is the 7th most common cancer worldwide in men and the 17th most common cancer worldwide in women.*Methods*: The present study was undertaken in the Department of Pathology, King George's Medical University, Lucknow in collaboration with The Department of Urology, King George's Medical University, Lucknow, after getting approval from Institutional Ethical Committee. Samples were collected from the department of urology with their clinical details. The study design was Retrospective and Prospective Cross-sectional study

Results: Majority of the cases were Conventional UC (83.8%), other common types were Squamoid, Glandular and Signet ring (5.0%, 6.3% & 2.5%). Apart from these, 1 (1.3%) case each was differentiated as Sarcomatoid and Sarcomatoid with glandular variant.

Conclusions: Majority of cases with tumour recurrence showed strong positive PD-L1 expression and this association was found to be significant suggesting that degree of PD-L1 expression may be a crucial determinant of tumour invasiveness not only for primary tumours but also for recurrent tumours.

Keywords: urothelial bladder carcinoma;glandular;histopathological

Introduction

Urothelial bladder cancer is a disease of significant morbidity and mortality. It is ninth most common malignancy worldwide[(1)]. It is the 7th most common cancer worldwide in men and the 17th most common cancer worldwide in women. Approximately 75% of newly diagnosed urothelial bladder carcinomas are non-invasive. Males are more often affected than females. Each year, approximately 1,10,500 men and 70,000 women are diagnosed with new cases[(2)]. In India, as per the National Cancer Registry Programme, the overall incidence rate of the urinary bladder cancer is 2.25% (per 100,000 annually): 3.67% among males and 0.83% for females[(3)]. Age of onset is most often between 65 and 85 years of age[(4)]. Smoking is the most common risk factor and accounts for approximately half of all urothelial bladder cancers[(5)]. Occupational exposures to aromatic amines and

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polycyclic aromatic hydrocarbons are also some of important risk factors.Other causal factors include chronic irritation, indwelling catheters, Schistosoma haematobium infestation, and pelvic irradiation[6]. The main aim of this study is to assess the utility of PD-L1 immunohistochemical expression and its correlation with clinicopathological parameters in urothelial carcinomas.

Material and Methods

The present study was undertaken in the Department of Pathology, King George's Medical University, Lucknow in collaboration with The Department of Urology, King George's Medical University, Lucknow, after getting approval from Institutional Ethical Committee. Samples were collected from the department of urology with their clinical details. The study design was Retrospective and Prospective Cross-sectional study over period 1st September 2018 – 31st August 2019 (1 year) with study sample being TURBT (Transurethral resection of bladder tumor) and/or Radical cystectomy specimens diagnosed as cases of urothelial carcinomas of 80 patients with

Inclusion Criteria

A. Histologically diagnosed cases of bladder cancer
B. Patients who gave consent to enroll in the study.
C. Availability of clinical details at presentation.

Exclusion Criteria

A. Patients who were not willing to give consent to be a part of the study
B. Cases in which tissue may be lost during antigen retrieval or insufficient tumor tissue.
C. Poorly preserved tumor tissue.

Results

The present study was conducted in the Department of Pathology in collaboration with Department of Urology at King George's Medical University, Lucknow in urothelial carcinoma cases diagnosed after analysis of TURBT (Transurethral resection of bladder tumor) and/or Radical cystectomy specimens to explore the Immunohistochemical (IHC) expression of Programmed death-ligand 1 (PD-L1) marker in urothelial carcinomas, in different variants of urothelial carcinoma and find any correlation between IHC expression of PD-L1 marker and clinico-pathological parameters of urothelial carcinomas.A total of 80 cases of urothelial carcinoma fulfilling the inclusion criteria were included in the study after taking an informed consent. Profile of patients enrolled in the study was as under.

Age of patients enrolled in the study ranged between 18 to 86 years. Mean age was 55.25±12.65 years. Majority of the patients were aged 51-75 years (66.3%), only 3 (3.8%) were aged >75 years and 4 (5.0%) ≤25 years of age, rest were aged 25-50 years (25.0%).

Of 80 patients enrolled in the study only 14 (17.5%) were females and rest 66 (82.5%) were males. Male: Female ratio was 4.71:1.

Most common clinical feature of the study population was Hematuria (86.3%) followed by Dysuria (62.5%) and Urinary frequency (42.5%). Majority of the patients presented with more than one clinical symptoms (n=48; 60.0%).

Most common clinical feature of the study population was Hematuria (86.3%) followed by Dysuria (62.5%) and Urinary frequency (42.5%). Majority of the patients presented with more than one clinical symptoms (n=48; 60.0%).

Case-sheet records for Location of tumour were available only for 63 patients. No records regarding tumour location could be retrieved for remaining 17 cases. Out of 63 cases, in majority of the cases tumour was located at lateral wall (76.2%) while that in bladder neck in only 6.3% of cases and in rest of the 17.5% cases tumour was located at other sites.

Majority of the tissue specimens analysed in the present study were of TURBT (92.5%) and rest were of Radical cystectomy (including 1 partial cystectomy).

Majority of the specimens were graded as Low grade tumours (58.8%). Only 41.3% tissue specimens were graded as High Grade tumours.

None of the patient was found to be stage pT3/T4. Most common pathologic stage of tumour was pT1 (42.5%), followed by pT2 (32.5%) while least

common pathologic tumour stage was pTa (7.5%), followed by pTis (17.5%).

No lymphocytic infiltration was observed in 19 (23.8%) cases. Focal infiltration and diffuse infiltration were observed in 38.8% and 37.5% cases, respectively.

Majority of the cases were Conventional UC (83.8%), other common types were Squamoid, Glandular and Signet ring (5.0%, 6.3% & 2.5%). Apart from these, 1 (1.3%) case each was differentiated as Sarcomatoid and Sarcomatoid with glandular variant.

Expression of PD-L1 was found to be negative (≤1% tumour cells expressing PD-L1) for one-fourth of the cases (25.0%). Weak expression (2%-50% tumour cells expressing PD-L1) was observed for 48.8% cases and Strong expression (51%-100%tumour cells expressing PD-L1) for only 26.3% cases.

Out of 80 (100.0%) cases of Urothelial carcinoma enrolled in the study, 23 (28.8%) expired during the study period, rest were alive.

Out of 80 cases of Urothelial carcinoma 23 expired during the study and 57 remained the part of the study till completion. Of these 57 cases recurrence of urothelial carcinoma was observed in 9 (15.8%) cases only.

Strong expression of PD-L1 was observed among higher proportion of cases of lower age groups *i.e.* aged ≤25 years (14.3% vs. 0.0% negative & 2.6% weak) while Weak expression was observed in higher proportion of patients of older age *i.e.* 51-75 age (74.4% vs. 60.0% negative & 57.1% Strong). Proportion of negative expression of PD-L1 was higher among age extremely older patients *i.e.* >75 years (15.0% vs. 0.0% Weak & strong each). This association was found to be statistically significant (p=0.020).

Though Strong expression of PD-L1 as compared to negative expression and Weak expression was observed in higher proportion of females (28.6% vs. 15.0% & 12.8%) but this association was not found to be statistically significant (p=0.292).

Among cases presenting with hematuria proportion of Weak expression of PD-L1 was higher as compared to negative and Strong expression (87.2% vs. 85.0% & 85.7%) but statistically this difference was found to be comparable (p=0.971). Similar findings were observed for patients presenting with Other clinical features (5.1% weak vs. 5.0% negative & 0.0% strong), this association too was not found to be significant statistically (p=0.574).

Proportion of PD-L1 strong expression was higher as compared to negative expression and weak expression among cases presenting with dysuria (71.4% vs. 55.0% & 61.5%) and Urinary frequency (47.6% vs. 40.0% & 41.0%), none of the above associations were found to be significant statistically (p>0.05).

Weak expression of PD-L1 was observed in higher proportion as compared to negative and strong expression in tumours located at lateral wall (82.76% vs. 68.7% & 72.2%), while strong expression of PD-L1 was observed in higher proportion of tumours located at Bladder neck (11.1% vs. 6.25% negative, 3.45% weak). Among patients with tumour located at other sites negative expression was higher as compared to weak and strong expression (25.0% vs. 13.79% & 16.7%). This association too was not found to be statistically significant (p=0.718).

Among High grade tumours Strong PD-L1 expression was more prevalent as compared to Negative and Weak expression (100.0% vs. 10.0% negative& 25.6% weak). This association was found to be significant statistically (p=0.003).

Strong PD-L1 expression was observed in higher proportion of pT2 stage tumours (61.9% vs. 15.0% negative & 25.6% Weak). Weak PD-L1 expression was observed in higher proportion of pT1 stage tumours (51.3% vs. 35.0% negative & 33.3% strong) and pTa (10.3% vs. 10.0% negative & 0.0% strong) while proportion of Negative PD-L1 expression was higher among patients of tumour stage pTis (40.0% vs. 12.8% weak & 4.8% strong). Association of Tumour stage was found to be significant statistically (p=0.003). Majority of patients of pT1 and pT2 stage had weak (76.9%) or strong level of expression (95.2%).

All the cases with strong PD-L1 expression had diffuse tumour lymphocytic infiltration. Majority of the cases with Weak expression had Focal tumour lymphocytic infiltration (76.9%) and rest had diffuse tumour lymphocytic infiltration (20.5%). While

majority of the cases with negative PD-L1 expression had no tumour lymphocytic expression (90.0%). This association was found to be statistically highly significant (p<0.001).

No statistically significant association of PD-L1 expression with nuclear pleomorphism, mitosis, necrosis and LVI was observed.

Negative expression was observed in higher proportion of Sarcomatoid & Sarcomatoid with glandular variants (5.0% vs. 0.0% weak & 0.0% strong).

Weak expression was observed in higher proportion of Conventional UC cases (92.3% vs. 90.0% negative vs. 61.9% strong).

Strong expression was observed in higher proportion as compared to negative and weak expression in cases of Signet ring (4.8% vs. 2.6% weak & 0.0% negative), Squamoid (9.5% vs. 0.0% negative and 5.1% weak) and Glandular variants (23.8% vs. 0.0% weak & 0.0% negative).

Association of PD-L1 expression and differentiation of tumours was found to be statistically significant (p=0.006).

Proportion of Strong PD-L1 expression as compared to negative and weak expression was higher in expired cases (47.6% vs. 30.0% negative& 17.9% weak), but this association was not found to be statistically significant (p=0.053).

Proportion of Strong PD-L1 expression as compared to negative and weak expression was higher in cases with recurrence of urothelial carcinoma (45.5% vs. 7.1% negative& 9.4% weak), this association was found to be statistically significant (p=0.011).

Discussion

In the beginning an unknown co-stimulatory molecule was identified known to be involved in the negative regulation of immune mediated responses, which was later studied and defined by *Dong H et al.* (1999)[19] as PD-L1 (Programmed Death-Ligand 1) in 1999. Since then, PD-L1 is emerging as a potential biomarker in various carcinomas including urothelial carcinomas. Various studies have been carried out addressing PD-L1 expression in urothelial carcinomas.

The diagnosis and prognosis of urothelial carcinomas is highly dependent on histopathology and immunohistochemical markers. Thus, keeping in mind the above fact we have conducted our present study where correlation of PD-L1 expression with various clinic-pathologic parameters of urothelial carcinomas has been analysed.

This study included a total of 80 cases of urothelial carcinoma whose histopathology and PD-L1 immunohistochemistry was performed and assessed in The Department of Pathology, King George's Medical University.

Majority (70%) patients were aged >50 years. The median age was 56 years (Age range 18-86 years). The study had predominantly males (82.5%) as compared to females (17.5%) with a Male: Female ratio of 4.71:1.

The most common clinical feature was Hematuria (86.3%) amongst the study population, followed by dysuria (62.5%). Majority (76.2%) of the tumours were located at the lateral wall of the urinary bladder and were received predominantly as TURBT (Transurethral Resection of Bladder Tumour) specimens (92.5%).

Conclusion

Majority of cases with tumour recurrence showed strong positive PD-L1 expression and this association was found to be significant suggesting that degree of PD-L1 expression may be a crucial determinant of tumour invasiveness not only for primary tumours but also for recurrent tumours.

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Original Research Article

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Pattern of Heart Rate Variability in Somatoform Disorder and Its Association with Anxiety level: An Analytical Study

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Abstract

Background: Somatoform disorder (SD), nowadays considered as the most frequent psychiatric diagnosis in general practice has strong association with anxiety. Though there are a handful of studies showing heart Rate variability (HRV) in SD patients, as such no studies according to author's knowledge had been addressed to the anxiety component hidden in the SD patients applying HRV tests so far.

Aims: Aim of the current study was assess the presence and extent of Heart rate variability in SD patients and to find out it's possible relationship with their anxiety level.

Materials and Methods: An analytical observational cross-sectional study was done among fifty newly diagnosed somatoform disorder patients of eighteen to forty years age attending Psychiatry OPD and fifty age and sex matched healthy control. After assessing their anxiety level using State Trait Anxiety Inventory, Short term Heart rate Variability tests were performed. Appropriate Statistical tests were applied using SPSS 20 version.

Results: The SD patients showed reduced heart rate variability as SDNN and RMSDD were less, LF and LF/HF ratio were more in them than controls and significant differences were there. Both SAS and TAS scores were more in cases and there was positive correlation of TAS score with LF and LF/HF ratios.

Conclusions: The results of this study actually set an alarm for controlling their symptoms as well as their hidden anxiety underneath, as reduced HRV poses the risk of developing cardiovascular disease and hidden anxiety has influence on heart rate variability.

Keywords: Somatoform disorder, Heart Rate variability. Anxiety level, Sympathetic and parasympathetic functions.

Introduction

Somatization is a ubiquitous human phenomenon that at times becomes problematic and warrants clinical attention and it is extremely common in medical settings.[1] Sometimes somatic

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symptoms are expression of an identifiable emotional disorder.[2] The term somatization has been used to describe the tendency of certain patients to experience and communicate psychological and interpersonal problems in the form of somatic distress and medically unexplained symptoms for which they seek medical help.[3] ICD 10 description of somatoform disorders emphasized on repeated presentation of physical symptoms, together with persistent requests for medical investigations, in spite of repeated negative findings and reassurances by doctors that symptoms have no physical basis.[4] DSM 5 has constituted a new category named somatic symptoms and related disorder replacing previous somatoform disorders which includes the diagnosis of somatic symptom disorders, illness anxiety disorder, conversion disorder etc.[5] The interaction between "psyche and "soma" are well known. This interaction happens through a complex network of feed-back and modulation among the central and autonomic nervous system (ANS), the endocrine system, immune system and the stress system.[6] A model by Brown (2004) addressed on this issue by showing how physical symptoms can arise and the autonomic control of action is over determined by typical presentation of illness.[7] Clinical symptoms of these disturbances are frequently non-characteristic[8] Different studies had indicated that autonomic arousal increases the likelihood of misinterpretation of bodily signals.[9]

So far very few works have been undertaken to find the influence of autonomic nervous system in developing, maintaining and determining the course of somatoform illness. There are many tests to assess cardiovascular autonomic function and measurement of heart rate variability (HRV) is a useful non-invasive tool among those. The heart rate variability denotes variations in instantaneous heart rate as well as RR intervals in consecutive cycles. Increased vagal activity decreases heart rate and produces heart rate variability, but increased sympathetic activity has opposite effect. So, heart rate and its fluctuation according to need indicate autonomic control over cardiovascular system. A long term measure of HRV parameters gives the idea about the challenges faced by cardiac autonomic functions in daily life. As recordings are not stationary in this situation, so standardisation cannot be maintained. Short term HRV analysis solves this limitation as it can be performed and interpreted from 5 min ECG recording maintaining standard criteria excluding the exogenic influence on cardiovascular autonomic tone.[10]

There are studies involving heart rate variability tests in somatoform disorder patients and most of them revealed altered HRV in somatoform disorder patients. Still how autonomic dysfunction contributes to the pathophysiology of somatoform disorder is not clearly understood. A study in Seoul had shown correlation of HRV with alexithymia in somatoform disorder patients.[9] Another study showed negative correlation between alexithymia and HRV.[11] Alexithymia is deficit in cognitive processing of emotional information. Different studies have shown that somatoform disorder has strong association with pathological personality traits as well as anxiety and depression. Not only that a study also showed that Anxiety has a greater effect on emotional feeling of somatoform disorder patients than depression.[12]

As such no studies according to author's knowledge had been addressed to the anxiety component hidden in the somatoform disorder patients applying HRV tests so far. The current study intends to explore this hidden component in somatoform disorder patients.

So, the research hypothesis is the presence of reduced heart rate variability among somatoform disorder patients and those measures of HRV are associated with higher anxiety level.

Materials and Methods

Study type, design and population: An analytical observational cross-sectional study was done in one year in Autonomic function Laboratory of Department Physiology of a Govt. Medical College and Hospital. We had selected study group from newly diagnosed somatoform disorder patients of eighteen to forty years age group attending Psychiatry OPD according to ICD 10 and age and sex matched control subjects were selected from accompanying persons of those patients without having any psychiatric comorbidities in 1: 1 ratio (case: control).[4]

Sample size and sampling design: To select study subjects, one day per week was selected randomly using computer program during the study period. On that day, all persons with diagnosis of new case of somatoform disorder were approached for participation in the study. The sample size was fifty maintaining inclusion and exclusion criteria. An equal number of age and sex matched control without any psychiatric comorbidities were selected from the

accompanying persons of the said patients who were voluntarily willing to participate and general health questionnaire (GHQ-28) was used for screening of those subjects.[13]

Exclusion criteria: (applied in selecting both case and control groups) – Individual having Cardiac disease, Hypertension, Diabetes mellitus, Neurological disease, Retinopathy, Nephropathy, Autoimmune diseases, any other acute or chronic systemic disease(s) or associated factor(s) that may affect the autonomic reflexes and individual who did not give consent.

Method of data collection: The study was commenced after getting Institutional ethical clearance. The cases were selected by psychiatrists after having clinical and general examination of the patients. After maintaining the inclusion and exclusion criteria written informed consent was taken from each individual participating in the present study. A pre-test instruction was given to avoid consumption of any medicines that may alter the autonomic function 48 hours prior to the test. The subject was advised to have a sound sleep without using elasticized or tight garments at the previous night. On the day of the test, no cigarette, nicotine, coffee, food or medicines orally or other routes was permitted for two hours prior to the test.[14] The subjects were asked to wear loose gowns, and tight under clothing, metallic objects like rings, watches etc. On the day of the tests State - Trait Anxiety Inventory (STAI) was applied among the study subjects.[15]

Short term (5 min) heart rate variability (HRV) tests were performed with the help of Polyrite-D machine in the Autonomic research laboratory room. Polyrite-D, an electrical device with multi-channel physiograph recording with in-built electrocardiograph (ECG) channel was used for recording electrocardiogram, and the machine has its inbuilt system for analysis of RR intervals. Lead II of the ECG was selected for recording heart rate. Calibration was undertaken before the start of recording heart rate and maintained throughout the procedure. Tracing speed used was 30 mm/sec. ECG tracing was recorded in supine position by conventional method during normal quiet breathing for a period of five minutes. The ECG tracings were screened for any suspected pathological waveform configuration.

HRV analysis was done by using time domain or frequency domain analysis. For time domain analysis of short term HRV, among different parameters SDNN and RMSDD values are preferred. SDNN is the standard deviations of the RR intervals of the recording and represents the overall HRV. RMSDD is the square root of the mean of sum of the squares of differences between adjacent RR intervals and pNN50 is the percentage of number of pairs of adjacent RR interval differing by more than 50 ms. Both reflect high frequency variations of heart rate indicating parasympathetic effect on heart, but RMSDD is preferred and most commonly used measure. In frequency domain analysis of short term HRV, HF (0.15 – 0.4 Hz), LF (0.04 – 0.15 Hz), LF/HF ratio can be calculated. Normalized units of HF and LF component indicate parasympathetic and sympathetic tone of cardiovascular activity respectively and LF/HF ratio, a marker of sympatho-vagal imbalance. The physiological explanation of VLF (< 0.04) is not known properly. But it is important that measures of HRV irrespective of time domain or frequency domain measures do not represent the exact level of autonomic nerves activity but their combination indicates an alteration and interaction of sympathetic and parasympathetic nerve activity.[10] In this study we used SDNN, RMSDD and pNN50 for time domain analysis and LF, HF, LF/HF ratio for frequency domain analysis.

Statistical analysis:

All the collected data were at first entered a Microsoft Excel spreadsheet and data cleaning/ filtration were done. Further analysis was conducted with the help of IBM SPSS (Software Package for Social Sciences) Statistics Version 20.0. Descriptive information was calculated in frequencies, percentages. For describing the central tendencies and dispersions of various observations Mean & SD (Standard Deviation) were calculated. For comparing mean values of various parameters between case & control groups, unpaired t test was applied to find out statistical significance. Likewise for finding correlation of two independent groups Pearson correlation test was applied. Test results were considered statistically significant at p value < 0.05.

Results

Table 1: Distribution of study subjects according to their Resting Heart Rate (RHR)

Resting HR of Cases		Resting HR Control	
Male (mean + SD)	**Female (mean + SD)**	**Male (mean + SD)**	**Female (mean + SD)**
81.10 + 6.60	84.47 + 11.62	74.29 + 8.01	71.63 + 6.60

Table 1 of this study shows that mean resting heart rate was found more in male (81.10 + 6.60) and female (84.47 + 11.62) somatoform disorder patients than their control counterpart (male 74.29 + 8.01and female 71.63 + 6.60) and a significant difference (p = 0.006) was there between case and control subjects.

Table 2: Distribution of study subjects according to their Resting Blood Pressure

Resting BP of Cases		Resting BP of Control	
SBP (mean ± SD)	**DBP (mean ± SD)**	**SBP (mean ± SD)**	**DBP (mean ± SD)**
118.12 ± 11.28	77.0 ± 7.15	117.28 ± 10.32	78.88 ± 4.80

In table 2 mean systolic blood pressure was more and diastolic blood pressure was less in somatoform disorder patients, but no significant difference was found.

Table 3: Comparison of mean score of different study variables between cases and controls

Variables	t-test for Equality of Means				
	t	**df**	**p**	**Mean ± SD**	**Mean ± SD**
SAS	2.108	81	.038	38.49 ± 11.614	33.18 ± 10.805
TAS	3.173	81	0.002	43.22 ± 10.695	35.56 ± 11.007
SDNN	-3.970*	36.609	.000	31.60 ± 14.279	65.02 ±46.720
RMSDD	-3.213*	46.472	.002	23.31 ± 15.972	41.444 ± 29.245
PNN50	-1.877*	58.694	.066	8.625 ± 13.851	15.693 17.912
LF nu	3.998	82	.000	65.696 ± 43.470	34.376 ±16.752
HF nu	-8.505*	76.207	.000	34.519 ±24.421	77.716 ±21.716
LF/HF	5.641	82	.000	2.348 ±1.912	0.479 ±0.292

*Equality of variances not assumed

Table 3 shows that both State anxiety score (SAS) and Trait anxiety score (TAS) were more in somatoform disorder patients [SAS case (38.49 ± 11.614) and control (33.18 ± 10.805)] and [TAS case (43.22 ± 10.695) and control (35.56 ± 11.007)] and both the groups were significantly different (SAS p=0.038) and (TAS p=0.002).

While comparing different HRV parameters in table 3, it was found that SDNN was less in somatoform disorder patients (31.60 ± 14.279) than control subjects (65.02 ±46.720) and a significant difference (p=0.000) was there between the two. RMSDD was less in case (23.31 ± 15.972) than control (41.444 ± 29.245) and was also significantly different (0.002). pNN50 was also less in somatoform disorder patients than control and it was not statistically significant. In frequency domain analysis of HRV, LF was more in somatoform disorder patients (65.696 ± 43.470) than control subjects (34.376 ±16.752) and a significant difference (0.000) existed between the two. The case had less HF values (34.519 ±24.421) than their healthy counterpart (77.716 ±21.716). LF/HF ratio was more in somatoform disorder patients than Controls) and it was also significantly different (0.000).

Table 4: Correlation between dependent and independent variables

		SDNN	RMSDD	PNN50	LF	HF	LF/HF
SAS	Pearson Correlation	-.174	-.108	-.106	.093	-.120	.098
	Sig. (2-tailed) (p)	.135	.355	.365	.402	.280	.379
TAS	Pearson Correlation	-.200	-.025	.017	0.246	-.164	0.223
	Sig. (2-tailed) p)	.086	.833	.884	0.025	.138	0.42

In table 4 while assessing correlation between different components of HRV parameters with SAS and TAS score as dependent variable, it was found that there was positive correlation in LF (0.246) and LF/HF ratio (0.223)) with TAS score ie. High trait anxiety score is associated with high LF and LF/HF ratios and both of these are significant ie for LF (p=0.25) and LF/HF ratio (p=0.42). High SAS and TAS score were associated with low HF in frequency domain and low SDNN, pNN50, RMSDD in time domain, though they were not statistically significant (p>0.05).

Discussion

An analytical observational study was conducted among fifty newly diagnosed case of somatoform disorder and fifty age and sex matched healthy adults as controls to assess and compare the heart rate variability. Anxiety status of the subjects was also assessed and different parameters of heart rate variability were correlated with the anxiety level of the patient.

In this study the somatoform disorder patients showed reduced heart rate variability and there was positive correlation of LF values and LF/HF with trait anxiety score.

The study subjects consisted of different age groups ranging from 18 – 40 years with the mean age 29.04 ± 6.8 years and no significant difference (p > 0.05) existed between case and control groups regarding age distribution, to conclude that both the groups were age and sex matched. A study conducted by Deka K et al showed that 57.5% were in the 18-29 years age range.[16] However a few studies like that of Deveci A. et al in Turkey, showed the peak incidence in the mid to late thirtys.[17] According to DSM 5 Somatic symptom disorder may be underdiagnosed in older adults either because some symptoms are considered part of normal aging.[5]

While assessing anxiety level SAS and TAS was more in somatoform disorder patients than control subjects. Banks MH et al in 1975 also showed that patients without having significant illness and consistently seeking medical care have high trait anxiety score.[18] A case control studies conducted showed that higher prevalence of anxiety was present in somatoform disorder patients than control and it was clinically significant (odds ratio in the range of 2.3 – 3.5).[19,20]

Both parasympathetic and sympathetic nervous system control heart rate, blood pressure and maintain the balance. Resting heart rate can be used to assess both SNS and PNS reactivity. In the present study, mean resting heart rate was higher in both male and female than control. This higher resting heart rate may be due to associated anxiety in the somatoform disorder patients and also have reduced PNS activity. It has been seen that most cases of somatoform disorder are also associated with anxiety and depression.[21] Resting systolic and diastolic blood pressure was in the normal range. This may presumably because of multiple blood pressure regulatory systems running in parallel and autonomic disturbances might have been counterbalanced by other regulatory mechanisms.

In this study among different parameters of HRV, Somatoform disorder patients had lower SDNN, RMSDD values. SDNN reflects the overall lower HRV and RMSDD, the reduced PNS activity. LF value, LF/HF ratio was more and HF was less in somatoform disorder patients than control with statistically significant differences between two groups. These indicate sympatho-vagal imbalance with high LF and low HF measures in somatoform disorder patients. So, our study has shown reduced HRV with high SNS, low PNS activity indicating sympatho-vagal imbalance. Somatoform disorder patients had reduced parasympathetic activity which may be explained by the presence of comorbid

anxiety in these patients.[22] Low SDNN was found in somatoform disorder patients while performing some tasks in another study.[23] In a study by Zimmermann V et al (2016), using HRV in different psychological disorder like somatoform disorders, adjustment disorders, major depression, anxiety disorders, a shift of autonomic balance towards sympathetic predominance was found.[24] A study in Seoul supports our study finding by showing low SDNN, RMSDD, HF and high LF, LF/HF ratio values in somatic symptom disorder patients.[9] However, a study by Chaudhary K. et al (2016) showed a negative correlation of LF/HF ratio with somatization of stress, which should have been positive.[25] This may indicate that subjective and objective measures may not always show direct relationship to each other. It has been suggested that RMSDD, HF parameter of HRV indicating PNS activity is related to the activities in cingulate, prefrontal cortex and patients with somatoform disorder also develop significant changes in functional interconnection among prefrontal, cingulate cortex, insula.[9] From this we can say that somatoform disorder patients in our study have low HRV parameters mediated by decreased PNS activity.

While performing correlation test, positive correlation was found between LF and LF/HF parameters with trait anxiety score of somatoform disorder patients in present study. In a study among anxiety disorder patients by Yeragani VK et al, symapatho-vagal imbalance showing sympathetic predominance was found.[26,27] Watkins LL et al found an association between trait anxiety score and parasympathetic activity in adults with anxiety disorder patients.[28] Recently a study has shown that levels of anxiety have no effect on HRV parameters in somatic symptom disorder patients.[9] However, in a study conducted among children and adolescents with generalized anxiety disorder at All India Institute of Medical Sciences by Sharma RK et al, no correlation was found between state and trait anxiety scores and the autonomic function parameters.[29] A study had shown specific interactions among higher trait anxiety, abnormalities of sympathetic activity, and endothelial dysfunction, which may clarify the association of anxiety with increased risks for atherosclerosis and cardiovascular disease.[30] Till date, there is practically a handful of studies to find out the effect of anxiety in somatoform disorder patients on their HRV parameters. So, in support of the current study finding it can be said that emotions involve a mix of cortical (e.g., frontal, temporal and parietal) and subcortical/limbic (e.g., basal ganglia, thalamus, amygdala and hippocampus) regions of the brain and there is a relationship between emotions and changes in the ANS. Porge's Polyvagal Theory suggests that the vagus nerve connects to various brain regions and serves as a brake or modulator. Conditions of extreme stress break down this highly sensitive means for stabilizing the human organism causing decreased parasympathetic activity in somatoform disorder patients.[31] In response to fear, exercise and other types of stress, the sympathetic division produces a massive and coordinated output to all end organs simultaneously and parasympathetic output ceases.[32]

So, to summarize this study revealed somatoform disorder patients had sympatho-vagal imbalance resulting in reduced heart rate variability and that might be influenced by their trait anxiety underneath.

Conclusion

This study showed that somatoform disorder patients had reduced heart rate variability. Their anxiety level was more and that might influence their HRV parameters. This fact actually sets an alarm for controlling their symptoms as well as their hidden anxiety underneath. Different studies had shown that reduced heart rate variability poses the risk of developing cardiovascular disease. As hidden anxiety has influence on heart rate variability, so effort should be there to treat their anxiety component along with their symptoms.

Limitations

Study was conducted in a small sample and was of cross-sectional type. Longitudinal study involving large sample may give better result.

Conflict of Interest: None declared

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Original Article

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Bacterial Profile and Antimicrobial Susceptibility Pattern of Gram Negative Bacteria Isolated from Skin and Soft Tissue Infections in a Tertiary Care Hospital of Western Uttar Pradesh

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Abstract

Background: Pyogenic infections are one of the most common causes of morbidity and mortality among hospitalized patients. Gram negative bacteria (GNB)are predominantly isolated in Hospital settings across India. A study was planned to determine the profile and susceptibility pattern of Gram negative bacteria isolated from pus samples in a tertiary care Hospital.

Material and Methods: This prospective hospital based study was conducted over a period of one year. A total of 1623 pus samples received in Clinical Microbiology Laboratory were subjected to culture and identification of aerobic bacterial pathogen as per standard bacteriological method and antimicrobial susceptibility was carried out by Kirby-Bauer disk diffusion method as per CLSI guidelines 2020.

Result: The culture positivity rate was 467(28.77%).There was predominance of GNB (78.59%). *Klebsiella* species was the predominant GNB isolated. Most of the GNBs showed good susceptibility against imipenem. However, lower susceptibility was observed against cephalosporins, quinolones, aminoglycosides and cotrimoxazole. None of the isolated GNB exhibited resistance to colistin.

Conclusion: *Klebsiella* species was the predominant GNB isolated from pus samples from our hospital. Knowledge of bacterial profile and their antimicrobial susceptibility pattern is important for institution of empirical antimicrobial therapy for better patient outcome.

Keywords: Antibiotic susceptibility testing, Gram negative bacilli, Pus culture.

Introduction

Skin and soft tissue infections (SSTIs) are caused by invasion and multiplication of pathogenic microorganisms. *Staphylococcus aureus, Streptococcus pyogenes, Escherichia coli, Klebsiella* species, *Proteus* species and *Pseudomonas* species are the common etiological agents implicated in pyogenic infections[1]. These infections are characterized by local inflammation, abscess and pus formation[2]. Both aerobic and anaerobic bacteria are among the causative agents of pyogenic infections which occur in hospital environment and result in significant morbidity, prolonged hospitalization and economic burden[3].

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Knowledge of bacterial profile and their antimicrobial susceptibility pattern is important for institution of empirical antimicrobial therapy for better patient outcome till the laboratory culture reports are awaited[4]. The major concern in hospital environment is pyogenic infections due to more virulent strains circulating in healthcare setting, that are resistant to multiple antibiotics. These infections are difficult to treat because of their capacity to adapt to the changing environment[5,6]. Though the bacterial profile from pus samples remains more or less similar in various studies, there is a variation in the antibiotic susceptibility pattern of the isolates, highlighting the emergence of multidrug resistant (MDR) bacterial strains in pyogenic infections. This study was planned to determine the profile and susceptibility pattern of Gram negative bacteria isolated from pus samples in in our hospital setting.

Materials and Methods

This prospective hospital based study was conducted in a tertiary care Hospital of Meerut, Uttar Pradesh for a period of one year. A total of 1623 pus samples received in Clinical Microbiology Lab from various IPDs & OPDs were subjected to culture and identification of aerobic bacterial pathogen as per standard bacteriological method. [7] The pus samples werecultured on Blood agar, Chocolate agar and MacConkey agar plates. Isolates grown on culture after incubation at 37°C for 48 hours were identified by colony morphology and conventional biochemical tests[7]. Antimicrobial susceptibility was carried out by Kirby-Bauer disk diffusion methodon Mueller Hinton agar as per CLSI guidelines 2020[8]. Standard antibioticdisks of Ampicillin-sulbactum (10/10µg), aztreonam (30µg), ceftriaxone (30µg), cefotaxime (30 µg), ceftazidime (30 µg), cefuroxime (30 µg), imipenem (10 µg), meropenem (10 µg), ertapenem (10 µg), doripenem (10 µg), tobramycin (10 µg), ciprofloxacin (5 µg), gentamicin (10 µg), amikacin (30 µg), and piperacillin/tazobactam (100/10 µg) from HiMedia, Mumbai, India were used for AST.

Results

The culture positivity rate was 467(28.77%). There was predominance of GNB 367 (78.59%) followed by Gram positive bacteria 88 (18.84%) and *Candida* species 12 (2.57%)[Figure 1]. The GNBs were isolated predominantly from indoor samples (61.85%) as compared to outdoor samples (38.15%) [Table 1] and from male patients (57.22%) [Table2]. On location wise distribution most of the isolated GNBs were from surgery (43.17%) followed by Orthopedics (13.21%) and Surgical ICU (11.45%) [Figure 2].

The profile of Gram negative bacteria isolated from pus was almost similar in IPD and OPD samples. *Klebsiella* species was the predominant GNB isolated from IPD and OPD (39.20% and 37.85%) followed by *Escherichia coli* (35.24% and 32.14%), *Pseudomonas* species (15.41% and 21.43%), *Acinetobacter*species (5.28% and 7.14%)*Proteus* species(1.77% and 0.72%), *Citrobacter* species (1.77% and 0.72%) respectively. *Burkholderia* spp (1.33%) was isolated only from IPD samples.[Figure 3& Figure 4].

Most of the GNBs showed good susceptibility towardscarbapenems like imipenem & meropenem. However, lower susceptibility was observed against cephalosporins, quinolones, aminoglycosides and cotrimoxazole. None of the isolated GNB exhibited resistance to colistin except for the intrinsic resistant ones. [Table 3 & 4]

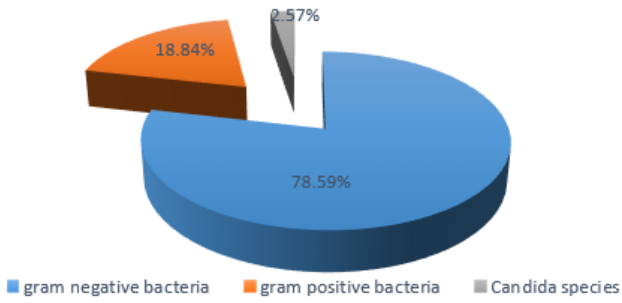

Figure 1: Distribution of culture positive isolate

Table 1: IPD and OPD Distribution of isolated GNB (n=367)

Unit	Number	Percentage (%)
IPD	227	61.85%
OPD	140	38.15%
Total	367	100%

Table 2: Gender wise distribution of Gram negative bacteria (n=367)

Gender	Number	Percentage (%)
Male	210	57.22%
Female	157	42.78%
Total	367	100%

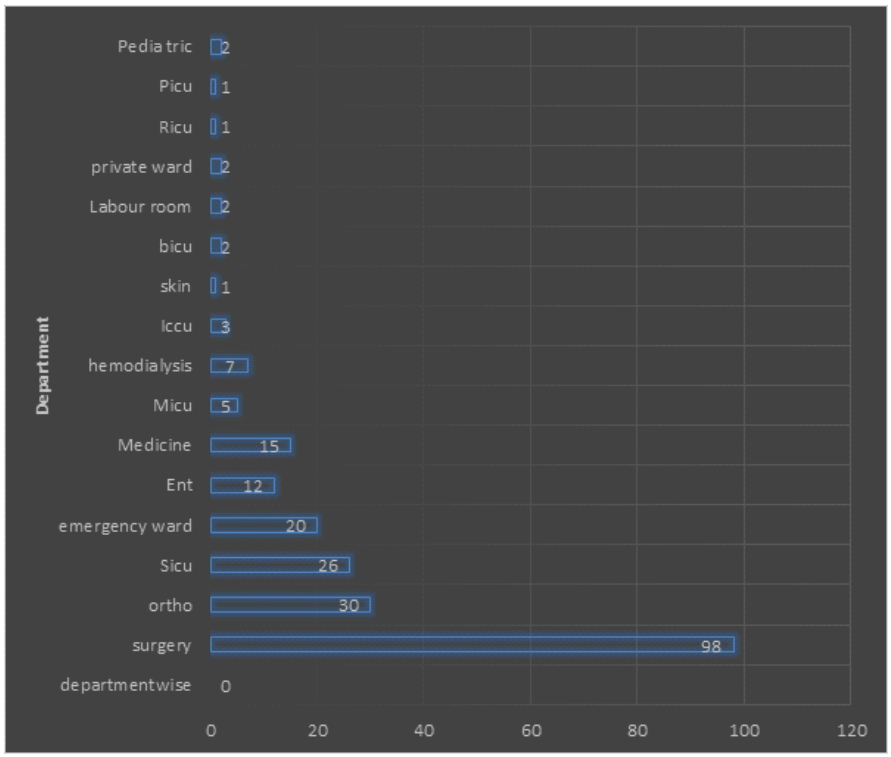

Figure 2: Location wise distriburion of isolates

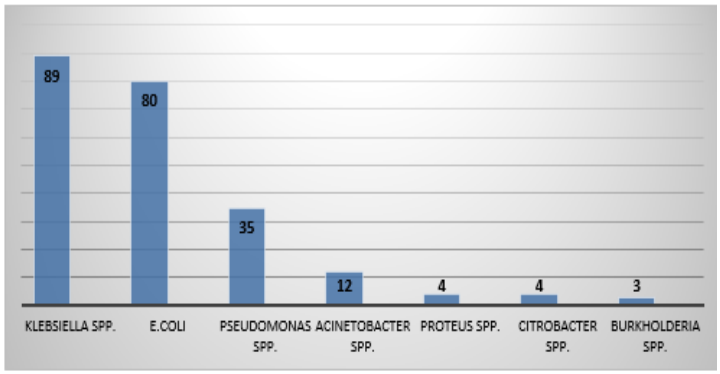

Figure 3: Profile of GNB from IPD samples

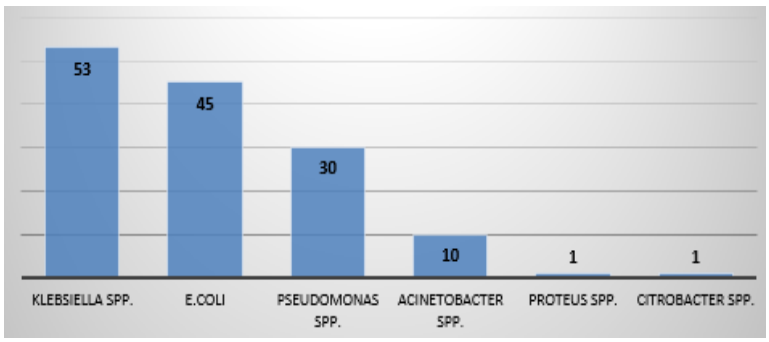

Figure 4 : Profile of GNB from OPD samples

Table 3: Sensitivity pattern of isolates from IPD samples (n=227) (%)

Antibiotics	*Klebsiella* species	Escherichia coli	*Acinetobacter* species	Proteus species	*Citrobacter* species	*Pseudomonas* species	*Burkholderia* species
AMP	3	0	NT	40	4	NT	NT
PI	4	0	14	42	3	4	2
AMC	30	16	NT	34	6	NT	NT
A/S	10	0	12	50	6	NT	NT
PIT	15	48	20	5	15	19	15
TE	10	32	NT	IR	10	NT	NT
COT	8	16	25	16	12	NT	NT
CIP	4	24	22	20	13	25	NT
CFM	12	4	NT	10	13	NT	NT
CAZ	5	6	40	9	13	4	5
CTR	4	9	36	6	25	NT	NT
AT	4	4	NT	8	30	8	5
CPM	8	6	31	25	30	34	29
GEN	22	20	40	39	25	39	40
AK	18	21	40	40	30	40	42
TOB	20	30	42	44	31	45	40
C	60	60	NT	50	30	NT	NT
ETP	88	79	NT	75	82	NT	NT
MRP	90	79	90	79	82	89	81
IPM	90	80	90	85	92	88	88
CL	100	100	100	IR	100	100	100

NT- Not Tested IR- Intrinsically resistance

Table 4: Sensitivity pattern of isolates from OPD samples (N=140)(%).

Antibiotics	*Klebsiella* species	Escherichia coli	*Acinetobacter* species	*Proteus* species	*Citrobacter* species	*Pseudomonas* species
AMP	8	1	NT	10	0	NT
PI	0	1	5	8	2	8
AMC	0	0	NT	4	2	NT
A/S	6	2	4	4	10	NT

Continue.....

PIT	8	2	4	4	10	4
TE	5	0	NT	5	15	NT
COT	6	13	0	8	20	NT
CIP	15	13	6	9	35	10
CFM	18	13	NT	6	20	NT
CAZ	20	0	15	18	42	12
CTR	13	8	10	15	30	NT
AT	13	6	NT	14	30	30
CPM	18	2	10	35	36	28
GEN	20	18	9	40	55	15
AK	12	19	12	30	42	16
TOB	18	20	11	20	50	15
C	17	23	NT	25	60	NT
ETP	55	60	NT	30	65	NT
MRP	60	65	70	30	65	70
IPM	80	82	85	75	85	75
CL	100	100	100	IR	100	100

NT- Not Tested IR- Intrinsically resistant

(AMP-ampicillin, PI-piperacillin, AMC-amoxicillin/clavulanic acid, A/S-ampicillin-sulbactam, PIT-piperacillin/tazobactam, TE-tetracycline, COT-cotrimoxazole, CIP-ciprofloxacin, CFM-cefixime, CAZ-ceftazidime, CTR-ceftriaxone, AT-aztreonam, CPM-cefepime, GEN-gentamicin, AK-amikacin, TOB-tobramycin, ETP-ertapenem, MRP-meropenem, IPM-imipenem, CL-colistin).

Discussion

The rate of culture positivity in the present study was 28.77%. Culture positivity rate varying from 89.47% to 93% have been reported in different Indian studies.[5,9,10,11] Comparatively high rate (71.23%) of culture negativity in the present study may be due to following reasons; firstly, our center being a tertiary care hospital patients usually come to us after having sought medical advice from local doctors and having taken multiple or incomplete course of antibiotics, which might have led to sterile cultures in clinically suspected cases of SSTIs. Secondly, these infections may have been caused by certain other microorganisms which were not looked for like the anaerobic bacteria.

Our study showed predominance of Gram negative bacilli (GNBs) (78.59%). Similar findings have been reported by various authors.[10,12,13,14] Male predominance was seen in this study in both IPD and OPD patients. Similar findings were observed in previous studies[14,15]. Higher incidence in males may be due to more indulgence of males in outdoor activities thus more prone to trauma leading to suppurative infections.

In the present study, maximum number of pus samples were received from Surgery (43.17%) followed by Orthopedics (13.21%), SICU (11.45%), Emergency ward (8.81%), Medicine ward (6.60%) and ENT 12 (5.28%). Similar findings have been reported by other workers.[11,14,15]

In both the IPD & OPD samples, *Klebsiella* spp, was the predominant isolate followed by *E.coli*, *Pseudomonas* spp, *Acinetobacter* spp, *Proteus* spp, *Citrobacter* spp and *Burkholderia* spp. These findings are in complete agreement to several earlier studies done by Sharma *et al*[7], Grace *et al*[10], Rao *et al*[11] and Rameshkannan *et al*[4]. They also reported *Klebsiella* species as the predominant organism present in wound infections.

Majority of the clinical isolates of GNBs were resistant to various groups of antimicrobial agents. Emerging antimicrobial resistance towards high end antimicrobials is a matter of great concern. Such high level of resistance to newer drugs like meropenem and imipenem is an alarming situation and calls for the judicious use of carbapenems. Knowledge of the spectrum of microorganisms causing SSTIs and their susceptibility pattern is important for constitution of antibiogram of a particular hospital and to formulate antibiotic policy which is important while selecting appropriate empirical antibiotic therapy to prevent misuse and overuse of antibiotics. However, all our clinical isolates of GNB showed 100% susceptibility towards colistin.

Limitation

Due to lack of resources microorganisms like anaerobes, fungi and other atypical organisms were not looked for in this study. Mixed etiology of infection was not looked for and this also requires attention as these cases need to be treated with both the antibiotic and antifungal agents.

Conclusion

High level of resistance to various antimicrobial agents was observed in cases of SSTI and the emergence of antibiotic resistant strains has led to treatment failure. Therefore, knowledge of the bacterial profile and their antimicrobial susceptibility pattern is important for institution of empirical antimicrobial therapy for better patient outcome and reduction in treatment costs.

Source Of Funding: Nil

Conflict Of Interest: Nil

Ethical Clearance: Approval from the University Ethics Committee (Medical) of Swami Vivekanand Subharti University Meerut was taken before the commencement of this study via letter No: SMC/ UECM/2019/55/68/04, dated:26/12/2019

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Original Article

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Perspective Study of Spontaneous Resorption of Lumbar Disc Herniation in Female Population of Telangana State, India

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Abstract

Background: Herniation of the disc is the one of the disadvantages human population is facing due to the erect posture. Herniation is the abnormal protrusion of nucleus pulposus from weak site in the annulus fibrosus of the intervertebral disc. It impairs the locomotion of the patients affected with herniation of the disc until the resorption occurs.

Method: 30 females aged between 35 to 55 years treated with conservative treatment for low back pain were included in the study. MRI was done to confirm diagnosis and to know the degree of herniation. Routine blood investigations were done to rule out any associated diseases.

Results: Out of 30 (12 (40%) were normal, 10 (33.3%) had type-II DM and 8 (26.6%) had HTN. Comparison of spontaneous resorption (in months) 7.5 (±2.4) mean value in large disc, 12.2 (±2.6) in small disc and p value was highly significant ($p<0.001$).

Conclusion: Spontaneous resorption of herniated disc can occur by different mechanisms(retraction, dehydration, and inflammatory mediated mechanism). Early clinical recovery is usually associated with quick resorption of herniated disc.

Keywords: MRI, Herniation, Spontaneous,Lumbar disc, Telangana

Introduction

Lumbar disc herniation is (LDH) is most common type of degenerative disc disease. It is mainly treated with conservative treatment.If conservative treatment fails then only surgical intervention is indicated for LDH.Surgical treatment for LDH was described almost sixty year ago, but still controversy remains between opting surgical and non-surgical treatment in symptomatic patients(1).

Key JA (1945) described the first case of spontaneous regression of herniated lumbar disc using myelography(2). Teplick and Hack (1985) detected disc regression in computed tomography scan (3).The development and advances of MRI encouraged many studies to evaluate the phenomenon of spontaneous resorption of herniated lumbar disc and its impact on clinical outcomes(4)(5).

Hence phenomenon of spontaneous resorption of herniated lumbar disc in females without surgery was evaluated to study mechanism, predictive

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factors, time for spontaneous resorption and proper time needed for conservative treatment.

Material and Method

30 adult females visited to Orthopaedic departments of Mallareddy Institute of Medical Sciences, Suraram, Hyderabad and Surabhi Institute of Medical Sciences, Siddipet, Telangana State, India were included in the study.

Inclusive Criteria: Female patients aged between 35 to 55 years suffering fromlow back pain with sciatica.

Exclusion Criteria: Low back painpatients due to other pathologies of lumbar spine like trauma, malignancy, infectionwere excluded from the study.

Method: Every patient's history was studied in detail. Majority of patients belonged to middle socio-economic group. Routine blood examination was done in every patient to rule out any other pathologies, MRI was taken in all the patients to confirm the herniation of disc, the straight leg raising test was positive in all cases (30^O to 40^O degree) No motor deficits were detected in any case.Apart from herniation, any associated diseases were also studied.

Duration of study was from September-2020 to August-2022

Statistical analysis: Herniation and resorption in large and small disc herniations were compared with z test apart from herniation association with other diseases were studied with percentage. The statistical analysis was carried out in SPSS software.

Observation and Results

Table 1: Associated diseases in lumbar disc herniated patients – 10 (33.3%) had Diabetes Mellitus, 8 (26.6%) had Hypertension and remaining 12 (40%) were normal.

Table 2: Mean value of recovery was (in weeks) 6.4 (±1.2) in large disc herniations, and 6.2 (±1.4) in small disc herniations, t test value was 0.59 and p value was >0.52

Mean value of resorption (in months) in large disc herniations was 7.5 (±2.4) and 12.2 (±2.6) in small disc herniations, t test value was 7.2 and p<0.001 (p value was highly significant)

Table 1: Disease associated with spontaneous resorption of lumbar herniated disc

Total No of patients: 3

Sl. No	Associated diseases	No. of patients (30)	Percentage (%)
1	Diabetes Mellitus	10	33.3
2	Hypertension	8	26.66
3	Normal	12	40

Table 2: Comparison between Large and small herniated disc regarding time of recovery and time spontaneous resorption

Total No of patients: 30

Variable	Large Disc	Small Disc	t test	p value
Mean time of recovery (in weeks)	6.4 (±1.2)	6.2 (±1.4)	0.59	P>0.52 (Insignificant)
Mean time of resorption (in months)	7.5 (±2.4)	12.2 (±2.6)	7.2	P<0.001 (highly significant)

Discussion

In this study of spontaneousresorption of lumbar disc herniations (LDH) in female population of TelanganaState in India - out of 30 female patients of LDH 12 (40%) were normal, 10 (33.3%) had type-II DM and 8 (26.6%) had HTN (Table-1).

In comparison of Mean time of absorption (in months) between large disc herniations 7.5 (±2.4),

12.2 (±2.6) in small disc herniations, t test was 7.2 and ($p<0.001$) p value was highly significant (Table-2). These findings are more or less in agreement with previous studies [6][7][8].

It can be hypothesized that (a) There may be appositional and interstitial growth when intervertebral disc remains vacant.During the interstitial growth cartilage divides mitotically and merges with herniated material resulting into thickened intervertebral disc. (b) Its well known that cartilage in the intervertebral disc isavascular, non-lymphatic, lacks perichondrium and isfibrocartilaginousin nature[9]. Hence there is no any barrier which limits the relocation. As I. V disc degenerates, it will be occupied by fibrous annulus by resorption. (c) As age advances there will be calcification of cartilaginous tissue, as this tissue lacks nutrition via diffusion and less vascularity in the periphery of I. V disc which leads to degeneration of disc by leaving vacuum space which leads to herniation. The first mechanism depends on the retraction of the herniated disc back to disc space because it is not separated from the annulus fibrosis. The second mechanism stated that, disc resorption is because of dehydration and shrinkage of herniated nucleus pulposus. The third mechanism proposed that, the sequestrated nucleus pulposus in the epidural vascular space is recognised by the autoimmune system as a foreign material and induces an inflammatory reaction resulting in neo-vascularisation, enzymatic degradation and macrophage phagocytosis of the herniated disc material [10]. The third mechanism was evaluated and supported by different studies [11]. These threemethods explain the resorption of LDH.

In the present study resorption of LDH is followed by improvement in inflammation, edema, and congestion by conservative treatment [12].

Summary and Conclusion

Present study of resorption of LDH is very much important to Orthopedicians and Neurosurgeons because conservative approach can be adapted for large extruded lumbar disc as it can resolve in the selective group of patients. In the cases of failure of resorption of LDH repeated MRIs of spine to assess the degree and severity of protrusion before making plan for any surgical intervention or further continuous conservative treatment can be done. Sometimes there may be voluminous thickness of rim of resorption, which causes more pressure on nerve roots of lumbar plexus warrants surgical interventions to alleviate the clinical symptoms.

Limitation of study: Owing to the remote location of the tertiary centres,small number of patients and lack of latest techniques used in this study may have limitations on the results we got. May need further studies in large number of patients, in higher centres, with more sophisticated investigations to confirm these results we have obtained.

This research work was approved by Ethical committee of Mallareddy Institute of Medical Sciences, Suraram, Hyderabad and Surabhi Institute of Medical Sciences, Siddipet, Telangana State, India

Conflict of Interest: No

Funding: No

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Original Article

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Correlative study of COPD, Rheumatoid Arthritis and Type-II Diabetes Mellitus in South Karnataka Population

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Abstract

Background: Chronic diseases like COPD, RA and DM impair the social and physical activities. Hence their mental status and physical conditions has to be ruled out.

Method: 30 COPD, 30 RA, 30 DM, (total 90 patients) were compared with each other and controlled group also. Their base line features, physical activity, ED-5D index after discharged from ICU / hospital since last six months. Mental status was also compared in at three groups and controlled group also with percentage.

Results: Higher physical activity was observed in DM patients (20.2 ±1.8) and low level physical activity in COPD (9.4 ± 3.1). ED-5D Index value was least in COPD (0.60 ± 0.20) andhigh index was in DM (0.72 ± 0.26). Mobility problem self care deficiency, pain / discomfort were higher in COPD patient.

Conclusion: This comparative of chronic diseases like COPD was compared with RA and DM and severity of disease was observed in COPD which is significantly involved in respiratory distress which creates multiple problems like dyspnoea,anxiety, discomfort need to be treated with more meticulously to avoid morbidity and mortality.

Keywords: COPD, RA, DM, ED-5D Index, GHQ-12

Introduction

Chronic diseases like COPD, RA and DM play vital role in morbidity and mortality. An ageing population will result in an increased burden of disease and death. It is reported that 72% of chronic disease cause morbidity and mortality globally(1). Thus the consequences of chronic illness are considerable for well being of the individual and for society.

Modern treatment of chronic disease like COPD, RA and DM are treatable not yet curable hence life style of patients having chronic disease should include promoting of a more healthy life style i.e., prevent physical inactivity, tobacco usage and poor food habits(2). Physical activity is an important factor to prevent and treat chronic diseases(3)(4). Health related quality life is low in many chronic conditions and many subjects experience fatigue anxiety / depression, sleep disturbances, Pessimistic attitude(5) hence attempts is made to describe and compare the level of physical activity health related quality of life in subjects with chronic obstructive pulmonary

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disease (COPD) Rheumatoid arthritis (RA) and diabetes mellitus (DM) and compared with healthy subjects too.

Material and Methods

90 patients aged between 35 to 65 years regularly visiting to Akash Institute of Medical Sciences and research centre hospital Devanhalli-5621001 were studied.

Inclusive Criteria: The patients having COPD, RA and DM are confirmed by investigations are selected for study.

Exclusive Criteria: Patients having both diseases such as COPD and DM, DM with RA, and immune compromised patients were excluded from study.

Methods: 30 DM, 30 COPD, and 30 RA patients were selected for study and same number of healthy volunteers was also included in the study. (a) Physical activities sedentary mode of exercise (moderate regular or occasional, weekly, (b) health related quality of life very good, good, poor, very poor, (c) Euro Q01, Five dimension questionnaires ED-5D consists activities, pain / discomfort and anxiety / depression. The Index of ED-5D was computed according to Burstorm et.al (1= full health, 0= death) psychological health and symptoms GH Q (General health questionnaires) to study psychological disorders mainly anxiety / depression spectrum 0 = equal or better than usual, 1=worse than usual psychological defined as present when the total score was 3 or higher. The following questions were asked during the past three months – anxiety, worry and depression. The subjects answering yes to the questions has happened since last six months were noted and compared in all three groups and controlled groups also.

Duration of study was from January-2022 to December-2022

Statistical analysis: Various parameters of COPD, RA, DM were compared with controlled group. The statistical analysis was carried out in SPSS software. The ratio of male and female was 2:1.

Observation and Results

Table-1: Baseline features of chronic disease in all three groups – current smokers 14 COPD, 11 RA, 9 DM and 10 controlled groups.

- Ex: smokers-16 COPD, 9 RA, 12 DM, 12 controlled
- Retired people – 19 COPD, 18 RA, 13 DM, 49 Controlled
- Working – 11 COPD, 12 RA, 17 DM, 41 Controlled
- AP2 – 14 COPD, 13 RA, 16 DM, 52 Controlled
- BPL – 16 COPD, 17 RA, 14 DM, 38 Controlled

Table-2: Comparison of physical activity in all three groups with controlled

- High activity – 9.4 (± 3.1) in COPD, 12.8 (± 1.9) in RA, 20.2 (± 1.8) in DM, 60.2 (± 4.4) in controlled group
- Low activity – 16.4 (± 3.9) in COPD, 9.2 (± 2.4) in RA, 6.2 (± 2.6) in DM, 12.8 (± 1.4) in controlled group

Table-3: Comparison of ED-5D Index to measure the quality of life after six months discharge from ICU / hospital

- ED-5D Index value – 0.60 (± 0.26) in COPD, 0.62 (± 0.26) in RA, 0.72 (± 0.26) in DM, 0.92 (± 10) in controlled
- Mobility problems – 46.3 (± 1.28) in COPD, 54.2 (± 1.38) in RA, 35 (± 0.48) in DM, 35 (± 0.10) in controlled
- Self care deficiency –8.3 (± 1.3) in COPD, 11.4 (± 0.96) in RA, 64 (± 0.78) in DM, 0.3 (± 0.2) in controlled
- Pain / discomfort rate – 85.4 (± 1.6) in COPD, 94.4 (± 2.8) in RA, 72.8 (± 2.4) in DM, 32.2 (± 0.6) in controlled
- Anxiety / depression rate – 5.14 (± 2.28) in COPD, 45.4 (± 2.2) in RA, 33.9 (± 0.32) in DM, 15.2 (± 0.12) in controlled group

Table 4: Comparison of mean value of mental status in all three groups

- GHQ-12 – 21.4 (± 1.4) in COPD, 20.6 (± 0.6) in RA, 12.4 (± 0.8) in DM, 64 (± 0.12) in controlled group
- Anxiety / Worry – 25.4(± 1.6) in COPD, 22.4(± 0.58) in RA, 13.3(± 0.50 in DM, 5.2 (± 0.10) in controlled group

- Fatigue score – 47.6 (± 1.4) in COPD, 5.04 (± 1.16) in RA, 30.6 (± 0.5) in DM, 8.2 (± 0.10) in controlled group
- Sleeping Problems – 33.6 (± 1.2) in COPD, 40.4 (± 1.2) in RA, 23.4 (± 6.6) in DM, 10.2 (± 0.2) in controlled group
- Depression – 24.4 (± 1.2) in COPD, 20.2 (± 0.32) in RA, 11.2 (± 0.5) in DM, 3.8 (± 0.1) in controlled group
- Pessimistic score – 17.2 (± 0.1) in COPD, 11.6 (± 0.5) in RA, 7.8 (± 0.2) in DM, 2.2 (± 0.6) in controlled group

Table 1: Baseline features of chronic diseases in all three groups of patients

Sl. No	Baseline features	COPD (30)	RA (30)	DM (30)	Controlled group (90)
1	Current smokers	14	11	9	10
2	Ex-smokers	16	9	12	12
3	Retired	19	18	13	49
4	Working	11	12	17	41
5	APL	14	13	16	52
6	BPL	16	17	14	38

APL = above poverty line

BPL = below poverty line

Table 2: Comparison of physical activity in all three groups with controlled group

Sl. No	Activity levels	COPD (30) Mean value ±SD	RA (30) Mean value ±SD	DM (30) Mean value ±SD	Controlled group (90) Mean value ±SD
1	High activity score	9.4 (±3.1)	12.8 (± 1.9)	20.2 (± 1.8)	60.2 (± 4.4)
2	Low activity score	16.4 (± 3.9)	9.2 (± 2.4)	6.2 (± 2.4)	12.8 (± 1.4)

Table 3: Comparative study of ED – 5D Index to measure quality of life after 6 month discharged from ICU / Hospital

Particular	COPD	RA	DM	Controlled group
ED-5D Index value	0.60 (± 0.26)	.60 (± 0.20)	0.72 (± 0.22)	0.92 (±0.10)
Mobility problems	46.3 (± 1.28)	54.2 (± 1.38)	35 (± 0.48)	35 (± 0.10)
Self care deficiency score	8.3 (± 1.3)	11.4 (± 0.96)	6.4 (± 0.78)	0.3 (± 0.02)
Pain discomfort rate	85.4 (± 1.6)	94.4 (± 2.8)	72.8 (± 2.4)	32.2 (± 0.6)
Anxiety / depression	51.4 (± 2.28)	45.4 (± 2.2)	33.9 (± 0.32)	15.2 (± 0.12)

ED-5D Index score was less (0.60 ± 0.26) in COPD and highest in DM patients (0.72 ± 0.26) mobility problem was least (35) in DM, and highest in RA (54.2 ± 1.38) self care deficiency was highest in RA, (11.4 ±0.96)

and least DM (6.4 ±0.78) pain discomfort was highest in RA (94.4 ±2.8) Anxiety was depression was highest I COPD (51.4 ± 2.28) and least in DM (33.9 ±0.32)

Table 4: Comparison of mean value of mental status all three groups with controlled groups

Mental Status	COPD (30)	RA (30)	DM (30)	Controlled (90)
GHQ-12	21.4 (± 1.4)	20.6 (± 0.6)	12.4 (± 0.8)	6.4 (± 0.12)
Anxiety / worry	25.4 (± 1.6)	22.4 (± 0.58)	13.3 (± 0.50)	5.2 (± 0.10)
Fatigue score	47.6 (± 1.4)	50.4 (± 1.16)	30.6 (± 0.50)	8.2 (± 0.10)
sleeping problems	33.6 (± 1.2)	40.4 (± 1.2)	23.4 (± 0.6)	10.2 (± 0.2)
Depression	24.4 (± 1.2)	20.2 (± 0.32)	11.2 (± 0.50)	38 (± 0.1)
Pessimistic score	17.2 (± 0.2)	11.6 (± 0.5)	7.8 (± 0.2)	2.2 (± 0.6)

COPD has highest (21.4 ±1.4) score of GHQ and DM has 10 west score (12.4 ±0.8)

Fatigue score was highest in RA (50.4 ± 1.6) and least in DM (30.6 ± 0.50)

Sleeping problems was highest in RA (40.4 ± 1.2) and least in DM (23.4 ± 0.6) but rate of depression was highest in COPD (24.4 ± 1.2) and least in DM (11.2 ± 0.50)

Discussion

Present correlative study of COPD, RA and DM in south Karnataka Population. The Base line features of chronic diseases in all three groups were – current smoking 14 in COPD, 11 in RA, 9 in DM and 10 in controlled group. Ex-Smokers – 16 in COPD, 9 in RA, 12 in DM and 12 in controlled group. Retired – 19 in COPD, 18 in RA, 13 in DM and 49 in controlled group. Working – 11 in COPD, 12 in RA, 17 in DM and 41 in controlled group. APL – 14 in COPD, 13in RA, 16 in DM and 52 in controlled group. BPL – 16 in COPD, 17 in RA, 14 in DM and 38 in controlled group (Table-1). In comparison of physical activity, High activity score 9.4 (±3.1) in COPD, 12.8 (± 1.9) in RA, 20.2 (± 1.8) in DM and 60.2(± 4.4) in controlled group In low activity score 16.4 (± 3.9) in COPD, 9.2 (± 2.4) in RA, 6.2 (± 2.6) in DM and 12.8 (± 1.4) in controlled group (Table-2).In comparison of ED-5D Index to measure six months after discharged from ICU / hospital ED-5D Index value 0.60 (± 0.26) in COPD,0.62 (± 0.20) in RA, 0.72 (± 0.22) in DM, 0.92 (± 10) in controlled group.

Mobility problems –46.3 (± 1.28) in COPD, 54.2 (± 1.38) in RA, 35 (± 0.48) in DM, 35 (± 0.10) in controlled. In self care deficiency score 8.3 (± 1.3) in COPD, 11.4 (± 0.96) in RA, 6.4 (± 0.78) in DM, 0.3 (± 0.02) in controlled pain / discomfort rate 85.4 (± 1.6) in COPD, 94.4 (± 2.8) in RA, 72.8 (± 2.4) in DM, 32.2 (± 0.6) in controlled group. Anxiety / depression rate 51.4 (± 2.28) in COPD, 45.4 (± 2.2) in RA, 33.9 (± 0.32) in DM, 15.2 (± 0.10) in controlled group (Table-3). Comparison of mean value of mental stating in all three groups with controlled groups GHQ-12 – 21.4 (± 1.4) in COPD, 20.6 (±0.6) in RA, 12.4 (± 0.8) in DM, 6.4 (± 0.12) in controlled. Anxiety or worry – 25.4 (± 1.6) in COPD, 22.4 (±.58) in RA, 13.3 (± 0.50) in DM, 5.2 (± 0.10) in controlled groupFatigue score– 47.6 (± 1.4) in COPD, 50.4 (± 1.2) in RA, 23.4 (± 0.6) in DM, 10.2 (± 0.2) in controlled. Depression score –24.4 (± 1.2) in COPD, 20.2 (±0.32) in RA, 11.2 (± 0.5) in DM, 38 (± 0.1) in controlled. Pessimistic score – 17.2 (± 0.2) in COPD, 11.6 (±0.5) in RA, 8 (± 0.2) in DM, 2.2 (± 0.6) in controlled (Table-4) These findings are more or less in agreement with previous studies [6][7][8].

The Euro Q01 five dimension questionnaire (ED-5D) consists of dimensions of mobility self care, usual activities pain / discomfort and anxiety / depression each of offered three possible responses. No problem some or moderate problems / extreme problems. GHQ General Health information is self reported questionnaires designed to identify psychological disorders [9].

It is observed that, conditions of COPD patients are worse than RA and DM. COPD is largely dependent on age distribution their smoking habits,middle socio – economic status also aggravate the severity of COPD conditions. It is also reported that, the patient who never smoker or rare smokers also develop COPD as age advances. Moreover family history, type of occupation, exposure to dust, cause cough, sputum production, wheezing and dyspnoea cause severe impact on mobility physical exercise leads to sedentary life and patients turn to depression and pessimistic attitude [10]. As compare to RM and DM patients, COPD patients use airway medicines include gluco-corticoids and /or expectoration. The guide lines definition of COPD does not exclude asthma as a cause of chronic obstruction and the proportion of non-smokers COPD. The severe COPD reflect poor survival as it loads on cardio-vascular system. RA (Rheumatoidarthritis) is a chronic inflammatory disease of un-known aetiology but RA has submittal impact on HRQo1 (Health related quality of life), Spanning both physical and menial domains of well being [11]. Pain stiffness and fatigue reduction in body function is observed and controlled by medication which gives temporary relief. Diabetic mellitus being a hormonal impairment disease can be regulated by insulin and other hypoglycaemicdrugs, regular check-up of glucose levels drugs. Keep the patients healthy and active. In COPD patients dyspnoea, respiratory distress keep the patients anxious, pessimistic and sedentary hence clinical manifestation are severe in COPD patients as compare to RA and DM.

Summary and Conclusion

Correlative study of COPD, RA and DM in south Karnataka population is observed that, chronic disease patients often have low level of physical activity. COPD and / or RA have higher negative impact on quality of life than DM patients. It is established fact that chronic disease are treatable but not curable or yet to curable. Hence regular medical follow up is needed to keep such patients under control / normalcy but it is not possible for middle or low income family patients. Hence government hospital must have separate wings for such chronic patients so that personal attention and proper treatment can be given such patients. But this study demands further genetic, nutritional, patho-physiological, immunological, studies because exact pathogenesis of COPD, RA and DM is still unclear.

Limitation of study: Owing to tertiary location of research centre, small number of patients and lack of latest techniques we have limited findings and results.

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Conflict of Interest: No

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Original Article

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Can Uric Acid be Used as a Surrogate for Urinary Albumin in Type-2 Diabetes? A Prospective Observational Study

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Abstract

Background: Elevated serum uric acid and increased urinary albumin excretion are manifestations of common underlying pathogenesis of insulin resistance.The present study explores the relationship between uric acid level and urinary albumin in diabetic patients.

Methods: A prospective cross-sectional study was carried out in 100 diabetes patients attending BharatiVidyapeethHospital, Pune. Midstream urine spot test and urinary albumin-creatinine ratio (ACR) along with serum uric acid, fasting blood glucose (FBG), cholesterol, triglyceride, high-density lipoprotein cholesterol(HDLC), low density lipoprotein cholesterol (LDLC), albumin, and creatinine levels were estimated.

Conclusion: A significant association was observed between uric acid levels with duration of diabetes more than 10 years in presence of dyslipidemia and poor glycemia control (P value 0.05). On multivariate regression analysis, serum uric acid (OR - 2.498;1.51-4.12) and duration of the diabetes (OR - 1.258: 1.049-1.51) were observed to be significant predictors of Albumin-Creatinine ratio. The present study strongly suggests a close link between uric acid and increased urinary albumin excretion rate in type 2 diabetic patients.

Key words: Diabetes, Uric Acid, Urinary Albumin

Introduction

Diabetes mellitus has become a major health problem in India. It has been estimated that by the year 2030, 87 million of the Indian population would be suffering from this disease. Long-standing type 2 DM has considerable impact on various organs of the body. It increases morbidity and mortality by decreasing the quality of life.[1-2] Currently, India leads the world with the largest number of diabetic subjects and this is expected to further rise in the coming years.[3] Studies on diabetes-related complications are, therefore, vital to assess the burden of diabetes.

Diabetic Nephropathy (DN) is one of the common chronic micro-vascularcomplications (MVC) of Type 2 diabetes mellitus). It is the commonest cause of end-stage renal disease in the developed countries and the number is growing each year.[4] The magnitude of impact of type 2 DM on kidney is such that nearly 25-40% of patients develop kidney damage and chronic kidney disease. [5] Additionally, among these

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patients, the risk of cardiovascular disease (CVD), the morbidity and premature mortality associated with DM and CD is greatest with attendant economic burden on the individual and the country. [6-7]

The pathogenesis of nephropathy associated with diabetes is complex and still not well Understood. [8] It has been postulated that it occurs as a result of the interplay of metabolic and hemodynamic factors in the renal microcirculation. Evidence from numerous longitudinal studies have pointed that hyperuricemia is associated with an increased risk of cardiovascular events and death in both non-diabetic and type 2 DM individuals. [9-10]

Uric acid is an end product of purine metabolism, and approximately, one-third of it is degraded in the gut, and two-thirds is excreted by the kidneys. [11-13] Although decreased kidney function can be associated with hyperuricemia based on some epidemiological studies, hyperuricemia is an independent risk factor for kidney dysfunction in patients with diabetes mellitus (DM). [14]It is suggested that increased serum level of uric acid is an injurious factor for kidneys as it is shown that hyperuricemia-induced endothelial dysfunction, glomerular hypertension, and renal hypertrophy decrease renal perfusion via stimulation of the afferent arteriolar vascular smooth muscle cell proliferation. [15]

The main pathophysiological mechanism by which uric acid causes renal dysfunction involves an inhibition of endothelial nitric oxide bioavailability, activation of rennin angiotensin system and direct action on endothelial cells and vascular smooth muscle cells. [16-17] In some studies on diabetic patients, it has been reported that hyperuricemia is associated with kidney damage independent of hypertension. On the other hand, higher levels of serum insulin may decrease uric acid clearance by the kidneys.

Hyperinsulinemia is the basis of type 2 Diabetes Mellitus pathophysiology. Therefore, diabetic patients are more prone to uric acid kidney injury. Both elevated serum uric acid concentration and increased urinary albumin excretion rate may be manifestations of common underlying pathogenesis of insulin resistance. Hyperinsulinemia resulting from insulin resistance can decrease renal excretion, increase renal absorption and increase the production of uric acid.

We know that albuminuria is one of the main and early marker of diabetic nephropathy in this group of patients. The present study thus aimed to explore the relationship between uric acid level and urinary albumin in diabetic patients.

Materials and Methods

A hospital based cross-sectional study was conducted on 100 cases presented with diabetes mellitus at BharatiVidyapeeth Medical College, Pune. One standard questionnaire was used for each subject which included personal data, drug usage, disease history and physical examination. Urinary albumin-creatinine ratio (AR) was calculated by dividing the urinary albumin concentration in microgram by the urinary creatinine concentration in milligram. An ACR of 30.0 ug/mg or lower was considered as "normal," an ACR between 30 ug/mg and 299 ug/mg was considered as "microalbuminuria." Very high ratios (ACR ≥ 300 ug/mg) were defined as "overt albuminuria." Urine albumin was measured in a morning sample by an immunoturbidometry assay (Parsazmon, Karaj, Iran). Urine creatinine was measured by an enzymatic colorimetric assay (Parsazmon, Karaj, Iran).

Blood samples were collected after 10 hours fasting. They were evaluated for fasting blood glucose (FBG), uric acid, cholesterol, triglyceride, high-density lipoprotein cholesterol (HDLC), low density lipoprotein cholesterol (LDLC), albumin, and creatinine levels. Fasting blood glucose was measured by the glucose oxidase method (Human, Freital, Germany). Uric acid, total cholesterol, triglyceride, and HDL levels were measured by an enzymatic method (Parsazmon, Karaj, Iran). The LDLC was calculated according to Friedwall formula in participants with a triglyceride level less than 300 mg/dL. The GFR was calculated using the Cockroft-Gault formula. For all enrolled patients a questionnaire was filled out about age, gender, duration of DM and hypertension.

Stastistical Analysis

The quantitative data was represented as their mean + SD. Categorical and nominal data was expressed in percentage. The t-test was used for

analysing quantitative data, or else non-parametric data was analysed by Mann Whitney test and categorical data was analysed byusing chi-square test. The significance threshold of p-value was set at <0.05. All analysis wascarried out by using SPSS software version 21.

Results

Present study was carried out on 100 type 2 diabetic patients, where maximum (55%) were in the age group of 51-70 years. Mean age of the study cases was 62.1 years. Dyslipidemia was reported in 51% cases. Hyperuricemia was reported in 27% cases while 28% and 8% cases had micro-albuminuria and macro-albuminuria respectively. A significant association was observed between uric acid levels with duration of diabetes more than 10 years (7.26 vs 6.11 mg%), presence of dyslipidemia (6.99 vs 6.32 mg%) and poor glycemia control (7.33 vs 6.05 mg%) (Table 1).

Table 1: Association of meanuricacidlevelswith duration of diabetes, dyslipidemia and glycemic control.

Duration of DM	N	Mean UA	SD	P-value
<10 years	74	6.11	0.99	< 0.05
>10 years	26	7.26	1.19	< 0.05
Dyslipidemia				
No	49	6.32	1.21	0.309
Yes	51	6.99	1.17	0.309
Glycemic control				
Good	53	6.05	1.27	< 0.05
Poor	47	7.33	1.12	< 0.05

Table 2: ***Association of hyperuricemia and micro-albuminuria***

	Hyperuricemia		Total
ACR	**No**	**Yes**	
Normal	51	13	64
Micro albuminuria	20	8	28
Macro albuminuria	2	6	8
Total	73	27	100

Out of 27 cases of hyperuricemia, 14 (51.9%) had albuminuria as compared to 22 (30.1%) cases out of 73 non-hyperuricemic cases (p<0.01) (Table 2). On pearson correlation analysis, uric acid was correlating significantly with increased duration (r-0.41), glycated haemoglobin levels (r-0.71) and ACR (r-0.69) (Graph 1-3). On multivariate regression analysis, serum uric acid (OR - 2.498; 1.51-4.12) and duration of the diabetes (OR - 1.258; 1.049-1.51) were observed to be significant predictors of Albumin-Creatinine ratio.

Discussion

Present study observed a highly significant relation between albuminuria and hyperurecemia. Various studies have reported similar findings, Jalal DIet al. [18]reported that for every I-mg/dl increase in serum uric acid levels at baseline, there was an 80% increased risk of developing micro- or macroalbuminuria at 6 years (odds ratio 1.8: 95% confidence interval 1.2. 2.8; P = 0.00S). Another study by Bonakdaran S HM et al. [19] found that the association between serum uric acid concentration and degree of urinary albumin excretion was significant even after adjustment for estimated GFR. Also, Bonakdaran and coworkers have reported that hyperuricemia is associated with insulin resistance and onset or progression of nephropathy in type 2 diabetic patients.

Increased levels of serum uric acid was also seen to be significantly associated with the increased duration of the diabetes and poor glycemic control among the patients in present study. Similar findings were also observed by Neupane, Set al. [20] in their study on association between serum uric acid, urinary albumin excretion, and glycated hemoglobin in Type 2 diabetic patient in Nigeria. Another study by Venishetty S et al. [21]saw highly significant association between HAle and Uric acid levels (p<0.001). With increasing levels of uric acid observed in subjects with HbAle levels of ≥ 6.5. Significant correlation between HbAlc level and serum uric acid in the study group (PCC-0.353, p value < 0.001) has also been observed by Prabhuswamy K M ct al. [22]The US Third National Health and Nutritional Survey (NHANES III) during |988-94 assessing 14664 individuals found a lower serum uric acid levels and the bell-shaped relation of fasting glucose levels with association was larger among men (p-value for serum uric acid levels. Individuals with diabetes interaction, 0.007).

The study by Prabhuswamy et al. findings were also similar to the current study where they found correlation between these two variables. Another study done by SunitaNeupane and colleagues reported that serum uric acid concentration corresponded conclusively withUrinary Albumin Excretion (UAE) with an r-value of 0.323, and P value less than 0.05. They also observed Positive correlation with age (r-value-0.337, p-value < 0.05). age at onset (r- value = 0.341. p-value < 0.05) and total duration of diabetes (rvalue=0.312, p-value < 0.05), which shows that duration of diabetes and poor glycemic control are strong predictors ofcomplications.

Multiple regression analysis done by SunitaNeupane and colleagues showed that serum uric acid concentration, systolic blood pressure, HbAle and total duration of DM were independent determinants of UAE. Present study also observed similar findings, on multivariate regression analysis, serum uric acid and duration of the diabetes were observed to be significant predictors of Albumin-Creatinine ratio. Another study done by Suryawanshi and associates [23] showed a positive association between urine microalbumin and levels of uric acid in serum (p<0.001), This was also shown in study by Latif H et al. in their study patients having diabetes of less than 5 years duration, mean uric acid level and microalbuminuria were 7.0740.98 (mg/dL) and S.661.07 (mg/mmol) respectively (r- value-0.164) while in patients with duration of diabetes more than 5 years values were 6.87+1.05 (mo/dL) and 5.581.09 respectively (r-value= 0.060).

Many studies have shown that hyperuricemia may have a pathogenic role in the development and progression of chronic renal failure, rather than simply exhibiting decreased uric acid excretion from kidneys .Further study in nondiabetic subjects with large sample size may be ofclinical significance to clarify the role of uric acid in the development and progression of diabetic nephropathy.

Conclusion

The present study strongly suggests a close link between uric acid and increased urinary albumin excretion rate in type 2 diabetic patients. Since hyperuricemia is very common in type 2 diabetics and the treatment of elevated uric acid is relatively easy, it is worthwhile to study if lowering of uric acid levels with medications can help us prevent progression of diabetic nephropathy.

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Ethical Clearance: Take from Institutional Ethical Committee

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A Clinical Study of Ventilator Associated Pneumonia

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Abstract

Background: Ventilator Associated Pneumonia is a significant cause of mortality and morbidity in the critical care setting. Ventilator Associated Pneumonias are highly preventable owing to identification of risk factors, causes and best practices in the ICU.

Aims and Objectives : The present study is aimed at determining the incidence of Ventilator Associated Pneumonia and their associated risk factors.

Materials and Methods: The present hospital based observational study included 50 cases on ventilator support from the ICU of Apna Hospital, Hyderabad. All the cases were included after consent and underwent detailed history taking, relevant clinical examinations and necessary laboratory investigations. The incidence of VAP's was determined and the data was analysed to find the related factors. Data was collected in MS Excel, presented in as numbers and percentages in the form of tables and charts.

Results: The incidence of Ventilator Associated Pneumonia was found to be 38%. Early Onset VAP was estimated to be 47.3%, Late Onset VAP to be 52.7%. There was male predominance(64%) in our study group. Age groups 40-60 years contributed the most of the study population. Diabetes, Hypertension, CVD, alcoholism and tobacco use were associated in VAP cases.

Conclusion : There is a high incidence of Ventilator Associated Pneumonia in the critical care setting. Further research should be conducted to evaluate the causes and detailed risk factors as Ventilator Associated Pneumonia are a major cause of mortality, morbidity and increase the financial burden of the patient and the hospital.

Key Words: Ventilator Associated Pneumonia, Critical Care, ICU, Incidence

Introduction

Ventilator Associated Pneumonias are a major challenge for the critical care physicians as they are a significant cause of mortality. The prevalence of Ventilator Associated Pneumonias is estimated to be around 30% among intubated patients[1]. Ventilator Associated Pneumonias are highly preventable owing to identification of risk factors, causes and best practices in the ICU.

Ventilator Associated Pneumonia is defined as an ICU acquired pneumonia occurring within 72 hours of mechanical ventilation. According to the Centre for Diseases Control (CDC), USA, the criteria for diagnosis of Ventilator Associated Pneumonia include mechanical ventilation within 24 hours, lung infiltrates on radiographs, fever, leukopenia or leukocytosis and culture positive endotracheal aspirates. Ventilator Associated Pneumonia can be classified as Early onset VAP and Late onset VAP.

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Early onset VAP is defined as the one occurring in the first four days of ICU intubation. Late onset VAP is defined as VAP occurring at fifth day or thereafter of mechanical ventilation. Early onset VAP has been identified to be caused by antibiotic sensitive micro-organisms and to have a better prognosis. Late onset VAP has been linked with drug resistant variants and increased mortality.[2]There is no identified gold standard for diagnosis of Ventilator Associated Pneumonia which is a cause of poor outcomes and increased mortality.

The present study was thus undertaken to determine the incidence of Ventilator Associated Pneumonia and their associated risk factors in our setting.

Materials and Methods

Study Design: The present study was a hospital based observational study.

Study Setting: The present study was conducted at the ICU, Critical Care Unit of Apna Hospital, Hyderabad, Telangana.

Sample Size: 50 ICU patients who underwent endotracheal intubation and mechanical ventilation were included in the study.

Inclusion Criteria: All intubated patients in ICU on mechanical ventilation for more than 48 hours.

Exclusion Criteria: Cases with lung diseases and pneumonia prior to mechanical ventilation/ICU admission.

All the cases were included after consent and underwent detailed history taking, relevant clinical examinations and necessary laboratory investigations. The incidence of VAP's was determined and the data was analysed to find the related factors.

Statistical Analysis: Data was collected in MS Excel, presented in as numbers and percentages in the form of tables and charts.

Results

Table No. 1 Gender Distribution

Gender	No. Of Patients
Male	32(64%)
Female	18(36%)

Male cases were higher and accounted for 64% of the total study group.

Table No. 2 Age Distribution

Age Group	No. Of Cases
20-40 Years	16(32%)
41-60 Years	28(56%)
>60 Years	6(12%)

Most of the cases belonged to the age group 41-60 years. The elder population, above 40 years comprised of most of the cases.

Table No. 3 Incidence Of VAP

Group	No. Of Cases
VAP	19(38%)
No VAP	31(62%)

The incidence of VAP in our study group was around 38% which accounted for 19 patients.

Table No. 4 Early Onset VAP vs Late Onset VAP

Group	No. Of Cases
Early Onset VAP	9(47.3%)
Late Onset VAP	10(52.7%)

There was an almost even distribution of early onset VAP and late onset VAP among the total VAP cases.

Table No. 5 Associated Factors

Factor	VAP Group
Diabetes	11(57.8%)
Hypertension	7(36.8%)
CVD	5(26.3%)
Lung Disease	5(26.3%)
Renal Disease	4(21.0%)
Alcoholism	10(52.6%)
Tobacco Use	8(42.1%)

The associated factors in the Ventilator Associated Pneumonia have been depicted in the above table.

Discussion

The present study was a hospital based observational study which aimed at determining the incidence of Ventilator Associated Pneumonia in the critical care units ICU. The incidence of Ventilator

Associated Pneumonia in our study was found to be 38%. Similar results were obtained in a study conducted by D. Mohanty and colleagues[3]. In a study by S. Golia[4] the incidence of Ventilator Associated Pneumonia was found to be 35%. An incidence of 38% was also reported in a study by Mathai and colleagues[5]. HinaGadani and co[6] also studied Ventilator Associated Pneumonia in Indian setting and their results depict an incidence of 37% among the 100 patients they studied. In our study 64% of the total subjects were males. Similar results have been obtained by a few other studies[7]. The elder age groups, above 40 years were the ones to be affected the most. Ventilator Associated Pneumonia can be classified as Early onset VAP and Late onset VAP. Early onset VAP is defined as the one occurring in the first four days of ICU intubation. Late onset VAP is defined as VAP occurring at fifth day or thereafter of mechanical ventilation. Early onset VAP has been identified to be caused by antibiotic sensitive micro-organisms and to have a better prognosis. Late onset VAP has been linked with drug resistant variants and increased mortality. In our study Early Onset VAP and Late Onset VAP were evenly distributed, their frequency being 47.3% and 52.7% respectively. In our study, the VAP group, 58% were diabetics, 37% were hypertensives, 26% had lung diseases(chronic). Alcoholism and tobacco use were also common habits in those who acquired Ventilator Associated Pneumonia.

Conclusion

There is a considerable incidence of Ventilator Associated Pneumonia in the critical care setting. Further research should be conducted to evaluate the causes and detailed risk factors as Ventilator Associated Pneumonia are a major cause of mortality, morbidity and increase the financial burden of the patient and the hospital.

Conflict Of Interest: Nil

Funding: Self

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Study of Quality of life (QoL) of Patients with Common Skin Diseases

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Abstract

The pattern of skin diseases varies from one country to another. In particular, in India, where customs, religions, languages, climate and socioeconomic conditions vary across different parts of the country.It is very important to measure the impact of dermatologic disease on the quality of life. Measurement of the quality of life can be used in clinical research as well as for political and financial purposes relating to the development of dermatological services. Quality of life measures may also be effectively used in auditing clinical activities.

