INDIAN JOURNAL OF PUBLIC HEALTH RESEARCH & DEVELOPMENT
NEW DELHI

Indian Journal of
Public Health Research & Development

An International Journal

Indian Journal of Public Health Research & Development

Contents

Volume 12, Number 4   **October-December 2021**

II

IV

Webinar Training: A panel discussion on "Endgame of Tobacco" for Protecting the Next Generation

Anil Purohit[1], Priyakanta Nayak[2], Rhea Gupta[3], Manu Mathur,[4] Pankaj Chaturvedi[4], Rati Godrej[4], Jagdish Harsh[5]

[1]Founder & Chairperson, [2]Associate Professor, [3]Intern, [4]Visiting Professor, [5]Associate Professor, Jodhpur School of Public Health (JSPH)

Abstract

Background: Jodhpur School of Public Health, Poornima University hosted an interactive and live global webinar session on the topic of "Endgame of Tobacco: Protecting Next Generation" on 6th June 2020. Eight panelists gathered to discuss the use of new innovative technology, prevention efforts, and future directions to address India's tobacco epidemic

Finding: It was revealed that tobacco kills 13.5 lakh people every year and if the tobacco epidemic is not controlled, 1 billion people will die in this century. The tobacco industry and the challenges in India's healthcare system to promote tobacco cessation services play a significant role in fueling this tobacco epidemic. Smokeless tobacco and second-hand smoke are also significantly contributing to negative health outcomes, particularly amongst women and children. Although there have been efforts to increase the number of cessation clinics, there has been a lack of concerted integration to equip the health system with tobacco cessation services

Conclusion: Going forward, it is suggested that cessation efforts should be combined into one integrated program with the use of technology to create effective strategies to increase quit attempts and ultimately reduce the prevalence of tobacco use.

Key words: *Webinar, Tobacco, JSPH, Poornima*

Introduction

Poornima University and Jodhpur School of Public Health hosted an interactive and live global webinar session on the topic of "Endgame of Tobacco: Protecting Next Generation" on 6th June 2020. Tobacco use has become a significant epidemic, particularly in India, with almost 27 crore users. Research has also shown links between tobacco use and threatening health conditions. This epidemic has particularly impacted women and the youth. Although prevention efforts have been carried out for several years, there has been little measurable success. The emphasis of preventive measure on future generations, and its regard for the interests of existing stakeholders, makes it worthy of consideration as a surer path to the ultimate eradication of tobacco supply in jurisdictions where the social climate is conducive[1].

Therefore, 8 panelists gathered to discuss the use of new innovative technology, prevention efforts, and future directions for the long-awaited success of the "endgame" of India's tobacco epidemic.

Finding

In India, Tobacco kills 13.5 lakh people every year and if the tobacco epidemic is not controlled, 1 billion people will die in this century. Every 3rd Indian uses tobacco (27 crores) and one third of them will die prematurely. People with significant co-morbid conditions like preexisting asthma and respiratory diseases attributable to tobacco use are susceptible to life threatening infections. This highlights the need to

strengthen our health systems to provide curative and preventative health promoting services like tobacco cessation.

The tobacco industry plays a significant role in fueling this tobacco epidemic. It was said that the tobacco industry is savvy in working around legal hurdles in order to reach its target audiences. The tobacco industry spends close to $10 billion on marketing in the US alone, the kind of marketing muscle that undercuts tobacco control measures. It was argued that the tobacco control community should also demonstrate the same degree of sophistication, agility, and aggressiveness to counter tobacco industry's tactics and influence. The industry has exploited the large time interval in which smoking can lead to detrimental health affects to advance their business. Some examples include, dismissing the effect of smoking on cancer as simply 'statistical association' and declaring under oath that nicotine is not addictive. However, in regards to smoking, the Covid-19 case fatality rate is up to 50% compared to the case fatality of <3% in non-smokers. The hospitalisation rates are also much higher for individuals who smoke.

There has also been prevalent tobacco promotion amongst the youth despite measures to prevent this. The laws on not having tobacco vendors within 100 yards of schools and the bans on the sale of tobacco to minors have been implemented, yetthere have been difficulties in enforcing them. Even the signboards on the ban of sale to minors are missing at most points of sale. Attractive display in showcases and high density of tobacco vendors also create an encouraging atmosphere. Typically, endgames are plausible for countries where existing prevalence has historically been low or where there has been a sharp decline in tobacco use in recent years, and where there is public support and demonstrated political commitment to reduce tobacco use[2].

Tobacco is the only legal consumer product that can harm everyone exposed to it – and it kills up to half of those who use it as intended. Yet, tobacco use is common throughout the world due to low prices, aggressive and widespread marketing, lack of awareness about its dangers, and inconsistent public policies against

its use[3,4,5]. Tobacco use takes away many productive years from individuals, firms and therefore a country's entire population. A 2013 study found that in the United States, the difference in terms of annual health insurance premiums for insuring a smoker as opposed to a nonsmoker is estimated to be $5816[6,7].

A particular population that has seen increased rates of cigarette smoking is young women in India. The average Indian girl is taking up smoking at 17.5 years as compared to 18.8 years for boys. India is second to the US in the highest absolute numbers of women smokers and this number is rising steadily. Some reasons for this particular increase include:

- Weakening of social and cultural constraints with rising acceptance of women smokers

- Hectic work culture and coping with stress

- Peer pressure

- Aspirations to emulate their "liberated" Role Models and create an identity

- Glamorous advertising of female smokers portraying vitality, slimness, modernity, emancipation, sophistication and allure.

- Living with a smoking parent or sibling

- Sign of Rebellion/Independence/Power

- Socially and economically marginalization

Non-smoking Tobacco Consumption

Smokeless tobacco use is also a significant and challenging problem especially in South Asia. For example, studies in Rajasthan have revealed that 40% of adult men in Rajasthan use tobacco.One in every ten adult women use tobacco (70% smokeless 30% smoking). 55% of smokers and 51% of smokeless tobacco users are not interested in quitting tobacco use. Only 36% of smokers and 38% of smokeless users believe that tobacco use has harmed their body.

There is a great diversity of smokeless tobacco products and smokeless tobacco use patterns. Some

examples include, gutkha, with betel quid, khaini, snuff, and tooth powder. All smokeless tobacco products have nicotine as a major constituent and are potentially addictive with other ingredients which are carcinogenic substances and heavy metals. Health problems related to smokeless tobacco include the following; addiction, cancer, precancerous mouth lesions, heart disease, dental disease, pregnancy risk, anaemia, and poison risk for children.

Second-hand Smoke (SHS)

Studies show that children whose parents smoke get sick more due to stunted growth in their lungs. Children whose parents smoke around them are also more likely to experience ear infections due to increased fluid in their ears. Additionally, children exposed to SHS appear to have increased respiratory problems and decreased lung function as adults. Wheezing and coughing are more common in children who breathe SNS which can also trigger an asthma attack. SHS exposure increases the risk that a child will potentially develop cancer. SNS for teens may produce higher cholesterol levels and may be more likely to get heart disease, poorer lung functions, more asthma episodes, more respiratory infections as adults.

Smokers miss out on a huge incentive - ranging from 15-50% - because of their cancer-causing habit of smoking, say insurance experts. "A person who smokes an average of 8 cigarettes a day would spend an average of Rs 23,360 per year (on his addiction). With this amount, a 35-year-old smoker could get a life insurance cover of around Rs 1.27 crore for 15 years"[8].

Discussion

Drawbacks of current interventions

This challenges regarding tobacco use have been discussed and worked on for over 10 years. However, efforts have not been entirely successful. One of the major reasons for this is the inadequate attention to strengthen India's health systems to provide tobacco cessation to the people who intend to quit but find it difficult to do so. The analysis of the data from GATS 1 and 2 reveals that many indicators of tobacco control have improved

in the past decade, however there has been only a marginal increase in health providers providing advice for quitting tobacco. The immediate fallback of this statistic is the reduction in the quit attempts, especially by rural female smokers for both smoke and smokeless forms of tobacco. Although there has been an increase in number of cessation clinics, there has been a lack of concerted integration efforts to equip the health system with tobacco cessation services.

Tobacco Cessation and Prevention Strategies

Various studies have shown that a mix of varied interventions have shown higher quit rates than using a single method. Multi-sectoral engagement – integrating with other health programs (TB, HIV-AIDS) with development programs (education) – can go a long way to implement effective tobacco cessation practices.

The government of India started its own quit line (in partnership with the WHO Be Healthy Be Mobile program) a few years back where individuals can register via a missed call to the line. There have been some positive results coming out of it. They received almost 2 million calls in one year and the self-reported quit rate was almost 19%. 66% made a quit attempt and 77% said program was helpful. Rajasthan has itsquit line and it has also shown encouraging results. A number of reviewshave shown if that m-cessation is coupled with other cessation interventions, it is very helpful in increasing quit attempts. All these cessation efforts should be combined into one integrated program which would potentially be the most beneficial in increasing quit attempts.

It has also been suggested that customized strategic communication campaigns such as "participatory" strategies and engaging the target audience, particularly the youth, should be developed. Additionally, there need to be efforts taken to counter the tobacco industry. One suggested strategy includes focusing on the tax write-offs on the marketing expenses of the tobacco industry. Advocacy of counter-marketing strategies should be developed to ensure that advertising and marketing budgets of the tobacco industry are publicly available.

Additional effective measures include:

- Behavioral interventions — such as telephone services, self-help materials, counseling or professional advice

- Nicotine replacement therapy with nicotine gum or lozenges,

- Drugs like Varenicline.

- Encourage healthy habits good nutrition, exercise, stress management early in life

- Focus on harm-reduction (lung disease, cancer, reproductive issues, heart disease etc.,)

- Offer and promote counseling support

- Doctors need to shift from "telling" to "asking" about smoking

Targeted Solutions amongst the Youth

Education and teachers specifically can play a crucial role in prevention and cessation of tobacco amongst the youth[9,10].It has been shown that teachers can be engaged as role model, knowledge providers, trainers and training module developers.Teachers can be revolutionary not only for their students but also for the communication of information between generations. Talking about the harmful effect of tobacco at early stages of education can not only prevent children from future indulgence, but also prevent their parents to quit tobacco. Therefore, there is a need trainers or teachers (TOT) programs to train teachers and prevent them from encouraging tobacco use. At school level, adolescents can be trained using real life case studies. In Medical or Public health school levels, the curriculum will require a comprehensive approach.

Additional preventative efforts the youth include:

- Parents and their Guests must not smoke at home or in car or around children

- Explanation of risks of smoking to children

- Active encouragement of quitting smoking

- Encouragement of motivation and support programs.