This study was conducted in the field practice areas of the Urban and Rural Health Centres, Department of Community Medicine, Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh, Uttar Pradesh. It was community based and cross- sectional study. The study period was one year i.e. from June 2016 to May 2017. *Inclusion criteria*: All individuals of the household. *Exclusion Criteria*: All who did not gave consent. *Sampling Method*: Systematic random sampling with Population Proportionate to Size (PPS) was used to draw sample size. Ethical clearance was obtained from ethical committee, JNMC, AMU, Aligarh. Informed verbal consent was taken from each subject before interview(Copy of ethical committee is attached).

Results reported that the overall mean QoL Indices score of the study population, the mean for the urban and rural population is almost equal. There was overall moderate effect on quality of life of both males and females in the study population. There was significant moderate effect on quality of life of patients in the older age groups (most affected-51-60yr, followed by 41-50yr, 31-40yr, and 19-30yr) compared to the age group 6-10 years.

Measuring the impairment of the quality of life in dermatology patients is an important aspect of management. It allows clinicians to assess the extent and nature of the disability so that an appropriate management regimen can be implemented and its effectiveness assessed.

Key Words: skin diseases, quality of life, rural, urban

Introduction

The pattern of skin diseases varies from one country to another. In particular, in India, where customs, religions, languages, climate and socioeconomic conditions vary across different parts of the country. Due to lack of education, patients may not report for treatment of the skin disease. Up to 80% of the populace suffering from skin problems may not seek medical help. Knowledge of this hidden

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section of population is important as it can affect the delivery of health care[1].

It is very important to measure the impact of dermatologic disease on the quality of life.It allows patients to express their feelings and appreciate their physicians' concerns. It improves doctor patient communication. It also helps in disease management, including the risk/benefit assessment of alternative therapeutic interventions. Measurement of the quality of life can be used in clinical research as well as for political and financial purposes relating to the development of dermatological services. Quality of life measures may also be effectively used in auditing clinical activities[2].

Material and Methods

This study was conducted in the field practice areas of the Urban and Rural Health Centres, Department of Community Medicine, Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh, Uttar Pradesh. It was community based and cross- sectional study.The study period was one year i.e. from June 2016 to May 2017.

Inclusion criteria: All individuals of the household.

Exclusion Criteria: All who did not gave consent.

Sampling Method: Systematic random sampling with Population Proportionate to Size (PPS) was used to draw sample size.

Sample size calculation:

$n = Z^2p\ (100- p)/l^2$

$n = (1.96)^2p(100- p)/l^2$,

$n \sim 4pq/l^2$

$q = 100- p$

p= prevalence of common skin disease(s) found in the pilot study

The sample size was calculated on the basis of pilot study conducted on 50 household each in RHTC and UHTC. As per pilot study, the prevalence of common skin diseases in registered areas of RHTC and UHTC came out to be 20% and 17% respectively.

Sample size calculation:

$n = Z^2p\ (100- p)/l^2$

l=(absolute allowable error)=2% at 95% confidence interval

Substituting the values for **RHTC**

$(1.96)^2p(100- p)/l^2= 4* 20(100- 20)/2^2$

$= 1600$

Substituting the values for **UHTC**

$(1.96)^2p(100- p)/l^2= 4* 17(100- 17)/2^2$

$=1411$

≈ 1420

Applying PPS for both RHTC and UHTC

- Data was entered and managed in SPSS-20 (Statistical Package of Social Science). For descriptive purpose frequency and percentage were used.
- To test associations chi square test, independent t test and one way ANOVA was applied.P value <0.05 was considered significant

Ethical clearance was obtained from ethical committee, JNMC, AMU, Aligarh. Informed verbal consent was taken from each subject before interview(Copy of ethical committee is attached).

Dermatological Life Quality Index/Children's Dermatological Life Quality Index questionnaire

10 item questionnaire with response score range from 0(min) to 3(max) for each item.

Cumulative scoring for individual subject graded as

GRADE I 0-1 (NO EFFECT ON PATIENT LIFE)

GRADE II 2-5 (SMALL EFFECT ON PATIENT LIFE)

GRADE III 6-10 (MODERATE EFFECT ON PATIENT LIFE)

GRADE IV 11-20 (VERY LARGE EFFECT ON PATIENT LIFE)

GRADE V 21-30 (EXTREMELY LARGE EFFECT ON PATIENT LIFE)

Results

Table 1: QoL Index mean score comparison with area

AREA	QoL indices score	
	Mean	S.D
Urban	5.78	3.55
Rural	6.17	3.13
t value= -1.48 df=661 p = 0.14		

Table 2: Gender wise association of DLQI/CDLQI score.

DLQI	Urban		Rural	
	Male	Female	Male	Female
Mean	5.55	5.99	5.96	6.38
S.D	3.27	3.77	2.99	3.26
t value = -1.00, df = 269, p = 0.317			t value = -1.35, df = 391, p=0.179	

Table 3: Association of QoL indices score with age.

Age (Years)	Urban		Rural	
	Mean	S.D	Mean	S.D
6-10	4.39	2.14	4.52	2.59
11-18	5.59	3.13	5.84	3.21
19-30	6.24	3.59	6.51	3.13
31-40	5.88	4.44	6.43	2.47
41-50	5.00	1.86	6.73	3.66
51-60	6.50	4.56	7.48	3.16
<60	9.50	6.59	5.93	3.81
f = 2.953, df = 6, p = 0.008			f = 3.419, df = 6, p=0.003	

Discussion

Table 1: shows the overall mean QoL Indices score of the study population, the mean for the urban and rural population is almost equal i.e. 5.55 ± 3.66 (Mean ± S.D) for urban and 5.72 ± 3.39 (Mean ± S.D) for rural, depicting moderate effect on the overall quality of life (QoL) of population in both the areas. No statistically significant difference was observed for the rural and urban mean scoring of QoL indices in the study area. The mean score was observed in other studies as; Astudy[3] evaluated the impact of psoriasis on the quality of life in patients with psoriasis. It was reported that the mean DLQI score was 8.95 ± 8.48 (Mean ± SD).

Another study[4] found theprevalence of skin diseases in the hilly population of Nepal and reported the mean DLQI score to be 10.7 ±3.2 (range 7-19), indicative of a very large impact on QoL.

Cross-sectional study conducted in Saudi Arabia[2]observed aoverall mean DLQI of 8.32 ± 7.1 (Mean ± S.D), shows a moderate impact on quality of life among patients affected with dermatological conditions.

The DLQI mean (SD) score was 6.5 (5.6) in the study population of a study[5].

Dermatology Life Quality Index (DLQI) questionnaire was used in Iranian patients with vitiligo in a study[6] andreported DLQI scores ranged from 0 to 24 (mean ± SD, 7.05 ± 5.13), showing an overall moderate impact of skin diseases in the study population.

From table 2, it was observed that in urban population, the mean scores of QoL indices for males was 5.55 ± 3.27 (Mean ± S.D) and for females it was

5.99 ± 3.77 (Mean ± S.D) while in rural population it was 5.96 ± 2.99 (Mean ± S.D) for males and 6.38 ± 3.26 (Mean ± S.D). It can be inferred that there was overall moderate effect on quality of life of both males and females in the study population.

Other study[2] observed a significant difference of DLQI mean with sex of the population and reported it to be among females (9.02) than males (6.46).

Table 3 shows that lowest mean QoL indices score in urban population i.e.

4.39 ± 2.14 (Mean ± S.D) was observed for 6-10 years group and highest i.e. 9.50 ± 6.59 (Mean ± S.D). The difference of the mean between different age groups appeared to be significant. On further analysis by applying post hoc test, significance was observed between age groups i.e. 6-10 years compared to 11-18 years, 41-50 years and > 60 years. this shows that in urban area the patients of older age had poor quality of life as compared to younger ones.

The mean of the rural area was also found to be lowest i.e. 4.52 ± 6.59 (Mean ± S.D) in the age group 6-10 years but the highest QoL indices mean score i.e. 7.48 ± 6.59 (Mean ± S.D) was observed in the age group 51-60 years. The difference in the means of

different age group came out be significant in rural population also. On post hoc test analysis the mean QoL indices score was found to be significantly less for 6-10 years group compared to 19-30 years, 31-40 years, 41-50 years, and 51-60 years age groups. This clearly depicts that there was significant moderate effect on quality of life of patients in the older age groups (most affected-51-60yr, followed by 41-50yr, 31-40yr, and 19-30yr) compared to the age group 6-10 years.

This can be attributed to the fact that children are less bothered about their illness and looks compared to adults who are more sensitized for their looks and also concerned what others may think about skin problems they have.

As far as variation of mean QoL indices with age is concerned in other studies, Mishra et al[7] in their study on 100 patients of vitiligo did not find any significant correlation with age.

Same was observed in the study of Al-Hoqail,[2] that age had no influence on the degree of impairment in patients affected with skin diseases in Saudi Arabia.

Recommendation

Measuring the impairment of the quality of life in dermatology patients is an important aspect of management. It allows clinicians to assess the extent and nature of the disability so that an appropriate management regimen can be implemented and its effectiveness assessed. Improvement in the environmental conditions by community participation can bring down the morbidity profile. Proper education should be given.

Ethical committee: Atttached

Funding: Self

Conflict of interest: Nil

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Original Article

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A Cross Sectional Study of Antimicrobial Resistance in Medical College Affiliated Tertiary Health Care Hospital

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Abstract

Background and Objectives: The study conducted involves reviewing the current scenario of antimicrobial resistance in the community by obtaining collected data from patients suffering from ongoing infective disorders andanalyzing their culture and sensitivity reports.

Methods: We have collected the samples from 56 patients with infective disorders such as cellulitis, wound infection, pneumonia, cultured the samples and checked for the sensitivity of various different antibiotics using the disc diffusion methods according to CLSI standards. We have also checked for the morphology of the organism by routine microscopy using gram stain.

Results: We have noted that the Gram-positive Cocci infections are more prevalent in our community settings and there was also a high level of resistance seen in both gram-negative and gram-positive organisms, towards the standard empirical antibiotic Cefotaxime used in such patients. Hence, we had to switch to a more effective antibiotic according to the patterns of resistance. The presence of resistance to other antibiotics was also noted.

Interpretation & Conclusion: There is an increased level of resistance towards once considered highly effective broad-spectrum antibiotics in the community. This may be a result of inappropriate and overzealous usage of antibiotics by patients. This may be a result of improper supervision or no strict guidelines when it comes to the prescription of antibiotics. Hence many different strategies must be deployed in order to tackle the development of resistance to useful antibiotics.

Keywords: Antibiotic resistance, infection, culture, gram-positive cocci, gram-negative bacilli, sensitivity.

Introduction

Just 100 years after the discovery of the first antibiotic, we find that weare threatened by the emergence of multi-drug resistant bacterial organisms. Antimicrobial resistance (AMR) is huge burden not only on healthcare system of the country

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but also increases expenses and poor health to community It is necessary and important to know the mechanism of these resistance and how to impede the occurrence. To curb these incidence and proper usage guidelines are utmost necessary to get rid of non-judicious practice. However, the misuse and overuse of antibiotics have allowed resistant bacteria to thrive, while wiping out sensitive bacteria. To address AMR effectively, a multi-disciplinary health approach is necessary. The Global Action Plan on AMR[1] is popular and valid to counter these world-wide healthcare problem.

Considering the origin and dissemination of these organisms, healthcare facilities are most common sensitive places. In these outset various high dependency units, isolation units, surgical theatres are not uncommon sites for emergence of resistant. Healthcare system is facing recently challenging scenario of various hospital acquired infections. It mandates continuously changing the guidelines by infection control committee of hospitals and national disease control committee. Both developing and developed nations are spending high expenses for identification, surveillance and control of the antibiotic resistance.[2]

Materials and Methods

This study has taken place in a Municipal CorporationTeachingHospital after the approval by Institutional Research Board. With a sample size of 56 patients from different wards in different specialities all these patients had diseases with infective aetiology and had been administered empirical antibiotic Cefotaxime according to the antibiotic protocol of the hospital. All the patients included in the study had undergone a culture and sensitivity test with inoculation techniques done in the microbiology department of this hospital.

The method of resistance analysis was determined with the Kirby Bauer method of disc diffusion according to the CLSI standards[3]. The diameter of no growth surrounding the different antibiotic discs was noted and this will give us the required information about the sensitivity of the bacteria to the antibiotic. The larger the diameter is the more the sensitivity and the smaller the diameter the greater the resistance. Mueller Hinton agar plates have been used for this study. The antibiotic susceptibility discs had been acquired from reputable suppliers. The inoculum had been prepared with 0.5 McFarland standard of turbidity. We have a standard set of antibiotic discs tested for susceptibility which are routinely used. According to the size of the diameterswhich is measured with a calliper, we are able to categorize the antibiotic susceptibility as sensitive, moderately sensitive and resistant. The reference standards for the diameters are different for different isolated organisms we use standards as used in the American Society for Microbiology. Usually, after an incubation of 24 hrs is completed we are able to infer the results. The usual temperature will be 35°C.

The nature of the organism is also determined with the help of routine microscopy and gram staining techniques which help give us a clear idea of and morphology of the bacteria isolated.

A proper history of the patients including their demographic information had been obtained which could help with clinical suspicion and in the analysis of data. Data had been collected in the form of a proforma, which also included necessary investigations such as total blood count,ESR and CRP along with others.

After the culture and sensitivity report was obtained, if resistance to cefotaxime was noted then the antibiotic was changed based on susceptibility. The overall outcome of the patient was noted along with other data and the number of days antibiotics have been given in intravenous route or oral route. Data was compiled and analysed.

Results

We have conducteda study of over 56 patients having an infection. In this study, we have collected data from culture and sensitivity reports from the laboratory. We have used cefotaxime as an empirical drug. The method of resistance analysis was determined with the Kirby Bauer method of disc diffusion. The diameter of no growth surrounding the different antibiotic discs was noted and this will give us the required information about the sensitivity of the bacteria to the antibiotic. We have a standard set of antibiotic discs tested for susceptibility which are routinely used. According to the size of the

diameterswhich is measured with a calliper, we are able to categorize the antibiotic susceptibility as sensitive, moderately sensitive and resistant. The reference standards for the diameters are different for different isolated organisms we use standards as used in the American Society for Microbiology. Usually, after an incubation of 24 hrs is completed we are able to infer the results. The usual temperature will be 35°C (1 and 3-Kirby Bauer). In our study, 37 patients showgram-positive cocci and 19 patients shows gram-negative bacillusin which 15(40.54%) gram-positive cocci patients shows mild resistance and 16(43.24%) gram-positive coccishow resistance to certain antibiotics. Among 19 gram-negative bacillus positive patients, 8(16.66%) show resistance and 5(41.66%) show mild resistance. (Fig 1)

Individual antibiotic testing also showed the increased incidence of antibiotic resistance in gram negative bacilli to all different groups as compared to the gram positive cocci. (Table 1 and 2)

Table 1: The sensitivity of Gram Positive Cocci according to individual antibiotics being tested

GPC	Sensitive	Mild Sensitive	Resistance
AMPICILLIN	30	1	6
COTRIMOXAZOLE	28	6	3
CEPHALEXIN	32	2	3
TETRACYCLINE	34	0	3
CEFOTAXIME	24	9	4
CIPROFLOXACIN	22	9	6
LEVOFLOXACIN	35	1	1
LINEZOLID	35	1	1
CLOXACILLIN	29	5	3
ROXITHROMYCIN	27	5	5
LINCOMYCIN	32	1	4
GENTAMYCIN	35	0	2

Table 2: The sensitivity of Gram Negative Bacillus according to individual antibiotics being tested.

GNB	SENSITIVE	MILD SENSITIVE	RESISTANT
AMPICILLIN	17	0	2
COTRIMOXAZOLE	13	3	3
CEPHALEXIN	14	2	3
TETRACYCLINE	11	4	4
CEFOTAXIME	10	7	2
CIPROFLOXACIN	13	2	4
LEVOFLOXACIN	17	0	2
LINEZOLID	17	0	2
CLOXACILLIN	14	3	2
ROXITHROMYCIN	14	2	3
LINCOMYCIN	12	3	4
GENTAMYCIN	16	1	2

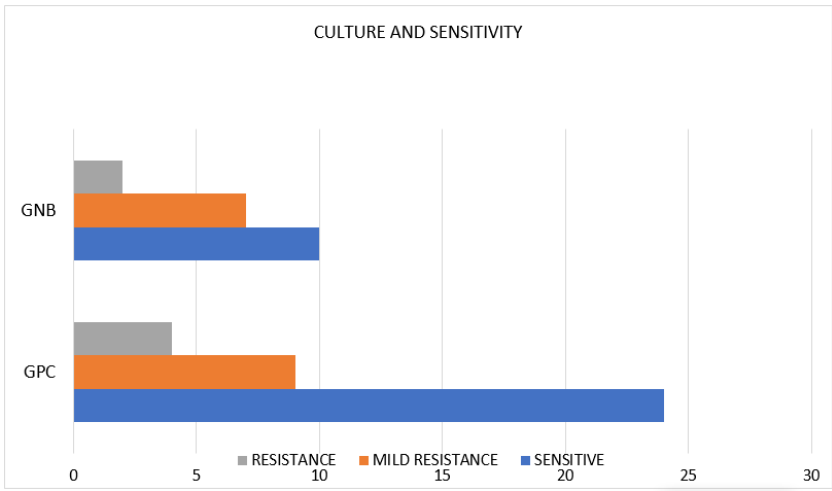

Figure 1: Gram positive cocci resistance to Cefotaxime:

Sensitive: 24 patients. Mild resistance : 9 patients. Resistant: 4 patients

Gram negative bacilli resistance to Cefotaxime:

Sensitive: 10 patients. Mild resistance : 7 patients Resistant: 2 patients

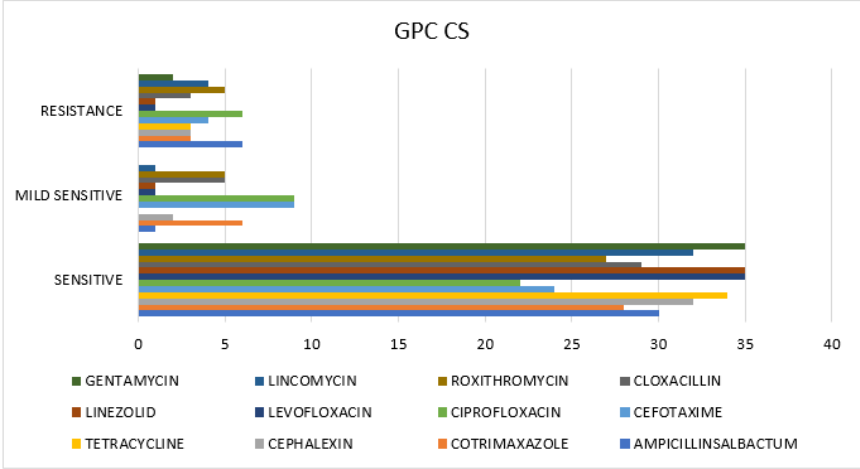

Figure 2: The sensitivity of Gram Positive Cocci according to individual antibiotics being tested.

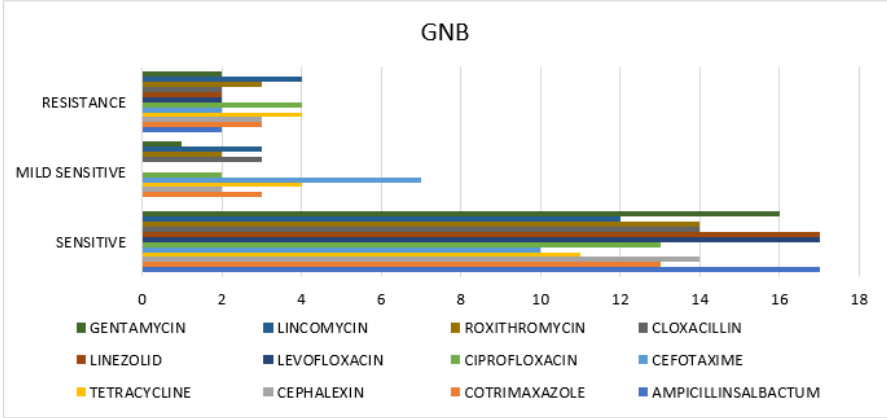

Figure 3: The sensitivity of Gram Negative Bacillus according to individual antibiotics being tested.

Discussion

GPC are most commonly encountered pathogens for endogenous and exogenous infections in hospital setup. Owing to virulence of the organisms, which signal characteristics and genesis of unprecedented resistance of antibiotics[4]. To decreases most virulent MRSA infection resurgence in hospital and healthcare systems, judicious and lesser antibiotics prescriptions and monitoring and supervision by infectious disease specialist[5]. The global threat of MRSA outbreak primarily found in tertiary care institutions followed by all health care system which render difficulty in on going treatment[6]. This necessitate provision of infection control committee and formation of guidelines of hand hygiene, wearing personal protective equipment, biomedical waste management, control cross infection by healthcare worker and improve sanitization and cleaning methods. First generation antibiotics deemed safer if used in indicated case for shorter duration dampen outbreak of MRSA strains and need for next generation antibiotics.

Beta-Lactam group of antibiotics were trusted and most versatile group of antibiotics which were used since inception two membrane bacteria like P. Aeruginosa and Escherichia species. These group of antibiotics have unique mechanism like disabling proteins attached to cell membrane and this in turn impede multiplication.[7]Addition and augmentation of another molecule clavulanate further promote efficiency of this group of antibiotics[8,9]. The other associated molecules which are commonly used in intensive care setting is tazobactam along with piperacillin. Common hospital acquired infections are best treated with optimal use of aminoglycosides which inhibit protein formation and evidence based bactericidal effect on gram negative bacteria and other anaerobic infections. Mechanism action of Quinolones with fluorine in its constitution has reliable and precise cidal effect on entire positive and negative micro-organism. That is why fluroquinolones group of antibiotics are globally used in immunocompromised and patients with deep infections. Sulphonamide group of antibiotics with additive effect ofTrimethoprim inhibits resistant staphylococcus infections in immunocompromised patients.[10]

Antibiotics impede cellular wall generation, de magnetize other cell structure. Cohesion and adhesion to micro-organism surface is essential to achieve destruction.The fundamental of evolution of resistance of various group of antibiotics are idiopathic. The possible way to find out various drugs resistance to target micro-organism is to be understood. While treating deep infections with prolong usage of antibiotics, chemical destruction by enzyme makes it ineffective. Genetic alteration of proteins in micro-organism also produces same resistance. Entrance of antibiotics is also impeded due to membrane alteration.

The impact of antimicrobial resistance has been shown to cause a negative impact on thepatient's morbidity and mortality, leading to a clinically poor outcome. This has also been analysed in a study of MRSA[11]. It was also inferred that MRSA and other resistance can occur with poor hygienic standards and handwashing techniques.

In our study we have noted that infections by gram positive cocci are more prevalent(66%) in the community settings as compared to the infections by Gram negative bacilli (34%). The empirical drug we had used for these patients initially was cefotaxime, which was once considered to be abroad spectrum and highly effective drug. We noticed that in the patients selected for our study, out of 37 patients infected with GPC organisms, around 4 cultures showed complete resistance to the antibiotic cefotaxime and 9 showed mild resistance. Also in the GNB infected patients, 7 patients showed mild resistance and 2 patients showed complete resistance. It was also noted that the gram negative bacilli showed a higher rates of resistance development as compared to the gram positive cocci.(Fig 2 and 3)

Resistance to antimicrobials is a natural phenomenon. When any antibiotics is administered for any diagnosed infection, bio-availability and concentration in plasma is monitored. If optimum level is not found, the micro-organism study for resistance shouldn't be overlooked. Genetic drift and shift and various mutations are also to be considered for developing in cases of emergence of resistance. These also involve similar congener of group of antibiotics.

In the outset, antibiotic administration, need and prolong treatment shouldn't be overlooked in making organisms resistant. Proper training, understanding and surveillance is utmost important for antibiotic prescription system.Over the counter and undue higher antibiotic consumption needs to be addressed. Patient education and understanding about proper intake of prescribed antibiotic dose for proper duration should be done. Healthcare workers are sensitized periodically for hand hygiene and hand rub techniques, sanitation and dis infection, proper handling of patient care items to decrease cross infection and resistance.

Recently we are facing globally challenges of Methicillin resistance staphylococcus aureus, vancomycin resistance, multidrug resistance anti-tubercular drug therapy. Immunocompromised patients such as HIV, cancer patients, post-transplant patients have higher chances to develop these resistance. These hospital acquired infection if uncured and not addressed, can lead to spread into healthy population.

Widespread inappropriate antibiotic usage which is prescribed by health care officials has proven to be the highest cause of antibiotic resistance. Improper sanitation and poor basic hygiene have also encouraged the increase.The need for multidisciplinary coordination is of utmost importance to counteract these difficulties. Inputs from hospital administrators, infection control teams, microbiologists and physicians from various specialities have been deemed necessary.

Monitoring by ongoing surveillance, implementation of proper hygiene control, evaluation of the causes of antibiotic resistance and right harnessing of technology will improvethe resistance control. Ogoina et al[12] have researched and shown evidence that the major mismatch in antibiotic resistance and antibiotic prescriptions, especially in tertiary care hospitals in the major contributor in his large multicentric study. Limitation of the study is our sole general hospital and non-inclusion of other general hospital of similar demography.

Education of doctors and the patients on the importance of rational usage of antibiotics. But education should also be extended to the common people and discourage the habit of self-medication with antibiotics as well as the importance of completing a course of antibiotics if started. The supervision of antibiotic usage is also very important and the use of audits and comparison ofprotocols with other hospitals in the community is also important.

It is role and goal of designated infection committee and inter-disciplinary inter-departmental frequent meeting and auditing of rational use of antibiotics in their institute. Junior and trainee doctors should be well educated and taught about mechanism, efficacy, bio-availability, clearance, and duration of dosing of various group of antibiotics. Unjust prescription of the antibiotics without any indication and evidence of organism should be avoided. They should form proper guidelines for collection of specimen of body fluids along with their proper transport and inoculation methods.

For minor and clean surgical procedures without evident infection, no prophylaxis of antibiotics should be given. Superficial and deep wound cultures, bone-marrow aspirates and broncho-alveolar lavage specimen should be sent first to the microbiology lab for culture and sensitivity report before commencing any antimicrobial agents. Over use and irrational antibiotics use can cause damage to normal colonic bacterial flora, which can further cause malabsorption of essential elements and vitamins.

Conflict of Interest: Nil

Source of Funding: Nil

Ethical Approval: Taken from NHL Institutional Review Board(NHLIRB) committee.

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Original Article

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Role of CBNAAT in Diagnosing of Extra-Pulmonary Tuberculosis at a Tertiary Care Centre in a City of Karnataka: A Cross Sectional Study

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Abstract

Background: Cartridge based nucleic acid amplification test(CBNAAT) detects the presence of TB bacilli and also Rifampicin susceptibility.This test is currentlyrecommended as a ''first line'' fast diagnostic test inhigh TB burden countries like India.

Aim & Objective: 1. To assess the yield of CBNAAT in detecting extra-pulmonary tuberculosis for patient attending S.S.I.M.S & RC, Davanagere.

2. To assess the Rifampicin susceptibility in samples of presumptive extra-pulmonary TB patients using CBNAAT.

Settings and Design: Cross sectional study was conducted among the patients after screening them with symptoms suggestive of extra-pulmonary TB coming to S. S.I.M.S & RC. Davangere.

Methods and Material: 107 samples were collected and subjected to CBNAAT for detection of Mycobacterium tuberculosis and Rifampicin Susceptibility.

Statistical analysis used: chi square test was applied to find out the association between Extra-pulmonary Tuberculosis with demographiccharacteristics and to find out the association between CBNAAT with demographic characteristics.

Results: The yield of CBNAAT was of sensitivity of 100%, specificity of 98.7%, Positive predictive value (PPV) of 96.9%, Negative predictive value(NPV) was 100% and Accuracy was 99.1%.

Conclusions: This study reinforces the importance of CBNAAT which has an impact on early detection, treatment and outcome of Extra-pulmonary Tuberculosis.

Keywords: Extra-pulmonary Tuberculosis, CBNAAT, Davanagere.

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Introduction

Tuberculosis is one of the dreaded diseases which accounts for 9.6 million cases globally as per the WHO Global TB Report 2015. India contributes to 2.2 million incidence cases. It has high morbidity and mortality with 0.22 million deaths in India in 2015.[1] pulmonary involvement is the most common presentation, it can potentially affect any organ or system of the body.[2] TB affecting other sites-known as extra-pulmonary TB is rarely smear positive. It is generally accepted that the contagious potential of this form is negligible, and it has, therefore, never been a priority in the campaigns undertaken by national TB control programs.[3, 4] Extra-pulmonary tuberculosis forms a significant proportion of the total TB cases and is a major health problem in both developing and developed countries. Diagnosing EPTB is challenging due to its varied clinical presentations and pauci-bacillary nature of the disease.[5] CBNAAT is cartridge-based nucleic acid amplification test which detects the presence of TB bacilli and tests for resistance to Rifampicin also. CBNAAT i as it is a very cost-effective and rapid test. Hence our study aimed to define the role and Yield of CBNAAT in clinical decision-making in suspected EPTB cases.

Objectives:

1. To assess the yield of CBNAAT in detecting extra-pulmonary tuberculosis for patient attending S.S.I.M.S & RC, Davanagere
2. To assess Rifampicin susceptibility in samples of presumptive extra-pulmonary TB patients using CBNAAT

Materials and Methods

A cross sectional study was conducted among the patients after screening them with symptoms suggestive of extra-pulmonary TB coming to S. S. Institute of medical sciences and research centre, Davangere during 1st April 2019 to 31st July 2020. Ethical clearance was taken from institutional ethical committee. Patients aged above 18 years and patients with clinical history and physical findings or chest X-ray lesions suggestive of extra-pulmonary tuberculosis were included in study. Patients who were not given consent and those on anti-tubercular treatment were excluded from the study. Ethical clearance was obtained from Institutional Ethical Review Board. Informed consent was obtained from each respondent prior to the interview. Details of the patients like name, age, sex, HIV status and previous history of Pulmonary TB were taken. 107 samples from the patients were collected depending on clinical suspicions the samples were collected which includes Pleural fluid, CSF, Lymph node, Pus, synovial fluid, Ascitic fluid, endometrial tissue, urine and Laryngeal mucous. The collected samples were subjected to CBNAAT(which is at Chigateri district Hospital, Davanagere) for detection of Extra-pulmonary Tuberculosis and Rifampicin Susceptibility.

Data was entered in MS EXCEL and statistical analysis was done using SPSS version 20 and results were expressed in terms of percentages and proportions. Analysis was carried out by chi square test to find out the association between Extra-pulmonary Tuberculosis and demographic characteristics and also to find out association between CBNAAT test with demographic characteristics, Rifampicin susceptibility, samples and type of extra-pulmonary Tuberculosis. Yield of the CBNAAT test was assessed by calculating Sensitivity, Specificity, Positive predictive value, Negative predictive value and Accuracy.

Results

In this study, majority of the patients were in the age group of 31-50 years(36.4%), males were more in number(59.8%), HIV status of the all the patients was Non reactive and majority of the patients were not had the History of Previous Pulmonary Tuberculosis and 24.3% had history of Previous Pulmonary Tuberculosis. Socio-demographic features of the patients are explained in Table 1.

In this study 31(28.9%) of the patients samples subjected to CBNAAT were found to be positive for Extra- Pulmonary Tuberculosis and all samples were found to be Rifampicin sensitive. MTB detected in different samples received from the patients were explained in Table 2.

In this study no significant association was found between CBNAAT results with risk sex, age, religion and previous history of Tuberculosis but significant association was found between Rifampicin susceptibility and CBNAAT results. The association of CBNAAT results with risk factors are explained in Table 3.

In this study the yield of CBNAAT as follows which includes sensitivity of 100%, specificity of 98.7%, Positive predictive value(PPV) of CBNAAT test was 96.9%, Negative predictive value(NPV) was 100% and Accuracy was 99.1%. the yield of the CBNAAT is explained in Table 4.

Table 1: Socio-demographic features of study participants

Age (Years)	No. of Cases	Percentage
<=30	33	30.8
31-50	39	36.4
51-70	26	24.3
>70	9	8.4
Sex		
Male	64	59.8
Female	43	40.2
HIV Status		
Non Reactive	107	100
Reactive	0	0
Total	107	100

Table 2: MTB detected in different samples received from the patients

Samples	Total no of sample received	Positive by CBNAAT
Pleural Fluid	46	11
CSF	15	2
Ascitic Fluid	12	0
PUS	6	2
Urine	6	2
Lymph node	16	11
Mucous	1	1
Synovial Fluid of Knee	2	1
Endometrial Curratage	3	1
Total	107	31

Table 3: Association of CBNAAT results with risk factors.

Variables		CBNAAT Results		Total(122)	$\chi 2$ Value	P value
		Positive	Negative			
Sex	Male	16(25%)	48(75%)	64(100%)	1.221	0.269
	Female	15(34.8%)	28(53.2%)	43(100%)		
Age	<= 30	12(36.3%)	21(63.7%)	33(100%)	1.526	0.676
	31-50	11(28.2%)	28(71.8%)	39(100%)		
	51-70	6(23.1%)	20(76.9%)	26(100%)		
	>70	2(22.2%)	7(77.8%)	9(100%)		
Religion	Hindu	25(26.3%)	70(73.7%)	95(100%)	0.412	0.521
	Muslim	6(50%)	6(50%)	12(100%)		
Previous H/O Pulmonary TB	History of Pulmonary Tuberculosis	9(34.7%)	17(65.3%)	26(100%)	0.532	0.466
	No history of previous pulmonary tuberculosis	22(27.2%)	59(72.7%)	81(100%)		
Rifampicin Susceptibility	Resistant	0(0%)	76(100%)	76(100%)	102.29	0.000
	Sensitive	31(100%)	0(0%)	31(100%)		
	Total	31(29%)	76(71%)	107(100%)		

Table 4: Yield of CBNAAT test

Yield	Percentages
Sensitivity	100%
Specificity	98.7%
Positive Predictive Value(PPV)	96.9%
Negative Predictive Value(NPV)	100%
Accuracy	99.1%

Discussion

This study which was conducted on patients after the screening with symptoms suggestive of extra-pulmonary TB coming to S.S.I.M.S & RC, Davanagere. In this study 107 samples of presumptive extra- Pulmonary Tuberculosis cases were collected and subjected to CBNAAT for detection of Extra-

Pulmonary Tuberculosis and to assess the Rifampicin Susceptibility. Total of 107 samples were received among them 31(29%) of samples were positive for extra-pulmonary Tuberculosis and all samples were sensitive for Rifampicin Susceptibility. In this study the HIstatus of the all the patients was non reactive. In contrast to this a study done by Yadav k et al[6] showed that 8.54% of the patients were HIV positive and a study done by Gaur PS et al [7] showed that 4.7% of the patients were HIV positive. In present study among different samples received, maximum number of samples were of pleural fluid(43.0%). Similar results were found by Yadav k et al [6], Bankar s et al [8] Mathur RB et al[9]and Kumar R[10] et al. In contrast to this a study conducted by Ulla et al [11] showed that maximum number of pus samples were received. A study done by Uria GA et al [12]showed that maximum samples were from CSF. In this study 29% of the samples were positive for extra-pulmonary Tuberculosis which was subjected to CBNAAT. A study conducted by Yadav K [6] et al showed that 23.8% were positive for extra-pulmonary Tuberculosis. In this study no significant association was found between CBNAAT results with age, sex, previous History of pulmonary Tuberculosis but significant association was found between CBNAAT result and Rifampicin susceptibility.

In this study the yield of CBNAAT as follows which includes sensitivity of 100%, specificity of 98.7%, Positive predictive value(PPV) of CBNAAT test was 96.9%, Negative predictive value(NPV) was 100% and Accuracy was 99.1%. A study conducted by Komanapalli SK et al[13] showed that the sensitivity 85.71%, specificity 96.8%). A study conducted by Bankar S et al [8] showed that the sensitivity and specificity Xpert MTB/RIF assay was 84.91% and 86.72%. A study conducted by Rao CM et al [14] Showed that overall CBNAAT sensitivity was 100% and specificity was 87.5%. A study conducted by Lawn et al [15] showed that sensitivity of CBNAAT was 81.3% and specificity was 99.8%.

Conclusion

CBNAAT is a rapid test to confirm presence of MTB with simultaneous detection of rifampicin resistance in EPTB. Introduction of CBNAAT for EPTB, plays important role on early detection, treatment and outcome as most presumptive cases have a confirmed diagnosis. This test has not only yields good sensitivity but also specificity ,Positive predictive value(PPV), Negative predictive value(NPV), and Accuracy was 99.1%.

Recommendation CBNAAT test is a better for early diagnosis, early detection of Rifampicin resistance and gives good yield.

Limitation of the study

1. Sample size was small. Larger the number of cases to undergo CBNAAT test for better diagnostic predictability.
2. This study had no clinical follow-up of the patients which does not give a clinical reference for the samples tested by CBNAAT.
3. In this study yield of CBNAAT was not compared with AFB Smear, culture and LED microscopy.

Relevance of the study: CBNAAT is a good diagnostic test which early detects extra-pulmonary TB ,its drugs sensitivity and yield.

Conflict of interest: None

Source of funding: Self

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Original Article

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Assessment of Prevalence of Malnutrition among Under-Five Children in Rural Area of Haldwani

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Abstract

Background: Malnutrition in children is global issue that may have both short- and long-term irreversible negative health consequences.

Objectives: To determine the prevalence of under-nutrition among the under-five children inrural area of Haldwani.

Material and methods: Community-based cross-sectional study.

Results: Four-hundred children were examined. The prevalence of undernutrition among children was depicted as underweight, stunting and wasting was 7.75%, 9.25% and 4% respectively.

Keywords: under-five children, malnutrition, Haldwani

Introduction

Malnutrition refers to deficiency or excess in nutrient intake, imbalance of essential nutrients or impaired nutrient utilization as per WHO[1]. Fundamental need for the development of each childis an adequate nutrition during infancy and early childhood[2] and thus malnutritionplays an important role in their mortality and morbidity amongunder-five population and would lead to delayed mental and motor development during these determining years. Eventually malnutrition decreases the educational achievement, labor productivity and economic growth of a country.[3]

According to United Nations Inter-Agency Group for Child Mortality Estimation (UNIGME), Report 2021, in 2020,more than 5.0 million under 5 children, including 2.4 million newborns died due to preventable or treatable causes[4] while WHO said that around 45% of deaths among under 5 children are linked to undernutrition and that of mostly occur in low- and middle-income countries.[5]To combat this public health issue, Sustainable development goals were set by United Nations to achieve better health by 2030[6].

The current study uses the WHO Z-score system[7] and the composite index of anthropometric failure

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(CIAF) and Mid upper arm circumference (MUAC)[8,9] to estimate the magnitude of under nutrition. On the bright side, improvement was seen in the number of underweight children in the country, rates of underweight have decreased from 66.0% to 58.1% for boys and 54.2% to 50.1% in girls in between 2000 and 2016.[10] In NFHS-5 (2019-21) the prevalence of underweight, stunting and wasting among under 5 children in the country was 32.1%, 35.5% and 19.3% respectively[11] while in Uttarakhand, the prevalence of underweight, stunting and wasting among under 5 children was found to be 21%, 27% and 13.2% respectively[12] while no such details was available for Haldwani and that to rural area, hence the study is planned to determine the prevalence and associated risk factors for malnutrition among under five children of this region.

Objectives:

To determine the prevalence of under-nutrition among the under-five children in a rural area of Haldwani.

Material and Methods

This was a cross-sectional, community based study on Under-5 children (study population) conducted from January 2020 – July 2021 in the rural field practice area of the Department of Community Medicine, Government Medical College, Haldwani. Ethical clearance was obtained from the Institutional Ethics Committee.

Inclusion criteria: Those under five children whose parents or guardian'shad given consent.

Exclusion criteria: Those who refused to participate or didnot give consent**,** those household that would remain locked even upto 3 visitsand those children having congenital anomaly.

Sampling method: Simple random sampling

Sample size:

The total sample size is estimated using the formula: n = $4pq/d^2$,

Where, n = sample size

p = prevalence of malnutrition in Uttarakhand (33.5 = 0.335) according to NFHS-4[13]

q = 1-p (0.335)

d = error in estimation (5%)

The required sample size is calculated as:

n = (4 × 0.335 × 0.665) / (0.0025)

= 356

After adding 10% non-response rate, n=396

After rounding of final sample size will be 400

Tools and Techniques:

A pre-tested, semi structured questionnaire on malnutrition from previous literatures[14,15,16] was formed.It includes: Performa, Weighing machine – spring type, infantometer, stadiometer , non-stretchable measuring tape.

Anthropometric indices[7] Used:

- **Weight -** The weight of the subjects was taken using spring scale weighing machine after adjusting the scale at'0'.
- **Length** of children less than 2 years old is measured lying down by using infantometer standing **height** is measured for children age 2 years or older by using stadiometer.
- **Underweight (Weight-for-age)** - Defined as the percentage of children whose weight for age is -2 SD to < -1 SD (mild UW), <−2 SD and ≥−3 SD (moderate UW) and <-3SD (severe UW) of the median of the WHO Child Growth Standards.
- **Stunting (Height-for-age)**: Defined as the percentage of children whose height for age is -2 SD to < -1 SD (mild stunting), <−2 SD and ≥−3 SD (moderate stunting) and <-3SD (severe stunting) of the median of the WHO Child Growth Standards.
- **Wasting(Weight-for-height):** Defined as the percentage of children whose weight for height is -2 SD to < -1 SD (mild wasting), <−2 SD and ≥−3 SD (moderate wasting) and <-3SD (severe wasting) of the median of the WHO Child Growth Standards.
- **Mid upper arm circumference (MUAC):**[8,9] Between 6 months to five years of age, the arm circumference remains fairly constant.

  Measurement is performed on the left arm, midway between the acromion and the

olecranon. The measuring tape isheld gently without pressing the soft tissues. The tape must be flexible andnon-stretchable and unaffected by temperatures.

- The reading should be accurate to the nearest 0.1 cm. Reading below 11.5 cm indicates severe malnutrition,>12.5 - 13.5 is moderate malnutrition, 12.5 - 11.5 cm is mild malnutrition and above 13.5 cm is normal.
- **Composite Index of Anthropometric Failure (CIAF):** The above mentioned indices only help in classification of children to various categories of under-nutrition but do not provide an estimate of overall prevalence of under-nutrition as a single measure. Moreover, the issue of multiple anthropometric failures was not addressed by these standard indices. The Svedberg's model [17]of the CIAF includes all children who are wasted, stunted, or underweight, and their combinations. It therefore provides a single measure with which the overall prevalence of under-nutrition can be estimated.

Results

The present study titled "**Prevalence of malnutrition and associated risk factors amongUnder five Children in Haldwani district-Nainital"** was conducted in the rural field practice area of Department of Community Medicine, GMC Haldwani. It was a community based cross-sectional study. A total of 400 subjects were included in the study. In present study, no overnutrition was found and only normal and undernutrition were found. So, undernutrition was further classified in moderate and severe category and further association was applied while mild were not consider in community studies.[8]

In the present study, a total of 400 under five children were examined. Females were more (53.2%) as compared to 46.8% of male children. The mean age of the participants was 2.76± 1.42 months. Majority of the families were nuclear that comprises of approximately half (62%) of the children with family size upto 2. Maximum number of parent's education found to be graduate and above in approximately a quarter (24.5% in mothers and 25.2% in fathers) of study subjects.Maximum number of the study subjects were belong toclass II according to B.G. Prasad socio economic classclassification2021and that comprises of half of them (52.5%).

Table 1: Nutritional status according to age and gender of study subjects(n=400)

Variables	Total n (%)	Underweight n (%)	Stunting n (%)	Wasting n (%)
Gender				
Male	187 (46.8)	18 (9.6)	15 (8)	07 (3.7)
Female	213 (53.2)	13 (6.1)	22 (10.3)	09 (4.2)
Age group				
0-11 m	80 (20)	01 (1.2)	06 (7.5)	04 (5)
12-23 m	107 (26.7)	09 (8.4)	09 (8.4)	03 (2.8)
24-35 m	63(15.8)	10 (15.8)	09 (14.2)	02 (3.2)
36-47 m	82 (20.5)	08 (9.7)	10 (12.2)	04 (4.8)
48-59 m	68(17)	03 (4.4)	03 (4.4)	03 (4.4)

There was 53.25% females out of which 6.1% were underweight, 10.3% were stunted while 3.7% were wasted as compared to 46.8% males, out of which 9.6% were underweight, 8% were stunted while 4.2% were wasted. Maximum number of participants were in 12-23month age group followed by 36-47 months while underweight was maximum in age group of 24-35 months, stunting was found highest among age group of 36-47 months and wasting was most in 0-11 months and 36-47 months.

Table 2: CIAF Classification (B–Y) ofstudy subjects (n=400)

ANTHROPOMETRIC FAILURE	Group	Description	Frequency (%)
	A	No failure	330 (82.5)
	B	Wasting	12 (3)
	C	Wasting & Underweight	01 (0.25)
	D	Wasting + Stunting + Underweight	03 (0.75)
	E	Stunting & Underweight	09 (2.25)
	F	Only stunting	25 (6.25)
	Y	Only underweight	20 (5)
		Total	400 (100)

In the present study, the under five children in which malnutrition was not seen were 82.5%. The prevalence of undernutrition among children was depicted as underweight, stunting and wasting was 7.75%, 9.25% and 4% respectively. Out of those who were found to be underweight, only underweight was seen in 5% while underweight and stunting in 2.5%, underweight and wasting in 0.2% and underweight, stunting and wasting in 0.7% subjects. Out of those who were found to be stunted, only stunting was present in 6.2% subjects. Out of those who were found to be wasted, only wasting seen in 3% subjects.

Table 3: Distribution of undernourished children according to severity (WHO)

Indicators	Total No. (%)	Moderately Undernourished No. (%)	Severely undernourished No. (%)
Underweight	31 (7.8)	28 (7)	03 (0.8)
Stunting	37(9.3)	37 (9.3)	00
Wasting	16 (4)	16 (4)	00

In the present study, moderate and severe underweight was found to be 7% and 0.75% respectively while moderate stunting and wasting was found to be 9.25% and 4% respectively.

Table 4: Nutritional status according to mid upper arm circumference (MUAC) (n=357)

Variables	Total No. (%)	Study Subjects No. (%)		
Gender		**Normal (n=336)**	**Mild-moderate (n=17)**	**Severely malnourished (n=04)**
Male	167 (46.8)	157 (94)	07 (4.2)	03 (1.8)
Female	190 (53.2)	179 (94.2)	10 (5.3)	01 (0.5)
Age(months)				
6-12	44 (12.3)	36 (81.8)	08 (18.2)	00
13-36	194 (54.3)	184 (94.8)	07 (3.6)	03 (1.5)
37-60	119 (33.4)	116 (97.4)	02 (1.6)	01 (0.8)

In the present study, 357 children were above the age group of 6 months, so there mid upper arm circumference was taken. Out of 5.8% children that had decreased mid upper arm circumference, 4.8% were mild-moderately undernourished as having mid upper arm circumference found between 11.5 cm-13.5 cm while 1.1% were severely undernourished as having mid upper arm circumference found less than 11.5 cm. Out of 357, majority were females i.e., 53.2%. 5.3% females and 4.2% males were mild to moderately undernourished while 1.8% males were severely undernourished.

Approximately half of the children were under the age group of 13-36 months while in age group 6-12 month, 18.1% were mild to moderately undernourished.

Discussion

In this study is a total of 400 under five children were studied children of rural field practice area, Department of Community Medicine, Haldwani, Distt. Nainital. Out of these, there were 53.3% female and 46.8% male. The mean age of the participants was 2.76± 1.42 months. Similar findings were shown in study by Bhavsar S et al., (2012)[18] conducted in urban slums of Mumbai, Meshram II et al., (2012)[19], P stalin et al.,(2013)[20], Sharma A et al., (2015)[21] found females more than males, while in study by Purohit L et al.,(2017) [22], Akhade KS et al., (2019)[23] found more males than females.

Majority of the study subject's (62%) belongs to nuclear families.Similar findings were shown in study byMeshramII et al.,(2012)[19], Purohit L et al.,(2017) [22], Sharma A et al., (2015)[21]found more belong to nuclear family.

Regarding parent's education, 24.5% in mother's and 25.2% in father's of study subjects were found to be graduate and above. Similar findings were shown in study by Gandhi Set al.,(2014)[24] depicted that mother's and father's education was more than highschool and above, P Stalin et al.,(2013)[20] showed mother's education was upto highschool and above, while different findings were shown in study by Bhavsar S et al., (2012)[18] conducted in urban slums of Mumbai, Meshram II et al., (2012)[19] as parent's education was illiteracy or upto primary level.

Out of 52.5% of the study subjects were belong to II class according to B.G. Prasad socio economic class.Studies showed different findingas in Bhavsar S et al., (2012)[18] showed more study subjects belonged to class IV and V, P Stalin et al.,(2013)[20] showed more belonged to class IV, Purohit L et al.,(2017) [22] showed more belonged to class V.

In the present study, out of underweight, stunting and wasting, moderate undernutrition more than that of severe undernutrition. Similar result found in study conducted by Chaudhary P and Agrawal M, (2018) [25] in Slum Area of Jaipur City, Rajasthan. Another study conducted byLaghari ZA et al., (2015)[26] among children under five years in district Sanghar, Sindh, Pakistan showed similar results and in study conducted by Idowu SO et al., (2020)[27]information on anthropometric characteristics and associated factors among displaced under-five children is important to strengthen strategies to ameliorate malnutrition and promote child health. This study was conducted to identify the determinants of anthropometric indices among under-five children in internally displaced persons' camps in Abuja, Nigeria. Methods: this cross-sectional study involved 317 mother-child (0-59 months] among underfive children in Nigeria while different results were found in study conducted in under-five Nepalese children of Borbote village,Ilam by Niraula SR et al., (2013)[28] in Nepalassevere undernutrition more than moderate undernutrition.

Out of those who were found to be underweight, only underweight was seen in 5% while underweight and stunting in 2.5%, underweight and wasting in 0.2% and underweight, stunting and wasting in 0.7% subjects. Out of those who were found to be stunted, only stunting was present in 6.2% subjects. Out of those who were found to be wasted, only wasting seen in 3% subjects. Similar result found in study conducted by Seetharaman N et al., (2007)[29] in Coimbatore as no failure is found in maximum(31.4%) study subjects while another study conducted by Akhade KS et al., (2019)[23] found that 58% of the study subjects were suffering from one or other form of "Anthropometric Failure".

In the present study, 357 children were above the age group of 6 months in which mid upper arm circumference was taken. Out of 5.8% children that had decreased mid upper arm circumference, 4.8% were mild-moderately undernourished while 1.1% were severely undernourished as having mid upper arm circumference. Out of 357, majority were females i.e., 53.2%. 5.3% females and 4.2% males were mild to moderately undernourished while 1.8% males were severely undernourished. Similar results found in study conducted by Sethy G et al., (2017) [9] in urban slum area of Berhampur city found that severe malnutrition was lower than that of normal, in Bhadoria AS et al., (2017)[30] which is one-third of the world's share. We planned a study to identify the prevalence of severe acute malnutrition (SAM]

found that MUAC for age varied significantly and in Oguizu AD and Okafor CA, (2019)[31].

Conclusion

This study reveals mild prevalence of malnutrition status among underfive children of rural field practise area of Dept. of Community Medicine, Haldwani, Uttarakhand. Out of which, stunting is most prevalent parameter for undernourishment. In this, females were more undernourished than males, and in age of child between 12 and 23 months were more undernourished.

Ethical clearance: Taken from Institutional Ethical Committee, Govt. Medical College, Haldwani, Uttarakhand

Source of funding: Nil

Conflict of Interest: Nil

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Original Article

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Knowledge Regarding Yellow Fever Vaccination and Satisfaction with the Yellow Fever Vaccination Outpatient Department Services among International Travelers

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Abstract

Background: Globalization has brought the world closer and at the same time has unleashed spread of various diseases. Yellow Fever is an important disease of public health concern especially as an aspect of ergonomics, because it is endemic to specific regions of the world. Yellow Fever vaccination has been a boon in Yellow fever prevention. This study aimed to determine the knowledge of the international travelers attending the Yellow Fever vaccination outpatient department (OPD) along with their satisfaction with the OPD services and out of pocket expenditure incurred to get the vaccine.

Methods: After obtaining Ethics clearance from the Institutional Ethics Committee, this cross sectional study was conducted among 234 international travelers, who attended the Yellow Fever vaccination OPD from May, 2021 to November, 2021. Data collection was done using a study questionnaire and analysis was done to obtain following results.

Results: Only 16% (n=38) attending the Yellow Fever Vaccination OPD had satisfactory knowledge regarding Yellow Fever and its vaccination. Those availing the services of the Yellow Fever vaccination center were satisfied with the services provided for most of them had a good (52.6%) experience. Average total expenditure incurred was INR 4141.25 only.

Conclusions: A lack of knowledge regarding Yellow Fever and its vaccination among the international travelers was found. They were satisfied with the services at the OPD. Out of pocket expenditure to get the vaccine is substantial.

Keywords: Knowledge; Yellow Fever; Yellow Fever vaccination; Outpatient department (OPD); Patient satisfaction; Out of pocket expenditure.

Introduction

Yellow Fever disease is caused by an arbovirus[1] (a virus transmitted by vectors such mosquitoes, ticks or other arthropods). It is transmitted to humans by the bites of infected *Aedes* and *Haemagogus* mosquitoes[1]. This acute hemorrhagic disease is a high-impact

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high-threat disease, with risk of international spread, representing a potential threat to global health security. Forty-seven countries in Africa and Central and South America are either endemic for yellow fever[1].

The live-attenuated 17D Yellow Fever vaccine is safe and effective against Yellow fever[2] and is recommended for people aged ≥9 months who are traveling to or living in the endemic areas[3]. It is contraindicated in pregnant women, those allergic to egg, and immunocompromised people[3]. Given as a single subcutaneous dose of 0.5ml, this vaccine induces neutralizing antibodies in 90% of vaccine recipients within 10 days after inoculation and in 99% within 30 days after inoculation. Immunity is very durable and probably lifelong[3-6]. With globalization, travelling for study, employment, business, and recreational activities has become convenient and easier. Lot of travelers visit the Yellow Fever endemic countries, but they are prevented of Yellow fever which may be attributed to the vaccine[6].

The Government of India has set up 40 Yellow Fever Vaccination (YFV) centers across the country and charges INR 300 for a dose[7]. But, an average additional expenditure incurred by the beneficiaries is around 8 times of the direct cost of the vaccine, a study suggests[8].

The study was designed to address the prevailing gaps in knowledge regarding Yellow Fever and its vaccination among the International travelers attending the Yellow Fever Vaccination OPD. It also aimed to determine the out of pocket expenditure incurred and satisfaction of services provided at the Yellow Fever vaccination OPD.

Methods

- Study Design: Observational Cross Sectional study.
- Study Site: Yellow Fever Vaccination OPD of a tertiary care hospital in Metropolitan city.
- Duration of Study: 6 months (May, 2021 to November, 2021)
- Sampling method: Universal Sampling-Complete enumeration of the vaccine beneficiaries attending the Yellow Fever vaccination OPD over 3 months from the date of IEC clearance was done and those fulfilling the inclusion criteria and giving informed consent were recruited in the study.
- Sample Size: The Yellow Fever vaccination OPD is held on every Tuesday and Thursday in the tertiary care centre where the study was carried out. About 10 beneficiaries attend the OPD each day. Since this population was known to be dynamic and floating, a fluctuation in the number of beneficiaries was anticipated. Around 25% population was considered to be floating; taking all the above factors under consideration, approximately, 234 subjects were available for interviews during the study period. We included all the participants fulfilling inclusion criteria using complete enumeration method.
  - Inclusion criteria:
    - ⇒ Direct beneficiaries of the Yellow Fever vaccination OPD.
    - ⇒ Those who could comprehend English/Hindi.
    - ⇒ Age > 18 years.
  - Exclusion criteria: Those who could not receive the vaccine due to contraindications. For eg, Pregnant females, persons with egg allergy, immune-compromised etc.
- Tool of assessment:

Study questionnaire:

- The purpose of the questionnaire was to assess the knowledge of the participants regarding Yellow Fever and its vaccination ; secure information about satisfaction of the OPD services and out of pocket expenditure incurred.

Data collection: Data Collection was done after Ethics Clearance from the Institutional Ethical Committee.

- Procedure:
  - Step 1: After explaining the format of study to the participant, informed consent was taken from them.
  - Step 2: Data collection was done using the study questionnaire.
  - The entire data collection took 15-20 minutes of time of the study participants.
- Ethical considerations: Privacy was

maintained at the time of interview by conducting it in a separate room available in the Yellow Fever vaccination OPD. All study records were kept confidential in a password protected device.

- Statistical analysis:
  - Questionnaire data was be coded and entered into computer using Microsoft Excel.
  - For descriptive data, frequencies and proportions were calculated.
  - Categorical variables were measured as percentages and continuous variables were expressed as mean ± standard deviation.
  - Degree of statistical significance was declared at a p value ≤0.05

Operational Definitions:

Direct beneficiary – An individual taking the vaccine at the vaccination OPD.

Indirect beneficiary – Parents/Guardians/those accompanying the direct beneficiary.

Results

- Out of the total of 234 study participants 62 were females and 172 were males.
- The average age of study participants was 49.1±18.6 years. Over, one third of them were destined to Africa followed by throughout world (sea fearers) and South America (26 & 7%, respectively).
- Employment (61%, n=142) was found to be the most common reason for travelling to foreign destinations followed business (31%, n=73), tourism (5%, n=12) and personal reason (3%, n=7).
- It was found that 52% (n=122) of the study participants were unaware of Yellow Fever and its vaccination before they were advised for Yellow Fever vaccination. These 122 knew that taking the vaccine would prevent them from the disease whereas only 41% (n=100) of the study participants knew that taking the vaccine would both protect them from the disease and help in preventing its transmission.
- Approximately, 92% (n=215) of the study participants did not know about the causative organism and vector for yellow fever. None of the participants knew about the endemic regions for Yellow Fever and took the vaccine inorder to comply with the travel requirements.
- Of all, 93.3% (n=218) did know the various preventive strategies and methods to avoid Yellow Fever infection (like avoid travelling or trekking to the high risk zones for Yellow Fever in the endemic countries/ Wear full sleeved shirts and full pants/ Use insect or mosquito repellent creams etc).
- Nearly one fifth of the study participants (n=47) knew that Yellow Fever vaccine provides protection for life time, most of them believed (n=89) that it protects for up to 10 years only, others did not know about it. Hundred and one study participants believed that the validity of the Yellow Fever vaccination certificate is for 10 years.
- Only 16% (n=37) of the study participants knew that the Yellow Fever vaccine starts providing protection after 10 days.
- None of them were aware of the other symptoms of Yellow Fever expect for fever; contra-indications and side-effects of the vaccine.
- There were a total of 10 questions assessing knowledge (each question carried 1 mark). Any participant scoring more than or equal to 5, were known to have satisfactory knowledge and those less than 5 were known to have unsatisfactory knowledge. There were 83.7% (n=196) belonging to the unsatisfactory group. There was no statistically significant association found between the Sociodemographic factors of age (p=2.012), gender (p=0.231), profession (p=0.197) and the knowledge of the study participants regarding Yellow Fever vaccination. Table no.I gives details of satisfaction regarding the regarding the Yellow Fever vaccination OPD service.
- Overall, it was found that those availing the services of the Yellow Fever vaccination center were satisfied with the services provided for most of them had a good (52.6%) experience.
- The expenditure incurred towards direct

cost of Yellow Fever Vaccine was INR 300 only. Average total expenditure incurred for Yellow Fever Vaccination was INR 4141.25 only. Most of the study participants were from Maharashtra (n=198) and the remaining were from Karnataka (n=27) and Madhya Pradesh (n=09). Out of the 198, twenty seven were from the location same as that of the vaccination center. Table no.II shows the details of the expenditure incurred by the study participants.

Table no. 1: Satisfaction regarding the regarding the Yellow Fever vaccination OPD service:

Sr. No.	Domain	Frequency of study participants (N=234) responding as:			
		Poor	Satisfactory	Good	Excellent
1	Behavior of Doctor	00	30	133	71
2	Information provided by Doctor	00	12	124	98
3	Waiting Area				
3.1.	Seating facility	04	121	109	00
3.2.	Drinking water facility	Not available at the center			
3.3.	Toilet facility (Out of 49 study participants who availed the facility)	20	29	00	00
3.4.	Magazines/TV etc	Not available at the center			
3.5.	Cleanliness	06	80	136	12
4	Time management	09	31	133	61
5	Cleanliness of vaccination OPD	00	46	142	46
6	Procedure of actual Vaccination	00	59	126	49
7	Overall experience of vaccination	00	53	123	58

Table no. 2 Expenditure incurred by the study participants to get the Yellow Fever Vaccine.

Expenditure Head	Expenditure in INR Mean (range)
Travel to reach to Vaccination Centre	1768.2 (100 – 36000)
Food	289.05 (0 – 2500)
Lodging & Boarding	1500 (0 – 3500)
Loss of salary or wages	284.33 (0 – 5000)
Vaccination Charges	300.00
Total expenses	4141.25 (500 – 36950)

Discussion

This study highlights that out of the 234 study participants, only 16% (n=38) attending the Yellow Fever Vaccination OPD had satisfactory knowledge regarding Yellow Fever and its vaccination. A study done in Punjab[9], reported that 75% of their study participants were unaware about yellow fever. The lack of awareness regarding yellow fever in study group may be due to the reason that yellow fever is not endemic to India. None of the participants knew about the endemic regions for Yellow Fever and took the vaccine in order to comply with the travel requirements similar to the finding of another study done in India[9]. Only 8% of the study participants were aware about the causative organism for yellow fever, comparable with the findings of the other Indian study[9].

Of all, 93.3% (n=218) did know the various preventive strategies and methods to avoid Yellow Fever infection (like avoid travelling or trekking to the high risk zones for Yellow Fever in the endemic countries/ Wear full sleeved shirts and full pants/ Use insect or mosquito repellent creams etc) as against findings of a study[9] wherein a higher percentage of study participants (40%) were aware about the various methods to prevent yellow fever infection. According to the recent guidelines[1], yellow Fever vaccination certificate is has lifelong validity, a fact known to only 101 study participants. Only

16% were found to be aware that the vaccine starts providing protection after 10 days of vaccination; a higher percentage of study participants were aware in the study carried out by Tiwari et al and Krief et.al.

It was found that those availing the services of the Yellow Fever vaccination center were satisfied with the services provided for most of them had a good (52.6%) experience. Domains for improvement included provision of drinking water, recreation facilities like magazine/TV, bettering the time management and maintenance of cleanliness of toilet facility.

Most of the study participants were from Maharashtra (n=198) and the remaining were from Karnataka (n=27) and Madhya Pradesh (n=09). Better proximity to this center than the one in their state was the reason for them to travel from their home state. This average total expenditure incurred by the study participants was 13 times of the direct cost of the vaccine; similar higher out of pocket expenditure was reported in a study done in Mumbai[8].

Conclusions

- The knowledge of most of the study participants is not upto the mark, since 92% (n=215) of the study participants did not know about the causative organism and vector for yellow fever. More than half of the study participants were unaware of Yellow Fever before they were advised for Yellow Fever vaccination.
- The sociodemographic factors of age, gender and profession were not significantly associated with the knowledge regarding yellow fever.
- Most of the study participants are satisfied with the services of the OPD with scope for improvement in cleanliness of toilets facility, and provision of facility of drinking water, magazines; needs to be done.
- Out of pocket expenditure incurred by the study participants is significantly higher in comparison to the cost of vaccine as fixed by the Government of India.

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Ethical Clearance: The study was approved by the Institutional Ethics Committee

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Study of Facial Nerve Palsy in Maharashtra Population

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Abstract

Background: Facial nerve palsy is uncommon mainly lower motor Neuron palsy but had significant involvement of Oto-laryngeal and Opthalmic complications too. Surgical innervations are the most viable way to overcome complications of Facial Nerve palsy.

Method: 30 adults patients (17 left side, 13 right side) had facial palsy associated with ORL disorders were studied with CT scan, routine blood examination, to know any other pathogenesis. Examination was done to rule out tympanic membrane perforation, Herpes Zoster.

Results: 13 (43.3%) Otalgia, 6 (20%) impaired hearing, 5 (16.6%) Ear discharge, 3 (10%) Dysphagia, 1 (3.33%) Jaw pain, 1 (3.33%) Nasal bleeding, 1 (3.33%) throat pain. The diagnosis involved 9 (30%) CSOM, 8 (26.6%) otitis media, 4 (13.3%) AOM, 4 (13.3%) otitis externa, 1 (3.33%) Ramsay Hunt syndrome, 1 (3.33%) Herpes Zoster, 1 (3.33%) chronic Rhino- sinusitis uveitis / anterior, 1 (3.33%) acute tonsillitis, 1 (3.33%) sensorineural hearing loss.

Conclusion: These associated complications need surgical corrections and onset of proper antibiotic treatment to have better prognosis because, it is LMN (lower Motor Neuron) palsy.

Keywords: CSOM, AOM, Otoscopy, ENoG (electroneuronography)

Introduction

Facial nerve is a mixed nerve having motor, sensory and secretomotor function. It also carries taste sensation from anterior 2/3rd of tongue. Facial nerve palsy causes physical as well as functional deformities and psychological problems that may lead to social and professional impairment. The most common or frequent cause is idiopathic other being trauma, tumour, infections, neurological, congenital or iatrogenic [(1)].

It has significant complications in otolaryngeal (ORL) disorders although the prevalence of facial nerve has reduced due to use of antibiotics but the prevention remains a challenging problem. It is reported that, the frequency of facial nerve palsy in ORL disorder ranges from 0.16 to 5.1% in India and abroad [(2)(3)]. Although the mechanism of Facial nerve palsy and results of ORL disorders is not fully under stood, Treatment recommendations have focussed on both antibiotic therapy as well as surgery, including myringotomy, mastoidectomy and nerve decompression in order to re-establish the physiological state of facial nerve [(4)(5)]. Hence attempt

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is made to evaluate the clinical findings in different clinical manifestations of facial nerve palsy.

Material and Method

30 (thirty) adult patients aged between 20 to 50 years of age visiting to Vedantaa Institute of Medical Sciences, Saswand (post), Dahanu (Ta), Palghar (dist), Maharashtra-401606 were studied.

Inclusive Criteria: Patients having facial nerve palsy with otolaryngeal disorders were selected for study.

Exclusion Criteria: Patients undergone oral surgery, patients with type-II DM, patients with in-complete information relevant to the study such as diagnosis, clinical features immune-compromised patients were excluded from the study.

Method: Every patient was made to undergone CT scan study, routine blood examination was carried out in every patient. Out of thirty, 17 (seventeen) had left side and 13 (thirteen) had right side palsy was noted. Patients complained of drooling of saliva from either right or left side of the mouth while drinking water and eating food, along with asymmetry of the face and inability to close the eyes, some patients right eye and some left eye. Facial Nerve palsy was Lower motor Neuron (LMN) palsy, Grade-II as per Brackmann scale.

Local examination was done to rule out Herpes zoster, otoscopic examination to study perforation of tympanic membrane, suppuration. Hearing loss was revealed by tuning fork test. The prognosis of palsy was based on electrophysiology tests with Hilger stimulator or ENoG (electroneuronography) study.

The duration of study was December–2019 November–2022.

Statistical analysis: various clinical manifestations, diagnosis were classified with percentage. The ratio of male and female was 2:1.

Observation and Results

Table-1: Study of clinical Manifestation observed in facial palsy 13 (43.3%) had Otalgia, 6 (20%) had impaired hearing, 5 (16.6%) had ear discharge, 3 (10%) dysphagia 1 (3.33%) Jaw pain, 1 (3.33%) Nasal bleeding, 1 (3.33%) throat pain.

Table-2: Clinical findings (diagnosis) of patients of Facial Nerve palsy 9 (30%) CSOM , 8 (26.6%) otitis media, 4 (13.5%) AOM, 4 (13.3%) otitis externa, 1 (3.33%) Ramsay, hunt syndrome, 1 (3.33%) Herpes zoster, 1 (3.33%) chronic Rhino-sinusitis / anterior uveitis, 1 (3.84%) acute tonsillitis, 1 (3.84%) Sensorineural hearing loss.

Table 1: Clinical manifestations in patients of facial Nerve palsy

(Total No. of patients: 30)

Sl. No	Clinical Manifestation	No. of patients (30)	Percentage (%)
1	Otalgia	13	43.3
2	Impaired hearing	06	20
3	Ear discharge	05	16.6
4	Dysphagia	03	10
5	Jaw pain	01	3.33
6	Nasal bleeding	01	3.33
7	Throat pain	01	3.33

Table 2: Clinical findings (diagnosis) of patients of Facial Nerve palsy

S l . No	**Clinical findings diagnosis**	**No. of patients (30)**	**Percentage (%)**
1	CSOM chronic suppurative otitis Media	9	30
2	Otitis Media	8	26.6
3	AOM	4	13.3
4	Otitis Externa	4	13.3
5	Ramsay – Hunt syndrome	1	3.33
6	Herpes Zoster	1	3.33
7	Chronic Rhino-sinusitis	1	3.33
8	Acute tonsillitis	1	3.33
9	sensorineural hearing loss	1	3.33

Discussion

Present study of facial nerve palsy in Maharashtra Population. The clinical manifestation were 13 (43.3%) Otalgia, 6 (20%) impaired hearing, 5 (16.6%) ear discharge, 3 (10%) dysphagia, 1 (3.33%) jaw pain, 1

(3.33%) Nasal bleeding, 1 (3.33%) throat pain (Table-1). The clinical findings were 9 (30%) CSOM, 8 (26.6%) otitis media, 4 (13.3%) AOM, 4 (13.3%) otitis externa, 1 (3.33%) Ramsay Hunt syndrome, 1 (3.33%) Herpes Zoster, 1 (3.33%) chronic Rhino-sinusitis uveitis anterior, 1 (3.33%) acute tonsillitis, 1 (3.33%) sensor-neuronal hearing loss (Table-2). These findings are more or less in agreement with previous studies [6][7][8].

Acute inflammation of middle ear is one of the most common diseases observed in childhood and early adulthood. Tympanic cavity and mastoid if un-treated, inflammation spreads to neighbouring structures, infection comes from Eustachian tube to middle ear [9]. It is also reported that, peripheral facial nerve palsy is secondary to otitis media [10].

The possible factors causing facial nerve palsy in acute suppurative otitis media are likely to alter middle ear micro environments, such as elevated pressure, osteitis or acute inflammation may affect physiology of facial nerve [11]. It is also reported that, retrograde infection within the bony canal of facial nerve or retrograde infection within the tympanic cavity can spread via chorda-tympani nerve to facial nerve. It was also noted that, reduced immunity due to latent viral infection in middle ear may be the cause of facial nerve palsy. It is also observed that, demylination of facial nerve is secondary to the presence of bacterial toxins.

Infections causing facial nerve palsy spread through dehiscence and neuro vascular communication between middle ear and facial nerve [12]. Moreover anatomical variations of facial nerve may make it prone to severe nerve palsy. Another theory suggests that, compression of blood vessels that nourish the facial nerve may lead to palsy of facial nerve due to ischemia / infarction.

Most organisms recovered from cultures of patient with suppurative complications of acute otitis media (AOM) have been gram positive cocci (S. pneumonia and staphylococcal series). Broad spectrum (antibiotics) of 3rd generation Cephalesporins can be useful as first line of treatment. But non-responding cases require surgical interventions.

Summary and Conclusion

The present study of facial nerve palsy involved ORL disorders can be managed with 3rd generation antibiotic with cortico steroids as first line treatment. Careful management with early surgical intervention has proven to have decisive effects on the recovery of facial function. But the study demands further genetic, immunological, nutritional, patho-physiological, pharmacological, neuro-vascular studies because exact pathogenesis of Facial nerve palsy is still un-clear.

Limitation of study: Due to tertiary location of research place, small number of patients and lack of latest technologies we have limited findings and results.

This research work is approved by the Ethical committee of Vedantaa Institute of Medical Science, Dahanu, Palghar (dist), Maharashtra

Conflict of Interest: No

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Original Research Article

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Comparison of Results of Myringoplasty with Temporalis Fascia and Perichondrial: Cartilage Composite Graft in High Risk Perforations

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Abstract

Background: The objectives of this study were to compare the graft uptake and post-operative hearing results of underlay myringoplasty with temporalis fascia and perichondrial-cartilage composite graft in high risk perforations.

Materials & Methods: Patients of ages of 13 years and above with diagnosis of chronic otitis media – mucosal type with high risk perforations undergoing myringoplasty were included. Criteria of high risk were >50% perforation of tympanic membrane, revision cases, absent/eroded handle of malleus, oedematous/unhealthy middle ear mucosa and marginal perforation of any size. Pure tone audiometry was done within 1 week before surgery. Seventy cases included for myringoplasty were randomly allocated by lottery method into two groups with 35 cases each in temporalis fascia group and perichondrial - cartilage composite graft group. After 6 weeks graft uptake results were assessed and post-operative hearing was evaluated and compared within and between the groups.

Results: Graft uptake rates in temporalis fascia group and perichodrial - cartilage composite graft group were 88.57% and 91.43%, respectively with no statistically significant difference between the groups (p = 0.69). The mean pre- and post-operative air bone gaps in temporalis fascia group were 31.81 ± 10.49 dB and 17.87 ± 7.96 dB. The mean pre- and post-operative air bone gaps in perichondrial - cartilage composite group were 35.19 ±7.26 dB and 22.62 ± 8.77 dB. These differences in both the groups were statistically highly significant (p < 0.001) showing improvement in the hearing after surgery. The mean post-operative ABG gains were 13.94 ± 8.36 dB and 12.57 ± 8.21 dB in temporalis fascia and perichondrial - cartilage composite groups respectively.

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Conclusion: The graft uptake rates and hearing results after perichondrial - cartilage composite graft are similar to those of temporalis fascia graft. Perichondrial- cartilage composite graft even though more rigid and thicker than temporalis fascia did not affect post-operative hearing results adversely.

Keywords: Myringoplasty, chronic otitis media, high risk perforation, temporalis fascia, perichondrium - cartilage, pure tone audiometry.

Introduction

Mucosal type of chronic otitis media (COM) is a common disease worldwide. There is no uniformity regarding nomenclature of this disease. Terms like chronic otitis media tubotympanic or non cholesteatoma type are also used synonymously.[1, 2] The mucosal type of disease may pass through acute, inactive, quiescent or healed stages. There is discharge in middle ear and external auditory canal with congestion of middle ear mucosa in acute stage. Absence of otorrhoea and normal looking middle ear mucosa are seen in inactive stage.[3]

Oral antibiotics and/or ototopical antibiotics mixed with steroid are prescribed to stop otorrhoea which may take a period of days to weeks.[4] Small perforation may heal by this treatment only while others may need surgical intervention. Surgical treatment of chronic otitis media-mucosal type is myringoplasty wherein the closure of perforation of pars tensa is done mainly to prevent recurrent ear discharge and to improve hearing.[5]

Success of myringoplasty is related to the intactness of pars tensa and improvement in hearing after operation. Hearing improvement is assessed either in terms of closure of air bone gap (ABG) or improvement in threshold of air conduction. There are various factors responsible for success of myringoplasty like experience of surgeon, size of perforation, status of middle ear (dry or wet), presence of infection in perioperative period, technique (underlay or overlay), and status of opposite ear etc.[6]

Currently indications of cartilage tympanoplasty include all revision cases as well as certain high risk primary tympanoplasties, which include a subtotal perforation, a perforation in a patient with previously repaired cleft palate, and an ear draining at the time of surgery. Use of cartilage in these cases is also supported by the findings of others.[7] So, there was the necessity of a prospective study regarding the comparison of results of myringoplasty using temporalis fascia and tragal perichondrial - cartilage composite graft in high risk perforations. This is the first study of its kind in the country.

Materials & Methods

It was a prospective, comparative, randomized study at Ganesh Man Singh Memorial Academy for ENT-Head and Neck Studies, Institute of Medicine, Tribhuvan University, Kathmandu, Nepal.

Inclusion criteria:

- Both gender
- Age : 13 years & above
- Chronic otitis media - mucosal with >50% perforation of TM
- Chronic otitis media - mucosal with <50% perforation of TM with one or more of the following situations:
  - ⇒ Revision surgery
  - ⇒ Absent/eroded handle of malleus
  - ⇒ Oedematous/unhealthy middle ear mucosa
- Any size with margin involvement

Exclusion criteria:

- Frank otorrhea at the time of surgery
- Patients with sensorineural hearing loss

Non probability convenient sampling method was applied. With the confidence level of 95% and confidence interval of 5%, the sample size calculated was 70. Detail history, general physical examination, ear examination with otoscope and tuning fork test with 512 Hz was done and confirmed by faculty if done by resident. Examination under microscope was done before surgery.

Pure tone audiometry test was performed within 1 week before surgery and at 6-8th week after surgery by trained audiometrician. It was tested in sound treated room. Hugson and Westlake technique was

used for audiometric evaluation. Test was performed through air conduction and bone conduction. Air conduction included the frequencies 250, 500, 1000, 2000, 3000, 4000 and 8000 Hz and bone conduction included 250, 500, 1000, 2000, 3000 and 4000 Hz. Four frequencies pure tone average was calculated from 500, 1000, 2000 and 3000 Hz.

Air Bone Gap (ABG) was measured by the difference of average of air conduction and bone conduction threshold done at the same time. It was documented both pre- and post-operatively. Examination under microscope was done before surgery. Both type of myringoplasty were performed by the faculty. Informed consent was taken from all the patients' pre-operatively after explaining the procedure.

Study population was randomly divided into two groups by lottery method.

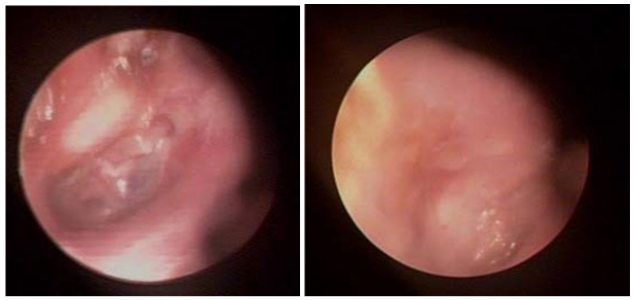
A: Tragal Perichondrial - Cartilage Composite grafting – 35

B: Temporalis fascia grafting – 35

Either permeatal, postauricular or endaural approach was used to access the tympanic membrane and middle ear according to necessity or convenience of the surgeon.

Follow-up

Patients were given oral antibiotics (ciprofloxacin 500 mg 12 hourly) for 10 days and antihistamines fexofenadine in post-operative period. Follow up was done in 6th postoperative day and after 6-8th weeks after surgery. In 6th post-operative day, suture and pack were removed. Topical antibiotic and steroid ear drops were given for 2 weeks. Patients were followed at or after 6th to 8th weeks. Graft uptake results were noted (Fig. 1 A & B) and PTA was performed. Any residual perforation from pin point to total rejection was reported as failure. Pure tone audiometry was done only for successful graft uptake cases at 6-8th week.



A B

Figure 1: Post-operative graft status A) temporalis fascia graft B) perichondrial - cartilage composite graft

Results were analysed as graft uptake rate and change between pre- and post-operative hearing. Data were analyzed using Fisher's exact test, Chi square test, dependent and independent '*t*' test on a SPSS statistical package version 16.0. The level of statistical significance was set at the $p < 0.05$.

Results

Ages of the patient ranged between 13 to 53 years in temporalis fascia group (Group A) with mean age of 28.2 years and 15 to 55 years in cartilage composite group (Group B) with mean age of 29.48 years. The most common age group was 21-30 year (34.28 % in each group), which was followed by 13-20 year age group (28.58 % in group A and 25.72% in group B), 31-40 year age group (22.85 % in each group) and >41 year age group (14.29 % in group A and 17.15 % in group B).

Table 1: Clinical outcomes in Group A (temporalis fascia) and Group B (cartilage composite)

Characteristics	Group A (Temporalis fascia) (n=35)	Group B (Cartilage composite) (n = 35)
Frequency of bilateral disease	U/L 19 (54.28 %) B/L 16 (45.72 %)	U/L 17 (48.58 %) B/L 18 (51.42 %)*
Post-operative graft status	Uptake 31 (88.6%) Failure 4 (11.4%)	Uptake 32 (91.4%) Failure 3 (8.6%)**

*Chi-square test: $p = 0.632$ - statistically not significant

**Fisher's Exact test (p = 0.690) – Statistically not significant

Sixteen (45.72%) patients of temporalis fascia group (Group A) had bilateral disease while 18 (51.42%) patients of composite cartilage group (Group B) had bilateral disease, no statistically significant difference in frequency of disease distribution. In temporalis fascia group (Group A), there was graft uptake in 31 (88.6%) cases and failure in 4 (11.4%) cases whereas in cartilage composite group (Group B), graft uptake was observed in 32 (91.4%) cases and failure in 3 (8.6%) cases (Table 1).

Comparison of pre- and post-operative hearing in between two groups

The mean preoperative air bone gap was 31.81 dB (SD = 10.48) and post-operative air bone gap was 17.87 dB (SD = 7.96). Hearing improvement after surgery was found to be statistically highly significant. ($p < 0.001$). For the comparison of hearing results in this group, only 32 cases with graft uptake were taken. The mean pre-operative air conduction threshold was 51.06 dB (SD = 8.281) and post-operative air conduction threshold was 36.69 dB (SD = 9.845). The mean preoperative air bone gap was 35.19 dB (SD = 7.26) and post-operative air bone gap was 22.62 dB (SD = 8.77). Hearing improvement after surgery was found to be statistically highly significant ($p < 0.001$) (Table 2).

Table 2: Comparison of pre- and post-operative hearing in temporalis fascia group (Group A) and Group B (n = 31)

Group A	Mean (Db) Std.	Deviation Std.	Error of Mean
Pre-operative PTAAC threshold	48.45	14.413	2.589
Post-operative PTAAC threshold	33.52	14.962	2.687
Pre-operative PTAAB Gap	31.81	10.489	1.884
Post-operative PTAAB Gap	17.87	7.961	1.430*
Group B			
Pre-operative PTAAC threshold	51.06	8.281	1.464
Post-operative PTAAC threshold	36.69	9.845	1.740
Pre-operative PTAAB Gap	35.19	7.267	1.285
Post-operative PTAAB Gap	22.62	8.772	1.551**

Paired T-test

*PTA-AC threshold: t = 8.828, df = 30, p < 0.001 – Statistically highly significant.
*PTA-AB Gap: t = 9.283, df = 30, p < 0.001 – Statistically highly significant
Paired T-test -
**PTA-AC threshold: t = 9.550, df = 31, $p < 0.001$ – Statistically highly significant.
**PTA-AB Gap: t = 8.659, df = 31, $p < 0.001$ – Statistically highly significant.

Comparison of pre- and post-operative hearing between two groups

The mean pre-operative PTA-AC threshold were 48.45 dB and 51.06 dB and postoperative PTA-AC threshold were 33.52 dB and 36.69 dB in temporalis fascia group (Group A) and cartilage composite group (Group B) respectively. Similarly, preoperative PTA-ABG were 31.81 dB and 35.19 dB and post-operative PTA-ABG were 17.87 dB and 22.62 dB in temporalis fascia group (Group A) and cartilage composite group (Group B) respectively. Mean AB gain was 13.94 dB in temporalis fascia group (Group A) and 12.57 dB in cartilage composite group (Group B). Applying independent T-test, the difference in means between the groups in each category was found to be not significant statistically (Table 3).

Table 3: Comparison of pre- and post-operative hearing between two groups

Mean	Group A Temporalis fascia (n = 31)	Group B Cartilage composite (n = 32)	***p* value**
Pre-operative PTA-AC threshold (dB)	48.45	51.06	0.324
Post-operative PTA-AC Threshold (dB)	0.276	36.69	0.276
Pre-operative PTA-AB Gap (dB)	35.19	35.19	0.141
Post-operative PTA-AB Gap (dB)	17.87	22.62	0.074
ABG gain (dB)	13.94	12.57	0.513

Comparison of pre- and post-operative hearing in terms of percentage of ABG closure in two groups

ABGs were divided into different bins of 0-10 dB, 0-20 dB, 0-30 dB and >30 dB. It was noted that 41.93 % in temporalis fascia group (Group A) and 43.75 % in cartilage composite group (Group B) had ABG closure within 10 dB. 67.74% of temporalis fascia group (Group A) and 84.37% of cartilage composite group (Group B) had ABG closure within 20 dB and 100% of temporalis fascia group (Group A) and 96.87% of cartilage composite group (Group B) had ABG closure within 30 dB (Table 4).

Table 4: Comparison of pre- and post-operative hearing in terms of percentage of ABG closure in two groups

ABG closure within	**Group A (Temporalis fascia)(n = 31)**	**Group B (Cartilage composite) (n =32)**
0-10 dB	13 (41.93%)	14 (43.75%)
0-20 dB	21 (67.74%)	27 (84.37%)
0-30 dB	31 (100%)	31 (96.87%)
>30 dB	31 (100%)	32 (100%)

Discussion

In the present study, underlay technique was used in all cases. It is acknowledged that underlay technique remains the most common technique nowadays. It has advantages of ease of assessment the middle ear cavity including ossicular chain and its mobility. Underlay technique is easier and is less time consuming. It avoids anterior blunting and lateralization of graft.[9, 10]

The patients were of in between 13 to 53 years of age in temporalis fascia group (Group A) with the mean age of 28.2 years and were of 15 to 55 years of age in cartilage composite group (Group B) with mean age of 29.48 years. The most common age group was 21-30 year with 12 patients (34.28%) in each group. This group of patient is probably very much concerned about the nuisance created by ear discharge and decrease in hearing and is willing to undergo surgery with ease. There was almost homogenous distribution of the patients in both the groups. The most common age groups undergoing myringoplasty are similar in other studies also.[11, 12] There were 16 (45.72 %) cases of bilateral disease in temporalis fascia group (Group A) and 18 (51.42 %) cases in cartilage composite group (Group B). There was no statistically significant difference in frequency of bilateral disease in both the groups. (p = 0.632) Status of contralateral ear is a negative prognostic factor in some studies and especially in children.[13, 14]

In our study, we included only high risk perforations, that is >50% perforation of tympanic membrane, perforation underwent revision surgery, perforation with absent/eroded handle of malleus, oedematous/unhealthy middle ear mucosa but not actively discharging and perforation with margin involvement. This is a slight modification of high risk criteria used by Dornhoffer.[15]

There was almost equal distribution of high risk criteria in both the groups, the criteria of >50% TM perforation being the commonest. Out of 35

patients in each group, in group A, 27 cases had >50% TM perforation and in group B, 23 cases had >50% perforation of TM. Both the groups had 5 cases each of oedematous/unhealthy middle ear. Status of middle ear at surgery is one of the important factors that influences graft uptake in myringoplasty.[6] Graft uptake was assessed after 6 weeks of surgery. By this time, Gel foam is expected to have dissolved completely. Prasad *et al.*[16] had also used 6 weeks as the minimum postoperative follow up period after myringoplasty, the time required for complete healing and good hearing results. Brown *et al.*[6] used minimum of 4 weeks from the date of operation to assess the results. A short period of follow up is the limitation of our study. Uptake rate of myringoplasty using temporalis fascia as graft was 88.6% and with tragal perichondrial - cartilage composite graft it was 91.4%. This observed difference was not statistically significant (p= 0.690). Our results are similar to those of Ulku[17] who had found graft uptake rate of 88.2% with temporalis fascia and 91.3% with perichondrium cartilage in subtotal perforations in his retrospective study. Also, Ozbek *et al.*[18] reported graft uptake rate of 70.2% in temporalis fascia group and 100% in cartilage group in >50% TM perforation but this study was done in children. Kazikdas *et al.*[19] achieved graft uptake rate of 75% in temporalis fascia and 95.7% in perichondrium cartilage group in subtotal perforations with palisade technique.

Among failure cases, 5 cases had unilateral disease whereas 2 cases had bilateral disease in our study. Out of 5 cases with unilateral disease, one was revision surgery and in one, middle ear was unhealthy and oedematous at the time of surgery. This is in contrary to the findings of other authors who had concluded that diseased contralateral ear is associated with poor surgical outcome.[6] Caylan observed success rate of surgery in the bilateral diseased group to be 10/18 (55%) and in unilateral group 32/33 (96.9%).[14]

Pure tone audiometry was done in sound treated room with calibrated equipment. Although environmental noise was minimum in our set up, sound proof room would have been ideal. Four frequencies pure tone average was calculated from 500, 1000, 2000 and 3000 Hz. Same frequencies were used by Kazikdas *et al.*,[19] Cabra *et al.*[20] and Brown C *et al.*[6] These four frequencies are the speech frequencies that keep the importance of subjective hearing. Use of only 3 frequencies 500, 1000 and 2000 Hz for measurement is also common.[21]

Conclusion

The graft uptake rates and hearing results after perichondrial - cartilage composite graft are similar to those of temporalis fascia graft. Perichondrial-cartilage composite graft even though more rigid and thicker than temporalis fascia did not affect post-operative hearing results adversely. Therefore, we recommend the use of perichondrial - cartilage composite graft for tympanic membrane reconstruction in high risk perforation.

Conflict of Interest: None

Ethical clearance: Ethical approval was taken from Institutional Review Board of TUTH, IOM.

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Original Research Article

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A Cross Sectional Study on Prevalence and Pattern of Murmur and CHD in Children of District Shopian

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Abstract

Background: Congenital heart defects (CHD) are among the common congenital birth defects with an estimated incidence of 8–10/1000 live births which can be easily identified on occasions on routine checkup visits on auscultation and confirmed by echocardiography. With the advanced diagnostics and corrective therapies for CHDs, the percentage of individuals surviving to adulthood has increased over past few decades, it is imperative to identify the disease at the earliest.

Methods: This was a hospital-based outpatient study conducted in the pediatric OPD of the hospital in children aged 12 years or less with no previous known heart disease. Children were seen for any murmur or features of heart disease. A total of 14000 patients were attended with 100 having murmur and an echocardiogram was advised.

Results: Of the 14000 children seen in the OPD, 100 had a murmur on auscultation accounting for about 0.714% patientsi.e 7 per 1000 children. Of the 100 patients with murmur, 60 patients came back with an echocardiogram of which38 had an abnormal echo corresponding to 63.33% cases. Hence the murmur was present in approximately 7 per 1000 children and the incidence of heart lesions among those with murmur was 63.33% with VSD & ASD in combination as the most occurring lesion.

Conclusion: The prevalence of murmur in children was approximately 7 per 1000 and the sensitivity of auscultation in finding a heart disease was 63.33%. However, a large study over a greater period of time with a good follow up of the patients is recommended.

Keywords: Murmur, CHD, Echocardiogram, VSD, ASD, PDA.

Introduction

Congenital heart diseases (CHD) are the commonest congenital defects affecting approximately 1–2% of live births globally with an estimated incidence of 8–10/1000 live births. Regional differences do occur in prevalence and incidence due to many factors[1]. CHD is defined as a structural abnormality of the heart or intrathoracic great vessels that causes significant functional impairment[2]. If appropriate steps arenot taken, it can affect the quality of life of the individual and can potentially lead to a premature death. Murmur could be the first and sometimes the onlysign of a heart disease. A murmur

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can be innocent or pathologic in nature. Some of the neonatal and many pediatric murmurs do not have pathological importance, and they are considered as innocent[3]. Approximately 20% of CHD incidence can be attributed togenetic syndromes, teratogen exposure or maternal diabetes, the risk factors for the remaining 80% are uncertain. Improved medical and surgical care haschanged the quality of life of the children born with CHD especially in developed countries[4]. CHDs are classified into acyanotic and cyanotic defects according to the pathology. The acyanotic lesions includes septal cardiac defects like ASDs, VSDs andAV canal defects &left ventricular outflow obstructive lesions like aortic stenosis and coarctation of aorta with complexities. Cyanotic CHD include Tetralogy of Fallott, transposition of great arteries, total anomalous pulmonary venous returns, hypoplastic left heart syndrome, truncusarteriosus, and tricuspid atresia[5]. Presentations can range from poor suckling, cyanosis and shortness of breath to frank heart failure, however asymptomatic presentation is common and usually discovered accidentally on routine checkup visits[6]. Infants and children present with breathlessness, clubbing, cyanosis, murmur, syncope, history of squatting, heart failure, rhythm disorder, and failure to gain weight[7]. With the modern management of these patients, the percentage of individuals surviving to adulthood has increased over past few decades and are more likely to reproduce, leading to an increased incidence rate[8]. The burden of CHD in India is high owing to ahigh birth rate. Estimates show that around 180,000 children in India are born with congenital defects every yearandin only a very meager percentage the intervention is done, the number of young adults with CHD is steadily increasing[9]. Currentliterature available shows that an ECG and a chest X-ray can have a sensitivity as low as 10% in the identifying a CHD of well children with heart murmurs[10]. Hence an echocardiogram is better advised to confirm or refute a possible diagnosis of a congenital heart disease. Since there is no current study on CHDs in this region, we undertook this study to find the prevalence of murmur, and CHD incidence among these children with murmur on auscultation and finding the pattern of lesions in the children of district Shopian.

Aims and objectives: To make a cross sectional study on prevalence and pattern of murmur and Congenital Heart Disease in children of District Shopian.

Material and Methods

This was a hospital-based outpatient study conducted in the pediatric patients at district hospital Shopian between January 2022 and September 2022. A proper consent was taken from the guardians or the parents of the patients participating in the study whose confidentiality was maintained. A total of 14000 children were seen for any murmur or features suggestive of any heart diseasein the OPD. Most of the patients had come for reasons other than the cardiac disease like fever, respiratory tract infection including otitis media, gastroenteritis, UTI, etc. Of the 14000 patients attended only 100 patients had murmur on auscultation and an echocardiogram was advised which was done by a pediatric cardiologist. Only 60 patients returned with the report and rest 40 didn't follow up at all and hence were the actual subjects of the research.Data was tabulated and analyzed using SPSS Version 20. Frequency and percentages were used for qualitative analysis.

Inclusion & exclusion criteria.

Any child aged aged 12 years or lesswith no previous known heart disease was included and looked for any murmur or signs of heart disease.

Results

Of the 14000 children seen in the OPD only 100 had a mumur accounting for about 0.714% patients i.e 7 per 1000 children. Of these100 patients with murmur, only 60 patients came back with an echocardiogram.Of these 60, 38 had an abnormal echocardiogram corresponding to 63.33% cases of all murmurs. VSD & ASD together was the commonest lesion found in the children on echocardiogram accounting for a total of 31.6% of the cases followed by solitary ASD and PDA with 21% each, VSD & PDA, TR/MR, ASD & PDA, PFO and complex heart lesion with 5.3% each. The youngest child with a congenital heart lesion was a six day old neonate with ASD & PDA and the oldest child was just above 11 year old

girl with a PDA who was planned for an elective closure. The patternof Congenital Heart Disease and incidence of true heart lesions by echo in clinically felt murmurs on auscultation in the children can be summarized below in tables 1 & 2 respectively:

Tables 1. Murmurs.

Total Murmurs clinically	60	%age
Innocent Murmurs	22	36.67%
Pathological Murmurs	38	63.33%

Tables 2. Type & pattern of lesion found finally.

Type of lesion	No. of cases found	%age of cases of the individual CHDs	Total cases of clinical murmur	Total CHDs found on echo (%)	%age of cases of the individual CHDs
VSD & ASD	12	31.6%	60	38(63.33%)	31.6%
ASD	8	21%			21%
PDA	8	21%			21%
VSD & PDA	2	5.3%			5.3%
ASD & PDA	2	5.3%			5.3%
VSD, CoA, PDA, Arch hypopoasia	2	5.3%			5.3%
TR/MR	2	5.3%			5.3%
PFO	2	5.3%			5.3%
Total	38	100%			100%

Discussion

Congenital heart defects (CHD) are the most common congenital birth defects commonly found on routine checkup visits on auscultation as asymptomatic presentation is common. Improved medical and surgical care has transformed the prognosis for CHD especially if identified early. Not all murmurs are CHDs, some are innocent. To differentiate the pathological ones from the innocent ones, an echocardiogram is very important. There is not a single study conducted to find the pattern of the congenital heart defects at Shopian, hence it was imperative to conduct this study.

Our study found murmur in children accounting for about 0.714% patients i.e a prevalence of 7 per 1000 children which is consistent with studies conducted by Ainsworth[11] et al with 0.6% of babies having murmurs. Most of the murmurs were of grade 3 intensity. Only few had cardiomegalyon chest X-ray, none of the children was in CCF and rest all children had normal chest X-ray. Except for one child with a history of CHD in cousin, no child had a history of familial CHD. Thus given that murmurs are rare and with no overt symptoms or signs of disease, a murmur can be the only clue to an underlying congenital heart disease and hence it seems appropriate to advise an echo in such cases for a definitive diagnosis. The percentage abnormal echocardiogram in children who had clinical murmur was approximately 63.33% cases of all murmurs indicating that if a murmur is heard, there is a 63.33% chance of an underlying cardiac malformation as has been in different studies like one conducted by Ainsworth[11] et al 54% chance of being an underlying cardiac malformation in case of a murmur heardand 75% chance of an underlying cardiac disease if a murmur is heard in a studyconducted by Pillai[10] et al Rest 36.67% murmurs were innocent. In this study, VSD (VSD& ASD together) was the commonest lesion found at 31.6% as has been found in studies like one conducted by Kishore[7] et al with ventricular septal defect (VSD) constituting 31% of the total CHD cases and atrialseptal defect (ASD) as the second most common CHD comprising 23% of all CHD cases.

Recommendation: Since the percentage of abnormal echocardiogram in children who had clinical murmur was approximately 63.33% of all

murmurs indicating that if a murmur is heard, there is a 63.33% chance of an underlying cardiac malformation. Thus given that murmurs may be the only clue to an underlying congenital heart disease and it seems appropriate to advise an echocardiogram in such cases for a definitive diagnosis and to intervene accordingly at the earliest.

Limitations of the study:

1. The main limitation of the study was that a good number of the patients didn't follow back with the echo report even though we explained them the situation very well.
2. The other limitation of the study was that we couldn't find many more patients with murmur to undergo an echocardiogram although we saw a huge number of patients.

Conflict of interest: None declared.

Funding: None.

Ethical approval: The study was approved by the Institutional Ethics Committee.

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Subject Experts View Points from World Antimicrobial Awareness Week 2022 to Combat Antimicrobial Resistance in India

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Abstract

Background and Aim: Antimicrobial resistance (AMR) is a global health problem that can lead to longer hospital stays, higher medical costs and increased mortality. The aim of this study was to document the challenges and viewpoints of multidisciplinary subject experts participated in the World Antimicrobial Awareness Week (WAAW) 2022 program to combat AMR in India.

Material and Methods: This was an observational study conducted during the celebrations of WAAW 2022. Subject experts from departments of microbiology, pharmacology, community medicine, general medicine and obstetrics and gynecology were invited to deliver talks on the different aspects of AMR. Questions asked by the delegates to the subject experts during the sessions and the responses given by the subject experts were documented. The data obtained was arranged in the tabular form as per the objectives of the study.

Results: All the subject experts emphasized the urgent need to reduce the incidence of AMR. Subject expert from microbiology reiterated the importance of institutional antimicrobial stewardship program with the aim of restricting the use of broad-spectrum antibiotics only to the critically ill patients. Regulations framed to dispense antimicrobials under schedule H1 must be strictly followed according to the subject expert from pharmacology. An urgent need to increase the awareness on rational use of antimicrobials to all the stakeholders involved in the health care was opined by the subject expert from community medicine. Subject expert from general medicine emphasized on timely deescalating the dose and duration of antimicrobials. Maintaining proper aseptic measures in the operating room is key to reduce surgical site infections (SSIs) according to the subject expert from obstetrics and gynecology.

Conclusion: Strict surveillance from the drug regulatory authorities on antimicrobial dispensing combined with effective implementation of antimicrobial stewardship at every health care institution will only play a key role in bringing down the AMR burden in the country.

Keywords: Antimicrobial resistance, Public awareness, Empirical antimicrobials, Surgical site infections

Introduction

Antimicrobial resistance (AMR) is a global problem posing challenges to health care professionals in treating common infections[1]. It occurs when bacteria, viruses, fungi and parasites

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undergo changes in their genetic makeup and no longer respond to previously effective antimicrobials making common infections harder to treat. AMR increase the risk of disease spread, prolongs duration of illness and increased mortality. AMR also increases the health care costs as well as the economic burden on families and societies.

The main causes of AMR recognized by World Health Organization (WHO) include the misuse and overuse of antimicrobials in agriculture, veterinary, and human medicine due to lack of awareness and knowledge; lack of access to clean water, sanitation and hygiene (WASH); poor infection and disease prevention control measures; poor access to quality, affordable medicines, vaccines and diagnostics; and leniency in the enforcement of government regulations[2].

In recognition of this growing problem, WHO has adopted a global action plan in the year 2015 aiming to ensure prevention and treatment of infectious diseases with safe and effective medicines across multiple sectors, especially human health, animal health and agriculture. Part of the plan is to celebrate World Antimicrobial Awareness Week (WAAW) every year from 18 to 24 November to increase awareness of antimicrobial resistance worldwide and to encourage best practices among the general public, health workers and policy makers to avoid the further emergence and spread of drug-resistant infections[3].

The Indian Council of Medical Research (ICMR), New Delhi, initiated the Antimicrobial Resistance Surveillance & Research Network (AMRSN) in 2013 to collect nationally representative data on trends and patterns of AMR to the commonly used antibiotics in pathogens of public health importance[4]. The data emanating from this network has been used to develop evidence based treatment guidelines for treatment of common syndromes in India. Additionally, the Central Drugs Standard Control Organization (CDSCO) amended the Drugs and Cosmetics Rules in 2013 to include antimicrobials of importance under schedule H1 which deals with the rules for dispensing of these drugs across the pharmacies in the country[5].

An urgent multisectoral and multidisciplinary action is needed to prevent the emergence of new resistance mechanisms in pathogens, to improve the quality of patient care and to bring down the AMR burden in the country. The objective of this study was to document the challenges and viewpoints of multidisciplinary subject experts participated in the WAAW 2022 program to combat antimicrobial resistance in India.

Material and Methods

It was an observational study conducted during the celebrations of WAAW 2022 organized from 18.11.2022 to 24.11.2022 at Chirayu Medical College and Hospital, Bhopal. Subject experts from the departments of microbiology, pharmacology, community medicine, general medicine and obstetrics and gynecology were invited to deliver talks on the different aspects of AMR. Questions asked by the delegates to the subject experts during the sessions and the responses given by them were documented. The data obtained was arranged in the tabular form as per the objectives of the study.

Results and Discussion

The categorization of delegates is depicted in Figure 1.

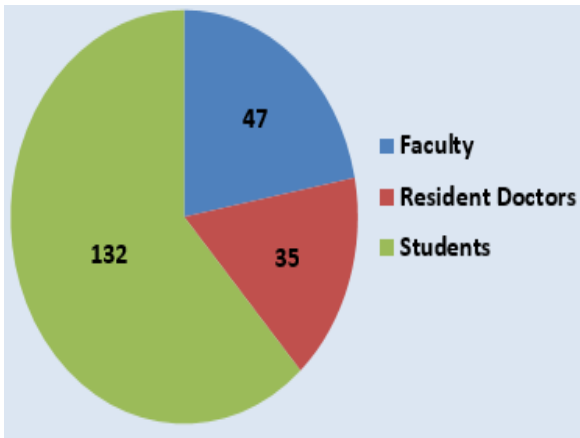

Figure 1: Categorization of delegates

The subject experts' challenges and viewpoints to the questions asked by the delegates are shown in Table 1.

Table 1: Subject expert challenges and viewpoints to the questions asked by the delegates

Specialization of subject experts	Questions asked by the delegates	Viewpoints of subject experts
Microbiology	What is the most important challenge being faced?	Reducing the time to detect sensitivity and resistance patterns of antimicrobials.
	How to reduce AMR?	Restricting the use of broad spectrum antibiotics only to the critically ill patients.
Pharmacology	What is the most important challenge being faced?	Easy availability of counterfeit or spurious antimicrobials.
	How to reduce AMR?	Strict vigilance on dispensing of antimicrobials by government regulatory authorities.
Community Medicine	What is the most important challenge being faced?	Lack of guidance and awareness on antimicrobial resistance among general public and pharmacists.
	How to reduce AMR?	Using antimicrobials judiciously and responsibly in humans and animals.
General Medicine	What is the most important challenge being faced?	Selection of empirical antimicrobials.
	How to reduce AMR?	Timely de-escalation of the dose and duration of antimicrobial therapy.
Obstetrics and Gynecology	What is the most important challenge being faced?	Determining the need of repeat dosing of antimicrobials after surgical procedure.
	How to reduce AMR?	Maintaining proper aseptic measures in the operating room.

According to the WHO, antimicrobial resistance has been considered as one of the top 10 global public health threats facing humanity[2]. Resistance has rapidly emerged to most classes of antibiotics including sulphonamides, penicillins, tetracyclines, macrolides, fluoroquinolones, and early generation cephalosporins as soon as they were released into market by the innovators of these drugs[6]. This shows the rampant and irrational use of antibiotics. Multi-drug resistant strains of Mycobacterium tuberculosis are hindering progress in containing the global tuberculosis epidemic[7]. Resistance has also developed to most antivirals, antimalarials, and antifungals[8].

Subject expert from microbiology highlighted the unmet need of fast, robust, and affordable antimicrobial susceptibility testing (AST) as a challenge to curtail the unnecessary use of antimicrobials and better control the spread of AMR. Study done by Maurer FP et al., noted that early availability of AST is of key importance for restricting the overuse of reserved antimicrobial agents including glycopeptides and broad-spectrum beta-lactams such as piperacillin-tazobactam or carbapenems[9].

Subject expert from pharmacology highlighted the easy availability of counterfeit or spurious antimicrobials as a challenge to control the spread of AMR. According to the WHO, about 10% medical products in low- and middle-income countries are substandard or falsified[10]. Emergence of AMR as a result of low-quality antimicrobials has been reported by many studies[11,12]. Using poor-quality antimicrobials by the patients to treat common infections can increase the chances of escalating to broad-spectrum antibiotics by the physicians. This may lead to increased economic burden on the patients and also increases the risk of developing AMR by the broad-spectrum antibiotics towards pathogens causing common infections. Additionally, regulations to dispense antimicrobials across the pharmacies must be strengthened[5]. Manufacturers

of antimicrobial preparations must be instructed to pack the drugs in blue color strips or boxes for unique identification and surveillance thereby echoing the "Go Blue" theme of the WHO[13]. The implementation of the 'track and trace' mechanism by affixing Quick Response (QR) Code from August 1, 2023 onwards by the MOHFW, Government of India is being considered as a step in right direction[14]. Regular visits by the drug inspectors to the manufacturers as well as the pharmacies must be done to monitor the adherence of rules described under Drugs and Cosmetics Act. Persons violating the rules must be strictly penalized.

Subject expert from community medicine highlighted about the lack of guidance and awareness on antimicrobial use among general public and pharmacists as a challenge to control the spread of AMR. Many studies conducted across the world to assess the awareness and knowledge of antimicrobial usage and AMR among the general public and pharmacists concluded that one campaign at a point in time does not sufficiently promote the awareness and there is a need for continual awareness campaigns on judicious use of antimicrobials in humans and animals[15,16].

Subject expert from general medicine highlighted on the selection of right empirical antimicrobials as a challenge to control the spread of AMR. Although many studies encouraged health care institutions to conduct Antimicrobial Stewardship Programs (ASPs) to optimize antimicrobial therapy[17,18], lack of coordination between multidisciplinary physicians, microbiologists, epidemiologists and drug regulators end up in choosing broad-spectrum antimicrobials as empirical drugs for common infections. Timely de-escalation of the dose and duration of antimicrobial therapy helps to maintain clinical effectiveness of broad-spectrum antimicrobials towards susceptible infections while reducing the chances of AMR spread.

Subject expert from obstetrics and gynecology highlighted on determining the need of repeat dosing of antimicrobials after surgical procedure to prevent SSIs as a challenge to control the spread of AMR. Although there is some inconsistency between studies whether a single dose of surgical antibiotic prophylaxis (SAP) can increase antibiotic resistance, many studies concluded that the relationship between SAP and post-operative antibiotic-resistant infection depends on the type of surgical procedure with the risk being high in immune compromised patients and low in patients undergoing elective surgical procedures [19-21]. Maintaining aseptic standards in the operating rooms as well as during the surgical procedures must be ensured to prevent SSIs and the need of post operative antimicrobials.

Conclusion

Although most of the subject experts' viewpoints in the study were in line with published data and recommendations, some others were not. Strict surveillance from the national and state drug regulatory authorities on antimicrobial dispensing combined with effective implementation of antimicrobial stewardship at every health care institution as recommended by ICMR and WHO will only play a key role in bringing down the AMR burden in the country.

Limitations

This was a single center study, and it is possible that challenges and viewpoints of subject experts could differ in a different hospital settings. Therefore cross sectional hospital based studies should be considered in future to explore new challenges and ideas for preventing AMR in the country.

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Original Article

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Assessment of Antimicrobial Prescribing in Ophthalmology Outpatient Department of a Tertiary Care Hospital

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Abstract

Background: Analysing drug prescribing pattern is crucial to prevent antibiotic resistance in community. The study aims to analyse the pattern of antibiotic drug prescription in outpatient department (OPD) of Ophthalmology.

Methods: It was an observational study done over 3 months period in OPD of Ophthalmology DMGMC & H. Data were collected from case record form for demographic profile, nature of disease and type of antibiotic prescribed and route of administration.

Results: A total of 250 patients were analysed from Ophthalmology OPD. Maximum patients belonged to 20-50 years (66.8%). The proportion of male (58%) as compared to females (42%). Average drug prescription was 1.08. Most commonly used antibiotic was Moxifloxacin. Maximum patients were diagnosed with conjunctivitis (22.8%) followed by external hordeolum (16%), cataract (12%) blepharitis (10%) and dacryocystitis (10% each). Among antibiotics fluroquinolones were used most (42.08%), followed by broad spectrum antibiotic chloramphenicol (20.8%) followed by aminoglycosides (16.8%). Maximum number of drugs were administered in topical form (64.8%).

Conclusion: The present study found that fluroquinolone antibiotic was prescribed maximum. Most common dosage form of prescribed drug was eye drop. Antibiotics need to judiciously used in all OPD set up to prevent drug resistance.

Keywords: Prescribing patterns, Out-patients in Ophthalmology, drug resistance.

Introduction

Prescribing pattern of drugs needs to be periodically monitored to identify the irrational and inappropriate use of drugs in medical practice which might affect the therapeutic efficacy and safety of prescribed medicines.[1,2] Rational use of drugs indicates that the patients are prescribed drugs according to their clinical needs at adequate doses for the appropriate duration. Irrational use of drugs

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in the form of overprescribing, under prescribing or misuse might result in health risks to the patients and wastage of limited resources in the health care system. Thus, evaluation of prescribing pattern helps prescribers to improve their prescribing practice and consequently promotes rational use of drugs.[3,4] To achieve that goal, WHO and International Network for Rational Use of drugs (INRUD) have defined some standard drug prescribing indicators.[5] Topical antimicrobials play a significant role in treatment of several eye problems like acute conjunctivitis, infective corneal ulcers, blepharitis, hordeolum, ophthalmia neonatorum, iridocyclitis etc. as well as for postoperative prophylaxis after eye surgeries. Fluoroquinolones (moxifloxacin, ciprofloxacin, gatifloxacin) aminoglycosides (tobramycin, neomycin), chloramphenicol, polymyxin B antibiotics, acyclovir, ganciclovir, amphotericin B, nystatin etc are commonly used ophthalmic antimicrobial agents in ocular therapy. Overuse, inappropriate use of ocular topical antibiotics has always been a concern over countries which may lead to the development of antimicrobial drug resistance alongside increasing the cost burden too.[6-10] Keeping this in mind, the present study was done with the aim to evaluate the prescribing pattern of ophthalmic antimicrobial drugs in patients presenting to Ophthalmology outpatient department of a tertiary care hospital.

The study aims to analyse the prescription pattern of ophthalmic antimicrobials in outdoor patients of ophthalmology department and to analyze the socio demographic parameters of the patients.

Methodology

Patients attending Ophthalmology outpatient department (OPD) of tertiary care hospital prescribed at least one ocular topical antimicrobial agent was included the study. 250 study participants were included in three months after getting ethics committee clearance. It was an observational study, data collected from case record form, patient consent form and informed consent form after getting ethics committee approval. Relevant information was noted down in case record form.

Inclusion Criteria were patients prescribed with at least one ocular topical antimicrobial agent in ophthalmology OPD, age ≥ 18 years.

Exclusion Criteria were patients not willing to participate or not giving informed consent. pregnant and lactating women. patients with associated psychiatric illnesses.

Data Analysis: Data will be entered in Microsoft Excel. Data will be analysed in SPSS version 21, through appropriate statistical tests.

Ethical Considerations: The study proposal along with other relevant documents would be submitted to institutional ethics committee (IEC) for review and approval. The study will commence after such approval is obtained.

In case of multiple antibiotic usage, each drug was noted with its route of use. In case of corneal ulcer, scraping was done and sent for microbiological evaluation. After immediate analysis of bacterial or fungal element, only fungal ulcers were excluded from the study. After 7 days of culture sensitivity if there was any change in sensitivity pattern, different antibiotic was included. Sampling was sent for suppurative diseases and endophthalmitis patients also.

Results

There are 250 patients in the study group, 105 (42%) females and 145 (58%) males.

Table 1 showed age distribution of study sample. It is evident that highest number of cases presenting in OPD are between 20 to 50 years of age.

Table 1: Age Distribution

Age	
< 20	31 (12.4%)
20-50	167 (66.8%)
50	52 (20.8%)

Distribution of diseases are shown in table 2. Its evident from this that most common usage of antibiotics is conjunctivitis (22.8%) followed by external hordeolum (16%), cataract (12%)blepharitis (10%) and dacryocystitis (10%each), blepharitis(10%).

Table 2: Distribution of disease

External hordeolum	40 (16%)
Blepharitis	25 (10%)
Corneal Ulcer	20 (8%)
Conjunctivitis	57(22.8%)
Cataract (pre-operative)	30 (12%)
Chemical burn	5 (2%)
Internal hordeolum	18 (7.2%)
Preseptal Cellulitis	23 (9.2%)
Dacryocystitis	25 (10%)
Endophthalmitis	5 (2%)
Orbital cellulitis	2 (0.8%)

Table 3 described the usage of different classes of antibiotics. It depicted that fluroquinolones were used most in OPD (42.08%), followed by broad spectrum antibiotic chloramphenicol (20.8%) followed by aminoglycosides (16.8%). Among fluroquinolones, Moxifloxacin is used most commonly 26%.

Table 3: Antibiotic usage Pattern

Fluroquinolones	Moxifloxacin	65 (26%)
	Ciprofloxacin	30 (12%)
	Gatifloxacin	35 (14%)
	Basifloxacin	2 (.08%)
Aminoglycosides	Tobramycin	35 (14%)
	Gentamycin	5 (2%)
	Amikacin	2 (.8%)
Cephalosporin	Cefazoline	3 (1.2%)
	Ceftazidime	2 (.8%)
	Ceftriaxone	5 (2%)
Tetracycline	Doxycycline	14 (5.6%)
Macrolides	Azithromycin	15 (6%)
Miscellaneous	Chloramphenicol	52 (20.8 %)
	Vancomycin	5 (2%)

It is seen from table 4 that most common mode of delivery is topical (36.8%), followed by oral (34.4%) and ointment (28%), intracameral was least commonly used (in this study). It was used in only refractive corneal ulcer with hypopyon.

Table 4: Routes of drug use

Drop	92 (36.8%)
Ointment	70 (28%)
Oral	86 (34.4%)
Intravenous	10 (4%)
Sub conjunctival	5 (2%)
Intravitreal	5 (2%)
Intracameral	2 (0.8%)

Discussion

In our study, we have analysed prescriptions of total 250 patients in opthalmology outpatient department who were prescribed a total of 410 drugs out of which 270 drugs were antibiotics. Our Study showed 66.8% patients were in the age group of 20-50 with male preponderance (58%). Similar demographic data were found in other studies.[11-13]

We found an average of 1.08 antibiotics per prescription. Multidrug therapy was in 35.2% prescriptio ns and polypharmacy was less in our study (5.2 %). The degree of polypharmacy is average number of drugs per prescriptions. This index is an important tool to analyse cost effectiveness of therapy. It was also low in our study. It was comparable to previous studies.[14,15] It is higher in Vaniya et al.[16]

The antibiotics were all prescribed in generic name considering mostly availability of medicine in health care facility. There are various brands of same antibiotics available. Their bioavailability, potency and variability in clinical response may be one of the major contributors to drug resistance. These are confounding factors for clinical outcome and need for multidrug therapy and potential cause of drug resistance.[17]

Analysis of total 250 patients prescription showed that 22.8% patients were diagnosed with conjunctivitis followed by external hordeolum (16%), cataract (12%) blepharitis (10%) and dacryocystitis (10% each). Shakuntala et al found 34% of patients were diagnosed with conjunctivitis (maximum no), followed by dacryocystitis (21%), blepharitis (16%).[17] The study conducted by Vaniya et al. showed that eyelid diseases (30%) were diagnosed maximum in their study.[16]

In our study antibiotic monotherapy was most commonly used. Among 250 patients, only 4(1.6%) patients had two antibiotics and another 4 patients had three antibiotics. This is significantly lower than previous studies where two-drug therapy was the most common pattern used.[14-17] Monotherapy was used due to various reasons. First was disease spectrum. Conjunctivitis, cataract, hordeolum, preseptal cellulits included majority of disease requiring only monotherapy, corneal ulcer treatment had specific therapy. Whereas, diseases like Endophthalmitis, orbital cellulitis requiring polytherapy were less in number.

Secondly, poor patient profile, dependency on hospital available drugs only.

Thirdly, to avoid polypharmacy during rational prescribing.

Fluroquinolones were used most in OPD (42.08%), followed by broad spectrum antibiotic chloramphenicol (20.8%) followed by aminoglycosides (16.8%). Cephalosporins were used in 4% of cases. Among fluroquinolones, Moxifloxacin is used most commonly 26%. It is similar to previous studies.[14-17]They found Fluoroquinolones were most commonly used class of antibiotics with 86% followed by aminoglycosides (21%), next is beta-lactam antibiotics (28%), shows similar prescription by Vaniya et al. (66.7%)and Jadhav et al. (60%) and a study by Jai et al. (68%).[14-17]

Other commonly used antibiotics are broad spectrum chloramphenicol (208%), Gatifloxacin (14%) which is similar to study by Jadhav et al.[14] In this study, ciprofloxacin is used in 12% of cases, it was most commonly used by Vaniya et al. and Jai et al.[15,16]

Among 270 were antibiotics prescribed, Most common mode of administration was eye drops (36.8%), followed by oral (34.4%) and ointment (28%). In Shakuntala et al 69% of drugs prescribed in the form of eye drops followed by ointment (15%) and 12% were prescribed in the form of tablet/capsule and parenteral use is 4%. In a study by Vaniya et alalmost same findings were found.[16]

Conclusion

Rational use of drugs implies that drugs are given for appropriate indications, dose, duration to appropriate patients which enhances efficacy, safety, tolerability, compliance and minimise side effects, misuse, cost burden in therapy. Evaluation of prescribing pattern, helps to evaluate several aspects of drug use which ultimately helps prescribers to improve their prescribing practice and consequently promotes rational prescribing. Irrationalities in antimicrobial prescribing habits has been linked to emerging resistance of ocular antimicrobials specially antibiotics. Topical ophthalmic antimicrobials contribute a major chunk in managing several eye conditions as there is always high chance of secondary microbial infections in eye which if not controlled can impose a threat on vision. The choice of the appropriate antimicrobial agent should depend on clinical diagnosis, suspected infective agent, and its predicted sensitivity. There is dire need to use topical antimicrobials for eye diseases judiciously as many of them have no suitable formulation for ocular use till date and drug resistance will create a serious issue in patient management. Thus, it becomes necessary to study the prescription pattern of antimicrobial drugs for ocular use at periodic intervals.

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Original Article

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Learning via Reflection: Studying the Covid-19 Pandemic Experiences of First-Year Medical Students

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Abstract

Background: Reflective writing allows for a thorough analysis of something learned or an event had. In medical education, reflective writing is of utmost importance. The Competency-Based Medical Education (CBME) curriculum of the Medical Council of India (MCI)/National Medical Commission (NMC) endorses reflective writing as a learning technique, especially in the emotive domain. Writing reflections is a form of experiential learning, where the experience could be a seminar, conference, natural disaster, or epidemic. Due to the covid-19 outbreak, the Indian government was forced to institute a nationwide lockdown.

Due to pandemics and the uncertainties surrounding the reopening of medical institutions, the return of onsite teaching activities, and the administration of exams, the medical students are experiencing a difficult time. As part of their schooling, the kids were encouraged to express their experiences by writing thoughts on the present pandemic. The first-year medical students reflected on the COVID-19 pandemic using Rolfe G. et al's(2001) three parts reflective approach, which comprises of three simple questions: what happened, so what, and what's next? This article is an attempt to summarize their thoughts.

Aims and Objectives: Learning via reflection: Studying the Covid-19 Pandemic Experiences of First-Year Medical Students

Materials and Methods: To encourage reflective writing among the first-year MBBS and BDS students at the GMC Jammu, they were told to apply Rolfe's reflection model to the COVID-19 pandemic. 200 medical students from the class of 2021-22 were polled for their insights. In order to refresh the students' memories, a quick outline on "how to write reflection" was provided based on Rolfe's reflection. To empower students to freely express themselves, responses were voluntary and anonymous. The responses were collected and submitted in an anonymous way to the authors.

Results: In the present study, students were told to evaluate the situation via the lens of Rolfe's model. Approximately two hundred students took part in the activity. We have merely compiled and provided samples from the reflections of several pupils.

Conclusion: This one-of-a-kind experience of the pandemic and lockdown will linger in the minds of the medical students and us as educators for the remainder of our careers. Some students are hopeful about the future, whilst others fear falling behind on their assignments and contracting the illness.

Keywords: Covid-19, CBME curriculum, Pandemic, Reflective writing

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Introduction

The more modern Competency-Based Medical Education (CBME) curriculum encourages the use of reflective writing for formative evaluation of students.[1] Reflective writing is the discipline of learning from experience and engaging in conversations about the event to improve one's personal judgement. It can be argued that reflecting serves as a stimulant for subsequent growth and paves the way for reflective practise.[2] The experiences of a person, the reflecting process that enables them to learn from those experiences, and the action ensuing from the new perspective gained via reflection.[3]It is feasible to assert that reflective writing is more personal than other forms of academic writing. Due to the exceptional character of the Covid-19 epidemic, the environment of educational institutions has been significantly impacted, resulting in highly unpredictable conditions for professional education, including medical education. The disappearance of in-person classes and their replacement with online lectures has been one of the most substantial changes. Loss of collaborative experiences in demonstration classes and practical sessions is a matter for concern. The accompanying emotional suffering cannot be ignored. In this essay, we have sought to aggregate some of the observations written by first-year MBBS students on this terrifying pandemic.

Aims and Objectives: Learning via reflection: Studying the Covid-19 Pandemic Experiences of First-Year Medical Students.

Materials and Methods

To stimulate reflective writing among GMC Jammu's first-year MBBS and BDS students, they were instructed to apply Rolfe's reflection model to the COVID-19 pandemic crisis.[4] The reflections were gathered from 200 medical students of the class of 2021-22. Although the students are familiar with writing reflections, they were given a brief outline on "how to write reflection" based on Rolfe's reflection in order to refresh their memory. To encourage students to express themselves freely, responses were anonymous and voluntary. The replies were collected and provided to the writers in an anonymous format.After reviewing the responses, it was decided to make them accessible to others. Therefore, the Institutional Ethics Committee's approval was sought before publishing the data. For the qualitative study, two authors evaluated and thematically analyzed the replies. After extensive talks, the authors achieved a final agreement. The findings were organized according to three themes: what happened, so what, and what next. There are few expressive codes presented in Italics.Students were instructed to reflect using Rolfe's model for reflection (Fig.1). This is a straightforward, beginner-friendly design.

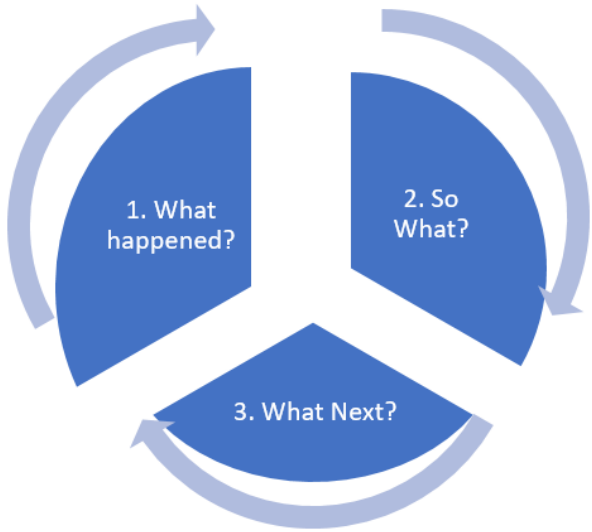

Fig. 1: Rolfe's Model of Reflection, Rolfe 2001

The components of the three steps are given in Table 1.

Table 1: The Rolfe Model's Steps for Reflective Writing

S. No.	Sub-heading of reflection	Event	To do
1.	What happened?	The narrative	Description of events. Set the scene and summarize.
2.	So what?	The learning	Analyzing the event. Ask yourself what it means.
3.	What next?	The change	Following the event, suggested action.

Results and Discussion:

There are a variety of formats for reflective writing. Among others, there are the Gibbs Model of Reflection, the Schon Model of Reflection, the Kolb reflective cycle, and the Borton Model.[5-8]

The model of Rolfe was derived from the model of Borton. The Borton model was proposed in 1970, but it was improved by Rolfe in 1988 and has since been utilized by both professionals and students. It is thought to be the most effective model for writing reflections.

In the current study, students were instructed to consider the circumstance in light of Rolfe's model. Approximately 200 pupils participated in the activity. We have simply summarized and are giving excerpts from several of the students' reflections.

What Happened?

The reflections of students in this article demonstrated that Covid-19 has the same yet unique appearance for each student. The students, reflecting on the current situation, discussed the commencement of the COVID-19 pandemic, the statewide lockdown, the closure of the medical college, the cessation of onsite teaching activities, and the inception of an online teaching-learning program.

"The word of the Covid-19 epidemic in our nation spread like a forest fire. Everyone was anxious and terrified."

"As a result of the Covid-19 pandemic, all colleges, theatres, and shopping malls are closed, and the government of India imposes a lockdown, requiring us to remain at home."

"We were on the college campus when the news of the Covid-19 new strain broke, and the first case was reported in Jammu. In a matter of days, the government decided to impose lockdown, all students were sent home from their hostels, and the college staff and faculty made certain that each and every student reached home safely; they kept in touch with us periodically."

"Normal college lessons were cancelled and students were sent home due to the rapid emergence of the Covid-19 epidemic. A further extension of the lockdown halted all activity across the country."

"Because of the Covid-19 pandemic in India, we were unable to attend our regular college classes, causing us to fall behind in our curriculum."

"We were unable to bring all of our books with us due to the covid-19 pandemic, and it is uncertain when the college will reopen."

"The situation appeared grave, the entire college was evacuated, and we all returned home." Eventually, everything was placed on lockdown. The rising number of Covid patients was truly frightening to observe. There was widespread panic. Doctors have given their all to protect the public."

"We were about to take our terminal 1 exam when a virus known as covid-19 began to spread in India, prompting our return home. I did not have sufficient time to assess the situation and was unaware of when we would be sent home."

"Due to an unexpected emergency, we left the college hostel in a hurry and were unable to bring all of our books and study materials with us because we did not know we would be gone for so many days. As this is the first time that we have stayed in the same enclosed setting day and night for so long, productivity and efficiency have also decreased."

So What?

The students have mostly mentioned the good features of lockdown, such as improving personal cleanliness, following interests and hobbies, training themselves to be future doctors, appreciating the efforts of instructors to give online lessons, etc. Negative analysis included impacted research, the economic downturn, and more.

"The shutdown has afforded folks the opportunity to improve their personal talents and clear accumulated backlogs. The online classes have proven to be a boon for the students, despite the fact that finishing the curriculum has been an inconvenience."

"It has taught us the value of cleanliness and encouraged us to become devoted and helpful physicians."

"It will eventually be a part of the doctor community, therefore I promoted awareness through social media, took precautions, and encouraged those

around me (my family) to do the same. Nonetheless, there are many who do not comprehend the gravity of the situation and who freely walk the outdoors."

"Our online classes have begun, which originally caused some issues, but I believe that everything is currently running smoothly. In this period, numerous individuals revealed their talents. I have been able to devote some time to drawing and painting, something I never would have been able to do otherwise. My life has undergone several similar transformations."

"It is a commendable effort by our college instructors to instruct us online. It was a great experience to learn through online classes as we were able to focus more on the app."

"Despite the pandemic, online classes came as a relief, and we're attempting to learn as much as we can."

"Our research have been adversely affected by this pandemic."

"Our institute offers online lessons, but they are not as effective as college lectures, and I'm having trouble with network issues and a shortage of books."

"Concerns have turned from supply-side manufacturing challenges to diminished business in the services sector as the Covid-19 has spread around the world. More than a third of the world's population at the time was placed on lockdown because to the epidemic, which produced the greatest global recession in history."

What Next?

The pupils think that the pandemic has taught them to overcome obstacles, to live a simple life, to assist those in need, to remain optimistic, and to have faith in the best possible outcome. This is an anxious period for all of us, yet it affects everyone of us in a unique way.

"I've learned that no matter how difficult situations become, we can overcome them together. If necessary, online classes can be performed efficiently. I've learned that we race after the materialistic world and forget that life can be lived simply."

"This lockdown has not been the same for everyone; daily bettors have endured plenty. My family has assisted local needy individuals by providing them with food and rations. When my nation needs me in times of struggle, I will continue to follow the rules and do what is required."

"After the pandemic has ended, we must remember the importance of hygiene and social manners. Respect the medical practitioners and healthcare professionals. Be proactive in compensating the education losses caused by the lockdown."

"I am really positive about the future, and there is a remedy for worry. The hope that will carry us through these challenging times. By having faith that this virus will pass, listening to medical professionals and authorities, staying indoors, maintaining good hygiene, social distancing, and being mindful and supportive of those profoundly affected physically or emotionally, I am confident that we will emerge stronger than ever."

"In the following days, I hope that everything will be resolved so that we can resume our studies as before." Because online courses cannot substitute for classroom instruction."

"I hope that everything returns to normal so that we may resume our studies as before. Negative experience. As the period of lockdown increases, interest in everything, including schoolwork, decreases."

"After the end of this epidemic, we will continue hygienic procedures and social isolation to prevent a recurrence of this crisis in the future."

"As soon as the current issue is resolved, professors should restart classroom instruction and provide extra time for practical work, where we are falling behind."

"I am currently reviewing previously taught material and reading what is being taught in class. The number of Covid-19 cases will hopefully reduce, India's health care system will be able to deal with the impending crisis, and our college will reopen so that we can return to our usual lives."

Conclusion

This unique experience of the pandemic and lockdown will remain etched in the brains of the

medical students and us as educators for the rest of our lives and professions. Some students are optimistic about the future, while others are fearful of falling behind on their coursework and acquiring the sickness itself. The Covid-19 outbreak is functioning as a spur for the India's medical educators to make significant adjustments to incorporate the new age of learning, as uncertain times require tougher measures. It is quite likely that the epidemic will alter the preferences of educators and students away from traditional classroom learning and toward digital learning. In addition to the curriculum covered in the online lectures, we should encourage our students, who are the future healers, to be resilient and to contribute to society by keeping their family members, friends, neighbors, and acquaintances in a positive frame of mind; by reducing their stress and anxiety through counselling.

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Original Research Article

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Study of Self Esteem and Factors Associated among Medical Students of a Private Medical College of Karnataka: A Cross Sectional Study

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Abstract

Background: Self-esteem refers to a person's overall sense of his worth or value. It is how much a person "values, approves of, appreciates, prizes, or likes him or herself. "Medical Education is quite demanding in terms long duration, lack of time, vastness. Medical students experience various forms of stress due to financial, and social pressures which could affect their levels of self-esteem.

Objectives: 1. To assess the level self-esteem among medical students of a private medical college in South India using Rosenberg Self-esteem scale. 2. To find out the factors associated with the levels of self-esteem among medical students of a private medical college in South India.

Materials and Methods: This is a cross-sectional observational study. UG and PG students of the college were participants**.** The pre structured questionnaire was used to collect the socio demographic details and Rosenberg Self-esteem scale (RSES) was used to assess the self-esteem among the medical graduate and post graduate students. Descriptive and inferential statistical analysis has been carried out in the present study. Results were presented as percentages for categorical data. Significance is assessed at 5% level of significance. Chi-square test has been used to find the significance of study.

Results: In the study 72 (20.86%) had low self-esteem, 258(74.78%) scored between (16-25) that shows normal self-esteem and only 16 (4.63%) scored >25 indicating high self-esteem.

Conclusion: This study found that the majority of medical students had normal self-esteem The factors such as sex of the student, age, marital status, type of course, socio economic status class were found to be significantly associated with the levels of self-esteem. Other factors like place of residence, religion was found to be insignificant.

Keywords: Medical students, Self -Esteem, Socio demographic factors ,India.

Introduction

Self-esteem refers to a person's overall sense of his worth or value. It is how much a person "values, approves of, appreciates, prizes, or likes him or herself."[1] Self-esteem is one non-cognitive trait that is gaining attention for being one of the key determinants shaping academic achievement,

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which is an indicator of cognitive development.[2] It is considered as an important attribute for health care professional to become successful.[3]Medical Education is quite demanding in terms long duration, lack oftime,vastness. Medical students experience various forms of stress dueto financial, and social pressures which could affect theirlevels of self-esteem.[4]There are no studies on self-esteem among medical students conducted in this region. so, through this study we wanted to assess the levels of self -esteem and factors which are associated with the levels of self-esteem.

Objectives:

1. To assess the level self-esteem among medical students of a private medical college in South India using Rosenberg Self-esteem scale
2. To find out the factors associated with the levels of self-esteem among the medical students of a private medical college in South India.

This is across-sectional observational study. The studywas conducted in a private medical college, Tumkur, Karnataka. Study was conducted among medical students of the college. The study was conducted after it got approved by the institutional scientific review board and ethics. Medical students of all the years and post graduate students from all the years pre-clinical, Para clinical and clinical subjects were included in the study The participants who gave written informed consent were included in the study. Total participants were 345, out of which UG students were 302 and PG were 43.

Thepre structured questionnaire was used to collect the socio demographic details, we used modified BG Prasad's scale for 2020 for socio economic class. Rosenberg Self-esteem scale (RSES) was used to assess the self esteem among the medical graduate and post graduate students. The RSES was developed by sociologist Morris Rosenberg.[5] It is a 10-item Likert-type scale with items answered on a four-point scale from strongly agree to strongly disagree. For items 1, 3, 4, 7, 10: Strongly Agree = 3, Agree = 2, Disagree = 1, and Strongly Disagree = 0. For items 2, 5, 6, 8, 9 (which are negative statements; hence reversed in score): Strongly Agree = 0, Agree = 1, Disagree = 2, and Strongly Disagree = 3.16,18 A total is obtained by adding these markings which ranges from 0–30. A score less than 16 indicates low self-esteem, more than 25 indicated high self-esteem and scores from 16 to 25 shows normal self-esteem in the respondents.

Hard copies were disseminated by the data collector team and class leaders. The questionnaire was self-administered. Questionnaire had two sections, first was to collect socio demographic variables age, sex, religion, socio economic status, marital status, place (Rural or Urban), other variables were year of study, Post graduate or graduate, in case of post graduate whether pre, para or clinical branches. Data was entered in MS excel.Descriptive and inferential statistical analysis has been carried out in the present study. Results were presented as percentages for categorical data. Significance is assessed at 5% level of significance. Chi-square test has been used to find the significance of study parameters on categorical scale between two or more groups.P value of less than 0.05 was considered significant. Epi Info was used for statistical analysis.

Results

Total participants under the studywere 345including both post graduate and undergraduate .215 (68.3%) of the participants werefemales,130 (37.68%) were males. Majority of them **182 (**52.7%) belonged to the age group 20-25 years, followed by 120 students (34.5%) were in 18-20 years age group, only 43 students (14.23%) were above 25 years of age.222(**64.34**%) belonged to urban area followed by 123 (35.65%)who were from rural area.Majority belong to class 2 i.e.,185 (53.62%) followed by class 3 97 (28.11%), 45 of them belonged to class 1 (13.06%). Class 4 had least number of study participants 18i.e.,5.21%**.** Only 14 were married and 331 (95.94%) were unmarried.Majority 240(69.56%) belonged toHindu religion, followed by Muslim 56 (16.23%) and Christian 28(8.11%), 21 belonged to other religionS

Table 1: Levels of self -esteem and associated factors among the participants under the study

Variable		Rses Scores			Total	P Value
		<16 N (%)	16-25N (%)	>25N (%)		
1. SEX	MALE	16 (12.3)	103 (79.23)	11 (8.46)	130	0.0142
	FEMALE	56 (26.04)	155 (72.09)	4 (1.86)	215	
2. TYPE OF COURSE	UG	66 (21.85)	226 (74.83)	10 (3.31)	302	0.036
	PG	6 (13.95)	32 (74.41)	5 (11.62)	43	
3. LOCATION	RURAL	25 (20.32)	93 (75.60)	5 (4.06)	123	0.672
	URBAN	47 (21.17)	165 (74.32)	10 (4.5)	222	
4. RELIGION	HINDU	48 (20.0)	188 (78.33)	4 (1.66)	240	0.980
	MUSLIM	12 (21.42)	40 (71.42)	4 (7.14)	56	
	CHRISTIAN	6 (21.42)	18 (64.28)	4 (14.28)	28	
	OTHERS	6 (28.57)	12 (57.14)	3 (14.28)	21	
5. MARITAL STATUS	MARRIED	5 (35.71)	8 (57.14)	1 (7.14)	14	0.0081
	UNMARRIED	67 (20.24)	250 (75.52)	14 (4.22)	331	
6. AGE	18-20	40 (33.33)	77 (64.16)	3 (2.5)	120	0.024
	20-25	29 (15.93)	148 (81.31)	5 (2.74)	182	
	>25	3 (6.97)	33 (76.74)	7 (16.27)	43	
7. SES SCALE	CLASS 1	8 (17.77)	35 (77.77)	2 (4.4)	45	0.012
	CLASS 2	35 (18.91)	144 (77.83)	6 (3.24)	185	
	CLASS 3	24 (24.74)	68 (17.10)	5 (5.25)	97	
	CLASS 4	5 (27.77)	11 (61.11)	2 (11.11)	18	

SELF ESTEEM

In the study 72 (20.86%) had low self-esteem, 258(74.78%) scored between (16-25) that shows normal self-esteem and only 16 (4.63%) scored >25 indicating high self esteem.

Among UG students low self-esteem was 21.85% whereas among PG'S low self-esteem was around 14%. The difference was found to be statistically significant.High self esteem was also more among PG students (11.62%) as compared to UG students (3.3%).The difference was found to be statistically significant.

Students with rural (20.37) urban(21.17) background had similar percentages of low self-esteem. Place of residence was not significantly associated with levels of self-esteem.

Married students under the study were having high level of low self-esteem(35.7%) when compared to unmarried (20.2%) which was found to be statistically significant.

The students aged between 18-20 years had highest level of self-esteem (33.3%), followed by students between 20-25 years of age which was about 16%, least was seen in students aged more than 25 years (7%). 16.27% of students aged >25 years had high self-esteem. The age was found to be significantly associated with level of self-esteem.

Low socioeconomic status class 4 and class 3 had high levels of low self-esteem which was 27.7%, 24.7%, followed by class 2(18.9%). Least levels are seen among class 1 (17%).

Low levels of self-esteem were significantly associated with socioeconomic status.

Students from other religion (28.5%) had low self-esteem followed by Christian and Muslim (21.42%). Least was seen among students belonging to Hindu religion (20%). Religion was not significantly associated with levels of self-esteem.

Discussion

Self-esteem refers to individuals overall sense of worth. Like our study findings with low self-esteem of (21%), the study conducted by Shrestha B in 2021 in Kathmandu[6] has low self-esteem of 19%. In a study conducted amongst medical students in Maharashtra by Aarif et al [7] the levels of low self-esteem were 21% which is consistent with our study findings.

Similar findings were seen in a study done across six different professional programs done in Caribbean health country with 21% of students having low self-esteem[8]. In other study involving nursing students by Chris E et al in Karnataka the prevalence of low self-esteem was 52% which is higher than our study[9].

In our study females had higher percentage of low self-esteem scores (12.3%) than males and which is contradictory to the finding from studies from Haryana by Virk A et al done in 2019 where males (9.6%) had high levels low self-esteem than females (7.2%)[10] and Maharashtra which had low self-esteem of 20% among male participants and only 15.75% among female participants[7]. But similar findings were seen in nursing students of Kathmandu where females had higher level of low self-esteem[6]

Unlike our study findings higher level of low self-esteem was found in age group of 21-25 years (19%) than 17-20 years age group, though the difference was not significantly in the study done by Aarif et al at Maharashtra in 2009[7]. Similar to this study, a study was conducted by Virk A et al at Haryana in2019 shows high level of low self-esteem in students aged more than or equal to 20 years compared to the students of less than 20 years of age which is contradictory to our findings.

Unlike our study where Hindus had low levels of low self-esteem study done at Haryana shows high levels of self-esteem among Hindus[10]. In a study done by Chris E et al Christians had higher self-esteem scores[9]

Contradictory to our study where high levels of low self esteem was found in lower socio-economic status classes a study in Haryana shows higher levels of low self esteem among high income students followed by Hindus and Muslims[10].

Limitations

In our study Response rate was very low. we did not include presence of psychiatric illness and parents background details like education, profession.

Conclusion

This study found that the majority of medical students had normal self-esteem. The factors such as sex of the student, age, marital status, type of course, socio economic status class were found to be significantly associated with the levels of self-esteem. Other factors like place of residence, religion were found to be insignificant.

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Review Article

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Tele-Dentistry And Public Health Dentistry: A Literature Review

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Abstract

Tele-dentistry has a history going back to 1994. The main concept of tele-dentistry proposes the application of information and communication technologies (ICT) to facilitate oral healthcare for geographically distant patients and/or practitioners. It also allows dental professionals to communicate with one another over long distances. It not only has the potential to increase accessibility of specialists, but also decreases time and cost associated with speciality consultations. The aim of this article is to present an overview of the uses of information and communication technologies in oral health.

Keywords: Public health dentistry, real-time video conferencing, telecommunications, tele-dentistry, telemedicine.

Introduction

There is a long history of the use of various tele-communication technologies in improving availability of a good quality of healthcare and in reducing inequalities in health. A link between health and tools of communication has always been there. A few examples, including the use of various sounds (drums, instruments), use of *quipu* (or speaking knot, a complex recording system fashioned from strings and historically used by various cultures in the region of Andrean South America), and the use of smoke signals (one of the oldest forms of long-distance communication) have all been used to exchange health informations, stories related to major calamities and noteworthy events such as spread of bubonic plague (black death) in European nations.[1.2]Though all these cannot be considered to be typical examples of telemedicine. The word *tele* has been derived from a Greek word which means "far away". Thus, telemedicine simply means "practice of medicine from a distance", and this term "telemedicine" was first mentioned in a newspaper article in 1927.[3]Telemedicine has now become a common term in healthcare due to a recent rapid introduction of electronic and communication technology into the healthcare[4] and a growing familiarity of patients with such technologies has now created an urgent need for access to information related to healthcare at one's convenience.[5] However, there is still no universally accepted, comprehensive definition of telemedicine. Out of all the definitions given in literature, the most fitting definition of telemedicine is the one developed by AAMC (Association of American Medical Colleges), which defines telemedicine as, "*the use of telecommunication technology to send data, graphics, audio, and video images between participants who are physically separated (i.e.,*

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at a distance from one another) for the purpose of clinical care[6,7]. Although tele-dentistry is still in a very early stage in its use by the dentists, but its inclusion as a branch of medicine allows it to fit very well into this definition of telemedicine.

What is Tele-dentistry?

Many explanations and elucidations of tele-dentistry can be found on reviewing the literature, and each of these highlights its specific aspect. In the year 1997, *Cook* described tele dentistry as "*the practice of using telecommunication technology to make a diagnosis and subsequently provide an advice on treatment from a remote distance.*"[8] Tele-dentistry is useful in providing consultation with dental specialists, supervising dental healthcare providers in remote areas and for their education through the use of various telecommunication tools like electronic health records, digital imaging, internet etc. Tele-dentistry is a combination of tools of telecommunication technology and the dentists and it involves exchanging clinical data (including images) from far-away areas for providing consultations and treatment planning.

The Need for Tele-dentistry

Tele-dentistry possibly has the potential to enhance availability of oral healthcare, improving the oral healthcare delivery, and to reduce costs related to dentistry by facilitating prompt diagnosis, well timed management of diseases and to reduce seclusion of healthcare providers by allowing regular peer-to-peer communications. Tele-dentistry can also reduce inequalities in availability of oral healthcare between urban and rural areas.[9] There are many barriers in providing access to a good quality of oral healthcare in the rural communities which includes the shortage of oral healthcare providers in these rural areas, a long travelling distance to reach the limited healthcare providers available and the scanty local resources.[10] Most of the rural communities do not have the financial and clinical resources needed to attract oral healthcare specialists. The patients who live in rural areas when referred to dental healthcare specialists (mostly in urban settings), have to travel long distances to reach them, which more often than not is expensive as well as time-consuming. Tele-dentistry has the potential to bridge this gap as it allows the oral healthcare providers of rural areas to take advice from urban dental specialists. [10] Currently, most of the tele-dentistry programs have their primary focus on distance management in administering oral healthcare in rural institutions, continuing dental education and learning programs and providing referral services after thorough tele-consultations. Tele-dentistry is still not used as a direct program for providing oral healthcare.[11]In order to allow such a widespread implementation of these tele-dentistry initiatives political support, in addition to implementation of appropriate health policies and strategies is a must.

Tele-dentistry Methodologies

There are two forms of tele-consultation.[12] First one is "real-time consultation", which uses direct online video communication between a dentist, a hygienist, and/or a patient from a remote area and a dental specialist from a larger community who will the provide the necessary support or supervision. Also, a very common form is "store and forwarding method", which uses electronic health records and videos available in the form of stored data which can then be retrieved and can then be scrutinised by an expert, who will then give his/her opinion. Real-time consultation allows a more in-depth discussion and a better personal communication when compared to the store and forwarding method. Store and forwarding method also has the potential to provide sufficient benefit for a wide range of applications, and is considered to be almost as effective as real-time consultationin presentation of cases.

In a classic real-time videoconferencing technique, special videoconferencing tools and internet connections are set up at both the hub site and the remote site. A major challenge in real-time videoconferencing visit is the timely cooperation between the representatives of the hub and the remote site. Fig.1 shows the process of communication between the remote site and the specialist clinical setup.[13] Teams of dentists at both sites must always work together to enable smooth processing of the tele-dentistry visit. The challenge begins with making the simultaneous appointments on both sites, progressing with patient information collection and transferring this information to the specialists, which then facilitates the "long-distance" real-time assessment of the patient, and ending with

facilitating future treatment and care. As the specialist cannot examine the patient himself or herself, he or she has to rely on the examination performed by the dental team at the remote site and so confidence and a good working relation must be established between the numbers of dental teams at both the sites. Proper training, practice, and patience are all essential for a satisfying outcome, just like any other learning process. A reliable network for tele-dentistry can be established with an effective hands-on training and repeated practice of dental team members at both the sites.

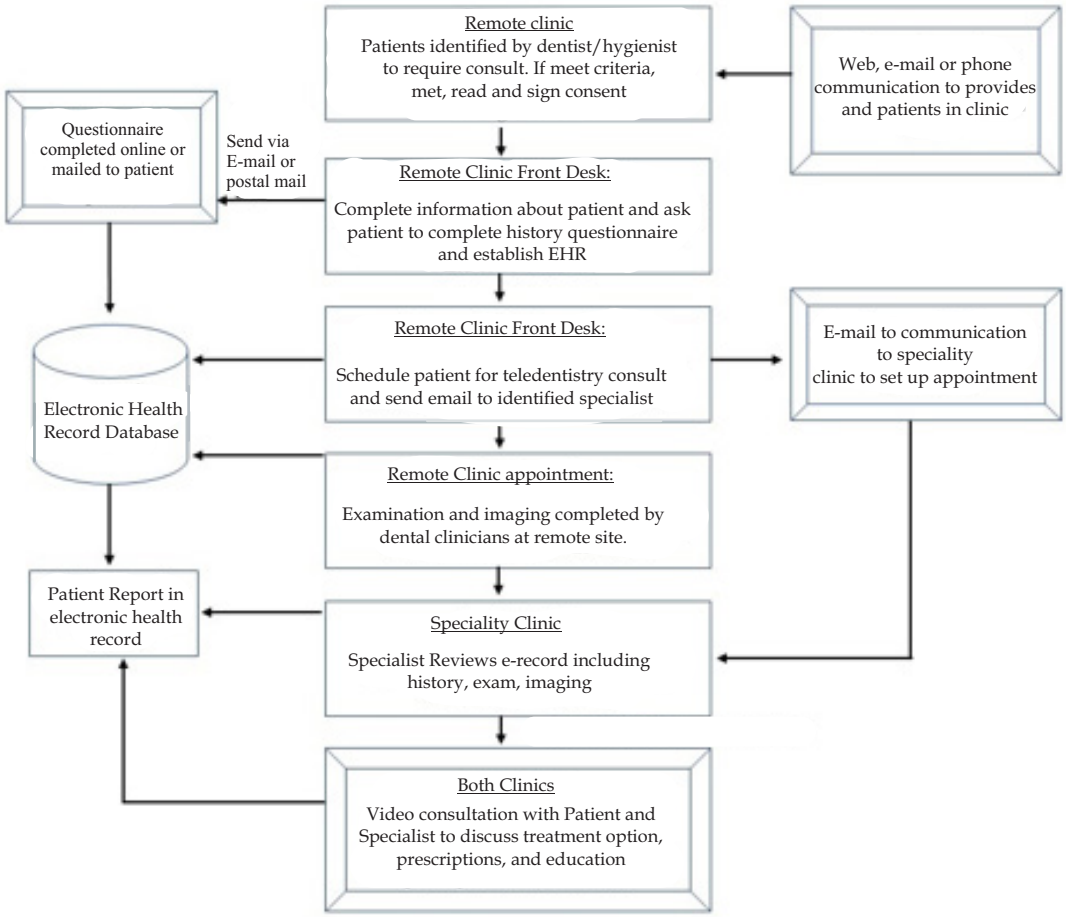

Fig. 1. Illustrating the process for communication between the remote site and the specialist clinical setup.

Tele-dentistry in Public Dental Health Services

Tele-dentistry allows for the dynamic dissemination of knowledge in the public health field of dentistry by using its applications such as tele-education and tele-assistance to achieve all these objectives and hence, acts as an instrument of standardisation, development, and equity.[14,16] The main advantages of tele-dentistry include reducing the waiting time and treatment costs. [20,21] Tele-assistance is a very helpful method which helps in delivery of health services and has the potential to enable the prompt distribution of information to the practitioners who are locally based and hence, improves their decision making capabilities. It also helps to provide consultation services in case a second opinion is necessary, to effectively prioritise the patients who require referrals, and to reinforce these locally based treatment centres.[19] Most of the dental practitioners and the patients have reported to experience more optimism and satisfaction regarding tele-dentistry and its inclusion into the present dental practices as there is a resulting possibility of saving time and a possibility of having faster access to dental care and treatment planning. [15,23] Tele-dentistry systems may prove to be very helpful in managing the patients with conditions such as, oral mucosal disease (stomatology and oral medicine)[24], periodontitis[20], malocclusions,

orthodontic disorders[25,26], temporomandibular joint disorders, and oral pain.[24] Tele-dentistry is a system that has not only reduced the costs related to dental care but has also enabled remote dental examinations in case an oral medicine ward is not available[18,23] and is especially useful to assist primary dental care providers.[15,17] It also has the potential to allow an easy access to efficient dental consultations. Additionally, it also enables the underprivileged public to receive treatment earlier, which also results in reduction of the burdens faced by such patients who would have to otherwise travel long distances to receive a dental consultation. [27,28] It was demonstrated that when these techniques of tele-dentistry were employed in experiments carried out in certain countries, there was a reduction of approximately 30% in the treatment costs when compared to those of traditional treatment techniques. These estimated savings may be the result of reduced salary bill of the dental therapists and also due the costs avoided by both the patients and the professionals towards travel and accommodation.[19,20] These financial resources and the time thus saved by tele-dentistry can be used to help the patients who are at a higher risks of suffering from oral diseases.In the present scenario when there are limited resources for dental services, tele-dentistry can prove to be a crucial contributing factor to reduce the existing oral health inequalities by reorienting public health services.[17]

Conclusion

In conclusion, tele0dentistry may prove to be a very practical and useful tool for dental public health providers as well as for the patients. Although, tele-dentistry does not have a very long history of use but surely it has a great potential for further development. Tele-dentistry can also prove to be useful for the training and continuing dental education of the professionals, for facilitating remote patient care, to enable exchange of information amongst health professionals, and also provides them orientation. It results in benefits such as reducing the waiting time for both general as well as specialised dental care, avoiding the expenses related to movements in seeking dental care, and hence saving the involved financial resources. In this way, it enables an improved access to quality dental care especially for patients who live in far-away areas or those who do not have access to specialists in their localities. It enhances peer-to-peer interactions amongst oral health care professionals and thus, improves the quality of the care being provided and also boosts satisfaction amongst patients. Tele-dentistry is a relatively new technique but it has animmense potential for continued growth and expansion in the current setting of public health care systems. In order to achieve this goal, an outstanding and serious governmental support is necessary, and strategic focused action plans are a must to not only improve the technological resources available, but also to increase the acceptance of these information & communication tools (ICT) among the general patient population and health professionals. In addition to this, the use of ICT requires increased training and continuing professional development for the general dentists, dental specialists, dental auxiliaries, nurses, and other oral health care professionals who deal with oral health issues. Furthermore, to enhance the adoption of tele-dentistry in public dental health services, these strategic action plans must form an inherent portion of the various public health policies, which must advocate tele-dentistry as an evidence-based and cost-efficient way of improving oral health.

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Review Article

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Post Mastectomy Wound Complications with or Without Neo-Adjuvant Chemotherapy: An Observational Study

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Abstract

Background: Breast cancer is the most common cancer diagnosed in women and the second most common cause of death from cancer among women in the world. Diagnosis is usually made by the clinical examination, USG Breast & mammography, and confirmed by FNAC, true cut biopsy, and incision biopsy.

Materials and Methods: The study was an observational study which was carried out at tertiary care Medical Centre (BMCH) Day today patient admitted in Department of Surgery with a breast lump and was diagnosed as breast carcinoma, took neoadjuvant chemotherapy or not and operated. The present study was done to observe the incidence of wound complications after mastectomy following neoadjuvant chemotherapy within 6 weeks and to compare the incidence of wound complications that occurs after breast surgeries following neo adjuvant chemotherapy with the same without neoadjuvant chemotherapy.

Results: The mean age of this study population was 50.8 yrs. Histological type distribution showed that invasive ductal carcinoma consists of 64 patients (80%). Histological grade distribution showed that most of the patients were Grade 2 (76.25%). Most of the patients had undergone modified radical mastectomy. About 77 (96.25%) patients underwent a modified radical mastectomy of which 36 (46.73%) took neoadjuvant chemotherapy and 41 (53.24%) were not taken neoadjuvant chemotherapy. In our study, we found that among the 36 patients who received neoadjuvant chemotherapy 27 patients (75%) developed complications after surgery whereas it was much lesser in patients without neoadjuvant chemotherapy which was 21 among 44 patients (47.7%). It has been found that the chance of complications is slightly more in the case of neoadjuvant chemotherapy patients.

Conclusion: It was concluded that post-operative complications of MRM included wound dehiscence, seroma, surgical site infection, hematoma, altered sensation, and pain. Seroma formation is the most frequent and common complication after mastectomy. The present study showed that the rate of wound complications after mastectomy was slightly high in the case of patients taking neo adjuvant chemotherapy.

Keywords: Breast carcinoma, neoadjuvant chemotherapy, mastectomy, complications.

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Introduction

Breast cancer is the most common cancer diagnosed in women, accounting for more than 1 in 10 new cancer diagnoses each year. It is the second most common cause of death from cancer among women in the world.[1] Breast carcinoma is the most common of the all cancer and is the leading cause of cancer death in women. In 2004, breast cancer caused 519,000 deaths worldwide (7% of cancer deaths; almost 1% of all deaths).[2] Breast cancer is the most frequent cancer among women in the world with an estimated 1.67 million new cancer cases diagnosed in 2012 which constituted about 25% of all cancers.[3] It is the 2nd leading cause of cancer related death. One million case diagnosed in one year.

In India age adjusted incidence rate is 25.8/10000 and 95/10000 in UK but mortality rate is high in India, because majority of patient in India present at the stage 3 or 4 which could be due to lack of screening program and lack of frequent self-examination or breast awareness. There is a significant increase in cancer related morbidity and mortality in India earlier, cervical cancer was the most common and leading cause of cancer death, but now breast cancer is the main common cause. The survival rate improves with early diagnosis. The tumour tends to spread lymphatically and haematologically leading to distant metastasis and poor prognosis. This explains and emphasizes the importance of breast cancer screening programs.[1,4, 5]

Diagnosis is usually made by the clinical examination, USG Breast & mammography and confirmed by FNAC, true cut biopsy and incision biopsy. Prognosis and treatment is depends on: stage, lymph node status, estrogen and progesterone receptor, measure of tumour proliferation status such as ki-67 growth factor analysis and oncogene; women age, general health and menopausal status and the type of breast cancer. Tissue biopsy is an important step in the evaluation of breast cancer patient. There are different ways to take a tissue specimen, and these include fine needle aspiration cytology, core biopsy (Truecut), and incision or excision biopsy.[6-8]

Several treatment options are available for breast carcinoma depending upon the stage of disease. The complete removal of the tumour is definitive therapy but it is not possible every time. So several treatment options are available .neo adjuvant chemotherapy for breast cancer to shrink which is not operable in its current status, so it can be surgically removed. When there is a risk for metastatic relapse, systemic therapy is indicated in the form of hormonal therapy, chemotherapy, targeted therapy, or any combination of these. In locally advanced disease, systemic therapy is used as a palliative therapy with a small or no role for surgery.[9-11]

Neo adjuvant can be considered as treatment option for any patient who is expected to require systemic treatment. Therefore there is a need to understand post- operative complications in recipient of neo adjuvant chemotherapy. Neutropenia is most common side effect of chemo therapeutics; this has raised concerns regarding post- operative wound complications. Various post mastectomy wound complication occur as follows. The most common direct post-surgical complications following MRM are the formation of a hematoma, the infection of the surgical wound and the formation of a seroma. These direct post-surgical complications can, at least in part, be attributed to the drainage of the surgical wound.[12-13]

Present study was done to observe the incidence of wound complications after mastectomy following neoadjuvent chemotherapy within 6 weeks and to compare the incidence of wound complications that occurs after breast surgeries following Neo adjuvant chemotherapy with the same without neo adjuvant chemotherapy.

Materials and Methods

The study was an observational study which was carried out at tertiary care Medical Centre (BMCH) Day today patient admitted in Department of Surgery with breast lump and was diagnosed as breast carcinoma, took neo adjuvant chemotherapy or not and operated. They were observed the patients to search for wound complications occur or not. Period of study was between May 2019 to November 2020.

Inclusion Criteria:

1. Female/Male patient with breast lump diagnosed as breast carcinoma by pathological examination.

2. Stage of disease which require mastectomy or breast conserving surgery.

Exclusion Criteria:

1. Recurrent cases
2. Patient who has taken previous chemotherapy/radiotherapy

A written informed consent was taken from all patient included in the study. A detailed history taking, through clinical examination was done for these patients. The data collected like lab investigations, radiological investigations Chest X-ray, Echo, Bone scan, USG abdomen; tissue diagnosis by true-cut biopsy, FNAC and histopathological examination of incisional biopsy of breast tissue and axillary lymph node. Administration of chemotherapy prior to or after breast surgery was also noted. Descriptive statistics was done comparison of non parametric data by using Chi square test, Mann Whitney test. Parametric data was compared by using Students T test.

Results

This study had included total 80 patients. Among the 80 patients 36 patients (45%) got neoadjuvant chemotherapy and 44 patients did not get neoadjuvant chemotherapy. All the patients were followed up after operation for 6 weeks and the complications regarding surgery (mastectomy) was tabulated and result analyzed [Table 1].

Table 1: Age distribution of study population

Age group(yrs)	Patient No. (%)	Neoadjuvent (%)	No neoadjuvent (%)
<40	22 (27.5%)	14 (63.36%)	8 (36.36%)
>40	58 (72.5%)	22 (37.93%)	36 (62.06%)

In this study 58 (72.5%) patients were more than 40 yrs. Among these patients 22 patients which was 37.9% of these group, got chemotherapy before operation and 22 patients (27.5%) were less than 40 years age, included 14 (63.36%) patients who got neoadjuvent chemotherapy [Table 1]. About 36 patients among those 58 patients which were 62.06% of this group did not get have chemotherapy before operation and 8 (36.36%) patients among the 22 patients who did not got neoadjuvent chemotherapy [Table 1].

Table 2: Histological type distribution of study population

Histological type	No of patients	Percentage (%)
IDC Nos.	64	80
Other	16	20
Histological grade		
Grade 1	8	10%
Grade 2	61	76.25%
Grade 3	11	13.75%

Among the study population, 64 patients were invasive ductal carcinoma type where as other 16 patients included invasive lobular 10 patients, medullary carcinoma 3 patients, mucinous carcinoma 2 patients and metaplastic carcinoma 1 patient. Among the study population 61 patients were diagnosed with grade 2 tumor, followed by 11 patients of grade 3 and 8 patients of grade 1 [Table 2].

Table 3: Distribution of patients according to type of mastectomy

Type of surgery	No of patients		Neoadjuvent given	Neoadjuvent not given
	no	Percentage (%)		
Modified radical mastectomy	77	96.25	36(46.73%)	41(53.24%)
Toilet mastectomy	3	3.75	0	3

All the 80 patients were underwent mastectomy. About 77 patients were underwent modified radical mastectomy and 3 patients need toilet mastectomy [Table 3].

Table 4: Distribution of patients according to post operative complications

Complications	No of patients	Percentage (%)
Yes	48	60
No	32	40
Seroma	27	56.25
Wound infection	8	16.67
Skin flap necrosis	6	12.5
Wound dehiscence	3	6.25
Upper limb lymph edema	4	8.33
Hematoma	0	0
Venous thromboembolism	0	0
Injury to vital structure	0	0
Stuart Treves Syndrome	0	0

Among the 80 post operative patients 48 patients had developed different type of post operative complications where as 32 patients discharged and followed up without any visible complications. Among the post operative complication patients, it was noted that most common post operative complications was seroma formation. Among the 48 patients 27 patients (56.25%) developed seroma formation, 8 patients (16.67%) wound got infected, 6 patients (12.5) skin flap got necrosed, 3 patients (6.25%) wound dehiscence occurred and rest 4 patients (8.33%) developed upper limb lymph edema [Table 4].

Table 5: Distribution of neoadjuvant chemotherapy among patients with post operative complications (n=48)

Complications	No of patients	Neo-adjuvant	No neo-adjuvant
Seroma	27	15(55.55%)	12(44.44%)
Wound infection	8	5(62.5%)	3(37.5%)
Skin flap necrosis	6	3(50%)	3(50%)
Wound dehiscence	3	1(33.33%)	2(66.6%)
Upper limb lymph edema	4	1(25%)	3(75%)
Hematoma	0	0	0
Venous thromboembolism	0	0	0
Injury to vital structure	0	0	0
Stuart Treves syndrome	0	0	0

Among the 27 patients producing seroma formation, 15 (55.55%) patients taken neoadjuvent chemotherapy and 12 (44.44%) patient not take any neo adjuvant chemo therapy. Among the 8 patients producing wound infection, 5(62.5%) patients taken neoadjuvant chemotherapy and 3(37.5%) patients not take any neo adjuvant chemo therapy. Among the 6 patient producing skin flap necrosis, 3(50%) patients taken neoadjuvant chemotherapy and 3(50%) patient not take any neo adjuvant chemo therapy. Among the 3 patients producing wound dehescence, 1(33.33%) patient had taken neoadjuvant chemotherapy and 2(66.66%) patient did not take any neo adjuvant chemo therapy. Among the 4 patients producing upper limb lymphadenoma, 1(25%) patient had taken neoadjuvent chemotherapy and 3(75%) patients did not take any neo adjuvant chemo therapy [Table 5].

Discussion

In present study total 80 patients with breast carcinoma were included. All were female patient and no male patient seen during my study. Breast carcinoma is strongly related to age and more common in female. In my study it is also seen that 58 (72.5%) are above 40 yrs and 22 (27.5%) are below 40 yr. Age specific incidence rate highly increase from 35 yrs to 39 yrs, then rise further age 65 yrs to 69 yrs, drop slightly for aged 70 yrs to74 yrs of women, then steadily to reach an overall peak in the age 85+ age group. In my patient group age group below 40 yrs. Mean age of this study population is 50.8 yrs. In the study done by Vinod Raina et al[14] showed 49.7% of cases occurred in less than 45 years and in the study done by Sunita Saxena et al[15] of New Delhi reported that the median age of occurrence was 47.8 years which is similar to our study.

The commonest histological type in our study is invasive ductal carcinoma consists 64 patients (80%). In the study done by Vinod raina et al [14], Meneka Ds lokuhetty[16], Lobana et al[17] were respectively 92.8%, 86.3% and 83.8% which is almost similar to our study.

In our study most of the patients were grade 2(76.25%). It is similar to the study done by Lobana et al[17]. Stage of a cancer does not change over time, even if the cancer progress. Modified radical mastectomy and axillary clearance is the most the most common surgical procedure performed for early

breast carcinoma. In the present study 77 (96.25%) patient undergone modified radical mastectomy of which 36(46.73%) taken neo adjuvant chemotherapy and 41(53.24%) are not. and 3(3.75%) undergone toilet mastectomy who are not taken any neo adjuvant chemotherapy.

Post operative Complications

Seroma formation is the most common complication seen after mastectomy (MRM or toilet mastectomy). In the present study seroma formation had occured in 27 patients (33.75%). A study done by Naman Chandrakar et al[18] showed seroma formation in 26% of patients, a study by Wedgwood KR et al[19] showed 25% seroma formation, and a study by Dahri FJ et all[20] showed 33.33% seroma formation in post operative cases, which was almost similar to our study.

Superficial surgical site complications is the another notable complications in our study include 8 patients (10%) of the study population. Study done by Ashok Kumar et al[21] showed 6.66% surgical site infection, Decar's et al[22] and Vilar-Compte et al[23] showed respectively 1.8%, and 20.5% surgical site infection. Skin flap necrosis is another complication includes 6 patients (7.5%) among the study population. Study done by Shaikh FB et al[24], Shaikh K et al[25], and Alam Jan W et al[26] showed respectively 5.1%, 7%, and 3.9%. Wound Dehiscence was another complication occurred in 3 patients (3.75%). The study done by Naman Chandrakar, Raju Kar Sindhe[18] and Vilar-Compte et al[23] showed respectively 3.3% and 11.2%. Our study was almost similar to Namanchandrakar study[18]. In our study we found 4 patients (5%) having upper limb lymphedema. It is a least found complication in other studies.

In the present study we have found among the 36 patients received neoadjuvant chemotherapy 27 patients (75%) developed complications after surgery where it is much lesser in patients without neoadjuvant chemotherapy which was 21 among 44 patients (47.7%). It has been found that the chance of complications is slightly more in case of neo adjuvant chemotherapy patients.

Limitations

A relatively small study population might not have reflected the manifestations in the whole population, so the study may be related with a large population. Some other risk factor could have been studied, but due to lack of availability of infrastructure and time, they had to be omitted from the study.

Conclusion

It was concluded that post-operative complications of MRM included wound dehiscence, seroma, surgical site infection, hematoma, altered sensation and pain. Seroma formation is the most frequent and common complication after mastectomy. Many other complications are seen in the present study were skin flap necrosis, wound infection, wound dehiscence, and upper limb lymphedema respectively. The present study showed that the rate of wound complications after mastectomy was slightly high in case of patient take neo adjuvant chemotherapy.

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Original Article

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Study of Prevalence of Appendicitis in children of Bihar Population

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Abstract

Background: Appendicitis is quite common surgical emergency in children because it is longer in children ranges from 2-20 cm than adult 6-10 cm. Moreover it is most constricted part of GIT like pharynx.

Method: 80 children (40 male and 40 females) below 10 years having symptoms of appendicitis and confirmed byUSG/ST scan were operated by General anaesthesia and dissected part was sent to histo-pathology test to rule out the exact pathology.

Results: Highest incidence of acute appendicitis was observed in both sexes 23 (57.5%) male, 20 (50%)female and least number of perforated appendicitis 10 (25%) in male, 4 (10%) in female was observed.

Conclusion: Present pragmatic study of appendicitis having acute, chronic and perforation will help the surgeon to treat efficiently to avoid morbidity and mortality in children.

Keywords: Chronic, acute, perforated, Mac Burney's point USG/CT

Introduction

Appendicitis and pharynx are more constricted part of GIT hence they more prone to get infected [(1)]. In children the length of appendicitis is proportionally more than adults because there is no any other lymphatic organ in children except thymus. Appendicitis is quite common disease in children due to lack of development of peritoneum and omentum[(2)]. It is suggested that, in the childhood there is peak of development of lymphoid tissue which leads to increased liability of appendix to obstruct [(3)]. As lymphoid organ is called solder of the abdomen due to lack of any other lymphoid organs except thymus more responsibility of defence is with appendix [(4)], hence it has to change its position to combat with infection with its extreme length leads to appendicitis. If undiagnosed or delayed approach to medical aid causes perforation of appendix which alarms the surgical intervention.

Material and Methods

80 children aged between 5 to 10 years (40 male and 40 females) visited to surgery department of Mata Gujri Memorial Medical College hospital Kishanganj – 855107, Bihar were studied.

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Inclusive Criteria: Children of both sexes below ten years having the symptoms of appendicitis and confirmed by USG and / CT scan were selected for study.

Exclusion Criteria: Children diagnosed as Mickels diverticulum, volvulus,and malignancyin right iliac fossa children having any congenital anomalies were excluded from the study.

Method: Every patient presented abdominal pain with Mac Burney's tenderness; Appendicitis was confirmed by USG/CT scan. Routine blood examination was carried out to rule out any other clinical manifestations and dissected appendix was sent to histo-pathology liberty

Duration of study was August-2021 to July-2022.

Statistical analysis: Types of appendicitis in both sexes were classified with percentage. The statistical analysis was carried out in SPSS software. the ratio of male and female children was 1:1.

Observation and Results

Table-1: Prevalence of appendicitis in male children

(a) Perforated appendicitis – 7 (17.5%) were aged between 5-6 years, 3 (7.5%) were aged between 9-10 years

(b) Acute appendicitis – 10 (25%) were aged between 5-6 years, 8 (20%) were aged between 7-8 years, 5 (12.5%) were aged between 9-10 years

(c) Chronic appendicitis – 2 (5%) were aged between 5-6 years, 2 (5%) were aged between 7-8 years, 3 (7.5%) were aged between 9-10 years

Table-2: Prevalence of appendicitis in Female children (aged between 5 to 10 years) –

(a) Perforated appendicitis – 3 (7.5%) were aged between 5-6 years, 1 (2.5%) were aged between 9-10 years

(b) Acute appendicitis – 7 (17.5%) were aged between 5-6 years, 11(27.5%) were aged between 7-8 years, 2 (5%) were aged between 9-10 years

(c) Chronic appendicitis – 6 (15%) were aged between 5-6 years, 7 (17.5%) were aged between 7-8 years, 3 (7.5%) were aged between 9-10 years

Table 1: Prevalence of appendicitis in male children (aged between 5 to 10 years)
No. of patients: 40

Sl. No	Types of Appendicitis	Age group	No. of	Percentage (%)
1	Perforated appendicitis	a) 5-6 yrs	7	17.5
		b) 9-10	3	7.5
2	Acute appendicitis	a) 5-6 yrs	10	25
		b) 7-8 yrs	8	20
		c) 9-10	5	12.5
3	Chronic Appendicitis	a) 5-6 yrs	2	5
		b) 7-8 yrs	2	5
		c) 9-10	3	7.5

Table 2: Prevalence of appendicitis in Female children (age between 5 to 10 years)

Sl. No	Types of Appendicitis	Age group	No. of children (40)	Percentage (%)
1	Perforated appendicitis	a) 5-6 yrs	3	7.5
		b) 9-10	1	2.5
2	Acute appendicitis	a) 5-6 yrs	7	17.5
		b) 7-8 yrs	11	27.5
		c) 9-10	2	5
3	Chronic Appendicitis	a) 5-6 yrs	6	15.1
		b) 7-8 yrs	7	17.5
		c) 9-10	3	7.5

Discussion

Present study of prevalence of appendicitis in Bihar were studied, Children – In the study of male children 7 (17.5%) aged between 5-6 years, 3 (7.5%) were aged between 9-10 years had perforated appendicitis. In acute appendicitis 10 (25%) were aged between 5-6 years, 8 (20%) were aged between 7-8 years, 5 (12.5%) were aged between 9-10 years. In the case of Chronic appendicitis – 2 (5%) were aged between 5-6 years, 2 (5%) were aged between 7-8 years, 3 (7.5%) were aged between 9-10 years (Table-1). In females below ten years – In the case of perforated appendicitis 3 (7.5%) were aged between 5-6 years, 1 (2.5%) were aged between 9-10 years. In the case of acute appendicitis – 7 (17.5%) were aged between 5-6 years, 11(27.5%) were aged between 7-8 years, 2 (5%) were aged between 9-10 years. In chronic appendicitis – 6 (15%) were aged between 5-6 years, 7 (17.5%) were aged between 7-8 years, 3 (7.5%) were aged between 9-10 years (Table-2). These findings are more or less in agreement with previous studies [5][6][7].

The percentage of perforated appendicitis in male children was 25% while in female children it was just 10% and in acute appendicitis 57% in male children while in female children it was 50%. It clearly indicates that, severity and medical emergency of appendicitis is more in male children than female children [8]. In the children of both sexes aged between 5-6 years having perforated appendicitis can cause serious complications such as peritonitis and abscess formation which increases morbidity and long stay at hospital, hospital cost too [9]. Because of delay in diagnose and mis-interpretation of history and physical examination hence radiological study becomes ultimate diagnostic factor for appendicitis in children [10].