- Educating Pediatricians, nurses, healthcare workers to speak to families about the harms of secondhand and third hand smoke.

Conclusion

India has more than 100 million adult smokers due to the significant influence of the tobacco industry and the deficiencies in India's health system. The opportunities and strategies to encourage people to quit smoking in India needs to drastically change. Currently, existing smoking and tobacco cessation services operate from only limited number of clinical settings and there are not enough trained specialist smoking cessation advisors nationally. A multi-sectoral engagement strategy should be implemented to effectively promote smoking cessation. Innovation is key and a technological approach also needs to be taken so that these services can be delivered consistently and at scale across the population.

The webinar is now freely available on you tube through the following link: https://www.youtube.com/watch?v=VWBof0NFn9U .

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Webinar Training – A Panel Discussion on 'Hepatitis Free Future' with Elimination of Hepatitis by 2030

Anil Purohit[1], Priyakanta Nayak[2], Riddhi Kapasi[3], Jagdish Harsh[4], Rahul Singhi[5]

[1]Founder & Chairperson, [2]Associate Professor, [3]Intern, [4]Associate Professor, Jodhpur School of Public Health (JSPH), [5]Co-founder, Poornima University, Jaipur, Rajasthan

Abstract

Background : Poornima University, in collaboration with Jodhpur School of Public Health, hosted an insightful and interactive live global webinar on "Hepatitis Free Future" on 1st August 2020. Four speakers and six panellists addressed the current situation, preventive measures, and future directions for achieving the target of hepatitis elimination by 2030

Findings: Globally, Hepatitis B and C (HBV & HCV) accounts for 96% of all hepatitis mortality and more than 300 million people are living with viral hepatitis. The World Health Organization (WHO) estimates that 1 in 3 people worldwide has been infected with either HBV or HCV.Global uptake in childhood vaccination is significant for HBV, but the birth dose for all infants is too low (nearly 39% percent). Despite vaccination, 1.8 billion 5-year-old get infected every year with HBV.Various programs and projects are contributing to the elimination of the Hepatitis to reach the international goal. Due to COVID-19 there would be setbacks however we have all the tools within our reach and we must use them to get elimination, most importantly deliver it to the people who need it the most, if we plan to succeed by 2030.

Conclusion: Hepatitis claims the lives of millions of people globally each year.With prevention, treatment, diagnostics, and vaccination hepatitis elimination is attainable. Greater investment in eliminating hepatitis will generate higher long-term returns. We have the tools, treatments, and strategies to combat this infectious disease. We need the support of various sectors to execute the plan, proper implementation of the idea, training, and awareness to the public domain. With leadership, resources, and multi-stakeholder collaboration, elimination of viral hepatitis is achievable

Key words: *Hepatitis, COVID 19, PMTCT*

Introduction

An engaging and live global webinar on "Hepatitis Free Future" was hosted by Poornima University and Jodhpur School of Public Health (JSPH) on August 1st, 2020. The webinar aims to highlight on a 10-year set goal for Viral Hepatitis Elimination. Unlike covid-19, hepatitis has all the critical tools that are needed to combat the infectious disease. Global elimination of hepatitis is within reach with all the prevention measures, appropriate treatment facilities, and with a sense of awareness, we can pass on a world free of hepatitis to our next generation[1].Therefore, four speakers and six panellists got together to discuss the current global situation of hepatitis, challenges and preventive measures, and future directions for long term victory to eliminate hepatitis by 2030.

Overview and Findings:

Celebrated on 28 July, World Hepatitis Day enhances awareness of viral hepatitis. There are five strains of viral hepatitis (A, B, C, D & E), a blood-borne infection of the liver that can cause several health issues and may be fatal. Unlike COVID-19, hepatitis has all the necessary treatment, preventive measures, oral care diagnostics, curative medicines, and vaccines. However, over 80% of people with hepatitis lack awareness and resources

for testing, prevention, and treatment[2]. Hepatitis affects the life of 325 million people, causing 1.34 million deaths in a year. Cirrhosis and hepatocellular carcinoma accounts for 96% of the total death due to viral hepatitis globally. In the Asia-Pacific region, more people die from viral hepatitis than from HIV, tuberculosis, and malaria together each year. In India, estimated hepatitis C virus infection cases are between 6 to 12 million[3]. All these highlights the need for awareness generation, mass immunization, and promotion of preventive strategies.

There's good evidence that eliminating HCV and HBV is technically feasible. Many countries have achieved outstanding coverage with the hepatitis B vaccine. Also, the recent development of highly effective antivirals has cure rates exceeding 95%[4]. Preventive measures and safety have considerably reduced the threat of both hepatitis B and C virus infections. However, 325 million people globally are carriers of hepatitis B or C virus, which can remain asymptomatic for decades. Each year, 1.75 million people acquire hepatitis C virus infection. These people are at risk of severe liver disease and death unless they receive timely testing and treatment. Unfortunately, access to affordable care is disturbingly low.

Global uptake in childhood vaccination is high for hepatitis B but, the birth dose for all the infants is too low (nearly 39%). Despite all the availability of treatment, vaccination, and prevention, 1.8 billion 5-year-old age gets infected every year with Hepatitis B virus (HBV), with a 31% death rate[5]. Routine infant hepatitis B vaccination, with 90% coverage and the first dose administered at birth, would prevent 84% of global HBV-related deaths. A concerted effort to screen, treat, and vaccinate at-risk individuals has the potential to eliminate Hepatitis as a public health threat by 2030.

Preventive Measures and Strategies:

World Health Assembly adopted the Global Health Sector Strategy to eliminate cases of hepatitis by 2030. The five strategic directions are Information for focused action, Interventions for impact, Delivering for equity, Financing for sustainability, and Innovation for acceleration. Preventive measures and strategic planning

can help us draw a roadmap to elimination[6]. There is a need for a 65% decrease in death from chronic HBV and HCV and a 90% reduction in new cases in coming years. Low and middle-income countries account for the largest proportion of persons living with HBV (96%) and HCV (72%), yet access to testing and treatment is more limited in these countries. In order to increase access and reduce health inequities, the delivery of hepatitis and harm reduction services can be tailored to different populations and settings through integration, decentralization and task-shifting. The five-core intervention should be scaled up to reach elimination. The five key indicators consider the diagnosis, treatment, and viral suppression or the effectiveness of treatment which includes Hepatitis B vaccinations, HBV prevention of mother -to- child transmission (PMTCT), blood & injection safety, harm reduction and diagnoses and treatment services

Why is Prevention of Mother-to-Child Hepatitis B Transmission important?

One of the major causes of infants becoming infected with such a large number is the transmission of HBV from mother to child. Over 180,000 new-born babies in the western Pacific region are newly infected by hepatitis B through mother-to-child transmission. It is imperative to prevent mother to child transmission of the virus since the risk of chronic hepatitis infection varies inversely with the age at which it occurs. 90% of affected infants develop chronic infection in the first six months of age[7]. They carry a 25% risk for the development of chronic liver disease, cirrhosis, or hepatocellular carcinoma. The statistical data for the universal immunization program mentions that the prevalence of HBV in children less than five years was reduced from 4.7% in 2000 (pre-vaccine era) to 0.8% in 2017, the major reason was the inclusion of hepatitis vaccine. Antiviral Therapy (tenofovir) plays a significant role in preventing mother to child transmission of HBV. As per WHO's new guidelines on prevention from mother to child hepatitis B transmission, all infants receive a first dose of the hepatitis B vaccine preferably within 24 hours of birth, followed by minimum two additional doses. In countries that have already achieved high coverage of hepatitis B immunization, including timely birth dose,

routine screening for HBV infection among pregnant women and antiviral prophylaxis for those in need is an additional opportunity to prevent transmission from mother to child.

Programs and Projects Contributing to elimination of Viral Hepatitis:

1. **National Viral Hepatitis Control Program (NVHCP):** The National Viral Hepatitis Control Program, launched by the honorable Union Minister of Health and Family Welfare, aims to reduce morbidity and mortality due to all types of viral hepatitis and to eliminate Hepatitis C by 2030. The program's key strategies include awareness-raising, prevention, diagnostic promotion, treatment delivery, safe blood and blood products, free drugs and serological screening, and safe socio-cultural practices. This program has a close-knit with all other Indian programs like Swachh Bharath Abhiyan, MCH program, Immunization Programs, National AIDS Control Program, National Tuberculosis Elimination Program, and Viral hepatitis Surveillance Program.

2. **Project ECHO – Extension for Community Healthcare Outcome:** It is a non-profit mechanism that uses technology in disease management. At ECHO, the mission is to democratize the implementation of best practices for healthcare to underserved people in the world. The goal of this project is to touch the lives of one billion people by 2025. The project has a model to bring access to care everywhere. The model has four ideas A, B, C & D. **A**mplification, Share **B**est practices, **C**ase Based Learning, Web-based **D**atabase. ECHO uses a force multiplier, a technique of assisting and training the existing community clinicians to reach the desired goal of elimination. ECHO can help to eliminate HCV by educating, vaccinating, treating, diagnosing, and ultimate care.

3. **Sustainability -Making Elimination Affordable:** The prices of medicines and diagnostics are the key drivers that influence the economic analysis of viral hepatitis elimination plans. Though the pricing of screening tests is 1$ US, no manufacturer would like to invest in FDA registrations for such a low cost because of the lack of profit. So, the status quo laboratory-based serology testing is at higher costs. Shockingly, tenofovir disoproxil fumarate (TDF) became generic in 2018. Patients paid up to $125 a month, while its median prices on the international market are $32 for a year supply. The system created today is a barrier for our hepatitis patients. By 2030, barely less than ten countries around the world will be able to eliminate hepatitis at current rates of diagnosis and treatment. The cost of pre-qualified serological testing varies from US$ 0.5 to US$ 3, while the cost of nucleic acid testing is higher (US$ 25-200). There is a need to be made these significant tests available at a lower expense. There are opportunities for the public sector to optimize procurement of generic medicines at the country level and quality assured diagnostics on the international market at low cost. The private sector can also support the national goals through provision and services and training the healthcare force. The government has done its job by giving us a platform now it is also the job of private sectors to not only identify the missing million but also to link with the care government has provided.

Furthermore, other sectors, such as corporate, education, financial services, and infrastructure, will play a pivotal role in increasing awareness and highlighting the importance of investment in an area with high socio-economic returns. With visionary leadership, multi-stakeholder collaboration, and full integration of existing solutions, elimination of viral hepatitis by 2030 is achievable.

Challenges:

We appear close to the finish line, yet we still have miles to run in the race against Hepatitis B. There are many barriers to overcome to reach our goal of elimination. Unfortunately, those most likely to be infected with HBV are also those with the most difficulties to health care access, including limited English proficiency, lack of health insurance, and difficulty navigating the complicated health care system. These are intensified by financial, labor, transportation, and time-related barriers.

The following are some of the challenges facing the prevention of mother-to-child transmission of

hepatitis. Availability of immunoglobin because of cost, poor penetration of the first birth dose of Hepatitis B, maintaining cold chain, awareness and acceptance by the society of a Hepatitis B mother. Although the WHO has provided guidelines for the use of antivirals in pregnancy with a high viral load, the problem is how not to stigmatize and avoid discrimination on the part of society[8].

Some challenges in scaling up HCV testing also exist. Effective testing policies and national guidelines are there still are not implemented strictly. There is a need to establish a strong hepatitis awareness and surveillance program. Inadequate quality testing is a big challenge. It is necessary to expand the quality assured testing for hepatitis[9]. Further, a powerful system is needed to maintain the confidentiality to overcome the stigma and discrimination associated with Hepatitis. For rational testing and reporting the most important thing for an institute is to adhere to the guidelines.

Also, lack of awareness and lack of perceived risk is a crucial challenge in adult vaccination. To overcome this, corporate hospitals and medical schools should use the SOPs and aim to vaccinate health care providers, doctors, nurses, housekeeping staff, and all those working in the hospital. People must receive a complete schedule of vaccines, followed by serology testing post-vaccination to know about the non-responders or delayed responders.

Conclusion

Researchers have made great strides towards addressing this serious liver disease. There is now a safe vaccine that has saved millions of lives. We have effective prevention-to-vaccination strategies that could help us dramatically reduce new cases of acute hepatitis B and C infections. We are at an exciting time in the world of Hepatitis, where researchers speak of a cure within a decade, and the World Health Organization has set a goal for the elimination of this deadly disease by 2030. Yet, there is more work to be done. There is a need to increase market transparency to mitigate market barriers and accelerate progress towards HBV and HCV elimination. Major innovations in the field of testing,

technology, and medicines have made the commitment to elimination possible. The need for awareness, affordability, and training is of utmost importance to reach the set goal.

Ethical Clearance: Taken from institutional Ethics Committee of Poornima University

Source of Funding: Self-Funded

Conflict of Interest: Nil

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Assessment of Knowledge, Attitude and Practice Regarding Blood Donation among Paramedical Personnel in a Teaching Hospital, Hassan, Karnataka

Anjan Sreeranga[1], Maliakel Steffi Francis[2], Posima Jaisai[3], Priyanka Aggarwal[3]

[1]Assistant Professor, Department of Community Medicine, Hassan Institute of Medical Sciences, Karnataka,
[2]Senior Resident/Tutor, Department of Community Medicine, Chamarajanagar Institute of Medical Sciences,
Karnataka, [3]Postgraduate, Department of Community Medicine, Hassan Institute of Medical Sciences, Karnataka

Abstract

Background: Voluntary, non - remunerated blood donation is the foundation for safe and sustainable blood supply. Health care providers, especially non physician personnel or paramedical personnel, play an important role in motivating and promoting blood donation as they come more in contact with public as representatives of the health system and hence need to possess a comprehensive and accurate knowledge regarding blood donation. **Methodology:** A Cross–sectional study was conducted to assess the knowledge of blood donation among 285 paramedical personnel working in Hassan institute of medical sciences, Karnataka which is a tertiary care teaching hospital. A pretested Questionnaire regarding blood donation KAP (knowledge, attitude and practice) were administered to all the paramedical personnel who consented to take part in the study after adequate sample size estimation. **Results:** More than 90% of staff had good knowledge regarding the blood groups and the eligibility criteria. 253 (88.8%) respondents considered blood donation as good and 205(71.9%) believed it was safe to donate blood but in practice only 116(40.7%) had ever donated blood. Male workers were more likely to donate blood (p<0.0001) **Conclusion :** It was observed that although there is a reasonably good level of knowledge and positive attitude among the paramedical personnel, the practice of donating blood was not adequate, especially that of regular voluntary donation. Hence it is important to conduct sensitization programs to improve practice of blood donation and various incentives as suggested by the staff themselves and several international bodies maybe considered to promote blood donation among them.

Keywords: Voluntary blood donation, paramedical personnel, awareness

Introduction

Voluntary, non - remunerated blood donation is the foundation for safe and sustainable blood supply. The World Health Organisation targets at achieving 100% voluntary non - remunerated blood donation which can be realised even in settings with limited

resources. [1] However it is not possible without good community participation and proper knowledge and awareness.Our country has a high demand for blood and blood components owing to the high proportion of nutritional anaemia, maternal haemmorhagic conditions, viral haemorrhagic fevers, trauma and other medical, surgical, maternal and pediatric indications.[2] The estimated clinical demand for blood in 2018 was 14.6 million units whereas the blood collection was 12.4 million units which indicates a significant mismatch between the demand and availability of blood in our country.[2,3] Although India has a large number of eligible

Corresponding author:
Dr. Anjan Sreeranga
Assistant professor, Department of community medicine, Hassan institute of medical sciences, Hassan, Karnataka. Email: anjusiri25@gmail.com

population (425 million) for blood donation, only a small proportion actually donates.[2] Against a requirement of voluntary blood donation of 34.3 per thousand eligible population only 31.9 per thousand eligible population had donated.[2,3] This may be due to misconceptions or lack of awareness regarding blood donation.[4]

Health care providers, especially non physician personnel or paramedical personnel, play an important role in motivating and promoting blood donation as they come more in contact with public as representatives of the health system and hence need to possess a comprehensive and accurate knowledge regarding blood donation.[5]This study is intended to assess the knowledge, attitude and practice regarding blood donation among paramedical personnel and to promote awareness about blood donation and blood safety and achieve the missed target of 100% voluntary blood donation by 2020.

Study Objectives:

The objectives of this study were to assess the knowledge, attitude and, practice of voluntary blood donation among paramedical personnel, to identify and recruit potential voluntary blood donors and to determine the association between blood donation, gender and category of staff.

Methodology

A Cross–sectional descriptive study was conducted to assess the knowledge of blood donation among all paramedical personnel working in Hassan institute of medical sciences, Karnataka which is a tertiary care teaching hospital with a large functioning blood bank. The study subjects included the nurses, laboratory technicians, X-ray technicians, OT technicians and pharmacists. All physicians and house surgeons working in the institute were excluded.The nature of the study and information needed was explained and oral consent was taken from those willing to participate in the study. A pretested Questionnaire regarding blood donation KAP (knowledge, attitude and practice) were administered to all the paramedical personnel who consented to take part in the study. The questions were designed to evaluate the responder's knowledge and awareness regarding blood

donation. A total of 285 respondents were included in the study after sample size estimation.

Sample size estimation:

As the objective of the study was to increase the practice of blood donation, proportion of those who did not practice blood donation was taken. As per Mullah F et al study on healthcare personnel, 61% did not practice blood donation.[5] Hence p was taken as 61, allowable error (d = 10%) with confidence interval of 95% (i.e. Z= 1.96). Using the formula for sample size estimation of z^2pq/d^2

$= 4* 61* 39 / 6.1 * 6.1 = 255.8$ i.e. minimum 256 study subjects should be included.

Statistical Analysis: The responses were collated and analysed with the Statistical Package for Social Sciences (SPSS) 16. The association between blood donation practice and gender of respondents and category of staff was tested using Chi-square and Fisher's tests where appropriate. $P< 0.05$ were considered statistically significant.

Results

Out of 285 respondents who participated in the study, 121(42.5%) were males and 164(57.5%) females. The mean age of participants was 31± 2.1years and majority (84.5%) belonged to the 20-40 years age group. 71.9% of them were staff nurses. 170(63.2%) respondents had a work experience of 5 to 15 years.

The knowledge regarding blood donation among the respondents is depicted in Table 1. The basic level of knowledge among the paramedical personnel, regarding few common aspects of blood donation, was satisfactory in majority of respondents.

Table 2 shows the attitude and level of practice of the respondents. There was a positive attitude regarding blood donation among 89% of respondents. Contrary to their attitude, only 136(47.7%) had donated blood in their lifetime. The reasons for nondonation by those who have not donated include; nobody approached them for donation 67 (23.5%), unfit to donate 51 (17.9%) and fear of acquiring infection 19 (6.5%).There was a significant

association between male gender and blood donation ($\chi^2 = 52.67$, p < 0.0001). However their years of experience did not show any significant association.

Table 1: Knowledge regarding blood donation among respondents.

	Knowledge about blood donation	n(%)
1.	**Do you know the common blood groups?**	
a.	Yes	276(96.8)
b.	No	9(3.2)
2.	**Do you know your blood group?**	
a.	Yes	285(100)
b.	No	0(0)
3.	**Can a person be infected by receiving blood transfusion?**	
a.	Yes (correct)	201(70.5)
b.	No (incorrect)	82(28.8)
c.	Don't know	2(0.7)
4.	**How often can an individual donate?**	
a.	3 monthly	153(53.7)
b.	6 monthly	56(19.6)
c.	Annually	40(14)
d.	Don't know	36(12.6)
5.	**Which screening tests are done before a blood donation?**	
a.	HIV	278(97.5)
b.	Hepatitis B & C	275(96.5)
c.	Syphilis	85(29.8)
d.	Don't know	7(2.5)
6.	**What is the lower age limit of Blood donation (BD)?**	
a.	18 years (correct response)	265(93)
b.	Others (incorrect response)	20(7)
7.	**Upper age limit**	
a.	60 years (correct response)	186(65.3)
b.	Others (incorrect response)	99(34.7)
8.	**Who cannot donate Blood?**	
a.	Children, elderly, diseased (Correct response)	280 (97.7)
b.	Healthy individuals(18-60 yrs) (incorrect response)	5 (2.2)
9.	**Can a women (18-60yrs) be allowed to donate when menstruating?**	
a.	Yes	45(15.8)
b.	No	199(69.8)
c.	Don't know	41(14.4)
10.	**Is blood donation safe :**	
a.	Yes	205(71.9)
b.	No	21(7.4)
c.	Don't know	45(15.8)

Table 2: Attitude towards blood donation and the level of practice

Attitude towards Blood donation		n(%)
1.	**What do you think about blood donation?**	
a.	Good	253(88.8)
b.	Bad	0(0)
c.	Neutral	32(11.2)
2.	**What do you think is the best source of blood donors?**	
a.	Voluntary donor	224(78.6)
b.	Replacement donor	16(5.6)
c.	Remunerated/paid donor	7(2.5)
d.	Self-donor	5(1.8)
e.	Don't know	33(11.6)
3.	**Can something harmful happen to a blood donor during or after donation?**	
a.	Yes	167(58.6)
b.	No	70(24.6)
c.	I don't know	48(16.8)
	Practice of blood donation among respondents	
1.	**Have you donated before?**	
a.	Yes	116(40.7)
b.	No	169(59.3)
2.	**If donated, how often do you donate?**	
a.	Donated only once/ rarely	95(33.3)
b.	Once a year , regularly	21(7.4)
c.	2-3 times a year , regularly	0(0)
3.	**Reasons for not donating blood by non- donors**	
a.	Unfit to donate	51(17.9)
b.	No one asked for blood / approached for blood donation	67(23.5)
c.	Fear of needle prick	10(3.5)
d.	Fear of acquiring infection/ adverse effects on health	19(6.7)
e.	Others	22(6.3)
4.	**Are you willing to donate blood in future?**	
a.	Yes	213(74.7)
b.	No	72(25.2)

Discussion

The present study conducted on the 285 paramedical staff of the institute showed adequate knowledge and good attitude towards blood donation; however the practice of donating blood was poor. More than 90% of staff had good knowledge regarding the blood groups and the eligibility criteria. 253 (88.8%) respondents considered blood donation as good and 205(71.9%) believed it was safe to donate blood but in practice only 116(40.7%) had ever donated blood. Although the practice of blood donation is higher compared to some previous studies there is a wide disparity in the knowledge, attitude and their practice. The number of blood donors were higher in our study probably due to frequent blood donation camps conducted in our institute.