Abdominal pain is the most common presenting symptoms followed by vomiting fever and anorexia on examination localised right lower quadrant tenderness predominate over diffuse tenderness. Other physical signs include involuntary guarding, rebound tenderness and temperature greater than $37^{O}c$[11]. Increased WBC count, and elevated neutrophil count is one of the laboratory diagnoses but c-reactive (CBP) is non-specific. It has sensitivity from 43% to 92% only in children appendicitis [12], hence ultimately radiological (USG/CT scan) are decisive or confirmatory factors.

Summary and Conclusion

Present study of prevalence of appendicitis in children below ten years had incident of acute appendicitis and least incidence of perforated appendicitis. It needs proper physical examination complete blood examination (CBC count) study and ultimately radiological examination to confirm the appendicitis in children. Delayed approach to medical aid will causes higher rate of morbidity and mortality.

Limitation of study – Owing to tertiary location of research centre, small number of patients and lack of latest techniques we have limited findings and results.

This research paper was approved by Ethical committee of Mata Gujri Memorial Medical college Kishanganj – 855107 Bihar

Conflict of Interest: No

Funding: No

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Original Article

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Study of Hearing loss in Diabetes Mellitus in Maharashtra Population

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Abstract

Background: High blood glucose levels are found to derange the vessels found in the stria vascularis and adjacent nerves thus it results into diminished ability to hear Early diagnosis and treatment can prevent the severity or permanent hearing loss.

Method: 40 adult patients aged between 30 to 50 years were studied by pure tone audiometry. By audiometry the degree, type and configuration of hearing was assessed. Ear examination was done by otoscopy followed by pure tone audiometry.

Results: 20 (50%) patients had moderate, 12 (30%) had moderate severe, 8 (20%) severe hearing loss. The associated clinical manifestations were 13 (32.5%) parasthesia, 10 (25%) skin disease, 8 (20%) visual problems, 9 (22.5%) lack of sleep.

Conclusion: This pragmatic study with different degree of hearing loss will be helpful to ENT surgeon to assess the severity and treat efficiently to prevent the complications of hearing loss.

Keywords: Otoscopy, Audiometry, HbsA^{1}c, Maharashtra

Introduction

As per WHO, 5% of the world population (360 million) of Diabetes Mellitus (DM) is suffering with hearing loss. It is also reported by WHO that, half of the hearing loss is preventable [(1)]. The pioneer to associate between DM and hearing loss was Jardo in 1857. He observed hearing loss in Diabetic patients. He concluded loss of hearing is one of the symptom of DM [(2)(3)]. It is reported that DM has adverse effect on hearing. It varies from 13.3 to 60% globally [(4)(5)]. Pathogenesis of hearing loss in DM is due to mitochondrial mutation derangement, neuropathy, microangiopathy. DM complications are associated with abnormal serum cholesterol and serum creatinine which impairs the vascularity to vestibulo-cochlear apparatus and leading to hearing loss in DM patients.

Moreover in diabetic microangiopathy diffuse thickening of basal membrane endothelium is considered to be the one of causal factor that leads to hearing loss. It is also reported that hyperglycemias result in to myelinic degeneration and axonal damage of nerves related to auditory apparatus may lead hearing loss in DM patients [(6)], but these

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factors are still un-clear to illustrate the facts due to variable hyperglycaemic parameters. Hence attempt was made to rule out the severity and associated clinical scenario in these DM patients having hearing problems.

Material and Methods

40 adult patients aged between 30 to 50 years regularly visiting to ENT department Vedantaa Institute of Medical Sciences Dahanu, Palghar (dist)-401606 were studied.

Inclusive Criteria: Patients having hearing loss having DM, diagnosed as per the national diabetes data group and WHO (world health organisation) diagnostic criteria.

Exclusion Criteria: The patients having history of Noise induced hearing loss and history of cognitive function disability, meniere's disease, labyrinthinitis, immune- compromised patients were excluded from study.

Method: Two methods were used for hearing assessment (1) Ear examination, (2) Pure tone audiometry. By audiometry the degree, type and configuration of hearing loss was documented. Otoscopy was used for general ear examination. This was followed by pure tone audiometry, in which manual audiometry was used. The instrument was made to deliver the pure tone of different variable frequency and various intensity using ear phones.

Duration of study was March–2020 to September–2022

Statistical analysis: Various grades of hearing loss and associated clinical manifestations were classified with percentage. The statistical analysis was carried out using SPSS software. The ratio of male and female was 2:1.

Observation and Results

Table-1: Classification based on hearing threshold 26-40 decibel mild, 41-55 decibel Moderate, 56-70 decibel moderately severe, 71-90 decibel severe, >91 is profound.

Table-2: Distribution of patients with hearing loss – 20 (50%) moderate, 12 (30%) moderately severe, 8 (20%) severe

Table-3: Associated clinical manifestations hearing loss in DM patients- 13 (32.5%) parasthesia, 10 (25%) skin disease, 8 (20%) visual problems, 9 (22.5%) lack of sleep.

Table 1: Classification based on the hearing threshold

Sl No	Decibels	Degree of hearing loss
1	26-40	Mild
2	41-55	Moderate
3	56-70	Moderately severe
4	71-90	Severe
5	> 91	Profound

Table 2: Distribution of patients with hearing loss

(No. of patient: 40)

Sl No	Detail of degree of hearing loss	No. of patients	Percentage (%)
1	Moderate	20	50
2	Moderate severe	12	30
3	Severe	08	20

Table 3: The associated clinical Manifestations in hearing loss in DM patients

Sl No	Details of Clinical Manifestations	No. of patients (40)	Percentage (%)
1	Parasthesia	13	32.5
2	Skin disease	10	25
3	Visual problems	8	20
4	Lack of sleep	9	22.5

Discussion

In present study of hearing loss in DM patients of Maharashtra 20 (50%) had moderate, 12 (30%) were moderately severe, 8 (20%) had severe hearing loss (Table-2). The associated clinical manifestations were 13 (32.5%) had parasthesia, 10 (25%) had skin diseases, 8 (70%) had visual problems 9 (22.5%) had lack of sleep (Table-2). These findings are more or less in agreement with previous studies [7][8][9].

Skin disease observed in the present study involved prurits, urticaria, angioderma, dermatitis etc. The visual problem included blurred vision due to increased intra-ocular pressure; sleep disorders included difficulty in falling asleep, early awake (or rise) in the morning.

Hearing loss in DM patients due to micro-vascular insufficiency of the cochlea, like sclerosis of internal auditory artery, thickened vessel walls of stria vascularis basilar membrane, damage to outer sheath of cochlear nerve and atrophy of spinal ganglion [10]. It was reported that, there is a significant correlation between hearing loss and hyperglycemias. The hearing impairment is sensorineural type because hearing loss was found in both air and bone conduction. Since sensorineural hearing loss is a gradually progressive and the threshold for hearing was greater in higher frequency. Duration of DM also increases the severity of sensorineural hearing loss. Moreover age is also confounding factor, but DM is alone responsible for loss of hearing in young and adult patients.

It was also reported that majority of hearing loss patients with DM had renal and Urinary tract infection complication [11].

In the DM patients due to hyperglycaemia there is increased viscocity in blood flow that leads to ischemia, infarction to the respective organs. There is ischemia or infarction to cochlear apparatus which contains endolymph and perilymph, which are vital part of auditory pathway.

Although presbycusis is observed in elderly patients but bilateral hearing loss was observed in DM patients because physiological degeneration becomes accelerated in DM patients. Hence hearing loss problems in the elderly patients has to be investigated for type-II DM and the severity of hearing can be easily assessed.

Summary and Conclusion

Present study of hearing loss in Maharashtra population. It is mandatory for every clinician to explain the consequences and risk factors of DM, if any onset of hearing loss among DM patients. Detailed history of central nervous system, ear examination has to done along with related blood examination in DM patients having hearing loss. This study demands further hormonal, genetic, nutritional, immunological studies, as DM is a hormonal disease. The quantum of release of hormone, duration of release of hormone is yet to be known; hence pathogenesis of DM is still un-clear.

Limitation of study: Due to tertiary location of research centre, small number of patients, lack of latest technologies we have limited findings and results.

This research work is approved by Ethical committee of Vedantaa Institute of Medical science, palghar (dist), Dahanu, Maharashtra-401606.

Conflict of Interest: No

Funding: No

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Original Article

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A Longitudinal Study on Oral Potentially Malignant and Malignant Lesions in a Tertiary Care Teaching Hospital

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Abstract

Objectives: This study aims to qualitatively and quantitatively over five years using a clinical spectrum of presentation and frequency distribution, prevalence, and malignant transformation rates of Potentially malignant disorders.

Methods: This study follows a longitudinal prospective study design which was conducted in the Department of Oral Medicine, Oral Diagnosis and Radiology, at SCB Dental College and Hospital, Cuttack over 5 years, from January 2013 to December 2017.

Results: The frequency of OPMDs was 55% with 36.88% males. The most and least frequently encountered OPMDs included Pouch keratosis (30.96% of OPMDs) and Discoid Lupus Erythematosus (0.002% of OPMDs). The mean age of malignant transformation was 41 years with a male predilection (68%) and was largely habit associated (72%). Over the 5 years, the highest rate of malignant transformation was observed for actinic cheilitis (20.66%) and the least for oral lichen planus (0.35%).

Conclusion: The significantly higher rate of transformation noted in our population can be attributed to late presentation for treatment, rampant production and continued use of smokeless forms of tobacco. To the best of our knowledge, this study is one of the few to recruit a large population presenting with varied lesions.

Keywords: Potential malignant disorders, Malignant lesions, Head and neck cancer.

Introduction

Potentially malignant disorders (PMDs) of the oral mucosa, with the risk of conversion to oral squamous cell carcinoma (OSCC), are described in the literature as 'pre-cancer'[1,] 'precursor lesions'[4], 'premalignant', 'intraepithelial neoplasia'[5], and 'potentially malignant'[6]. The clinical concept of malignant transformation in oral mucosa has been proposed for more than 100 years. Sir James Pagetfirst described the malignant transformation of an oral lesion into tongue carcinoma in 1870.[7] Schwimmeralso reported the same finding in 1877. [8] Several years later, the term "potentially malignant disorders" [6] was defined by the World Health Organization (WHO) as the risk of malignancy is present in a lesion or condition either during the time

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of initial diagnosis or at a future date. WHO earlier has also classified PMDs into two subgroups[9] as follows: a) precancerous lesion, a benign lesion with morphologically altered tissue, which has a greater than normal risk of transforming into malignancy; b) precancerous condition, a disease or patients' habit that does not necessarily alter the clinical appearance of local tissues but is associated with a greater than normal risk of precancerous lesion or cancer development in that tissue.

Despite the ability to identify PMD, clinicians have been unable to predict the behaviour of lesions or quantify the risk of malignant transformation. Overall estimates of outcomes are mostly anecdotal and retrospective. Moreover, the natural history of PMDs is, unfortunately, not only inconsistent but also unpredictable.This study aims to address the above shortcoming qualitatively and quantitatively over 5 years using the clinical spectrum of presentation and frequency distribution, prevalence, and malignant transformation rates respectively, following a longitudinal prospective study design.

Material and Methods

The present longitudinal study was conducted in the Department of Oral Medicine, Oral Diagnosis and Radiology, at SCB. Dental College and Hospital, Cuttack.The period of study was 5 years, from January 2013 to December 2017. This study aims:

- To observe the clinical spectrum of the presentation of OPMDs
- To document the 5-year frequency distribution of various OPMDs and malignant lesions of the head and neck region
- To estimate the prevalence of these lesions in the presenting population
- To observe the gender predilections of the above OPMDs and malignant lesions
- To estimate the malignant transformation rates of various OPMDs into OSCC
- To put forth a comparative evaluation of malignant transformation rates amongst the studied OPMDs
- To calculate the net 5-year cancer burden

Patients presenting with any OPMD as per the new classification proposed by Sarode et. al[10] were included in the study. Also included were patients who presented with malignant pathologies of the head and neck region. The present follow-up study was based on clinical, cytological, histopathological, radiographic, haematological or other needful investigations, all part of the routine treatment and follow-up protocol. The follow-up time for this study is defined as the duration between the initial diagnosis and the occurrence of confirmed oral cancer. Institutional Review Board recommended that ethical approval was not deemed necessary as protocols adopted were part of routine patient care and follow-up. The patients were treated under the domain of implied consent. However, due information was provided to each patient about the nature of the disease, treatment protocols and its effects.

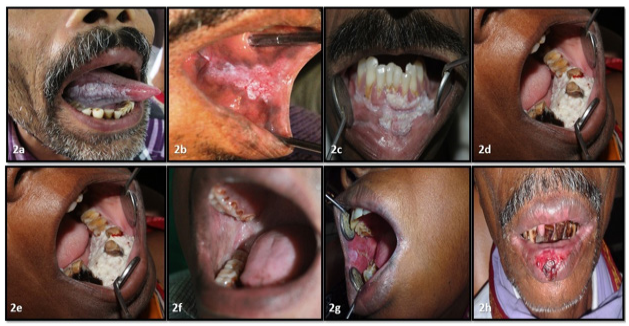

Figure 1: Spectrum of clinical presentation of various OPMDs; 2a: Homogenous Leukoplakia, 2b: Nonhomogenousnodulo-speckled Leukoplakia, 2c: Verrucous Leukoplakia, 2d: Proliferative Verrucous Leukoplakia, 2e: Oral Submucous Fibrosis, 2f: Tobacco pouch keratosis, 2g: Erosive Oral Lichen Planus, 2h: Actinic Cheilitis

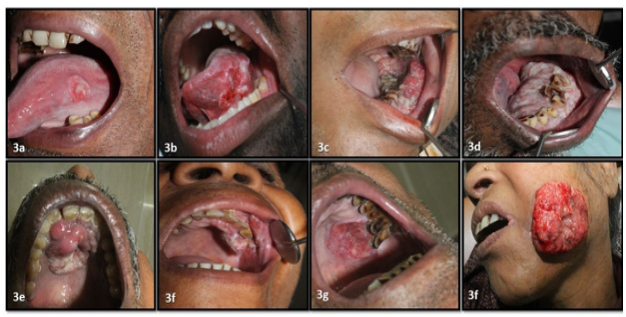

Figure 2: Varied clinical presentations of oral squamous cell carcinoma; 3 a,b: OSCC tongue, 3 c,d: OSCC mandibular gingivobuccal complex, 3 e,f,g: OSCC palate, 3h: OSCC left buccal mucosa perforating left cheek

Results

The study included all patients who were clinically and/or histopathologically diagnosed as any one of the OPMDs (Figure 1, 2). Patients lost to follow-up were excluded from the study. The net patient inflow over 5 years (January 2013 to December 2017) was 2,51,702. The frequency distribution has been depicted in Table 1. The frequencyof patients with OPMDs was 55% with 17.06% females and 36.88 % males. The lesions with a male predominance included Leukoplakia (74.24%), Oral Submucous Fibrosis (83.55%), Pouch keratosis (71.26%) and Actinic cheilitis(82.75%) while Oral lichen planus (77.63%)had a female preponderance (Figure 4). Cases of Discoid Lupus Erythematosus occurred exclusively in females. In our study, patients with Epidermolysis Bullosa were equitably distributed among males and females.

Table 1: Annual and 5-year frequency distribution with 5-year prevalence.

Year	Leukoplakia	Oral submucous fibrosis	Pouch keratosis	Oral lichen planus	Actinic cheilitis	Smokers palate	Discoid Lupus Erythematosus	Epidermolysis Bullosa
2013	5307	5565	7400	4866	4	1098	0	1
2014	6060	5937	9533	5171	5	2380	0	0
2015	6342	4139	8578	5241	6	2036	2	0
2016	6450	5964	8633	5370	6	2206	1	1
2017	7253	6168	8731	5392	8	2617	0	2
5 yr Burden	31412	27763	42875	26040	29	10337	3	4
5 yr Prevalence	12.47%	11.03%	17.03%	10.34%	0.011%	4.10%	0.001%	0.002%

The most and least frequently encountered OPMDs included Pouch keratosis (30.96% of OPMDs) and Discoid Lupus Erythematosus (0.002% of OPMDs)respectively while Oral Submucous Fibrosis (20.05% of OPMD's) and Oral Lichen Planus (18.80% of OPMD's) presented nearly equally in patients reporting at our tertiary care centre. The male:female ratio of various OPMDs reported was 2.88 for Leukoplakia, 5.08 for Oral Submucous Fibrosis, 3.16 for Pouch keratosis, 0.28 for Oral Lichen Planus, 4.8 for Actinic cheilitis, 23.96 for Smokers Palate, and 1 for Epidermolysis Bullosa(Figure 3). The mean age of presentation of OPMDs was 33.6years. Amongst males, the mean age was 29.6 years while for females it was 37.5years. The age group most commonly affected by any of the OPMDs was 20-40 years. Patients with lichen planus presented early (mean age 28 years) while cases with leukoplakia presented late (mean age 36 years). Smokers palate was more of an incidental finding (79%) than a primary presentation(21%).

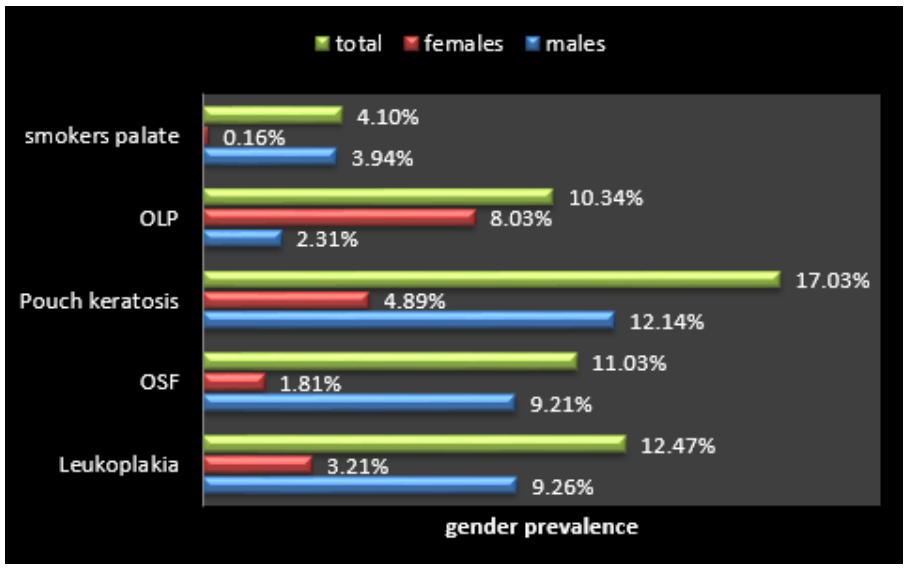

Figure 3: Gender distribution of various OPMDs.

Concerning site predilection, the lower left buccal vestibule (53%) and left buccal mucosa(28%)were the chief sites for Leukoplakia, lower left buccal vestibule was the primary site for Pouch keratosis(77%), bilateral buccal mucosa (42%) and gingivae(32%) for Lichen planus and lower lip for Actinic cheilitis (100%). The remaining patients had involvement of multiple intraoral sites. Oral submucous fibrosis had more pastoral involvement. About 47% of the OPMDs showed candidal colonization. The various predictors for malignant transformation in our study included age, gender, site, appearance and presence of deleterious habits. The net 5-year malignant transformation rates of various OPMDs to oral squamous cell carcinoma have been depicted in Figure 4.

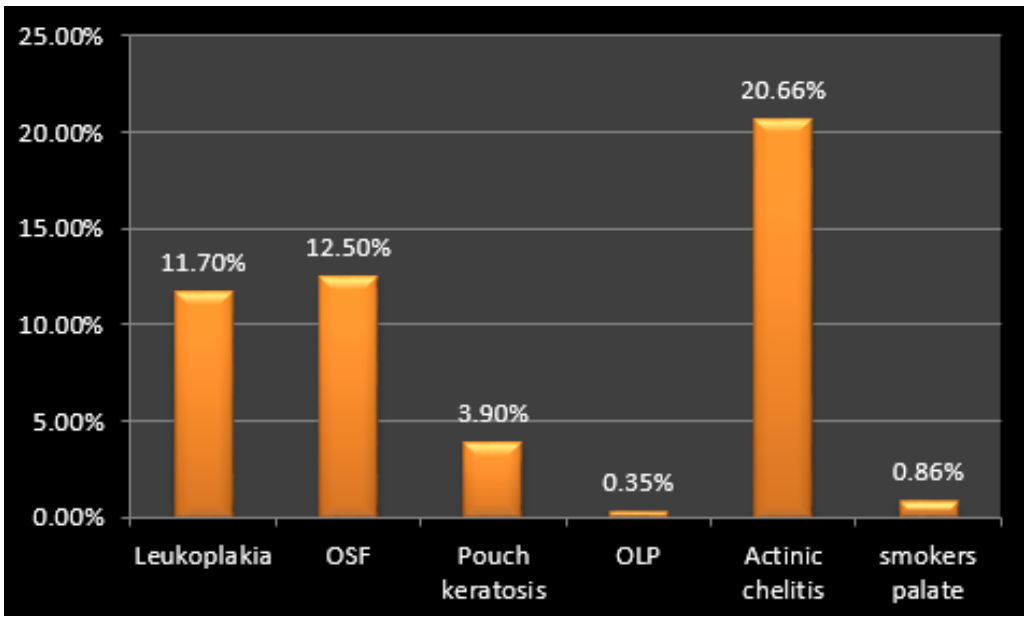

Figure 4:5-year malignant transformation rates of various OPMDs.

The lesion with the highest rate of malignant transformation wasActiniccheilitis (20.66%) while Oral lichen planus (0.35%) hadthe least conversion in our population. 2 cases of idiopathic OSMF and 3 cases of cryptogenic leukoplakia were encountered throughoutthe study. The mean age of malignant transformation was 41 years with a male predilection (68 %) and was largely habit associated (72%). The type of tobacco consumed and other relevant attributes have been summarized in Table 2. Smokeless tobacco forms were consumed by 66.25% while smoking by 35.08%. Overall, 22.99% were addicted to both. Cessation of tobacco habits was reported in 8.24%. Lesions presenting with erosions, ulcerations, surface elevations, nodularity or other features contributing to clinical non-homogeneity in the appearance of the lesions were more susceptible to malignant transformation (66%). Cases presenting primarily as malignancy were 6.34%. Out of these, 8(0.05%) were of salivary origin, 2(0.012%) melanoma, 1(0.006%) metastatic carcinoma, 2(0.012%) lymphoma, 3(0.018%) malignant ameloblastoma. The remaining cases 15949 (99.9%) presented as a primary intraoral malignancy (Figure 4).

Table 2: Type of tobacco consumed and other relevant attributes

SMOKING FORMS OF TOBACCO	Age of initiation	Duration since	Average number/ day	The predominant type of smoking
USERS	<20Y 18062	1-3Y 9312	1-5 18992	Crude 36520
	20-30Y 20173	3-5Y 10462	5-10 17609	Filtered 12056
	>30Y 10341	5-10Y 11340	>=I pack 11975	
		10-20Y 12622		
		>=20Y 4840		

Continue....

EX-USERS Cessation since	**Age of initiation**	**Duration since**	**Average number/ day**	**Type of smoking**
Few days 674	<20Y 1588	1-3Y 597	1-5 3688	Crude 2647
Few wks 908	20-30Y 3609	3-5Y 3422	5-10 1533	Filtered 3066
Few mon 2991	>30Y 516	5-10Y 972	>=I pack 492	
Few yrs 1140		10-20Y 593		
		>=20Y 129		
Smokeless Forms of Tobacco	**Age of initiation**	**Duration since**	**Average frequency/day**	**Mode of use of smokeless tobacco**
USERS	<20Y 36106	1-3Y 11059	1-5 24375	Sw 14934
	20-30Y 41530	3-5Y 18153	5-10 37305	Po 21215
	>30Y 14107	5-10Y 24618	>10 30063	Sp 12876
		10-20Y 27112		All 42718
		>=20Y 10801		
EX-USERS Cessation since	**Age of initiation**	**Duration since**	**Average frequency/day**	**Mode of use of smokeless tobacco**
Few days 233	<20Y 671	1-3Y 1740	1-5 1204	Sw 562
Few wks 562	20-30Y 3802	3-5Y 506	5-10 3008	Po 2254
Few mon 2650	>30Y 1228	5-10Y 2628	>10 1489	Sp 452
Few yrs 2256		10-20Y 455		All 2433
		>=20Y 372		

SW-swallow, po-pouch, sp-spit

Discussion

During the 5 year study period (January 2013 to December 2017), 55.01% were OPMD and 6.34% were head and neck cancers (HNCA). According to various studies, the estimated prevalence of HNCA concerning total body malignancies varies from 9.8% to 42.7%.[11-13]The diverse spectrum of clinical presentations of various oral potentially malignant disorders was encountered. The overall prevalence over 5 years was 55% with a mean yearly prevalence of 11%. This was higher than the rates observed in other studies.[14-16]

The most frequently encountered OPMD was leukoplakia (12.47%). The majority cases of the cases were habit associated with only 3 being idiopathic. The 5-year malignant transformation rate was 11.70%. The transformation occurred in the habit-associated group and 1 case in the cryptogenic group. The noted malignant transformation rate (5.374%) was higher compared to the study by Tung-YuanWang et al.[17] According to a study by Gupta PC et al, the overall malignant transformation rates were very low (0.3%–2.19%)[18]. Warnakulasuriyaand Ariyawardana[19]carried out a systematic review of 24studies and found an overall malignant transformationrate of 0.13% to 34% making our observation conformant to this range.

The next most common disorder encountered was oral sub-mucous fibrosis (11.03%). All but 2 cases were habit associated. The 2 idiopathic cases gave no history of tobacco habits, both presented in females in the late second decade, with 1 giving a similar familial history. None of the idiopathic cases showed malignant transformation. The five-year transformation rate was documented as 12.50%, in agreement with the often cited metric of a 7-13% malignant transformation rate of OSF stems from a Taiwanese study.[20]As demonstrated in a long-term follow-up study in India, scrutinizing 99 patients with OSF for 17 years, a malignant transformation rate of 7.6% was documented.[21] In contradistinction, more recent, larger studies have suggested a lower rate; in a recent review by Ray et al the transformation rate varied from 1.9% to 7.6%.[22] The significantly higher

rate of transformation noted in our population can be attributed to late presentation for treatment, rampant production and continued use of smokeless forms of tobacco, ease of availability at cheaper costs and lower tax rates and ill belief that smokeless tobacco is good for health increasing appetite and vigour.

Oral lichen planus, presented in our population with a prevalence rate of 10.34%, chiefly manifesting amongst women (77.63%). The overall 5-year malignant transformation rate documented was only 0.35% entirely sparing the reticular variant. As reported by Sana Maher Hasan Aghbariet al[23], 1.1% of OLP patients developed OSCC, while the rate of malignant transformation among OLL cases was 2.5%. Studies by IngafouM et al[24], Carbone M et al[25]. During this study, dysplastic changes were also documented in lesions originally diagnosed as tobacco pouch keratosis (3.90%).

Conclusion

To the best of our knowledge, this study is one of the few to recruit a large population presenting with varied lesions. It serves to present an overview of a few epidemiologic associations between disease, gender, site, age and deleterious habits. However, owing to large sample recruitment, various parameters remain unaddressed which can be a potential ground for future research. Association between the diseases studied and various systemic co-morbidities can be introspected. Chances of underestimation of transformation rates do exist which can be ruled out with a longer follow-up period. Also,the integration of chairside screening and histologic prognostic factors into routine diagnostic and treatment procedures might serve to change the natural course of the disease.

Conflict of Interest: There is no conflict of interest

Source of funding: Nil

Ethical clearance: Approved by Institutional Ethics Committee

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Viewpoint/ Perspective

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Medical Education in India - Need to Rethink!

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Abstract

Sustainable Development Goal number three advocates for a healthy life for all and a significant part of achieving this is the availability of Doctors across all landscapesequitably. But there has been a lack of healthcare force, particularly in rural areas. The medical curriculum in India is exhaustive and emphasizes the need for higher education than serving as medical officers in primary health centers. Many aspects of undergraduate teaching are rarely utilized, if at all. So it's high time to relook at our MBBS curriculum to incorporate more practical real-life education needed for managingprimary health centers and cutting the extra burden.

Keywords: Undergraduate Medical Education, Competency-Based Education, Curricula, Rural Health

Medical Education in India - Need to Rethink!

Medicine has long attracted the best brains available in society; hence doctors have been viewed as the cream among intellectuals and regarded as the noblest profession[1]. Medicine is not only a profession but a passion[2]. There are two broad domains as far as medicine in India is concerned; Allopathy and Alternative-Indigenous medicine, also known as AYUSH. The focus of this article is on allopathy medical education. India follows the system of Bachelor of Medicine and Bachelor of Surgery (MBBS) for bachelor & and Doctor of Medicine (MD)/Master of Surgery (MS)/ Diplomate of National Board (DNB) for Master, which are of three years. Two year Post graduate diploma has also been recognized in many disciplines as an alternative to a Master's. Magister Chirurgiae (MCH) and Doctorate of Medicine (DM) represent the Super specialty and are akin to Ph.D. in other fields. Also, few institutions in India have permitted Ph.D. in different disciplines[3]. India has suffered from a Lack of doctors as per norms and to cater to public demand, especially in the rural belt[4], so pursuing MBBS ensures a govt Job and secure life. However, the situation has changed significantly in the past decades, with many issues crippling medical education and the profession. Also, the rise in corporate hospitals owned chiefly by business people has changed the public perception of doctors from God-like figures to self-oriented money-making machines, especially in urban India.

MBBS is unique as it represents an assured carrier only after the 12th standard. Students enter the MBBS with broadly two sets of ideas. First, those without doctors in their family /relatives see this as

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a noble profession sufficient for a quality livelihood superadded by parental pressure. On the other hand, those with physician relatives who Joined MBBS to pursue post-graduation and super specialties from the beginning[5] 408 from 271 medical schools. However, after the initial years in MBBS, almost all the students are forced to think that their life is of no value without post-graduation, which might be somewhat true but not the absolute truth. With nearly 20% of the peripheral hospitals without a doctor, an MBBS can Significantly impact the Health Care System in these areas earning up to 12 LPA.

The MBBS Curriculum has 14 broad subjects for which they appear in exams. Other allied subjects are also taught, but no formal assessments are being done. The initial years cover human anatomy, physiology & biochemistry. Subsequently, they taught about pharmacology, pathology, and Microbiology. Forensic Medicine and Community medicine are covered in the third year. In the final One and half years, clinical subjects like Medicine, Surgery, Orthopaedics, Obstetrics-Gynaecology, and Paediatrics are taught. Second year onwards, the students are exposed to hands-on training in the outpatient departments & indoor wards, where they can interact with actual patients[6].

There have been many attempts at charging the MBBS curriculum, initially five years followed by one year of compulsory rotating internship. The introduction of the semester system led to a curtailment of the tenure by six months of Nine semesters. Again, attempts were made to change the Curriculum to Competency-based medical education (CBME) four years back in 2018 to help produce better medical graduates[7]. Now another Googly is being tried by the attempted change in the medium of medical education based on Local Language, which has the potential to seriously hamper the performance of Indian medical graduates in the international scenario[8]. Another question we should ask is whether the curriculum is optimum for creating doctors to serve society. Most of the textbooks used in medical colleges across the country are written by international authors covering a wide range of conditions of the western world that an Indian medical graduate may never see in their lifetime.

Like in pharmacology, almost all medications being used Currently are given in textbooks, including obsolete drugs. However, A MBBS will hardly use 10% of the drugs. They rarely use drugs for cardiac and neurological diseases and anesthetics in the Peripheral health institutions for which many study hours are spent. Instead, they should be taught about medication used in a PHC or CHC, focusing on essential medicines. A postgraduate in pharmacology can go through all the medical formulations in these textbooks, but there is no need to overburden the MBBS students. Similarly, in pathology, much of the time is spent on things that a medical graduate will not practice after passing out from medical school. Almost no MBBS will be making and examining slides in the peripheral hospitals; these are being done by the Pathologists who are postgraduates.

The same is true of Community Medicine, which seeks to instruct students on health management, monitoring & evaluation, prevention and control of public health issues, and the National health program in India. However, as described earlier, the textbooks suffer from similar faith to others. Reproductive, Maternal, New-born, Child, and Adolescent Health (RMNCH+A), National Vector Borne Disease Control Programme (NVBDCP), National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular diseases, and Stroke (NPCDCS), among other programs, are dedicated to addressing the public health issues that are prevalent in Indian society and have the potential to lower morbidity and mortality there. However, these programs are non-functional in most medical colleges because of multiple factors that need a separate discussion. So practical exposure to these highly effective programs is not feasible during the MBBS tenure. Also, Community Medicine is supposed to be the gateway to research in the medical field by incorporating knowledge, skills, and attitude. But, it is hardy the case in medical schools. Instead, too much stress is given to insects, nutrition (theoretical aspects) & other topics that are of no use in the peripheral health institutions.The situation is almost the same in other subjects taught in medical colleges. An MBBS graduate practically cannot perform any surgery in PHC/CHC due to lack of practical exposure, lack of facilities in these hospitals, and legislative constraints as per the MCI/NMC act. So, devoting a vast amount of time to surgical subjects in medical schools is of no practical use to the graduates except for their Postgraduate entrance preparation.

The subject that needs to be delineated and taught is Emergency Medicine with practical exposure in the emergency departments, including labor rooms. The MBBS graduates will see general OPD patients or emergency cases (Convulsion, Poisoning, snake envenomation) after passing if posted in peripheral hospitals. So they should be well-versed in identifying the danger signs and stabilizing the patients before referral to higher centers[9].

Another serious issue is the unhealthy budding of private institutions imparting tuition to MBBS Students starting from the first year. These institutions are not only doing crores of business but also corrupting the entire generation of future doctors. MBBS period is not intended only to study books but to practice medicine, problem-solving attitude, and skill development in real-world scenarios. However, these institutions are brain-draining the students into mere students of MCQ Questions and answers rather than doctors. Students are bunking their MBBS classes in medical school to attend these tuitions. Govt should take stringent action against this kind of institution to keep the standards of medical graduates high.

Discussion

So there is an urgent need to relook at the Content of different subjects taught in MBBS courses, as suggested by many authors previously[5,10–12]408 from 271 medical schools. The course needs to produce competent doctors capable of managing a PHC with a positive attitude toward society, focusing on the public health problems prevalent in the country. The specialties need to be rearranged based on actual and factual needs and not on the western curriculum. Reducing course content can quickly reduce the time required for graduation, which would also play a part in reducing the shortage of doctors in the periphery. Finally,the government is responsible for providing basic infrastructure and services so that doctors can render their services hassle-free to achieve sustainable health goals across all ages.

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Original Article

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A Study of Road Traffic Accident Reported at Tertiary Care Hospital BPSGMC (W) Khanpur Kalan, Sonepat

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Abstract

Background: Injury and deaths due to road traffic accidents (RTA) are a major public health problem in developing countries where more than 85% of all deaths and 90% of disability-adjusted life years were lost from road traffic injuries.

Objectives: To study the type of injuries in Road Traffic Accidents reported at a tertiary care hospital and to determine the various factors for the occurrence of the accidents.

Method: Study was planned to study the major causes/risk factors as well as nature, type and mode of occurrence of road traffic accidents in sonepat city and study demographic profile and injury pattern among RTA victims. Road traffic accidents are responsible for a substantial proportion of deaths &injuries and are responsible for more years of life lost than most human diseases. The WHO has defined road traffic accident (RTA) as when a vehicle collides with another vehicle, pedestrian, animal, road debris, or other stationary obstruction.

Results: The data were summarized using percentages. There is a high percentage of RTA among males (86.4%) and no experience of driving were important risk factors identified for accidents. Total of 140 injured patients were seen in the emergency department. More than 80% accident cases were two wheelers. The most common site of the RTA was found at state highway.

Keywords: Road Traffic Accident, injury pattern, Prospective, Retrospective, Mode of travel.

Introduction

According to WHO, "an accident is defined as an unpremeditated event resulting in recognizable damage." It is an unexpected unplanned occurrence which may involve injury.[1] The total number of road accidents increased by 2.5 per cent from 4, 89,400 in 2014 to 5, 01,423 in 2015. Road traffic fatalities are increasing day by day at about 8% annually for the last ten years and show no signs of decreasing. An estimated 1.2 million people are killed in road crashes every year as many as 50 million are injured occupying 30-70% orthopedic beds in developing countries. Road traffic injuries are predicted to be third leading contributor to the global burden of disease and injury by 2020.[2] The total number of persons killed in road accidents increased by 4.6 per cent from 1,39,671 in 2014 to 1,46,133 in 2015. Road accident injuries have also increased by 1.4 per cent

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from 4,93,474 in 2014 to 5,00,279 in 2015. The severity of road accidents, measured in terms of number of persons killed per 100 accidents has increased from 28.5 in 2014 to 29.1 in 2015.[2] Motorization has enhanced the lives of many individuals and societies, but the benefits have come with a price. Although the number of lives lost in road accidents in high-income countries indicate a downward trend in recent decades, for most of the world's population, the burden of road-traffic injury in terms of societal and economic costs is rising substantially. Injury and deaths due to road traffic accidents (RTA) are a major public health problem in developing countries where more than 85% of all deaths and 90% of disability-adjusted life years were lost from road traffic injuries[3]. As a developing country, India is no exception. Not a day passes without RTA happening in the roads in India in which countless number of people are killed or disabled. Often members of the whole family are wiped out. Those who are affected or killed are mostly people in their prime productive age[3,6,7]. The highest burden of injuries and fatalities is borne disproportionately by poor people, as they are mostly pedestrians, cyclists, and passengers of buses and minibuses. The data for fatal accidents presented to the Parliament by the Ministry of Road Transport and Highways for year 2008 shows that 119,860 people perished in mishaps that year and the national and state highways accounted for nearly half of all road accidents[3]. Deaths due to road accidents in 2009 were reported to be 126,896 and in 2010 it increased to 133,938 which is about 5.5% over and above the previous year's deaths. Tamil Nadu, Andhra Pradesh, Maharashtra, Karnataka, and Rajasthan have accounted for 11.5%, 10.5%, 7.1%, and 6.8%, respectively, of total "Road Accident" deaths in the country. The trend is alarming and is leading to a frightening situation day by day.[10]

Methodology

This cross-sectional study was conducted at BPS GMC Khanpur Kalan sonepat. A sample of 140 was collected from the RTA victims who reported in the emergency wing of the hospital were study population. Information was collected through a pre-tested questionnaire, perusal of hospital records and visit to the accident area to assess the nature of turnings, road conditions, etc for corroborative evidence. Comatose cases, OPD cases and fatalities were excluded from the study. Limitation of this study was the exclusion of deaths and comatose cases which had to be done because it was difficult to obtain record from relatives/eye-witnesses, the exact factors which were operating during the accident. Incorrect information rendered by patients on drug/alcohol or helmet use due to fear of punitive action can be a problem in such studies but the patients were taken into confidence for giving the correct information. The data was collected regarding RTA from emergency wing of the tertiary care hospital BPSGMC(W), Khanpur kalan, sonepat and Microsoft excel& SPSS(ver. 20) was used for data analysis.

Table 1: Characteristics of the study subjects (n=140)

Characteristics	Frequency	Percentage
Sex		
Female	19	13.6
Male	121	86.4
Education		
Not literate	35	25.0
Middle	58	41.4
Secondary	35	25.0
Sr. Secondary	12	8.6
Type of family		
Joint	101	72.1
Nuclear	39	27.9
Marital status		
Married	116	82.9
Unmarried	24	17.1
Habit		
Alcoholic	23	16.4
Alcoholic/Smoker	25	17.9
Smoker	31	22.1
None	61	43.6

Table 2: Distribution of Accident Cases as per experience

Exp in year	Number	%age
No Experience	54	38.57
2-4 Year	27	19.29
4-6Yrs	26	18.57
6-8Yrs	15	10.71
8-10Yrs	7	5.0

Continue ....

10-12yrs	3	2.14
12-14Yrs	3	2.14
14-16Yrs	2	1.42
16-18Yrs	2	1.42
>18Yrs	1	0.71

Table 3. Distribution of Accident Cases as per type of vehicle

Type of vehicle	n (%)
2 wheeler	84(60.0)
3 three wheeler	4(2.86)
4 wheeler	52(37.14)

Table 4: Distribution of accident cases as per site of injury

Site of injury	n (%)
Leg	47(33.57)
Head	42(30.0)
Arm	30(21.43)
Shoulder	11(7.86)
Back	4(2.85)
Chest	6(4.28)

Results

There is a high percentage of RTA among males (86.4%) and having high speed (>80km/hr) of two wheeler was 78%. More than 80% accident cases were two wheelers. The most common site of the RTA was found at state highway (70%). The commonest type of injury seen in RTA is fracture and the most common site of is lower limb, Alcohol consumption, poor maintenance of the vehicle and no experience of driving were important risk factors identified for accidents.

Conclusion

Implementation of speed management program i.e. to match speeds to conditions, warn drivers of changes, and then enforce posted limits to reduce speeding related accidents (Speeding, the most influential human error contributed of the road accidents).Rulemaking, educating road users the concept of right of way, strict law enforcements to inculcate the practice of right of way among road users and stop rule breaking practices. Public awareness campaigns educating the consequence of distracted driving, stringent rules against mobile driving, incorporating advanced vehicle technologies and improved road engineering to reduce RTA.

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Original Article

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Study of Serum Uric Acid Levels in Essential Hypertension and its correlation with the severity of Hypertension

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Abstract

Background: Uric acid is thought to play a pathogenic role in hypertension mediated by several mechanisms such as inflammation, vascular smooth muscle cell proliferation in renal microcirculation, endothelial cell dysfunction etc. The study was carried to see the relationship between serum uric acid and hypertension and its correlation with components of metabolic syndrome as it is thought that hyperuricemia is more common in hypertensive patients probably because hyperuricemia may be also a component of metabolic syndrome.

Methods: The present observational cross sectional study was conducted in the department of Medicine in a tertiary care hospital in Assam from June 2021 to May 2022. A total of 150 patients who were diagnosed as hypertensives following ACC/AHA guidelines, 2017. Newly detected hypertensives were enrolled for the study. Relevant clinical and laboratory data were recorded using proforma and statistical analysis were done accordingly.

Results: 20% cases were found to be hyperuricemic in the study population out of which 67% of the cases who had metabolic syndrome had hyperuricaemia.

Conclusion: There can be a direct relation between hypertension and hyperuricemia, hyperuricemia was found in 20% of hypertensive cases. Serum uric acid level correlates significantly with variables like BMI, Dyslipidemia, stage 2 hypertension, which are components of metabolic syndrome. Thus, hyperuricaemia can be an index of suspicion for the concomitant presence of metabolic syndrome.

Key words: Hypertension, Hyperuricemia, Uric acid, AHA- American Heart Association

Introduction

Hypertension is one of the most common causes of mortality and morbidity amongst adults from all over the world whose prevalence is more than 1.13 billion worldwide[1]. Hypertension is a major contributing risk factor for neurological,cardiac,renal and peripheral vascular diseases.

Hypertension is an emerging health problem in India. When majority of people come to know that they have hypertension they have already advanced into a stage with target organ damage – a fatal stroke or myocardial infarction or irreversible renal failure. Unfortunately even in developed countries like United States, 78 million people are found to have hypertension[2]

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The association between Hypertension and hyperuricemia were found when a family with an unfortunate pedigree attended Hammer Smith hospital in the United States in 1957. The father and six of the seven progeny had hyperuricemia, while the mother and all of the progeny had hypertension[3]

This incident incited interest in finding the correlation between serum uric acid levels and hypertension

The relationship between hyperuricemia and hypertension has been recognised for a long period of time. However it is an unsolved doubt if the relationship of hyperuricemia and hypertension is purely because of underlying renal and metabolic defects. Uric acid is thought to play a pathogenic role in hypertension mediated by several mechanisms such as inflammation,vascular smooth muscle cell proliferation in renal microcirculation, endothelial cell dysfunction etc.[4-16]

Decreased blood flow to the kidneys and reduced tubular secretion of uric acid are found to be the predominant mechanism as the cause of hyperuricemia in hypertension[17]. Moreover it is thought that hyperuricemia is more common in hypertensive patients probably because hyperuricemia may be also a component of metabolic syndrome[18].

Different studies done till date has shown that hyperuricemia is common in hypertensive patients.

According to a study done in Bangladesh, the observed prevalence of hyperuricemia in hypertensive was 9.7%[19].

According to another study done in Medicine department of Agartola government medical college, Agartola in 2020, the prevalence of hyperuricemia was 47.5%[20]

According to a study done in Uttar Pradesh in the Department of Medicine, GS Medical College and Hospital, Pilkhuwa, Hapur showed that mean serum uric acid levels in cases was 7.14 mg/Dl[21]

Here an attempt will be made to study the prevalence of elevated uric acid levels in hypertensives.

Methods

The present study was an observational cross sectional study which was conducted in the Department of Medicine, Tezpur Medical College and Hospital,Assam from June 2021 to May 2022. A total of 150 patients of 26-65 years of age who were diagnosed as hypertensives following recent ACC/AHA guidelines were taken only after giving written informed consent after full explanation of nature and purpose of the study.

Aims and objectives:

1. To study the clinical profile of hypertensives.
2. To study the relationship between hypertension and serum uric acid level

Excluded those patients who were known case of gout, patients with malignant diseases and patients on chemotherapy and antimetabolite, Pregnant patients, patients of end-stage renal diseases, Patients on uricosuric drugs, patients of secondary hypertension, Patients on drugs known to cause hyperuricaemia and Patients who did not give consent.

A prior written and informed consent (annexure) was obtained before evaluating the cases. Demographic data, history and physical examination were obtained and documented using the designated protocols.

Data was recorded in preformed and pretested proforma. Statistical analysis was done using Microsoft Excel, 2017. P value <0.05 was considered to be statistically significant.

Anthropometric measurements included height and body weight, waist circumference, waist hip ratio which were measured while the subject was wearing light clothing without shoes. The body mass index was calculated as the weight in kilograms divided by the height in m^2.

Essential hypertension was diagnosed in the absence of an identifiable cause.The patients were classified into various stages of hypertension according to recent ACC/AHA guidelines, 2017. Hyperuricemia was defined as serum uric acid levels >7mgs/dl in males and >6mgs /dl in females. Serum uric acid was measured by photometric method after taking early morning venous sample.

Declaration of Ethical clearance: Taken from ethical committee of Institute

Results

In this cross sectional study, serum uric acid was studied to correlate with the risk factors of hypertension and with other variables. The patients were divided broadly based on their blood pressure levels into two stages-stage 1 hypertensives and stage 2 hypertensives. Mean systolic blood pressure and mean diastolic blood pressure in this study was found to be 150.84 and 91.4 respectively.

Among the 150 patients who were studied,101(67.33%) were males and 49(32.66%) were females.Male to female ratio was 2.06:1

Out of 101 male patients,80 had normal serum uric acid level and 21 had high serum uric acid level

Out of 49 female patients, 40 had normal uric acid level and 9 had high uric acid level.

***p* value is statistically not significant**

Out of 101 male patients, 60 were in stage 1 hypertension and 41 were found to be in stage 2 hypertension, Out of 49 female patients, 22 were in stage 1 hypertension and 27 were in stage 2 hypertension

Table 1: Sex distribution and stages of hypertension

	MALE	FEMALE	TOTAL
STAGE 1	60	22	82
STAGE 2	41	27	68

10 out of 82 stage 1 hypertensives were found to have high uric acid level while 20 out of stage2 hypertensives had high uric acid level.

Table 2: stage of hypertension and uric acid

	NORMAL URIC ACID	HIGH URIC ACID	*p* value
STAGE 1 (82)	72/82(87.80%)	10/82 (12.19%)	0.008684
STAGE 2 (68)	48/68(70.58%)	20/68 (29.41%)	

***p* value is 0.008684 which is statistically significant**

Patients of 46-55,56-65 year age groups have the highest number of hyperuricemic cases. Percentagewise it is equal in all the age groups except for 26-35 years age group who has the lowest percentage of 13.63%.

Out of 150 cases,73 were smokers of which 18 had high uric acid level and 12 out of 77 had high uric acid who were non smokers,p value of this correlation is 0.1649 which is insignificant for the study

Table 3: serum uric acid and smokers

Smoking Habit	Normal uric acid	High uric acid	P value
Smokers(73)	55/73 (75.34%)	18/73 (24.65%)	0.1649
Non smokers(77)	65/77 (84.41%)	12/77 (15.58%)	

Out of 50 alcoholics,high serum uric acid was found in 22 cases and 8 cases were found to have high uric acid among non-alcoholics.p value of this correlation was calculated to be 0.00001 which is significant in this study.

Table 4: serum uric acid level and alcoholics

	Normal uric acid	High uric acid	P value
Alcoholic(50)	28/50(56%)	22/50 (44%)	0.00001
Non alcoholic(100)	92/100(92%)	8/100 (8%)	

20 out of 56 patients who had dyslipidemia were found to have high uric acid level while 10 out of 94 patients who did not have dyslipidemia had high uric acid level.*p* value was calculated to be 0.000204 which is statistically significant

7 out of 30 diabetics had high uric acid level while 23 out of 120 non-diabetics had high uric acid level.*p* value for this correlation was found to be0.2604 which is non-significant for the study.

Table 5: serum uric acid and glycemic status

Glycemic status	NORMAL URIC ACID	HIGH URIC ACID	p value
DIABETICS(30)	23/30 (76.66%)	7/30 (23.33%)	0.2604
NON DIABETICS (120)	97/120 (80.83%)	23/120 (19.16%)	

19 out of 49 cases who had BMI>25 were found to have high uric acid,on the other hand 11 out of 101 cases who had BMI<25 were found to have high uric acid level.

Table 6: serum uric acid and BMI

	NORMAL URIC ACID	HIGH URIC ACID	p value
BMI>25 (49)	30/49 (61.22%)	19/49 (38.77%)	0.000062
BMI<25 (101)	90/101 (89.10%)	11/101 (10.89%)	

20 out of 51 cases who had metabolic syndrome were found to have high uric acid, on the other hand 10 out of 99 cases who did not have metabolic syndrome were found to have high uric acid level. **P value was 0.000024 which is statistically significant**

There was a strong correlation between serum uric acid and BMI, change in BMI correlates with change in serum uric acid level. There is also positive correlation between BMI and serum uric acid , that is any increase in BMI will increase serum uric acid and decrease in BMI will decrease uric acid.

Discussion

Hyperuricemia has been associated with an increased risk for cardiovascular disease; enhanced platelet aggregation and inflammatory activation of the endothelium[22] are the mechanisms by which SUA may directly affects cardiovascular system.Some studies showed, the association of SUA with cardiovascular disease was uncertain after multivariate adjustment as in the Framingham Heart Study (1985) and the ARIC study (1996), but in others the association remained certain and significant. As because hyperuricemia is correlated with several risk factors including hypertension, renal dysfunction, insulin resistance, hyperlipidemia and hyperhomocystenemia, it is a major debate whether SUA independently causes cardiovascular risks. Various other reports have also shown that increased Serum Uric Acid levels were seen in hypertensive patients.

Kinsey et al. (1961) in his study with 400 hypertensive patients reported a 46 % incidence of hyperuricemia in hypertensives[23]. Kolbe et al. (1965) in his study of 46 hypertensive patients found 26 to be having increased SUA levels (56%)[24].

Breckinridge et al. (1966) demonstrated that 273 out of 460 patients on antihypertensives, 57% had elevated hyperuricemia and 92 of the 323 patients 28% attending the hospital for the first time had hyperuricemia. C. J. Bulpitt et al.(1975) showed in his study that 41% female hypertensivesand 47% male hypertensives had hyperuricemia[25] .

A study by Ramsay et al. (1979) showed that 73 men with untreated hypertension had raised serum uric acid levels 25%[26]. Meserli et al. (1980) proved an incidence of 71% hyperuricemia in their case population of 38 established hypertensives. Meserli and Frolich et al. demonstrated that the significant presence of hyperuricemia in hypertensives construes to underlying renal failure[27].

There is enough evidence that uric acid is sensitive and early marker for renal failure than creatinine. Serum UA has a role in the generation of free radicals. Free radicals inhibit vasodialation of endothelium[4-16].

Therefore, it is unlikely that hypertension arises as a result of raised serum UA levels, but there is a possibility that uric acid which plays a role in the production of oxidative stress and free radicals must correlate with elevated formation of free radicals.

Hence the fact that raised serum UA levels can lead to Hypertension cannot be entirely ruled out.

Among the 150 cases of hypertension, hyperuricemia was seen in 30 cases, which is 20% of the cases. Canon et al (1996) showed a prevalence of hyperuricemia in 25% of untreated hypertensive cases. The Framingham study observed that the correlation of blood pressure with uric acid was reduced in the case population as they increased in age (source: Feig and Johnson 2003)[28]

The mean serum uric acid level in stage1 hypertensives is 5.56 while in stage2 hypertensives it is 6.64. This correlates with the study done by Ghosh Atanu et al.(2020) in which they have shown that the serum UA level was more in stage 2 hypertensives when related to stage1 hypertensives[20]. Overall mean and standard deviation of serum uric acid was 6.05 and 1.16 respectively in this study.

Conclusion

Based on the results of our study, we found that there can be a direct relation between hypertension and hyperuricemia.Hyperuricemia is found in 20% of hypertensive cases. Serum uric acid level correlates significantly with variables like BMI,Dyslipidemia, stage2 hypertension, which are components of metabolic syndrome.Thus,we can conclude that high serum uric acid level can be an index of suspicion for the concomitant presence of metabolic syndrome. Physicians should thus recognize that the metabolic syndrome is a frequent comorbidity of hyperuricemia and one should be aware of its complications.

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Original Article

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Laryngeal Mucosal Changes in Patients in Laryngo-Pharyngeal Reflux before and after Treatment with Proton Pump Inhibitors

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Abstract

To evaluate pre and post treatment results based on Laryngeal mucosal changes as assessed by direct video laryngoscopy/stroboscopy using Belafsky scores. In our study we have evaluated laryngeal changes in patients with dysphonia and RSI 10 before treatment and after 6 months of treatment with Tab. Pantoprazole and Tab. Mosapride. This prospective study was carried out on 50 patients attending the ENT out patient department of a tertiary care referral centre over a period of 18 months i.e. from Nov 2008 to Apr 2010. The study showed that prolonged therapy is required to treat laryngopharyngeal reflux (LPR) effectively and 24 h ambulatory dual probe pH metry and videolaryngoscopy to assess RFS are the most preferred diagnostic tools in LPR. Dr Speech software for voice analysis can give an objective assessment of voice changes in LPR before and after treatment. The treatment consisting of proton pump inhibiter (PPI) and prokinetic drugs proved to be effective in laryngopharyngeal reflux disease as improvement was seen in all the parameters including reflux findings score. According to results of our study, 24 h ambulatory dual probe pH-metry, Reflux Finding Score (RFS), can be used as indicators of efficacy of treatment.

Keywords: Laryngopharyngeal reflux (LPR), Prokinetic drugs, Dysphonia

Introduction

Laryngopharyngeal reflux (LPR) is the retrograde movement of gastric contents (acid and enzymes such as pepsin) into the laryngopharynx leading to symptoms referable to the larynx/hypopharynx. Typical LPR symptoms include dysphonia/ hoarseness, globus pharyngeus, mild dysphagia, chronic cough nonproductive throat clearing and some times Laryngospasm. Hoarseness is a common disorder. A recent study[1] suggested that up to 55% of patients with hoarseness have acid reflux, which affects their larynx. The diagnostic work of patients with LPR begins with thorough history and meticulous physical examination. Investigations for LPR include oesophagogram, oesophageal endoscopy (UGI endoscopy), manometry study, radionucleide scanning and acidification tests. Continuous pH monitoring studies are felt to be the gold standard study for LPR. Probes that sense pH changes can be placed at different locations in oesophagus and pharynx or hypopharynx. Dual pH

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probes can be used with one probe 5 cms above site of lower oesophageal sphincter and second probe above upper oesophageal sphincter to detect any reflux. Anti-reflux therapy includes drugs, lifestyle changes and sometimes surgery. These treatments are often used for patients with hoarseness, where no other cause has been found on examination. The treatment of laryngopharyngealreflux (LPR) has seen phenomenal changes over time, often following the development of new medications. Initial treatment regimens involved antacids and dietary and lifestyle changes. The elimination or marked suppression of acid production by PPIs accomplished two things: It reduced exposure of damaged tissues to an acidic environment and, more importantly, it reduced the activity of pepsin, which requires an acidic pH level for activation. Pepsin retains 70% of its activity at a pH level of 4.5. Clinical trials confirmed the superiority of PPIs to H2 receptor antagonists. H2 receptor antagonists competitively inhibit histamine induced gastric secretion. All phases of secretion (basal,psychic,neurogenic and gastric) are suppressed whereas it has no effect on gastric and oesophageal motility. Patients with LPR have prolonged symptoms and delayed healing [2]. Unlike GERD, treatment for LPR must be more aggressive and prolonged to achieve resolution[3].

LPR may manifest with other symptoms such as asthma exacerbations, otalgia, excessive throat mucus, halitosis, neck pain, odynophagia, postnasal drip etc. Such symp- toms, however, are also nonspecific and extend along a broad range that can be seen in other medical conditions. Conversely, this same list cannot be treated as an inclusiveone, either, as not all patients who experience LPR will be afflicted with all of the aforementioned symptoms.

There are no set guidelines for a definitive diagnosis of LPR. Much of the literature considers ambulatory 24-h.This study entails measuring the pH in the proximal and distal esophageal regions. A positive event isdefined as a pH-drop in the proximal probe accompanied by a simultaneous decrease in the distal one. Although there does not appear to be a significant difference in results between sedated and unsedated individuals, dual- probe pH studies are susceptible to false positives that require manual correction.

Impedence studies are one developing technological advance that expands on the principles behind pH monitoring. This technique involves arranging multiple electrode pairs on a pH-probe-type catheter capable of tracking retrograde bolus transits suggestive of reflux.

Mucosal biopsies have been notable for its ability to measure the concentration of pepsin and CA-III. A pepsin immunoassay being developed has been postulated to be 100% sensitive and 89% specific for LPR. Spectro-photometric analysis of refluxate has garnered attention for its potential to evaluate for bile and pancreatic enzymes, two biochemical compounds that may possibly aggravate the laryngeal mucosal damage incited with LPR in addition to gastric acid and activated pepsin.

Treatment options for LPR can be divided into three main modalities: lifestyle modifications, pharmacological, andsurgical. Lifestyle modifications are similar to changes suggested for individuals experiencing GERD. Patients should be instructed to avoid oral intake 2–3 h prior to lying supine and to elevate the head of the bed. Elevation should be undertaken with the placement of bed blocks as opposed to the use of additional pillows. In addition, patients are encouraged to sleep on their left side as the diaphragmatic crura is said to cause a natural kink in the gastroesophageal junction when a person is in the left lat- eral decubitus position. Weight loss is usually helpful if symptoms of both LPR and GERD are present. Patients are educated to avoid alcohol, caffeine, carbonated beverages, chocolate, tobacco, and foods that are fried, spicy, or contain citrus as these factors have been noted to exacerbate reflux.

Antacids and histamine-2 receptor antagonists (H2RA) were the mainstays of pharmacological therapy prior to the development of proton pump inhibitors (PPI) in the 1980^0s. Aside from the symptomatic relief that antacids afford against the acidic component of gastric refluxate, H2RA's were prescribed to combat a histamine-regulated nocturnal acid breakthrough (NAB) that is felt to further exacerbate symptoms due to LPR. Early studies had concluded that thecombination of H2RA and PPI therapy effectively con- trolled NAB only during the initial part of treatment, while later ones had suggested that there was an equivocal difference

with the addition of H2RA to an established twice daily PPI regimen.

The nonspecific nature of symptoms and the lack of set criteria for diagnosis, leaves LPR susceptible to a couple of foci of controversy. Although there are hallmark findings and symptoms associated with LPR, not all patients will present with these complaints nor exhibit all of the classic features. Consequently, these patients may be erroneously evaluated for allergies, asthma, sinusitis, smoking, and vocal abuse. In addition, up to 87% of healthy individuals have been noted to have at least one LPR physical exam finding despite remaining asymptomatic. Conversely, Ylitalo et al. in 2001 had shown that some people possessed a benign laryngeal examination despite complaints indicative of reflux [4]. Further compounding the problem posed by the absence of diagnostic guidelines, there is a poor level of inter-rater reliability which leads to a subjective diagnosis of LPR.

Materials and Methods

This prospective study was carried out on 50 patients attending the ENT OPD of a tertiary care referral centre complaining of dysphonia due to Laryngopharyngeal reflux (with reflux score/ symptom index more than 10) over a period of 18 months i.e. from Nov 2008 to Apr 2010.All the patients were subjected to detailed history taking, general physical examination, ENT examination, video laryngoscopy.

Inclusion Criteria

All patients having reflux score index more than 10 and reflux symptom index more than 10 were included in the study.

Exclusion Criteria

No local laryngeal pathology in the past.

Not having been treated for LPR with PPI and prokinetic drugs.

No previous history of surgery, Radiotherapy, intubation.

Known case of peptic ulcer/GERD on regular treatment

Study Protocol

This prospective study was carried out on 50 patients attending the ENT OPD of a tertiary care hospital complaining of dysphonia due to Laryngo-pharyngeal reflux (with reflux score index more than 10) over a period of18 months i.e. from Nov 2008 to Apr 2010.

All the patients were subjected to detailed history taking, general physical examination, ENT examination, 24 h ambulatory dual probe pH monitoring, video laryngoscopy to assess RFS, pre and six months post treatment with Tab. Pantoprazole (40 mg BD) and Tab. Mosapride (5 mg TDS) and findings recorded. The other PPI and prokinetics were not given to avoid ambiguity.

Videolaryngoscopy to assess RFS was performed with the following devices: 8.0 mm rigid laryngeal telescope at 90° (Hopkins); 3.2 mm flexible fibro laryngoscope (Storz); light xenon source 350 watts (Storz); micro-camera (Karl Storz, ICCD, endocam, Germany). The examinations were carried out under topical anesthesia with 2 percent lidocaine spray. We instructed the subjects to produce deep breathing, comfortable production of sustained vowels/e/ and /i/, and inspiratory phonation. The reflux finding score (RFS) was used to assess laryngopharyngeal reflux (LPR) signs (subglottic edema, ventricular obliteration, erythema/hyperemia, vocal fold edema, diffuse laryngeal edema, posterior commissure hypertrophy, granuloma, and others).A score greater than 7 was strongly considered suggestive of LPR.

Observations and Results

50 Patients presenting with dysphonia, Reflux Symptom Index [10 and Reflux Score Index [10 which is suggestive of LPR underwent complete ENT examination including ambulatory 24 h pH monitoring using a dual channel antimony probe, video laryngoscopy perceptual voice analysis using GRBAS score, SZ Ratio , pre and six months post treatmentwith Tab. Pantoprazole (40 mg BD) and Tab Mosapride (5 mg TDS) and findings recorded. The followings observations were made:-

- *Age and Sex Distribution* 50 patients were included inthe study. 64% were females (n = 32) and 36% were males (n = 18). The ages

were ranging from 23 to 60 years with mean age of 41.4 years.

- *24 h pH metry Findings* Double probe 24 hr pH studies were conducted on 50 patients, of these 13 patients (26%) had negative or normal findings and 37 patients (74%) had abnormal pharyngeal reflux before taking treatment. After taking treatment for six months 26 patients (52.0%) showed no reflux episodes.

The data revealed that 13 patients had normal pH findings pretreatment out of which 11 patients (84.6%) remained asymptomatic after treatment and 2 patients (15.4%) showed abnormal reflux episodes. 37 patients had more than 1 reflux episodes pretreatment out of which 15 patients (40.5%) showed no abnormal reflux episode after taking treatment. *Video laryngoscopy and Reflux Finding Score Findings* The Reflux Finding Score was recorded in all patients, pretreatment and 6 months after treatment. The pre-treatment Reflux Finding Score 7.88 improved to 3.96 post treatment. The Paired T-Test revealed *p* value to be 0.000 which is significant.

Discussion

LPR is known as the main factor for various laryngeal diseases such as reflux laryngitis, subglottic, stenosis, contact ulcer, or granuloma, vocal polyps and laryngeal cancer [5]. Almost half of the patients with dysphonia have LPR as a common causative factor [6] but its definite role in etiology or pathophysiology of dysphonia has not been clearly identified.

In our study we have evaluated and compared voice and laryngeal changes in patients with RSI 10 before treatment and after 6 months of treatment with Tab. Pantoprazole and Tab. Mosapride. In this study 50 patients with ages ranging from 23 to 60 participated (Mean 41.4 years) out of which 64% were females. 26% patients had normal findings on pH metry before starting the treatment and after taking the treatment 52% patients showed no reflux episode, the remaining 48% showed decrease in number of reflux episode.

LPR should never be considered physiologic, even a single pharyngeal episode of pH less than 4 is diagnostic of LPR . Therefore ambulatory 24 double probe pH monitoring is the most suitable diagnostic method. On the other hand several studies proved that evident signs of LPR can be detected, even in patients with negative 24 h pH monitoring. It was also proved that pepsin is activated in values of pH higher than 4 [7]. For the esophagus, upto

An endoscopic laryngeal examination usually reveals the signs of LPR. Belafsky et al. [8] developed RFS and reported that it could be used effectively and reproducibly in the diagnosis and follow up of LPR. RFS has been widely used for its measuring efficacy of treatment and high reproducibility between observers. In the great majority of studies the RFS was used in the evaluation of clinical severity of LPR [8]. The score of more than 7 is indicative of LPR [9]. Videolaryngoscopy is a very simple method which can be easily repeated and well tolerated by the patients. The treatment of LPR needs to be more aggressive and prolonged as it usually takes 6 months or more for the laryngeal findings of LPR to resolve and some patients may require prolong treatment.

The results of our study confirmed that the treatment with Tab. Pantoprazole and Tab. Mosapride is very suc cessful. In our study pretreatment mean RFS was 7.88, which became 3.96 after treatment which shows that the improvement was significant.

Conclusions

50 patients with RSI 10 (suggestive of LPR) participated in this prospective study. All patients underwent 24 h ambulatory dual probe pH metry,videolaryngoscopy to assess Reflux Finding Score(RFS), perceptual and acoustic analysis of voice using GRBAS scale and Dr Speech software respectively to compare and evaluate laryngeal changes in patients with dysphonia in laryngopharyngeal reflux before and after treatment with proton pump inhibitors (PPI) and prokinetic drugs.All patients were given PPI (Tab. Pantoprazole 40 mg 1BD) and prokinetic (Tab. Mosapride 5 mg 1 TDS)for 6 months. After completion of the treatment all patients again underwent pH metry, videolaryn- goscopy to assess Reflux Finding Score (RFS).

Informed Consent: written informed consent was taken from patients.

Ethical Approval: ethical committee approval was taken from the AIMSR institutional committee of ethics.

Source Of Funding: funding source was self

Conflict Of Interest: there was no conflict of interest

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Original Article

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Effect of microbes on Patterns of Labeled White Blood Cells in Osteomyelitis

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Abstract

Aim: This study investigates the effect of microbiological characteristics of causative organisms on the scintigraphic patterns of labelledwhite blood cell (WBC) scans in cases of proven osteomyelitis.

Methods: Retrospective analysis of 25 patients referred with suspected osteomyelitis and had both bone and labelled WBC scans performed and complete records of the microbiological culture of the causative organism. The bone and labelled WBC scans were retrieved and reviewed by two nuclear medicine physicians. Any definite focal accumulation of labelled WBCs within the bone was considered positive for osteomyelitis. Diagnosis of osteomyelitis in the discharge summary was considered the reference standard and was based on a combination of the clinical scenario, imaging, and laboratory findings including microbiology. A correlation of the pattern of labelled WBC and the type of microorganisms was done.

Results: A total of 16 patients were included in this study, seven females and nine males. Of these, seven patients had Gram-positive whereas nine patients had Gram-negative organisms. The majority (85.7%) of Gram-positive organisms showed increased accumulation of labelled WBCs, whereas only one-third (33.3%) of patients with Gram-negative organisms had such findings.

Conclusion: The pattern observed in this study shows that the falsenegative results of labelledWBC scans were mainly noted in patients with Gram-negative as opposed to Gram-positive infections. This confirms the experimental animal study findings that the secretion of anti-chemotactic factors by Gram-negative organisms, seems to be inhibiting the migration of labelled WBCs to the site of infection. The inhabitation is decreasing the accumulation of labelled WBCs and consequently resulting in a falsenegative finding. The study adds to evidence that microbiological characteristics of the causative organisms are another explanation for the falsenegative WBC in proven osteomyelitis.

Keywords: Bone scan, Gram-negative bacteria, Gram-positive bacteria, labelled white blood cells, osteomyelitis.

Introduction

The diagnosis of osteomyelitis can be challenging and depends on clinical findings, laboratory tests, and imaging studies supported by tissue culture. Gram-positive bacteria are the primary causative agents of osteomyelitis and *Staphylococcus aureus* is by far the most common in all age groups.[1] Osteomyelitis can

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also be caused by Gram-negative bacteria, especially in patients with certain predispositions such as sickle cell disease, diabetes, and trauma.[2] Multiple morphologic and functional imaging modalities have been used with different sensitivities and specificities. Conventional radiographs are usually used first due to their wide availability and low cost. However, plain radiographs usually have limited value due to their low sensitivity for acute infections as the anatomical changes are usually seen in the late stages of the disease.[3] Computed tomography (CT) provides good anatomical information. However, its ability to differentiate bone from softtissue infection is limited. In addition, its value is diminished in postsurgical cases with a metallic implant.[3] On the other hand, magnetic resonance imaging (MRI) provides high-resolution images with a good ability to differentiate soft tissue from a bone infection.[4] It has high sensitivity in detecting osteomyelitis, but its specificity is limited by many causes of false positive results such as postsurgical changes, bony infarction, and Charcot's joint.[5] Multiple nuclear medicine procedures are used in diagnosing osteomyelitis. Multi-phase bone scintigraphy using technetium99 mdiphosphonates (Tc99 m) provides an early diagnosis with comparable sensitivity to MRI. However, it has low specificity as multiple potential causes can result in false positive results.[6] The specificity of a bone scan can be improved when it is combined with a labelled white blood cell (WBC) scan. The labelled WBC study is the most accurate in diagnosing acute osteomyelitis. The combined approach using bone and labelledWBC scans provide comparable sensitivity and superior specificity in comparison to MRI.[7] Although the combined approach has generally acceptable accuracy (ranging from 79% to 100%), many factors should be considered before choosing this approach. The duration (acute or chronic) and the location (axial or appendicular) of the infection may affect the accuracy of this technique.[8] Furthermore, the microbiological characteristics of the causative organisms may also influence the accuracy of the procedure.

Multiple studies reported low sensitivity of labelled WBC scans for the detection of vertebral osteomyelitis. Palestro *et al*. reported a low sensitivity (39%) of In-111 WBC in 28 patients with proven vertebral osteomyelitis.[9]Another study on 22 patients with spine infections reported asensitivity of only 17%.[10] Hovi also reported three cases of histologically proven osteomyelitis detected by MRI but none by Tc-99 m-hexamethyl-propylene-amine oxime (99mTc-HMPAO)-labelled WBC studies.[11]

The exact reason for this observation has been uncertain, and there are several possible explanations. The diagnosis of vertebral osteomyelitis is often delayed, and most infections become chronic which lowers the sensitivity of labelled WBC scans.[12] Another possible explanation is that infection results in very high pressure in the vertebra and therefore, labelled WBCs could not migrate to the focus of infection during the available time for imaging. Palestro and Love proposed that marrow uptake of labelled WBCs in the normal spine may be greater than in the infected bone, masking the abnormality or causing a relative photogenic region.[13]Finally, Fernandez-Ulloa *et al*. suggested that Gram-negative organisms could be behindthis finding since they secrete anti-chemotactic factors.[14]A preliminary animal study with rabbits confirmed that Gram-negative infections in vertebral and femoral osteomyelitis are associated with low to no accumulation of labelled WBCs.[12] This study aims to investigate the microbiological characteristics of labelledWBC scans in cases of nonvertebral osteomyelitis since the high-pressure theory is not a factor in such sites.

Materials and Methods

Retrospective review of cases referred to the Department of Nuclear Medicine for suspected osteomyelitis from September 2009 to September 2013. Only 25 patients, who had both bone and labelledWBC scans performed were diabetics, and only two out of the seven patients with Gram-positive infections are diabetics (Table 1). Seven patients had Gram-positive bacterial infection, whereas nine had Gram-negative infection (Table 2). Out of the seven cases with Gram-positive infection, six (85.7%)had increased uptake of labelled WBCs [Table 3]. The majority of the positive labelledWBC scan cases of Gram-positive bacterial infection were due to *eus* (83.3%). Out of the nine Gram-negative bacterial-infected cases (Table 4), only three had increased uptake (33.3%), whereas the other six had nouptake (66.7%) on their labelledWBC scans. Two of the three patients with increased

labelled WBCs uptake were infected with *Enterobacter aerogenes* while the third patient was infected with multiple Gram-negative organisms (Table 3). Figure 1 illustrates an example of Gram-negative bacterial infection at the foot with nouptake of labelled WBCs and complete records of the microbiological culture of the causative organism, were included in the study. The data were collected and attained from the nuclear medicine Department picture archiving and communication system, patients' hospital files and Laboratory Information System. Data from these selected 25 patients with complete records were analyzed.The three-phase bone scan was performed following the intravenous administration of 740–1,110 MBq (20–30 mCi) of Tc-99m-methylene diphosphonate. The dynamic blood flow images were acquired immediately after the radiotracer administration over the region of interest. The blood pool images were obtained after 5 min. Delayed whole-body images, as well as spot images, were obtained after 3 h. Single-photon emission CT (SPECT) and SPECT/CTimages were also obtained on selected cases when an accurate anatomical correlation was needed.

Labeled-WBC scan was performed the following day. The patient WBCs were labelled with 25 mCi of 99mTc-HMPAO and re-injected intravenously. Whole-body and spot images of the area of interest were acquired at 2 and 4 h after the radiotracer administration. Furthermore, SPECT andSPECT/CT images were acquired on selected patients for correlation with the bone scan.The bone and labelledWBC scans were retrieved and reviewed by two nuclear medicine physicians. The images were interpreted based on a visual assessment of the uptake pattern of labelled WBC in correlation to the bone scan. Any definite focal accumulation of labelled WBCs within the bone was considered positive for osteomyelitis. All patients selected in the analysis had also microbiological and inflammatory markers performed. The final diagnosis of osteomyelitis in the discharge summary was considered the reference standard and was based on a combination of the clinical scenario, imaging, and laboratory findings including microbiology.

Results

Among the 25 patients studied, seven patients were excluded from further analysis since osteomyelitis was not their final diagnosis. In addition, two patients with proven osteomyelitis were excluded from the final analysis as they had a combination of mixed Gram-positive and Gram-negative bacteria in the culture. The remaining 16 patients including seven females and nine males with ages ranging between 20 and 75 years (mean 51.2) were included in the final analysis. None of the patients was given antibiotics for >48 h before scans. In the investigatedcases, the osteomyelitis was located at the tibia in fivecases, three cases at the metatarsal, two at each of thetalus, femur, and calcareous, as well as one case at each ofthe radius and posterior talocalcaneal joint. Eight out of the16 patients included were diabetics. The majority of the patients withGram-negative infections (six out of nine, 66.7%) were diabetics, and only two out of the seven patients with Gram-positive infections are diabetics (Table 1). Seven patients had Gram-positive bacterial infection, whereas nine had Gram-negative infection (Table 2). Out of the seven cases with Gram-positive infection, six (85.7%) had increased uptake of labelled WBCs (Table 3). The majority of the positive labelledWBC scan cases of Gram-positive bacterial infection were due to *eus* (83.3%).

Table 1: Demographics Data of patients

No. of Patient	Scan	Gram stain	Site of infection	Diabetic
1	+	+	Talus	-
2	-	-	Metatarsal	+
3	+	+	Femur	-
4	-	-	Tibia	+
5	+	-	Tibia	+
6	+	+	Tibia	-
7	-	-	Talus	-
8	-	-	Tibia	-
9	-	-	Metatarsal	-
10	+	+	Calcaneus	+
11	+	+	Calcaneus	+
12	-	-	Metatarsal	+

Continue.....

13	+	-	Posterior talocalcaneal Joint	+
14	-	+	Radius	-
15	+	+	Femur	-
16	+	-	Tibia	+

Table 2: Type of micro-organisms and labelled white blood cells scan findings

Organism	Number ofcases	Positivescan (%)	Negativescan (%)
Gram-positive	8	6(85.7)	2(14.3)
Gram-negative	7	3(33.3)	4(66.7)

Table 3: Results of labelled white blood cell scan in patients with Gram-positive bacterial infections

Patient number	Scan results	Organism
1	+	Staphylococcus aureus
2	+	Enterococcus faecalis
3	+	Staphylococcus aureus
4	+	Enterococcus faecalis
5	+	Staphylococcus aureus
6	+	Enterococcus faecalis
7	+	Staphylococcus aureus

Table 4: Results of labelled white blood cell scan in patients with Gram-negative bacterial infections

Patient number	Scan results	Organism
8	-	Morganella morgagnii *Bacteriods spp.*
9	-	*Klebsiella pneumoniae*
10	-	Enterobacter sakazakii
11	-	Enterobacter aerogenes Morganella morgagnii
12	+	Escherichia coli Pseudomonas spp. Bacteriods fragalis
13	+	Enterobacter aerogenes
14	-	Enterobacter aerogenes
15	+	Enterobacter aerogenes
16	-	Citrobacter koseri

Out of the nine Gram-negative bacterial-infected cases (Table 4), only three had increased uptake (33.3%), whereas the other six had nouptake (66.7%) on their labelledWBC scans. Two of the three patients with increased labelled WBCs uptake were infected with *Enterobacter aerogenes* while the third patient was infected with multiple Gram-negative organisms (Table 3). Figure 1 illustrates an example of Gram-negative bacterial infection at the foot with nouptake of labelled WBCs.

Discussion

Gram-positive organisms are known to be the main causeof osteomyelitis; however, Gram-negative organisms suchas *Pseudomonas aeruginosa* and *Klebsiella pneumoniae*can also cause osteomyelitis, especially in the diabeticfoot, hospital-acquired infections, and intravenous drugabusers.[15,16] In this study, seven of the 16 patients withproven osteomyelitis were infected with Gram-positiveorganisms while nine patients had Gram-negativebacterial infections. The majority of patients (85.7%)with Gram-positive infections had positive labelledWBCscans. As well, the majority of patients (66.7%) withGram-negative infections had negative labelledWBC scans.The majority of patients in this study were infectedwith Gram-negative organisms which were likely due tothe higher presence of diabetes (66.7%) in this group.However, the main goal of this study was to investigate thepattern of labelledWBC uptake in Gram-negative-causedosteomyelitis. The pattern observed in our small groupof patients with nonvertebral osteomyelitis is consistentwith the findings advocated by Fernandez-Ulloa *et al*. intheir five cases of vertebral osteomyelitis. They notedthat the abnormally decreased uptake of labelled WBCs inpatients with proven vertebral osteomyelitis was mainlyobserved in the presence of Gram-negative organisms.[14]Kim *et al*. in 1987[17] and Palestro *et al*. in 1991[9] havealso reported false-negative labelledWBC scans in patientswith proven osteomyelitis mainly in cases associated with Gram-negative infections. It has been proposed that false-negative labelled WBCscans of vertebral osteomyelitis are likely due to increasedcompartmental pressure which may prevent the accumulationof labelled WBCs.[14] However, observing the same trend ofdecreased accumulation of labelled WBCs in nonvertebralosteomyelitis in animal and human studies indicates.

Conclusion

The pattern observed in this study shows that the falsenegative results of labelledWBC scans were mainly noted in patients with Gram-negative as opposed to Gram-positive infections. This confirms the experimental animal study findings that the secretion of anti-chemotactic factors by Gram-negative organisms, seems to be inhibiting the migration of labelled WBCs to the site of infection. The inhabitation is decreasing the accumulation of labelled WBCs and consequently resulting in a falsenegative finding. The study adds to evidence that microbiological characteristics of the causative organisms are another explanation for the falsenegative WBC in proven osteomyelitis.

Ethical statement: This study was approved institutional ethical committee

Conflict of Interests: The authors declare that they have no conflicts of interest

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Original Article

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Patient Satisfaction with Services of the General Outpatient Department of a Tertiary Care Hospital in a Metropolitan City

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Abstract

Introduction: Patient satisfaction is at the center of the patient-centered care and is also one of the indicators of the quality of care. Assessment of satisfaction of the patients attending the general out patient department (GOPD) of the tertiary care center (government sector) in a metropolitan city helped us identify the potential areas for improving the health care services and their delivery, which was at the core of carrying out this research study.

Methods: After obtaining Ethics clearance from the Institutional Ethics Committee, this cross sectional study was conducted among 1377 patients attending the GOPD of the tertiary care centre for a period of a month. Data collection was done using a study questionnaire.

Results: Of the total study participants, 99% (n=1363) of the patients who visited the GOPD were satisfied with their doctor. We also found that 75.7% and 95.1% of patients respectively, were of the view that doctors didn't explain the side effects of medication and the reason for advising prescription. Ninety seven percent of the patients responded positively regarding revisiting the hospital; good medical care at an affordable cost was the main reason for their choice.

Conclusion: The patients were highly satisfied with their doctors and the services at the tertiary care centre. Depending on the results of the study, recommendations were made in order to be implemented for better delivery of services.

Keywords: Patient satisfaction, General Outpatient Department, Tertiary care hospital, Metropolitan City.

Introduction

Globally, fifty percent of the population is still unable to access essential health services[1]. So, as a part of the recent Sustainable Development Goals, the World Health Organization has recommended that all United Nation members, achieve Universal Health coverage (UHC) status by 2030[1]. India also aims to achieve UHC. Its focus is on providing a level of quality that aids to improve the health of the service seeker[2]. For low and middle income countries, Timely and equitable access of safe and effective evidence-based treatments is validated by quality, and without discrimination by socioeconomic and financial status[2].

Patient satisfaction is an important aspect for assessing the quality of patient care services[3]. Patient

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satisfaction depicts the felt need, surmise from the healthcare system, and worldliness of health care. Patient satisfaction is degree of match between expectations and perception of the care received by the patient. This multidimensional concept includes medical as well as non- medical aspects of healthcare[4]. Various theories of patient satisfaction in healthcare emphasize on patients reliance, utility and expectations to influence it. Healthcare quality theory highlights the importance of interpersonal process of care in patient satisfaction[5].

Quality of health services was historically based on professional practice standards, however recently; patient's perception about healthcare has been agreed upon as an important indicator for measuring quality of health care [6]. Thus, patient satisfaction deserves all special mention because it is linked to acquiescence, and better comprehension and sustaining information provided by the healthcare service providers. This ensures desired health outcome. Outpatient department (OPD) is usually first place of encounter of patients in any hospital. It is believed that the care given at the OPD services indicates the quality of services of a hospital[7]. Patient satisfaction is thus a substitute but a very effective indicator to measure the success of doctors and hospitals. In the findings of the "Crossing the Quality Chasm" report, the Institute of Medicine (IOM) set forth 6 aims for a quality health care system for patient safety, depicted in figure 1. The latter three factors directly influence patient satisfaction.[8]

A patient is the consumer of the hospital who expects care and comfort while in distress. Patient forms certain expectations prior to visit[9]. Indifferent treatment of patients, unofficial perks for healthcare providers, lack of privacy of patient, and insufficient provision of medicines and supplies are common, yet are less acknowledged by traditional quality assessment methods[10]. Patients carry certain expectations before their visit and the resultant satisfaction or dissatisfaction is the outcome of their actual experience[10-12]. Thus patient satisfaction study can be a learning in giving proportion to problem areas and a reference point for making management decisions. And therefore, patient satisfaction, needs to be assessed to aid in the improvement of healthcare services delivery[13]. The same was at the core of carrying out this research study.

Methods

- Study Design: Observational Cross Sectional study.
- Study Site: General OPD of a tertiary care hospital in Metropolitan city.
- Duration of Study: January, 2022 to February, 2022
- Sampling method: Universal Sampling- Complete enumeration of the patients attending thegeneral OPD.
- Sample Size: We interviewed 1377 patients over a period of 1 month. We included all the participants fulfilling the following inclusion criteria using complete enumeration method.
- Inclusion criteria:
  - ⇒ Those who attended the general OPD during the study duration.
  - ⇒ Age > 18 years.
- Exclusion criteria:
  - ⇒ Those critically ill/those who needed immediate referral forspecialty care.
  - ⇒ Those who could not comprehend English/Hindi/Marathi.
- Tool of assessment: Study questionnaire:
  - o The purpose of the questionnaire was to assess determine the satisfaction of the OPD services.
  - o Pre-formed pre-tested semi-structured questionnaire was used which was validated by the experts in the department.
  - o Three native speakers fluent in English translated the questionnaire in Hindi and Marathi.
- Data collection: Data Collection was done after Ethical Clearance from the Institutional Ethical Committee.
- Procedure:
  - o Step 1: After explaining the format of study to the participant, informed consent was taken from them.
  - o Step 2: Collection of demographic details

and patient satisfaction using the study questionnaire.

- The entire data collection took 10-15 minutes of time of the study participants.

- Statistical analysis:
  - Questionnaire data was coded and entered into computer using Microsoft Excel.
  - For descriptive data, frequencies and proportions were calculated.
  - Categorical variables were measured as percentages.

Results

One thousand three hundred and seventy seven patients were included in the study. Most of the patients were employed and (n=1099; 79.81%) belonged to lower socioeconomic status, as per modified (2021) B.G.Prasad classification of socioeconomic status. Figure no. 2 gives the details of the time spent in the queue by the patient to get the OPD ticket. Most of the patients (n=950) had to wait for more than 30 minutes in the queue to obtain the OPD ticket.

Responses of patient's towards general aspects of hospital and staff are shown in Table no. 1. Majority agreed that hospital was tidy 1294 (94%) and ventilated properly 1239 (90%). Out of the total 1377 patients, 121 (8.79%) used the parking facility. Only 23 (19%) of those who used the parking facility were satisfied with the services, rest were not. Out of the total 1377 patients, 511 (37.10%) used the cafeteria. Most of them 445 (88.07%) were satisfied with the services. A 5- point Likert Scale including: 1= strongly agree, up to 5= strongly disagree was used to analyze doctor-patient interaction (including respect, communication skills, informed consent, privacy, confidentiality, and addressing the patients' queries). Figure no.3 gives the details of overall patients' satisfaction with the doctor; 1335 (97%) patients would like to visit the hospital again.

Table 1: Responses of patient's towards general aspects of hospital and staff

1. The reception desk was--	Yes	No
easy to locate	1290	87
patient faced problem in obtaining OPD ticket	1267	110
2. Patient is satisfied with Signage system of the hospital	1296	81
The waiting area --		
Was comfortable	1299	78
Adequate sitting was available	1269	108
Drinking water was available	00	1377
Magazines/TV was/were available	00	1377
The staff in waiting area was respectful towards patients	1321	56
The staff in waiting area treated patients on fair ground	1333	44
The toilets in the OPD were clean	1342	35

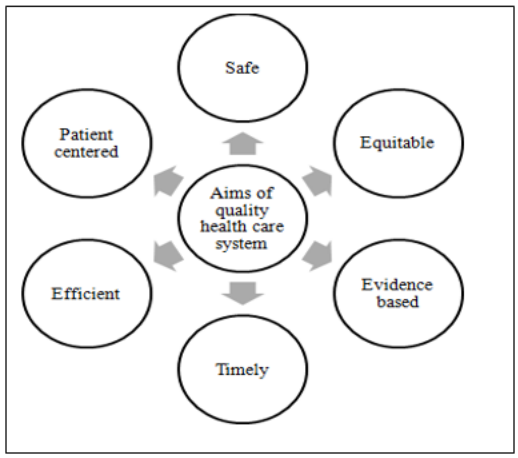

Figure 1: The six aims for a quality health care system for patient safety according to the 'Crossing the Quality Chasm' report, the Institute of Medicine (IOM).

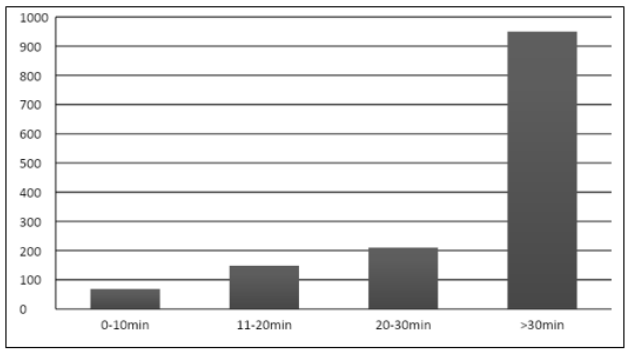

Figure 2: Details of the time spent in the queue by the patient to get the OPD ticket.

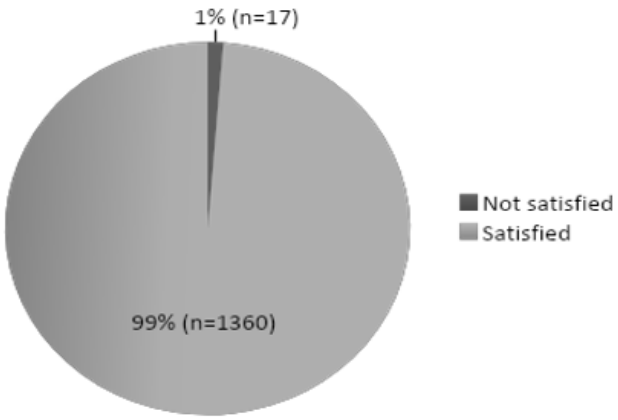

Figure 3: Details of overall patients' satisfaction with the doctor.

Discussion

This study assessed the patient satisfaction in among the patients attending a tertiary care (government) center. This study evaluated the satisfaction of patients with their doctor, which was 99%. Thus, greater compliance with follow up visits and prescribed medicine intake can be attributed to this fact. Contrasting were the results from various studies carried out[14-16] with mere 52% patients happy with the services.

The doctors were found to be courteous (99.7%), gave a patient ear to them (99.05%), gave an opportunity to speak about their illness and concerns (98.9%), dose and time of medication specifications were provided (98.9%), follow up to the patients (97.2%) was advised and took care of patient's comfort during examination (99.7%). This is in line with other international studies which stated 88–92% patients were treated with due respect and dignity[17&18]. Results of a study carried out in Karachi,[17] consent was taken 58.6% patients before examination and 62.4% of the patients agreed that the doctor maintained privacy; whereas in our study, both consent was taken and privacy was maintained for all the patients. The quality communication with the patient has an effect on the health of the patient[18].

We found that 75.7% and 95.1% patients respectively, were of the view that doctors didn't explain the side effects of medication and didn't explain the reason for advising prescription. Patients were asked about hospital cleanliness, adequate ventilation, location of the registration desk and availability of seats and toilet facility in the waiting area. Majority of the patients were found satisfied with respect to these facilities. Drinking water facility was not available in the OPD. Also, magazines/TV was not there.

In a study conducted in Armenia[19], patient satisfaction with waiting time, accessibility of services, and cleanliness of the facility was also high. Patient satisfaction with waiting time, accessibility of services, confidentiality and cleanliness of the facility was only 99%. According to the protocol followed in the hospital, patients have to obtain a slip from the reception desk before they proceed for their check-up by the doctor. Most of patients found the reception desk easy to locate. Though the time for getting the registration slip was more than 30 minutes for most of the patients, that wasn't seen to impact their satisfaction levels, which may be attributed to the behavior of the doctors and staff. Once in the waiting area the patient interacts with the attendant who is responsible for sending patients inside the doctor's room according to their slip numbers. Patients reported being treated fairly and respectfully by the staff in the waiting area. Such issues involving the attitude of hospital staff with patients can greatly influence the reputation of a hospital and is an important factor towards patient satisfaction. Similar results were obtained in the study conducted in Rawalpindi, Pakistan where according to 92.3% of patents, registration and documentation at the hospital reception was convenient and 96% were satisfied with reception staff attitude[20].

A large proportion of patients (97%) were found to be satisfied and willing to re-visit the hospital. Good medical care provided at an affordable price, was the reason given by most of the study participants to re-visit the hospital. This was found to be a very encouraging response and portrays a high satisfaction of the patients with the hospital.

Conclusions

- The patients were highly satisfied with their doctors.
- They found them courteous and attentive towards the patients

- The health facility was clean and adequately ventilated.
- Majority of the patients were ready to re-visit the hospital.

Recommendations

- The code of conduct of doctors and supporting staff is good enough as per the patients attending the OPD and the same should be maintained in future too.
- Drinking water should be provided at the OPD.
- Doctors should make efforts to explain the dosing pattern and schedule of medicines to be followed. Also, explanation for investigations should be given to the patients.
- Efforts should be made to get regular feedback from the patients.

Conflict of interest: None.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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Original Article

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Assessment of Cardiorespiratory Dysfunctions of Health Professionals above the Age of 40 years by means of Electrocardiography and Spirometry

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Abstract

Background: The increasing prevalence of chronic respiratory diseases, particularly chronic bronchitis and emphysema (COPD), is reflected as a growing concern regarding its diagnosis and control. Moreover medical personnel working in different medical set up are at greater risk of stress and disease related susceptibility.

Materials and Methods: Descriptive observational study based on 'convenience sampling done on Health professional viz. Doctors, Nurses and Technicians attached with Medical College, Kolkata and Ruby General Hospital, Kolkata between Feb 2015 to May 2016. Overall 50 doctors, 25 nurses and 25 technicians were taken from Medical College, Kolkata. Pulmonary function tests were done by Spirotech ©, a software after rest for 10-15 min and briefing about to the technique of FVC (maximum inhalation followed by maximum exhalation) and MVV (voluntary hyperventilation for 15 seconds) tests were carried out. Spirometric parameters recorded for analysis were FVC, FEV^1, FEV^1/FVC, PEFR, $FEF^{25\%-75\%}$ and MVV. The controls were selected from relatives of Out Patient Department (OPD) of Medical College who were non-health professionals. They followed the same procedure as the cases.

Results: It shows among cases of Medical College, 8 people are hypertensive and 42 people are normotensive, whereas in control group 5 people are hypertensive and 44 people are normotensive and 1 person had hypotension, which is not statistically significant (P Value 0.419). It shows among Medical college cases Mean FEV1 / FVC ratio is 114.50 (SD 12.63) whereas that of control is 103.90 (SD 15.94), which is statistically significant (P Value 0.000).

Conclusion: Medical personnel are more obese particularly in corporate hospital. Medical personnel have similar blood pressure level as in general population. RBBB pattern is the most predominant QRS abnormality which is not uncommon. Medical personnel have lower mean FEV^1%, FEV^1/ FVC and PEFR % than general population. Predominant spirometry abnormality in our study is restrictive pattern.

Keywords: Cardiorespiratory system, spirometry, electro-cardiography (ECG), cardiorespiratory dysfunctions, Health care professionals.

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Introduction

Abnormalities of the cardiorespiratory system above the age of 40 years in some form may not be very uncommon. This is especially true for health care professionals like doctors, nurses & technicians who discharge their day to day duties under good deal of stress at work places, under the threat of contagious diseases and unfavourable environment, though they might be otherwise nutritionally protected and conscious about their health.

The increasing prevalence of chronic respiratory diseases, particularly chronic bronchitis and emphysema (COPD), is reflected as a growing concern regarding its diagnosis and control. It rank behind Arteriosclerotic Heart Disease and Arthritis as a cause of early disability payment under social security administration.[1] India is experiencing a rapid health transition with a rising burden of non-communicable diseases (NCDs) like cardiovascular and respiratory diseases etc. It is causing significant morbidity and mortality, both in urban and rural population with considerable loss in potentially productive years (35 to 64 years) of life. NCDS are estimated to account for about 53% of all deaths.[2]

Health awareness is the foremost precondition to have disease free and good quality of life. There are some modifiable risk factors for cardio-respiratory diseases like smoking, hypertension, dyslipidemia, diabetes mellitus, obesity, sedentary habits and stress.[2] So, proper clinical evaluation and some basic medical test like ECG and PFT can quantify the cardio-respiratory functional burden in affected individual. People above 40 years of age irrespective of sex are quite susceptible to have ill-effect of hypertension, diabetes, dyslipidemia, COPD, coronary artery disease, stroke etc and the related physical disabilities. Moreover medical personnel working in different medical set up are at greater risk of stress and disease related susceptibility. But their awareness of diseases and their preventive aspects are supposed to be better than the same for the general non-medical population. Our endeavor was to find out the fact in respect of doctors, nurses and technician attached to the Medical College Kolkata compared with the non-health care providers from the respective premises.

Materials & Methods

Descriptive Observational Study based on 'convenience sampling done on Health professional viz. Doctors, Nurses and Technicians attached with Medical College, Kolkata and Ruby General Hospital, Kolkata between Feb 2015 to May 2016. Overall 50 doctors, 25 nurses and 25 technicians were taken from Medical College, Kolkata. Similar controls not belonging to Health care delivery system were also considered for comparison. Health Professionals above the age of 40 years with the aforementioned criteria who gave consent were assessed. Exclusion Criteria were any cardio respiratory emergency; any surgical cause relating to cardio respiratory system; heart failure; stroke and acute exacerbation of bronchial asthma or chronic bronchitis.

Study proposal (synopsis) including the questionnaire approved by the Institutional Ethics Committee of Medical College, Kolkata Memo No. MC/KOL/IEC/NON–SPON/377/11-2014 dated 6.11.2014. The height of the subject was measured by a wall mounted measuring scale.

The weight was measured by a bathroom weighing scale. Mercury sphygmomanometer was used to record blood pressure. Thorough examination of the subject's of respiratory system as well as cardiovascular system was done. A Stethoscope was used for auscultation. The detailed history along with assessment of pulse rate, blood pressure recording, ECG and PFT findings were noted down in data sheet. Subjects came early in the morning after proper night rest. Then a short history was taken and clinical examination was done. The subjects were enquired for any acute respiratory problem or cardiac problem, and subjected to anthropometry at the point of entry using the standard procedure and instruments.

Pulmonary function tests were done by Spirotech©, a software installed in a desktop computer in the Department of Physiology, Medical College, Kolkata. After rest for 10-15 min and briefing about to the technique of FVC (maximum inhalation followed by maximum exhalation) and MVV (Voluntary hyperventilation for 15 seconds) tests were carried out in a private and quiet room, in a sitting position with the nose clip held in position on the nose. All pulmonary function tests

were expressed as percentage of Predicted for that particular age, sex, height and weight. Spirometric parameters recorded for analysis were forced vital capacity (FVC), forced expiratory volume in 1st second (FEV^1), FEV^1/FVC, peak expiratory flow rate (PEFR), forced expiratory flow 25%-75% ($FEF^{25\%-75\%}$) and maximum voluntary ventilation (MVV). A multi channel ECG machine (semi automatic type) of clarity brand supplied to our department was used to perform electro-cardiography. The controls were selected from relatives of Out Patient Department (OPD) of Medical College who were non-health professionals. They followed the same procedure as the cases.

In the present study the statistical methods were used as follows:

(a) Nominal data was analyzed by "Chi-square Test"

(b) Parametric data was analyzed by "Unpaired Students T-Test". A value of p "<0.05" was to be taken as significant.

Results

In cases Medical College mean age is 48.20 years (SD 6.06 yrs) whereas that of control is 49.34 years (SD 7.64 yrs). In cases of Medical college 14 people have history of treatment (diabetes, hypertension, asthma and other disease), whereas in control of medical college 16 people have treatment history, which is statistically significant (P Value 0.000) in both cases and control.

Table 1: History of disease, addiction, awareness, treatment among study participants

		Case	Control
Family History	Hypertension only	9	5
	T2-DM only	4	5
	Heart Disease only	2	0
	CVA only	0	0
	Tuberculosis only	0	1
	Cancer only	1	4
	None	18	22
	More Than One	16	13

Continue table 1....

Addiction History	Smoking only	11	12
	Alcohol only	2	3
	Both	4	3
	None	33	32
Awareness	Absent	0	17
	Present	50	33
Treatment History	Asthma	2	1
	T2-DM	3	7
	HTN	3	5
	More Than One	3	2
	Others	3	1
	None	36	34

Table 1 shows among cases of Medical College 17 people are addicted to either alcohol or smoking or both, whereas in case of control 18 people are addicted which is statistically significant (P Value 0.000). Table 2 shows among cases of Medical College all, people have life style awareness and in control group 33 people have life style awareness which is statistically significant (P Value 0.000).

Table 2: Clinical characteristics among health care professionals

		Cases	Controls
Pulse	Normal	47	48
	Tachycardia	2	0
	Bradycardia	1	2
Rhythm	Irregular	0	3
	Regular	50	47
BP	Hypertension	8	5
	Hypotension	0	1
	Normal	42	44
Edema	Absent	43	44
	Present	7	6
Murmur	Absent	49	49
	Present	1	1
Breath Sound	Abnormal	0	1
	Normal	50	49

Table 2 shows mean BMI of cases of Medical college is 24.20 (SD 2.92) whereas that of control is 23.06 (SD 3.57) which is not statistically significant (P Value 0.084). It shows among cases of Medical College, 8 people are hypertensive and 42 people are normotensive, whereas in control group 5 people are hypertensive and 44 people are normotensive and

1 person had hypotension, which is not statistically significant (P Value 0.419).

Table 3: E.C.G. findings among

		Cases	Controls
Axis	Normal	48	42
	Right	0	8
	Left	2	0
P-Wave	Abnormal	0	0
	Normal	50	50
PR-Interval	Abnormal	0	0
	Normal	50	50
QRS-Complex	Abnormal	9	5
	Normal	41	45
ST-Segment	Abnormal	0	0
	Normal	50	50
T-Wave	Abnormal	1	0
	Normal	49	50
QT-Interval	Abnormal	0	1
	Normal	50	49

Table 3 shows among cases of Medical college 41 people have normal QRS and 9 people have abnormal QRS, whereas in case of control of Medical College 45 people have normal QRS and 5 people have abnormal QRS, which is not statistically significant (P Value 0.249). It shows among cases of Medical College 50 people have normal QTc and none have prolonged QTc whereas 49 people have normal QTc and 1 people has prolonged QTc which is not statistically significant (P Value 0.466).

Table 4: Pulmonary function test findings among healthcare professionals

PFT Parameters (Predicted %)		Case	Control
FEV1	Abnormal	14	25
	Normal	36	25
FEV1/FVC	Obstructive	1	4
	Normal	35	29
	Restrictive	14	17
FVC	Abnormal	22	30
	Normal	28	20

Table 4 shows among cases of Medical college mean FEV 1 is 91.92 (SD 32.50) whereas that of control is 75.98 (SD 28.65) which is statistically significant (P Value 0.011). It shows among Medical college cases Mean FEV1 / FVC ratio is 114.50 (SD 12.63) whereas that of control is 103.90 (SD 15.94), which is statistically significant (P Value 0.000). Study shows among Medical college case mean PEFR is 63.46 (SD 26.339) and that of control is 50.39 (SD 22.430) which is statistically significant (P Value 0.009).

Table 5: Analytical statistics of health care professionals (cases) versus controls Unpaired T-Test

Variable		Mean	Standard Deviation	Standard Error Mean	p-Value
Age	Cases	48.20	6.061	0.857	0.411
	Control	49.34	7.644	1.081	
BMI	Cases	24.20	2.921	0.413	0.084
	Control	23.06	3.571	0.505	
FEV1	Cases	91.92	32.505	4.597	0.011
	Control	75.98	28.650	4.093	
FEV1/FVC	Cases	114.50	12.630	1.786	0.000
	Control	103.90	15.944	2.301	
PEFR	Cases	63.46	26.339	3.725	0.009
	Control	50.39	22.430	3.204	

P<0.05 is considered as statistically significant.

Table 5 shows FEVI[1], FEV[1]/FVC and PEFR are significantly increased / higher in cases compared to controls.

Discussion

Cardio-respiratory fitness (CRF) is not only an objective measure of habitual physical activity

but also a useful diagnostic and prognostic health indicator for patients in clinical settings. Although compelling evidence has shown that CRF is a strong and independent predictor of all–cause and cardiovascular disease mortality, the importance of CRF is often over looked from a clinical perspective compared with other risk factors such as hypertension, diabetes, smoking or obesity.[3]

Generalized obesity is defined as BMI ≥ 25 kg per m^2 for both genders (based on the world health organization Asia Pacific guidelines) with or without abdominal obesity.[4] Rajendra Pradeepa et al published a study in Indian journal of Medical Research in 2015 regarding prevalence of generalized and abdominal obesity in urban and rural India.[4] They observed incidence of obesity increased significantly with income. An increasing trend in obesity was observed with increasing educational status. Table 5 shows there is significant difference between BMI, addiction & awareness. In a study published in Nigerian Journal of Clinical Practice in 2013 B Ordinioha found prevalence of hyper tension among lecturers of Medical school was lower than that of general population in urban centers.[5] But in a similar study published by Kurtul S et al[6] found that despite a tendency to have lower prevalence of hypertension among physicians, the difference found with the rest of the population did not reach statistical significance.

Abhishek Ghosh et al[7] published study in International Journal of Medical Science and Public Health in 2016. They have found that the prevalence of pre-hypertension and hypertension in doctors is not at all less than general Indian population. Rather the risk factors such as raised BMI and smoking are very common among doctors. But result of our study need not show such trend. In our study we assessed the knowledge of life style awareness about cardio vascular disease during history taking.

In our study also we have found that doctors, sisters and technician of Medical College (cases) have better knowledge of lifestyle awareness than general population (Control). In another study published in Central Asian Journal of Global Heath in 2015 by Nidhi Goel et al[8] conducted a Multicentric Cross-Sectional study among Medical students of 8 Medical colleges across India. They observed prevalence of alcohol consumption in undergraduate and post graduate student was 16.6% and 31.5% respectively. Tobaco usage for undergraduate and post graduate was found to be 8% and 14.5 % respectively. In our study we have found that addiction of alcohol and smoking is statistically significant among doctors and technicians and similar in control group of Medical College and Hospital. Result of our study is similar to earlier studies.[7, 8]

Barbara E. Bussink et al[9] published a study in European Heart Journal in 2012. They have found prevalence of RBBB was twice as high in men compared to women. Prevalence of RBBB is associated with higher blood pressure but not consistently with other cardio vascular risk factors. Similarly FLEG JL et al[10] published a study in Journal of American College of Cardiology in 1983. They have found RBBB in asymptomatic men is a manifestation of a primary abnormality of cardiac conduction system but has no demonstrable adverse effect on long term cardiac morbidity and mortality. In our study majority of QRS abnormality is of RBBB pattern. Though there is no statistical significant QRS abnormality among cases or control, 13% of our study population have RBBB pattern (complete and incomplete) which is a bit higher than earlier study.

Basavarajaiah S et al[11] published a study in European Heart Journal in 2007 on prevalence and significance of long QT interval in elite athlete. Incidence of QTc prolongation among athletes was 0.4%. In our study we have found incidence of asymptomatic prolonged QTc is 1% which is much higher than earlier studies. But no obvious cause was found in our study.

During our study we have measured 4 parameters in PFT viz., FEV^1 %, FEV^1/ FVC%, FVC% and PEFR %.V.K. Vijayan and K.V. Kuppurao et al[12] published a study in Thorax 1990 on pulmonary functions in healthy young adult in Madras. They have found mean FEV^1% in South Indian men and women are 85.87 (SD 7.05) and 87.53 (SD 6.17) respectively. S.R. Kamat and Tyagi NK[13] have done a study of lung function in Indian adult subject and published in Lung India in 1982. They found that there is a distinct relationship between FVC, FEV1% and socio-economic status, the values being lower ($P<0.005$) in the males of lower socioeconomic strata. There was no clear relationship

with daily physical activity, the values being lower in those doing strenuous exercise. In contrast to above mentioned studies we have found opposite result. S.K. Chhabra & R.Kumar[14] published a study in 2014 on PFT among adult population of northern India. They have found mean FEV 1 / FVC is 80.37 in case of male and 84.27 in case of Female. In our study we have found much higher mean FEV1/ FVC in medical personnel and control group of Medical College. Jung Yeon Lee et al[15] published a study on prevalence of spirometrically defined restrictive ventilatory defect in Korea in 2015. They have found prevalence of restrictive ventilatory defect among the nationwide population in Korea was 11.3%.

Laura Kurth and Eva Hnizdo in a study[16] among US population found that over all age-standarized prevalence of restrictive pattern decreased significantly from 7.2% (1988-1994) to 5.4% (2007-2010). Factors positively associated with restrictive pattern on Spirometry include age, female sex, white race, lower education, former and current smoking and comorbidities like cardiovascular disease, Diabetes and Abdominal Obesity. Ravi B. Solanki et al[17] in a study among petrol filling workers in India found that prevalence of restrictive pattern abnormalities was 14% and obstructive pattern was 1%. In our study, we have found predominant spirometry abnormality was restrictive pattern which was 45%, much higher than earlier study. But obstructive pattern was found in 4.5% among study population. High prevalence of restrictive pattern in our study may be due to poor effort or confounding factor like obesity/ overweight which needs further study.

Conclusion

Doctor, nurses and technicians are more health conscious than general population. Medical personnel are more obese particularly in corporate hospital. Doctors and technician are addicted to smoking and alcohol similar to general population. Medical personnel have similar blood pressure level as in general population. RBBB pattern is the most predominant QRS abnormality which is not uncommon. QTc prolongation is rare. Medical personnel have lower mean FEV^1%, FEV^1/ FVC and PEFR % than general population. Predominant spirometry abnormality in our study is restrictive pattern.

Conflict of Interest: None

Ethical clearance: Approved by Institutional Ethics Committee, Medical College & Hospital, Kolkata

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Original research Article

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Effect of SSRI on C-Reactive Protein in Case of Depression

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Abstract

Introduction: Depression can present with several symptoms, such as loss of pleasure, feelings of guilt, low self esteem, and disturbed sleep or appetite. In recent socio- economic scenario incidence & prevalence of depression is on increasing trend. SSRIs are the mainstay of treatment of depression.

Objective: the anti-inflammatory role of escitalopram in freshly diagnosed depression case and also to find any correlation between depression & inflammation.

Material & Methods: It was a cross-sectional analytical study conducted at College of Medicine and Sagore Dutta Hospital by Department of Biochemistry in collaboration with Department of Psychiatry. 71 Patients attending psychiatric OPD who are newly diagnosed as Major depressive disorder (MDD) were selected. 73 Age and sex matched healthy family members of the patients were taken as controls.Before starting treatment C reactive protein (CPR) & Hamilton depression rating scale (HAMD) was assessed. After 12 weeks of treatment same parameters were assessed again.

Results: after 12 weeks of treatment mean CPR & HAMD score is significantly reduced in case group as compared to the baseline values respectively. The reduction of HAMD score is negatively correlated with the baseline CPR.

Conclusion: Escitalopram significantly reduce the CPR value which may have a role in improvement of HAMD score.

Keywords: Major Depression, CPR, HAMD.SSRI

Introduction

Depression is a serious psychiatric disorder that can lead to emotional and physical problems, including loss of interest or pleasure, feelings of guilt or low self-worth, and disturbed sleep or appetite[1]. Recently it is emerging as a major public health problem affecting large number to human populations worldwide irrespective of age. Women are significantly more prone to develop depression

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than males and often have a more chronic course[2]. Furthermore, the lifetime risk of developing depression increases to as high as 40% when comorbid chronic medical illnesses such as diabetes and cardiovascular disease (CVD) are present[3]. The immune system, particularly the inflammatory response, plays an important role in depression and its pharmacological treatment. Recently several studies have been conducted to find the role of inflammation in psychiatric illnesses like depression[4-5]. Some studies have shown that inflammatory markers are elevated in central nervous system tissues collected from individuals with depression than compared to healthy controls, including increased concentrations of pro-inflammatory cytokines and immune mediators in cerebrospinal fluid[6-7]. CVD is the leading cause of morbidity and mortality worldwide, which is further influenced by an abundance of modifiable risk factors. CRP is one among them These factors also appear to be involved in the pathophysiology of depression, and may account for the higher cardiovascular risk observed in this disorder[8].

A combination of psychological and pharmacological therapies is the predominant treatment modalities for depression. Antidepressants are the mainstay of pharmacological intervention for moderate to severe depression which is used to alleviate mood and behavioral symptoms. Most of the widely prescribed classes of antidepressants are selective serotonin reuptake inhibitors (SSRIs) such as fluoxetine, paroxetine, escitalopram and sertraline. Other drugs like serotonin–norepinephrine reuptake inhibitors (SNRIs) such as venlafaxine, desvenlafaxine, and duloxetine[9–11], and tricyclic antidepressants (TCAs) such as imipramine, clomipramine, and desipramine[12–14]are also used.

Aims & Objectives: To assess the anti-inflammatory role of escitalopram in freshly diagnosed depression case and also to find any correlation between depression & inflammation

Materials & Methods

Ethical Clearance: Valid ethical permission was taken from institutional ethics committee of College of Medicine & Sagore Dutta Hospital.

The original work was from here only after the permission of ethical committee.

Study type and design: A cross-sectional analytical study

Study setting: It was conducted at College of Medicine and Sagore Dutta Hospital by Department of Biochemistry in collaboration with Department of Psychiatry.

Study population: Patients attending psychiatric OPD who are newly diagnosed as Major depressive disorder (MDD).

Inclusion criteria of cases: Patients,aged between 18-55 years newly diagnosed to have MDD (fulfilling DSM V criteria**)** or RDD (unipolar)

Inclusion criteria for controls: Age and sex matched healthy family members (brothers, sisters) of the patients

Exclusion criteria:

Patients with other acute or chronic disorder e.g Diabetes mellitus, Hypertension, Hypo or hyperthyroid, Seasonal Affective Disorder, other psychiatric disorder, dyslipidemia, malabsorption disorders, malignancy, liver cirrhosis or previous treatment with other anticonvulsants, patients having bipolar depression.

Sample size:71 cases & 73 control

Study duration with time scheduling: December 2021 to May 2022

Tools and techniques:

Every individual in both case & control group were asked to be give written consent after explaining the whole process in language which is understandable to them. The confidentiality of the statement and reports were maintained with utmost priority.

5ml overnight fasting blood sample was collected along with the detailed history and fulfilling the exclusion criteria. Serum was separated & collected after centrifugation.

Blood samples were analyzed for serum C-reactive protein by following manufacturer's instruction with ERBA EM360/640 Autoanalyzer.

Data was collected and analyzed by using statistical software.

Control and cases were grouped. At the beginning of starting treatment the biochemical parameters were measured and clinically assessed for psychiatric function using HAM-D criteria. After 12 weeks of treatment with escitalopram 20 mg daily ,again the patients were reviewed and assessed by the same criteria to know the effect. Exposure variable and descriptive analysis weredone. Mean, median, standard deviation and distribution of data was assessed. Depending on the distribution of data statistical tools were used to find further significant analysis.

Results

Table 1: Descriptive epidemiology & Comparison of CRP in case & control

	Case(n=71)	Control (n= 73)	p
CRP Mean ±SD	3.10±0.89	1.17±0.67	<0.0001*

P <0.05 * significant

Table 2: Comparing CRP & HAMD values in case group before & after 12 weeks of starting treatment

	Case before starting treatment	Case after 12 weeks of treatment	p
CRP Mean ±SD	3.10±0.89	1.41±0.29	<0.0001*
HAMD ±SD	23.23±2.87	9.38±2.30	<0.001*

P <0.05 * significant

Table 3: Association between baseline CRP & HAMD along with treatment response

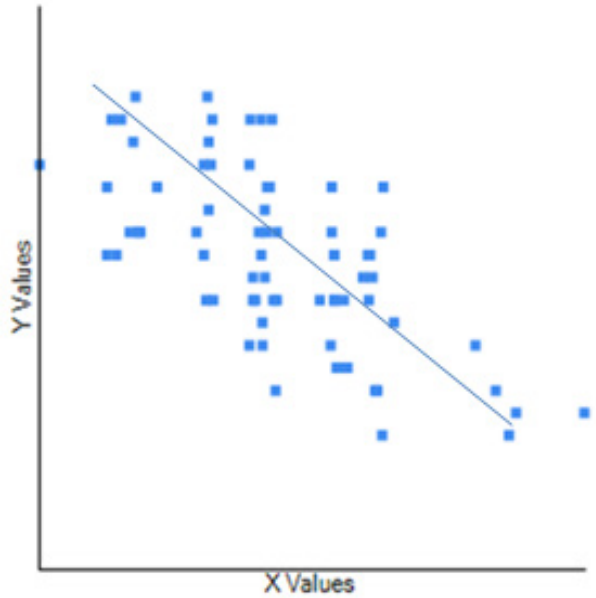
Baseline CRP	Baseline HAMD	Pearson correction coefficient	p
3.10±0.89	23.23±2.87	0.59	<0.001
Treatment response			
CRP after 12 Weeks	**HAMD after 12 weeks**	**Pearson correction coefficient**	**p**
1.41±0.29	9.38±2.30	0.1389	0.04

P <0.05 * significant

Table 4: CRP baseline & reduction in HAMD

Baseline CRP	Reduction in HAMD	Pearson correction coefficient	p
3.10±0.89	3.10±0.89±3.91	-0.6566	<0.05

P <0.05 * significant



Discussion

In our study we found that CRP is significantly high in the case group when compared to the control. Moreover it was being correlated with the HAM-D scoring at the point of diagnosis before starting any treatment. whereas after 12 weeks of treatment with escitalopram the decrease in HAM-D score is negatively correlated with the baseline CRP level.

CRP is an inflammatory biomarker of that can serve as a prognostic indicator of MDD patients. Patients with MDD showed characteristically elevated CRP levels[4].Smith et al., 2018 along with several other studies also found that CRP predicted depressive symptoms at follow-up assessments in adjusted models, similar to our findings[15-17]. On the contrary, several other studies did not show any causal association between genetically increased CRP and the development of depression[18-20].

The decrease in CRP following initiation of SSRI treatment indicates the role of this acute phase inflammatory reaction protein as a definite marker of depression. Since antidepressant therapy

significantlydecreased CRP concentration, it also proves that antidepressants inhibit this pro inflammatory protein.

The mechanism of reduction of CRP bySSRIs is due to the fact that there are some pathways through which inflammatory cytokines can lead to reduced synaptic availability of the monoamines. These are by decreasingtetrahydrobiopterin, by stimulating glutamate release, by activating the enzyme indoleamine 2, 3-dioxygenase, or by decreasing Brain Derived Neutrotrophic Factor[21]. SSRIs block these pathways of proinflammatory cytokines leading to reduction of CRP. Another possible mechanism involves serotonergic pathways .Low concentration of extracellular serotonin is necessary for optimal production of cytokines and normal immune functions, whereas higher concentrations of serotonin are immunosuppressive and inhibits cytokine production. SSRIs inhibit the reuptake of serotonin resulting in high extracellular serotonin concentrations and the subsequent inhibition of cytokine production[22].This is the explanation why in our study, we have got similar results using escitalopram, an SSRI[23-28].

Conclusion

Baseline evaluation of pro-inflammatory marker like CRP can predict the prognosis and progression of disease. Evaluating the pro-inflammatory stage treatment modality can be planned or modified.

Limitations: Small sample size along with lac of prolonged follow-up**.**

Conflict of interest: The authors declare that there is no conflict of interest in the study.

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Study of Dosage of Prophylactic Intravenous Ephedrine for Spinal-Induced Hypotension During Caesarean Section in Andhra Pradesh Population: Retrospective Study

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Abstract

Background: Spinal anaesthesia is widely used for caesarean surgery because it provides a fast and profound sensory and motor block, on the other hand Hypotension is very common complication of spinal anaesthesia. Hence Ephedrine infusion has to be used to control hypotension.

Method: Out of 60 (sixty), 30 were administrated with ephedrine 30 controlled group was administrated same quantity of normal saline during spinal anaesthesias. Hemodynamic and neonatal outcomes were noted and compared.

Results: In comparison of systolic BP time interval between both group at 1, 3, 4, 5 had significant values ($p<0.001$). Moreover rescue Ephedrine dosage in group-A 3.02 (± 0.2), 4.05 (± 0.3) t test 15.6 and $p<0.001$ (p value was highly significant) but agar score at different interval and umbilical cord blood PH remained the same value.

Conclusion: The present has proved that, IV infusion Ephedrine after spinal was more effective than crystalloid preloading in prevention of hypotension in parturient undergoing caesarean section with causing hemodynamic complications.

Keywords: Caesarean section, Ephedrine, hypotension, spinal anaesthesia, apgar score

Introduction

Anaesthesia of caesarean delivery should take in consideration safety of the mother and foetus Regional anaesthesia used for 95% of planned caesarean deliveries globally(1). Spinal anaesthesia has many advantages as it provides fast, profound sensory and motor block and adequate muscle relaxation(2), better air way control with obstruction or aspiration of gastric contents. Post-operative vein thrombosis and pulmonary emboli are less common following spinal anaesthesia due to earlier ambulation and discharge.

However spinal anaesthesia has its complications. The most common complications of spinal anaesthesia is hypotension(3), which can cause significant morbidity and mortality as it may cause serious complication for the mother as nausea, vomiting un-consciousness and pulmonary aspiration and for the baby as hypoxia acidosis and

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neurological injuries[4]. Hypotension occurs due to the sympathetic nervous system blockade leading to decreased vascular resistance and peripheral pooling of blood which reduces cardiac output[5].

Different technique have been tried to reduce hypotension incidence and severity. This includes the routine use of lateral decubitous position, infusion of up to 2 litres of fluids for intra vascular volume expansion, which may reduce the risk of hypotension but does not eliminate and use of vasopressors such as ephedrine which may be effective alternative for hypotension prevention. Ephedrine is a sympathomimetic agent, non-catecholamine mediated which directly stimulates alpha and Beta adrenergic receptors and predominantly indirectly produces its effects through releasing nor-epinephrine from nerve endings in the autonomous nervous system. Hence intravenous Ephedrine was used in spinal anaesthesia to control hypotension and evaluated the outcomes in both mother and foetus.

Material and Methods

60 (sixty) female patients admitted at obstetrics and gynaecology department of GSL medical college hospital rajahmundry-533296 Andhra Pradesh were studied.

Inclusive Criteria: The age between 20-48 years old, with Body Mass Index (BMI) between 25 to 45 years. As A grade-I and II were selected for caesarean study.

Exclusion Criteria: Patients refused spinal anaesthesia patients having allergic reaction to local anaesthetics and opoids patients with coagulopathy (due to blood disease liver diseases or on anticoagulants) patients with severe cardiac respiratory hepatic or renal disease and patients with pre-eclampsia and eclampsia were excluded from the study.

Method: Out of sixty (60) patients Group-I was received 1 ml of 5mg injection Ephedrine intravenously. Group-II (controlled group) received on equal volume of normal saline intravenously immediately after the sub-arachnoids block with 10 mg of 0.5 % injection Bupivacaine.

A through pre-anaesthetic evaluation was done a day before the scheduled operation to all patients and tablet PPI (Ranitidine 150 Mg) orally was advised let night before surgery.

On the day of operation injection Metaclopromide 10 mg and injection Ranitidine 50 mg was given intravenously, 20 minutes before the induction of spinal anaesthesia.

Upon arrival of the patients at the operation theatre, baseline parameters were recorded with the help of multichannel cardiac monitor pre loading was done with injection ringer lactate solution 15 mg / Kg body weight about 15 Minutes before the intended time of intrathecal drug administration.

Under strict asceptic and antiseptic precautions, lumbar puncture was performed at L3-L4 inter vertebral space using midline approach with a 25 gauge quinke spinal needle in the lateral decubitus position and 10 mg of 0.5% injection bupicaine was administrated intrathecally. Immediately, either 1ml of 5mg injection Ephedrine or an equal volume of normal saline was given intravenously on the parturient according to the computer generated randomization method.

The hemodynamic parameters such as heart rate systolic BP, percentage saturation of oxygen (SPO^2) and electogram were recorded at 1 minute interval till delivery of the baby and thereafter 5 min. intervals until. The end of surgery I.V fluid was administrated in the form of Ringer lactate at the rate of 10 mg / kg body weight per hour. A decrease in systolic BP of more than 20% from baseline was considered as "hypotension" and treated with rapid infusion of ringer lactate and 5 mg intravenous Ephedrine and heart rate < 60 beats per minute or bradycardia was also treated with intravenous 0-6mg Atropine sulphate. Apgar scores of babies were recorded at 1 and 5 minutes.

Duration of study was August-2013 to Novembe-2016

Statistical analysis: Various parameters e.g. demographic hemodynamic, agar score in both groups were compared with z test and noted. The statistical analysis was carried out in SPSS software.

Observation and Results

Table-1: Age groups (in years)

- 26.10 (± 3.33) in group-A, 25.8 (± 2.80) in group-B, t test was 0.35 and p value was insignificant (p>0.72)
- Height (cm) – 158.2 (± 3.30) group-A, 158.5 (± 4.30) in group-B, t test level was 0.36 and p value was insignificant (p>0.71)
- Weight (Kg) – 62.03 (± 6.80) group-A, 64.50 (± 6.80) in group-B, t test level was 1.5 and p value was significant

Table-2: Comparison of systolic Blood pressure at different interval at 1, 2, 3, 4, 6, 10, 15, 20, 25, 30, 35, 40, 45 in both groups and p values was insignificant

Table-3: Comparison of hemodynamic profile and clinical manifestation

- Hypertension – 18 (60 %) group-A, 22 (73.3%) in group-B
- Rescue Ephidrine in – 18 (60 %) group-A, 22 (73.3%) in group-B
- Rescue Ephidrine dosage – 3.02 (± 0.2) group-A, 4.05 (± 0.3) in group-B, t test level 15.6 and p value was highly significant (p<0.001)
- Average time for delivery – 4.90 (± 0.6) group-A, 4.87 (± 0.7) in group-B, t test level was 0.17 and p value was insignificant (p>0.85)

Table-4: Comparison of Neonatal outcome

- Agar score 1 minutes – 8.95 (± 0.95) group-A, 8.86 (± 0.31) in group-B, t test level was 1.35 and p value was insignificant (p>0.18)
- Agar score 5 minutes – 9.94 (± 0.81) group-A, 9.84 (± 0.31) in group-B, t test level was 1.52 and p value was insignificant (p>0.13)
- Umbilical cord PH – 7.32 (± 0.03) group-A, 7.31 (± 0.02) in group-B, t test level was 1.51 and p value was insignificant (p>0.93).

Table 1: Comparison of demographic variables parameters both group

Sl. No	Parameters	Group-A Study group (30)	Group-B Controlled (30)	t test	p value
1	Age (years)	26.10 (± 3.33)	25.82 (± 2.80)	0.35	p>0.72
2	Height (cm)	158.22 (± 3.30)	158.58 (± 4.30)	0.36	p>0.71
3	Weight (kg)	62.03 (± 5.19)	64.50 (± 6.80)	1.5	p>0.12

Table 2: Comparison of systolic Blood pressure in both groups

Time Interval	Group-A(30)	Group-B(30)	t test	p value
0	123(± 5.98)	121.22(± 4.30)	1.48	p>0.14
1	120.79(± 15.60)	100.03(± 22.30)	2.97	P<0.005
2	119.15(± 16.2)	88.79(± 13.60)	7.86	P<0.001
3	119.26(± 10.80)	87.3(± 8.89)	12.5	P<0.001
4	118.30(± 5.50)	114.40(± 7.30)	2.33	P<0.002
5	112.40(± 7.40)	114.22(± 7.81)	0.92	p>0.35
6	114.80(± 5.10)	115.10(± 7.30)	0.18	p>0.85
10	110.40(± 6.02)	109.42(± 3.70)	0.76	p>0.77
15	112.10(± 6.72)	108.78(± 3.30)	2.42	P<0.02
20	111.08(± 5.40)	109.40(± 3.90)	1.38	P>0.91
25	110.02(± 5.11)	110.38(± 5.30)	0.26	p>0.78
30	11.10(± 6.12)	110.18(± 3.09)	0.16	p>0.87
35	110.38(± 6.12)	110.36(± 3.19)	0.016	p>0.98
40	111.18(± 6.79)	111.25(± 3.90)	0.056	p>0.95
45	113.18(± 8.00)	111.42(± 3.66)	1.09	p>0.27

Table 3: Comparison of Hemodynamic data and clinical manifestations

Parameter	Group-A (30)	Group-B (30)	t test	p value
Hypotension	17 (60%)	22 (73.3%)	--	-
Reactive Hypertension	--	--	--	--
Rescue Ephedrine	18 (60%)	22 (73.3%)	--	--
Rescue Ephedrine dose (mg)	3.02 (± 0.2)	4.05 (± 0.3)	15.6	P<0.001
Bradycardia	--	--	--	--
Nausea and vomiting	--	--	--	--
Average time for Baby Delivery	4.90 (± 06)	4.87 (± 0.7)	0.17	p>0.85

Table 4: Comparison of Neonatal outcome in both groups

Parameter	Group-A	Group-B	t test	p value
Agar Score at 1 min	8.95 (± 0.19)	8.86 (± 0.31)	1.35	p>0.18
Agar Score at 5 min	9.94 (± 0.18)	9.84 (± 0.31)	1.52	p>0.13
Umbilical cord blood PH	7.32 (± 0.03)	7.31 (± 0.02)	1.51	p>0.93

All the parameters are more or less in agreement with each other

Discussion

Present study of dosage of prophylactic IV Ephedrine for spinal induced hypotension during caesarean section in AP population. 30 parturient were administrated IV Ephedrine and 30 parturient was controlled group administrated same quantity of normal saline. Both groups had more or less same demographic variables (E.g., age, height and weight) (Table-1). In systolic blood pressure comparison in both groups at different internal 1, 2, 3, 4 minutes had significant variables in both groups (p<0.001) p value was highly significant (Table-2). In comparison of hemodynamic study hypotension was observed in 18 (60%) in group-A, 22 (77%) in group-B. Rescue ephedrine dose (mg) had significant p value (p<0.01) (Table-3), but neonatal outcomes parameters agar scores at different intervals and umbilical cord blood PH were more or less in agreement with each other (Table-4). These findings are more or less in agreement with previous studies [6][7][8].

The incidence of hypotension is higher in caesarean section due to cardiac changes of the parturient. Compression of inferior venacava by hypertrophic uterus and developing collateral venous plexus circulation in the epidural space, leading to decrease in the amount of CSF (cerebro spinal fluid) in the lumbo-sacral area and higher cephalad spread of local anaesthesia [9].

Since the storage of endogenous norephinephrine is depleted in patients under long term treatment with ACE inhibitors (or angiotension II receptor antagonists). This leads to the proposal that these patients would benefit from use of a direct acting sympathomemitic drug such as ephedrine. Ephedrine is the vasopressor of choice for hypotension prevention after spinal anaesthesia during caesarean section because of its ability to keep utero placental blood flow maintained as ephedrine's action is mainly indirect, through Stimulating norephinephrine release from sympathetic nerve endings and the

utero placental circulation is largely devoid of direct sympathetic innervations, so it is considered resistant to the vaso-constrictive effects of ephedrine [10].

It is also reported that Ephedrine was injected intramuscularly and observed hypertension whenever spinal anaesthesia was not successful [11] hence prophylactic IV ephedrine administrated either by infusion or multiple bolus has been considered as gold standard method for preventing hypotension. Moreover the effect of IV bolus of ephedrine on arterial pressure is transient and it lasts for only 10-15 minutes [12]. Hypotension after the delivery of foetus usually ignored, as it may be related to excessive blood loss during c-section.

Summary and Conclusion

A short period of hypotension (less than 2 minutes) frequently associated with spinal anaesthesia for caesarean section. Prophylatic IV Ephedrine infusion is more effective than fluid preload in prevention of hypotension due to spinal anaesthesia without causing significant tachycardia (or) hypertension.

Limitation of Study: Owing to tertiary location of research centre, small number of patients and lack of latest techniques we have limited findings and results.

This researchpaper was approved by Ethical committee of GSL Medical college Rajahmundry-533296 Andhra Pradesh.

Conflict of Interest: No

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Original Article

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A Longitudinal Observational Study on Micronutrient (Zinc) in Antenatal Women in Tertiary Center of Central Hospital, Bhopal

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Abstract

Background: Zinc is the crucial micronutrient that is essential for the normal embryogenesis process. It also supports fetal brain development during pregnancy, as well as with being an assist to the mother during labour. Changes in zinc homeostasis have been related to several outcomes in pregnancy including prolonged labour, fetal growth restriction, fetal death, preeclampsia, and preterm birth.

Aim: Aim of this study was to evaluate the level of zinc in 1st to 3rd trimester of pregnant women.

Material and Methods: The present study conducted at Department of Biochemistry and collaboration with the Department of Obs. & Gynaecology LN Medical College & J.K.Hospital. Total 300 cases attended from ANC Clinic were screened for the study. Estimation of serum zinc concentration was done by automated colorimetric kit method.

Results: Findings were, that there was significantly decrease in serum zinc concentration ($p<0.05$) in 1st to 3rd trimester of pregnancy period.

Conclusion: Zinc is most important micronutrient for the proper course of pregnancy and fetal development. Any changes in their concentrations can leads to adverse pregnancy outcomes. Therefor serum zinc concentration should be investigated, thereby reducing adverse pregnancy outcome.

Key Words: Pregnancy. Zinc level, Trimester period.

Introduction

Zinc is the second most abundantly distributed trace element in the body after iron. It is found in a wide range of foods, including beef, poultry, seafood, and grains [1, 2] Zn is a co-factor of more than 300 enzymes that regulate a variety of cellular processes and cellular signaling [3]. Zn is an essential micronutrient that is that is required for a variety of biological processes such as enzyme activity, immune function, neurological function, and reproduction. It is essential for cellular division and differentiation and is important for many aspects of metabolism due to its incorporation in antioxidant proteins (Cu/Zn superoxide dismutase). Zinc is also known as an "intelligence" element.

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It plays a dynamic role in a diversity of enzymes, like as carbonic anhydrase, DNA polymerase, RNA polymerase, etc., participating in important biochemical nucleic acids, proteins and other metabolic processes [4]. It is the crucial nutrient that is essential for the normal embryogenesis process [5]. It also supports fetal brain development during pregnancy, as well as with being an assist to the mother during labour [6]. Changes in zinc homeostasis have been related to several outcomes in pregnancy including prolonged labour, fetal growth restriction, fetal death, preeclampsia, and preterm birth [7- 8] . Zn plays an important role in the absorption, synthesis, and biological activation of folate; thus, Zn deficiency during pregnancy may result in folate deficiency, which can lead to neural tube defects (NDTs) and other fetal disorders [9-10]. Zn is involved in the formation of the fetus, its deficiency may result in impaired development and affect the final phenotype of the newborn's organs [11, 12]. During progression of pregnancy circulating zinc level decline due to decrease in zinc binding and increased transfer of zinc from the mother to the fetus [13, 14]. As a result, zinc deficiency in pregnant women can directly or indirectly impact the fetus's growth and development. Pregnant women who are zinc deficient may experience loss of appetite, which invariably affects nutrient intake and leads to poor fetal development [15]. Therefore monitoring of serum zinc levels in pregnant women during pregnancy is essential to ensure proper fetal development.

Material and Methods

This was a Longitudinal observational study conducted at Department of Biochemistry and collaboration with the Department of Obs. & Gynaecology LNMC & J.K.Hospital, Bhopal. The study period was 2019 to 2021.

Present study included total 300 cases attended ANC Clinic at the department of Gynaecology LNMC & J.K.Hospital, Bhopal. Pregnant women divided in three groups. Group A: n = 100 pregnant women of 1st trimester of pregnancy. Group B: n = 100 pregnant women of 2nd trimester of pregnancy, Group c: n = 100 pregnant women of 3rd trimester of pregnancy. Pregnant women were taken from 20-40 years of age group. In this study included, pregnant women first to third trimester of pregnancy, excluded pregnant women of thyroid disease and suffering from asthma / hypertension / diabetes mellitus and / any other systemic disease. Study was approved by the Ethical committee, dated on 31/05/2019, Ref: LNCTU/Ph.D./2019/BC/055, L.N. Medical College, Kolar road, Bhopal M.P. Informed written consent was obtained from all patients,

Total 3-5 ml of blood sample was withdrawn from the anticubital vein, and the blood sample was collected in plain vacutainers. The blood sample was centrifuged for 15 minute, at 3000 rpm at room temperature. The serum was stored at 4°C for biochemical investigations. Estimation of serum zinc was done by automated colorimetric kit method. Statistical analysis was done by Graph Pad Prism version 5. Analysis was done by Anova followed by Tukey test. $p<0.05$ was considered as statistically significant.

Distribution of Pregnant Women at Different Trimester

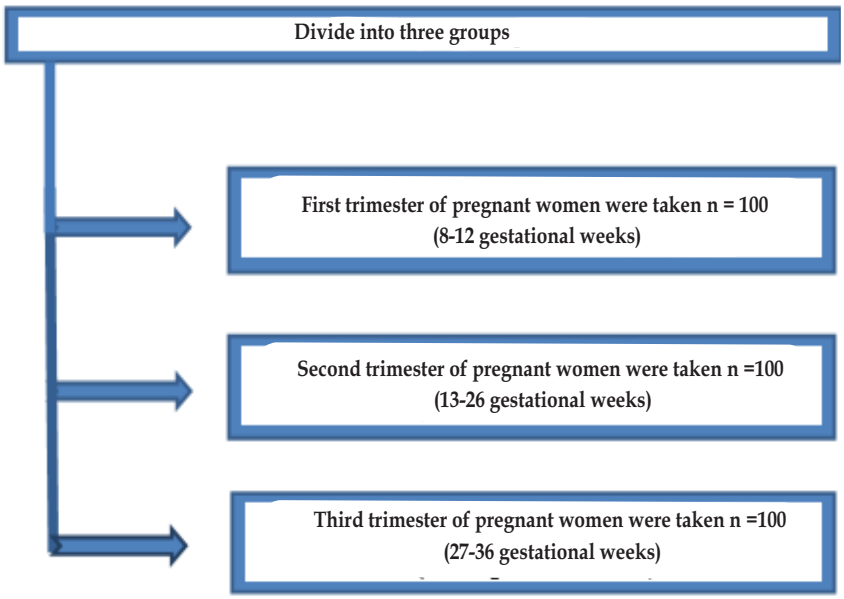

Figure 1: Number of pregnant women included in the detection at different trimesters.

Observation and Results

Table 1: Serum Zinc Concentration 1st To 3rd Trimester Of Pregnant Women (Mean ± Sd)

Groups	Pregnant women -1st trimester Zn ug/dl Mean ±SD	Pregnant women -2nd trimester Zn ug/dl Mean ±SD	Pregnant women -3rd trimester Zn ug/dl Mean ±SD	P value (<0.05)
Zn ug/dl Level	78.54 ±3.05	75.62 ± 2.05	69.04 ± 4.05***	< 0.05

Compared with 1st to 3rd trimester of pregnancy p <0.05

Table 1:

In 1st trimester, serum zinc (Zn) level was (78.54 ± 3.05) ug/dl, 2nd trimester (75.62 ± 2.05) ug/dl while in 3rd trimester serum zinc (Zn) level was (69.04 ± 4.05) ug/dl.

Although, difference between 1st trimester to 3rd trimester zinc level was significant.

Serum Zinc level (Zn) was significantly decreased in 1st trimester to 3rd trimester.

Discussion

In this study the concentration of Zn significantly decreased 1st trimester to 3rd trimester (<0.05).This is an agreement with previous studies by Tamura T et al (2000) [16], Reyes H et al (2000) [17] Gibson et al (2007) [18], Tabrizi et al (2014) [19], Choi R et al (2016) [20]. Lewicka et al (2017) [21] showed in these study serum zinc concentration significantly decreases in 1st to 3rd trimesters.

There are several causes of a decrease in serum or plasma Zn level during pregnancy, like first, low serum albumin and high estrogen levels; second, increased maternal blood volume has been suggested as a factors lowering plasma Zn level, and other reasons due to low Zn levels were prominent in women with dietary Zn deficiency [22]. Due to the fact that intestinal absorption is not increased during pregnancy, an additional Zn requirement for fetal and placental tissues must be covered by increased intake and from maternal tissues. As a result, daily requirements for Zn during pregnancy range from 7.3 to 13.3 mg [23]. Zn deficiency causes low dietary bioavailability [31], or very high amounts of copper or iron in the diet that compete with zinc at absorption sites [24].

Conclusion

Zinc is most important micronutrient for the proper course of pregnancy and fetal development. Any changes in their concentrations can cause interactions that are dangerous to the health of the mother and fetus. The present article highlights the importance of role played by micronutrient zinc during pregnancy and its outcome. Therefore, during pregnancy should maintain nutritional balance; have regular medical examination; serum zinc concentration should also be investigated, thereby reducing adverse pregnancy outcome.

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Conflict of Interest: Nil

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Original Research Article

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A Qualitative Study on Factors Associated with Low Academic Performance among Medical Students

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Abstract

Introduction: To ensure optimal quality of health care for the community, it is important to produce an efficient primary care provider. In order to attain this quality we must ensure that all students achieve the required standards. In spite of pre-set prescribed standards, the academic performance varies among medical students.

Objectives: 1. Describe the factors affecting the learning of medical students. 2. Explore the possible solutions to improve their academic performance.

Materials and Methods: A total of 18 students and 12 faculties participated in the study. Among them, five Focus Group Discussions (FGD) were carried out (three FGDs with students and two FGDs with faculties). The discussion was guided by a facilitator and audio-recorded. Information from the audio was transcribed.

Results: Factors affecting learning include content of the class, class schedule, attention span, assessment pattern, audio-visual aids, level of integration of classes, ability of the teacher and teaching learning methods used. Solutions include field visits, hands-on training, appropriate use of audio-visual aids, integration of classes, active participation in research, communication with peers, strict maintenance of attendance and motivation of the students, etc,.

Conclusion: Addressing all the factors hindering the learning process by incorporating solutions suggested by faculties and students may help the learners to improve their academic performance. It is important to teach the topics with its practical application with an appropriate assessment pattern.

Key-words: Academic performance, Medical students, Focus Group Discussion, Assessment, Communication, Integration.

Introduction

To ensure optimal quality health care for the community, it is important to produce an efficient primary care provider. In order to attain this quality we must ensure that all students achieve the required standards prescribed by the National Medical Commission (NMC). Studies have shown that the low academic performance in the preclinical years is strongly associated with professional misconduct in the later years of practice[1]. Hence it is important to identify in detail the factors affecting learning and

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teaching for undergraduate medical students. In a focus group discussion, many students have felt that the volume of the subject made the learning difficult[2]. Quality of medical education is also very important for learning. A study by Dipta Kanti Mukhopadhyay revealed the quality gaps to be in the areas of physical facility, educational and audio-visual aids and appearance of the faculty members[3]. Lack of motivation was found to be a significant negative factor affecting the Grade Point Average[4]. Regular sleep positively correlated with academic performance[5]. Hence this study is needed to explore the experiences of the students and the teachers.

The objectives of the study were to describe the factors affecting the learning and to explore the possible solutions to improve the academic performance of students.

Methods: This study was undertaken using the exploratory study design. Focus Group Discussion (FGD) was conducted with students and faculties of our college in the Department of Community Medicine during Oct 2017-Feb 2018. Participants were third year undergraduate medical students and faculties of KAP Viswanatham Government Medical College (KAPVGMC), Trichy, Tamil Nadu, India.

Purposive sampling technique was used. Students with low academic performance, high achieving students and faculties were included. A list of all the third year medical students, their attendance of the last six months, and their last three internal marks were obtained from the Department of Community Medicine. From the list, students with low and high attendance as well as faculties were called to take part in the study. Separate FGD guide for faculties and students was prepared after an In-depth- interview with few faculties and representatives of exam going batch students. Faculties of KAPVGMC, Trichy from various departments in first, second, and third year subjects were called to take part in the FGD. The time and place of the discussion was decided after consulting with the participants. Totally, two FGDs with faculties and three FGDs with students were conducted by the facilitator in a non-threatening environment with six participants in each Focus Group Discussion. The discussion was guided by the facilitator and also audio recorded. Each FGD lasted for 45-75 minutes. The end point of the FGD was attained upon getting repeated information from the discussion. Refreshments were served at the end of each group discussion. All the participants were informed individually about the study result.

Data analysis: Information from the audio was transcribed for analysis. Data analysis was done manually using thematic analysis method.

Ethical clearance: Ethical clearance was obtained from the Institutional Ethical Committee of KAP Viswanatham Government Medical College, Trichy. Informed written consent was obtained from each of the study participants before the start of the discussion. Strict confidentiality was maintained throughout the study.

Results

Study subjects: Of a total of 150 students, 22 students were eligible to take part in the study. Out of the 22 eligible students, only 18 consented and participated in the study. A total of twelve faculties participated in the study.

Results of focus group discussion: Students and faculties discussed about the perceived factors affecting learning among the students and their suggestions to improve the same. These factors and solutions are described under various heading below;

1. Content of the class: Students are expecting to learn a variety of cases and not be restricted to a few exam cases. They also expressed a desire that the teacher focus more on the most prevalent and common diseases. It was suggested that the number of integrated classes to be increased as this would give more opportunity to learn about a condition in a shorter period. Also the integration would help them to have better clinical orientation while learning Pre and Para clinical subjects. Even in the theory classes, the discussion should be more case or problem oriented. Hands-on experience is needed wherever applicable. Students feel that they learn better when they have more field visits and hands-on-training.

2. Class schedule: Clinical postings are started from the second professional year onwards. They are divided into batches to attend the various clinical postings. Students prefer that postings of exam related subjects be assigned just prior to the university exam.

3. Attention span: To improve the attendance, it was suggested that sessions may be modified to suit the attention span of the students. To achieve this, interactive lectures may be introduced. One hour theory class may be reduced to forty minutes and the remaining time may be utilised for active interactions with the students. To make the teaching student centric, it is important to assess the needs of

the students. Creative teaching will help the students to be attentive throughout the session. It was felt that sometimes a change in environment from a typical to informal lecture hall for theory classes would be beneficial. Instead of including all the points in a topic, considering only the important aspects of the topic will increase the attention span. Focussing on common problems will arouse interest among the students.

4. Assessment pattern: There should be a change in the assessment pattern to make it more competitive. Apart from the knowledge component other domains like skills, attitude & communication have to be assessed at the undergraduate level. To achieve this we should have a variety of assessment instruments to address all domains of learning like- Multiple Choice Questions, Problem solving exercises, Objective Structured Practical Examination, Objective Structured Clinical Examination, Direct Observation of Procedural Skills, etc. Undergraduate scores may be utilised for further career progression like for postgraduate entrance. This will motivate the students to perform consistently. Faculties suggested that the use of problem solving questions may be increased to enhance the deep learning among the students.

5. Audio-visual aids: Correct usage of audio-visual aids by the faculties is essential to deliver the content. Repeated use of the same PowerPoint will reduce the interest of the students. It is mandatory to update the PowerPoint with necessary changes according to the previous experiences and latest guidelines.

6. Integrated teaching: It is important to teach the basic medical sciences along with the corresponding clinical subjects to enhance learning. Integrated teaching is one such way to incorporate the clinical aspects of a disease with the Pre clinical and Para clinical subjects. Clinical orientation can promote better understanding of pre and Para clinical subjects.

7. Teachers training: There should be some parameters to enhance the ability of the faculties. All the teaching faculties in the medical college may be given an induction training in Medical Education Technologies through Faculty Development Programme while joining the institution. Since teaching faculties are required to have a post-graduation degree it will be more appropriate to incorporate this training in the postgraduate curriculum. Sometimes it may be interesting to introduce performance assessment for the faculties by their peers.

8. Mentorship: The faculties are of the opinion that mentorship programmes may be strengthened to improve the student- teacher relationship. Giving students an opportunity to share their difficulties will help them to overcome their problems. Regular mentorship programmes will help them to be better focused on the day to day learning and will help avoid any deviation because of peer pressure and poor guidance.

9. Training / teaching methods: Faculties and students feel that some subjects are monotonous and require adaptations in the teaching methodologies. Along with chalk and board and PowerPoint teaching, other methods like sharing of materials, flipped class and e-learning may be added. Faculties strongly feel that for many reasons students dislike the use of PowerPoint. Regarding the content of the class, more focus may be given to practical topics and we must not attempt to teach the entire topic. Case oriented teaching / problem oriented teaching / practical application is required in many places. Hands-on training is needed wherever applicable. Student-patient interaction has to be taught. Interactive teaching methods may be used to break the monotony and increase the attention of all students. Students should be made aware about their role in learning.

10. Research activities: In the current system, there is less funding and opportunity for medical research for both students and faculties. Sources of funding may be increased to improve the research activities especially among the students.

11. Communication skills: As suggested earlier, it is important to improve communication skills among the medical students who are future doctors. This may be strengthened by increasing the student-patient interactions. Implementation of the Attitude, Ethics and Communication module suggested by the National Medical Commission will enhance the communication skills. Personal enhancement training may also be given to the students.

12. Attendance: To encourage consistent performance of the students, attendance of the students can be verified regularly. Punching may be introduced so that the administrators can monitor the attendance at any time.

13. Motivation of the students: Students are from various socio-cultural and economic backgrounds. Healthy interactions between the students and

frequent student-teacher interaction will help them to remain motivated.

Discussion

Integrated classes give clarity of subject to the learner. The prevalent infectious and non communicable diseases in India could be selected, and integrated classes or mini exhibitions of one day duration can be conducted involving all the concerned clinical and Para clinical departments. This method will also convey to the students the importance of the topic and hence ensure that they pay extra attention to it. In a study by Sharma P et al., it was found that the majority of the students (80.4%) agreed that integration of topics helps in improving the understanding[6]. Students can also participate by preparing flipcharts, models, etc. which can be used as teaching aids.

Clinical postings can be scheduled according to exam going students' priorities as flexibility in preparing the schedule is given to the individual colleges. Attention span of students depends on how much importance the learner attaches to the topic. A medical student is more focussed on diagnosis and treatment. Hence in an integrated class these points should be highlighted, followed by the preventive aspects. The relevant Pre and Para clinical subject matter has to be crisp and highly relevant to diagnosis and treatment.

Arousing the learners' interest in a topic is an art to be practised by the teaching faculty. The induction to the topic of discussion is very important. Those words must make the student recall what he knows already about the topic and identify the lacunae in knowledge that he has. He should be inspired to try to fill those lacunae by paying good attention to the teaching.

Majority of the students perform satisfactorily when they learn in a problem based manner[7]. Problem solving exercises are thought provoking and apt to be used for assessment. By this method the student should be able to put to use whatever he has learnt in all the relevant subjects so far to solve the given problem. The teaching faculty in turn must regularly update the questions given for these exercises by incorporating the newer developments in the medical field.

Audio visual aids especially PowerPoint must be used only to the extent required. Updating the PowerPoint before every class is very important. The same old PowerPoint should not be used, as it will be boring not only for the learner but also to the teacher. In a study by Nirmalya S et. al., in Tripura, it was demonstrated that a mix of audio-visual aids was more appreciated by the students[8].

Teacher's training in the form of regular faculty development program is a must for sharpening of skills. Mentorship is successfully followed in many institutions. Not only faculties, senior student mentors also play an important role in shaping the students. As suggested by Bhatia A et. al[9]., formal mentoring programmes may be conducted by trained students and faculties. Volunteer student mentors may be identified and trained. Mentor program at regular intervals may help the students to learn better. As suggested by Devi V et. al.,[10] majority of the students (62%) preferred mentored student projects. This will help the students to understand and be able to conduct scientific research. A few long term researches must be ongoing in all departments. Students can be involved in data collection, data entry and also final interpretation of results. This will make them a part of the process, feel useful to the institution and also learn about research.

Communication skills are needed in every walk of life and are useful not only for professional life but for life in general. Students can sharpen their communication skills by interacting with patients to a good extent. Also, good communication skills can be developed by encouraging students to mingle more with their peers through regular recreational and literary activities. Here the students will get a chance to develop respect towards fellow beings and also learn the right use of language. A study by Choudhary A et. al.,[11] also found that the majority (78.1%) of the students had a positive attitude towards communication skills learning.

Absence from class was the most common factor related to low academic performance[12]. Biometric attendance systems can be used for students. Students will come to class on time because the biometric will record the time of entry. It is time saving and makes it easy to know the attendance percentage whenever needed.

Appreciation, encouragement and positive attitude from the part of the teaching faculty will help the students to stay motivated. They should be made to realise their goals in life and they should be guided towards reaching the goal. In a study by Wu H et. al[13]., also suggested that intrinsic motivation has a larger effect on academic performance. Another study by Yousefy A et. al.,[14] also observed that motivational factors significantly affect academic achievement. Students perceived that factors like guidance by teachers, frequent class tests, feedback, appreciation from teachers, interactive lectures, integration of topics and problem based learning improves their academic performance[6].

Conclusion

Here we conclude that while teaching, it is pertinent to teach all the topics with their practical applications. Interactive teaching-learning techniques will enhance academic performance. It is also vital to make necessary changes in the assessment pattern. The recent implementation of Competency-Based Medical Education by the National Medical Commission will help medical students to learn better and improve their academic performance.

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Original Article

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Species Distribution and Antifungal Susceptibility Pattern of Candiduria in a Tertiary Care Hospital of Western Uttar Pradesh

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Abstract

Background: Urinary tract infection (UTI) is one the most common infections encountered in clinical practice. Bacteria and fungus are the common microorganisms associated with UTI. This study was carried out with the aim to identify the species distribution and anti-fungal susceptibility pattern of candiduria in a tertiary care Hospital of Western Uttar Pradesh.

Methods: This prospective hospital-based study was conducted over a period of one year. A total of 6250 urine samples were subjected for isolation and identification of microorganisms as per standard microbiological method. The antifungal susceptibility testing was performed for fungal isolates as per Clinical and Laboratory Standards Institute (CLSI) M44-A document recommendations.

Result: The culture positivity rate was 58.43%. Among the culture positive, Candida species was isolated from 141(3.86%). There was predominanceof Non-albicans candida(NAC) species 131 (92.91%) as compared to *Candida albicans* 10(7.09%). The positivity was more in the females in the age group of >60 years. *C. tropicalis*, was the predominant NAC species isolated. The isolates showed good susceptibility towards azoles such as fluconazole and voriconazole. However, high level of resistance was seen towards clotriomazole.

Conclusion: Predominance of NAC species in cases of candiduriaand emerging resistance towards azoles over the years is a matter of concern. Knowledge regarding the species distribution and its antifungal susceptibility tests will help the clinicians in empirical therapy for better patient outcome.

Keywords: Urinary tract infection, Candiduria, NAC, anti-fungal, azoles.

Introduction

Urinary tract infection (UTI) is one the commonest infections encountered in clinical practice both in the community and as part of healthcare-associated infection (HCAI). The latter are most often caused by the placement or presence of a catheter in the urinary tract[1]. Infections of urinary tract can be caused by a range of pathogens such as bacteria, fungi, parasites, and viruses.[2,3]

Candiduria is the presence of candida in urine and it is an increasingly common finding in patients admitted in intensive care units (ICUs), patients on

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immunosuppressive agents, and patients on broad spectrum antibiotic therapy.[4] Diabetes mellitus, genitourinary tuberculosis, prior use of antifungals and extreme of age are other risk factors associated with candiduria.[5]

Identifying Candida upto species level is clinically important due to the fact that they differ in virulence and susceptibility to antifungal agents.[6] Candida pyelonephritis is a severe nosocomial upper UTI which may lead to candidemia and sepsis[7]. Early identification of Candidal infection in clinical sample helpsin early initiation of antifungal therapy. This study was planned to know the species distribution and anti-fungal susceptibility pattern of *Candida species* isolatedfrom urine samples of patients suffering from UTI.

Materials and Method

This prospective hospital-based study was conducted in a tertiary care Hospital of Meerut, Uttar Pradesh for a period of one year. A total of 6250 urine samples received in Clinical Microbiology Lab from various IPDs & OPDs were subjected to culture to isolate various microorganisms causing UTI as per standard microbiological methods.[3,4] The urine samples were cultured on Cysteine lactose electrolyte deficient agar(CLED) plates and incubated at 37°C overnight. The growth on the culture plates were identified by Gram stain, colony morphology and biochemical tests.[3,4]

Isolation and identification of Candida species:

Only the yeast like colonies resembling *Candida* species was included in this study and further processed for identification. Gram's stain was prepared from the yeast like colonies to look for the morphological arrangement of yeast cells followed by urease test. Germ-tube test (GTT) was performed for presumptive identification of *C. albicans* in urease negative isolates. Further, the *Candida* species were sub-cultured on cornmeal agar (CMA) (Dalmau technique) and Hi-chrome agar plates (Hi-Media) [Fig.1] for further identification of species on the basis of morphology and colour production respectively[4]. The acid & gas production in sugar fermentation tests using Glucose, Maltose, Sucrose and Lactose in 2% concentration with Andred's indicator and Durham's tube and sugar assimilation tests were also performed to identify the species.[4,9][Fig 2]

Antifungal susceptibility test (AST):

AST for all the isolates of Candida was performed using disc diffusion method on Mueller.

Hinton agar supplemented with 2% glucose and 0.5 µg/ml of methylene blue as per CLSI guidelines[9]. The standard disks used and their disk concentration are: voriconazole (1 µg), fluconazole (10 µg), ketoconazole(10 µg), Clotriomazole (10 µg). (HiMedia, Mumbai, India).

Results

The overall culture positivity rate in urine was 58.43%. Among the culture positives, candiduria was present in 141 (3.86%) samples. *Candida* species were isolated predominantly fromurine samples received from indoor patients (92.2%) as compared to those from outdoor patients (7.80%). The positivity rate was more in elderly females >60 years of age (31.9%) followed by in the age group of 21-30 years (16.3%). However, candiduria was uncommon in children in the age group of 1-10 years (1.4%). Overall, in our study the youngest patient was a neonate 1 day old and the oldest patient was 92 years old showing that candiduria is prevalent in extremes of ages with the average mean age of 51.7 years. There was a female predominance in cases of candiduria 77 (54.61%) followed by males 64 (45.39). The female: male ratio was 1:1.2.

There was predominance of Non-albicans Candida (NAC) species 131 (93%) as compared to *C. albicans* 10 (7.09%). [Table 1]*C. tropicalis* 83 (58.86%) was the predominant NAC species isolated followed by *C.parapsilosis* 18 (12.76%), *C.guillirimondii* 13 (9.21%), *C.krusei* 7(4.96%), *C.glabrata* 4 (2.86%) , *C. kefyr* 2 (1.42%) and *C.cerevisiae* 2(1.42%). Out of 12 GTT positive *Candida* species, 2(1.42%) isolates were *C.dubliniensis* and the remaining 10 (7.09%) were *C. albicans.*

Resistance to various antifungal agents was observed.Out of 141 Candida isolates total 18 (12.76%) isolates were resistant to fluconazole, 27(19.14%) were resistant to ketoconazole and 10 (7.09%) isolates were resistant to voriconazole. Highest level of resistance was seen against clotrimazole in 106(75.17%) isolates of *Candida* species.

Table 1: Species distribution of candida species isolated in candiduria (n=141)

Species		No. of cases	Percentage (%)
Non albicans Candida (NAC) species	*C. tropicalis*	83	58.86
	C. parapsilosis	18	12.76
	C. guillirimondii	13	9.21
	C. krusei	07	4.96
	C. glabrata	04	2.86
	C. kefyr	02	1.42
	C. dubliniensis	02	1.42
	C. cerevisiae	02	1.42
***Candida albican*s**		10	7.09

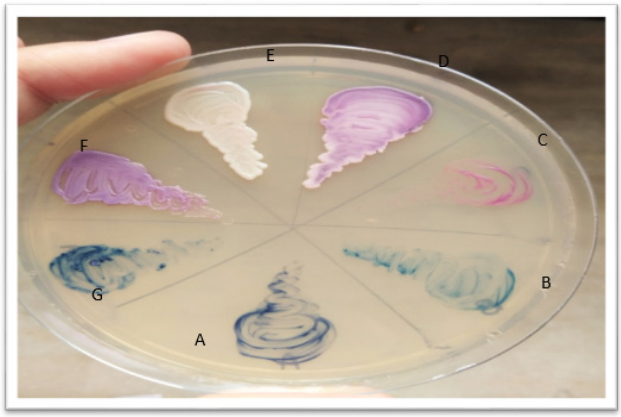

Fig 1: CHROMAgar:A)*C.albicans* B) *C. dubliniensis* C) *C.krusei* D) *C. kefyr* E) *C. glabrata*F) *C. parapsilosis* G) *C. tropicalis*

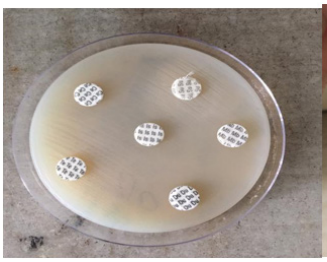

Fig 2: Sugar assimilation test for Candida species

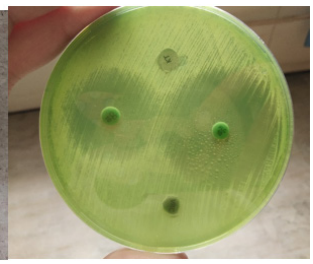

Fig 3: Anti-fungal susceptibility test by disk diffusion method MHA supplemented with 2% glucose and 0.5 µg / ml of methylene blue

Discussion

The culture positivity rate in our study was 58.43%. Among the culture positive, *Candida* species was isolated from 141 (3.86%) urine samples. Similar study done by Yashavanth *et al*[10] and Ragini *et al*[11] showed candiduria in 2.27% and in 1.37% cases respectively, which is slightly lower than our observation.

The positivity rate was more in elderly females >60 years (31.9%) of age followed by age group of 21-30, which is concordant to study done by Wanjare *et al.*[12] On the contrary Abishek *et al.*[13] reported candiduria to be more prevalent in age group of 21-40 years (46%) followed by in the elderly age group of 50-60 years (18%). Our study showed candiduria in the youngest patient, a neonate and the oldest in 92 years old proving the fact that candiduria is prevalent in extremes of ages. Candiduria was more prevalent in female patients 77 (54.61%) in our study. Similar findings were reported by other workers in the past[14] .

Candida species were isolated predominantly from urine received from indoor (IPD) patients (92.2%) which is concordant with the study carried out by Rengaraj *et al.*,[15] where they also found 40 (66%) isolates were from IPD samples.

There was predominance of Non-albicans Candida (NAC) species 131 (93 %) as compared to *Candida albicans* 10 (7.09%). Similar findings of predominance of NAC species was reported by other workers Gharanfoli *et al.*[14] and Yashavanth *et al.*[10] Among the NAC species, *C.tropicalis* 83 (58.86%) was the predominant species isolated followed by *C.parapsilosis* 18 (12.76%), *C.guillirimondii* 13 (9.21%) , *C.krusei* 7(4.96%), *C.glabrata* 4 (2.86%) , *C. kefyr* 2 (1.42%) and *C.cerevisiae* 2(1.42%). This finding is concordant to the studies done by Adhikary *et al*[16], Chakrabarti *et al*[17] and Rani *et al.*[18] Out of 12 GTT positive *Candida species*, 2(1.42%) were *C.dubliniensis* and the remaining 10 (7.09%) were *Candida albicans.*

We evaluated the antifungal susceptibility pattern by using disk diffusion method according to CLSI M44 guidelines[9]. Resistance to various antifungal agents was observed in our study. A total of 18 (12.76%) isolates were resistant to fluconazole, 27(19.14%) were resistant to ketoconazole and 10 (7.09%) isolates were resistant to voriconazole. Highest resistant pattern was seen against clotrimazole as 106 (75.17%). Similar study done by Sumana *et al*.[19] found 14% of candida species showing resistance to fluconazole, 8% showed resistance to Voriconazoleand 4% showed resistance to Ketoconazole. However, a study by Rengaraj *et al*.,[15] found 100% susceptibility to fluconazole and voriconazole in all species except *C. albicans* and *C. glabrata*. Singh *et al*.[20], observed overall sensitivity of 95.6% and 100% among Candida isolates to fluconazole and voriconazole respectively. As compared to our study, in the above studies resistance against clotrimazole was not evaluated and reported.

Conclusion

The present study shows a changing trend in patients of candidudria with predominance of NAC species from Meerut city in Uttar Pradesh. As NAC species are more resistant to antifungal agents, knowledge regarding the species distribution and its antifungal susceptibility tests will helpthe clinicians in empirical therapy for better patient outcome.

Source of Funding: Nil

Conflict of Interest: Nil

Ethical Clearance: Approval from the University Ethics Committee (Medical) of Swami Vivekanand Subharti University Meerut was taken via letter No: SMC/IEC/2019/98/09, dated: 18/02/2019.

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Routine Immunization Uptake During the COVID-19 Pandemic: A Cross-Sectional Study at an Urban Health Training Centre in Sangli District

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Abstract

Background: The COVID-19 pandemic has strained the health systems, resulting in around 25 million children missing out on immunization in the year 2021 globally with a sustained drop since 2020. Our study aimed to estimate the proportions of delayed and missed routine immunization with respect to the COVID-19 pandemic, among beneficiaries at an Urban Health Training Centre (UHTC) in Sangli district.

Methodology: A cross-sectional observational study was conducted at the immunization clinic of a UHTC in Sangli district, among beneficiaries that availed services of routine immunization & six-monthly vitamin A dose during the month of October 2022 at the center. Study participants were enrolled following predefined inclusion and exclusion criteria. Data on the complete vaccination status of each participant was collected from the vaccination cards and details of delayed & missed immunization were analyzed and statistical tests applied.

Results: 548 beneficiaries were included in the study. Among them, 196 beneficiaries had at least one vaccine dose that was missed and 295 of them had at least one vaccine that was delayed. 352 of them, i.e. 64% of the study participants received all age-appropriate vaccination. There was a statistically significant increase in delayed immunization during the COVID-19 pandemic from 32% to 60% & missed immunization increased from 11% to 43%.

Conclusion: Immunization services have been disrupted severely during the pandemic, putting children at risk for vaccine-preventable diseases. Disrupted vaccination peaked during the peak of the pandemic. There is an urgent need to intensify efforts for catch-up vaccination to address backsliding on routine immunization.

Keywords: Routine immunization, vaccine, COVID-19 pandemic, missed immunization, delayed immunization.

Introduction

Immunization is a global health and development success story that has been saving millions of lives every year. Vaccines reduce the risk of getting a disease by working with the natural defenses of the body to build protection. We have vaccines to prevent more than 20 life-threatening diseases, helping people of all ages live longer and healthier lives. Immunization currently prevents 3.5 to 5 million deaths every year from diseases like diphtheria, tetanus, pertussis, influenza, and measles. Immunization is a key component of primary health care and an indisputable human right and also the

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best health investment that money can buy. Vaccines are critical to the prevention and control of infectious disease outbreaks. Yet despite tremendous progress, vaccination coverage has plateaued in recent years and there has been a sustained drop since 2020.[1]

In India routine immunization services are provided under the Universal Immunisation Programme (UIP). Immunization is provided free of cost against 12 vaccine-preventable diseases, which include diphtheria, pertussis, tetanus, polio, measles, rubella, severe forms of childhood tuberculosis, hepatitis B, meningitis & pneumonia caused by Hemophilus influenza type B, rotavirus diarrhea, pneumococcal pneumonia, and Japanese encephalitis; of which Japanese encephalitis vaccine is provided only in endemic districts.[2] To strengthen and re-energize UIP and to achieve full immunization coverage for all children and pregnant women at a rapid pace, the Government of India launched "Mission Indradhanush" in December 2014. Under this additional four rounds of immunization activity excluding the RI days were conducted with flexible timing, mobile session, and mobilization by other departments with a special focus on left-outs, dropouts, resistant families, and hard-to-reach areas. India's full immunization coverage increased by 6.7% per year through the first two phases of Mission Indradhanush compared to earlier 1% per year increase. To further intensify the immunization programme, Intensified Mission Indradhanush (IMI) was conducted in October 2017, and Intensified Mission Indradhanush 2.0 from December 2019 - March 2020.[3]

Then the Covid-19 pandemic, its associated disruptions, and Covid-19 vaccination efforts strained health systems in the year 2020 and 2021, resulting in around 25 million children missing out on immunization in the year 2021 globally. This was 2 million more than in 2020 and 6 million more than in 2019 and the highest number since 2008.[4] Immunization coverage in the WHO South-East Asian Region had the sharpest decline during the COVID-19 pandemic years of 2020 - 2021 with a drop of 9% over two years. India tops among countries with the burden of most unprotected children in 2021, with 2.7 million & 2.5 million children not receiving DPT-1 & measles vaccines respectively. After two years of lower-than-usual routine immunization coverage, and the postponement of many supplementary immunization activities/campaigns, the risk of large outbreaks like measles is now very real.[5]

The objective of our study was to estimate the proportions of delayed and missed routine immunization with respect to the COVID-19 pandemic, among beneficiaries at an Urban Health Training Centre (UHTC) in Sangli district.

Methodology

A cross-sectional observational study was conducted at the Immunization Clinic of UHTC under the Government Medical College, Miraj in Sangli district of Maharashtra. The study population was beneficiaries that availed services of routine immunization & six-monthly vitamin A dose at the study site during the month of October 2022. A time-bound complete enumeration of the study population was done. All those of age less than 6 years coming to the immunization clinic and those that brought immunization cards along, and their parent/guardian gave consent for participation in the study were included as study participants. Those that did not have immunization cards available at the time of their routine immunization and those whose parent/guardian are unwilling to give consent were excluded from the study. The minimum sample size for the study calculated using formula $n = z^{21-\alpha/2}(1-P)/\varepsilon^2P$ was 384.[6] Population proportion was taken as 50% as NFHS-5 shows 56% children received all age appropriate vaccinations[7], Confidence level as 95% and relative precision as 10%.

Data collection was done every Monday, Wednesday & Friday (these were the days the immunization clinic was functional) in the month of October by complete enumeration method of those fulfilling the eligibility criteria. Data on the complete vaccination status of each participant was collected from the vaccination cards, including information regarding date of birth, sex, and details of each vaccine taken/not taken with dates as per the schedule. Data were entered into a Microsoft excel sheet and delayed & missed immunization among the study participants were analyzed. In this study, we defined missed immunization as any vaccine under UIP that was not received by the study participant and cannot

be administered on the day of data collection because the maximum age limit for the administration of the vaccine as recommended under UIP[8] has been crossed. And delayed immunization was defined as any vaccine under UIP that was received by the study participant with a delay of more than 14 days from the recommended age/date for that vaccine as recommended under UIP. All ethical principles as per Helsinki Declaration were followed during the study. [9]

Results

586 beneficiaries availed of the services of routine immunization during the study period at the study center. 38 of them did not meet the eligibility criteria & were excluded from the study and the remaining 548 beneficiaries were included in the study. These included 279 male and 269 female beneficiaries. 205 (male=109, female=96) of them were under 1 year of age. 183 (male=89, female=94) in 1-to-2-year age group, 49 (male=27, female=22) in 2-to-3-year age group, 33 (male=13, female=20) in 3-to-4-year age group, 14 (male=7, female=7) in 4-to-5-year age group, and 64 (male=34, female=30) in 5-to-6-year age group. Among the 548 participants, 96 of them had missed Bacille Calmette-Guerin (BCG) vaccine, 138 of them Hepatitis-B birth dose, 107 of them Oral Poliovirus Vaccine (OPV) zero dose, 114 of them Pentavalent Vaccine, and 118 of them Fractional Inactivated Poliovirus Vaccine (fIPV). 458, 206 and 74 participants were eligible for Rotavirus vaccine (RVV), Pneumococcal conjugate vaccine (PCV) & PCV booster respectively, of these 156, 23, and 2 of them missed their doses respectively. None of the eligible participants had missed their OPV, Measles-Rubella (MR), and Diphtheria-pertussis-tetanus (DPT) booster-1 vaccines. Vaccine wise delayed & missed immunization is shown in Table 1.

The age-wise distribution of delayed & missed immunization is shown in Table 2. 196 beneficiaries had at least one vaccine dose that was missed and 295 of them had at least one vaccine that was delayed beyond two weeks from the vaccine due date. Table. 3 shows the distribution of delayed and missed immunization in those born before and during the COVID-19 pandemic. Results of the two-sample proportion test indicated there is a significant medium difference between percentages of delayed immunization in those born before (32%) and during (60%) the COVID-19 pandemic, $Z = 5.67$, $p < .001$, and percentages of missed immunization in those born before (11%) and during (43%) the COVID-19 pandemic, $Z = 6.58$, $p < .001$.

Table 1. Vaccine-wise distribution of delayed and missed immunization

*Vaccines (n)	Delayed Immunization (%)	Missed Immunization (%)
BCG (548)	189 (34)	96 (18)
HEP-B birth (548)	55 (10)	138 (25)
OPV-0 (548)	72 (13)	107 (20)
OPV-1,2,3 (548)	213 (39)	0
Pentavalent-1,2,3 (548)	181 (33)	114 (21)
RVV-1,2,3 (458)	101 (22)	156 (34)
fIPV-1,2 (548)	212 (39)	118 (22)
PCV-1,2 (206)	73 (35)	23 (11)
MR-1 (425)	174 (41)	0
PCV-Booster (74)	23 (31)	2 (3)
MR-2 (303)	169 (56)	0
OPV-Booster (303)	161 (53)	0
DPT-Booster-1 (303)	161 (53)	0
DPT-Booster-2(67)	0	–

* In case of vaccines administered as a series as in OPV-1,2,3, Pentavalent-1,2,3, RVV-1,2,3, fIPV-1,2, and PCV-1,2, they are considered as a single unit and if any single dose in the series was missed or delayed, they were classified under delayed or missed immunization accordingly.

Table 2. Age-wise distribution of delayed & missed immunization

Age in years (n)	Delayed Immunization (%)	Missed Immunization (%)
0-1 (205)	89 (43)	29 (14)
1-2 (183)	129 (71)	112 (61)
2-3 (49)	38 (78)	41 (84)
3-4 (33)	20 (61)	4 (12)
4-5 (14)	3 (21)	3 (21)
5-6 (64)	16 (25)	7 (11)
Total (548)	295 (54)	196 (36)

Table 3. Delayed and missed immunization before and during the pandemic.

Variable (n)	Delayed immunization (%)	P - value	Missed Immunisation (%)	P - value
Born Pre-pandemic (126)	40 (32)	< 0.05* (Z = 5.67)	14 (11)	< 0.05* (Z = 6.58)
Born during the pandemic(422)	255 (60)		182 (43)	
Total	295		196	

**Statistically Significant*

Discussion

In our study of the 548 study participants, 51% were male & 49% were female. 70% of the participants were in the 0-2 years age group.64% of the study participants received all age-appropriate vaccination. 36% of the study participant had at least one vaccine dose that was missed. While 54% of them had at least one vaccine delayed beyond two weeks from the vaccine due date. The proportion of missed and delayed vaccine doses in the study participants increased significantly during the COVID-19 pandemic years. Those with missed vaccine doses increased from 11% to 43%, while those that received delayed vaccine doses increased from 32% to 60%. Missed immunization was more in the 1-3 years age group and delayed immunization in the 1-4 years age group. Those in these age groups had the most doses due during the peaks of the pandemic when there were strict lockdowns and restrictions on movement and gatherings.