According to study conducted by **Rao Pet al** on 132 nurses in Mangalore also showed that majority had good knowledge but only 61.36% wished to donate blood.[6] In the study conducted by **Mullah F et al** on healthcare support staffs of a tertiary healthcare hospital in Gujarat it was seen that there was a poor knowledge of donor eligibility among the staff, 91% of them did not consider blood donation as safe and only 39% of them have donated blood.[5] Despite having better attitude and perception in the present study, the number of respondents who donated are similar.

This trend was also seen in some studies conducted overseas. In the study by **Nwogoh B etal** on healthcare workers a teaching hospital in Nigeria, it was seen that 92 – 95% had good knowledge regarding most basic aspects of blood donation, 81.6% had a positive attitude but only 22.1% had donated blood at least once in their life time.[7]

Similarly in a cross- sectional study done on 218 health care workers in Ethiopia by **Malako D et al**, it was found that 82.6 % had good knowledge, 99.1% considered that blood donation was good and 58.7% respondents in general had a good attitude towards blood donation, however only 21.6% had practised blood donation.[8]

Further in the present study, those who had donated blood also had donated only once or twice in their lifetime, when some friend or relative needed replacement, and do not donate on a regular basis. This was similar to the findings of **Sreedevi D et al** study in blood banks of Kurnool and Hyderabad, where 70-80% of blood donated was for replacement by family members.[9] This has to be corrected in order to achieve 100% voluntary unpaid blood donation to meet the requirement forblood and blood products.

The major reason for not donating among non-donors was because no one had approached them to donate as stated by 67(23.5%). This highlights the need to sensitise the healthcare workers regarding the significance of regular voluntary blood donation. The next common reason was their ineligibility to donate (17.9%) which may be due to the high prevalence of anaemia and malnutrition in our population. Some other reasons mentioned were fear of needle prick, fear of adverse effects on health, fear of knowing their screening status or cultural and religious beliefs.231 (74.7%) respondents expressed willingness to donate blood in future but only 102(35.8%) of them gave their contact number which indicates a reluctance or resistance to donate due to various reasons. Similar findings were seen in studies by **Kanani AN et al**, **Nwogoh B et al** and **Malako D et al.** [7,8,10]

There was a significant association seen between blood donation and gender. Males have donated more as compared to female staff (p<0.0001) which may be due to certain factors such as monthly menstruation, pregnancy and lactation which limit their eligibility to donate blood. Also there is more prevalence of anaemia among females, which again is an ineligibility criteria. This finding was also seen in similar studies conducted by **Solanki SL et al**, **Nwogoh B et al** and **Malako D et al.**[7,8,11]

Among the incentives suggested by them to increase the practise of blood donation, the most favoured was considering it for promotion/appraisal (47%) or providing extra leaves for the same (43.2%). Institute can promote regular voluntary donation by giving a day

off on the day of donation. This is already effective in certain places.[5]

As seen in this study, we have an advantage of having a large number of personnel in the eligible age group. This potential has to be tapped in the right direction by increasing the awareness regarding voluntary blood donation, dispelling misconceptions and motivating them for voluntary blood donation. As the paramedical personnel involved in the study have satisfactory level of knowledge, they may be able to educate the patient and their attenders regarding the same.

Conclusion

It was observed from the present study that although there is a reasonably good level of knowledge and positive attitude among the paramedical personnel, the practice of donating blood was not as expected, especially that of regular voluntary donation. Hence it is important to conduct sensitization programs to improve practice of blood donation and various incentives as suggested by the staff themselves and several international bodies maybe considered to promote blood donation among them.

Conflict of Interest –None

Source of Funding- None

Ethical Clearance – Obtained from the institutional ethical committee

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Prevalence of Stress Level in Physiotherapy Working Profession During Covid-19 Pandemic

Aparna Nautiyal[1], Meena Gupta[2], Sipra Bhatt[1]

[1]Master of Physiotherapy Student, [2]Assistant professor, Amity Institute of Physiotherapy, Amity University Noida, Uttar Pradesh, India

Abstract

Background-Coronavirus disease COVID-19 become the 5th pandemic disease since 1918 which is reported first in Wuhan, China after that its affect all over the world. In India, it is confirmed January 30, 2020. Professionally, also being challenged during this pandemic as we are moving under pressure in new model which involves re-skilling and redeploying staff for intensive care units, also reconsider of standard approaches for assessment and management. All things persist stress which leads to anxiety and depression. Purpose of the study to analyse the prevalence of perceived stress in physiotherapy profession who's practicing in hospitals, healthcare centres or rehabilitation centres.

Methods- Samples collected from online survey and expected sample size more than 30 clinical physiotherapist who's working in different setups. Perceived stress scale -10 used under the inclusion and exclusion criteria. Inclusion Criteria- must be clinical therapist working in different setups as hospitals, rehabilitation centres, and multispecialty clinics and exclusion criteria is physiotherapist who working in academic field. Analysis carried out by Microsoft Excel 2007.

Conclusion-Analysis found prevalence of perceived stress level 13% high, 68% moderate, and 19% low stress in the total respondent physiotherapist.The high prevalence of moderate perceived stress in clinical physiotherapist population which is lies under 18-29 year of age criteria. Study also depicting male perceiving high stress rather female.

Keywords- *Covid-19 pandemic, clinical physiotherapist, perceived stress, perceived stress scale-10.*

Introduction

Coronavirus disease COVID-19 become the 5th pandemic disease since 1918. It is reported first in Wuhan, China after that affect all over the world. The World Health Organization (WHO) named Novel Corona-Virus (2019-NCOV) and official named as COVID-19[1].

Corresponding author:
Meena Gupta
Assistant Professor, Amity Institute of Physiotherapy, Amity University Noida, Uttar Pradesh.
mgupta@amity.edu, meenaguptaphysio@gmail.com

In India, it was confirmed January 30, 2020. Government introduced social distance after that lockdown with strict precautionary measures to avoid the large population possibilities to affect from Coronaviruses but essential public services like hospitals, police, and grocery still giving services under precautionary measures. This virus outbreak in all over the world, it has disrupted the health, economy and change the many aspect of lives[2].

In our health care profession, this is impacting our personal and professional. In personal aspects we experiencing economic, mental, social, mental and physical health as including concerns about re household job security and business viability(in case of private

practitioners), others like cancelation marriage and travelling plans. All things persist stress which leads to anxiety and depression[3]

Over the years the stress defined in different ways .The accepted definition of stress today's scenario is the one of interaction between individual and the situation. "When the individual resources are not sufficient to manage the demands and pressures of circumstances which results due to psychological and physical state." In stress people have seen especially with change in behaviour. Its acute responses may be in the behaviour (as being aggressive, withdrawn, unmotivated), areas of feelings -anxiety, depression, irritability, fatigue, thinking like difficulties in concentration and solving problem or physical symptoms -nausea, headache, palpitation. When stress persists, change the autonomic, neuroendocrine, cardiovascular and immunological function which affect mental and physical health for example anxiety, depression, heart disease and the situation causing stress and it could be from unpredictable or uncontrollable situation , ambiguous or unfamiliar or conflict, expectation, work load pressure , job insecurities, loss of performance[4].

In Professional aspect, also being challenged during this pandemic as we are moving under pressure in new model which involves re-skilling and redeploying staff for intensive care units. In outpatient and private practice, treatment giving through telehealth technology and we are required to work within control of new confines of infection, also reconsider of standard approaches for assessment and management. With all of this also confined the urgency and non- urgency condition[3].

Studies were conducted on perceived stress, anxiety and depression on healthcare professionals where they includes various medical related professions. Here, the study aim to analyse the perceived stress prevalence on physiotherapist those practicing in hospitals, healthcare centres or rehabilitation centres.

Material and Methods

Study design- Cross-sectional Survey

Samples- Samples collected from online survey method.

Sample size- More than 30 number of population.

Gender- Male and Female

Source- Clinical physiotherapist working in different setups

Methods of Data Selection- A google form has made to data collection based on inclusion and exclusion criteria and participants who willingly wants to participate, coming under this criteria were part of this study.

Inclusion Criteria- Age between three different category i.e.18-29yrs; 30-44yrs and 45-54yrs must be clinical therapist working in different setups as hospitals, rehabilitation centres, and multispecialty clinics.

Exclusion criteria – Physiotherapist who working in academics.

Survey data collected from the individual sample in the form of questionnaire asked in the google form. The google form has made, the purpose and need of the study mentioned. Form included all the necessary details including contact details and others descriptive variables including Name, Age, Gender, Place and questionnaire including Perceived stress test for stress. Form were circulated through online mode via mail and WhatsApp, FB messenger, Telegram and those who were agree to participate were participated in the study by agreeing the inform consent attached in the form.