The global proportion of disrupted immunization reported by WHO was 61%.[10] The NFHS-5 2019-21 reported thatof children aged 12-23 months 76.6% received all basic vaccinations, i.e., BCG, MCV/ measles/MMR/MR, and three doses each of DPT/ Penta and polio vaccine (excluding polio vaccine given at birth) & 56% received all age appropriate vaccinations, i.e., BCG, MCV/ Measles/ MMR/ MR, four doses of hepatitis B, and three doses each of DPT/Penta and polio vaccine (excluding polio vaccine given at birth). For the state of Maharashtra, it was reported at 73.6% & 42.1% respectively.[7,11] The proportion of children that were fully vaccinated with all age appropriate was higher than NFHS-5 in our study.

NFHS-5 reported that among children aged 12-23 months in India, BCG was missed in 5%, Hepatitis-B birth dose in 32.6%, OPV zero dose in 14.5%, OPV primary series in 19.5%, Pentavalent in 18.9%, and RVV in 65.6%. Maharashtra reported missed BCGin 6.2%, Hepatitis-B birth dose in 49.5%, OPV zero dose in 13.7%, OPV primary series in 21%, and Pentavalent in 16.4% of children aged 12-23 months.[7,12]

In our study RVV was the vaccine that was missed the most with 34% of those eligible under UIP having missed it. BCG was missed in 18%, hepatitis B birth dose in 25%, OPV zero dose in 20%, Pentavalent in 21%, fIPV in 22%, PCV primary in 11%, and PCV booster in 3% of the eligible study participants. Measles vaccine (MR1 at 41% & MR2 at 56%) was the one that was mostly delayed in our study. OPV primary series and OPV booster doses were delayed in 39% and 53% of the eligible study participants respectively. DPT booster-1 was delayed in 53% of the eligible study participants. None of the study participants in our study missed their OPV primary and booster, and measles vaccines as these vaccines are given until the age of 5 years if missed earlier, and our study enrolled only children under 6 years of age as study participants. Also, the proportions of those that missed or had delayed DPT booster-2 could not be studied due to the age limit of study participants. Maharashtra NFHS-5 data reported lesser missed immunization for all basic vaccines except Hepatitis-B birth dose compared to as seen in our study. This could be because NFHS-5 data collection for Maharashtra state was completed in Phase 1 in the year 2019-20.[13] Thus, disrupted immunization due to the COVID-19 pandemic might not have been completely captured. Also, there is a possibility of district-to-district variations based on local policies and practices. The NFHS-5 included both urban and rural children while ours was a study

in an urban setting. Similar studies should be carried out at different centers to know locally prevalent vaccine coverage so that necessary policies and resources are directed at a local level.

With disrupted immunization services cyclical, large and disruptive measles outbreaks are again being detected in the African and Eastern Mediterranean regions.[5] Also there has been a current multiple measles outbreak in Maharashtra with more than 3000 reported cases & 17 deaths. [14] Coordinated campaigns across India targeting children who missed routine immunization, as well as targeting low-coverage areas, need to be undertaken. Prioritizing measles vaccine catch-up would be prudent given the outbreak potential witheven marginal reduction in herd immunity.[15] Intensified Mission Indradhanush 4.0 conducted in 416 of 736 districts of India in 3 phases from Feb 2022 onwards needs to be expanded to cover all districts to catch up on the gaps.[16]

Conclusion

Immunization services have been disrupted severely during the pandemic, putting children at risk for vaccine-preventable diseases. Disrupted vaccination peaked during the peak of the pandemic. There is an urgent need to intensify efforts for catch-up vaccination to address backsliding on routine immunization. Microplanning based on the local situation is essential, as state/national statistics might not reflect the local situation. Similar studies need to be carried out at different centers to know locally prevalent vaccine coverage.

Ethical clearance: Taken from Institutional Ethics Committee.

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Conflict of Interest: Nil.

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Original Article

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Safety and Efficacy of Drains in Orthopaedic Surgeries

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Abstract

While drains have been routinely used in orthopaedic surgery for postoperative wound drainage following inpatient surgical procedures, there are no published reports on the efficacy of drains for outpatient orthopaedic surgeries. This review reports our experience between July 2021 and January 2022 with the use of drains for 35 patients having outpatient orthopaedic surgery. Consequences of drain usage were determined by medical chart review and a follow-up telephone survey in which patients were asked a series of questions regarding the drains used for their operation. None of the patients had an infection or any other medical problem as a result of drain usage and there were no problems with wound healing. Patients were quite capable of managing and removing their own drains. We conclude that drains are effective and can be used safely for outpatient orthopaedic surgical procedures.

Keywords: Outpatient surgery; Drains; drains; orthopaedics

Introduction

Drains have been routinely used in orthopaedic surgery for postoperative wound drainage following certain inpatient surgical procedures[1–4]. Some surgeons have recently also started to use drains for selected outpatient surgical procedures. There are, however, no published reports on the safety or efficacy of drains for outpatient orthopaedic surgeries.

Much has been written about the advantages and disadvantages of postoperative wound drainage. Advantages of drain usage include improved apposition of tissue surfaces by removing excess blood, protection of the skin from irritating discharges, and for intraarticular drains, decreased joint swelling which facilitates early range of motion. Disadvantages of drain usage include foreign body effects, mechanical problems (such as entrapment by a misplaced suture), promotion of fluid and electrolyte losses, and the potential for an increased incidence of wound infection.

Despite the potential risks most orthopaedic surgeons use drains routinely in certain situations. We routinely use drains for patients having selected outpatient orthopaedic operations. Some of these patients stay overnight in our inpatient ward and have the drain removed by the surgical team in the morning before they are discharged, but others are sent home with the drain in place and are given instructions for follow up the day after surgery. The purpose of this review is to report our experience with the use of drains in the ambulatory surgery setting.

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Materials and Methods

Between July 2021 and January 2022, 117 outpatient orthopaedic operations were performed by the senior consultant at Hind institute of medical sciences, sitapur.

Thirty-five of these surgeries involved the placement of at least one polyvinylchloride or silastic drain in or around the surgical site. The group of patients who had these drains placed at surgery comprises the study group for this review. There were 28 males and seven females in the group. The average age of the patients was 31 years with a range from 16 to 59 years.

Twenty-six patients stayed overnight after their surgery at the center. Twenty-one of these patients had their drain removed by a member of the orthopaedic surgery team on the morning after their surgery. Five of these patients were followed up day after with their drain in place and were given instructions about the drain themselves. Nine patients went home on the day of their surgery and they were also given instructions about drain removal. All 14 patients sent home with a drain in place received clear written and verbal instructions about when, how, and what to expect regarding the removal of the drain.

There is a wide variety of outpatient orthopaedic operations for which drains are useful. In this review there were 12 anterior cruciate ligament reconstructions, five open reductions of fractures or joint dislocations treated with internal fixation, four open Bankart repairs, three hardware or loose body removals, three minor bony resections, two lateral retinacular releases, two ulnar nerve transpositions, two extensive arthro- scopic knee joint debridements, one lysis of adhesions between quadriceps muscle and femur fracture callous, and one elbow lateral epicondylar release.

A total of 44 drains (36 hemovacs and eight silastics) were used for the 35 procedures reviewed. Two drains were placed in nine of the operations and one drain was placed in the other 24 operations. One open reduction with internal fixation of a metatarsal, one hardware removal of tibial screws, two of the minor bony resections, one of the ulnar nerve transpositions, and the lateral epicondylar release were the only procedures for which we used a silastic drain. The rest of the opera- tions involved the placement of a hemovac drain.

In order to assess the efficacy of the drains used for these outpatient surgeries we conducted a follow-up survey by telephoning each patient after their last post- operative visit to ask them questions regarding the drain used for their operation. Specifically, we asked each patient what the elapsed time was between their surgery and drain removal, if they had any problems or medical complications as a result of the drain and, finally, we asked if our instructions about drain management were clear and easy to follow or if they needed to call the office about any drain related questions.

Results

None of the 35 patients in this review had an infection or any other medical problem as a result of drain usage and none had any problem with primary wound healing. Additionally, none of the 14 patients who removed the drain on their follow up reported any significant pain with drain removal, whereas two of the 21 patients who had their drain removed on day by orthopaedic team reported severe pain with drain removal.

The average time elapsed between surgery and drain removal was 21 h (range from 8 h to 30 h) for patients who had their drain removed at the surgery center before going home and was 46 h (range 6 h to 7 days) for patients who went home with their drain in place and removed it themselves.

Two patients who were sent home with their drain in place had unplanned drain removals. In one patient the drain was inadvertently removed after 6 h when the patient rolled over in bed on the evening after surgery. The other patient did not understand the instructions and left the drain in until the first postoperative visit at seven days. This patient was the only one in the review that either was not given or did not understand our instructions regarding the care and removal of the drain. All the rest of the patients felt that our instructions were clear and easy to follow and none needed to call the office with any drain related questions.

Discussion

Drainage of orthopaedic wounds has been strongly advocated for many years. In one of the first studies on the role of drains for orthopaedic surgeries, Waugh and Stinchfield [5] compared the postoperative complica- tions of 100 various orthopaedic operations using drains with a similar number of undrained matched controls. They reported a 1% infection rate for drained wounds compared to a 3% infection rate for undrained wounds and concluded that all wounds involving medullary bone as well as all wounds involving a potential dead space should be drained ‘to promote

a more benign and uncomplicated postoperative course'. This research supports the surgical principle that mini- mizing postoperative hematoma will minimize postop- erative infection [6,7].

Not all research, however, has supported the use of drains. Stevens [8] initiated concerns about drain usage when he reported an increased infection rate for ortho- paedic surgeries using drains. More recently, several studies have suggested either no benefit or even an increased risk from the use of drains for orthopaedic surgeries. Cobb [9], in a prospective randomized study on the use of drains after surgery for femoral neck fractures, concluded that drains did not seem to im- prove overall wound healing. Other studies on the role of drains in total joint arthroplasty surgery have come to the conclusion that the potential risk of increased infection may not be worth any advantages that may be afforded by drain usage.

All previous reports on the use of drains for orthopaedic surgeries have reviewed inpatient procedures. This report is unique in that it is the first to review the use of drains for outpatient orthopaedic surgeries. It is significant that there were no infections or medical complications as a result of the drain for any of the patients in our review. Perhaps the relatively short time for which a drain is needed after an outpatient surgery helps to minimize the potential increased risk of infection that drains may cause. Also, it may be that the drains themselves were the reason for the lack of infections in that they were effective in evacuating wound hematomas which have long been known to be a fertile source of infections.

We believe that surgeons should feel confident that patients can safely manage their own drain care should they need to be sent home with a drain in place. Only one of our patients who was sent home with a drain in place had any problem in following our verbal instructions about when to take the drain out and even then no untoward outcome occurred.

This study does not address the issue of whether or not drains should be used for particular surgical procedures. That is a question that has not been clearly answered by the current orthopaedic literature, and as such, is subject to the beliefs and experiences of individual orthopaedic surgeons. The current medical climate requires that more and more orthopaedic procedures be done in the outpatient setting. This study asks the simple question of whether or not drains can be used safely and effectively in the ambulatory setting. Our patients had the benefits of surgical wound drainage and there were no complications. It would seem that surgical drains can be used in outpatient orthopaedic procedures when the surgeon feels it is warranted. As long as the patient has clear written and verbal instructions, we feel that the use of drains is a safe and effective adjunct for outpatient orthopaedic surgical procedures.

Informed Consent: written informed consent was taken from patients.

Ethical Approval: ethical committee approval was taken from the AIMSR institutional committee of ethics.

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Conflict of Interest: there was no conflict of interest.

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Assessment of Prevalence and Factors Associated with Depression, Anxiety and Stress among Medical Students

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Abstract

Background: Medical students are challenged with academic, psychosocial, health factors which makes them easily prone for Depression, Anxiety and Stress. The study aims to assess the prevalence of Depression, Anxiety and Stress among medical students and to identify the associated factors.

Methods: A cross-sectional study involving all the medical students of ESIC Medical College, Kalaburagi who are willing to participate. DASS 21 scale questionnaire was used to collect data.

Results: The prevalence of Depression, Anxiety and Stress was found to be 17.75%, 29.91% and 12.13% respectively. Statistically significant association was found only between Stress and factors like gender and sleep hours.

Conclusions: Medical students have notable amount of Depression, Anxiety and Stress which has to be addressed at individual level involving peers and family, ensuring endurance in all the activities.

Key-words: Anxiety, DASS 21, Depression, Medical students, Stress.

Introduction

Medical students are one of the vulnerable groups as they are faced with long studying hours with sleep deprivation, surviving in a different environment.

The psychosocial factors and health factors make them easily susceptible for Depression, Anxiety and Stress.

From many previous studies which were conducted among the medical students the prevalence of Depression, Anxiety and Stress was found to be high[1-7, 9-13]. Hence this study aims to assess the prevalence of Depression, Anxiety and Stress among medical students and to identify the associated factors.

Materials and Methods

The study was a cross-sectional study conducted among medical students of ESIC Medical College, Kalaburagi over a duration of 3months from June – August 2022. All the medical students from first year to final year, who were willing to participate were included in the study.

DASS 21[8] questionnaire scale was used to collect data from the medical students. DASS 21 scale is a validated 21 item self-report measure consisting of

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7 questions for Depression, 7 questions for Anxiety, 7 questions for Stress. Each question was given a score of 0 (did not apply to me) to 3(applied to me very much or most of the time). The results for the pertinent questions in each area were added up to determine the scores for Depression, Anxiety, and Stress. Then, based on the suggested cut-off scores suggested by the DASS 21 scale for each domain, the individuals were classified as mild, moderate, severe, and extremely severe.

DASS21 scale questionnaire was circulated among students to collect data. Anonymity and confidentiality were maintained. Informed consent was obtained. The collected data was entered in Microsoft excel and analysed for frequency, percentage and chi-square test.

Results

Table no: 1 Distribution of the Respondents with Baseline Characteristics(n=231)

		Frequency [n]	Percentage %
Gender	Male	88	38.1%
	Female	143	61.9%
Accommodation	Day Scholar	38	16.5%
	Hosteler	193	83.5%
Sleep hours	≤3hrs	5	2.1%
	4-5hrs	45	19.5%
	6-7hrs	148	64.1%
	≥8hrs	33	14.3%
Physical activity per week	Nil	49	21.2%
	1-2times	114	49.4%
	3-4times	39	16.9%
	5times and above	29	12.5%
Smoking status	Never	220	95.2%
	Former	5	2.2%
	Current	6	2.6%

In the present study, majority of the participants were females (61.9%) and living in hostel (83.5%). They had sleep for 6-7 hrs (64.1%) with physical activity 1-2 times (49.4%), and 95.2% were non-smokers.

Table no 2: Prevalence of Depression, Anxiety and Stress among Medical Students (n=231)

	Depression	Anxiety	Stress
	[n] (%)	[n] (%)	[n] (%)
Normal	190 (82.25%)	162 (70.12%)	203 (87.87%)
Mild	26 (11.25%)	37 (16.04%)	27 (11.68%)
Moderate	14 (6.06%)	29 (12.55%)	1 (0.45%)
Severe	1(0.44%)	3 (1.29%)	0 (0%)
Total	231(100%)	231 (100%)	231 (100%)

The present study observed, the prevalence of Anxiety, Depression and Stress as 29.88%, 17.75% and 12.13% respectively.

Table 3: Association of Depression with demographic and baseline characteristics (n=231)

		Depression status			
		No	Yes	Total	P value
		n (%)	n (%)		
Gender	Male	12 (13.64%)	12 (13.64%)	88	1.64
	Female	29 (20.28%)	29 (20.28%)	143	
Accommodation	Day Scholar	8 (21.05%)	8 (21.05%)	38	0.55
	Hosteler	33 (17.10%)	33 (17.10%)	193	
Sleep hours	≤3hrs	1 (20.00%)	1 (20.00%)	5	0.16
	4-5hrs	13 (28.88%)	13 (28.88%)	45	
	6-7hrs	23 (15.55%)	23 (15.55%)	148	
	≥8hrs	4 (12.12%)	4 (12.12%)	33	
Physical activity per week	Nil	12 (24.48%)	12 (24.48%)	49	0.23
	1-2times	22 (19.30%)	22 (19.30%)	114	
	3-4times	4 (10.25%)	4 (10.25%)	39	
	5times and above	3(10.33%)	3(10.33%)	29	
Smoking status	Never	40 (18.19%)	40 (18.19%)	220	0.99
	Former	0 (0.00%)	0 (0.00%)	5	
	Current	1(16.66%)	1(16.66%)	6	

Table 4: Association of Anxiety with demographic and baseline characteristics (n=231)

		Anxiety status			
		No	Yes	Total	P value
		n (%)	n (%)		
Gender	Male	65(73.86%)	23(26.14%)	88	0.33
	Female	97(67.85%)	46(32.15%)	143	
Accommodation	Day Scholar	23(60.53%)	15(39.47%)	38	0.15
	Hosteler	139(72.02%)	54(27.98%)	193	
Sleep hours	≤3hrs	3 (60.00%)	2 (40.00%)	5	0.42
	4-5hrs	28(62.23%)	17(37.77%)	45	
	6-7hrs	105(70.96%)	43(29.04%)	148	
	≥8hrs	26(78.78%)	7(21.22%)	33	
Physical activity per week	Nil	37(75.52%)	12(24.48%)	49	0.24
	1-2times	73(64.04%)	41(35.96%)	114	
	3-4times	29(74.37%)	10(25.63%)	39	
	5times and above	23(79.32%)	6(20.68%)	29	
Smoking status	Never	155(70.46%)	65(29.54%)	220	0.49
	Former	4(80.00%)	1(20.00%)	5	
	Current	3(50.00%)	3(50.00%)	6	

In our study prevalence of Depression and Anxiety was found high in females (20.28%, 32.15%), day scholars (21.05%, 39.47%), those who had sleep less than 6 hours (48.88%, 77.77%), physical activity less than 2 times per week (43.78%, 59.44%), depression was high in never smoked (18.19%) and anxiety was high in current smokers (50%) but no statistically significant association was found.

Table 5: Association of Stress with demographic and baseline characteristics (n=231)

		Stress status			
		No	Yes	Total	P value
		n (%)	n (%)		
Gender	Male	83(94.32%)	5(5.68%)	88	0.01
	Female	120(83.30%)	23(16.70%)	143	
Accommodation	Day Scholar	33(86.84%)	5(13.16%)	38	0.89
	Hosteler	170(88.00%)	23(12.00%)	193	
Sleep hours	≤3hrs	4(80.00%)	1(20.00%)	5	0.0004
	4-5hrs	34(75.55%)	11(24.45%)	45	
	6-7hrs	134(90.60%)	14(9.40%)	149	
	≥8hrs	30(90.91%)	3(9.09%)	33	
Physical activity per week	Nil	42(85.71%)	7(14.29%)	49	0.21
	1-2times	97(85.09%)	17(14.91%)	114	
	3-4times	38(97.44%)	1(2.56%)	39	
	5times and above	26(89.65%)	3(10.35%)	29	
Smoking status	Never	193(87.50%)	28(12.50%)	220	0.92
	Former	5(100%)	0(0.00%)	5	
	Current	5(83.34%)	1(16.66%)	6	

In our study prevalence of Stress was found high in females (16.70%), day scholars (13.16%), those who had sleep less than 6 hours (44.45%), physical activity less than 2 times per week (29.2%), current smokers (16.66%).

A statistically significant association was found between stress and factors like gender (P=0.01) and sleep hours (P=0.0004).

Discussion

In our study, majority of the participants were females (61.9%) which was similar to the study conducted by C.K. Teh et al[12] (63.2%) and Wahed W.Y.A et al[13] (61.1%), but opposite to the study conducted by Melaku et al[9] where most of the respondents were males (63.1%).

Hostelers made up the majority of the participants (83.5%), which was comparable to the study done by Hossain M. M. et al[4]. (85.2%)[7] and Melaku et al[9] (91.5%).

In our study, those who don't do physical activity were found to be 21.2% which is less than the study conducted by Hossain M M et al[4] (61.5%).

In the present study prevalence of Depression, Anxiety and Stress was found to be 18.12%, 29.84%, 12.03% respectively which is less than the study conducted by Chakraborty et al[3] (45.3%, 52.4%, 31.9), Wahed et al[13] (60.2%, 64.3%, 62.5%), Hossain et al[7] (96.3%, 97.7%, 89.7%), Iqbal et al[5] (51.3%, 66.9%, 53%), Kumar et al[6] (37.6%, 52.1%, 33.7%), Shete et al[10] (20%, 80%, 52%).

Higher prevalence of Depression (20.2%), Anxiety (32.1%) and Stress (16.7%) was found in females which is similar to studies conducted by Chakraborty et al[3] and other studies[2,5,6,10] in India and developing countries[1,4,7,9,11]. This might be as a result of how emotionally vulnerable women are and how they respond to certain circumstances.

Those who were day scholar found to have higher prevalence of Depression (21%), Anxiety (39.4%) compared to those staying in hostel found to have less prevalence of Depression (17%), Anxiety (27.9%) and Stress status both hostelers and day scholar found slightly similar which was 12% and 13% respectively which was similar to the study conducted by Chakraborty et al[3] (43.3%, 51.1%, 30.8%) and Liaqat H et al[7] (34.42%, 45.08%, 36.06%). The reason might be because they have friends who are in the same age range with whom they can discuss personal issues and receive emotional support.

In the current study, we found that those who were involved in physical activity more often was found to have less prevalence of Depression, Anxiety and Stress which was found comparable to the study conducted by Chakraborty et al[3]. This could be as a result of the fact that exercise helps to reduce stress by raising endorphin levels.

In this present study, no statistical significance was found between demographic and baseline characteristics and Anxiety and Stress which was similar to the study conducted by C.K. Teh et al[12]. But conversely, we found a statistical significant association between stress and gender, sleep hours which was not found in the study conducted by C.K. Teh et al[12]. This may be because females have less stress coping mechanism. In the study conducted by Hossain M M et al[4] found a significant association between gender and anxiety status which was not found in our study.

Conclusion

Medical students have notable amount of Depression, Anxiety and Stress which has to be addressed at individual level involving peers and family, ensuring endurance in all the activities.

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Original article

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A Cross Sectional Study to Evaluate the Prevalence, Risk Factors and Comorbidities of Allergic Rhinitis among School Going Children

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Abstract

Background: Allergic rhinitis is a common disease affecting children and adults all over the world. The prevalence of allergic rhinitis has significantly increased among children in developing countries. It has a significant effect on the quality of life and performance of children. There are only a few studies in India on the prevalence of allergic rhinitis.This was a hospital based cross sectional study aimed to determine the prevalence, risk factors and associated co -morbidities among school going children.

Methods: This was a hospital based observational cross-sectional study conducted in a tertiary care medical college hospital of Kerala for a period of one year. A questionnaire was distributed to 200 parents of children aged 3 to 15 years attending the out-patient department. The questionnaire was prepared based on the one developed by ISSAC Steering committee (International Study of Asthma and allergies in childhood) with some additional questions. Questions regarding the symptoms, risk factors and co morbidities were asked and the responses were analyzed.

Conclusion: In our study we found a high prevalence of allergic rhinitis among children. Moderate - severe persistent was the most commontype. It was associated with various co- morbidities.

Key words: Allergic rhinitis, children, asthma,prevalence, risk factors

Introduction

Allergic rhinitis is an inflammatory Ig E mediated reaction of nasal mucosa against inhaled allergens.Patients usually present with symptoms of repeated sneezing, wateryrhinorrhea, nasal itching and nasal cogestion[1,2]. The feature of allergic rhinitis includes nasal crease/allergic salute, thin watery nasal secretions, swollen nasalturbinates, congestion and swelling of palpebral conjunctivae, retracted tympanic membrane. Allergic rhinitis affects over 400 million people all over the world[3].The prevalence of allergic rhinitis varies from 10 to 40 %[4-5]. It is a common chronic disorder in children affecting up to 40% of children[6]. Allergic rhinitis can be seasonal caused by airborne allergens like pollen or perennial caused by mites, household dustor fungal spore[9]. Allergic rhinitis is associated with various co-morbidities. It has a significant impact on the daily activities of children. It has a negative effect on

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the socioeconomic aspects of patient's life[6]. Allergic rhinitis has become a global health problem due to its increasing prevalence[7]. A population-based study showed that allergic rhinitis has got a significant adverse effect on both physical and mental health of the patients[2]. Allergic rhinitis has significant effect on children's social performance, emotions, memory, quality of sleep, and psychosocial interactions. Untreated and uncontrolled allergic rhinitis can lead to several diseases like conjunctivitis, sinusitis, middle ear infections and asthma[8]. Complications of allergic rhinitis includes sinusitis,adenoid hypertrophy,otitis media with effusion, persistent cough etc[10]. The prevalence of allergic rhinitis is increasing among school going children in developing countries. It is usually under diagnosed and treated with over-the-counter medications.The different health programs in our country should give importance to the diagnosis and treatment of allergic rhinitis. Since studies on the prevalence of allergic rhinitis are few, we conducted this study.

Materials and Methods

This was a hospital based cross sectional observational study conducted in a tertiary care medical college hospital of Kerala for a period of one year from September 2021 to August 2022. A questionnaire was distributed to 200 parents of children aged 3 to 15 years of age attending the out-patient department. Patients with nasal polyps, and rhinitis due to other pathologies were excluded from our study. All the participants were made to sign an informed consent before the study. The symptoms were analyzed using a questionnaire (Table 1). The questionnaire was read out to the participants and the response were marked by the investigator. The questionnaire was prepared based on the one developed by ISSAC[11] Steering committee with some additional questions. The questionnaire was distributed to 200 patients and the study population was decided from the 101 patients who responded positive to first item of the questionnaire. Patientswere divided into mild or moderate - severe groups based on ARIA(allergic rhinitis and its impact on asthma)guidelines. They were also categorized as intermittent or persistent depending on the duration of symptoms. Those patients with allergic symptoms less than 4 days per week or 4 weeks per year belonged to the intermittent group and the rest belonged to the persistent group.They were categorized into mild and moderate - severe groups based on their sleep patterns and daily activities.

Table 1: Questionnaire

SL No.	Questions	Response
1	In the past one year did your child have symptoms of sneezing/ running/blocked nose when they did not have cold/flu?	YES/NO
2	If yes were the symptoms more during specific months of the year? YES/NO	YES/NO
3	Does the child have accompanying congestion of eyes/itching/ watering? YES/NO	YES/NO
4	Do the symptoms occur in presence of pets/dust/when the child is outside? YES/NO	YES/NO
5	Do the symptoms interfere with child's daily activities? YES/NO	YES/NO
6	Does the child have bronchial asthma/allergic skin problem/ adenoids/recurrent ear infections? If yes specify the problem	YES/NO
7	Does any of the family members have allergy or bronchial asthma?	YES/NO
8	Mention the precipitating factor on which symptoms occur - dust exposure/firewood/smoke exposure/going outdoors/contact with animals/symptoms on awakening in the morning	

Results

Out of the 200 parents to which questionnaire was distributed 101 responded positive to the first question. The prevalence was found to be 50.5%. The mean age of the study group was found to be 8.65 years with a standard deviation of ±3.63. The minimum age was 3 years and the maximum age was 15 years. 70 patients were females (69.3%) and 31 patients were males (30.7%). In our study group the most common symptom of allergic rhinitis was sneezing (71.3%) followed by blocked nose (62.4%) and running nose (49.5%). 58.8% of the participants had accompanying itching/watering of eyes. 26.7% of the participants responded that the symptoms were more during specific months of the year. In our study majority of the subjects were from urban area (69.3%).23.8% responded that the symptoms interfered with daily activities. Most of the children (73.3%) responded that the symptoms occurred when they had contact with pets/dust/while playing outside. In our study 17.8% responded that symptoms were more in the early morning hours. The distribution of the trigger factors of allergic symptoms in our study group were dust exposure (43.6%), firewood smoke(9.9%), going outdoors(7.1%),contact with animals(10.9%). 36.6% of subjects had family members with history of allergic rhinitis or bronchial asthma.23.8% subjects reported that symptoms interfered with daily activities. The distribution of co-morbidities among the study subjects were bronchial asthma (25.7%) allergic skin problems(1,6.8%) recurrent ear infections (14.9%) adenoid problems(22.8%). In our study distribution of patients as per ARIA guidelines are as follows - moderate - severe persistent (30.7%) mild persistent(26.7%) moderate -severe intermittent(23.8%) mild intermittent (18.8%).

Table 2: Distribution of severity of symptoms as per ARIA Guidelines

Distribution of patients as per ARIA Guidelines	Frequency (percentage)
Moderate /severe/persistent	31(30.7%)
Mild /persistent	27(26.7%)
Moderate /severe intermittent	24(23.8%)
Mild /intermittent	19(18.8%)

Table 3: Distribution of symptoms of allergic rhinitis in the study respondents (n=101)

Variable	Categories	Frequency (percentage)
Sneezing	Present	72(71.3%)
	Absent	29(28.7%)
Running nose	Present	50(49.5%)
	Absent	51(50.5%)
Blocked nose	Present	63(62.4%)
	Absent	38(37.6%)
Eye itching/watering	Present	59(58.4%)
	Absent	42(41.6%)
Bronchial asthma/ skin allergy/recurrent sinusitis, ear infection/ Adenoids	Present	77(76.2%)
	Absent	24(23.8%)

Discussion

About 30% of total Indian population suffers from at least one allergic disease[12].The prevalence of allergic rhinitis was found to be 50.5% in our study. In our study allergic rhinitis was more in females(69.3%) compared to males(30.7%). This is similarto a study conducted by DimitriosGBalatsouras et al [13]. In a study conducted in Asian countries by Pawanker R, Bunnag C et al allergic rhinitis was more common in boys[14]. In our study group the most common symptom of allergic rhinitis was sneezing (71.3%) followed by blocked nose (62.4%) and running nose (50.5%). 58.8% of the participants had accompanying itching/watering of eyes. In a study conducted in Iran by Rasoul NasiriKalmarzi et al the most common symptomwas rhinorrhoea followed by itchy nose (82%) nasal congestion (70%) and watery eyes(69%)[15]. In a study conducted by Shariat et al 2012 nasal congestion was the most common symptom[16]. In our study 58.8% of the participants had accompanying itching/watering of eyes. This is comparable to the findings in a study conducted by J M Klossek et al which showed ocular symptoms in 52% of the patients[17]. In a Korean multicenter study 61.2% of patients had accompanying eye symptoms[18]. In our study 26.7% of the participants responded that the symptoms were more during specific months of the year. A study conducted by Monika Sultészet al showed a seasonal pattern of allergic rhinitis[19]. In our study majority of patients were from urban area. A

study conducted by S.N. Gaur et al in Delhi showed no significant differences in the prevalence of allergic rhinitis in urban and rural areas[20]. During the last few decades an increase in the prevalence of allergic rhinitis have been noted mainly in urban areas. Many factors like life style changes, increase exposure to pollutants and allergens have been implicated. In our study moderate- severe persistent type(30.7%) was the most common category based on ARIA guidelines. The reason for more percentage of persistent cases can be due to more patients presenting to hospital when the severity of symptoms has increased. This result is similar to a study conducted by Deb A et al in which 32% of patients had moderate/ severe persistent type of disease[21]. The distribution of the trigger factors of allergic symptoms in our study group were dust exposure (43.6%), firewood smoke(9.9%), going outdoors(7.1%), contact with animals(10.9%).In a study conducted by Dinesh Mehta et al the major allergens were pollen (51%), food (28.9%), insects(26.9%), fungus(12.6%) and dust(6.7%)[22].36.6% of subjects had family members with history of allergic rhinitis or bronchial asthma. Parents with allergic rhinitis was identified as a risk factor for allergic rhinitis in a study conducted by L.M Baumann et al[23]. In the present study the distribution of co-morbidities among the study subjects were bronchial asthma (25.7%) allergic skin problems(16.8%) recurrent ear infections (14.9%) adenoid problems(22.8%).In our study 23.8% subjects reported that symptoms interfered with daily activities. This is lower when compared to a study conducted by G Walter et al 42% reported decreased productivity in school activities[24].Thus allergic rhinitis leads to decreased night sleep, increased day time sleepiness and school absenteeism.

Conclusion

The prevalence of allergic rhinitis is high among school children. It is associated with various co morbidities and can adversely affect the performance of children. There should be further studies to identify the risk factors. The various healthprograms should give importance to the early diagnosis and treatment of allergic rhinitis.

Ethical clearance: The ethical clearance was obtained from the institutional ethical committee prior to the commencement of the study.

Conflict of Interest: Nil

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Original article

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Retrospective Comparative Study of Analgesia and Complications between Particulate (Triamcinolone) v/s Non-Particulate (Dexamethasone) Steroid in Transforaminal Epidural Injection at Tertiary care Hospital

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Abstract

Transforaminal epidural steroid injection (TFESI) is frequently used for the treatment of lumbar radiculopathy. A retrospective analytical study was conducted at a pain clinic among 100 adult patients more than 18 years of age who underwent 'Transforaminal epidural injection' for Lumbar radiculopathy from November 2017 to December 2020. Group A (50 patients) received Transforaminal epidural injection with Particulate corticosteroid (Triamcinolone) and Group B (50 patients) received non-Particulate corticosteroid (Dexamethasone). Pain intensity was assessed using the NRS score. T-test was used as a test of significance. The intensity of analgesia as measured by NRS score is similar in particulate (triamcinolone) and non -particulate (dexamethasone) in transforaminal epidural injection done for Lumbar radiculopathy patients immediately after the procedure as well as at three months follow-up.

Key Words: lumbar radiculopathy, TFESI, particulate steroids, non-particulate steroids

Introduction

Lumbar radicular pain due to a herniated intervertebral disc is a common and debilitating problem worldwide. A study conducted by Kuppuswamy S et al [1] reported a high prevalence (28.2%) of lumbar disc degeneration and herniation in asymptomatic Indian subjects using MRI. One of the early experimental studies conducted by Wilder DG et al. in 1988 showed that lumbar disc herniation's can be a direct mechanical consequence of prolonged sitting in static or vibration environments.[2]

A review article suggested strong evidence for transforaminal injections in the treatment of lumbar radicular pain for both short and long-term relief.[3] A transforaminal epidural steroid injection (TFESI) is frequently used for the treatment of Lumbar radiculopathy in patients that have not responded to conservative treatment. TFESIs are thus becoming a common procedure in pain management. Various studies have reported a significantly greater proportion of patients treated with a transforaminal injection of steroids achieve relief of pain than patients treated with a transforaminal injection of local anaesthetic. [4,5] Clinical studies evaluating the efficacy of different

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types of steroid injections have shown variable results without a definite conclusion.[6]

Aim:

Comparison of analgesia between Particulate steroidvs. Non-particulate steroid in transforaminal epidural injection done for Lumbar radiculopathy patients.

Comparison of incidence of complications of Particulate steroid vs. Non-particulate steroid in transforaminal epidural injection done for lumbar radiculopathy patients.

Objectives:

To compare the intensity of Analgesia Immediately post-procedure and after 3 months of TFESI with triamcinolone and dexamethasone.

To compare complications like changes in blood pressure and inadequate analgesia immediately post-procedure and after 3 months of TFESI.

Material and Methods

Type of study: This is a retrospective analytical study.

Study setting: Pain Clinic, Department of Anaesthesia, Medical College and tertiary health care Centre.

Study duration: Jan 2021 to June 2021

Study Population: Adult patients more than 18 years of age who underwent 'Transforaminal epidural injection' for Lumbar radiculopathy from November 2017 to December 2020.

Sample size: By using the formula,

$$n_1 = \frac{\left(z_{1-\frac{\alpha}{2}} + z_{1-\beta}\right)^2 \left[\sigma_1^2 + \frac{\sigma_2^2}{r}\right]}{\Delta^2} \quad r = \frac{n_2}{n_1} \quad , \Delta = \mu_1 - \mu_2$$

Where: n = sample size

$Z_{1-\frac{\alpha}{2}}$ = 1.96 (level of significance)

$Z^{1-\beta}$= 0.84 (critical value or power of test)

σ = standard deviation

Δ = difference of two means (0.5)

r = ratio of two means (1.007)

A sample size of 50 in each group was calculated.

Inclusion criteria:

- Adult (more than 18 years) patients with lumbar radiculopathy with pain intensity >4/10 on Numerical Rating Scale (NRS) and pain more than six months duration.
- The patients diagnosed on MRI with single level herniated nucleus pulposus below L3 that corresponded with the patient's clinical features.
- Patients with follow up record up to 3 months
- American Society of Anaesthesiologists (ASA) Grade I or II patients.

Exclusion criteria:

- Patients having Lumbar facetal arthropathy, Sacroiliac joint pain, Inflammatory spine disease like ankylosing spondylitis.
- Previous history of spine surgery.
- Bleeding disorders, and patients on anticoagulants.

Methodology

This is a record-based study conducted at a tertiary care centre. To retrieve the data Medical Records Department was approached. A pre-designed proforma was prepared for the documentation of required data. The Required sample size was 50 in each group. To achieve the required sample size and after application of inclusion and exclusion criteria data was screened retrospectively from December 2020 to November 2017. We found 231 records with lumbar radiculopathy.

No. of adult patients with lumbar radiculopathy = 231

No of patients with pain duration more than 6 months = 184

No of patients with pain intensity more than 4/10 = 173

No of patients in whom complete records with f/u data upto three months was available = 148

Among 148 study subjects, 83 underwent procedure with triamcinolone

Among 83 study subjects, 50 study subjects were selected randomly

Among 65 study subjects who received dexamethasone 50 study subjects were selected randomly

The demographic profile of patients was recorded along with detailed history regarding the site of pain, intensity and duration along with the history of co-morbidities. Numerical Rating scale (NRS) score was recorded prior to the procedure, immediate post-procedure, at one month follow-up and three months follow-up. General examination was done. Routine blood investigations and radiological investigations were done. Pre anaesthesia evaluation of patients was done prior to the procedure.

Patients in both groups were selected using computer generated random number table. Group A had received fluoroscopically guided transforaminal Triamcinolone acetate 40 mg epidural steroid injection whereas Group B received fluoroscopically guided transforaminal dexamethasone 8 mg epidural steroid injection. Written informed consent was taken from patients prior to the procedure.

An intravenous line was secured and Injection Ringer Lactate (10 ml/ kg) was given. Patients were placed in the prone position on the injection table. After sterile preparation, the area was draped and anaesthetized using 1 % lidocaine. Using fluoroscopic guidance, a spinal needle was advanced in an oblique view to the safe triangle. Both anterior-posterior and lateral views were obtained to confirm precise needle placement within the intervertebral foramen at 6 O'clock position under the pedicle; ideally, the needle was placed adjacent to the back of the vertebral body immediately inferior to the pedicle. At the target level, approximately 1 ml of contrast medium (Omnipaque 240) was injected while being visualized with real-time fluoroscopy to assure target medication flow and the absence of vascular or subdural or subarachnoid flow. After waiting for two minutes, to assure no adverse events, patients were injected with the 2ml of 0.5% Bupivacaine and treatment corticosteroid. Group A had received one ml of Triamcinolone acetate 40 mg/ml epidural whereas Group B received one ml of dexamethasone phosphate 8 mg/ml. These doses were chosen to have equal volumes of injectate as well as equal potency.

Data were entered in an excel sheet and analysed using Epi Info Version 7.2.5.0. Frequency and percentages were calculated for categorical data. Mean and standard deviation was calculated for continuous data. The Chi-square test was used as a test of significance for categorical data. An unpaired t-test was used to compare two means. P value less than 0.05 was considered to be statistically significant.

Results

The present retrospective study was conducted to compare analgesia between Particulate steroid (Triamcinolone acetate) vs. Non-particulate steroid (dexamethasone) in transforaminal epidural injection done for Lumbar radiculopathy patients.

Table 1 depicts the baseline characteristics of both groups. Both the groups were comparable concerning baseline characteristics like age, gender, level of vertebral involvement, duration of pain. Both the groups were similar when compared with the number of injections required for pain relief with most of the patients requiring a single injection.

Table 2 depicts a comparison of numerical rating scale scores between the two groups pre and post-procedure. There was a significant reduction in the mean NRS score immediately after the procedure, at one month and three months follow up ($P<0.001$).

There was no significant difference when intergroup comparison of mean NRS scores was done. Both the groups had comparable NRS scores.

Table 3 shows a comparison of complications among both groups. The incidence of complications was similar in both groups. Complications recorded immediately after the procedure was classified as

changes in blood pressure and inadequate analgesia. Both the groups had a comparable incidence of all the complications. At three months follow up, inadequate analgesia in the form of increased radicular pain was found among 4 (8%) participants in Group A and 3 (6%) participants in Group B which is similar.

Table 1: Baseline characteristics of both the groups

Sr No	Variable	Group A (n= 50)	Group B (n=50)	P value
1	Age (Mean ± SD) years	41.96 ± 10.8	42.24 ± 12.0	0.46*
2	Gender (Males: Females)	32:18	27:22	0.31#
3	Involvement of L4 or L5 vertebra n (%)	36 (72%)	33 (66%)	0.51#
4	Duration of pain (Mean ± SD) months	3.78 ± 1.53	3.70 ± 1.58	0.82*
5	The proportion of Protrusion n (%)	36 (72%)	31 (62%)	0.28#
6	The proportion of patients requiring two injections for intervention n (%)	10 (20%)	7 (14%)	0.42#

* t test # Chi square test

Table 2: Comparison of numerical rating scale scores between the two group's pre and post-procedure

	Group A (n= 50)	Group B (n= 50)	Intergroup P value (t-test)
Pre procedure	6.36 ± 1.43	6.26 ± 1.38	0.72
Immediate Post Procedure	2.27 ± 1.31	2.26 ± 1.29	0.96
1 month f/u	1.12 ± 0.75	1.41 ± 0.83	0.07
3 month f/u	0.92 ± 1.00	1.16 ± 0.91	0.21

Table 3: Incidence of complications among both the groups

	Group A (n= 50)	Group B (n= 50)	P value
Immediate Post Procedure	n (%)	n (%)	
Changes in blood pressure			
Hypotension	2 (4%)	3 (6%)	0.50#
Increased BP	5 (10%)	6 (12%)	0.74*
Vasovagal	3 (6%)	2 (4%)	0.99#
Analgesia			
Increased back pain	2 (4%)	0 (0)	0.49#
Increased local pain	12 (24%)	9 (18%)	0.46*
Increased radicular pain	4 (8%)	3 (6%)	0.99#
No complication	27 (54%)	30 (60%)	
Three months follow up			
Increased radicular pain	4 (8%)	3 (6%)	0.97#

* Chi-square test, # Fisher exact

Discussion

The present study found that the mean NRS score decreased significantly in both the groups (Group A Triamcinolone v/s Group B Dexamethasone) immediately post-procedure at one month and three months follow-up. In a study conducted by Madavi SK et al [7] after one month of intervention, the VAS score was 2.85 ± 0.83 in group Triamcinolone and 5.76

± 0.75 in group Dexamethasone and the difference was found to be statistically significant.

A randomized controlled trial conducted by Kennedy DJ et al[8] to determine if there was a major difference in effectiveness between particulate and nonparticulate corticosteroids for acute radicular pain due to lumbar disc herniation; Both triamcinolone and dexamethasone resulted in statistically significant improvements in pain and function at two weeks, three months, and six months, without clear differences between groups.

El-Yahchouchi C et al[9] conducted a retrospective observational study to assess whether a nonparticulate steroid (dexamethasone, 10 mg) is less clinically effective than the particulate steroids (triamcinolone, 80 mg; betamethasone, 12 mg) in lumbar transforaminal epidural steroid injections (TFESIs) in subjects with radicular pain with or without radiculopathy and revealed no evidence that dexamethasone is less effective than particulate steroids.

Shau DK et al[10] conducted a randomized controlled trial to compare the clinical efficacy of transforaminal epidural injection of dexamethasone and triamcinolone in the management of chronic low back pain with or without radiculopathy due to herniated intervertebral disc and found improvement in pain score was significantly better with transforaminal epidural injection of triamcinolone acetonide compared to dexamethasone.

The present study found that there were no major complications following the procedure in both groups. Serious complications can be avoided by the accuracy of the procedure using fluoroscopic guidance, use of dye spread for the confirmation of epidural space, placement of the needle in the safe triangle and negative aspiration of blood. Although various case reports and case series have reported paraplegia following infarction as a major complication following TFESI.[11,12,13,14] Few studies have reported that particulate steroids contain aggregates that can act as emboli. And therefore, lead to serious complications.[15,16]

The rate of complications with these types of epidural techniques is low.[17,18,19,20] Complications are related either to the procedure itself—mostly inadvertent placement of the needle off target—or the administration of the corticosteroid or local anaesthetic.[21]

Although the proportion of minor complications immediately after the procedure was slightly higher among triamcinolone group 28 (56%) as compared to dexamethasone group 23 (46%); this difference was not statistically significant. Also, there was no statistically significant difference between the incidences of radicular pain at three months follow up. A similar finding was noted by Madavi SK et al.[7]

Conclusion

The intensity of analgesia as measured by NRS score is similar in particulate (triamcinolone) and non -particulate (dexamethasone) in transforaminal epidural injection done for Lumbar radiculopathy patients immediately after the procedure as well as at three months follow-up.

There are no major complications in a carefully monitored procedure. The incidence of minor complications including changes in blood pressure and inadequate analgesia in both the groups are similar.

Limitations: The study has all the inherent limitations of an observational study.

Conflict of Interest: None.

Source of funding: Self

Ethical clearance: Approval of the Institutional Ethics Committee at Vasantraopawar medical college and research hospital, Nashik (Maharashtra) was sought (vide letter no: 62/2020-21 dated 21.01.2021). Permission from the head of the Institute as well as the medical record department was sought prior to the collection of data.

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Correlation of Anthropometric and Lipid Markers in GMC Jammu Medical Students

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Abstract

Background: The prevalence of cardiovascular diseases are likely to rise as a result of lifestyle-related risk factors. Due to their hectic schedules and lack of time for extracurricular activities, medical students were chosen for the study because they are more likely than other populations to develop lifestyle illnesses.

Objectives: To explore the connection of anthropometric and biochemical lipid profile markers to assess obesity risk in medical students.

Materials and methods: 180 MBBS students from Government Medical College, Jammu, participated in the study. The body mass index (BMI) was calculated using anthropometric measurements of body weight (BW), body height (BH), together with waist circumference (WC), and hip circumference (HC), as well as the waist-to-hip ratio (W/H ratio). Using blood samples, a lipid profile was calculated.

Results: According to the survey, 16.11% of Group 2 students were overweight, and 3.89 % were obese. Group 1 consisted of 80% normal subjects. Between two BMI groups and Lipid profile, a statistically significant difference was discovered. There was a negative correlation between Waist circumference and HDL cholesterol. The BMI was negatively correlated with HDL-cholesterol and positively correlated with triglyceride.

Conclusion: The prevalence of cardiovascular risk factors such as obesity, hypertension, and elevated triglycerides is high among medical students. Therefore, it may be deduced that healthy lifestyles should be adopted at a young age because medical students are the future medical professionals.

Keywords: Anthropometric measures, Lipid profile, Medical students, Obesity.

Introduction

There has been an upsurge in lifestyle problems in India as a result of increased urbanization and the effects of Westernization. Teenagers and younger age groups are increasingly affected by these diseases. Physical inactivity, technological stress, increased computer usage, and rising youth junk food intake have all contributed to an alarming rise in lifestyle problems.[1] Different metabolic illnesses as hypertension, diabetes, hypercholesterolemia, overweight, and obesity are brought on by lifestyle problem.[2] Anthropometric measurements, such as body mass index (BMI), waist circumference (WC), hip circumference (HC), and waist-to-hip ratio (WHR), have the advantage of being simple to measure and

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reproducible in daily clinical practice, especially in developing countries such as India.[3] Although the BMI indicates lean mass and fat mass, it does not reveal the distribution of fat mass.[4] As replacements to BMI, additional anthropometric indices such as WC, HC, and WHR have been utilized. The WC is becoming recognized as the most accurate anthropometric measure of abdominal fat and metabolic risk.[5] While some prior research published globally claim there are no such statistically significant relationships between the aforementioned anthropometric factors and lipid markers, others disagree.[6]Numerous Indian research have linked anthropometric measurements to lipid profiles in type 2 diabetes patients as well as hypothyroid ones.[7,8]

Due to their hectic schedules and lack of time for extracurricular activities, medical students were chosen for the study because they are more likely than other populations to develop lifestyle illnesses.

This study was conducted to examine the link between anthropometric and biochemical parameters of lipid profile in order to determine the risk of obesity among young medical undergraduates.

Materials and Methods

Type of study: A Cross-sectional research.

Study setting: Physiology department of GMC Jammu.

Duration of study: 3 months w.e.f. June to August 2022

Sample Size: 180 MBBS students (males & females) pursuing first phase MBBS and BDS in the academic year 2021-22 were selected as subjects. The participants were provided with a concise summary of the study and methodology, and their informed consent was acquired. This research was authorized by the Institutional ethics committee (IEC) of GMC Jammu (IEC/GMCJ/2022/1076 dated May 23, 2022).

Inclusion Criteria: Participants between the ages of 18 and 25 who gave their consent and appeared to have a healthy cardio-metabolic disposition were included in the study.

Exclusion Criteria: Diabetes mellitus, cardiovascular disease, cancer, liver or kidney disease, or the use of lipid-lowering medications disqualified participants from the study.

Using standard protocols, anthropometric measurements such as height (Ht) in centimeters, weight (Wt) in kilograms, waist circumference (WC), and hip circumference (HC) were taken on the same morning that blood samples were collected. BMI and WHR have been determined. The BMI was computed by dividing weight in kilogram by height in meter squared. Those with a BMI of less than 25 were considered healthy. Those with a BMI between 25.0-29.9 kg/m^2 were categorized as overweight, and those with a BMI exceeding 30 kg/m^2 were categorized as obese. In the supine posture, the hip circumference is measured at the widest point of the hips, whereas the waist circumference is measured at the umbilicus. The WHR was computed by dividing WC by HC. Version 26.0 of SPSS was utilized for statistical analysis. Comparing the lipid profiles of two BMI groups using the unpaired t-test.A p value less than 0.05 was considered statistically significant. The Pearson correlation coefficient between anthropometric variables and each lipid parameter was determined and displayed.

Observation and Results

In present study, 180 medical students were divided into two groups depending upon their BMI less than 25 as Group 1 & BMI equal or more than 25 as Group 2. 144 (80%) students were found in Group 1 whereas 36 (20%) students were found in Group 2. Out of 36 students 29 (16.11%) & 7 (3.89%) were found to be overweight & obese respectively. The analyzed data is presented in table 1-2.

Table 1: Comparison of two BMI groupsand lipid profile (mean levels)

BMI groups	TC	TG	LDL	VLDL	HDL	LDL/HDL
BMI<25	175.5	137.0	97.3	24.6	48.48	2.01
BMI ≥25	189.23	188.7	119.3	32.6	39.2	3.04
P-value	0.047	0.029	0.034	0.048	0.04	0.045

Table 2: Correlation of anthropometric variables with lipid profile

Anthropometric Variables	TC	TG	LDL	VLDL	HDL
BMI	0.305	0.387	0.369	0.394	-0.340
WC	0.325	0.445*	0.350	0.510	-0.667*
WHR	0.322	0.310	0.150	0.180	-0.340*

In the present study, a significant difference was observed between two BMI groups and lipid markers. BMI was most strongly linked with Total cholesterol, TG, LDL, and VLDL (positively) and HDL (negatively) among the anthropometric variables.

Discussion

Obesity refers to the condition of being overweight. It can be characterized as an excess of body fat that significantly impairs a person's health. Obesity is usually associated with hypertension, atherosclerotic heart disease, diabetes, arthritis, etc. Alterations in leptin, brown fat, insulin secretion, hypothalamic food intake center and physical activity all may cause obesity. Anthropometric measurements are frequently employed in studies to evaluate a population's susceptibility to non-communicable diseases. Dyslipidemia has long been related to a number of noncommunicable disorders, including diabetes, hypertension, and other CVDs.[9]

The current study's purpose is to investigate the relationship between anthropometric characteristics and lipid parameters in order to determine which anthropometric markers can be used consistently as the best predictor of an altered lipid profile in clinical practice and epidemiological studies. In addition to measures of abdominal fat distribution such as waist circumference (WC) or waist-to-hip ratio (WHR), the World Health Organization considers BMI measurement to be a universal criterion for overweight (more than 25 BMI) and obesity (more than 30 BMI). Waist circumference and body mass index had a significant positive association with blood pressure, according to a study conducted by Kurian S et al., and Deshmukh PR et al.[10,11] Gupta V et al., observed a substantial positive association between anthropometric measures in their study (BMI, WC, WHR).[12] Several anthropometric variables, including waist circumference, waist-to-hip ratio, and body mass index (BMI), have also been demonstrated to correctly predict cardiovascular risk.[13] Prashant V et al., found a connection between total cholesterol, triglycerides, and LDL cholesterol, as well as BMI, waist-hip ratio, and waist circumference, which lends support to our findings.[13]

Limitations of the study

The gender effect on anthropometric variables and lipid profile was not examined.

Conclusion

Even though it is difficult to evaluate the available data definitively, it is possible to draw a number of accurate conclusions. Although not all studied anthropometric parameters are associated with the lipid condition of the body, the waist circumference is one of the most straightforward and accurate indicators of the lipid profile. In a developing nation such as India, where it is still challenging to analyze cardiovascular risk indicators such as body fat saturation and lipid profile in the rural population, WC may be used as a supplement but not as a replacement.

Conflict of Interest: Nil

Source of Funding: Nil.

Ethical Clearance: Received.

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Original Article

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Poverty, Health and Malnutrition: A Study on Dam Displaced Families of Jammu Region, Jammu and Kashmir

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Abstract

Background: Involuntary displacement may create psychological depression among affected people and result in sickness, grief, and death. People are forcibly displaced and are bound to live in new atmosphere, new place with new people, and changed norms and values which leads to the change in the entire socio-economic life of displaced people.

Research Methods: The study was carried outamong displaced families in Pul Doda area of Jammu region(June,2022). In the study purposive and snowball techniques was used with the help of semi -structured interview schedule, focus group discussions and case study. The sample comprised of 60 displaced families in Pul Doda region.

Result: The study found that over the period of time poverty, health and issue of malnutrition among the displaced families had tremendously increased due to the lack of proper rehabilitation and resettlement plan.

Conclusion: It was clearly seen that majority of the displaced families are facing poverty, health and malnutrition issues. They are forced to live under miserable conditions due to low economic status.

Keywords: Dam, Displacement, People, Health, and Issues

Background

After the 1950s, first-generation leaders considered hydropower projects as 'the temples of modern India'. For national interest, a large number of development projects were constructed in different parts of the country. The first and second Five-Year Plans mainly focused on industrialization, irrigation, and dam projects, and the displaced people were neglected under such planning[4]. The temple of modern India has become temples of doom for the displaced people[3]. People are forcibly displaced and are bound to live in a new environment, a new place with new people, and with changing norms and values, which lead to a change in the entire socio-economic life of the displaced people[4].

Poverty forces many of them to fill the urban slums from which they are evicted to keep the city beautiful. During the last few years' evictions have taken place in Ahmedabad, Delhi, Mumbai, and other cities. Traditionally 65% of the slum dwellers in the major cities used to be Dalit's. But today also many of the tribal have moved towards the slums

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because of impoverishment by deforestation and displacement and they are among the groups that are evicted[2]. Women faced health, psychological problems, and family conflict that emerged about personal expenses[1].

Statement of the problem

In the state of Jammu and Kashmir, development-induced dam displacement has emerged as a major challenge due to the lack of proper rehabilitation and resettlement policy. Displacement, poverty and health issues have become invisible problems for the policy makers as well as the state government since last 13 years. Displaced families have been given only monetary compensation and left at the mercy of god. Majority of the displaced families are forced to live in un healthy environment without any resettlement plans. What happened to their socio-economic life after displacement? Were they properly rehabilitated? Such questions remain unanswered.

Research Methodology and Objectives

The present study was empirical in nature and it was based on both the primary and secondary sources. For conducting the study, sampling method was used particularly snowball technique to collect relevant data with the help of semistructure interview schedule, focus group discussions and case studies. The study was conducted in Pul Doda area of Jammu region where the people have been forcibly displaced due to Baglihar dam project. In the study, there were 60 displaced families who were easily approachable and thus were interviewed.The main objectives for conducting the study was to understand how the displaced families face socio-economic issues such as poverty, health and problems of malnutrition since last 13th years of displacement. Study further wants to examine how the displaced families were forced to live under below poverty line and what was its impact on their social life.

Finding and Discussions of the Study

Issue of Poverty among Displaced Families

Poverty is one of the biggest social issue in Indian society. But when people are forcibly displaced from their ancestral home land due to developmental projects they become more vulnerable group and are forced to live under impoverishment conditions. It was observed that for the policy makers' poverty is an insignificant issue and they only focus on monetary compensation and ignore other social issues which are the result of dam displacement. The study highlighted various economic issues which the displaced families are facing since last 13 years of the displacement and how they are living in poor conditions due to the loss of family business and regular sources of income.

Income and Occupation

Income and occupation are two important sources through which an individual can earn his social status into the society, and the standard of living is measured based on income and occupation of the family

Table 1. Occupation and Income of the Respondents

Before Displacement			After Displacement		
Occupation	**Income**	**Respondents**	**Occupation**	**Income**	**Respondents**
Big Business (wholescale Shops)	60,000-70,000	10(16.66)	small Business	20000-25,000	10 (16.66)
Dairy forming and daily wagers	18,000-22,000	12 (20.00)	Petty Business	8000-10,000	31 (51.67)
Small business	30,000-35,000	31 (51.67)	Daily wagers	4000-7000	12 (20.00)
Government Jobs	30,000-40,000	07 (11.67)	Government Jobs	50000-60,000	07 (11.67)
Total		60 (100)%			60 (100)%

Note: (i) Daily wager refers to working in big shops, crusher worker, carpenter, mason, etc.

(ii) The figure in parentheses shows the percentage.

(III) Small Business refers to krayana shops, readymade garments, clothes shops, chicken and meat shops, medical shops, etc.

Source: Field Work.

From the table 1. The study highlighted that how the family occupation and income has changed before and after displacement and how it affects the economic status of the family. From the study it was found that before the displacement there were 10 respondents (16.66 per cent) families who were working as a big businessmen (wholesalers) and they earned monthly income between 60,000-70000 rupees. But after the displacement, they earned 20,000-25000 rupees per month at the new place. It was observed that the wholesalers turned in to small businessmen due to the loss of social network and change in business location. Most of the families reported that the family income has tremendously decreased and this has resulted in low economic status of the family. There were 12 respondents (20 percent) families who were working as a dairy farmers and daily wagers and earned 18,000-22,000 rupees per month. But after displacement same families were forced to work as a daily wagers and they are earning 4000-7000 rupees per month. Due to the loss of land, home, and business the displaced families were forced to sell their livestock (cow and buffalo's). Now at the new place they are living in rented houses and earn their livelihood through daily wages.

The study has further seen that before the displacement there were 31 respondents (51.67 per cent) families who were working as small businessmen and earned between 30,000-35,000 rupees per month. They mostly ran Kirana (grocery) store, medical store, chicken and meat shop, garments and clothes shops etc.But after the displacement same number of families turned in to petty businessmen and they are earning 8,000-10,000 rupees per month.

It was also found that there were only 07 respondents (11.67 per cent) families who were working in government sector before and after displacement and their family income had not been affected due to displacement. Before displacement they earned 30,000-40,000 and now their family income is 50,000-60,000 rupees per month.

It was also observed that after the displacement majority of the displaced families are living in rented houses in different location since last 13 years. The state government is unable to rehabilitate them properly due to which the displaced families are living in poor conditions. It was also observed that declining economic status among displaced families has a direct impact on their social life, such as health, education of children, and way of living.

Health Issues

It was observed that the health issues emerged as a major problem among displaced families after the displacement. After the displacement majority of the displaced families focused their attention on getting compensation, resettlement, and rehabilitation process. They ignored their health issues which later on emerged as a major problem among displaced families. The study highlighted the various health issues faced by men, women, elderly and children of the displaced families.

Table 2: Health Issues among Displaced Men and Women after Displacement

Men		Women	
Health Issues	**Respondents**	**Health problem**	**Respondents**
Issue of Blood Pressure	12 (30.00)	Diabetes, weakness and Blood Pressuretyphoid	08 (40.00)
Thyroid, Diabetes	09 (22.50)	Psychological Depression and regular headache	12 (60.00)
Psychological Depression	19 (47.50)		
Total	40 (100)		20 (100)

Note: The figure in parentheses shows the percentage.

Source: Field Work

Table 3 highlighted the health issues which the displaced families are facing after the displacement. In the study both the men and women have been taken in to consideration and tries to examine the different kind of health problems which they are facing at the new places.

It was found that 12 (30.00 per cent) respondents reported that they aresuffering from blood pressure after the displacement. There were 09 (22.50 percent) displaced men who reported that they are suffering from thyroid and diabetes since last nine years. It was further observed that there were significant number of displaced men 19 (47.50 per cent) respondents who reported that they are suffering from psychological depression last 10 years due to the loss of the regular source of income, ancestral property, and low socio-economic status.

As far as displaced women are concerned, the study found that there were 08 (40.00 per cent) displaced women who are regularly suffering from diabetes, weakness and blood pressure and typhoid after being forcibly displaced from their native place. They further stated that since last one decade they are facing the above health problems which hasdirectly put on economic burden on their family. It was further seen that there were 12 (60.00 per cent) displaced women who are suffering from psychological depression and regular headache since last 10 years.Most of the displaced families reported that they are suffering from depression since the last decade as they are living in rented houses and do not have their own house. It was also observed that those displaced families who are living near river Chenab also suffer from typhoid, and malaria due to an unhealthy environment and polluted water.

Socio-economic condition of displaced women

After the displacement socio-economic condition of displaced women has become worse. It was observed that the above family is living near rive Chenab since last 12 years without basic facilities. They are living in unhealthy environment which has greatly detoriated their health. The women in the family reported that her husband is doing petty business in the nearby area and as such they cannot afford to live in a better place. She further said that there is no safe drinking water available her place and she has to travel about 6 km up and down every day to get spring water which is safe for drinking. It was also found that their economic condition is also not good due to which they are unable to send their children to school. The education of their children is suffering and they are helpless. Due to the unhygienic environment, the health of their family is deteriorating day by day. She further stated that since last 10 years, she is living under depression, anxiety and many times she and her children have suffered from typhoid and malaria disease. In the rainy season they are forced to drink polluted river water which has tremendously effected their health. She further stated that they are unable to provide good nutritional food to their children due to low economic status.As such their children are facing nutritional deficiency and suffering from various deficiency diseases.

Nutritional deficiency among lactating and pregnant women

After the displacementnew kind of problem emerged among displaced families especially women due to low economic status of the family.To highlight the issue, the study conducted a focus group discussion (FGD)among lactating and pregnant women. Because in front of the family members the women respondents did not give positive response. Therefore, the FGD was separately conducted to get proper response from the respondents. In the FGD, there were 12 displaced women (7 were lactating and 5 were pregnant women) who participated and shared their problems and experiences.

In the FGD, it was observed that most of the displaced women revealed that due to poverty with in the family, they are unable to consume good nutritional diet which is essential for the growth of the child. As a result, the children who are born suffer from malnutrition. They further reported that the

new born children are under weight and suffer from various growth related diseases. The mother also has nutritional deficiency due to the lack of good balance diet. In the FGD, most of the lactating mother revealed that since they are unable to consume good diet, thus they are not able to properly breast feed their children. Thus they are dependent on formula milk which is an additional economic burden on the family.

As far as the pregnant women are concerned they also face similar kind of problems such as deficiency of protein, calcium, multivitamin and low hemoglobin and BP issues. Since their families are unable to provide them proper balanced diet. This all affects their health and causes many complications during delivery time.

In the FGD, one of the displaced women stated that in her neighborhood one pregnant women died after giving birth to a baby due to low hemoglobin levels. She also said that there were many cases among displaced families where the new born babies died after birth due to nutritional deficiencies.In the FGD it was observed that most of the displaced women suffered from malnutrition and various deficiency diseases due to low economic condition of the family.

Health Issues among Displaced children

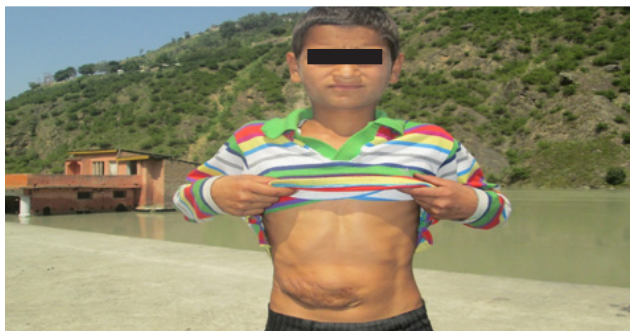
Displaced children become the most vulnerable group at the time of forced displacement. It has been observed that both the policy makers as well as displaced families particularly focus on compensation process and ignore the issue of displaced children.

To highlight the issue, the study conducted a focus group discussion among displaced children. There were 20 children who participated in the focus group discussion and shared their experiences. The age group of the children was between 11-17 years.

In the focus group discussion, most of the children reported that after the displacement, they are the ones who are facing health issue such as depression, anxiety typhoid and malaria. Some of the displaced children also revealed they are living near river Chenab with their families without basic facilities such as drinking water, road, school and health facilities since last 12 years.

The study also found that displaced children are indulged in child labor to contribute to the family income. Most of the children reported that due to the low income of the family, they are forced to work in different places and have thus left their education to support family income. The study also found that due to child labor, the displaced children were suffering from many diseases such as regular back pain and weakness, malnutrition due to lack of proper food. They were forced to work for long hours in different places such as Kirana shops, sand collection from the river Chenab, working in the crusher, etc. The health conditions of these children deteriorated further day by day. Most of the displaced children are suffering from malnutrition because of a lack of a well-balanced diet. Their families are poor and, as such, are not in a position to provide proper food to their children.

For the better understating of problems among displaced children the study conducted a case study of one of the displaced family.



The mother of the child reported that due to unhealthy environment her son is suffering from intestinal disease and water borne diseases since last 10 years. She further stated that she spent most of her compensation money for his treatment but still he is not well. Every year her children are suffering from typhoid and malaria disease which has resulted in more economic burden on them. She also said that since last 11 years her family is living near river Chenab after the displacement. There is no rehabilitation and resettlement plan from the state government since last 12 years which forced them to live in poor condition.

Conclusion

Forced displacement is thebiggest threat to human lives as it produces poverty among the displaced families. The state government and the policy makers only focus on monetary compensation

and ignore the other social problems child labor, education problems, unemployment which the displaced families face after displacement. From the above finding it was clearly seen that due to the lack of proper rehabilitation and resettlement plan, majority of the displaced families are facing poverty, health and malnutrition issues. They are forced to live under miserable conditions. The empathetic attitude of the government authorities towards displaced families led them to live under poor conditions.The displaced families were left helpless, hopeless, and homeless. It was also observed that it is not only the displaced families who are facing poverty issues but their coming generations also face serious socio- and economic problems.

Conflict of Interest: Nil

Source of funding: self

Ethical Clearance: Nil (IndependentResearcher)

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Role of Caudal Epidural Steroid in the Management of Low Back Pain in Telangana Population, India

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Abstract

Background: Low back pain (LBP) is a common condition seen in adult patients causing significant functional and psychological disability in addition to the variable amount of pain.

Method: Every patient was studied with x-rays, MRI of lumbosacral region and degree of pain was assessed by VAS scale. Routine blood investigations were done in every patient to rule out any otherpossible causes for this condition.

Results: 95 patients with LBP were included in this study. Among these 16 (16.8%) either had annular tears or no abnormality in MRI leading to acute back pain, 14 (14.7%) had spondylolisthesis, 25 (26.5%) had lumbar canal stenosis, 40 (42.1%) had degeneration of disc. As per VAS (Visual Analogue Score) at 3rd month -14 patients of Acute LBP, 12 patients with spondylolisthesis, 13 patients with lumbar canal stenosis, 26 patients with degenerative disc disease had significant improvement.

Conclusion: Present study used X-rays, MRI and VAS analogue Scorein addition to systematic clinical examination for evaluation of the low back pain patients. Patients who were resistant to conservative measures were treated with epidural steroid injection before subjecting them to any surgical intervention. Thisis important for the Orthopedicians to treat such patients efficiently with minimal invasion without subjecting them to more invasive measures like open surgical procedures.

Keywords: MRI, VAS, LCS, LBP, Caudal epidural steroid injection

Introduction

Low back pain is the most frequent and persistent cause of disability that occurs in 15-80% of the patients globally including, India[(1)]**.** It also has been reported that 13% of the population suffers with persistent low back pain of high intensity leading to moderate to severe disability[(2)]. Back pain is also prevalent in 12 % of children and adolescents, 15% of adults, 27% of elderly population. Introduction of caudal epidural steroid injection started around 1900[(3)]. Tissues of the low back are capable of transmitting pain which

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include muscles, ligaments, fascia, discs, nerve roots, dura and facets joints. It is difficult to identify the causative factors for low back pain (LBP) which may be either a facet joint or disc or another structure which is generally differentiated based on clinical features of somatic/ referred or radicular pain but persistent LBP is a diagnostic dilemma in majority of the patients even in experienced hands even with availability of all advanced technologies. It is believed that, the benefits of caudal epidural steroid injection may be multifold including clearing the adhesions or inflammation from the vicinity of nerve root sleeve and neurolytic or other unknown beneficialeffects[4 5]. Hence this study was under taken to evaluate the role of caudal epidural steroid injections in the patients with different clinical manifestations of LBP.

Material and Methods

95 patients regularly visiting Orthopaedic department of Surabhi Institute of Medical Sciences,Siddipet and Mallareddy Institute of Medical Sciences, Suraram, Telangana State, India wereincluded in the study.

Inclusive Criteria: Patients aged between 30 to 65 years having low back pain (LBP), radicular symptoms and neurogenic claudication not responding to symptomatic treatment for 4 to 6 weeks were selected for study.

Exclusion Criteria: The patients having osteoporotic fractures, traumatic lumbar spine fractures, patients younger than 30 years older than 65 years, having malignancy or infections of the spine were excluded. The patients having cardio-vascular or neurogenic diseases were also excluded from this study.

Method: After applying the exclusion criteria patients selected were evaluated thoroughly with both systematic clinical examination and investigations mentioned above. Conservative treatment was given initially and those who doesn't respond to it in a reasonable period of time were subjected for the caudal epidural steroid injection. Caudal epidural injection was given under full aseptic conditions by keeping an anaesthetist as a stand by. The patients were asked to lay down in prone position, on radiolucent table. The gluteal region was prepped and drapedfrom 4 cm above the proximal end of natal cleft. Needle was inserted straight through sacral hiatus. C-Arm image intensifier used to confirm the site of needle insertion. 20 G spinal needle was inserted into sacral hiatusand then directed into the sacral canal. Aspiration was done to confirm that that the needle did not pierce epidural blood vessels or the dura. Small amount of radiopaque water-soluble dye was injected through the syringe to confirm the needle was in the epidural space.Position of the needle in the sacralhiatus was also confirmed under C- Arm. 50 cc syringe containing 25cc of normal saline, 5cc of 2% lignocaine, and 80 mg of Depo-Medrol acetate was injectedslowly. It was stop and go procedure. After the injection patient was turned into supine position and vitals were monitored for 5-10 minutes. Then patients were asked to move toes and legs actively to check their muscle power. The patients in whom bloody tap was encountered, the procedure was abandoned and postponed for at least a week.

The patients were discharged on the same day and instructed to lie in supine position for next 6 hours to prevent headache, nausea and vomiting. They were called after 24 hours to know about the pain and note any adverse effects. Later conservative treatment was continued simultaneously. Subsequent follow ups in OPD were done at one week, three weeks and three months intervals and were assessed on VAS (Visual Analogue Scale) score during the follow-up.

Duration of study was September-2020 to August-2022

Statistically: Types of LBP was classified as per MRI picture with percentage, study of duration of improvement as per VAS score was noted. Different complaints of the patients were classified with percentage, and different grades of VAS score also classified with percentage. The statistical analysis was done in the 2007 micro software. The ratio of male and female was 2:1.

Observation and Results

Table-1: VAS score study- grade-I had 34 (35.7%), grade-II had 44 (46.3%), grade-III had 44, grade-IV had 9 (9.1%) and grade-V had 8 (8.4%) patients.

Table-2: Classification of LBP as per MRI picture- 16 (16.8%) had acute annular lesions or no lesions, 14(14.7%) had lumbar spondylolisthesis, 26(25.5%) had lumbar canal stenosis, 40(42.1%) had degeneration of disc.

Table-3: Study of improvement as per VAS score (4-8)- 14 patients with acute back pain, 12 patients with lumbar spondylolisthesis, 13 patients with lumbar canal stenosis and 26 patients with degenerative disc disease improved at three months after treatment.

Table 1. VAS score study

Total No. of patients: 95

VAS score rate grades	No. of Patients (95)	Percentage (%)
Grade-1	00	–
Grade-1I	34	35.7
Grade-1II	44	46.3
Grade-1V	09	9.4
Grade-V	08	8.4

Grade-III has significant number patients & grade-V has least Low Back Pain (LBP) as per MRI study.

Table 2. Classification of low back pain as per MRI study

Total No. of patients: 95

Sl No	Diagnosis	Number of Patients	Percentage (%)	Complaints
1	Annular tears or no cause found-Acute LBP	16	16.8	Back pain
2	Spondylolisthesis	14	14.7	Claudication and LBP
3	Lumbar canal stenosis	25	26.8	Claudication
4	Degenerative disc disease	40	42.1	Back pain and leg pain

Degeneration of disc with or without root radiation had more complaints and spondylolisthesis has least number of complaints.

Table 3. Study of improvement as per VAS score on caudal Epidural steroid injection

Total No. of Patients: 95

Sl. No	Diagnosis	At first visit	One week	After three weeks	At Three months
1	Acute Back Pain	12-14 (16)	0-4 (16)	4-6 (16)	4-8 (14)
2	Spondylolisthesis	4-3 (14)	0-4 (4)	4-6 (14)	4-8 (12)
3	Lumbar canal stenosis	4-7 (25)	4-8 (17)	0.4 – 4.8 (13)	4-8 (13)
4	Degeneration of Disc	8-12 4-10 (40)	0-4/0-4 (34)	0-4 / 4-8 (26)	4-8 / 8-12 (26)

The degeneration of disc with or without root radiation had duration of treatment and more patients to treat while spondylolisthesishad least number of patients.

Discussion

Present study done mainly to know the role of caudal epidural steroid injection in the management of low back pain in Telangana Population. In theVAS score study 0 patients in Grd I, 34(35.7%) were in grade-II, 44 (46.3%) were in grade-III, 9(9.4%) in grade-IV, 8(8.4%) in grade-V (Table-1). Classification of LBP as per MRI study was 16(16.8%)had acute annular lesions or normal MRI, 14(14.7%) had spondylolisthesis, 25 (26.3%) had lumbar canal stenosis, 40 (42.1%) had degeneration of disc (Table-2). In the study of improvement as per VAS score on caudal epidural steroid injection at three months, 14 had improvement in Acute LBP, 12 had improvement in spondylolisthesisand 13 in lumbar canal stenosis and 26 patientsimprovedwithdegenerationof disc (Table-3). These findings are more or less in agreement with previousstudies [6][7][8]

The exact mechanism of action of epidurally injected steroid and local anesthetic is unclear. It can be hypothesized that steroid injection achievedneural blockade, which alters or interrupts nociceptive input reflex mechanism of the afferent fibers, self-sustaining activity of the neurons andpatterns of the central neuronal activities[9]. Corticosteroids reduce the inflammation by inhibiting either the synthesis or release of number of pro- inflammatory mediators and by causing a reversible local anesthetic effect[10]. In contrast local anesthetics have been described to provide short to long term symptomatic relief based on various mechanisms.

The LBP could be due to excess release of neurotransmitters causing complex central responses including hyperplasia and phenotype changes which are considered as part of neuronalplasticity [11]. The administration of steroid could be effective for short term and in some cases, steroids have long term potency. Hence efficacy of the steroid is unpredictable [12]. Moreover, radicular pain can occur without disc herniation. Hence it is believed that radicular pain includes partial axonal damage, neuroma formation focal demyelination, intraneural edema, impaired microcirculation, chemical irritation and inflammation around discs and nerve roots which generate the pain.Such pain was relieved by administration of steroid and local anesthesia but duration of relief is un-predictable.

Hence caudal epidural steroid injection is an effective surgery sparing procedure that should be a part of conservative care in the management of LBP and radiculopathy.

In evolutionary point of view vertebral column was like cantilever bridge which has modified into pillar to transmit the body weight of erect posture. Hence there was re-orientation of vertebral column. This re-orientation depends on environmental and nutritional status which leads to variations in adoption resulting in spondylolisthesis, herniation, and degeneration of disc because every part of the vertebra has individual and different function.

Summary and Conclusion

Present study is to know the role of caudal epidural steroid injection in the management of LBP. The procedure can be performed easily as a day care procedure, less technically demanding and with low complication rates compared with surgical treatment. Moreover, it is cost effective alternative approach to the management of LBP. But this study demands further embryological, genetic, anthropological, nutritional, bio-mechanical study because the exact factors and mechanism of formation of primary and secondary curvatures of vertebral column is still un-clear.

Limitation of study Owing to tertiary location of research centres, small number of patients and lack of latest techniques, we have limited findings and results.

This research paper was approved by Ethical committee of Surabhi Institute of Medical Sciences, Siddipet & Mallareddy Institute of Medical Sciences, Suraram, Telangana state, India

Conflict of Interest: No

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Original research Article

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Determination of Insulin Resistance and Dyslipidemia after treatment with selective Anti-Depressants in case of Major Depression

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Abstract

Introduction: Depression can present a plethora of symptoms, such as loss of pleasure, feelings of guilt, low self esteem, and disturbed sleep or appetite. Selective Serotonin Re-uptake Inhibitors (SSRIs) are considered as the mainstay of treatment for depression. Several studies suggest that antidepressants increase the risk of developing metabolic complications including Insulin Resistance (IR) and dyslipidemia, thus leading to poor health outcomes. This study would provide a review of depression and IR and examine side effects of anti-depressants that are often used to treat depression.

Material & Methods: It was a cross-sectional analytical study conducted at the Department of Biochemistry, College of Medicine and Sagore Dutta Hospital, in collaboration with Department of Psychiatry. Patients attending the psychiatric OPD, who are newly diagnosed as Major Depressive Disorder (MDD) orrecurrent depressive disorder were selected. Age and gender matched healthy family members of the patients were chosen as controls.

Results: Significant alteration of Body Mass Index (BMI), Hamilton Depression Scaling (HAM-D), High Density Lipoprotein (HDL) and Low Density Lipoprotein (LDL)with non-significant variation of HOMA-IR, Total Cholesterol and Triglyceride levels were found.

Keywords: Major Depressive disorder, glycemic index, HOMA-IR, Dyslipidemia,SSRI

Introduction

Depression is a very serious psychiatric disorder that can lead to profound emotional and physical ailments, including loss of interest or enthusiasm, lack of feelings of pleasure, feelings of guilt or low self-worth, and disturbed sleep or appetite[1]. Recently it has emerged as a major public health problem affecting large number to human populations worldwide irrespective of age. Women have been foundto be more susceptible to develop depression than males and often have a more chronic course[2]. Furthermore, the lifetime risk of developing depression increases

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to as high as 40% when co-morbid chronic medical illnesses such as diabetes and cardiovascular disease (CVD) are present[3]. CVD is the leading cause of morbidity and mortality worldwide, which is further influenced by the abundance of modifiable risk factors. The metabolic syndrome (MS), which is a cluster of cardiovascular risk factors like obesity, hypertension, hyperglycemia & dyslipidemia all of which further significantly increase the risk of CVD and type 2 Diabetes mellitus. These factors also appear to be involved in the pathophysiology of depression, and may account for the higher cardiovascular risk observed in this disorder[4].

A combination of psychological and pharmacological therapies is the predominant treatment modalities for depression. Antidepressants are the mainstay of pharmacological intervention for moderate to severe depression which is used to alleviate mood and behavioral symptoms. Most of the widely prescribed classes of antidepressants are selective serotonin reuptake inhibitors (SSRIs) such as fluoxetine, paroxetine, escitalopram and sertraline. Other drugs like serotonin–norepinephrine reuptake inhibitors (SNRIs) such as venlafaxine, desvenlafaxine, and duloxetine[5–7], and tricyclic antidepressants (TCAs) such as imipramine, clomipramine, and desipramine[8–11] are also used.

SSRIs affect the lipid and carbohydrate metabolisms to a major extent. Symptoms including weight gain and dyslipidemia have been reported to be one of the most relevant reasons for the early discontinuation of anti depressant drugs[12].

Very little is known about thedevelopment ofinsulin resistance (IR) and dyslipidemia in major depression patients after treatment with of anti-depressant drugs. In some cases, depression is associated with physical inactivity and irregular dietary habits, which may further increase the risk of developing IR & diabetes. Studies suggest that many antidepressants increase the risk of developing metabolic complications including IR, thus leading poor health outcomes. This study would provide a review of depression and IR and examine side effects of antidepressants that are often used to treat depression. Here we've tried to asses & compare the effect of several SSRI on the lipid and carbohydrate metabolism.

Aims & Objectives: To determinethe occurrence of insulin resistance and dyslipidemia inpatients with major depression treated with SSRIs.

Materials and Methods

Study type and design: A cross-sectional analytical study.

Study setting: It was conducted at College of Medicine and Sagore Dutta Hospital by Department of Biochemistry in collaboration with Department of Psychiatry.

Study population: Patients attending psychiatric OPD who are newly diagnosed as Major depressive disorder (MDD) orrecurrent depressive disorder.

Inclusion criteria of cases: Patients 18-55 years newly diagnosed to have MDD (fulfilling DSM V criteria**)** or RDD (unipolar) at least three months of drug free period**.**

Inclusion criteria for controls: Age and sex matched healthy family members (brothers, sisters) of the patients.

Exclusion criteria:

Patients or controls with no other acute or chronic disorder e.g Diabetes mellitus, Hypertension, Hypothyroid or hyperthyroid, Seasonal Affective Disorder, other psychiatric disorder, dyslipidemia, malabsorption disorders, malignancy, liver cirrhosis or previous treatment with other anticonvulsants, patients having bipolar depression.

Sample size: 70 cases and 70 age and gender matched healthy controls.

Study duration with time scheduling: December 2021 to May 2022

Tools and techniques:

Every individual in both case & control group were asked to be give written consent after explaining the whole process in language which is understandable to them. The confidentiality of the statement and reports were maintained with utmost priority.

5ml of blood sample after overnight fasting was collected along with the detailed history and

fulfilling the exclusion criteria. Serum was separated & collected after centrifugation.

Blood samples were analyzed for Fasting plasma glucose, Fasting Insulin level and lipid profile by following manufacturer's instructions with ERBA EM 360/640 Autoanalyzer.

HOMA IR was calculated by the formula – [Fasting insulin(μIU/ml)×fasting blood sugarmg/dl)] /405

Data was collected and analyzed by using statistical software.

Control and cases were grouped accordingly. Case group was using one of the SSRIs namely fluoxetine, escitalopram and sertraline. At the beginning of starting treatment the biochemical parameters were measured and clinically assessed for psychiatric function using Hamilton Depression Rating Scale (HAM-D) criteria. After 12 weeks the patients were reviewed again and assessed by the same criteria to know the effect. Exposure variable and descriptive analysis were done. Mean, median, standard deviation and distribution of data was assessed. Depending on the distribution of data statistical tools were used to find further significant analysis.

Results

Table 1: Demographic profile of cases & controls

	Case (N=70)	Control (N=70)	P value
Age(Years) Mean ±SD	35±4	39±5	0.35
Gender	Male- 31 Female- 39	Male- 35 Female- 35	-
BMI Mean ±SD	27.93±0.66	28.11±0.11	0.43
HAMD	23.12±3.19	—	
HOMA-IR Mean ±SD	1.21±0.21	1.23±0.24	0.78
Cholesterol (mg/dl) Mean ±SD	203± 21	210±21.38	0.58
TG Mean ±SD	180±21	185±32	0.45
LDL Mean ±SD	97±5	98±9	0.78
HDL Mean ±SD	57.2±3.1	52±5.1	0.56

Table 2: 12 weeks after treatment with SSRI case group

	Before starting treatment	12 weeks after treatment	P value
BMI	27.93±0.66	30.12±0.23	<0.0001
HAM D	23.12±3.19	5.76±1.12	<0.0001
HOMA-IR	1.21±0.21	1.13±0.33	0.893
Cholesterol	203± 21	212±45	0.1317
TG	180±21	187±68	0.412
LDL	97±5	167±13.12	<0.0001
HDL	57.2±3.1	45±3.12	<0.0001

In our study, we saw that there was no significant statistical variation in TG, TC and HOMA- IR between the pretreatment and post treatment (after 12 weeks of SSRI treatment) findings.

However, there was significant alteration of BMI, HAM-D, LDL and HDL in the post treatment values. LDL was found to be significantly higher (167±13.12) after the 12 week treatment with SSRIs whereas HDL was significantly lower (45±3.12) after the treatment. The difference of BMI was also statistically significant. HAM-D scores after treatment was found to be lower (5.76±1.12) than the pre treatment values, which was statistically significant as well. It means that the patients responded well to the SSRIs.

This implies that the use of SSRIs in our study, attributed to the increase of LDL (bad cholesterol), decrease of HDL (good cholesterol), with decrease in depression symptoms, without affecting TG, TC and HOMA-IR significantly.

Discussion

In this study, we found that SSRIs have a negative impact on the lipid profile (LDL,HDL) and BMI with improvement of depression symptoms.

Depression induces certain pathophysiological pathways arising from the hypothalmic-pituitary-adrenal (HPA) axis. Inflammation can lead to lipid dysregulations like increased LDL, decreased HDL, hypertriglyceridemia, increased lipolysis and release of fatty acids. Deranged lipid profile pose as a risk factor for cardio vascular diseases. Disturbances in the HPA axis can lead to rise in cortisol and catecholamines which in turn increases heart rate and blood pressure.[13]

Pan SJ et al demonstrated the effects and mechanisms of the abnormalities in lipid metabolism caused by Fluoxetine (FLX) in patients and in a mouse model of depression. In the above mentioned study, they found that serum Triglyceride (TG), Total Cholesterol (TC) and Low Density Lipoprotein (LDL) levels were significantly increased in the depression patients after fluoxetine treatment. FLX treatment was found to significantly increase the hepatic TG levels in both control and depressive mice, compared to non-treatment , while the hepatic TC levels were not significantly altered by FLX treatment.[14]

Arain AA et al, in a 6 week study, observed that there was a significant reduction in total cholesterol and triglyceride levels following escitalopram treatment.[15]

In a partially randomized trial by Gasse C et al, conducted over a period of 3 years, an increase in total and free cholesterol and LDL correlated with improved antidepressant response, after treatment with escitalopram.[16]

Kesim M et al found an increase of insulin level but no change in blood glucose in patients treated with Sertraline for major depression. In their study, though insulin level increased but it was still in normal range (non-significant), so blood glucose level didn't change. unlike our findings, they did not observe any significant changes in the HDL and LDL levels from pre-treatment but TG levels were significantly increased which can be due to increased insulin secretion and it's anabolic effects.Sertraline, an SSRI, may increase insulin secretion as it increases insulin secretion in pancreas.[17]

Hepatic insulin sensitizing substance (HISS) is released from liver by the action of insulin. In the absence of HISS release, the response to insulin is decreased andmore insulin is secreted from the pancreas.[18] Sertraline might prevent the release of HISS from the liver and may cause an increased insulin secretion to regulate glucose.[17]

Isaac R et al in their experimental study found that long term use of SSRIs inhibit insulin secretion and action inducing apoptosis of beta cells of pancreas. Insulin resistance finally leads to diabetes which is a menace of 21st century.[19]

Weight gain, one of the frequent side effects of SSRIs, finally leads to obesity which is associated with dyslipidemia, Coronary Artery disease (CAD), insulin resistance and overt diabetes.[20,21]

Similar to our study, Olgunar Eker et al found that the baseline insulin values and HOMA index values were lower in the patient group than the control group although the difference was not statistically significant.[22]

Conclusion

Depression is emerging as one of the leading mental health problems affecting all age groups and genders, worldwide. SSRI being the main stay of treatment but its having some negative effect on lipid profile .So before choosing the drug, need to be more cautious about the patients overall health profile for a better outcome overall

Limitations:

A larger study group and longer study period could have reassured more concrete results.