Outcome Measures -Perceived Stress Scale-10 ,as per many researches and reliability and validity of scales Perceived stress scale for measuring stress has been choose for collecting data respectively of stress. Reliability and validity of scales (Cohen and Williamson 1988) reported PSS-10 score having internal consistent reliability $\alpha=0.78$ and validity of concurrent criteria with experience of stress during an average week r=0.32, p<0.05.[14]

Results and Dicussion

The outline survey has been done for the study

entitled "Prevalence of stress level in physiotherapy working profession during covid-19 pandemic". A total 38 no. of participant's physiotherapist among 31 were included in this study with response. The collected data has been analysed by using Microsoft excel 2007.Among respondents, majority were male 16 (52.61%) while the majority of age between18-29year (74%).Data analysis on the basis PSS 10 questionnaire found prevalence of perceived stress level 13% high 68% moderate and 19% low stress in the total respondent physiotherapist. **(Table No.1)**

Table 1: Total Sample with Stress Perceived

Total Sample	High Stress	Moderate Stress	Low Stress
31	12.90%	67.74%	19.35%

In socio-demographic, different age groups are selected i.e. 18-29 year in which perceived 74.19%, 30-44 year 22.58% and 45-54 3.23%. Further, in age group of 18-29 years stress perceived 12.9% high, 51.61% moderate and 9.68% low stress. Between 30-44 year of age stress perceived 0% high, 12.9% moderate and 9.60% low and in the last age group i.e. 45-54 year having 0% high stress, 3.23% moderate and 0% low stress. **(Table No. 2)**

Table 2: Stress level of Different Age Group

Based on individual data				
Row Labels	High Stress	Moderate Stress	Low Stress	Grand Total
18-29	12.90%	51.61%	9.68%	74.19%
30-44	0.00%	12.90%	9.68%	22.58%
45-54	0.00%	3.23%	0.00%	3.23%
Grand Total	12.90%	67.74%	19.35%	100.00%

On the basis of gender, female perceived 9.68% high 32.26% moderate and 6.45% low stress while in Male perceived 3.23% high, 35.48& moderate and 12.9% low. Total stress perceived 48.39% by female respondents and 38.7% by male respondents. **(Table No. 3)**

Table 3: Stress perceived in Male and Female

Based on individual data				
Row Labels	**High Stress**	**Moderate Stress**	**Low Stress**	**Grand Total**
Female	9.68%	32.26%	6.45%	48.39%
Male	3.23%	35.48%	12.90%	51.61%
Grand Total	12.90%	67.74%	19.35%	100.00%

Our study aim to find the prevalence of stress level in working physiotherapist during pandemic. Study is an online survey by using PSS-10 questionnaire measure which was created and circulated through social media platform via WhatsApp, Mail, and Facebook. Total 38 data were collected among 31 selected for this study under inclusion and exclusion criteria.

Results found moderate level perceived stress in clinical physiotherapist (68%) as compared to study [Aiyer et al 2020] on healthcare professional's mental impact in U.S population where they include physicians, Nurses, Respiratory therapist found high level perceived stress in nurse responders. Similarly leenong et al,2007 studied on stress and psychological impact after 1year of SARS outbreak, included non-healthcare workers and healthcare workers found that high prevalence of stress on healthcare worker.

Study explained in gender comparison, male perceived high stress 51.6% than female clinical physiotherapist 48.4% as comparative study by Aiyer et al 2020 found that high perceived stress more in female Nurses. Study defined majority of responder lies in the 18-29 year of age criteria which were under PSS inclusion age criteria, result summarised high perceived stress rather than other age group criteria similar to Aiyer et al study, found high perceived stress between 25- 30 years of participant.

In this study, different results are observed as separate group of population (Clinical Physiotherapist) has been selected for conducting the survey and less respondents had responded over the questionnaire.

Conclusion

This study disclose there is the high prevalence of moderate perceived stress in clinical physiotherapist population which is lies in 18-29 year of age criteria. Study also depicting male perceiving high stress rather female.

Conflict of Interest: the researchers claim no conflicts of interest.

The Funding Source: we have not received any funding for this research.

Ethical Clearance: Not required because data was collected from google form during epidemic time but took a consent from every participants.

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Immunisation Status of Under Five Children in a Tribal Colony of Northern Kerala

Arun T Mithrason[1], Arya Vikas[2], Ann Mary Thomas[2], Madhusudan M[3]

[1]Professor and Head, [2]MBBS Intern, [3]Associate Professor, Department of Community Medicine, DM Wayanad Institute of Medical Sciences, Wayanad District, Kerala

Abstract

Background: One of the most cost effective and easy methods for the healthy wellbeing of a child is immunization. Paniyans is one of the major tribes of Wayanad and are the largest single tribal community. The sociocultural, political, and topographical uniqueness of the tribal groups in Kerala, their needs of health care, attitudes, and health-care-seeking behaviors differ from the nontribal population and thus, challenge the present service-delivery system that has largely been based on the needs and priorities formulated for the nontribal population.

Methods: This was a cross-sectional study done between November 2018 to January 2019 at Jai Hind colony, Wayanad district among Paniyan tribes. All the under 5 children in the colony were the study subjects. The parents were approached individually in their houses and data was collected using a predesigned and pretested investigator-administered questionnaire. Responses were obtained from a total 21 parents of the subjects.

Results: The maximum coverage was for BCG (100%), followed by OPV_0 and hepatitis B_0 doses (95.23% for both) and the least was MR_2 and DPT_1 doses (52.94% for both). Majority of the children (52.38%) were partially immunized and there were no children (0%) who were non immunized. The most common reason for partial immunization was unawareness regarding the need for immunization (54.54%).

Conclusions: The proportion of fully immunized children was significantly lower in the study. The maximum coverage was for BCG and the least was MR_2 and DPT_1 doses. The most common reasons for partial/no immunization in the current study was lack of awareness regarding the need for immunization

***Keywords:** Immunization, under five children, Paniyan tribe, Wayanad, Kerala*

Introduction

Infectious diseases are a major cause of morbidity and mortality in children. One of the most cost effective and easy methods for the healthy wellbeing of a child

Corresponding Author:
Dr Madhusudan M,
Associate Professor, Department of Community Medicine, DM Wayanad Institute of Medical Sciences, Naseera Nagar, Meppadi Post, Wayanad District, Kerala-673577, Phone: 7892680415;
e-mail: madhusudan_kims12@rediffmail.com

is immunization. The goal of immunizing children against Tuberculosis, Polio, Diphtheria, Pertussis, Tetanus, Hepatitis B, and Measles, responsible for child mortality and morbidity, is indeed a noble one.[1] The most important indicators mentioned in the Millennium Development Goals (MDGs) and Sustainable Development Goals (SDGs) for which India is a signatory, are the under-five mortality rate (U5MR) and Infant Mortality Rate (IMR).[2] About one-quarter or 25% of the under-five mortality in India is due to vaccine preventable diseases.[3] In 1974, the WHO launched it's "Expanded Programme on Immunization" (EPI) against

six, most common, preventable childhood diseases, viz. diphtheria, pertussis (whooping cough), tetanus, polio, tuberculosis and measles. The Government of India launched its EPI in 1978 with the objective of reducing the mortality and morbidity resulting from vaccine-preventable diseases of childhood, and to achieve self-sufficiency in the production of vaccines. Universal Immunization Program was started in India in 1985.[4]

In India, immunization services are offered free in public health facilities, but despite the efforts of the government, the immunization rate at the national level remains 62%.[5]According to the National Family Health survey (NFHS)-5 data, the proportion of 12-23 months children fully immunized is 77.8% in Kerala state and 86.4% in Wayanad district.[6] Wayanad is predominantly a hilly district set high on the Western Ghats with altitudes ranging from 700 to 2100 meters and has a large proportion (>40%) of its surface area covered with forest. It is also among 250 most backward districts of India.[7] Wayanad has the largest tribal population in Kerala with 8 scheduled tribes residing here. Paniyans is one of the major tribes of Wayanad and are the largest single tribal community with a population of 92,787**.** It was a patrilinial slave tribe community until the 1970s Bonded labour act, distributed in Wayanad, Kannur, Kozhikode and Malappuram, and presently work mainly as agricultural labourers.[8] The sociocultural, political, and topographical uniqueness of the tribal groups in Kerala, their needs of health care, attitudes, and health-care-seeking behaviors differ from the nontribal population and thus, challenge the present service-delivery system that has largely been based on the needs and priorities formulated for the nontribal population.[9] Hence the assessment of difference in knowledge and practice of immunization programme by tribal and non-tribal communities in a similar rural set up is a topic of research relevance.[10]

In this context, the present study was conducted to assess the immunization status of children under 5, to find out the various reasons for partial or non-immunization of children in a tribal colony of Wayanad.

Materials and Methods

This was a cross-sectional study done between November 2018 to January 2019 at Jai Hind colony, Moopainad panchayat, Wayanad among Paniyan tribes. All the under 5 children in the colony whose parents were willing to participate in the study were the study subjects. After obtaining approval from the college administration, the parents were approached individually in their houses and briefed about the purpose of the study. Participation in the study was voluntary. Oral informed consent was obtained from the parents and data was collected using a predesigned and pretested investigator-administered questionnaire in the local language, which had questions pertaining to basic socio demographic details of the subjects, details about vaccination and reasons for not taking the same. Details about immunization were cross checked from the child's immunization card wherever available and in the event of the card being not available based on careful recollection of details (like site of administration, number of injections etc.,) related to immunization.

Responses were obtained from a total 21 parents of the subjects. The parents of under 5 children unavailable on the first visit were visited on subsequent 2 days. Data were kept confidential.

The following operational definitions were used

Fully immunized: a child who has received all vaccines as per the National immunization Schedule appropriate to its age

Partially immunized: A child who has missed any dose in National immunization Schedule appropriate to its age (and has not taken even after 6 months lapse from the ideal time)

Non-immunized: a child who has not received any dose as per the National immunization Schedule appropriate to its age (even after 6 months lapse from the ideal time)

The data collected was entered in MS Excel and analysed with the same. Descriptive statistics like numbers and percentage were used in the analysis

Results

Total number of subjects were 21. The mean age of the subjects was 34.13 ($\pm$34.72) months. 11 (52%) of the subjects were male and 10(48%) female.

Table 1: Immunization coverage of individual vaccines

Vaccine	Coverage
BCG (n=21)	21 (100)
OPV 0 (n=21)	20 (95.23)
Hepatitis B 0 (n=21)	20 (95.23)
Pentavalent 3 (n=20)	10 (50)
MR 1 (n=20)	16 (80)
MR 2 (n=17)	9 (52.94)
DPT 1 (n=17)	9 (52.94)

The maximum coverage was for BCG (100%), followed by OPV_0 and hepatitis B_0 doses (95.23% for both) and the least was MR_2 and DPT_1 doses (52.94% for both)[table 1].

Table 2: Overall Immunization coverage status

Immunization status	No (%)
Fully immunized	10 (47.62)
Partially immunized	11 (52.38)
Total	21 (100)

Majority of the children (52.38%) were partially immunized and there were no children (0%) who were non immunized (table 2).

Table 3: Reasons for partial/non immunization

Reasons for partial/non immunization	No (%) (n=11)
Unaware of the need for immunization	6 (54.54)
Unaware of the subsequent doses	4 (36.36)
Lack of motivation/Postponed until another time	1 (9.1)

The most common reason for partial immunization was unawareness regarding the need for immunization (54.54%).

Discussion

In the current study, 47.62% were fully immunized and 52.38% partially immunized. Similar findings were observed by Manglik CG et al in their study in rural Mangaluru.[11] However Khargekar et al., in their study in a tribal area of Thane district Maharashtra have observed that the proportion of fully, partially and non-immunized were 71.1%, 17.8% and 11.1%.[12] Kumar et al., in their study in slums of Mangaluru have observed that proportion of fully and partially immunized were 58.7% and 41.3%. The possible reasons for the difference could be the differences in the sociocultural and demographic characteristics of the study subjects.

In the current study the maximum coverage was for BCG and the least was MR $_2$ and DPT $_1$ doses. Similar findings were noted by Manglik et al., and Kumar et al.,[12,13] The most common reasons for partial/no immunization in the current study was lack of awareness regarding the need for immunization. Similar findings were observed by Manglik et al.,[11] But in the study by Kumar et al., the most common reason was lack of awareness about subsequent doses.[13] The possible reasons for the difference could be the differences in the sociocultural and demographic characteristics of the study subjects.

The limitations of the study is that it is based on a single colony of Paniyan tribe. Hence the findings cannot be generalized to the entire paniyan tribe or to the entire tribal population of the Kerala state or India.

Conclusions

The proportion of fully immunized children was significantly lower in the study and majority were only partially immunized. The maximum coverage was for BCG and the least was MR_2 and DPT_1 doses. The most common reasons for partial/no immunization in the current study was lack of awareness regarding the need for immunization

Recommendations

Efforts should be made by means of SMS reminders or phone calls for the vaccine doses after 1 year of age.

More IEC activities are to be conducted in the tribal colonies of Wayanad to increase the awareness about the need for immunization and also the services available in the Public health facilities

Conflicts of Interest: Nil

Ethical Clearance: This study was a student project, and had time constraints as it had to be submitted before their university exams. Hence though IEC approval couldn't be obtained, ethical issues were appropriately addressed as follows

1. Anonymity of subjects was ensured

2. No pressure/allurement of any sort was exerted on the subjects to participate in the study and participation was completely voluntary

3. Confidentiality of data was ensured. It was saved in password protected systems which had access only to the investigators

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A Comparative Study of the Nutritional Status of Adolescents in Residential and Non-Residential Tribal Secondary Schools

Ashwini Yadav[1], Shalini Rawat[2], Prachi Patil[3]

[1]Department of Community Medicine, Seth G S Medical College, Mumbai, Maharashtra, India (Ex –Resident Medical Officer), [2]Department of Community Medicine ,L.T.M.M.C ,Sion Mumbai (Contractual Asssistant Professor), [3]Department of Community Medicine, Seth G S Medical College, Mumbai, Maharashtra, India (Ex –Resident Medical Officer)

Abstract

Background: Tribal populations lack access to health services and proper educational opportunities due to geographical, social and economic reasons. Among tribal population, malnutrition is prevalent resulting in vicious cycle of morbidities and mortalities. To tackle these issues, various interventions are being done at all levels. Establishment of residential schools along with structured meals and Mid-Day Meal program for non-residential schools are few of many such strategies. This study was undertaken to study the effect of these interventions in a tribal district.

Materials and Methods: It is a record based retrospective cross-sectional study. Health records of class VIII students from a residential and a non-residential (40 each) were analysed for desired variables. Data was compiled using Microsoft Excel 2016 and analysed using SPSS version 22.

Results: More proportion of adolescent tribal students in non-residential schools had history of worm infestation and diarrhoea in the last six months. Similar pattern was observed for signs of deficiencies of Vitamin B and Vitamin C. Significant difference was observed between food consumption and food diversity pattern being followed.

Conclusion: The findings of the study reiterate the need of strengthening of nutrition and hygiene centric school health program for tribal adolescents**.**

Key words: Tribal, Adolescents, School, Residential, Nutrition, Health.

Introduction

In India, tribal population is characterised by lack of access to health services and proper education which puts them at risk of social and economic deprivation. Among tribal population, malnutrition is very common and has affected the general health of tribal children as it lowers the ability to resist infections, leads to chronic illness and sometimes leads to brain impairment. [1]

Corresponding author:
Dr. Ashwini Yadav
Flat no 1303 ,Valencia Apartment
Near Kem Hospital
Mumbai-12

The establishment of Ashram Schools was envisaged as a direct intervention to tackle the socio-economic and geographic inequalities of the tribal population particularly in sparsely populated areas by providing educational opportunities under the 'Establishment of Ashram Schools in Tribal Sub Plan Areas' by the Ministry of Tribal Affairs; operational since 1990-91 and revised with effect from financial year 2008-09. The Ashram Schools of the State Governments/Union Territories Administrations are mandated to provide all necessary facilities like drinking water, bedding and mattress, good quality food etc. With the notification of RTE Act, Ashram Schools also come under the purview of Ministry of Education ,[2] and have to follow the

prescribed norms of standards. [3]

In Maharashtra, government non-residential schools in rural and tribal areas are run under direct administration of Rural Local Governance. In every school, Mid-Day meal (100 grams of rice for standard I to V and 150 grams of rice for standard VI to VIII) is being given to students to prevent the malnutrition. [1]

To address the issue of poor quality of food being provided and its implications, a Centralised Kitchen Project was initiated in August 2015 on a pilot basis in Palghar and Nasik districts of Maharashtra. Under this, Ashram Schools in Palghar District are being provided the cooked food prepared at a Central Kitchen. Mid-day meal to tribal non-residential schools is also being provided through the same kitchen. [4]

Against this background, to study and compare the nutritional status of tribal adolescents in a tribal residential and non-residential secondary schools, the present study was undertaken in Palghar District of Maharashtra. The objectives were to study the sociodemographic profile of tribal school adolescents, to compare the nutritional status of a tribal residential and non- residential school adolescent students and to evolve recommendations based on study findings.

Materials and Methods:

This is a record based retrospective cross-sectional study based on data from school health records in Palghar district. Health records (February 2017) of class VIII students from randomly selected residential (ashram) and non-residential school (40 each) were obtained by purposive sampling method on a pilot basis. From these records, socio-demographic and nutritional status related data (Anthropometry, history of co-morbidities influencing nutrition, signs of vitamin and micronutrient deficiency, diet history). Ethical committee approval was taken .Collected data was compiled using Microsoft Excel 2016. Data was analysed using SPSS Version 22 for Descriptive Statistics values (frequencies, mean, standard deviation). Chi square test/Fisher exact test were used for comparison between categorical variables of two groups. For mean and standard deviation comparison, Open Epi was used.

Results: The background characteristics like mother's education, father's education and number of family members were comparable in both the groups. Most parents were illiterate and very few made it to higher secondary level. However, the difference in parents' occupation was observed ($p < 0.05$). Most parents were illiterate and involved in farming and other labour work to earn their livelihood.

Table 1: Anthropometric Parameters of School Children

Variable	Value		'p' value
	Residential School	**Non-residential School**	
Mean Age (SD)	14.18 (0.448)	13.70 (0.516)	0.000
Female students 'n' (%)	12 (30)	21 (52.5)	0.040
Mean Height in cm (SD)	151.38 (7.941)	148.70 (6.094)	0.094
Mean Weight in kg (SD)	34.90 (6.496)	35.78 (6.407)	0.543
Mean BMI kg/m2(SD)	15.113 (1.753)	16.188 (2.825)	0.044
Underweight 'n' (%)	29 (72.5)	20 (50)	0.069
Healthy weight 'n' (%)	11 (27.5)	18 (45)	
Overweight 'n' (%)	0 (0.0)	2 (5)	

Significant difference in the mean age of adolescent students of residential (Ashram) and non-residential schools. The percentage of girl students studying in ashram schools is found to be less (30%) compared to boys. (Table 1)

The difference in mean BMI of both the groups (15.11 for residential and 16.118 for non-residential school adolescents) was found statistically significant. When the adolescents were categorised into three categories for their nutritional status based on WHO Z score charts for BMI (viz. Underweight, healthy weight and overweight), the percentage of underweight students was found to be 72.5% in residential school. (Table 1)

Table 2: Morbidity profile of tribal adolescents

Variable Residential School		Value		'p' value
		Non-residential School		
History of worm infestation 'n' (%)		3 (7.5)	12 (30)	**0.011**
History of diarrhoea 'n' (%)		5 (12.5)	13 (32.5)	**0.032**
History of respiratory illness		17 (42.5)	19 (47.5)	0.653
Signs of Vitamin B Deficiency 'n' (%)		8 (20)	18 (45)	**0.016**
Signs of Vitamin C Deficiency 'n' (%)		3 (7.5)	20 (50)	**0.000**
Eye changes 'n' (%)		7 (17.5)	16 (40)	**0.026**
Pallor 'n' (%)		11 (27.5)	13 (32.5)	0.626
Hair changes 'n' (%)		8 (20)	14 (35)	0.133
Breakfast	Taken 'n' (%)	40 (50.0)	25 (31.2)	**0.000**
	Not taken 'n' (%)	0 (0.0)	15 (18.8)	
Evening snacks	Taken 'n' (%)	40 (50.0)	2 (2.5)	**0.000**
	Not taken 'n' (%)	0 (0.0)	38 (47.5)	

Table 3: Food groups

Food timing	Mean food groups (SD)		'p' value
	Residential School	Non-residential School	
Breakfast	2.35 (0.483)	1.18 (0.844)	0.000
Lunch	4 (0.000)	2 (0.000)	0.000
Evening snacks	1.98 (0.158)	0.08 (0.350)	0.000
Dinner	3.50 (0.877)	2.03 (0.158)	0.000

Percentage of episodes (Table 2) like worm infestation and diarrhoea was more in non-residential school adolescents (30% and 32.5% respectively) in the last 6 months. Occurrence of the symptoms of respiratory illness, clinical pallor and hair changes was almost similar in both the groups. Lesser number of adolescents from residential (ashram) school showed signs of vitamin B (20%) and vitamin C (7.5%) deficiency. The statistically significant difference was shown for vitamin B and vitamin C deficiency signs and eye changes (17.5% in residential adolescents and 40% in non-residential adolescents). Significant difference was observed between the food pattern and timely food consumption (Table 3) being followed by residential (ashram) and non-residential tribal school adolescents.