Conflict of interest: There was no conflict of interest in this study.

Source of funding: This study was self-funded.

Ethical Clearance: Approved by the institutional ethical committee of 'College Of Medicine & Sagore Dutta Hospital'.

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Original Article

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The Psychological Impact of the COVID-19 Pandemic and Online Teaching on the Academic Performance of Medical Students in Eastern India

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Abstract

Background: COVID-19 has spread throughout the world and has resulted in significant morbidity, mortality, and negative psychological impact. This cross-sectional study is exploring the effect of the pandemic on mental health and academic performace of medical students. Survey was done to solicit participants' feedback regarding their experience in academic difficulties during the COVID-19 pandemic.

Material and Methods: It was a cross-sectional observational study with a convenience sample conducted in Medical College at Eastern India. Study assessed the mental health of students' participants during the COVID-19 outbreak by using structured questionnaires and studies its impact on academic performance in upcoming WBUHS Professional Examinations. An online google form questionnaire link was shared with the participants. The final questionnaire for this study consisted of 17 questions (15 closed-ended and 2 open-ended) and a rating scale divided into three sections. After the filling of questionnaires, participants were followed up for their academic performances.

Results: Ability to focus on academic work (72-93%) and difficulties with online learning (17-31%) were the most commonly cited issues related to academics. Change of behavior in response to the pandemic was pervasive. Our respondents almost universally increased hand washing, limited social outings, and started wearing masks.

Conclusion: Study results indicate that college students who are experiencing considerable number of academic and everyday difficulties during the COVID-19 pandemic also report increased levels of mental health burden.

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This study will add to the existing body of literature on the impacts of the COVID-19 pandemic, lockdown and online learning on the social an sychological health of students.

Keywords: Novel coronavirus (COVID-2019), online teaching, mental health, psychological impact, academic performance

Introduction

The novel coronavirus (COVID-2019) has spread very rapidly all over China and several other countries, causing an outbreak of acute infectious pneumonia.[1] Several governmental measures have been taken to counteract the risk of disease spreading. These measures include travel restrictions, mandatory quarantines for travelers, social distancing, bans on public gatherings, schools and universities closure, business closures, self-isolation, asking people to work at home, curfews, and lockdown.[2, 3] Authorities in several countries worldwide have declared either lockdown or curfew as a measure to break the fast spread of virus infection.[4] These measures have a negative worldwide effect on the business, education, health, and tourism.[5]

Most of the medical colleges have quickly adapted to the online classes with shifting of live clinical exposure with the virtual one. Some schools also echoed concerns over clinical clerkships and assessment during these times. The COVID-19 pandemic represents a transformation in medicine with the advancement of telehealth, adaptive research protocols, and clinical trials with flexible approaches to achieve solutions.[6]

Challenges to online education reported in the medical literature so far include issues relating to time management, use of technology tools, students' assessment, communication, and the lack of in-person interaction.[7] Besides, online education may not be equitable in terms of access and the quality of teaching.[8]

Mental health issues are the leading impediment to academic success. Mental illness can affect students' motivation, concentration, and social interactions—crucial factors for students to succeed in higher education.[8] However, no detailed study on the mental health status of medical college students facing the epidemic has been conducted to date in Indian setup. The 7-item Generalized Anxiety Disorder Scale (GAD-7) is one of the most widely used instruments for the detection and screening of anxiety disorders to aid the diagnostic process of specific disorders.[9] The GAD-7 takes less than 3 min to complete and easy to score.[10] Today, the GAD- 7 is the most widely used measure of anxiety used in clinical practice and research due to its diagnostic reliability and efficiency (Johnson et al., 2019).[11]

Methods of guiding students to effectively and appropriately regulate their emotions during public health emergencies and avoid losses caused by crisis events have become an urgent problem for colleges and universities.[12] The impact of medical student psychological distress due to COVID 19 on academic performance has not been systematically examined. This study provided an opportunity to closely examine the potential impacts of study related stress factors on student's psychological distress and their academic performance during their professional exams and academic life. Therefore, in the present study investigated and analyzed psychological impact of the COVID-19 pandemic and online teaching on the academic performance of medical students in Eastern India.

Material and Methods

It was a cross-sectional observational study with a convenience sample conducted in Medical College at Eastern India. An online structured questionnaire was developed by using Google form, with a consent form appended to it. Project was approved by Institutional Ethics Committee before commencement of study. The target population comprised undergraduates of a medical college in different semesters. The respondents in the target population were sampled by a convenience sample. Present study assessed the mental health of students' participants [1st MBBS, 2nd MBBS and Final MBBS as because there were no students currently in 3rd Professional Part I] during the COVID-19 outbreak by using structured questionnaires and studies its impact on academic performance in upcoming WBUHS Professional Exams. The aim and uses

of data of the questionnaire was briefly explained at the beginning of the questionnaire. The final questionnaire for this study consisted of 17 questions (15 closed-ended and 2 open-ended) and a rating scale divided into three sections. After the filling of questionnaires, participants were followed up for their academic performances. Finally, those who completed the questionnaire were included in the final analysis (based on response rate). Participation was voluntary. Study tools used were structured questionnaire and 7-item Generalized Anxiety Disorder Scale (GAD-7).[13, 14]

The study instrument comprised a structured questionnaire packet that inquired information on demographics, knowledge levels and sources of COVID-19 information, behaviour changes, academic and everyday difficulties, and mental health measurements (depression, anxiety, somatization, and stress). Questionnaire survey was done using a multi-item questionnaire over a 4 months period (Dec 2020 to March 2021). A link to the survey was delivered to students via e-mail, and two to three reminders was sent in the subsequent week following the initial invitation. Participants provided informed consent to participate in an anonymous survey by completing and submitting the questionnaire electronically. By end of July/Aug/Sept 2021, their respective MBBS professional exams result was declared by Health University and was noted and correlated with the findings of questionnaire survey.

Results

Table 1: Descriptive statistics for observed indicators of academic difficulties and challenges of online teaching

Characteristics	Academic Year Final MBBS [n=100]	2ND MBBS [n=100]	First MBBS [n=100]	Chi-Square test (P-Value)
Academic difficulties encountered during the lockdown [May be single or multiple replies]				
Ability to focus on academic work	93 (93%)	72 (72%)	86 (86%)	0.003*
Completing assignments and tests	33 (33%)	19 (19%)	12 (12%)	
Difficulties with online mode of learning	23 (23%)	17 (17%)	31 (31%)	
Inadequate Wi-Fi/ Computer access	7 (7%)	9 (9%)	13 (13%)	
No academic difficulties	0 (0%)	0 (0%)	0 (0%)	
Challenges of online teaching [May be single or multiple replies]				
Communication	11 (11%)	18 (18%)	25 (25%)	
Student assessment	17 (17%)	12 (12%)	27 (27%)	
Use of technology tools (access to hardware and software)	23 (23%)	14 (14%)	19 (19%)	
Experience in online teaching/ learning	9 (9%)	17 (17%)	36 (36%)	
Mental health (stress, anxiety)	67 (67%)	51 (51%)	75 (75%)	
Learning curve (adapting to unfamiliar technology)	37 (37%)	13 (13%)	24 (24%)	
Time management	29 (29%)	42 (42%)	38 (38%)	
Students' evaluations of faculty	11 (11%)	18 (18%)	22 (22%)	
Technophobia	10 (10%)	6 (6%)	18 (18%)	
Others	03 (3%)	4 (4%)	7 (7%)	

Biggest challenges of online teaching were noted like mental stress [51-75%] followed by time management [29%-42%] and learning curve (adapting to unfamiliar technology) [13-37%]. Ability to focus on academic work (72-93%) and difficulties with online learning (17-31%) were the most commonly cited issues related to academics. Ability to focus on academic work was also a significant predictor of somatic problems, together with problems in completing assignments and tests. After checking the normality of the variables we performed. Non parametric tests (chi-square test) were used to make group comparisons. There was significant difference between the groups in academic difficulties, with p–value 0.003 [Table 1].

Table 2: Descriptive statistics for observed indicators of feedback on online teaching by medical undergraduates

Feedback on Online Teaching by Medical Undergraduates				**Chi-square test (P –value)**
Previously attended any online classes				
Characteristics	Academic Year Final MBBS [n=100]	2ND MBBS [n=100]	First MBBS [n=100]	
Yes No	27(27%) 73(73%)	11(11%) 89(73%)	5 (5%) 95 (73%)	3.452
Given the opportunity to ask questions during the e-classes				
Yes No	67(67%) 33(33%)	73(73%) 27(27%)	79(79%) 21(21%)	2.583
The material shared before/after e-classes was useful				
Yes No	33(33%) 67(67%)	64(64%) 36(36%)	42(42%) 58(58%)	5.472
Rating your interaction with the teacher during e-classes				
As good as physical class room Better than physical classroom Poorer than physical class room	19 (19%) 2 (2%) 79 (79%)	30 (30%) 4 (4%) 66 (66%)	16 (16%) 1 (1%) 83 (83%)	0.008*

The material shared before/after e-classes was useful responded by (33%-64%). Better rating of interaction with the teacher during e-classes was reported in the range of (1%-4%). Majority responded poorer than physical classroom by [66%-79%] in different semesters [Table 2].Change of behavior in response to the pandemic was pervasive. Our respondents almost universally increased hand washing, limited social outings, and started wearing masks. After checking the normality of the variables we performed Non parametric tests (chi-square test) were used to make group comparisons. There was significant difference between the groups in terms of interaction with the teacher, with p– value 0.008.

Table 3: Descriptive statistics for observed indicators of the impact of online teaching mental health burden

Characteristics	**Final MBBS [n=100]**	**2nd MBBS [n=100]**	**First MBBS [n=100]**	**Chi-Square test P -value**
Anxiety level according to Generalized Anxiety Disorder 7-item (GAD-7) scale				
No anxiety	14 (14%)	23 (23%)	19 (19%)	0.001*
Mild	73 (73%)	69 (69%)	70 (70%)	
Moderate	11 (11%)	8 (8%)	11 (11%)	
Severe anxiety	02 (2%)	0 (0%)	0 (0%)	

7-item Generalized Anxiety Disorder Scale scores of 5, 10, and 15 are taken as the cut-off points for mild, moderate and severe anxiety, respectively. Generalized Anxiety Disorder 7-item (GAD-7) scale in Final Yr MBBS (N=100) were reported as no anxiety 14%, mild 73%, moderate 11% and severe anxiety 2%. In 2nd MBBS participants' anxiety levels were noted as no anxiety 23%, mild 69%, moderate 8% and severe anxiety 0%. 1st MBBS participants' anxiety levels were noted as no anxiety 19%, mild 70%, moderate 17% and severe anxiety 0%. After checking the normality of the variables we performed Non parametric tests (chi-square test) were used to make group comparisons. There was significant difference between the groups in terms of interaction with anxiety level, with p – value 0.001[Table 3].

Table 4: Impact of COVID 19 pandemic, lockdown and online teaching on academic performance

Characteristics	Final MBBS [n=100]	2ND MBBS [n=100]	First MBBS [n=100]	Chi-Square test P -value
Results Passed Failed	87 (87%) 13 (13%)	88 (88%) 12 (12%)	75 (75%) 25 (25%)	0.001*
Above 70%	09 (09%)	11 (11%)	10 (10%)	0.001*
65-70%	13 (13%)	16 (16%)	12 (12%)	
60-65%	19 (19%)	14 (14%)	13 (13%)	
55-60%	26 (26%)	28 (28%)	23 (23%)	
50-55%	20 (20%)	19 (19%)	17 (17%)	
<50%	13 (13%)	12 (12%)	25 (25%)	

After checking the normality of the variables we performed non parametric tests (chi-square test) were used to make group comparisons. There was significant difference between the groups in terms of interaction with results (passed and failed), with p–value 0.001 [Table 4].

Discussion

Since the COVID-19 outbreak and lockdown, a few studies have emerged describing higher levels of anxiety and increased risk perception among college students during COVID-19 pandemic.[12,15,16] The current study is among the first to examine the impact of the COVID- 19 pandemic, lockdown and online learning on mental health and academic performance among undergraduate medical college students in a tertiary care teaching hospital, Haldia, West Bengal.

High levels of depression were associated with difficulties in focusing on academic work. Inability to focus on academic work during lockdown and negative impact of online teaching were more likely to be associated with higher levels of poor academic performace in the University Professional Exams. Cross-sectional, self-report data on psychological distress and COVID-19 exposure by Kibbey MM et al revealed that nearly half of the students reported elevated psychological distress, including health anxiety, general anxiety, and depression.[17] Khan AH et al study revealed that about 28.5% of the respondents had stress, 33.3% anxiety, 46.92% depression from mild to extremely severe, according to DASS 21 and 69.31% had event-specific distress from mild to severe in terms of severity according to IES.[18]

Sundarasen S et al cross-sectional online survey shown that out of 983 respondents, 20.4%, 6.6%, and 2.8% experienced minimal to moderate, marked to severe, and most extreme levels of anxiety. Researchers had used Zung's self-rating anxiety questionnaire during the COVID-19 pandemic and lockdown. The main stressors include financial constraints, remote online teaching and uncertainty about the future with regard to academics and career.[19]

Baloch GM et al study had shown that among the respondents, 125 (25.3%), 45 (9.1%) and 34 (6.9%) experienced minimal to moderate, severe, and most extreme levels of anxiety, respectively. The most prominent stressors attained from the qualitative feedback from the Pakistani students are associated with online teaching, concerns about their academic performance and completion of the current semester,

uncertainty related to exam dates, and the status of the following semester.[20]

Our results indicate that college students who are experiencing considerable number of academic and everyday difficulties during the COVID-19 pandemic also report increased levels of mental health burden. This is of potential concern as the pandemic is occurring against the backdrop of increasing mental health issues among college students.[21] As uncertainties about the future continue this may lead to worsening mental health status, particularly among young individuals.[22]

Conclusion

COVID-19 is imposing threat both on physical and mental health since its outbreak. All forms of mental health burden were significantly associated with online learning difficulties. Analyses indicated that economic hardship was the most significant predictor of depression among respondents, followed by difficulties with focusing on academics. Anxiety levels were significantly higher among final MBBS students. Ability to focus on academic work was also a significant predictor of somatic problems, together with problems in completing assignments and tests. Our results indicate that college students who are experiencing considerable number of academic and everyday difficulties during the COVID-19 pandemic also report increased levels of mental health burden.

Conflict of Interest: None

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Original Article

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Hematological Parameters: Manual vs Automated Method; Among the β-Thalassemia and other Haemoglobinopathies in a Tertiary Care Hospital in Kolkata

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Abstract

Background: According to a report of WHO in 2007, 7% of world populations are carrier for Haemoglobin disorder and accurate and timely detection of various Hb variants including beta thalassemia trait can prevent occurrence of more serious disorders like thalassemia major in new-borns. But in a developing country like us use of high pressure liquid chromatography (HPLC) is limited, manual testing is done and accurate assessment is quite impossible. So, an observational cross-sectional study was done among 117 β-thalassemia and other Hemoglobinopathies cases and carriers.

Objective: To find out the variation between the results of haematological tests obtained by automated counting chamber and manual method.

Materials & Methods: This Observational, cross-sectional study was done at Thalassemia control unit and Physiology department of R G Kar Medical College and Hospital, Kolkata. β-thalassemia and other Hemoglobinopathies cases and carriers detected by complete blood count with HPLC from Thalassemia Outpatient Department (OPD) and antenatal mothers from antenatal clinic (ANC) were the population of this study. Findings and variations of the features of different hematological parameters amongst the β-thalassemia and other hemoglobinopathies were reviewed. A finding by HPLC was HbA, HbA2, HbF, HbD, and HbE.

Results: Result of only Hb% obtained from HPLC and manual method was significantly different in β- THALASSEMIA Trait (p=0.0001), HbE Trait (p=0.0001), HbS trait **(**p=0.0001) and not significant in HbE disease and no other Red cell indices were significantly different in two methods. **Conclusion**: As hematological features like TC of RBC or PCV results by manual method shows no significant differences with HPLC/ Automated counter

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assessment, such methods can be utilized even at primary level cost effectively for assessment of hematological disorders. But significant difference is seen in estimating Hemoglobin percentage in between Shalli's method and HPLC/Automated counter assessment. So some alternate method may introduce at lower level of health system other than Shalli's method.

Keywords: Anaemia, haemoglobinopathies, thalassemia, automated counting chamber, manual method, Kolkata

Introduction

Anaemia is a major public health problem among the children, pregnant women and non-pregnant women in South East Asia, of which India is a part.[1] Thalassemia and Hemoglobinopathies are important amongst the causes of anemia. Abnormalities of haemoglobin (Hb) synthesis are extremely common inherited disorder worldwide, ranging from almost functionally normal Hb to severe transfusion dependent disorder and are quantitative (Thalassemia Syndrome) or qualitative (Hb variant) or a combination of both. Such diseases are prevalent in India also.

Hemoglobinopathies (Hb variant) and β-Thalassemia carrier constitutes 4.5% of world population-as per a report of World health organization (WHO) in 1989.[2] It shows an increasing trend and according to a report of WHO in 2007, 7% of world populations are carrier for Haemoglobin disorder.[3]Each year about 30,0000 infants is born with major Hb disorders.[4] Around 85% of sickle-cell disorders and over 70% of all affected births occur in Africa.[5]

Accurate and timely detection of various Hb variants including beta thalassemia trait can prevent occurrence of more serious disorders like thalassemia major in new-borns. Revolutionary changes have taken place in the last decade in the field of detection of β-Thalassemia and other Hemoglobinopathies. Automated high performance or high pressure

liquid chromatography (HPLC) plays an important role to detect those disorders.[6,7] Cation exchange HPLC offers a reliable tool for early, accurate detection thereby aiding in prevention and management of various Hemoglobinopathies. This is especially important in view of high incidence of ß-thalassemia trait in the Indian subcontinent.[8] Early detection of traits will prevent occurrence of thalassemia major in offspring. Detection of other variants becomes important due to complex interactions in cases with double heterozygous and homozygous states, which may lead to severe hematological abnormalities. Findings must be supplemented by hemogram findings, family/sibling studies, Hb electrophoresis, other confirmatory techniques and molecular studies based on HPLC findings and on a case-to-case basis.[8] But in a developing country like us use of HPLC is limited. In most of the health centres HPLC is not available and blood is tested manually. There are very few studies in West Bengal regarding the review of hematological features of HPLC study and comparison between the laboratory findings among manual and automated counter examination of blood, in the patients of Haemoglobin abnormalities. With this perspective this study aims to explore and compare the results obtained by HPLC and manual testing of some required haematological parameters and serves as a guideline for screening of Hb disorders in remote areas.

Aims & Objectives

- To explore and compare the results obtained by HPLC and manual testing of some required haematological parameters which may serve as a guideline for screening of Hb disorders in remote areas.
- To find out the variation between the results of haematological tests obtained by automated counting chamber and manual method

Materials and Methods

An Observational, cross-sectional study was conducted over a period of 1 year at thalassemia control unit and Physiology department of R G Kar Medical College and Hospital, Kolkata. Beta-thalassemia and other hemoglobinopathies cases and carriers detected by the thalassemia control unit by complete blood count with HPLC from thalassemia out patient department (OPD) and antenatal mothers from antenatal clinic (ANC) were the population

of this study. From the review of the records of last few years total number of ß-thalassemia and other Haemoglobinopathies detected per month on an average was around 14 (including special OPD, ANC and camp/camps). Thus, the expected number of patients of ß-thalassemia and other Haemoglobinopathies in the stipulated nine-month period of data collection for this study came to be 126. So in our study sample size was 120. In this study 127 patients were reviewed. Out of them 10 patients did not give their consent for giving blood for 2nd time. In this study multi phase sampling was done. In the first stage systemic random sampling was done to select 50 % of the targeted collection centre, while in the second stage purposive sampling was done to select the cases and carriers of β-thalassemia and other Hemoglobinopathies after considering exclusion and inclusion criteria.

Inclusion criteria:

1. Diagnosed case of β-thalassemia and other hemoglobinopathies by complete blood count (CBC) and high-pressure liquid chromatography (HPLC)
2. Both sexes

Exclusion criteria:

1. History of having recent transfusion (within 3 months)
2. History of having repeated transfusion
3. Patient on haematinics
4. Hospitalized patients
5. Patient aged over 60 years and below 6 months
6. Patient whose records are not filled up properly

Study technique: After getting ethical clearance, the descriptive cross-sectional study was done among the β-thalassemia and Hemoglobinopathies (both cases and carriers) detected at Thalassemia control Unit and Physiology department of R.G. Kar Medical College, Kolkata by HPLC and hemogram by automated counter. Thalassemia control Unit collected blood from Antenatal OPD, Thalassemia OPD. About 50% of such points were selected by simple random sampling within the period of study. All the cases and carriers detected at those points were approached for the study. Findings and variations of the features of different hematological parameters amongst the β-thalassemia and other Hemoglobinopathies were reviewed. During the time of collection of blood from new visitors (referred for diagnosis) for Complete Blood Count by automated chamber and HPLC, blood was also collected in EDTA vial from diagnosed cases revisiting for collection of their reports and haemoglobin (Hb%), Packed cell volume (PCV) and Total count (TC) of red blood cell (RBC) were manually tested at Physiology department and this manual examination was done after getting proper consent and after explaining the whole procedure to the patients. Reports of automated counter and manual procedure were compared. Haemoglobin estimations were done by Sahli's acid hematin method; TC of RBC were done by improved Neubauer counting chamber using normal saline as diluting fluid and Packed cell volume by using Wintrobes haematocrit tube and centrifuge machine (at 3000RPM for twenty minutes).

Parameter studied was medical history of study participants; and hematological findings – Hb%, TC of RBC, TC white blood cell (WBC), platelet count, mean corpuscular haemoglobin (MCH), mean corpuscular volume (MCV), mean corpuscular haemoglobin concentration (MCHC), red cell width (RDW). A finding by HPLC was HbA, HbA2, HbF, HbD, and HbE.

Special investigations: In this study for measurement of different haematological parameters and variant haemoglobin concentration two important & advanced procedure were used, one was HPLC technique for assessing type of Hb and another, automated blood cell counter (Sysmex Kx-21 type). Parameters measured by automated cell counter was complete blood count (CBC), TC of RBC, Hb%, PCV, RBC indices, and RDW.

Data analysis: Data were collected in a pre-tested and pre designed schedule from registers and record books of the control unit and screening sheet of the camps and the hematological tests performed manually. Data were put in a master chart and analysed by using SPSS Version 20.

Results

Table 1: Distribution of different hemoglobin disorders (n=117)

Type	Frequency	Percentage
β- Thalassemia Trait (BTT)	45	38.50
β- Thalassemia Major (BTM)	2	1.72
E- β- Thalassemia (E βT)	2	1.73
HbE Disease	3	2.60
HbE Trait	60	51.35
HbS Trait	5	4.30
Total	117	100.0

Table 1 shows the spectrum of different haemoglobin disorders in the present study. Maximum persons had HbE trait (51.3%) next to which β- Thalassemia trait (38.5%), HbS trait (4.3%), HbE Disease (2.6%), β- Thalassemia Major (1.4%) and E βThalassemia (1.4%).

Table 2: Findings of different hematological parameters measured by HPLC/ Automated Counter of different haemoglobin disorders

Sl. No.	Type of Hb Disorders	TC of RBC (millions/cmm) Mean ± SD 1	Hb % (gm/cmm) Mean ± SD	PCV (%) Mean ± SD	MCV (fl) Mean ± SD	MCH (ρg) Mean ± SD
1	β- Thalassemia Trait	5.1604 ± 0.91244 2	10.404 ± 1.4652	33.993 ± 5.9717	68.060 ± 5.9240	20.160 ± 2.1201
2	β- Thalassemia Major	2.4 ± 0.62225 3	4.950 ± 1.0607	17.250 ± 2.7577	72.850 ± 7.4246	20.750 ± 0.9192
3	E- β- Thalassemia	3.72 ± 1.08894	6.250 ± 0.9192	23.150 ± 2.7577	63.900 ± 11.3137	17.200 ± 2.5456
4	HbE disease	4.6333 ± 0.57073	9.233 ± 0.3786	29.900 ± 1.9925	64.867 ± 4.7343	20.067 ± 1.7243
5	HbE Trait	4.5727 ± 0.65601	11.185 ± 1.4537	35.552 ± 4.6692	77.997 ± 4.1348	24.675 ± 1.5050
6	HbS Trait	4.1380 ± 0.23805	10.684 ± 0.2971	33.420 ± 2.0474	80.760 ± 2.4583	25.560 ± 0.8142

Table 3: Shows result of HPLC/automated counter vs manual method of Hemoglobin % among the persons having different Hemoglobin disorders

Hematological disorders Mean ±SD	Automated Counter/HPLC n=45	Manual Method n=45	t and p value
β- Thalassemia Trait (n=45)	10.404 ± 1.4652	12.27 ± 2.137	t (88) = 4.8310 p=0.0001 Significant
Hemoglobin E Trait (n=60)	11.185 ± 1.4537	13.28 ± 2.248	t (118)=6.0618 p=0.0001 Significant
Hemoglobin E Disease (n=3)	9.233 ± 0.3786	11.17 ± 1.258	t (4)=2.5538 p=0.0631 Not Significant
Hemoglobin S Trait (n=5)	10.684 ± 0.2971	13.16 ± 0.329	t (8)=12.4895 p=0.0001 Significant

The above table 3 shows that result of Hb% is significantly different in β- Thalassemia Trait (p=0.0001), HbE Trait (p=0.0001), HbS trait (p=0.0001) and not significant in HbE disease.

Moreover two patients with β- Thalassemia Major and two patients with E β- Thalassemia have not been included as they were severely ill and could not come to Physiology department.

Discussion

A descriptive cross-sectional study was done among 117 persons having β-thalassemia and Haemoglobinopathies (both cases and carriers) detected at Thalassemia control Unit and subsequently their 2nd sample of blood was collected for manual examination of Hb%, PCV and TC of RBC at Physiology department of R G Kar Medical College, Kolkata. Three of them refused to give 2nd sample of blood.

In the present study out of total 117 persons having different Hb disorders, 60 were HbE trait (51.3 %), 45 were β-Thalassemia trait (38.5 %), 5 were HbS trait (4.3 %), 3 were HbE disease (2.6%), 2 were β-Thalassemia major (1.7%) and 2 had E-β Thalassemia (1.7%). In most of the studies Though β-Thalassemia trait is the commonest form of disorder, in our study Hemoglobin E trait took the first place and our findings are almost similar to the findings of Ghosh N et al – a study done among the antenatal mothers in Darjeeling district in West Bengal.[9] In a study in Bangladesh by M. Mesbah Uddin, et al in 2012 among 600 cases of anaemic patients referred from various parts of the country for diagnosis and counselling during 3 months (2011) of time the most common form of Hb formation disorder observed was β-thalassemia minor (21.3%) followed by E-β-Thalassemia (13.5), HbE trait (12.1%), HbE disease (9.2%), Hb D/S trait (0.7%), β-thalassemia major (0.5%), and δ-β-thalassemia (0.5%).[10] In the current study 37 (31.6%) were male and 80 (68.4%) were female. Most of our cases were seen within 39 years of age (98.3%).

Different haematological parameters in the different Hb disorders were examined in this study. Patients of Thalassemia major (n=2) had severe symptoms, so they and E- β- Thalassemia (n-2) who were also admitted, were unable to attend Physiology department and manual testing was not done. Among other cases, it was found that except Hemoglobin E disorder, significant difference was persistent regarding the result of hemoglobin percentage between manual examination and HPLC/ Automated counter examination. Regarding manual methods no significant differences were found with the results of HPLC/Automated chamber while measuring TC of RBC and PCV. These findings are similar to several other studies.[11-13] A study in West Bengal by I. Chakraborty et all found 3.4% beta thalassemia trait, 0.6% E-beta thalassemia. Various RBC indices were significantly low in them with concurrent iron deficiency.[14] An accurate RBC counting enables the MCV and MCH to be correctly calculated. In well-equipped laboratories, where these indices are provided by an automated system, they are of considerable clinical importance and are widely used in the classification of anemia. Where automated analyzers are not used, manual RBCs counting (and consequently, calculations of these red cell indices) are inaccurate and time-consuming.[15]

For assessing the hematological features like TC of RBC or PCV manual methods shows no significant differences with HPLC/Automated counter assessment. So, such methods can be utilized even at primary level cost effectively for assessment of such cases. But significant difference is seen in estimating Hemoglobin percentage in between Shalli's method and HPLC/Automated counter assessment. So some alternate method may introduce at lower level of health system other than Shalli's method. PCV and TC of RBC have no variation in results obtained by automated counting chamber and manual method in different haemoglobin disorders. So MCV can be done manually to differentiate between Iron deficiency anaemia where MCV is low and haemoglobinopathies where MCV is normal both of which are prevalent in rural Bengal. So at Primary health centre level iron can be prescribed only after performing such a minor test with a few instruments. So, if PHCs are provided with colorimeter for Hb estimation and assessment of MCHC can be done, preliminary treatment of anaemia can be started and possibility of Iron overload in haemoglobinopathies can be avoided at the root level.

Conclusion

From this study it can be said that the hematological features like TC of RBC or PCV results by manual method shows no significant differences with HPLC/Automated counter assessment. So, such methods can be utilized even at primary

level cost effectively for assessment of such cases. But significant difference is seen in estimating Hemoglobin percentage in between Shalli's method and HPLC/Automated counter assessment .So some alternate method may introduced at lower level of health system other than Shalli's method.

Recommendations

MCHC not MCH is more reliable for diagnosis of Iron deficiency anaemia and Haemoglobinopathies and haemoglobin estimation is also a must for this diagnosis. Manual method is not suitable for this purpose according to our study report. So, if PHCs are provided with colorimeter for Hb estimation and assessment of MCHC can be done, preliminary treatment of anaemia can be started and possibility of Iron overload in haemoglobinopathies can be avoided at the root level.

Limitation

Sample size was small due to time and manpower constrains.

Conflict of Interest: None

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Original Article

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A Comparative Study Between Oral Pregabalin and Gabapentin in Prolongation of Postoperative Pain Relief after Spinal Anaesthesia

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Abstract

Background: Management of pain and its complications in postoperative period still a major challenge. Generally, the pathophysiology and treatment of postoperative pain and neuropathic pain have been considered as separate and distinct, though, there is considerable overlap in their pathophysiology.

Materials & Methods: The present study was designed as randomized, double blinded, parallel group, open label trial to compare the efficacy of pregabalin and gabapentin as preemptive analgesics in surgery below umbilicus under spinal anaesthesia. This study was conducted under the Department of Anesthesiology, in the R.G. Kar Medical College & Hospital, Kolkata. Sixty two patients, aged between 20-50 yrs, ASA grade I and II, scheduled to undergo infra umbilical surgery, were randomly divided into 2 groups. In group G (n=31) they received 1200 mg gabapentin, in group P (n=31) they received 300 mg pregabalin capsules, orally with sips of water, 1 hour before the induction of anesthesia. Routine monitoring in the form of NIBP, Pulse oxymetry and ECG were instituted on arrival in Operation Theatre. All patients were preloaded with 10 ml/kg lactated Ringer's solution before being administered spinal anesthesia. Spinal anesthesia was instituted with 3 ml of 0.5% bupivacaine (15 mg) at L^3 – L^4 / L^4 - L^5 level.

Results: All the groups were comparable in respect to demographic data, ASA physical status, the mean duration of surgery and the type of surgeries performed between them. In the 24 hrs of post-perative period the mean VAS scores at rest of Groups P was always significantly lower than those of Group G. The time to first dose of rescue analgesic was compared between the groups, as in Group G (gabapentin group) rescue analgesic was given after 9.41±1.84 hrs, while in Group P (pregabalin group) rescue analgesic was required after 15.38±3.52 hrs. Hence, as comparison of pregabalin and gabapentin could be made for these parameters, and it was possible to come to a conclusion as the superiority of pregabalin over gabapentin.

Conclusion: In conclusion, a single oral dose of pregabalin given preoperatively provides better postoperative

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pain control and decreases postoperative rescue analgesic consumption compared to single dose of gabapentin, based on lower mean VAS scores at rest.

Keywords: Pain, postoperative pain, neuropathic pain, spinal anesthesia, pregabalin, gabapentin, VAS score

Introduction

Pain, which is often inadequately treated, accompanies the more than 23 million surgical procedures performed each year and may persist long after tissue heals.[1] Postoperative pain is not purely nociceptive in nature, and may consist of inflammatory, neurogenic and visceral components.[2] Surgical stimulation leads to sensitization of dorsal horn neurons, which are associated with augmentation of pain.[3]

Pre-emptive analgesia, an evolving clinical concept, involves the introduction of an analgesic regimen before the onset of noxious stimuli, with the goal of preventing sensitization of the nervous system to subsequent stimuli that could amplify pain. Surgery offers the most promising setting for preemptive analgesia because the timing of noxious stimuli is known. When adequate drug doses are administered to appropriately selected patients before surgery, intravenous opiates, local anesthetic infiltration, nerve block, subarachnoid block and epidural block offer benefits that can be observed as long as one year after surgery. The most effective preemptive analgesic regimens are those that are capable of limiting sensitization of the nervous system throughout the entire perioperative period. Anticonvulsants and tricyclic antidepressants were conventionally used for neuropathic pain.

Gabapentin, a structural analogue of gamma amino butyric acid (GABA), introduced in 1994 as an antiepileptic drug and later used for chronic pain conditions like neuropathic pain,[4] diabetic neuropathy,[5] post herpetic neuralgia,[6] complex regional pain syndrome,[7] exerts its effects by binding with alpha 2 delta sub unit of presynaptic voltage gated Ca^{2+} channels[8] and has antinociceptive, antihyperalgesic and antiallodynic properties.[9]

Several studies have shown the effectiveness of gabapentin as an agent for acute postoperative pain relief resulting in reduced postoperative analgesic requirement in abdominal hysterectomy[10], spinal surgery[11], radical mastectomy[12] and laparoscopic cholecystectomy[13].

Pregabalin, another analogue of gamma amino butyric acid, sharing some characteristics with its predecessor gabapentin, however with superior pharmacokinetic profile [14], introduced in 2004, already has an established role in treatment of peripheral neuropathic pain[15] associated with diabetes mellitus and post herpetic neuralgia. On review of recent literatures pregabalin is showing evidence that it might be efficacious in relieving acute pain similar to gabapentin[16, 17], although there is a relative paucity of studies comparing them.

In view of the above observations the present study was designed as randomized, double blinded, parallel group, open label trial to compare the efficacy of pregabalin and gabapentin as preemptive analgesics in surgery below umbilicus under spinal anaesthesia.

Aims and Objectives

1. To compare postoperative efficacy of gabapentin and pregabalin with respect to increase in duration of analgesia.
2. To compare reduction in total postoperative requirements of analgesics.
3. To compare side effects and complications of the drugs.

Materials & Methods

Study Area: Preoperative room, General Surgical operation theatre, Gynae and Obstetrics operation theatre, Orthopaedic operation theatre and postoperative care unit (POCU) of R.G. Kar Medical College & Hospital, Kolkata, West Bengal.

Study Population: Patient with physical status ASA-I and ASA-II undergoing infra umbilical surgery under spinal anaesthesia

Sample Size: As calculated from previous study[18] to get clinically relevant difference in duration of postoperative analgesia we need 31 patients in each group with a power of study 80% at 95% confidence interval (alpha=0.05). Total patients were 62. They were randomly allocated in two groups. Group –G (n=31) received single dose of gabapentin 1200 mg

and Group –P (n=31) had received single dose of pregabalin 300 mg.

Sample Design: Patients of sex (male & female), age between 20-50 years, weight between 50-75 kg and ASA physical status-I &II were included.

Inclusion Criteria: Patients of sex (male & female), age between 20-50 years, weight between 50-75 kg and ASA physical status-I &II for infraumblical surgery under spinal anaesthesia were included.

Exclusion Criteria: ASA physical status>II, patient with uncontrolled or labile hypertension, patient with allergy to the study drugs, pregnancy and lactation, patient with psychiatric illness, patient with hepatic or renal impairment, patient having any contraindication to spinal anaesthesia

Study Design: It was a randomized double blinded prospective study.

Parameters studied for comparing the quality of intraoperative and postoperative analgesia and sedation: For pain: a) Visual Analogue Scale (VAS)[1] between 0-10cm; 0=no pain, 10=most severe pain

Time elapsed after operation when the patient needs for rescue analgesic: for sedation: Filos numerical scale[3] [scale 1 = awake and nervous; scale 2 = awake and relaxed, scale 3 = sleepy but easy to awake and scale 4 = sleepy and hard to awake]

Parameters studied for comparing adverse effects: Dizziness/ somnolence, diplopia**, v**omiting {the severity of PONV was graded on a four-point ordinal scale; (0=no nausea / vomiting; 1=mild nausea; 2= moderate nausea; 3= severe nausea with vomiting)}[4]; confusion (was assessed by asking time, place, person)**;** urinary retention in a non catheterized patient **;** and respiratory depression [defined as ventilatory frequency <8 bpm and oxygen saturation < 90% without oxygen supplementation.

Study Technique: After approval from the institutional ethics committee the study was started. Sixty two consenting patients schedule for surgery below umbilicus were selected in this study. They were randomly allocated to one of the two groups [Gr-G & Gr-P] of thirty one each by allocating the patients alternatively to either group during preanesthetic assessment (for this study). Patient in group–G (n=31) were received single dose of gabapentin 1200 mg, where as in the group–P (n=31), patient were administered pregabalin 300 mg per oral 1 hour prior to administration of spinal anesthesia. No other premedication was instituted. A day before the scheduled operation the patients were visited pre-operatively in their wards for preanaesthetic check up. A thorough clinical history was obtained. They were physically examined, laboratory investigations were reviewed and a detail about VAS (0-10cm) was explained on the day before operation. The patients were also explained about the procedures of spinal anaesthesia and post-operative pain relief and all queries and doubts were answered to get their confidence and support.

Procedure:

In the group G, the bag contained four 300mg hard gelatin capsules of gabapentin belonging to one particular pharmaceutical company, in the group P the bag contained four 75 mg hard gelatin capsules of pregabalin belonging to the same pharmaceutical company (size, shape looked similar). The medication was given to the patient by an anaesthesiologist not involved in the study 1 hour before the induction of anaesthesia. Routine monitoring in the form of NIBP, pulse oxymetry and ECG were instituted on arrival in Operation Theatre. All patients were preloaded with 10 ml/kg lactated Ringer's solution before being administered spinal anaesthesia. Spinal anaesthesia was instituted with 3 ml of 0.5% bupivacaine (15 mg) at L^3-L^4/ L^4-L^5 level. Fluid administration was continued intraoperatively and hypotension, if any was treated with fluid replacement.

Pain was assessed postoperatively by visual analogue scale[1] in immediate postoperative period and every two hourly thereafter which was explained to the patient during preoperative visit. When patient was shifted to the ward one 1st year anaesthesiology post graduate trainee, unaware of the premedication was responsible for charting the pain score by VAS scale[1]. Pain charting was done separately and anaesthetic chart was not attached with the case sheet, so the observer was not find out to which group patient belong. Any patient with VAS score of more than three was received diclofenac 1 mg/ Kg intramuscularly. Time since spinal anesthesia to first dose of analgesic and total dose of analgesic

in first 24 hours was recorded. Any complications like dizziness, somnolence, diplopia, vomiting, confusion, respiratory depression, pain and urinary retention was recorded in first 24 hours postoperative period. Data were analysed using simple proportion, average (mean), standard deviation, independent 't' test and chi-square test, Odds ratio (OR) with its 95% confidence interval (CI). For this purpose, SPSS 19 and Epi info 3.4.3 version were utilized.

Results

Data derived from altogether 62 patients i.e. 31 in each arm were considered for analysis.

Table 1: Distribution of demographic and clinical parameters among participants as per groups (N=62)

Attributes		Group P(n^1=31) No. (%)	Group G (n^2=31) No. (%)	Chi-square, df, p
Age groups	<20 yr	7 (22.58)	10(32.26)	0.79, 2, 0.674
	20-40 yr	10(32.26)	8(25.81)	
	>40 yr	14(45.16)	13(41.94)	
Age (yr) (mean±SD)		38.42±9.77	36.61±9.19	0.750, 0.456 (unpaired t, p at df=60)
Gender	Male	13(41.94)	13(41.94)	0.00,1, 1,00
	Female	18(58.06)	18(58.06)	
BMI in kg/M^2 (mean±SD)		21.61±1.79	21.99±1.91	0.813, 0.420 (unpaired t, p at df=60)
Duration of surgery in minutes (mean±SD)		62.09±23.48	60.81±20.13	0.232, 60, 0.817 (unpaired t, p at df=60)

Table 1 shows that maximum number of participants was belonged to the age group of 40 years and above. No statistically robust difference could be observed in the age group distribution between the groups. Majority of the study subjects were in the age range of forty years and above. There was no significant difference in gender distribution of study subjects among two groups. As a whole, there were 41.94% male, being 41.94% in each arm. The male-female ratio was 1:1.38. The average age between two groups didn't show statistically sound difference. The mean body mass index had a uniform distribution in both the groups and no significant difference could be explored. The groups didn't vary in respect of the average time required for the surgical maneuver [Table 1].

Table 2: Distribution of participants as per the time elapsed after of surgery when VAS score was more than 3 (N=62)

Groups	Time (hrs) after OT when VAS was >3 (mean±SD)	Unpaired t, df, p
Gr. P (n^1=31)	15.38±3.52	8.364,60, 0.000
Gr. G (n^2=31)	9.41±1.84	
Total (N=62)	12.39±4.09	…

The study groups had a significant variation in the time interval after surgery when the VAS score was found to be 3 or more signaling the need of rescue analgesic. In group P, time interval was more compared to group G [Table 2].

Table 3: Distribution of participants according to the time of administration of rescue analgesic after surgical maneuver, i.e. postoperative analgesia time after giving preemptive pregabalin or gabapentin (N=62)

Groups	Time (hrs) (after operation) of administration of rescue analgesic (mean±SD)	Unpaired t, df, p
Gr. P (n^1=31)	15.38±3.52	8.364,60 0.000
Gr. G (n^2=31)	9.41±1.84	
Total (N=62)	12.39±4.1	…

The time required for the administration of the rescue analgesic postoperatively was found to be significantly earlier in case of group G compared to group P. That means pregabalin shows prolong postoperative analgesia compared to gabapentin [Table 3].

Table 4: Distribution of participants as per requirement of subsequent dose of analgesic

Attributes		Group P No. (%)	Group G No. (%)	Chi-square, df, p	RR (95% CI)
Subsequent dose	Required	02(6.45)	03(9.68)	0.22,1,0.64	1.50 (0.27-8.36)
	Not required	29(93.55)	28(90.32)		
Total		31(100)	31(100)	….	…

Above table 4 reveals that the groups was not significantly dissimilar in respect of the proportion of the subjects' required subsequent dosage of rescue analgesics. Study shows that subsequent dose of rescue analgesics was required by 6.45%, 9.68% and 8.06% of the participants in group P, G, and overall [Table 4].

Table 5: Distribution of adverse events among the groups

Attributes		Group P No. (%)	Group G No. (%)	Chi-square, df, p	RR (95% CI)
Adverse events	Present	7 (22.58)	13(41.94)	2.66, 1, 0.103	1.86 (0.86-4.02)
	Absent	24(77.42)	18(58.06)		
Total		31(100.0)	31(100.0)	…	....

It is clear that the groups didn't differ to the extent of statistically significant level in respect of proportion of study subjects showed adverse events [Table 5].

Table 6: Distribution of different types of adverse events among the groups

Adverse effects	Group P No. (%)	Group G No. (%)	Total No. (%)
Somnolence	4(12.90)	7(22.59)	11(35.48)
Dizziness	3(9.68)	6(19.35)	9(29.03)
Total	7(22.59)	13(41.94)	20(64.52)

The above table 6 shows adverse effects were more in gabapentin group than pregabalin group. The adverse events (AEs) were found in 22.58% and 41.94% of the study subjects in group P & G, respectively and as a whole among 32.26% of the participants [Table 6].

Discussion

Preemptive analgesia is a treatment that prevents establishment of the altered sensory processing that amplifies postoperative pain. The treatment should cover the entire duration of high-intensity noxious stimulation that can lead to establishment of central and peripheral sensitization caused by incisional or inflammatory injuries (during surgery and the initial postoperative period). Emphasis on the PRE versus POST design has led to a situation in which establishment of sensitization during inflammatory injuries in the initial postoperative period is excluded from consideration.

Pre-incisional analgesia has been shown to be more effective in control of postoperative pain

by protecting the central nervous system from deleterious effects of noxious stimuli and resulting allodynia, and increased pain. Gabapentin and pregabalin have antiallodynic and antihyperalgesic properties useful for treating neuropathic pain and may also be beneficial in acute postoperative pain. Several studies have reported the usefulness of gabapentin and pregabalin in perioperative settings resulting in reduced postoperative pain, postoperative analgesic requirement, side effects, prolongation of analgesia, and higher patient satisfaction. [19-22] Gabapentin, a structural analogue of gamma amino butyric acid (GABA), introduced in 1994 as an antiepileptic drug and later it was used for chronic pain conditions, has antinociceptive, antihyperalgesic and antiallodynic properties[9]. Several studies have shown the effectiveness of gabapentin as an agent for acute post-operative pain relief resulting in reduced postoperative analgesic requirement.

Pregabalin, another analogue of gamma amino butyric acid, sharing same characteristics with its predecessor gabapentin, however with superior pharmacokinetic profile[14], introduced in 2004, already has an established role in treatment of peripheral neuropathic pain[15]. On review of recent literatures pregabalin is showing evidence that it might be efficacious in relieving acute pain similar to gabapentin[16, 17], although there is a relative scarcity of studies comparing them. In view of the above observations the present study was designed as randomized, double blinded study to compare the efficacy of pregabalin and gabapentin as preemptive analgesics in any surgery done below umblicus under spinal anesthesia.

This study was conducted under the Department of Anesthesiology, in the R.G. Kar Hospital and Medical College, Kolkata. Sixty two patients, aged between 20-50yrs, ASA grade I and II, scheduled to undergo infra umbilical surgery, were randomly divided into 2 groups. In group G (n=31) they received 1200 mg gabapentin, in group P (n=31) they received 300 mg pregabalin capsules, orally with sips of water, 1 hour before the induction of anesthesia.

All the groups were comparable in respect to demographic data. There was no significant difference in the mean duration of surgery between the groups (table 2), nor there was any significant difference in the type of surgeries performed between them. The recommended starting dose of gabapentin for neuropathic pain is 300 mg on day 1, 300 mg twice daily on day 2 and then 300 mg three times daily thereafter. This dose is often insufficient and doses up to 1800 mg may be required. The practice of administering a first dose of 1200 mg or 600 mg immediately before anaesthesia and surgery is clearly in contravention to this recommendation.

In a recent review of 22 RCTs, meta-regression analysis suggested that the gabapentin induced reduction in the 24-h opioid consumption was not significantly dependent on the gabapentin dose.[19] Hence, single highest safe dose of gabapentin (1200 mg) and pregabalin (300 mg) was selected for this study, which is same as used in most of the studies. In animal models gabapentin has been reported to be more effective when given preoperatively, however, Pandey et al[23] in their study reported that gabapentin (600 mg), given preemptively or postincision did not have significant difference in fentanyl consumption between pre and postincision groups. However, we still used gabapentin and pregabalin preoperatively as analgesic consumption was lower in preoperative regimen.

The mean VAS scores at rest in the 0-10 cm scale were recorded at the following time points: 0, 1, 2, 3, 4, 5, 6, 8, 10, 12, 16, 20 & 24 hours in the first 24 hrs of postoperative period. Analysis of table 3 shows duration after operation when rescue analgesic becomes required was 15.38±3.52 hrs in case of pregabalin and 9.41±1.84 hrs in case of gabapentin, which was statistically and significantly lower in case of gabapentin. Table 4 shows subsequent dose required in case of pregabalin was 6.45% and in case of gabapentin was 9.68%. In the study conducted by Saraswat et al[24], time to rescue analgesic was 8.98 ±5.38 hrs for gabapentin group, which was significantly less(p value < 0.001) than pregabalin group (14.17 ±6.67 hrs). Whereas the total dose of rescue Analgesic (mg) in 24 hours postoperative period was 62.5± 28.43mg for pregabalin being lower than 5 ± 23.99mg for gabapentin, was statistically not significant between the groups. Thus they showed that pregabalin was superior to gabapentin in the above mentioned criteria.

The requirement of subsequent number of rescue analgesic doses in the 24 hours of postoperative period between the groups (Table 4) have shown that in group G (gabapentin group) and group P (pregabalin group) it was only for 3/0/0 and 2/0/0 (1dose/2 doses/3 doses) patients respectively. Thus, pregabalin and gabapentin were both effective in reducing need for rescue analgesic in the postoperative period, however no conclusion could be derived as to the superiority of pregabalin over gabapentin in this regard. This finding is in agreement with the results of study conducted by Saraswat et al[24] where the number of doses in 24h (0 dose/1 dose/2 doses) in gabapentin group was 2/26/2 and for pregabalin was 4/25/1(no discernible difference between the two groups like ours).

In 2002, Dirks et al[12], studied the effects of single-dose preemptive oral gabapentin versus placebo on post-operative pain and morphine consumption after mastectomy, while we studied on surgery below umbilicus. Our study was similar with this one as we also use 1200 mg gabapentin as they used. They concluded that in gabapentin group there was substantial reduction in movement related pain 2 and 4 hour after radical mastectomy, whereas in our study movement related pain was not recorded. 4 hour post-surgery morphine consumption was significantly lowered than control group in their study while we used diclofenac as the rescue analgesic which was required in the gabapentin group as subsequent rescue analgesic in only 9.68% cases in our study. The results differ from our study as pain at rest was reduced significantly by gabapentin, but this reduction was not statistically significant in their study.

In 2004 Pandey et al[25] undertook a randomized, double blinded, placebo controlled study to investigate whether gabapentin, could reduce postoperative pain and fentanyl consumption in patients after single-level lumbar discoidectomy. They used gabapentin 300 mg or placebo two hours before surgery while in our study 1200 mg gabapentin was used 1 hour before the surgery which was comprised any infraumblical surgery including orthopedic surgery. After surgery, the pain was assessed on a visual analogue scale (VAS) at intervals of 0–6, 6–12, 12–18, and 18–24 hr at rest, while it was recorded more frequently in our study. Fentanyl 2 μg•kg–1 intravenously was used to treat postoperative pain on patient's demand and total dose in 24 hours was recorded. In our study i.m. diclofenac was used as the rescue analgesic. Patients in the gabapentin group had significantly lower VAS scores at rest, at all time intervals than those in the placebo group and similar results were observed in our study. The total fentanyl consumed after surgery in the first 24 hr in the gabapentin group (233.5 ± 141.9, mean + SD) was significantly less than in the placebo group (359.6 ± 104.1; $P < 0.05$) whereas in our study diclofenac was required only in 9.68% cases as subsequent analgesic. They concluded that preemptive gabapentin 300 mg per oral significantly decreased the severity of pain postoperatively in patients who underwent single level lumbar discoidectomy which was very much similar to ours.

Turan et al[26] conducted a study in 2004 comparing 1200 mg preemptive gabapentin versus placebo, given 1 hour before lumbar spine surgery under GA. All patients received postoperatively patient controlled analgesia with morphine. It was much similar to our design except 1200 mg gabapentin and diclofenac (rescue) was used in ours. They found pain scores at 1, 2, and 4 hour and total morphine consumption was significantly lower in the gabapentin group when compared with the placebo group and they concluded preoperative oral gabapentin decrease pain scores in the early postoperative period in spinal surgery patients. In our study the results were almost similar. Postoperative morphine consumption was decreased much like ours where second dose of diclofenac was used in only 9.68% cases.

Peach et al[27] in 2007 conducted a study in 90 women having minor gynecological surgery involving the uterus. Patients received either oral pregabalin 100 mg or placebo approximately 1 h before surgery, whereas in our study 300 mg pregabalin was used in infraumblical surgery under spinal anesthesia. The primary outcome was pain score in the recovery unit and patients were followed for 24 h. There was no significant difference between groups for pain experienced in the recovery room or thereafter; nor for recovery room fentanyl requirement (42% Group pregabalin versus 27% Group placebo), p value=0.12) or the quality of recovery at 24 h postoperatively. This finding was different from ours as pain scores in the

pregabalin group were always significantly less than the gabapentin group. This difference may be due to a lower preemptive dose of pregabalin in their study.

Agarwal A et al[28] in the same year, i.e. 2008 conducted study to evaluate the efficacy of a single preoperative dose of 150 mg pregabalin when given 1 hour before surgery for attenuating postoperative pain and fentanyl consumption after laparoscopic cholecystectomy compared to placebo. Ours in contrast used 300 mg dose of pregabalin and that too in infraumblical surgery. Postoperative pain (static and dynamic) was assessed by a 100 mm visual analogue scale and the subjects received patient-controlled i.v. fentanyl analgesia during the postoperative period, while in our study only static scores were measured and diclofenac was used as rescue analgesic. Result of the study revealed that postoperative pain (static and dynamic) and postoperative patient-controlled fentanyl consumption were reduced in the pregabalin group compared with the placebo group ($p<0.05$) which was very much in agreement with our results where pregabalin shows more postoperative analgesia than gabapentin.

Sahu et al in 2010[29] conducted a study to evaluate the role of pregabalin in reducing postoperative pain and rescue analgesic demand in patients undergoing infraumbilical surgeries under spinal anesthesia. In Group I placebo capsules 12 hour before surgery and 1 hour before surgery and in Group II-pregabalin capsules (150 mg) 12 hour before surgery and 1 hour (150mg) before surgery were used. After giving anaesthesia patients were assessed every 2 hours for 24 hours for pain score by VAS scale, BP, pulse rate, respiratory rate, rescue analgesics demand (injection tramadol IV) and side effects if any. In our study only one preemptive dose of 300 mg pregabalin or 1200 mg gabapentin was used instead of two doses at 12 hour intervals. Post-operative respiratory rate was not seen in our study and rescue analgesic used was diclofenac. Patients in pregabalin group had significantly lower mean VAS post operatively and lower rescue analgesic consumption than placebo group (I) ($P<0.05$) which were near similar to our results. So a conclusion was drawn by them that a 300 mg dose of pregabalin in two divided doses before surgery provided better pain control than placebo, reduce the demand for rescue analgesics. 300 mg single dose of pregabalin, used in our study also accomplished these goals.

Saraswat V et al[24] in 2008 conducted a study on preemptive Gabapentin vs pregabalin for acute postoperative pain after infraumbilical surgery under spinal anesthesia. Patients in Group G were given single dose of gabapentin 1200mg, whereas in Group P were administered pregabalin 300mg one hour prior to administration of spinal anesthesia which was similar to our study. Pain was assessed by visual analogue scale immediate postoperatively and every two hourly thereafter, time since spinal anesthesia to first dose of analgesic (diclofenac) and total dose of analgesic in first 24 hours was recorded, similar to our study. The total postoperative analgesic time was 8.98h in Group G whereas 14.17h in Group P (HS, $P < 0.001$) and total dose of analgesics in first 24h was 62.5 mg in Group P and 72.5mg in Group G and was not significant ($P>.05$). In our study total postoperative analgesic time was 9.41±1.84 hrs in Group G whereas 15.38±3.52 hrs in Group P. From the study they concluded that gabapentin and pregabalin, both have been effective in prolongation of postspinal analgesia, but pregabalin more than gabapentin and either can be used as part of multimodal therapy if not as sole analgesic (table 3). In our study this conclusion could be derived.

Table 5 and 6 showed the comparison of the adverse effects between the study groups. In the pregabalin group incidence of somnolence and dizziness were 12.90% and 9.68% respectively, whereas in the gabapentin group incidence of somnolence and dizziness were 22.59% and 19.35%, which were lower in pregabalin group than other. Below we had compared our study with already published studies on preemptive analgesic use of gabapentin and pregabalin for their side effects.

Gajraj[30] reviewed the phamacology of pregabalin and found that somnolence (29.2%) and dizziness (22.2%) were the most common side effects which were similar to our study, but the % incidence was much lower (12.90% and 9.68%). The incidence of nausea and vomiting was not found in our study. Turan et al[26] showed that the use of oral gabapentin given preoperatively in patients of spinal surgery noticed significant reduction in incidence of vomiting

(P<0.05) compared to placebo. In 2002, Dirks et al[31], studied the effects of single-dose preemptive oral gabapentin versus placebo on post-operative pain and morphine consumption after mastectomy, while we studied on surgery below umblicus. There was no significant difference in side effects between study groups, whereas in our study vomiting and nausea were absent in the gabapentin group.

Conclusion

In conclusion, a single oral dose of pregabalin given preoperatively provides better postoperative pain control and decreases postoperative rescue analgesic consumption compared to single dose of gabapentin, based on lower mean VAS scores at rest. Also, the incidence of somnolence and dizziness were less in the pregabalin group than gabapentin group and their percentage was much lower than those reported in the literature and above all, they were not distressing to the patient. So it can be postulated that pregabalin may effectively be used as a part of multimodal analgesic approach to prevent acute postoperative pain, much like gabapentin, which already has an established role. However, it may be mentioned that further studies are warranted in regard to the most suitable preemptive dose of pregabalin and comparison of pregabalin with gabapentin as preemptive analgesic in other surgeries as well.

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Conflict of Interest: None

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Comparative Study of Epidural Ropivacaine 0.75% and Bupivacaine 0.5% with Fentanyl for Elective Caesarean Section in Andhra Pradesh Population

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Abstract

Background: Ropivacaine had clinical advantages over Bupivacaine with respect to cardiac toxicity and motor block and it was suitable for epidural caecerian section. This study was set-up to compare epidural ropivacaine with fentanyl with Bupivacaine / Fentanyl mixture in LSCS surgeries.

Method: Out of 90 patients 45 received 10 mg hyperbaric Bupivacaine with 20 microgram fentanyl and 45 (group RF) received 15 mg hyperbaric Ropivacaine with 20 microgram fentanyl Hemodynamic parameters sensory and motor blockade APGAR score were compared in both groups.

Results: Demographic profile i.e., Weight, Height BMI Duration of surgery was same in both groups ($p>0.001$ was insignificant) were motor and sensory blockades highly significant ($p<0.001$). VAS scores at 4 hours, 6 hours and 8 hours had significant p value ($p<0.001$). Apgar score at 1 minute was also highly significant ($p<0.005$).

Conclusion: In the present study it was proved that, Hyperbaric Ropivacaine with fentanyl is a better alternative to hyperbaic Bupivacaine with fentanyl in LSCS patients of c-section.

Keywords: Bupivacaine, Fentanyl, Ropivacaine, VAS analogue, Hemodynamic

Introduction

Caesarean sections are being increasingly done for maternal as well as foetal indication. The maternal indications are cephalopelvic disproportion, chorio-amnoitis, non-progression or obstructed labour and previous caesarean sections. The usual foetal indications include large for gestational age foetus, unfavourable lie and foetal distress due to any cause, Lower segment caesarean section (LSCS) is routinely done under spinal anaesthesia except in cases where either spinal anaesthesia is contraindicated such as patient refusal, injection site infections. (Severe thrombocytopenia and uncorrected hypovolemia), Regional anaesthesia is widely considered technique of choice for caesarean section and although de nova epidural anaesthesia is currently much less popular than spinal anaesthesia it is still an important technique [(1)].

Among all solutions for providing de nova epidural anaesthesia which included mixture of

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Ropivacaine 0.75 with fentanyl and / or Bupivacaine 0.5% with Fentanyl are most popular techniques in elective caesarean section. However any mixture of Bupivacaine and Fentanyl is unlicensed and since it is not commercially available, need to be made up on an individual basis.

Roipvacaine 0.5% has been shown to be an effective agent for providing epidural anaesthesia for caesarean section providing similar satisfactory conditions to 0.5% Bupivacaine [(2)] other workers used 0.75% Ropivacaine and also found it to be effective used along with fantanyl[(3)(4)].

Bupivacaine, ropivacaiue and Mepivacaine are the common drugs used for spinal anaesthesia to compare the duration of action and onset as well total duration of sensory and motor blockade and hemodynamic parameter of patients undergoing LSCS and receiving equipotent doses of Bupivacaine with fentanyl and Ropivacaine with fentanyl Maternal side effects and foetal outcomes were also studied.

Material and Methods

90 (Ninety) patients admitted at obstetrics and Gynaecology department of GSL Medical college hospital rajahmundry-533296 Andhra Pradesh were studied.

Inclusive Criteria: ASAI and ASA-II, aged 20 to 45 years patients willing to undergo elective LSCS were selected for study.

Exclusion Criteria: Patients ASA III not willing to undergo LSCS surgery, women who had undergone previous surgery, scoliosis', or injury to back patients who has allergy to amide local anaesthetics. Women history of still born babies was excluded from the study.

Method: Every patient was premedicated with oral Ranitidine 150 mg and metaclopromide 10 mg on arrival in the theatre suite they were given 25ml of 03 M sodium citrate orally. Out 90, 40 patients were classified in two groups.

Group BF – Received 10 mg hyperbaric bupivacaine with 20 microgram Fentanyl.

Group RF – Received 15mg hyperbaric Ropivacaine with 20 microgram Fentanyl.

Basic investigations such as CBC, Coagulation profile, HbsAg, and HIV were done in all cases if not already done. After shifting to operation theatre venous access was secured with 20 G intracanth and 500 ml ringer lactate was stated. ECG monitoring SPO2 and non-invasive blood pressure monitoring was started. Spinal anaesthesia was given using standard practice. All patients received 500 ml Ringer lactate and first dosage of third generation cephalosporin before giving spinal anaesthesia. Patients either received Bupivacaine and Fentanyl or Ropivacaine and Fentanyl depending upon the group they belonged. The onset and duration of analgesic were noted. Hemodynamic parameters such as HR (Heart rate), systolic as well as diastolic pressure respiratory rate and SPO2 were monitored APGAR scare at 1 minute and 5 minute was analysed to know immediate neonatal outcomes. VAS (visual analogue scale) was determined every 5 minutes than every 30 minutes up to 5 hours to assess the severity of post-operative pain. The incidence of complication such as hypotension, bradycardia nausea, vomiting and shivering was noted.

Duration of study was August-2019 to November-2022

Statistical analysis: Demographic profiles motor and sensory blockade VPS score APGAR score were compared in both groups with z test. The statistical analysis was carried out SPSS software.

Observation and Results

Table-1: Comparison of demographics profile in both groups

- Weight (Kg) – 61.30 (± 5.20) in group-B, 59.12 (± 6.28) in group-R, t test was 1.71 and p>0.95
- Height (Cm) – 152.59 (± 5.24) in group-B, 154.21 (± 4.50) in group-R, t test was 0.19 and p>0.84
- BMI – 24.09 (± 1.52) in group-B, 24.30 (± 1.60) in group-R, t test was 0.63 and p>0.52
- Duration of surgery (Minutes) – 58.10 (± 6.10) in group-B, 56.18 (± 4.90) in group-R, t test was 1.61 and p>0.9

Table-2: Comparison of motor and sensory blockades in both groups

- Onset of sensory Block (seconds) – 152.6 (± 15.30) in group-B, 186 (± 20.14) in group-R, t test was 8.15 and p<0.001
- Mean time to achieve highest level of sensory analgesia (sec) – 333.30 (± 24.5) in group-B, 382.66 (± 26.8) in group-R, t test was 9.11 and p<0.001
- Onset of motor Block (sec) – 322.4 (± 28.11) in group-B, 360.52 (± 36.22) in group-R, t test was 5.5 and p<0.001
- Mean time to sensory regression (minutes) – 132.5 (± 10.16) in group-B, 98.10 (± 9.30) in group-R, t test was 16.8 and p<0.001
- Duration of motor Block (Minutes) – 180.06 (± 20.6) in group-B, 122.6 (± 14.40) in group-R, t test was 15.3 and p<0.001
- Duration of analgesia (Minutes) – 276.88 (± 40.34) in group-B, 182.66 (± 30.10) in group-R, t test was 12.5 and p<0.001

Table-3: Comparison of VAS score in both groups

- At 180 Minutes – 1.20 (± 0.40) in group-B, 1.34 (± 0.53) in group-R, t test was 1.33 and p>0.18
- At 4 hours – 2.10 (± 0.62) in group-B, 2.90 (± 0.70) in group-R, t test was 5.7 and p<0.001
- At 6 hours – 4.10 (± 0.42) in group-B, 4.62 (± 0.44) in group-R, t test was 5.73 and p<0.001
- At 8 hours – 5.10 (± 1.10) in group-B, 5.32 (± 1.34) in group-R, t test was 0.85 and p>0.68

Table 4: Comparison of APGAR score in both groups

- APGAR at 1 minute – 8.8 (± 0.44) in group-B, 9.05 (± 0.48) in group-R, t test was 2.5 and p<0.005
- APGAR at 5 minute – 9.28 (± 0.40) in group-B, 9.32 (± 0.53) in group-R, t test was 0.40 and p>0.68

Table 1: Comparison of Demographic profile in both groups

Total No. of patients: 90

Particulars	Group-B Mean value ± SD 45	Group-R Mean value ± SD 45	t test	p value
Weight (Kg)	61.30 (± 5.20)	59.22 (± 6.28	1.71	p>0.95
Height (cm)	152.59 (± 5.24)	154.21 (± 4.500	0.19	p>0.04
BMI	24.09 (± 1.52)	24.30 (± 1.60	0.63	p>0.52
Duration of surgery (minutes)	58.10 (± 6.10)	56.18 (± 1.90	1.6	p>0.9

Table 2: Comparison of Motor and sensory blockades in both groups

Parameters	Group-B Mean value ± SD (45)	Group-R Mean value ± SD (45)	t test	p value
Onset of sensory blockades	152.6 (± 15.30)	186.39 (± 20.14)	8.15	P<0.001
Onset motor Block (seconds)	322.4 (± 28.10)	360.52 (± 36.22)	5.57	P<0.0001
Mean time to achieve highest level of sensory Analgesia (sec)	333.30 (± 24.52)	382.66 (± 26.80)	9.11	P<0.001

Continue....

Parameters	Group-B Mean value ± SD (45)	Group-R Mean value ± SD (45)	t test	p value
Mean time to sensory regression(Minutes)	132.52 (± 10.16)	98.10 (± 9.30)	16.8	P<0.001
Duration of motor Block (Minutes)	180.00 (± 20.60)	122.6 (± 14.40)	15.3	P<0.001
Duration of Analgesia (Minutes)	276.88 (± 40.34)	182.66 (± 30.12)	12.5	P<0.001

Table 3: Comparison of Mean VAS scores in both groups

Time	Group-B (45)	Group-R (45)	t test	p value
Immediate post-operative period	00	00	--	--
30 Minutes	00	00	--	--
60 Minutes	00	00		
90 Minutes	00	00		
120 Minutes	00	00		
150 Minutes	00	00		
180 Minutes	1.20 (± 0.40)	1.34 (± 0.53)	1.8	P<0.18
4 Hours	2.10 (± 0.62)	2.90 (± 0.70)	5.7	P<0.001
6 hours	4.10 (± 0.42)	4.62 (± 0.44)	5.73	P<0.001
8 hours	5.10 (± 1.10)	5.32 (± 1.34	0.85	p>0.89

Table 4: Comparison of Mean APGAR scores in both groups

APGAR	Group-B (45)	Group-R (45)	t test	p value
APGAR at 1 minutes	8.8 (± 0.44)	9.05 (± 0.48)	2.5	P<0.005
APGAR at 5 minutes	9.28 (± 0.40)	9.32 (± 0.53)	0.40	P>0.68

Discussion

Present comparative study of epidural ropivacaine 0.75% and Bupivacaine 0.5% with Fentanyl for elective caesarean section in Andhra Pradesh Population. The demographic parameters like weight, height BMI and duration surgery remained same in both studies (p>0.001 was Insignificant) (Table-1). Onset of sensory block (in seconds), onset of motor block

(in seconds) Mean time to achieve highest level of sensory analgesic (in seconds) Mean time to sensory regression (minutes), duration of analgesia (minutes) had highest p values in every parameter ($p<0.001$) (Table-2). Comparison of VAS score in both group (B and R) at 4 hours, 6 hours and 8 hours had highly significant p value ($p<0.001$) (Table-3). In comparison of Mean APGAR scores in both group at 1 minute had highly significant p value ($p<0.001$) (Table-4). These findings are more or less in agreement with previous studies [5][6][7].

Though Bupivacaine has been the very popular anaesthetic agent for various surgeries, for its long acting local anaesthetic profile. Its use however associated with side effects including central nervous system and neurotoxicity [8]. Ropivacaine is better in comparison to Bipuvacaine because of its least side effects like retention of urine bradycardia and hypotension. Moreover Ropivacaine is less lipohilic as compare to Bupivacaine hence it does not penetrate large mylienated causing a reduced motor blockade and least neurotoxicity but Ropivacaine is equally effective analgesic as Bipuvacaine[9]. Hence Ropivacaine is being preferred over Bupivacaine for various surgeries.

Ropivacaine is potentionally superior agent to Bupivacaine because of its lower toxicity and less motor block. Experiment in lower animals have also reported that, Ropivacaine is less cardiotoxic than Bupivacaine Ropivacaine produces fever arrhythmias than Bupivacaine in the isolated perfused rabbit heart [10]. The same study of comparison of Ropivacaine, fentanyl with Bupivacaine plus fentanyl was conducted by many authors and noted that, there was no any significant changes in hemodynamic parameters VAS scores except low diastolic pressure at 360 minutes in group R (Ropivacaine group) and no adverse effects like Nausea vomiting and hypotension were observed in R group [11].

In the present study it was observed that sensory block was shorter in the Ropivacaine group than Bupivacaine group. Moreover Ropivacaine also produced shorter duration of motor blockage than Bupivacaine but haemodynamic parameters such as systolic and diastolic blood pressure has no any significant difference but HR of patients in Bupivacaine group was higher than the Ropivacaine group. Hence Ropivacaine is better choice due to little influence on hemodynamic and shorter duration of sensory block and motor block which are useful for the recovery and also safe to the patients [12].

Bupivacaine being neurotoxic its groups patients has more nausea / vomiting bradycardia, hypotension was observed which causes panic in patients and worry for anaesthesiologist.

Summary and Conclusion

Present comparative study of epidural Ropivacaine 0.75% and Bupivacaine with fentanyl for elective caesarean section in Andhra Pradesh population. It was observed that, Ropivacaine is better alternative to Bupivacaine because of its least neuro and cardiotoxic side effects. Moreover Ropivacaine has shorter duration of sensory and motor blockage.

The present study demands such clinical trials in large number of patients to confirm the significant findings of present study.

Limitation of Study: Owing to tertiary location of research centre, small number of patients and lack of latest technologies we have limited findings and results.

This research work was approved by Ethical committee of GSL Medical College Rajahmundry–533296, Andhra Pradesh.

Conflict of Interest: No

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Original Research Article

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A Study on Body Mass Index, Physical Activity and Hypertension among Legal Practitioners

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Abstract

Background: Advocates practise for long hours with hectic work schedules. Work pressure, changing legal landscapes, uncertainty of legal cases is a great challenge to lawyers. They are unable to concentrate on their health related activities. Physical inactivity causes obesity leading to risk of hypertension. In view of above issues one of the main objectives of the study is to evaluate the relationship between physical activity, Body Mass Index and hypertension among practising advocates.

Methods: A sample of 300 practising advocates at Madurai district court was selected by simple random sampling method. Data was collected using structured interview schedule and analysed using SPSS.

Results: Nearly 90% advocates with raised body mass index were hypertensives and 68.42% advocates with inadequate physical activity developed hypertension. The difference of observation was found to be statistically significant (p=0.0000).

Conclusions: Practice of health fitness activities amidst busy schedule and Self- care management modifies the effect of Body Mass Index on hypertension risk.

Keywords: Hypertension, physical inactivity, Self-care management.

Introduction

Law is a noble profession which requires full time dedication. Advocates practice for long hours with hectic work schedules. Work pressure, changing legal landscapes, uncertainty of legal cases is a great challenge to lawyers. They are unable to concentrate on their health related activities. Therefore physical inactivity causes obesity leading to risk of hypertension. In view of above issues one of the main objectives of the study is to evaluate the relationship between physical activity, Body Mass Index and hypertension among practising advocates.

Methods

The current study is a cross sectional study conducted at bar association and law chamber, District court, Madurai from September 2015 to August 2016. Advocates in the age group of 30 years and above practicing in Madurai city were included.

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Inclusion criteria

Inclusion criteria were advocates in age group of 30 and above; regularly practicing advocates (attending court at least thrice a week); advocates practicing for a period of more than 5 years.

Sample size

According to available study [1], relating to prevalence of hypertension among advocates, the prevalence was 36%, considering it as 'p' with limit of accuracy as 16% of prevalence and with 10% attrition the sample size is calculated.

$N = Za^2 \times P \times Q / L^2$

$=1.96 \times 1.96 \times 36 \times 64 / 5.76 \times 5.76 = 266.72.$

With 10% attrition i.e., 26.6, minimum sample size calculated, (266+26.6) =293.32 rounded off to 300. Hence sample size for this study will be 300.

Sampling method

From Madurai Bar Association (M.B.A) Advocates voters' affidavit list, 600 advocates were selected by 'simple random sampling' technique using computerized random numbers. Out of that a sample of 300 advocates who satisfy the inclusion criteria were selected by enquiry through phone dialing. Permission from Madurai Bar Association Secretary was obtained prior to the data collection.

Data collection tool

Three blood pressure readings as per JNC VII were measured in all study subjects at an interval of 3 hours in sitting position and the average was calculated using 'sphygmomanometer' (mechanical type with a dial). The participants were advised to refrain use of tobacco in any form or ingestion of caffeine during the 30 minutes preceding measurement. Newly detected hypertensives were examined again after 2 days in the same manner to confirm hypertension. Apart from the known hypertensives, based on the blood pressure measurements, the remaining study subjects were classified according to JNC VII criteria. Data was collected using the final proforma, 'structured interview schedule' (modified after pilot study). Data on background characteristics and risk factors were obtained from all participants.

Statistical analysis

The data was entered and analysed using SPSS version 16.0. Descriptive statistical analysis done by calculating percentages and chi-square test and odds ratio for association of risk factor and 95% CI were computed. Among the factors evaluated, association between Body Mass Index, Physical activity and hypertension are discussed in this research article.

Results

Table 1: Distribution of hypertensive subjects and BMI:

BMI	Hypertensives	Normotensives	Odds ratio	95% CI	P value, X^2 static Degree of Freedom DF
Raised BMI (overweight & obese)	79	9	33.5	15.0-80.8	0.00001 $X^2 = 122.45$ DF = 1
Normal BMI	44	168			
Total	123	177			

Table 2: Distribution of hypertensives and their level of physical activity:

Level of Physical activity	Hypertensives	Normotensives	0dds ratio	95% CI	P value, X^2 static Degree of Freedom
Inadequate	65	30	5.5	3.1-9.6	0.00001 $X^2 = 43.21$ DF = 1
Adequate	58	147			
Total	123	177			

Hypertension and Body Mass Index (BMI):

Table 1 shows that, 88(29.33%) and 212(70.67%) study participants had raised BMI and normal BMI respectively. Among the participants with raised BMI 79(89.77%) were hypertensives (which constitutes 67(88.2%) of overweight and 12(100%) obese subjects) and only 44(20.75%) participants with normal BMI were found to be hypertensives. The difference of observation was found to be statistically significant (p=0.000). The odds ratio was 33.51, which indicates individuals with raised BMI (ie) who are overweight and obese are 33 times greater odds of developing hypertension as compared to individuals who are having normal BMI. Hence over weight and obesity are significant factors for development of hypertension.

Hypertension and Physical activity:

It is observed in table 2 that, among the study participants, a majority of 205 (68.33%) had adequate level of physical activity and 95(31.66%) had inadequate level of physical activity. Among the participants who had inadequate physical activity, a majority of 65(68.42%) developed hypertension, whereas only 58(28.29%) who had adequate physical activity developed hypertension. The difference of observation was found to be statistically significant (p=0.000). The odds ratio is 5.491, it indicates that hypertensives who had inadequate physical activity are 5.4 times greater odds of developing hypertension as compared to individuals who had adequate physical activity. Hence the level of physical activity has an association with hypertension.

Discussion

The following discussion is based on above findings obtained as a result of evaluation of association between Body Mass Index, level of physical activity and hypertension.

Hypertension and Body Mass Index

In the present study, 88(29.33%) and 212(70.67%) study participants had raised BMI and normal BMI respectively. Among the participants with raised BMI 79(89.77%) were hypertensives whereas only 44(20.75%) participants with normal BMI were found to be hypertensives. The above observation was found to be statistically significant (p=0.000). The odds ratio is 33.51, which indicates individuals with raised BMI (ie) who are overweight and obese are 33 times higher risk of developing hypertension as compared to individuals who are having normal BMI. Hence over weight and obesity are significant factors for development of hypertension. This evidence can be proved by previous literatures of similar findings as follows, obesity increases the risk of the development of hypertension. This linkage has been the subject of several reviews[2-5]. A study by Ghosh A et al[6], conducted in doctors community in Eastern India, nearly 48.15% of doctors show BMI >/=25 kg/m^2 and observed significant positive correlation between the BMI and mean BP of the subjects, which supports the fact that high body weight and high BMI increases the risks of hypertension. Several clinical studies[7-8] indicate that maintenance of a BMI <25 kg/m^2 is effective in primary prevention of hypertension and weight loss reduces blood pressure in most hypertensive subjects. Richard N. Re[9]in his review study discussed that, obesity is associated with increased blood flow, vasodilatation, cardiac output, and hypertension. Obesity predisposes to hypertension and alters the course of hypertensive cardiovascular disease. Even though this is difficult to achieve, weight loss must be the first preventive measure to reduce development of hypertension

Hypertension and physical activity

It was observed in the current study that among the study participants who had inadequate physical activity, a majority of 65(68.42%) developed hypertension, whereas only 58(28.29%) who had adequate physical activity developed hypertension. The above observation was found to be statistically significant(p=0.000). The odds ratio is 5.491; it indicates that hypertensives who had inadequate physical activity are 5.4 times greater odds of developing hypertension as compared to individuals who had adequate physical activity. Hence level of physical activity has an association with hypertension. This relationship between the physical activity and hypertension can be evidenced by the following literature. Keith M. Diaz and DaichiShimbo[10], reviewed prospective studies and reported that the most recent evidence for the role of physical activity in the prevention of hypertension, suggest that there is relationship between physical activity and incident

hypertension. Current guidelines recommend increasing physical activity as a means to prevent hypertension [11-14]. SubithaLakshminarayanan et al[15], in rural South India observed that out of 485 subjects, 265 (54.6%) complied with walking on more than four days / week, while 156 (32.2%) walked on one to four days / week, and 64 (13.2%) dropped out during the intervention period. This study has shown that a 10-week intervention to promote physical activity was effective in significantly decreasing the population's blood pressure by 1.56 / 0.74 mm Hg, fasting blood sugar levels by 2.82 mg%, body weight by 0.17 kg, and BMI by 0.06 kg / m^2.

Conclusion

In conclusion the study shows that 89.7% advocates with raised Body Mass Index had hypertensionand 68.42% advocates with inadequate physical activity developed hypertension. Advocates being well educated professionals, ideally should be health conscious and practice health fitness activities amidst their busy schedule. Pro-active self- care plays an effective role in performing day to day health related activities such as walking, jogging, yoga and exercise. Self- care management can be promoted among advocates by providingperiodic counselling services at bar council associations. Therefore adopting regular physical activities as daily routine could modify the effect of body mass index on hypertension risk. Family support too should facilitatein practising healthy life style.

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Original Article

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Gender Based Differences in Mental Health Outcomes among Young Adults in Srikakulam, Andhra Pradesh

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Abstract

Background: According to WHO " Health is a state of physical, mental & social wellbeing" but mental health needs are neglected due to the low availability of services & less community participation. Young adults are more prone to get mental health problems due to transition both physically & mentally. Females have more mood disorders & males have substance use disorders, gender disparities in mental health are not clear, so we aimed to investigate the gender differences in mental health outcomes.

Objective: To assess individual & social factors responsible for mental health problems & to estimate the level of awareness regarding mental health services available in the community.

Materials & methods: This cross-sectional survey was carried out among young adults (18-25 years). Participants were given (GHQ-12), a self-administered questionnaire. The collected data was stored & tabulated in Microsoft Excel. Mean, Percentages, and Chi-square tests were used to find the association & differences between various factors using Microsoft Excel.

Results: Out of 240 students only 29% were found to have awareness regarding mental health services at a community level. Female students were found to have higher stigma rather than males which is statistically significant (chi square-6.285, p-value-0.018).

Conclusion: Males & females have mental health issues but there are no significant gender differences. Females were found to have more stigma. Mental health awareness programs at institutes can promote good mental health.

Keywords: Gender differences, health-seeking behaviors, mental health awareness, stigma, young adults.

Introduction

Mental health is an integral part of health, not only mere absence of mental illness.[1]

According to WHO "Mental health is a state of wellbeing in which an individual realizes his or her potential, can cope with normal stress of life, can work productively and is able to make a contribution

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to his or her own community.[2] Mental health problems are universal, occurs in all countries, under all ages. Mental health issues are multifactorial, associated with various factors like standard of living, academic pressure, discrimination, myths, stigma, lack of awareness results in disease severity. [3,4] Adolescent years are peak time for the onset of common mental disorders if left untreated leads to suicides.[5] 1 in every 100 deaths is a suicide, one suicide for every 25 minutes, 90% of suicides are due to mental health issues.[6] Mental health issues increase with increasing age resulting in premature deaths, so it is necessary to investigate at the age when they are known to occur. The greatest population gets benefited by promoting factors for good mental health care, leaving the effective, yet little specialist care available for the people with adverse mental health issues. Women & men differ in terms of their role, responsibility, knowledge & position in the society, their access & use of health services influence the vulnerability to disease. Evidence linking gender socialization to mental health problems is rare, so the study was conducted to identify gender differences in mental health outcomes & to explore the factors associated with it.

Materials & Methods

Study design:Cross-sectional, descriptive type.

Study setting: Engineering & degree colleges of Srikakulam, Andhra Pradesh.

Study period: 4 months (1st April 2022 to 31st July 2022).

Inclusion criteria:

- All the available students from different departments were covered based on voluntary participation.

Exclusion criteria:

- Students absent on the day of our visit.
- Students who are writing exams on the day are also excluded.

Sample size: A total of 240 students were selected through conveinient sampling & also meeting the inclusion & exclusion criteria were considered as study subjects

Sampling method: First from the list of colleges near to Srikakulam town, 5 colleges were selected following multi-stage random sampling method and then 3 colleges have given permission for data collection, I have collected from 2 colleges thereby my sample size got completed.

Data collection tools: General health questionnaire (GHQ-12), is a self-administered questionnaire designed to detect current mental health disturbances and disorders as screening tools in primary care settings[7].

Methodology

This is a cross sectional, questionnaire based study carried out in an engineering & degree college of Srikakulam during the above mentioned study period, after explaining the research & its purpose, verbal consent was taken from all the participants, the consented participants were administered with general health questionnaire (GHQ-12) to identify the presence of nonspecific psychiatric morbidities like anxiety, depression & psychological distress & other common mental disorders [3]. The study tool was pretested & prepared after an extensive review of available literature. It is a tool with a 2 point scoring (Yes/No). Self-administered questions were added, Checking was done, that there was no discussion among them while filling, the questionnaire was filled with the help of PAPI (paper & pencil interview), the doubts were clarified by the investigator, and confidentiality was maintained throughout the study. Youth were asked regarding positive about life, suicidal ideation, capability of own decision making. For each item negative emotion was coded as 1 & 0 otherwise. The items were summed up for a total score ranging (0-12), indicating mental health problems with increased scores. Gender discrimination was questioned by asking any gender-based abuse & any biased allocation of domestic work at home[8].

The collected data was stored & tabulated in Microsoft Excel, the questions related to cognitive symptoms, anxiety, depression and somatic symptoms were categorized dichotomously as yes/ no. mean, percentages, chi square tests were used to find the association between various factors using Microsoft Excel.

Institutional ethics committee has approved to perform before the start of the study.

Results

A total of 240 students, 120 boys & 120 girls, participated in the study. The mean age of students is 21 years.

In this study, 40% of young adults reported three or more symptoms suggestive of mental health problems.

Among overall students, 50 (41.6 %) of males & 47 (39.2%) of females are affected [Table-1].

Inability to concentrate is the highest reported symptom next to facing trouble in overcoming difficulties & feeling depressed is the lowest recorded symptom among young adults based on the GHQ12 score.

Several factors have shown statistically significant associations in showing symptoms suggestive of mentally deviant behaviors.

Family history of mental illness has a strong statistical association; factors like feelings of disfigurement, sleeping problems, and lack of own decision-making, are associated with mental health problems which are significant with p-value <0.05. [Table-1]

Social factors like parental education, and type of family have no significant association, and factors like daily physical activity, awareness of mental health importance, duration of social media usage, addictions, and associated stigma have no association in causing mental health problems.[Table 1].

There are mental health issues in both males and females but gender differences in terms of suicidal ideas, own decision-making, gender abuse, and others remained neutral, females are more interested in learning new things than males, and females are less aware of mental health importance in day to day life, stigma is more associated with females which are statistically significant.[Table-4]

Table 1: Distribution of Young Adults Based on Their GHQ Score and Psychosocial Factors & Other Factors.

FACTORS	GHQ SCORE >3 97	GHQ SCORE <3 143	CHI SQUARE
Gender			
Males	50(48.5)	70(71.5)	P value-0.693
Females	47(48.5)	70(71.5)	
Parents education			
Primary education	54(55.6)	85(59.44)	P value-0.5
Secondary education	43(44.3)	58(40.55)	
Type of family			
Nuclear	73(75.25)	106(74.1)	P value-0.84
Joint	24(24.7)	37(25.8)	
Mental health awareness			
Yes	51(52.57)	92(64.3)	P value-0.68
No	46(47.4)	51(35.66)	
Stigma			
Yes	72(74.2)	116(81.11)	P value-0.2
No	25(25.7)	27(18.88)	
Family history of mental illness			
Yes	19 (19.50)	11 (7.69)	P value-0.006
No	78 (80.4)	132(92.3)	

Continue.....