Discussion

In the present study, differential age-wise and sex-wise enrolment pattern was observed. In a study conducted by Rose-Clarke K et al., [5]it was observed that girls dropped out of school because they were required for household work (37%) or work on the family farm or business (22%). In a study conducted by Rao KM et al, [8]4% adolescent girls were married and less than 1% were either pregnant (0.4%) or lactating (0.7%) at the time of the survey. Lack of formal education among parents, involvement of parents in work such as farming and labour work, loss of either parent were other background characteristics found in the present study. Similar findings were observed in a study conducted for diet and nutritional status of rural adolescents where the major occupation of the heads of the households surveyed was agriculture. [6]In the same study, it was found that more than a third (37.3%) of the families with adolescents did not possess any land. Majority adolescents in the present study belonged to smaller families. Poor nutrition of adolescents is linked with rural areas and large families with uneducated or unskilled parents from lower-income households. [7] A significant association between undernutrition and socio-economic parameters like type of family, size of land holding and occupation of head of household was observed by Rao KM et al. [8] In the present study, mean BMI of residential school adolescents was found

to be less than those studying in non-residential school. The proportion of underweight adolescents was 72.5% in residential and 50% in non-residential tribal school, which is comparable with other studies conducted for tribal adolescents and children. [8] [10]

More adolescents in non-residential schools had history of worm infestation and diarrhoea. Signs of vitamin B and vitamin C deficiency and eye changes were also more commonly observed in them. Pallor was observed in about one third students in both residential and non-residential schools. Findings of Comprehensive National Nutrition Survey suggest that in India in 2018, 18% of boys and 40% of girls in the age group of 10-19 years were anaemic. [9]

Fewer adolescents studying in non-residential school had breakfast or evening snacks and their all meals were constituted from fewer food groups when compared with residential school adolescents. It was observed by Rao KM et al that the mean intake of all the foodstuffs, especially the income elastic foods such as Pulses, Milk & Milk products, Oils & fats and Sugar & Jaggery were lower than the recommended levels of ICMR among tribal adolescents.[8] In the same study, it was also observed that the intake of all the nutrients were below the recommended level, while that of micronutrients such as iron, vitamin A and riboflavin were grossly inadequate in all the age and sex groups. [6][8] The dietary history in the present study suggests minimal food diversity among tribal adolescents studying in non-residential schools. The dietary recall data in a study conducted for tribal children in the same district revealed that 83% of the children had consumed food belonging to only 3 groups, the most common food eaten by the children was rice and dal (pulses) and only 13% of the children achieved a minimum level of diet diversity. [10]

The differential age-wise and sex-wise patterns of enrolment in both the residential and non-residential schools need to be studied further for the factors like underage and overage enrolment, delayed schooling and it's causes, gender bias, number of drop-outs and reasons for drop-out if any and difficulties faced while

availing the school facilities in residential schools.

The significant difference in the occurrence of worm infestation and diarrhoea signifies the need of strengthening of hygiene and sanitation practices in non-residential tribal schools. This needs to be studied on a larger scale involving more of such schools. Growth of adolescents needs to be monitored prospectively to differentiate growth disturbance because of poor nutrition from other growth disorders. Strategy for the involvement of teachers and parents can be evolved.

The study was undertaken on a pilot basis which is record based and sample size is too small. Quantitative assessment of calories consumed could not be done as details of food quantity were not available. Extensive multi-centric study with larger sample size needs to be undertaken to explore the determinants of nutritional status which will be considering parameters like childhood malnutrition history, nutritional status of parents (for inter-generational cycle of malnutrition), food security, accessibility to food, cooking practices, detailed quantitative assessment of actual food consumption and biochemical tests for the exact diagnosis of nutritional morbidities.

The findings of the study re-emphasize the need of systematic, well planned, culturally relevant well implemented programme of nutritional education, supplementation and hygiene in tribal schools.

Conflict of Interest : NIL

Source of Funding : Nil

Ethical Clearance : Taken form the institutional Ethics Committee

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Hygiene behavior among Female Garment Workers: a Pre-COVID-19 Cross-Sectional Study in Bangladesh

Bilkis Banu[1], Nasrin Akter[2], SujanaHaque Chawdhury[3], ZahidurRahim[4], Sarder Mahmud Hossain[5], FarhanaFaruqueZerin[6] Sayeeda Rahman[7]

[1]PhD Scholar, Heidelberg Institute of Global Health, Heidelberg University, Germany; Assistant Professor, Department of Public Health, Northern University Bangladesh, Dhaka, Bangladesh; [2]Lecturer, Department of Public Health, Northern University Bangladesh, Dhaka, Bangladesh; [3]Lecturer, Department of Public Health, Northern University Bangladesh, Dhaka, Bangladesh; [4]National Resource Person, Communicable Disease Control Unit, Directorate General of Health Services; [5]Professor and Head, Department of Public Health, Northern University Bangladesh, Dhaka, Bangladesh; [6]Research Fellow, Department of Public Health, Northern University Bangladesh, Dhaka, Bangladesh; [7]Associate Professor of Pharmacology and Public Health, School of Medicine, American University of Integrative Sciences, Bridgetown, Barbados

Abstract

This cross-sectional study was undertaken to delineate the hygiene behavior among the female garment workers in Bangladesh during pre-COVID-19 period. 500 female garments workers were selected for the study. Data were collected by face-to-face interview method using semi-structured questionnaire which include the information on socio-demography, different components of personal hygiene such as bathing, brushing teeth, washing feet, washing/ changing cloth, washing hair by soap/ shampoo, trimming nail and washing hand. The majority of the participants (>75%) had ideal knowledge and practiceon every considered hygiene behavior. Regarding hand-washing behavior, only 3% had appropriate knowledge and ideally practiced by 60.2%. Knowledge of the respondents was significantly associated with ideal practice of all components (p=0.01). Predictors identified according to age, BMI, education and marital status of respondents, were significantly associated with hygiene related to bathing, washing feet, clothing, hair and hand.

Keywords: *Hygiene behavior, COVID-19, pre-existing context, female garments workers*

Background

The Readymade Garment (RMG) industry drives the economic growth of Bangladesh in terms of employment, production and foreign exchange earnings[1] and contributing to an impressive 6 percent growth rate for nearly a decade.[2] Bangladesh is now one of the world's leading clothing exporters, second only to China.[3]Garment industry has become placed the largest export earning sector of Bangladesh where more than 5000 garment factories are running, employing over 4 million workers.[4]Women represent 85 percent of the total 2.4 million employees in the RMG industry.[5]

Garment factories in Bangladesh has been expanded mainly on the easy availability of labor especially of the female labor accessibility.[6]Young women often start work at the age of 18 and usually continue until they are 30-35 years old. Female workers in Bangladesh tend to have very little education as they drop out of school early to help, support their families; some are illiterate, and poor, their health also poses significant challenges.[7]

The workers in this sector are living from hand to mouth and they are unable to maintain their basic needs in their income for minimum health care, medical services, hygienic accommodation.[8]Paul-Majumder conducted a study on the physical and mental health

status of garment workers and how problem affect labor productivity, competitiveness of the garment industry in the world market and the working life of the workers, particularly of female workers.[9]

In developing countries, the major causes for morbidity are communicable diseasesand malnutrition.[10]The Cleanzine reported that WHOfound RMG workers in Bangladesh significantly suffering from diarrhea, dysentery, skin diseases, lung diseases and other health conditions, many of which are contagious and spreads through hands from one to others. As a solution the report showed the findings of UNICEF, hand washing with soap at critical timesincluding before eating and preparing food and after using the toilet –can reduce the rates of diarrhea rates by more than 40% and reduce the incidence of acute respiratory infections by around 23%.[11]The pandemic situation of Coronavirus Disease 2019 (COVID -19) is considered as the most crucial global health calamity of the century and the greatest challenge for Bangladesh.[12] This state might pose significant impact on Bangladesh garment industry if female workers would have poor hygiene behavior.[13]Bangladesh has gradually rolled back the lockdown restrictions despite an escalating coronavirus outbreak, allowing garment factories to reopen on a limited scale since April 25, 2020 subject to their compliance with health and safety guidelines to reduce the risk of contagion among workers.[14]Nevertheless, the health and hygiene protocols sets out by apparel exporters' lobby BGMEA and others owners' associations were not implemented in most of the cases initially. "We went through the media reports and found that more than one hundred workers have been infected with COVID-19 till May 12, 2020.Afterwards, the factories were decided to run again in the pandemic situation which had chances to increase infections in manifolds.[15]

Personal hygiene can help preventing the COVID -19 and flatten the epidemic curve.[16]Institute of Epidemiology Disease Control Research (IEDCR) of Bangladesh declared "there is nothing to be panicked about but we must be alert about maintaining personal hygiene to prevent deadly disease" through different mass media.[17] Frequent and proper hand hygiene with soap–water or alcohol based (minimum 70 percent) hand sanitizer is one of the most important measures that can be used to prevent infection with COVID-19.[17] Experts said daily showers essential to prevent spread of corona virus.[18]Taking shower every day or every other day is necessary to prevent any kind of communicable diseases include COVID-19.[19]Brushing teeth, Hand, nail, foot, hair cleaning is essential in protection against disease.[20]

In the current COVID-19 pandemic condition, it is essential to have sustainable hygiene behavior among female workers to maintain the growth in export of RMG. Research finding related to knowledge and behavior on personal hygiene among female garment workers in Bangladesh conducted during pre-COVID-19 period is scarce. This information is essential, especially during COVID-19 era and beyond, to identify the gap between knowledge and practice of personal hygiene as well as to plan and implement sustainable, comprehensive health programs to tackle the situation. Therefore, this study was aimed to delineate the hygiene behavior among the female garment workers in Bangladesh during pre-COVID-19 period.

Methods

Study setting:

The study was conducted in four different garment industries directed by two different owners, such as: Enayet Garments, Matrix Dresses, Probashi Knitwear and Auto-tex Fabrics Limited located in Dhaka city of Bangladesh. These garment industries were selected by considering research convenience because accessing the workers of RMG as interviewees was a big challenge as RMG contributes in national earning and occupies a unique position in the Bangladesh economy.

Study design and Sampling design:

This cross-sectional study was carried out from April to July 2019 under the research project entitled 'Empowerment of Female Garment Workers'. In this study, a total number of 500 female garment workers were selected from the four garment factories. The total sample were calculated by using the formula "n= 'Z^{2}pq/ d^2'" where, z = 1.96, p = 0.50 (as there is no reasonable

estimate of any prevalence rate, 50% was considered), q = 1-p, and d was considered as 0.05. In addition, 30% of the calculated number was added to consider non-response and questionnaire error factors. The inclusion criteria to select the study subjects were: (i) female workers working in the selected garment factories, and (ii) willingness to participate in the study.