FACTORS	GHQ SCORE >3 97	<3 143	CHI SQUARE
Physical activity			
Yes	66	31	P value-0.12
No	110	33	
Feel of disfigurement			
Yes	54(55.6)	25(17.4)	P value-<0.00001
No	43(44.32)	118(82.51)	
Difficulty in sleep			
Yes	40(41.23)	14(9.79)	P value <0.00001
No	57(58.76)	129(90.20)	
Own decision making			
Yes	60(61.85)	130(90.90)	P value <0.00001
No	37(38.14)	13(9.09)	
Addictions			
Yes	9	5	P value 0.67
No	41	65	

Table 2: Gender Differences in Mental Health Outcomes

Psychosocial factors	Males	Females	P- value
Difficulty in sleep	22(18.3)	32(26.6)	0.12
Feel of disfigurement	40(33.3)	39(32.5)	0.89
Difficulty in control of thoughts	35(29.1)	42(35)	0.333
Interested in learning things	105(87.5)	114(95)	0.039
Own decision making	99(82.5)	91(75.8)	0.203
Positive about life	81(67.5)	85(70.8)	0.57
Suicidal ideas	14(11.6)	10(8.33)	0.38
Level of awareness	81(67.5)	62(51.66)	0.012
Stigma	86(71.6)	102(85)	0.012
Gender-based abuse	5(4.16)	1(0.83)	0.9
Cooked or cleaned at homes	95(79.1)	94(78.33)	0.87
Physical activity	92(76.6)	84(70)	0.24
Academic adaptability	76(63.3)	81(67.5)	0.49

Discussion

Most of the earlier studies were done in early adolescence but late adolescence & young adulthood is the period of changing identity, where the gender gap emerges in mental health.

Earlier studies have used different scales to identify only depression, anxiety & psychological distress, which is practically difficult for screening purposes for different ages.

Mangal et al, used GHQ12 questionnaire which is a short, simple & reliable tool for identifying common mental health problems similar to the present study.[3]

- Mangal et al, Common mental disorders and their determinants in adolescent school girls found that almost half (48.78%) of adolescent girls reported 3 or more symptoms from GHQ12 score, feeling of disfigurement, difficulty sleep, academic pressure, comparison with peers has a statistically significant association with mental health problems as per GHQ scores which is similar to the present study.[3]
- Anjara et al, has found parents' education & occupation are not significantly associated but wealth has a negative association with reported mental health problems.[9]

- Substance use and suicidal ideation among adolescents in Kerala used a personal experience screening questionnaire (PESQ) & suicidal ideation scale (SIS) for screening.

  They approved that substance use is positively correlated with suicidal ideation,

  Substance abuse is more in males but suicidal ideation is more in females.[10]

- Swikruthi Behera, SrinikhilaSatyaSanthoshi Lakshmi Paluri, Alpana Mishra have done a cross-sectional study on students of professional colleges in Visakhapatnam to estimate the prevalence of psychological stress, anxiety, & depression using a self-administered questionnaire, they found that higher prevalence in males, nursing students are having more depression than other professional degrees, medical students are having lowest depression than any other non-medical professionals. [11]
- Earlier study examined 467 young adults to identify the impact of the duration of screen time on mental health and found that no harm & may be beneficial. [12]
- Young adults who are having social contacts are feeling secure & reported less depression & stress than others. [13]
- Bansal et al, reported that difficulty in coping with studies which is similar to the present study.[14]

Conclusion

The present study found the prevalence of common mental health issues among young adults(18-24 years) is 40%. The study concludes that there are mental health issues but gender differences are insignificant, and family history is showing a strong association, so targeted screening for individuals having a family history of mental illness is beneficial, stigma is less in males than females and mental health awareness is more in males than females, so there is a need for improving mental health importance awareness in the community.

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Osteoporosis, Its Pathophysiology and Effect of Nutraceuticals

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Abstract

Osteoporosis a classical age related disease that effects women more in comparison to men. Albright and colleagues were first proposed the hypothesis that estrogen deficiency is related to osteoporosis. Its a condition related to bone fragility resulting from micro-architectural deterioration and decreased bone mass, Nowadays typical Western diet (high in protein, salt and refined, processed foods) combined with an increasing sedentary lifestyle mainly contribute to the increasing incidence of osteoporosis in the elderly. Mediterranean diet (MD), proved very beneficial in chronic diseases and fragility related fractures. Thus for management of osteoporosis proper lifestyle is plays major role.Healthy, well-balanced nutrition can play an important role in the prevention and pathogenesis of osteoporosis, and in support of pharmacological therapy. Calcium plays major role in proper bone health.

Key Words: Osteoporosis, Spinal cord Injury, BMD, Fragility, Taurine, RANKL and osteoprotegerin.

Introduction

Osteoporosis, a systemic skeletal disease that is characterized by the loss of bone mineral density (BMD) and bone mechanical strength (BMS), it leads to fragility related fracturesin the wrist, hip, and spine. Nowadays Osteoporosis is major public health problem associated with aging. Bone density and bone quality mainly defines the strength of bone. There is a clear corelation between each standard deviation (SD) decrease in bone mineral density and the risk of fracture. Nowadays osteoporosis is a common health issue, and after ischemic heart disease, dementia, and lung cancer (IOF 2021) it is the fourth most burdensome chronic disease. Although, a higher prevalence of osteoporosis has been most common in postmenopausal women.According to the International Osteoporosis Foundation (IOF), one-third of females and one-fifth of males will suffer once in their lifetime from fragility related fractures[1], Age, dietary habits, menopause, long-term glucocorticoid therapy, inherited osteoporosis (osteogenesis-imperfecta), etc are the common risk factors that are related in the progression of this disease [1]. Two common type of osteoporosis,on the basis of their known cause are primary osteoporosis most common in postmenopausal women,andsecondary osteoporosis, with defined etiological mechanisms.

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Primary osteoporosis is characterized into two types i.e. 1 and 2, Primary osteoporosis is also known as postmenopausal osteoporosis (Type 1), bone loss mostly occurs due to estrogendeficiency, Type 2 or senile osteoporosisresults from systemic senescence[2] Nowadays currently employed therapies for the treatment of osteoporosis is bisphosphonates, denosumab (anti-RANKL monoclonal antibody), teriparatide (parathyroid hormone-PTH), and vitamin D supplementation exhibit the ability to modulate immune mediators. In case of postmenopausal women, there is an imbalance between RANKL and osteoprotegerin (increased RANKL and reduced osteoprotegerin), due to estrogen deficiency that leads to net bone loss, this similar imbalance occurs in rheumatoid arthritis, myeloma bone disease, and osteolytic metastatic bone disease;and subjects suffering from prostate cancer who are receiving androgen deprivation therapy, subjectsof breast cancer who are on aromatase inhibitors therapy have also imbalance between RANKL and osteoprotegerin levels and are also osteoporotic. RANKL is targeted by Denosumab a fully human monoclonal antibody[3]. By binding to RANKL, this drug prevents the maturation and differentiation of preosteoclasts and promotes apoptosis of osteoclasts, thus it almost suppress bone resorption process. In one of the pivotal phase 3 clinical trial Fracture Reduction Evaluation of Denosumab in Osteoporosis every 6 Months (FREEDOM) in postmenopausal women with osteoporosis showed that denosumab administration is effective and prevented vertebral, non-vertebral, and hip fractures [4]. There was a close relationship between femoral neck BMD change and fracture risk reduction [5], Denosumab had showed long term continuous effect atleastupto 10 years in preventing vertebral and non-vertebral fracture,and improving lumbar and proximal femoral BMD[6]. Elevation in BMD of 1/3 radius consisting of mainly cortical bone almost in a linear fashion due to denosumab, but this continuous increment in radial BMD was not seen in subjects who are receiving oral bisphosphonates[7]. These findings reveal that in comparison to bisphosphonates, denosumab has potent effects on both trabecular & cortical bones. Denosumab possess Anti-fracture effectson its long term use different from those of bisphosphonates.

After denosumab treatment, At sites of bone with microcracks or deteriorated strength RANKL expression by osteoblasts and osteocytes is expected to increase, so after 4 to 6 months,there is possibility of bone remodelling especially where RANKL expression is high. But it needs more future research. As RANKL-induced bone resorption is inhibited by denosumab so patients should be supplemented with enough vitamin D or calcium orboth, otherwise there will be a chances of hypocalcemia, especially during the first week after administration. The adverse effect of Denosumab is that it is associated with an increased risk of atypical femoral fracture; and osteonecrosis of the jaw. After discontinuation of Denosumab treatment with other anti-resorptive drugs is must as after discontinuation, of this drug there is a rapid increase in bone turnover resulting in a rapid loss of bone and a possible increase in fractures[8]

Consideration of targets in osteoporosis

The WHO criteria for determining Osteoporosis is as follows: T score must be –2.5 or below, standard deviations (SD) as assessed by dual-energy X-ray absorptiometry(DXA), Excess mortality rate (8 to 36%), within 1 year because of hip fracture is more common in men than women[9] additionally, hip fractures are followed by a 2.5-fold increased risk of future fractures[10] Almostlong-term nursing home care, is required in case of 20% of hip fracture patients, butonly 40% fully regain their pre-fracture level of independence, Initially majority of vertebral fractures are clinically silent, oftenly these fractures are mostly associated with symptoms such as pain, disability, deformity, and mortality[11]

According tothe UK National Institute for Health and Care Excellence (NICE), all women aged 65 and above, all men aged 75 and above, and younger patients with risk factorsshould receive osteoporosis risk assessment. BMD (Bone Mineral Density), is the gold standard investigation method of Osteoporosis.

Due to aging population Osteoporosis has rapidly increased in Taiwan including the rest of Asia, Asians and Caucasians are the two races that are considered at high risk for osteoporosis. In Taiwan the epidemiology of osteoporosis might be different from that of the Western world or the other parts of Asia due to rapid aging. Incidence of

Osteoporotic fractures havegeographic variations due to racial differences in skeletal size.With growing age incidence of osteoporosis and fracture associated with it also increases[12],The hip is the most common fracture site in both sexes in old age.

The T-score: T score is calculated by subtracting the bone mass value(BMD) of the subject from the reference value of normal subject of 30 years of age(YN), at this age bone mass is at maximum and the risk of fractures at maximum.The obtained value is divided by the standard deviation (SD).

T-score= (BMD-YN)/SD

Intranasal Calcitonin in osteoporosis:Calcitonin a naturally occuring peptide hormone which decrease the activity of specific receptors present on osteoclasts and suppress their activity, thereby reducing bone loss. Salmon calcitonin is the most popular product of recombinant & synthetic variants of calcitonin that was introduced in the market. Because of its convenience of administration, it is mostly administered as an intranasal sprayat a single daily spray providing 200 IU of the drug. Calcitonin therapy is used along with calcium and vitamin D supplementation[13], In case of osteoporotic vertebral fractures, calcitonin treatment helps in diminishing body Painand is usually reserved for patients with vertebral crush fractures and also for those patients who are not candidates for the other available osteoporosis treatments. Whereas there are few side effects of calcitonin like rhinitis, epistaxis and allergic reactions.

Estrogen deficiency promotes the number of osteoclastscells whereas declines the number of osteoblast cellsleading to anunbalanced activity of the basic multicellular unit in favour of bone resorption[14], This concept is now well accepted that estrogen deficiency is involve indirectly in bone resorption via the release of bone-active cytokines. These osteoclastogenic cytokines are inflammatory cytokines, that describes the role of interactionsof the immune system and bone tissue also in the pathophysiology of osteoporosis. Levels of Proinflammatory cytokines such as TNF, IL-1, IL-6, or IL-17 mostly elevated in the first ten years after menopause this finding strength there role in causing osteoporosis[15].In osteoporosis T-cells are major source of proinflammatory cytokines.In case of any inflammation,immune system cells such as T cells, B cells, macrophages or dendritic cells, become activated and began to produce inflammatory cytokines,that plays vital role or act as mediators in osteoimmunology[16], Among these cells, T cells are major stimulators of osteoclastogenesis as they increase the production of bone absorbing cytokines such as TNF-α and RANKL; thus activated T cells are suggested to play major role in progression of osteoporosis[16].

Osteoporosis after spinal cord Injury: After Injury in case of SCI bone loss begins Immediately and is mostly affected by age, immobilization, bed rest, and a lack of gravity environment[17], Regions rich in cancellous and cortical bones have reduced bone mineral density nearly 4% and 2% per month respectively, One of the studies on 41 SCI subjects have shown that 25 subjects WHO's criteria for osteoporosis (61%), whereas eight subjects were osteopenic (19.5%)and normal values were recorded only in 8 subjects(19.5%)[17]

In SCI Subjects bone loss in the epiphysis part of bone is almost double that of diaphysis 50% & 60% loss inthe epiphysis region of femur and tibia respectively, whereas 35% and 25%, respectively in the diaphysis region of both femur and tibia, this study also demonstrated that loss of bone in between both the compartments of trabecular and corticalbone occurs through different mechanism i.e. due to a decrease in trabecular, bone lossoccurs in the epiphysis bone. Because of endocortical resorption, bone loss happens inthe diaphysis. In contrast, cortical bone density is maintained in the diaphysis region of bone[17], Another study with the help of p QCT have shown that in case of complete paraplegics with a highand low neurological level of injury (thoracic D4-D7) and low (thoracic D8-D12), bone loss in the trabecular bone at the tibia was 57.5% vs 51%, in high vslow paraplegics, respectively.Whereas cortical bone loss was 3.6% and 6.5%, respectively. This data indicates that during the first year of paralysis the most affected bone is trabecular bone in comparison to cortical bone[17]. In case of SCI physical activity is very compulsory because it helps in increasing bone mass, As due to muscular activity blood flow increases in bone,thusBone vasculature is also increased, And

due to physical activity femoral blood flows almost doubles, due to exercise metabolic activity also changes in SCI Subjects thus blood flow in bones is enhanced and thus SCI-associated osteoporosis can be positively affected by physicalactivity via enhanced bone metabolism and regeneration.

Role of Nutrition in Osteoporosis

Nutrition plays major role in prevention and treatment of Osteoporosis. Calcium &Vitamin D plays major role as studies have proved that higher calcium uptake at various stages are associated with higherBMD.[18] In postmenopausal women, who are consuming calcium and vitamin D have least chances of bone loss. decrease bone turnover and reduced chances of nonvertebral fractures[19], Potassium plays major role in calcium homeostasis particularly in the urinary conservation and excretion of calcium. Therefore there is increase in urinary calcium lossif the subject is on low Potassium diets. Vegetables, fruits, legumes, and milkare richest source of Potassium and it tends to have alkaline ash characteristics.There have been some studies relating the Net Endogenous Acid Production (NEAP) to potassium intake and bone density[20], Consumption of high salt diet increases loss of calcium through urine, Research has suggested that inpostmenopausal women if they consume high salt diet then rate of bone resorption increases over a 4-week period,but consuming high potassium as potassium citrate changes this adverse event[20], Consumption of fruits & vegetables rich in potassium was associated withhigher baseline BMD and less bone loss[21], One of the study by demonstrated the relationship between the serum Vitamin K1 level in post menopausalosteoporotic women, women and BMD, in their study the enrolled 23 postmenopausal osteoporotic women, and in 15 postmenopausal healthy control women using ELISA, whereas Lumbar Spine BMD was assessed, and they observed that inpostmenopausal osteoporotic womenin comparison to normal healthy controls The mean serum vitamin k1 level was significantly lower (mean=0.794 vs3.61ng/ml, P< 0.0001), and concentration of serum Vitamin K1was positively corelated with BMD of Lumbar spine among postmenopausal osteoporotic women (R=0.533, p = 0.009), and in postmenopausal healthy control (R=0.563, p = 0.02). Thus their findings reveal that Vitamin K1 may contribute in Bone Mineral density and thus it can be established as therapeutic diagnosing biomarker in post-menopausal osteoporosis.

Nutrient	Recommended dietry allowance	Median intake
Vitamin D	600-800 IU	150-300 IU
Calcium	1000-1200mg	735 mg
Magnesium	320-420mg	243 mg
Silicon	*40 mg for bone health	21 mg
Vitamin K	90-120ugm	70-80 umg
Boron	*3 mg for bone Health	1mg
Vitamin C	75-90 mg	103 mg
Copper	0.9 mg	1.1mg
Zinc	8-11mg	9.6 mg
Manganese	1.8-2.3 mg	2.8 mg

Common Nutrients for Bone Health

Taurine and osteoporosis: Osteoporotic subjects possess lower serum taurine level in comparison to healthy subjects[22], lower taurine level in urine is a marker of post-menopause and osteoporosis where taurine levels in urine were decreased 1.9 fold in post-menopausal women with osteoporosis compared to pre-menopausal women with normal BMD [23], Taurine levels can be elevated by using drug bisphosphonates in osteoporotic subjects. One of the study on ovariectomized mice has shown that treatment with alendronate sodium, a bisphosphonate elevates taurine levels from 467.6 ± 116.0 uM to 669.2 ± 127.6 uM[24], Supplements that can be used to treat osteoporosis.

Supplement	Rationale	Safety
Taurine	Involved in intracellular calcium homeostasis and assists with absorption of vitamin D and vitamin K	3000mg a day**(Shao Aet al 2008)**

Continue .....

Supplement	Rationale	Safety
Calcium	assists with bone formation	600 mg of calcium is taken from calcium carbonate twice a day. The National Osteoporosis Foundation holds adequate calcium intake is 1200 mg/day for women 51 and older (**Cosman F et al 2014)**
Vitamin D3	promotes absorption of calcium	2000 IUs of vitamin D3 would be taken a day. The Institute of Medicine (US) has set the Tolerable Upper Level Intake for vitamin D at 4000 IUs for adults.(**Institute of Medicine (US) 2011**)
Vitamin K MK-7	needed for bone to bind calcium	No toxicity has been observed with vitamin K MK-7 supplementation which is better absorbed than other kinds of vitamin K [88]. Approximately 2 mg of MK-7 would be taken a day.(**Marles RJ et al 2017).**

In the United state of America the recommended dose for Vitamin D supplementation is 400 IU for adults aged between 51 and 70 years & and for 70+ the recommended dose is 600 IU, whereas dose recommended by the Commission of the European Communities is 400 IU daily for people over 65 years[25], 2000 IU/day is set as an acceptable upper limitfor vitamin D intake, The "no observed adverse event level" is 10,000 IUdaily and the "lowest observed adverse event level" is 40,000 IU/ day[26].Vitamin D intoxication level is still unknown,but is likely to be considerably higher than the above mentioned doses. Whereas supplementation of high dose carries a risk of hypercalcaemia that impaired Kidney function. Highcalcium intake, hypercalcaemia, idiopathic hypercalciuria, sarcoidosis, overproduction of vitamin D metabolites, reduced vitamin D binding and hyper responsivity to vitamin D are some of the predisposing factors that express vitamin D intoxication[27],

To, usevitamin D and calcium specifically in case of postmenopausal women is not compulsory or any major precaution, but it has been reported that if there is decrease in levels of 25(OH)D then there is increased chances of prevalence of albuminuria, which is a risk factor forprogression of chronic kidney disease[28], Another major cause of osteoporosis is Cigarette smoking, as we know Nicotine is the only chemical among the 4,700 chemicals found in the tar phase of cigarette smoke,various studies have proved the major role of Nicotine in causing osteoporosis as it is the only chemical that confirmed its deleterious effectson bone remodeling as it inhibits osteoblast activity and growth and promotes osteoclastic activity and it also induces oxidative stress as proved by many in vitro and in vivo animal studies[29], and this chemical also activatesNF-κB-signaling pathway thus indirectly involve in osteoclast differentiation,and it also elevates theproinflammatory cytokines IL-1 and IL-6 in animal model[29], High dose of vitamin E a group of potent, lipid-soluble, chain-breaking antioxidants proved beneficial in suppressing nicotine-induced elevation of IL-1 and IL-6, (Tocotrienol), where astocopherol had no significant effects on both cytokines thus in both forms of vitamin E Tocotrienol proves to be more effective in comparison totocopherol in terms of its action on bone resorbingcytokines thus Tocotrienol is more effective in reducing bone loss and inflammation[29],

Zinc has anabolic effect on bone metabolism because bone act as a zinc sink, zinc is released during skeleton breakdown and it is reincorporated into the skeleton,the vertebral calcium/ zinc ratio is inversely related to age in case of human, it suggest that in comparison to calcium, zinc is more conserved in later life. Zinc is present in the mineral component of bone hydroxyapatite, it may be complex with fluoride; and both zinc and the zinc-fluoride complex may improve the crystallinity of apatite, In case of osteoporosis subjects, level of zinc is found lower in their skeleton. Zinc is a marker of bone resorption as studies have proved that in postmenopausal women,urinary zinc concentration is very high, since women with osteoporosis excrete over than 800 ug zinc/g creatinine in urine[30], Trace mineral supplementation proves very beneficial in with or without calcium in postmenopausal women as it exerts its beneficial

impact on bone mineral density[30], Both invitroin vivo studies have proved anabolic effect of zinc on bone metabolism as supplementation of zincsulfate (5 and 10 mg Zn/kg body weight) for 3 days produced dose dependent increases in the contents of zinc, deoxyribonucleic acid (DNA), collagen and calcium, and the activity of alkaline phosphatase in the femoral diaphysis (cortical bone) of weanling rats[30], one of the interesting study by Park HM [31], showed that high dietry intake of calcium from plant source reduces the risk of osteoporosis and help in increasing bone mineral density in postmenopausal Korean women,thus it is concluded from their study that Vegetables might be a best source of calcium,vitamins and other minerals that exerts beneficial impact on bones. Another important nutraceuticals is curcumin as it prevents inflammation and oxidative stress, one of the controlled clinical trial by Hatefi M et al[32], on 100 subjects with spinal cord injuryin order to assess the effects of curcumin on biochemical markers of osteoporosis and and BMD, he demonstrated that administration of curcumin significantly inhibited the bone loss in patients with spinal cord injury and improved densitometric parameters at the lumbar spine, neck of femur and hip bone.Studies have shown that Curcumin Treatment revealed positive effect on certain Serum bone markers such as bone Alkaline Phosphatase, serum osteocalcin, serum CTX and procollagen type I N propeptide (PINP) in chronic spinal cord injury patients.

Conclusion

As we know nutritional supplementation is easy to administer and nutritional needs for optimizing bone health can be easily fulfilled by healthy dietwith adequate calcium and vitamin D intakes through dairy or calcium fortified foods. Different minerals and vitamin has different properties like some acts as antioxidant, some acts as anti-inflammatory etc, the beneficial impact of various nutrients have been proved by many studies but most of hem were done on animal model so it needs human trial to proves its efficacy.

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The Role of Smoking on Incidence and Prognosis of Covid-19 Patients Admitted to Tishreen University Hospital

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Abstract

Background: In February 2020, the World Health Organization identified Covid-19 and identified SARAS-COV2 as the cause of the disease. So far, the number of infected people has exceeded 633 million, while the death toll has exceeded 6.6 million. Since the start of the pandemic, there have been conflicting reports about smoking in terms of incidence and prognosis.

Objective: The aim of this study was to investigate the effect of smoking on incidence and prognosis of COVID-19 patients.

Patients and Methods: An Analytic Observational Cohort study was conducted in patients with a proven diagnosis of COVID-19. They are selected from Pulmonary Medicine department, Tishreen University Hospital in Lattakia-Syria between June 2020 and December 2020. Study population were divided into two groups according to the patient's smoking status; group I included smoker (237 cases), and group II included non-smoker (277 cases).

Results: The population of 514 patients was predominantly male (66.1%), with a mean age of 61.76±14.9 years. 46.1% of the patients were smoker with presence of associated chronic diseases in 341 cases (66.3%). There were no significant differences between two groups regarding gender and comorbidities (p>0.05). Patients were significantly older in group I than in group II (71.22±13.2 versus 60.88±15.2, p:0.001). The rate of oxygen-based treatment was higher in smokers compared non-smokers (84.8% versus 67.9%, p:0.03). Non-invasive mechanical ventilation was necessary in 31 patients (13.1%) in group I versus 73 patients (26.4%) in group II, p:0.04. The duration of hospitalization was longer in non-smoker group (7.2±4.1 versus 5.7±3.9, p:0.001). Recovery rate was higher in non-smoker patients (81.2% versus 68.4%). In addition to, 75 patients (31.6%) in smoker group died versus 52 patients (18.8%) in non-smoker group, p: 0.005.

Conclusion: The current study demonstrated presence of favorable inverse associations of smoking with duration of hospitalization and the need to non-invasive mechanical ventilation in COVID-19 patients.

Keywords: COVID-19, outcome, smoking

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Introduction

Coronavirus disease (COVID-19) represents a global pandemic caused by Severe Acute Respiratory Syndrome Coronavirus -2(SARS-CoV-2) virus[1]. It has resulted in high morbidity and mortality, in which approximately 73 million cases and 1.5 million deaths have been reported worldwide[2]. The clinical manifestations of COVID-19 vary from asymptomatic to severe respiratory failure which requires intensive care and advanced ventilator support[3]. Early detection of the disease has become crucial to prevent spread of infection, and more attention should be paid to risk factors for developing severe COVID-19 to prevent severity[4].

Smoking is the leading cause of preventable morbidity and mortality worldwide. It is estimated that there are approximately 1 billion smokers in the world, of whom 80% of them live in low- and middle income countries[5]. According to the World Health Organization(WHO), tobacco will kill more than eight million people worldwide annually by the year 2030 if the current trends continue[6]. It harms nearly every organ in the body, and is associated with a higher risk of viral respiratory infections, chronic diseases, and malignancies[7]. The mechanisms by which smoking increases the risk of respiratory infections are incompletely understood, which might include: structural changes in the respiratory tract, reduced lung function and a decrease in immunologic host defenses [8]. Growing epidemiological studies have reported an inverse relationship between tobacco smoking and COVID-19 occurrence, but these results are contradictory with the results of previous studies which found that smokers were more likely to develop serious illness from COVID-19 than non-smokers[9]. Therefore, the objective of the study was to: 1- explore the effect of smoking on COVID-19 prevalence 2- study the effect of smoking on prognosis and survival rate of COVID-19 patients.

Patients and Methods

This is an Analytic Observational Cohort study of a group of patients attending Department of Pulmonary Medicine at Tishreen University Hospital in Lattakia-Syria during six-months period (June 2020 and December 2020). The inclusion criteria were: patients older than 15 years, males or females, with a positive PCR, and who didn't receive vaccination. Complete history, review of systems, physical examination, and laboratory investigations were performed. Radiological investigation was performed, and laboratory confirmation of COVID-19 diagnosis was done based on using real-time PCR with a standard protocol. Patients were stratified according to the smoking status into two groups: group I included COVID-19 patients who were smoker, and group II included COVID-19 patients who were non-smoker. Demographic variables, requirement to respiratory support and final outcome were compared between two groups.

Ethical consideration: All patients were provided a complete and clear informed consent after discussion about the study. This study was performed in accordance with the Declaration of Helsinki.

Statistical Analysis

Statistical analysis was performed by using IBM SPSS version 20. Basic Descriptive statistics included means, standard deviations(SD), Frequency and percentages. To examine the relationships and comparisons between the two group, chi-square test was used. Independent t student test was used to compare 2 independent groups. All the tests were considered significant at a 5% type I error rate($p<0.05$), β:20%, and power of the study:80%.

Results

The study included a group of 514 patients with a diagnosis of COVID-19. The baseline characteristics of patients were as shown in Table (1). Age ranged from 19 to 92 years, with a mean age of 61.76±14.9 years. Patients were classified according to age into two groups: <70(42.6%) and ≥70(57.4%). Males represented 66.1% and females 33.9% of the patients. Of the 514 patients included for the analysis, 341(66.3%) presented some comorbidity, and 237 patients (46.1%) were smokers.

Table 1: Demographic characteristics of the study population

Variable	Result
Age (years)	61.76±14.9
Age groups(years)	
<70	219(42.6%)
≥70	295(57.4%)
Sex	
Male	340(66.1%)
Female	174(33.9%)

Continue .....

Variable	Result
Smoking	
Present	237(46.1%)
Absent	277(53.9%)
Chronic diseases	
Present	341(66.3%)
Absent	173(33.7%)

As shown in table (2), no significant difference was found between the two groups in terms of gender and presence of comorbidities (p>0.05). In group I, a mean age was 71.22±13.2 years versus 60.88±15.2, p:0.001 in group II, p:0.001. Males represented 76.8% and females 23.2% of the patients with presence of comorbidities in 168 cases (70.9%) in group I. In group II, males represented 62.1% and females 37.9% of the patients, with presence of comorbidities in 173 cases (62.5%).

Table 2: Demographic characteristics of the study population by comparison of the two groups

Variables	Group I Smoker (n=237)	Group II Non-smoker (n=277)	P value
Age (years)	71.22±13.2	60.88±15.2	0.001
Sex			
Male	182(76.8%)	172(62.1%)	0.8
Female	55(23.2%)	105(37.9%)	
Comorbidities	168(70.9%)	173(62.5%)	0.09

During hospitalization, 201 patients (84.8%) required high-flow supplemental oxygen delivered with nasal cannula in group I versus 188 cases (67.9%) in group II, p:0.03. Non -invasive ventilation was used in 31(13.1%) patients in group I versus 73(26.4%) patients in group II, p: 0.04, whereas invasive type was applied in 25 cases (10.5%) versus 34(12.3%) in group II, without significant difference, p:0.5. Hospital length of stay was significantly longer in in group II (7.2±4.1 versus 5.7±3.9 in group I, p:0.001). Patients were divided into three groups according to the length of hospital stay; 1-7 day (69.6%), 7-15(12.2%), and >15(18.2%) in group I versus 63.5%, 26%, and 10.5% in group II respectively, p:0.02. Recovery was occurred in 162(68.4%) patients in group I versus 225 cases (81.2%) in group II, and 31.6% of the patients died in group I versus 18.8% in group II, p:0.005.

Table 3: Outcome of the study population by comparison of the two groups

Variables	Group I (n=237)	Group II (n=277)	P value
Requirement for oxygen administration			
Present	201(84.8%)	188(67.9%)	0.03
Absent	36(15.2%)	89(32.1%)	
Mechanical ventilation			
Invasive	25(10.5%)	34(12.3%)	0.5
Non-invasive	31(13.1%)	73(26.4%)	0.04
Duration of hospitalization	5.7±3.9	7.2±4.1	0.001
Duration of hospitalization groups(day)			
1-7	165(69.6%)	176(63.5%)	0.02
7-15	29(12.2%)	72(26%)	
>15	43(18.2%)	29(10.5%)	
Final outcome			
Recovery	162(68.4%)	225(81.2%)	0.005
Death	75(31.6%)	52(18.8%)	

Discussion

The COVID-19 pandemic is a worldwide public health issue that has resulted in increased morbidity and mortality. To our knowledge, this study provides empirical evidence of the impact of smoking on prevalence of COVID-19 and final outcome of patients. The result of the current study revealed that approximately two-third of the patients were males with presence of smoking history in 46% of cases. Smoker patients were significantly older, and the rate of non- invasive mechanical ventilation was higher in non-smoker patients with presence of significant difference in non-invasive type. The duration of hospitalization was longer in non-smoker group. On the other hand, the rate of recovery was higher in non-smokers. The impact of tobacco smoking on outcome for participants with COVID-19 appear to be related to the differing effects of smoking that include: reduced production of pro-inflammatory cytokines (TNF, IL-1, IL-6) leading to protection effect against cytokine storm syndrome, decreasing the

risk of SARS/CoV-2 attachment through decreasing expression of ACE2, increasing production of nitric oxide that may inhibit potentially replication and entry of virus[10]. These findings are comparable with the results of previous studies.

Patanavanich et al (2020) demonstrated in a meta-analysis study conducted in 11590 patients with a diagnosis of COVID-19 presence of significant association between smoking and progression of COVID-19(OR:1.91, p:0.001)[11].

Albert et al (2021) revealed in an analytic study conducted in 402978 with a diagnosis of COVID-19 infection presence of association between smoking and the infection which modified by age. Smokers under age 69 year are at increased risk to exposure to SARS-COV-2 virus(RR:1.88), whereas older smokers were at higher rate of mortality from COVID-19 than non-smoker patients(RR:2.15)[12].

Meini et al (2021) demonstrated in a case-control study conducted in 218 patients with a diagnosis of COVID-19 infection who compared with 243 cases without COVID-19 infection that current smokers were significantly less likely to be hospitalized for COVID-19 compared with nonsmokers (OR: 0.23, p:0.001)[13].

Paleiron et al (2021) showed in a study conducted in 1279 participants with confirmed or suspected COVID-19 who were compared with 409 cases without COVID-19 infection that current smoking status was associated with a lower risk of developing COVID-19 (OR:0.59, p<0.001)[14].

In summary, the observed reduction in the rate of mechanical ventilation and shorter duration of hospitalization in smoker patients is consistent with a protective effect of smoking on the risk of COVID-19, but there is still considerable caution in interpreting this association as protective.

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Evaluation of the Care Costs for Non-Communicable Diseases Incurred by Patients in the Greater Tunis Area

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Abstract

Objectives: The objective of this study was to estimate the costs and expenses incurred by patients for the management of non-communicable diseases (NCDs).

Methods: The study was carried out in 7 Basic Health Centers (BHCs) distributed all over Greater Tunis and was conducted using a new tool: the COPAQ.

Results: According to the survey, the direct medical cost was estimated at 127 ± 204.4 TND, while the indirect cost was estimated at 21.58 ± 39.07 TND and the patient spend a total cost of about 149.1 ± 212.2 TND. Compared to the guaranteed interprofessional minimum salary, which is set at 378.560 TND, and to the monthly income of the interviewed patients, which varies between 300-600 TND, the total cost of chronic diseases seemed to be enormous and not affordable for most patients.

Conclusions: The Tunisian state should take into consideration the incurred expenses and move towards preventive strategies to decrease the spread of these diseases and thus reduce their costs.

Keywords: Direct costs, indirect costs, non-communicable diseases, COPAQ

Introduction

During the last decades, the prevalence of NCDs such as cancer, diabetes, hypertension, cardiovascular, neurological and respiratory diseases have been increasing in the world[1]. The World Health Organization (WHO) defines chronic diseases as conditions or diseases of long duration that usually progress slowly [2] and that are not caused by infectious agents[3].

According to WHO, the prevalence of NCDs is increasing exponentially with a morbidity rate that reached 57% in 2020, worldwide. Moreover, the NCDs are the leading cause of death in the word and lead to a deterioration of quality of life, which are associated with serious health complications with a disability that is sometimes a cause of socio-professional integration[4]. In Tunisia, 82% of cases of death are related to NCDs which are due to several factors, such as mainly bad eating habits, smoking, sedentary lifestyle and lack of medical follow-up and non-use of early detection[5].

NCDs in Tunisia have a significant impact on the public expenditure budget. Between 2005 and 2013

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the total health expenditures have been multiplied by 2.5 to reach 5362.7 million Dinars MTND according to the national health accounts of the Ministry of Health 2013. The dramatic increase in the number of chronically ill people, the deterioration of their quality of life as well as the increase in associated expenses requires a special attention in terms of public health policies[6].

Assessing the costs of NCDs is an important area of the of health bioeconomics, as this concept takes into account the overall impact of disease on society, which leads to a considerable increase in expenditures on drugs, devices, preventive or curative strategies. In addition, the costs related to consultations, drugs, therapies are increasing every year and are directly linked to inflation[7]. The evaluation of the cost of NCDs becomes a serious socio-economic problem and a proper analysis is necessary if we want to maintain a quality health care system, accessible to all. The treatment of NCDs also generates costs that are sometimes very heavy and constitute a socioeconomic burden for the patients [7].

Very few studies on the costs of care of chronic diseases of patients have been conducted in developing countries and in the Middle East. In Tunisia, the medico-economic evaluation of therapeutics and medical strategies whose management is costly but whose effectiveness is modest becomes essential in NCDs.

Because of the growing prevalence of NCDs in Tunisia and the lack of data, at least recent, of the cost of these diseases, we conducted this present study which aimed to assess the expenditure of Tunisians on health care for NCDs in health centers in the center of the capital of Tunisia, Tunis.

Patients and Methods

Study design, setting and study participant

We conducted a descriptive cross-sectional study. The research included seven BHCs located in center of Tunis, and was conducted over a period between February 3 and March 25, 2022.

Data collection

348 patients who were aged 19 or more, who had one or more NCDs and who declared their agreement to participate in the study were included in the study.

Evaluation of the costs of care

To evaluate the costs of care of NCDs in our patients, we used the COPAQ questionnaire to measure the costs associated with patients' health status[8]. This tool capture out-of-pocket costs of a condition for patients and their caregivers, standardize the way patient costs are collected. This device provides more information such as the costs associated with informal caregivers and could be used to calculate the cost of health interventions.

Statistical analysis

All the collected data were analyzed using SPSS Data Analysis version 19.0.

Findings

Participants' Characteristics (Table 1)

The results showed that the number of women (n=246) with NCDs appeared to be significantly higher than the number of men (n=102) and the sex ratio is 0.41. In addition the patients aged between 54-74 years (64.60%), were the most affected by NCD. In addition, the majority of the patients were married (73%).

We noted also that the number of women who were illiterate (51.62%) was significantly higher than those with high education level. Similarly for men, their education level was low. In addition, 58% of patients were currently unemployed.

The majority of employed patients have a low monthly income: 14.36% have an income less than 300 DNT and 16.37% have an income between 300 and 600 DNT.

Concerning the NCDs: hypertension (69.54%), diabetes (52.01%), dyslipidemia (23.85%) and osteoarthritis (22.12%) were the most common pathologies.

Population-Based Estimates of Caring for People with NCDs

The findings showed that the most of the patients (45.68%) are members of the National Health Insurance Fund (NHIF) and the National Pension and Social Security Fund (NPSSF) and use a NSSF/ NPSSF card (25.86%). However, 20.11% of patients surveyed used a white booklet cards (Table 2).

The expenses related to care (Table 3)

78% of patients surveyed said they spend money on medication. The average cost of purchasing drugs is estimated at 50.28 ± 45.83 TND. 95% of the patients surveyed reported that they were not being reimbursed for the purchase of medicines by the NHIF. The average cost for the purchase of non-reimbursed drugs was estimated at 115.14 ± 83.38 TND.

In addition, 12% of the patients said that they had expenses for home care. The average cost for home care was estimated at 49.29 ± 29.16 TND.

77% of the patients do not spend money on medical devices. The average cost for the purchase of medical devices was estimated at 132.96 ± 206.21 TND.

64% of the patients reported that they have no expenses for medical examinations. The average cost of medical examinations was estimated at 131.06 ±192.02 TND.

According to the current study, the average direct medical costs of patients was 127 ± 204.4 TND, the average indirect medical costs of the patients were 21.58 ± 39.07 TND and the average non-medical costs of the patients were 0.45 ± 1.74 TND.

Concerning the non-medical costs of family caregivers, the average found is 0.028 ±0.20 TND and the average total cost of care for the patients was 149.1 ± 212.2 TND.

Table 1: General population characteristics

Characteristics		%	
Sex	Men	29	
	Women	71	
Age (years)	18-34	0.86	
	35-54	22.37	
	55-74	64.6	
	75-and plus	6.89	
Marital Status	Married	73	
	Single	5	
	Divorced/ Widowed	22	
Education		Women	Men
	Illiterate	51.62	24.61
	Primary / Collegiate/ Secondary degree	43.94	62.73
	Graduate/ Professional degree	4.44	12.48
Employability			
	Employed	15	
	Retired	27	
	Unemployed	58	

Continue table 1.....

Characteristics		%
Monthly income		
	<300 DNT	14.36
	300-600 DNT	16.37
	>600 DNT	11.48
	No income	58
NCDs		
	Hypertension	69.54
	Diabetes	52.01
	Dyslipidemia	23.85
	Osteoarthritis	22.12
	Heart disease	13.21
	Other diseases	22.39

Table 2: Population-Based Estimates of Caring for People with NCDs

	%
Method of payment	
NHIF	45.68
NSSF/NPSSF	25.86
White booklet cards	20.11
Other cards	7.16
Pay the full rate	0.86

Continue .....

Drug purchasing	
Yes	78
No	22
Reimbursement for the purchase of medications	
Yes	4
No	95
Did not remember	1
Expenses for home care	
Yes	12
No	88
Medical devices	
Yes	23
No	77
Medical examinations	
Yes	36
No	64

NHIF: National Health Insurance Fund

NSSF: National Social Security Fund

NPSSF: National Pension and Social Security Fund

Table 3: The expenses related to care expressed in Tunisian dinars

	Costs
Purchasing drugs	50.28 ± 45.83 TND
Purchasing of non-reimbursed drugs	115.14 ± 83.38 TND
Home care	49.29 ± 29.16 TND
Purchasing of medical devices	132.96 ± 206.21 TND
Medical examinations	131.06 ±192.02 TND
Direct medical costs of patients	127 ± 204.4 TND
Indirect medical costs of patients	21.58 ± 39.07 TND
Non-medical costs of the patients	0.45 ± 1.74 TND
Non-medical costs of family caregivers	0.45 ± 1.74 TND
Total cost of care for the patients	149.1 ± 212.2 TND

Discussion

The present study was carried out in 348 patients distributed in 7 BHCs, in the greater Tunis area. 71% of them were women versus 29% men, i.e. a sex ratio of 0.41.This suggests that NCDs develop preferentially in women. In the same vein; the study conducted by Miszkurka *et al.*[9] showed that NCDs affect women more than men. This female predominance can be explained by physiological differences between women and men. In this context, research has shown a link between lack of activity (housewives) and certain NCDs, in particular cardiovascular diseases and cancers. Similarly, a recent study has shown that the significant reduction in sleep time, which affects women more than men, increases the risk of NCDs [10].

The findings of this study showed that patients with an age range between 55 and 74 years are the most affected with a percentage of 64.6%. The same results were highlighted by Zedini *et al.*[11]. These results could be attributed to the ageing process, which represents a major current event and a worrying phenomenon and is directly correlated with polymorbidity[12]. In fact, it has been found that patients aged 85 years or more are concerned by chronic pluripathiologies [13].

A high number of our patients were illiterate or with a low level of education. In addition, the population was characterized by a high proportion of "no occupation" (58%). In fact, the reduced level of education may be an important causal factor in the occurrence of NCDs, due to lack of prevention. Indeed, the education awareness with a preventive purpose decreases the risk of NCDs and improves the diagnosis[13].

In terms of diagnosed morbidity, the study showed that hypertension (69.54%), diabetes (52.01%), osteoarticular diseases (22.12%), dyslipidemia (23.85%) and cardiopathies (13.21%) leaded the list. Indeed, arterial hypertension is a common disease encountered in the first line. Several studies have noted a prevalence of hypertension ranging from 12% to 50%[14, 15]. This high prevalence could be explained by the ageing of the arterial wall or atherosclerosis, which is characterized by the replacement of elastic fibers by collagen. This structural modification leads to an increase in the stiffness of the arteries and results in an increase in systolic blood pressure and

a decrease in diastolic blood pressure. In this same investigation framework, Zedini *et al.* [11] reported a predominance of cardiovascular, respiratory, osteoarticular diseases with a statistically significant difference for the female sex. Similarly, the reports published by Nylenna [16] and Aylin *et al.* [17] have highlighted similar results, namely that these same diseases are among the top five in terms of morbidity.

Regarding the costs spent on NCDs management, the COPAQ model, a comprehensive tool for measuring the direct and indirect costs of a health condition for patients and their families in various outpatient contexts, showed that the total cost recorded in the present study corresponded to 149.1 ± 212.2 TND. As a reminder, the current guaranteed minimum wage in Tunisia (CGMW) is fixed at 378.560 TND; the total cost of NCDs seems enormous, 39.5% of the CGMW. Moreover, most of the interviewed patients (16.37%) who are professionally active stated that their monthly income is between 300-600 TND. Most of the retired persons (14.36%) reported that their pension is less than 300 TND. In the context of these data, the costs generated by chronic diseases seem to be beyond the means of most patients.

Our study is the first which have addressed the direct and indirect costs of NCDs in the greater Tunis area. There are no similar studies in the literature. However, it is known that these diseases generate enormous costs for the patient and the state. Indeed, the high rates of NCDs create cost challenges for public health and health care systems [18]. Worldwide, this socio-economic problem concerns both developed and less developed countries that dedicate a significant part of their budget to the treatment of chronic diseases[18].

It has been reported in European Union (EU) countries that the costs of NCDs would weigh heavily on their annual budgets [30]. These diseases cost the EU states more than 115 billion euro per year, or 0.8% of the gross domestic product (GDP) [18]. The economic burden of NCDs is increasing and is expected to be continued in the future, especially in less developed economies and among the poor in middle- and high-income countries [18].

The same report showed that health care expenditure in the EU was estimated at 9.9% of GDP in 2015. Some countries such as Germany, Sweden and France spend 11% of their GDP on health care, while the Netherlands and Denmark allocate10.8% and 10.6% respectively. In addition, EU countries spend 3% of their health budget on prevention campaigns[18].

Like other countries, Tunisia incurs considerable costs for the prevention, diagnosis and treatment of NCDs. These health expenditures have increased significantly over the last two decades to cope with NCDs [19]. According to the report of the Ministry of Health published in 2016, concerning the period from 2005 to 2013, the total health expenditures have been multiplied by 2.4, which made their cost increase from 2247.3 to 5362.7 MTND. Despite the remarkable progress made in extending the coverage of social protection mechanisms for health, the Tunisian healthcare system is still largely financed by direct payments from patients.

According to the survey, 45.68% of patients are members of the NHIF and use their booklet for care in the CSBs. 25.86% of patients use a NSSF or a NPSSF card. The NHIF ensures the care of patients with NCDs. Considering that these coverages are fully covered by the NHIF; they represent a huge financial burden and a significant challenge for the fund, according to the national health insurance fund report, (2018). In the end, the economic burdens of chronic diseases are heavy for most developed or developing countries [19].

Conclusion

In conclusion, this study allowed us to quantify the direct and indirect costs related to NCDs in Tunisia, in order to have an estimation of the impact of NCDs on the financial and psychological state of the patients. The results of the survey, which confirm the importance of the challenge of prevention, early detection and treatment of disease, could guide the state to health policy decisions.

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Conflicts of interest: There are no conflicts of interest.

Ethical Clearance: Ethical clearance of the current study was obtained from Institutinal Ethical Commitee of the Institute of Nutrition and Food Technology of Tunis.

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Awareness about Sickle Cell Disease among the Female Students in KAU-Rabigh, Saudi Arabia, 2020, A Cross Sectional Study

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Abstract

Background: In Saudi Arabia, Sickle cell disease (SCD) is a relatively common inherited disorder. In spite ofobligatorypremarital genetic counseling, no significant changes in SCD prevalence over the last 15 years. Awareness regarding SCD is a way in trying of controlling and modify the problem. The aimis to assess the level of awareness about people living with SCD among undergraduate female Students at King Abdulaziz University, Rabigh Branch.

Methods: A total of 351 female students were included in our cross-sectional study. Data were collected by a self-administered questionnaire.

Results: Good awareness regarding SCD was detected only in 26.78% of the participants. Association between awareness and socioeconomic data detected that most of the students with good awareness were unmarried (97.9%), a higher level of awareness was in the medical students (51.1%), and in the higher academic years (59.5% were in fifth and fourth years).

Conclusion: There was inadequate awareness of SCD, to reduce the incidence, we suggest effective public health education for sickle cell trait and SCD in strategic places such as schools, media,and health centers to address misconceptions and increase knowledge as well as an understanding of the risks of having a child with SCD and influence the personal reproductive decision.

Keywords: Sickle cell disease, Inheritance, female Students, Rabigh.

Introduction

Sickle cell disease (SCD) is an inherited autosomal recessive blood disorder[1], and it is associated with several life-threatening complications [1,2,3]. SCD is one of the most common monogenic diseases in the world, with more than 300,000 babies born with SCD every year [3,4].In Saudi Arabia, SCD is a relatively common genetic disorder. Up to 27% of the Saudi population have the sickle cell trait (SCT), with 2.6%–

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4.2% of which being manifested as SCD[2,5,6]. Despite, the implementation of obligatory premarital genetic counseling (PMGC), no significant changes in SCD prevalence in Saudi Arabia over the last 15 years as documented by many researchers[1, 7, 8, 9]. Moreover, the lack of KAP concerning SCD results in an increase in the disease prevalence and a poor quality of life among the diseased persons [1, 2, 7, 8, 9].

Different previous studies detected variable levels of awareness about SCD. In Saudi Arabia, Al-Qattan's study[10] detected good awareness only among 28.8% of the participant (general Saudi population in King Khalid University Hospital), while El-Hamzi's study [11] detected good awareness among 94.3% of participants who were attendees of conferences, symposia, and awareness lectures. Studies outside Saudi Arabia detected good levels of awareness among 93%, 96%, 17.8%, and 96% of the participant in Bahrain [12], Oman[13], Nigeria[1], and Sudan[14] respectively.

Nowadays, SCD is considered one of the major unspoken matters Facing Saudi Arabia. Even with the developments in public healthcare procedures, still many gaps to be filled concerning the knowledge, attitude, and practice of SCD[2,10]. Awareness regarding SCD is a way in trying of controlling and modifying the problem since society will be better prepared to take an informed decision regarding their marriage and the youths are a good entry point for interventions in a trial of controlling the prevalence of the disease [15].

The objective of this study is to assess the level of awareness and knowledge about people living with SCD among undergraduate female Students at King Abdulaziz University Rabigh Branch.

Materials and Methods

Study design

across-sectional study was conducted in between October 2020 and December 2021at King Abdulaziz University, Rabigh Branch, Female section, Saudia Arabia.

Sample size determination (Include power calculations or provide justification for their absence (pilot/feasibility study):

It was calculated by the sample size equation, the prevalence of good awareness about SCD in SA was approximately 29% [11], with a significance level of α=0.05.

The minimum required sample was 316 and we will approximate it to 350 to cover the response rate and the pilot study (10% of the sample size will be calculated for the pilot study and will be excluded from the final study result) to represent a population of students enrolled at colleges at King Abdul-Aziz University calculated by the equation:

$$X = (Z^{1-\alpha/2})^2 * p*(1-p) / d^2$$

Z1-a/2 = Is standard normal variate (at 5% type 1 error (P<0.05) it is 1.96 and at 1% type 1 error (P<0.01) it is 2.58). As in the majority of studies, P values are considered significant below 0.05hence 1.96 is used in the formula.

p = Expected proportion in population based on previous studies or pilot studies.

d = Absolute error or precision – This has to be decided bythe researcher.

SS= (3.841) *0.29* (0.71) / (0.0025)

Pilot study

Was carried out on 10% over a period of 15 days to test the applicability of the questionnaire. This pilot sample was excluded from the study analysis.

Sampling procedure

The randomizedsample was selected over 3 to 4 months in two stages, the first one did by the proportional allocation to choose a proportional number of students from different colleges. The second stage was performed by a systematic random technique to choose the students from the administration lists in each college included in the study.

Statistical methods and Data management:

We used a self-constructed questionnaire based on previous similar studies[15, 16]. The questionnaire was validated by experts and by a pilotstudy. Data were analyzed using:SPSSversion 24. The collected data wascoded, described, and cleaned, and quantitative data were described by means and

StanderDeviation (SD). Qualitative variables were described by proportions and Chi-Square. Regression models may be used for multivariable analysis.

Confidentiality:

Data wereanonymized once it has been collected. The original list of participants,all field assistant was trained in matters of confidentiality and had access to primary data only when necessary

Ethical Approval

This study was approved by the Unit of Biomedical Ethics and Research Committee**,** King AbdulazizUniversity with **Reference No 479-20.**

Data Analysis

Fifteen variables on the research questionnaire were analyzed to evaluate participants' awareness aboutSCD including source of information about SCD, etiology, role of consanguinity, modes of inheritance, component of blood affected by SCD,signs and symptoms, diagnosis, treatmentand methods of prevention. One mark was given for every question answered correctly while zero was given for each questionincorrectly answered or unanswered. Students correctly answered all the fifteen questions about SCD awareness were scored as 100%. Students who scored 50% and more were considered as having good or adequate awareness, while students scored lessthan 50% were considered as having bad or inadequate awareness.

Results

Our sample is Female university students only (351 students). 325 (92.6%) were singles. majority of age were 20 years The majority of participants(59.8%) study at the Scientific College, 53.3% are living in Jeddah.

297(84.6%) did not have any chronic diseases, about the sickle cell status the majority are not patients or have a patient from their family with314(89.5%) , 6(1.7%) were patient, 31(8.8%) have family member effected. The main source of knowledge about SCD from health professional community meetings which was about136 (38.7%)

A total of 244(69.5%) were aware that sickle cell is not a contagious disease, when asked about their opinion in what is the cause of sickle cell most of them agreed that it's inherited 271(77.2%), about the type of the of genetic disorder the sickle cell is 48(13.7%), 162(46.2%), 141(40.2%) chose autosomal dominant, autosomal recessive, don't know respectively, when asked about does consanguinity increase the risk of SCD 68.7% chose yes.

Minority of the participants who have the correct information about chances of sickle-cell disease in a child if both parents are carriers. Only 115(32.8%) of the participants had correct information in chance of getting a healthy baby with all parents have SCD. Most of the participants 242(68.9%) have a good awareness about that red blood cells are the component of blood that is affected in patients with sickle cell anemia.

51% of the participants answered about the signs and symptoms that comes with SCD is yellow eyes, 77.8% answered that SCD diagnosed by blood test which are the right answers

45.9% of the participants didn't know if SCD is curable or not.

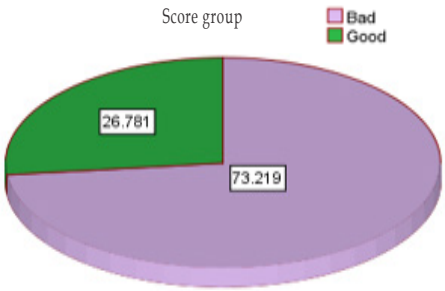
72.9% of the participants answered that can prevent SCD through genetic counseling, and 14.5% by testing before marriage. 61.5% of the participants answered the medications are herbal medicines and 2.6% by folic acid and blood transfusion. 44.4% of the participants answered can take any medicine and 8% there is a contraindication.

We found in our studythat marital status was statistically significant with the awareness about SCD, and the academic level also was statistically significant. Out of the participants who had good knowledge of SCD, 55.3% were residents of Jeddah, while 44.7% lived in other cities ($p= 0.66>0.05$).72.3% of the participants who had good knowledge of SCD were relatively low income. 89.1% of the participants not patient, with bad knowledge and the SCD status was statistically nonsignificant ($p>0.05$)

However, both residence, monthly income, and SCD status were statistically no nonsignificant $P > 0.05$).The majority heard about SCD 73.5% with bad knowledge, and this was statistically significant ($p<0.05$).The sample selected was all female college students (n=351). 59.8% of participants went to scientific college.83.8% of the participants reported

not having any chronic disease, and 92% reported not having any genetic disorders.

Of all the participants, only 26.7% had good knowledge of sickle cell. **Figure.1**



Only, 26.78% of the participats have good awareness regarding sickle cell disease.

Discussion

The present study aimed to assess the level of awareness about SCD among undergraduate female Students at King AbdulAziz University, Rabigh Branch. A total of 351 students were answered a self-administered questionnaire. Data analysis revealed that only 26.7% of the students had good awareness about SCD. This level of awareness were closely similar to a study held in Saudia at King Khalid University by Al-Qattan etal[11], who detected good knowledge among 28.8% of the participant. Similar level of awareness were also detected in closely related studies in Sudan (26.9%) [14] And in Nigeria (17.8%)[1]. But in contrast to our study higher levels of awareness were detected in other studies in Saudi Arabia (94.3%) [11], Bahrain(93%)[12], and Oman (96%) [13].

Explanation of large difference in the level of Knowledge between our study (26.7%) and El-Hazmi's study (94.3%)[11]. Despite both were in Saudi Arabia, is due to the participants of El-Hamzi's studies were health educated with awareness lectures, conferences and symposia, while our participants were young students. This also explained similar level of awareness (28.8%) in Al-Qattan etal[11] to our results, because their participant were people from the general Saudi community.

In our study, despite the fact that many of our participant heard about SCD (78.9%), and knew that SCD is an inheritance disease (77.2%) but unfortunately only few knew about mode of inheritance, manifestation of the disease, role of premarital counselling in disease prevention and 61.5% thought that SCD may be treated with herbal. This explained because only 38.7% obtained their knowledge from health professional community meetings, while many of them receive their knowledge from friends and internet. Similar observations were detected by Al-Qattan etal[11], who recorded that only 10% the participants got their awareness of Premarital genetic counseling clinic from healthcare workers. They stated that reason of bad SCD awarenessbetween the Saudi peoples is not only a shortage in seeking awareness butalso a shortage in receiving awareness from healthcare workers. However, WHO recommends that special genetic counseling facilities and carrier detection tests be offered at special centers located in regions where Hb disorders are common[1]. In our study and other related one [1]no respondents indicated screening/ counseling facilities as sources of information about SCD.

Similar to our finding that most (78.9%) of the participant heard about SCD, which is the result of more awareness about it in the last few years, Durotoyeetal[17], reported that 79.5% of their participants had heard about SCD this is possible due to the selected sample of university students only similar to our study.

77.2% of the participants agreed that the SCD is inherited and most of the participants 68.9% know that red blood cells are the component of blood that is affected, 77.8% answered the SCD is diagnosed by a blood test this is also the same as what was found by a Nigerian study published in 2016, 96.4% of participants were aware that SCD is an inherited disease; 93.9% were aware that SCD affects the red blood cells and can be diagnosed through a blood test [15].

Similarly in this research and previous Nigerian study [15] found the students from the faculty of medicine had significantly more adequate knowledge than students from other faculties. Association between knowledge and faculty was highly significant (p=0.00). Moreover, data analysis, showed association of awareness with academic level with the higher level of awareness detected in fifth years

(30.8%) and the lowest level was in first academic year(93.2%). The association between knowledge and the academic level was significant (p=0.02)

In our study, the participants were mostly unmarried young adults between 20 and 30 years, which made them ideal for studying SCD knowledge, as also suggested by previous related studies [15,18,19]. We found that good awareness was found mostly in unmarried (97.9%) with significant association (p=0.00) between awareness and marital status. But in contrast to our,Adewoyinetal[1] found that good knowledge about SCD was more in older and married participants, this is due to the fact thatunmarried people, did not move to the stage of marriage and the responsibility to know about genetic diseases. This is attributed that advancing age and marriage entails greater societal responsibility [1].

In spite of that, we support more related studies to be conducted in young unmarried due to the fact that the good knowledge of the disease will allow them to make informed decisions concerning their marriage so as to avoid having children affected by SCD.

Strength

Our research adds to the limited literature in the King Abdulaziz university's Rabigh branch

Limitations

This particular study targeted only female university students, so it restricted the sample.

Conclusion

There was inadequate awareness of SCD particularly on the pattern of inheritance. To reduce the incidence of SCD, we suggest effective public health education for SCT and SCD in strategic places such as schools, media (radio/Television), and healthcenters to address misconceptions and increase knowledge as well as understanding of the risks of having a child with SCD and influence personal reproductive decision.

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Original Artical

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Contraception Awareness and its Practise among Working Women in Institutions in North Karnataka: An Observational Survey

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Abstract

Introduction: Contraceptive choice is a critical component of women's reproductive health and rights. In contrast the social and economic correlates of contraceptive use are less well understood, particularly in low and middles income countries, where contraceptive use if often assessed in the contest of maternal and child health interventions.

Objectives: To study the Awareness about the contraceptive methods, to understand the practice of contraception regarding contraception & to find the Myths and Taboos regarding contraception among working population.

Methodology: This study was conducted among all working women belonging to the age group of 20-49 years in northern district of Karnataka state, using a pre-validated questionnaire which was used to assess the awareness and practices of contraception among working women.

Results: Among the total 2000 women taken into the study only 1409 participants participated in the study from that we observed that majority of them around 81.3% participants belonged to rural area, with 50.8% having a minimum graduate educational qualification & belonged to the age group of 20-29 years. They were aware of many factors about contraception such as the facilities where is it available the pros and cons associated with it but the association of disturbed cycles, its affectability to future pregnancy and weight gain were not known. Most of the women who practiced contraception commonly used condoms followed by permanent method of sterilization. Many women and their partners have the belief that contraception is associated with various side effects and hence they step back from using the various methods of contraception available to them.

Conclusion: the working women had awareness regarding the facilities where they could approach for contraception, the advantage of preventing sexually transmitted diseases and so on. But they needed better education of the various types of methods of contraception available to them and the best option they can choose.

Keywords: awareness, contraception, practice, working women.

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Introduction

Contraception is a key component of sustainable development, empowering women, reducing the risk of maternal and child mortality, and promoting economic growth. Ensuring universal access to sexual and reproductive health and reproductive rights for all women is Target 5.6 of the Sustainable Development Goals, promoted by the United Nations and adopted by 193 countries. A nationally representative study found that India's demand for family planning satisfied (DFPS) with modern contraceptive methods was 70% in 2005, with heavy reliance on female sterilization rather than reversible contraceptive methods.[1,2]

Family planning policies in India have historically been aimed at controlling population growth rather than advancing women's reproductive rights and choices. By allowing people to achieve their wishes regarding the number and spacing of children, contraception can reduce abortions, reduce the risk of maternal and child mortality, and promote economic growth and women's empowerment. [2]

Understanding of the relationship between contraception and employment at these more granular levels in India is very limited. India is an important context in which to examine this issue, owing to a unique, sterilization-skewed contraceptive method mix, low and stagnant female labour force participation and widespread gender inequalities. Contraceptive use among married women aged 15–49 in India declined by 7 percentage points between 2005–06 and 2015–16 (from 64% to 57%), with female sterilization comprising more than 60% of current use, and long-acting reversible contraceptives (e.g., intrauterine devices, injectables) comprising 4% of current use.[4]

Contraceptive choice is a critical component of women's reproductive health and rights. The health benefits of contraceptive use for women and their children are well documented, and include reduction of unintended pregnancies, pregnancy-related morbidity and mortality, delayed age at first birth among young women, and lengthened birth intervals. In contrast, the social and economic correlates of contraceptive use are less well understood, particularly in low- and middle-income countries, where contraceptive use is often assessed in the context of maternal and child health interventions. [1-4]

Methodology

This cross-sectional study was conducted by using a pre-structured and pre-validated questionnaire. Interview was done in person and through google forms in various parts of Vijayapura city located in northern district Karnataka for women working in various institutional settings and the responses were tabulated and analysed. With 95% confidence level and margin of error of ±5% and anticipated the percentage of adequate knowledge regarding contraceptive use among working women, a sample size of minimum 396 women by using the formula: $n=z^2p(1-p)/d2$ where Z= z statistic at 5% level of significance, d is margin of error 10%, p is the percentage of adequate knowledge regarding contraceptive knowledge (50%). All working women belonging in the age group of 20-49 years were enrolled in the study and those not willing to participate were excluded. Institutional Ethics Committee approval and informed consent from the participants were obtained before the start of the study.

Results

A total of 2000 working women were enrolled into the study but 591 were not willing to participate for the questionnaire nor the google form, hence the study was conducted with 1409 participants.

Table 1: Socio-demographic profile of the participants

Variables	Groups	frequency	Percentage
Education	Degree	242	15.4
	Graduate	800	50.8
	High school	72	4.6
	Intermediate	76	4.8
	Not literate	102	6.5
	Primary school	117	7.4

Continue.....

Occupation	Class IV worker	268	17.0
	Clerical staff	52	3.3
	Collage teacher	65	4.1
	Doctor	182	11.6
	Engineer	63	4.0
	IT professional	533	33.9
	Other	83	5.3
	Para medical staff	163	10.4
Type of family	Joint family	574	36.5
	Nuclear family	835	53.0
Marital status	Divorced	11	0.7
	Live-In Relationship	34	2.2
	Married	894	56.8
	Separated	18	1.1
	Unmarried	397	25.2
	Widow	55	3.5
Area	Rural	130	8.3
	Urban	1279	81.3
Religion	Christian	143	9.1
	Hindu	1060	67.3
	Muslim	157	10.0
	Other	49	3.1
Partner education	Degree	135	8.6
	Graduate and above	505	32.1
	High School	95	6.0
	Intermediate	83	5.3
	Not Applicable	441	28.0
	Not Literate	63	4.0
	Primary School	87	5.5
Partner education	Class IV worker	123	7.8
	Clerical Staff	61	3.9
	College Teacher	72	4.6
	Doctor	129	8.2
	Engineer	152	9.7
	IT Professional	109	6.9
	Not Applicable	460	29.2
	Other	254	16.1
	Para Medical Staff	35	2.2
	School Teacher	14	0.9

The source of information about contraception, 555 participants said it was through formal education, 778 participants said it was through friends/relatives, 454 participants said it was through internet, 246 participants said it was through social media.

Participants were questioned whether they are using any contraceptive methods at present, and 688 participants are currently not using contraceptive methods and 466 are using it. Among 466 participants decision of following contraception was mutual in

335, selected by partner in 28 and self in 103.Method of contraception was mutually selected by 299, by partner in 68 and self in 99.

Out of 466 participants using contraception at present, the most used method is condoms by 275 people followed by sterilization 116, Copper-T 107, calendar method 102, OCP 77, Injectable 20 participants. 9 participants felt Use of contraception is affecting job and 32 felt using contraception is financial burden. When questioned about use of contraception in past 44.4 % of people used it in past and condoms (26.9%) was most used method. 47.8% of people are aware of emergency contraception and commonly known method is emergency pills. 77.4% of participants are willing to recommend use of contraception to others.

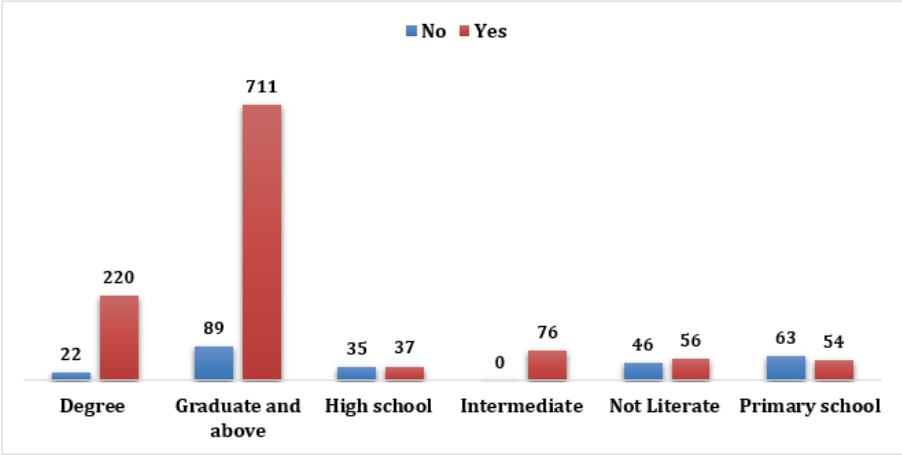

Figure 1: Bar diagram showing educational status in relation to contraception.

According to our study, we have observed that majority of the participants belonged to the age group of 20-24 years constituting 38% and 25-29 years constituting 37% of the total participants taken into the study and the age of awareness regarding contraception among the participants was between 20-29 years constituting 47% (Fig-1).

For educational status in relation to contraception majority of the participants were educated with a minimum education of degree, graduate and above with a significant p-value < 0.0001 hence proving us that educational status of the women and the partner has a direct relation to the knowledge and awareness about contraception and the methods available. Most of the working women had a minimum education of graduate and above constituting 711 women who took part in the study.

Table 2: Occupation in relation to contraception

Occupation	Awareness of contraception		Total	Chi – square test
	No	Yes		
Class IV worker	119	149	268	
Clerical Staff	21	31	52	x^2= 228.351
College Teacher	07	58	65	
Doctor	00	182	182	
Engineer	15	48	63	P < 0.0001
IT Professional	67	466	533	(significant)
Other	22	61	83	
Para Medical Staff	04	159	163	
Total	255	1154	1409	

For occupation in relation to contraception most of our participants belonged to IT professional which constituted 466 women followed by paramedical which was 466 women and medical profession around 182 women followed by class 4th worker which constituted 149 women, with a significant p value of <0.0001 (Table 2).

Table 3: Participants awareness about contraception use

Variables	Groups	Frequency	Percentage
Facilities	No	75	5.3
	Yes	1079	76.6
Prevents STDs	No	162	11.5
	Yes	992	70.4
Weight gain	No	470	33.4
	Yes	684	48.5
Disturbed cycle	No	555	39.4
	Yes	599	42.5
Spacing	No	233	16.5
	Yes	921	65.4
Affectability to pregnant	No	709	50.3
	Yes	445	31.6

Majority of the women were aware of many factors about contraception such as the facilities where is it available the pros and cons associated with it but the association of disturbed cycles, its affectability to future pregnancy and weight gain were not known to many hence, proper education about contraception, its types and methods and the pros and cons are needed to be educated to these women (Table-3).

The major reason for not using contraception in majority of the participants were desirous to have children followed by majority of the participants being unmarried and career oriented and the misconception about the side effects and no mutual agreeing on the contraception among partners. According to our data collected majority of the participants are still not aware about the various options or methods of contraception available to them and the misconception about the side effects of using contraception has a major role as to why partners don't prefer contraception. Hence education the women and their partners regarding the various methods and the advantages of the various methods will remove the social stigma that has been associated with contraception's.

Discussion

Findings from our study showed that the awareness regarding the use of contraception depends majorly on the socio-demographic profile of the country and the geographical area of the state. From our study we have observed that the educational status of the women played a major role on the impact of the awareness and the method of contraception being used. We have noticed that there was substantial variation in the relationship between contraceptive use and employment, based on the type of contraception used and the sector of employment.

This study also helped us to identify the ways women meet their need for family planning. According to our study majority of the women practised the use of modern contraception being the use of condoms by 275 women followed by female sterilization for family completed women which was 116, followed using IUCDs in 107 women followed by calendar method by 102 women, OCPs by 77 women, injectables by 20 women. When these women were questioned about their past contraceptive use, 44.4% of the women used contraception and barrier contraception was highest used among that. Another interesting fact we noticed from our study is that many working women had the use of contraception affecting their job and many felt using contraception is a financial burden.

According to Fernanda Ewerling et al [1] in their study, one of many benefits of contraception is that women's control over their own reproduction may enable participation in the labour market [8,9,10]. However, in India, contraception was historically used for reproductive completion, rather than reproductive control. In line with the general population in India, contraceptive use in this sample was dominated by female sterilization [11,12]. Changing this deep-seeded cultural norm is an ongoing process, and there are clearly populations that require additional attention and support.

According to Lotus McDougal et al [2] in their study, efforts to expand the method mix to include long-acting, reversible contraceptives are leaving important populations of women behind, and need additional targeted support. The variable associations between types of current contraceptive use and

employment by sector seen in this analysis emphasize what a complex interplay is at work. The most stark contrast, between women employed in professional vs. agricultural and production sectors, suggests that even after accounting for differential levels of social and gender equity, women who were sterilized or relied on traditional contraceptives were more likely to be employed in the agricultural or production sectors, and women using long-acting, reversible contraception, which overall has low prevalence of usage in India, were more likely to be employed in the professional sector.

Limitations of the study: Information about the use of modern contraceptives was self-reported by women, and this information could be skewed if interviewer bias or social desirability affected the estimates. However, in some cases the presence of a family member during the interview could still affect responses, especially among young women and those from highly conservative countries.

Conclusion

From our study we could conclude that most of the working women had awareness regarding the facilities where they could approach for contraception, the advantage of preventing sexually transmitted diseases and so on. But they needed better education of the various types of methods of contraception available to them and the best option they can choose.

Ethical clearance: Taken.

Financial support: Nil

Conflict of Interest: Nil

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Original article

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Obstacles and Challenges in Gaining Access to Family Planning Services in Covid Era: A Cross-Sectional Descriptive Study

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Abstract

Introduction: Although WHO recommended continuing sexual and reproductive health services during COVID-19 pandemic, the services were either stopped completely or limited. Hence our study aims to determine the challenges in the accessibility to family planning services as well as the impact on contraception and safe abortion services during COVID-19 era.

Methods: This is a cross-sectional descriptive study conducted in the department of Obstetrics & Gynaecology, SRM hospital, Chennai from September 2021 to November 2021. Random sampling method was used to enroll participants after considering the inclusion and exclusion criteria.

Results: Almost half of the study population (49.24%) faced difficulty in following any form of contraceptive measure amid pandemic. Non-availability of contraceptive supply (14.72%) was the major hurdle during the pandemic. Among the respondents who had terminated the pregnancy, the majority had done by general medical practitioner (66.67%) while only thirty-three percent terminated under specialist care. While comparing the complications during pregnancy termination, general medical practitioner approach led to more complications than specialist care.

Conclusion: Non-availability of contraceptive supplies, FP services amid COVID-19 pandemic has exerted detrimental impact on the women reproductive health. Continuing FP and safe abortion services are essential during pandemic to sustain the success of high-quality reproductive services.

Keywords: Abortion, Contraception, COVID-19 pandemic, Family planning, Unwanted pregnancy

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Introduction

The Coronavirus disease first started as an epidemic in China became the fastest growing public health pandemic of the century in due short course of time.[1] Since its onset, the debilitating impacts of coronavirus on health infrastructure have been documented globally which have exerted unequal health burdens among various populaces. As a preventive strategy, social distancing was adopted worldwide in order to control COVID-19 transmission which ultimately led to the implementation of partial or complete lockdown. This has hindered the accessibility to the contraceptive and safe abortion services along with contraceptive usages resulting in 2.7 million unintended pregnancies in the first year. [2] The upsurge in unwanted pregnancies, unsafe abortions and associated complications [3] thereby threatened the onerous progress on the contraceptive coverage targets defined by the Sustainable Development Goals (SDGs).[2]

Although World Health Organizations (WHO) has recommended the continuation of sexual and reproductive health services including family planning amid COVID-19 pandemic,[4] the routine reproductive health services were hindered due to the shift in the point of health care services towards COVID-19 patient management. Also non-compliance of patients due to COVID-19 fear, lack of clinical resources allocation, transportation as well as economical issues led to the decline in the uptake of reproductive health services contributing in the rise of unintended pregnancies and unsafe abortions. This forms the rationale for the healthcare professionals to actively implement reproductive healthcare services for women. Providing access to the reproductive health services via clinical resource allocation at the community level including contraception provision is the key to mitigate COVID-19 comprehensively along with high-quality family planning services. This will not only reduce the maternal morbidity and mortality, it will also improve newborn and child health.[5] Continuing safe abortion and family planning services during pandemic has been evidently challenging. Also, there are dearth of studies which specifically investigated the COVID-19 impact as a stress on reproductive health care services. Hence our study aims to determine the challenges in the accessibility to family planning services as well as the impact on contraception and safe abortion services during COVID-19 era.

Methods

This was a cross-sectional descriptive study conducted in the outpatient clinic of Obstetrics & Gynaecology, SRM medical hospital, Chennai for duration of 3 months (September 2021 to November 2021). Random sampling method was used to enroll participants. Every consecutive participant in the reproductive age group (18-45 years), willing to participate and are sexually active visiting outpatient clinic for various medical conditions were included after obtaining written informed consent. Women with psychiatric disorders or who are mentally challenged, those who already underwent permanent sterilization and who are not willing to participate were excluded. The ethical approval has been received from the institutional scientific committee. (Reference number- 2996/IEC/2021)

A semi-structured questionnaire containing questions regarding sociodemographic characteristics, awareness on contraception use, difficulties in gaining family planning and contraception access, reasons for avoiding contraception during COVID-19 pandemic and its outcome was formed after extensive review of literature.[4, 6, 7] The questionnaire was validated by the Gynecologists and pilot study was conducted prior to the commencement of the study to improve the clarity of the questionnaire.

The data was entered in the Microsoft excel sheet and the statistical analysis was performed by using SPSS version 20 statistical software. Mean as well as standard deviation was used for continuous data. For categorical data percentage was calculated. Chi square test was used to analyze the association of complications during pregnancy termination with age group, parity, method of termination and difficulty in accessing medical facility during covid time for pregnancy termination. The p value less than 0.05 was considered statistically significant.

Result and discussion

A total of 197 women participated in the study within the reproductive age group of 18-45 years. The mean age of the respondents was 26.27 years with predominant age group of 21-30 years (81.7%) (Table 1).

Table 1. Age of the respondents (years)

Age groups (Mean- 26.27, standard deviation- 4.190, Median- 26.00, Standard error of mean- 0.299)	No. (%) of respondents
< 20 years	11 (5.6)
21-30 years	161 (81.7)
> 30 years	25 (12.6)

Among the respondents, twenty-five percent were primi parity and seventy-five percent were multi-parity (Table 2). Majority of the respondents were reported to have contraception knowledge (96.95%) and seventy-five percent respondents were using various contraception methods. Among the contraceptive users, barrier method was the majorly used contraception measure (36.04%). During COVID-19 era, almost half of the study population (49.24%) faced difficulty in following any form of contraceptive measure. Non-availability of contraceptive supply was the major hurdle in following contraception during COVID-19 era (16.75%). Among the respondents with unplanned pregnancy, thirty-six percent continued the pregnancy and fourteen percent terminated the pregnancy. Non-availability of family planning (FP) services was the predominant reason for continuing pregnancy (70%). Among the respondents who had terminated the pregnancy, majority had done by approaching general medical practitioner (66.67%) while only thirty-three percent terminated under specialist care. The respondents who had approached general medical practitioner, difficulty in consultation with the specialist was the major reason (94.44%). However, only six percent of the respondents reported COVID-19 fear as the most probable reason. Respondents who had terminated their pregnancy, majority faced medical complications during pregnancy termination (55.56%) due to difficulty in accessing medical facility regarding pregnancy termination (55.56%).

Table 2. Contraceptive and family planning services implementation challenges reported by the respondents

Challenges	Sub-group	No. (%) of respondents
Parity	Primi	49 (24.87)
	Multi	148 (75.13)
Contraception knowledge	Yes	191 (96.95)
	No	6 (3.05)
Current contraception	Yes	148 (75.13)
	No	49 (24.87)
Methods used	Natural	34 (17.26)
	Barrier	71 (36.04)
	Hormonal Injection	8 (4.06)
	Hormonal pills	30 (15.23)
	IUCD*	5 (2.54)
	Not applicable	49 (24.87)
Difficulty in contraception	Yes	97 (49.24)
	No	42 (21.32)
	Not applicable	58 (29.44)
Type of difficulty	Consulting specialist	25 (12.69)
	COVID fear	15 (7.61)
	Non availability	33 (16.75)
	Transport	29 (14.72)
	Not applicable	95 (48.22)

Continue.....

Unplanned pregnancy	Yes	97 (49.24)
	No	100 (50.76)
Pregnancy continuation and termination (n=97)	Continued	70 (35.53)
	Terminated	27 (13.71)
	No pregnancy	100 (50.76)
Reason for continuing pregnancy (n=70)	Diagnostic delay	16 (22.86)
	Family pressure	5 (7.14)
	Non-availability of FP* services	49 (70.00)
Pregnancy termination method (n=27)	Gynecologist	9 (33.33)
	General medical practitioner	18 (66.67)
Reason for General Medical Practitioner (n=18)	Consulting specialist	17 (94.44)
	COVID fear	1 (5.56)
Complication in pregnancy termination (n=27)	Yes	15 (55.56)
	No	12 (44.44)
Difficulty in accessing medical facility for pregnancy termination (n=27)	Yes	15 (55.56)
	No	12 (44.44)

FP- Family planning, IUCD- Intrauterine Contraceptive Device

Table 3: Comparison between pregnancy termination method approached and associated medical complications with Chi-Square test

How pregnancy terminated	**Complications in pregnancy termination**		**Total**
	No	**Yes**	
Gynecologist	8	1	9
General medical practitioner	4	14	18
Total	12	15	27

	Value	**df**	**Asymp. Sig. (2-sided)**	**Exact Sig. (2-sided)**	**Exact Sig. (1-sided)**
Pearson Chi-Square	10.800[a]	1	.001		
Continuity Correction[b]	8.269	1	.004		
Likelihood Ratio	11.748	1	.001		
Fisher's Exact Test				.003	.002
N of Valid Cases	27				

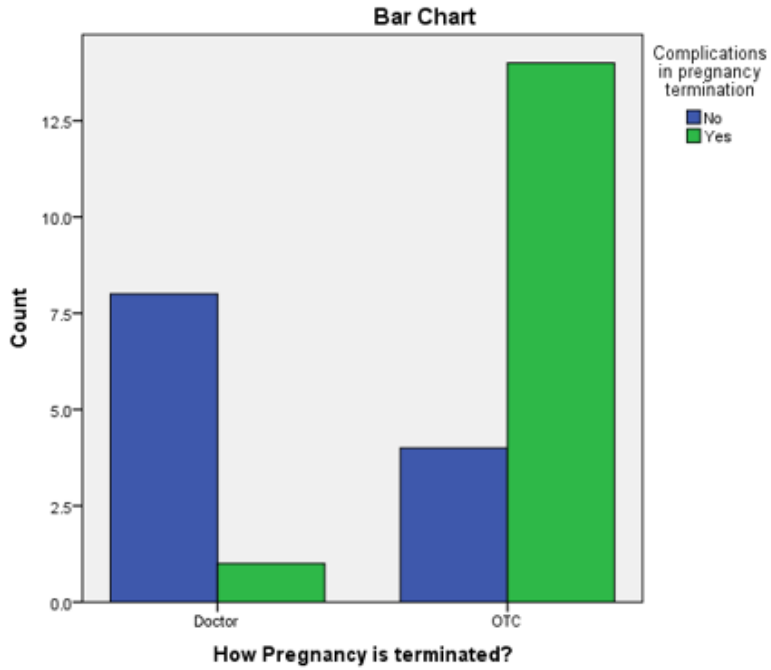

Figure 1. Relationship between pregnancy termination methods used with associated complications

This bar chart illustrates the relationship between pregnancy termination methods approached with the complications faced during pregnancy termination. Out of eighteen respondents who had approached general medical practitioner, fourteen respondents faced medical complications in pregnancy termination. However, out of nine respondents who had adopted the specialist care, only one faced medical complication during pregnancy termination.

Table 4: Comparison between difficulty in accessing medical facility and medical complications in pregnancy termination

Difficulty in accessing specialist medical facility for pregnancy termination	Complications in pregnancy termination		Total
	No	Yes	
No	10	2	12
Yes	2	13	15
Total	12	15	27

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	13.230[a]	1	.000		
Continuity Correction[b]	10.547	1	.001		
Likelihood Ratio	14.502	1	.000		
Fisher's Exact Test				.000	.000
N of Valid Cases	27				

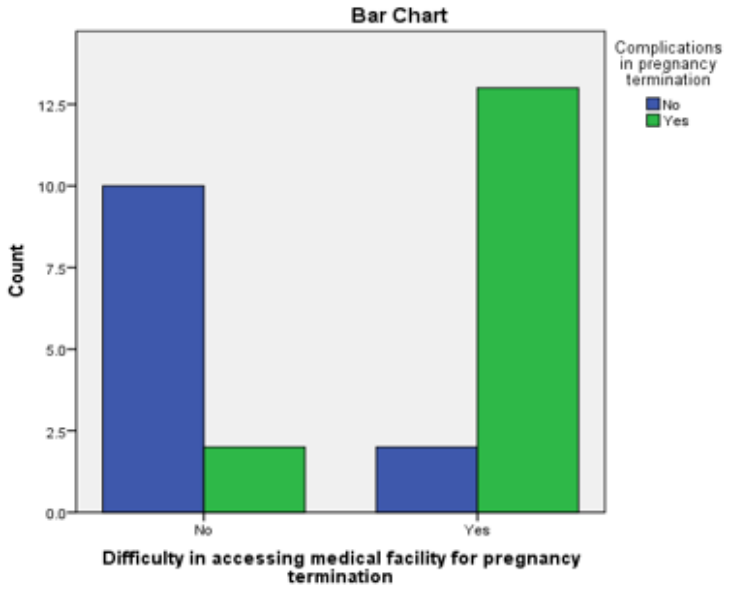

Figure 2. Relationship between difficulties in accessing specialist medical facility for pregnancy termination with complications in pregnancy termination

The bar chart depicts the relationship between difficulties in accessing medical facility for pregnancy termination with the associated medical complications. Among the fifteen respondents who faced difficulties in accessing specialist medical facility for pregnancy termination, thirteen respondents faced complications in pregnancy termination. On the other hand, only two respondents faced complications in pregnancy termination that have accessed specialist medical support for pregnancy termination.

While comparing the medical complication during pregnancy termination, general medical practitioner approach of medical termination led to more complication as compared to the specialist care which was found statistically significant ($p<0.001$) (Table 3) (Figure 1). Also, difficulty in accessing specialist medical facility for pregnancy termination was significantly associated with complication faced during pregnancy termination ($p<0.001$) (Table 4) (Figure 2). Our study reported that the majority of women had knowledge regarding contraception (96.95%) which was higher than the studies conducted in Nigeria (82%) and Pakistan (68.5%).[8,9] However, a study conducted among women in rural area of Nagpur (India) had comparable knowledge regarding contraception (100%).[10] These variations might be due to the differences in the sample size as well as socio-demographic profile of the respondents based on the geographical location with varied socio-cultural norms and customs.

Majority of the respondents in our study faced difficulty in following contraceptive method (49%) among which non-availability of the contraceptive supplies amid pandemic was the most probable reason (16.75%). According to the WHO survey done across 105 countries, 90% of the respondents have experienced health services disruptions during pandemic among which FP services were hindered the most (68%).[11] A study conducted in Uttar-Pradesh (India) reported the decline in the use of contraception up to sixty percent and also there was reduction in safe abortion care.[6] Almost half of the respondents in our study had unplanned or unintended pregnancy (49.24%) with the major reason being non-availability of family planning services (70%). Guttmacher Institute in its recent analysis reported a 10% decline in the Sexual and Reproductive Health (SRH) services in low and middle income countries (LMICs) owing to COVID-19 would led to an additional 15.4 million unintended pregnancies, unsafe abortions over 3.3 million and 28000 maternal mortalities. This will also result in the spike of 3,325,000 more unsafe abortions and 1,000 additional maternal mortalities.[12, 13]

COVID-19 has impacted women's ability to use contraceptive measure in numerous ways. Supply chain of contraceptive commodities got disrupted

which limited its production, distribution as well as availability resulting in market stock-outs.[14] Some health care facilities reduced the services and health care providers have been redirected from providing family planning service to COVID-19 management. [15-17] Also, lockdown and fear of getting exposed to COVID-19 prevented women from visiting health care facilities.[18] This is supported by the findings of our study where only 33% of the women underwent pregnancy termination under specialist care. Our study also showed a significant association between pregnancy termination methods used as well as difficulty in accessing specialist medical facility for pregnancy termination with the pregnancy termination related complications. This clearly highlights the difficulties faced by the women in accessing medical facilities for pregnancy termination during pandemic.

The COVID-19 pandemic has made the goal of achieving universal access to SRH services by 2030 more challenging. Most importantly for women who have experienced unintended pregnancies owing to lack of access to contraceptive measures amid COVID-19 pandemic, the impacts are chronic. This necessitates the countries to incorporate FP services as well as reproductive health services in the package of fundamental health services as well as to strategize the data collection process via health management information systems in order to understand the COVID-19 impact on contraceptive services and its usage. Our study has certain limitations. The small sample size might not be able to infer the gravity of challenges faced by the women in accessing FP services during COVID-era in the country. The reason might be the decreased patient flow in the outpatient clinic of the tertiary health care centre amid lockdown imposed by the governmental law due to upsurge in COVID-19 cases. Also, more longitudinal studies are required to analyze the patterns of challenges over time in accessing FP services during COVID-19 era.

Conclusion

The non-availability of contraceptive supplies, FP services amid COVID-19 pandemic have exerted detrimental impact on the women reproductive health as a whole. Health care professionals should proactively engage to ensure the continuation of reproductive health care services to women via clinical resource allocation at the community level. Continuing medical health services including contraception and safe abortion services are essential during pandemic to sustain the success of high-quality reproductive services which will significantly decrease maternal morbidity as well as mortality thereby improving newborn and child health.

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