Data collection:

Data were gathered by four trained data collectors through face-to-face interview method, using a pre-tested and semi-structured questionnaire. Knowledge and practices of different components of hygiene behavior were recorded by 7 days-recall method. Weight and height were measured by using tools.

Questionnaire:

The questionnaire comprised of several sections: (i) socio-demographic information: age, religion, education, parental education, marital status, parity, living arrangement, family type, monthly family income, family size, (ii) nutritional status: weight, height, body mass index (BMI), (iii) knowledge on hygiene behavior: taking bath, brushing teeth, washing feet, washing/ changing cloth, washing hair by soap/ shampoo, trimming nail, hand washing (importance, appropriate timing, materials, techniques), and (iv) practice on hygiene behavior: taking bath, brushing teeth, washing feet, washing/ changing cloth, washing hair by soap/ shampoo, trimmingnail and hand washing.

Measures:

Knowledge and practice: Knowledge and practices of hygiene behavior were categorized in this study by considering the standards of different components. The standard was for taking bath: once a day; for brushing teeth: twice a day; for washing feet: when necessary; for washing/ changing cloth: once a day; for washing hair by soap/ shampoo: thrice a week; trimming nail: once a week and for washing hand: when necessary.[21]

Socio-economic status: Socio-economic classifications were made according to the per capita Gross National Income and World Bank Calculations.

The income groups were: Low: BDT ≤5360; Lower-middle: BDT (5362-21270); Upper-middle: BDT (21271-65761); high: BDT ≥65762.[22]

Nutritional status: BMI was classified according to the World Health Organization (WHO) and the classification of nutritional status was as followed-Underweight: <18.5; Normal weight: 18.5-24.9; Overweight: 25-29.9; Obesity: >30.[23]

Data analysis:

Data were entered, checked for quality and analyzed using the SPSS (Statistical Package for Social Sciences) version 20. Respondent characteristics, level of knowledge and practice classification were described as percentage and presented with 95% confidence intervals (CI). A logistic regression was used to identify predictors related to practice to hygiene behavior. All independent variables were tested individually by Chi-square (X^2) and entered into the first model since they were associated with adherence <0.25 level of significance. A backward step-by-step binary logistic regression (simple and multiple) was used and only statistically significant variables (p<0.05) were kept in the final model. The odds ratios (ORs) of simple binary results were considered as unadjusted ORs (Crude ORs), whereas ORs of multiple binary logistic regressions were used as adjusted ORs (AORs). In some cases, after backward elimination, some logical variables showed highly significant association with the dependent variables which were added later in the model.

Ethical clearance:

The study complied with the Declaration of Helsinki and was approved by the Ethical Review Committee, Department of Public Health, Northern University Bangladesh, Dhaka, Bangladesh (Memo no. NUB/DPH/ EC/2020/01).

Results

Demographics of the respondents

A total of 500 respondents were included in this study with a mean (±SD) age of 22.09 (±6.58) years. Most respondents (87.2%) were aged >18years. Majority

of the respondents were Muslim(97%), completed <class VIII (90.2%), more than half (56.6%) married/separated/ divorced/widowed, and belonged the Low: BDT ≤5360income group (52.6%). Most of study subjects (58.2%) had Normal weight: 18.5-24.9calculated by Body Mass Index (BMI).(Table 1)

Knowledge and Practice

Out of 500 respondents, majority (88%) had ideal knowledge and practice of taking bathas well as knowledge significantly influenced the practice of taking bath (p=0.01). Whereas 97% respondent had correct knowledge of teeth brushing technique and surprisingly all of them practiced it. Washing feet, washing/ changing cloth and trimming nail were three important parameters in which more than 400 respondents had proper knowledge and practice ideally. Furthermore, these three hygiene practices significantly associated with having adequate knowledge respectively (p=0.01). Seventy five percent ofrespondents hadno knowledge onwashing hair by soap/ shampoo, although like other hygiene behaviors study observed knowledge of wasting hair also significantly dominant on the practice of it (p=0.01).

With respect to hand-washing behavior, only 3% had appropriate knowledge and ideally practiced by 60.2%(p=0.01) Knowledge on hand washing was assessed through measuring four components[24] i.e. importance, timing, materials used and technique. The study subjects (99.6%) were found to have knowledge on materials (water & soap), 80% had knowledge on importance of hand washing as prevent germ spreading, nearly half (46.2%) knew the appropriate timing of hand washing as when hand is dirty, before/after meal and after toilet use. Likewise, they also knew that hand washing can prevent worm, Diarrhea, Jaundice, Typhoid and Dysentery. Hand-washing practice was assessed through the measurement of three components as timing, used materials and technique. Study observed, more than half (60.2%) maintained appropriate timing of hand washing and all of them used proper materials however, none of them practiced ideal hand washing technique. Therefore, it is clear that although study subjects had

been practicing the use of proper hand washing materials as socio-demographically or culturally, they did not have exact knowledge and practice on ideal hand washing technique. (Table 2)

Predictors for not taking bath ideally

Study delineatedthat; ideallytaking bath was lesspracticed among unmarried women (AOR= 0.37; p= 0.002).Whereas, respondents of age group >18 and educational qualification with class 9 and above had a well practice of ideal bathingcomparedto younger(AOR= 1.32; p= 0.460) and lower educated subjects(AOR= 2.07; p= 0.24). In addition,underweight respondentsdid not take bath ideally (AOR= 1.16; p= 0.75).

Predictors for not ideally washing feet

Study also revealed thatamong unmarried non-Muslim respondents'ideal practice of washingwas significantly lower than Muslim(AOR= 0.34; p= 0.18) and married workers(AOR= 0.27; p= 0.01).Similarly,age group of<18 years (AOR= 1.22; p= 0.68) and educational qualification up to class VIII (AOR= 1.89; p= 0.41) also showedlower level of practicingideal feet washing.

Predictors for not ideally washing/ changing cloth

Respondents fromlow income group (BDT ≤5360) found less likely (AOR=1.22; p=0.42) tofollow ideal way of washing /changing clothes. On the other hand; ideally practice of washing /changing clothes was observed higher (AOR= 0.57; p= 0.02) among married/ separated/divorced/widowed respondents. In addition, underweight (AOR=1.72; p=0.16) and up to class VIII education level (AOR= 2.18; p= 0.12) showed significantly lower compliance withideallywashing / changing clothes.

Predictors for not ideally washing hair

Study identified that married (AOR= 1.54; p= 0.09) from low-income group (BDT ≤5360) (AOR= 1.67; p= 0.03) were less concern about washing their hair ideally. Similarly, respondents with educational qualification up to class VIII and above express less (AOR= 1.77; p= 0.21) concern about ideal hair washing technique. Whereas age group of >18 showed moreconcern

regarding washing their hair regularly.

Predictors for not ideally trimming nail

Trimming nail regularly was one of the essentials for a clean hand, but unfortunately ideal practice of this component was less among non- Muslim workers compared to Muslims(AOR= 0.37; p= 0.22). Additionally, age group <18 (AOR= 3.61; p= 0.01) with up to class VIII education (AOR= 3.62; p= 0.22) were also reluctant to this health behavior compared to others. Similarly, practice of trimming nail properlywas significantly less (AOR= 1.77; p= 0.14) among low socio-economic group.

Predictors for not ideally washing hand

Washing hand regularlyis a vital preventive practice for the health wellbeing and survival against the communicable diseases.However, this study found a depressive scenario regarding hand washing knowledge and practice among the study subjects. Ideal hand washing practice was more significantly maintained among the age group more than 18 years than the younger (AOR= 0.57; p= 0.04). Furthermore, Lower middle-income group(AOR= 0.62; p= 0.01) who were suffering from overweight/obesity(AOR= 0.71; p= 0.24 for Normal weight, AOR=0.76; p=0.39 for Underweight) found significantly concerned aboutideal hand-washing practice. (Table 3)

Discussion

This study examined the hygiene behavior among the female garment workers in Bangladesh during pre-COVID-19 period.The main findings of this study includes the following: (i) majority of the participants (>75%) had ideal knowledge and practice of hygiene behavior i.e. taking bath, brushing technique, washing feet, washing/changing cloth, trimming nail, and washing hair by soap/shampoo; (ii) regarding hand-washing behavior, only 3% had appropriate knowledge and ideally practiced by 60.2%, and (iii)predictors identified according to age, BMI, education and marital status of respondents were significantly associated with taking bath, washing feet, cloth, hair and hand.

It was impressive that majority of the respondents of this study had ideal knowledge on taking bathing (88%) and washing feet (94%) which pose significant impact on their ideal practice. However, bath-taking and feet-washing were significantly less practiced among unmarried and under aged (<18 years) workers compared to the other group (p<0.01). A similar study conducted among slum dwellers in Dhaka city, Bangladesh showed that (81%) of the slum dwellers take bath regularly for personal cleanliness.[25] These findings are in concurrence with a similar study conducted among Secondary School Students of Mymensingh SadarUpazilla, Bangladesh showing 97.7% of respondents to took bath daily.[26]In an Ethiopian study, approximately 34% of the respondents reported poor bathing practices.[34]

The present study depicted that all workers are habituated to brush their teeth regularly which found significantly associated with ideal knowledge. Similar impressive findings were identified for the component washing/ changing cloth and trimming nail where large proportion of workers had ideal knowledge (84%, 82% respectively)which significantly influenced ideal practice (82%, 93% respectively).However, underweight, unmarried and lower educated (<class VIII) workers belonged to lower monthly incomeremainedsignificantly less concernedfor ideally practice of washing/ changing cloth compared to the other groups.Another study showed higher monthly household expenditure was associated with better practice of covering coughs and sneezes.[32,33]Likewise, under aged female workers with lower income were more reluctant to trimming nail than the other group.

Concerning the component of washing-hair, respondents had poor knowledge (25%) in comparison to good practice (81%). Present study found that marriedfemale garment workersfrom low-income group were significantly (p<0.01) less concerned about washing their hair by soap/ shampoo ideally. A study in Ethiopia showed that approximately 21% respondents reported poor hair washing practices.[39]Another study showed that approximately 70% female garment workers in Bangladesh were not maintaining personal hygiene properly during menstruation and more than

85% were not satisfied about their washing facilities in their factories.[34]

These finding reflectedimproved knowledge and practice among garment workers and creating hygiene culture could significantly help to mitigate COVID 19 situation in Bangladesh. Hygiene behavior during the current COVID-19 pandemic includes covering cough and sneezes with a tissue or sleeve, avoiding close contact with affected people, wearing a face covering, cleaning and disinfecting commonly used objects like mobile phone, wallet etc. Poor hygiene knowledge and practices play vital roles in increasing the spread of communicable diseases in developing countries.

Our study revealed that only 3% respondents had knowledge about hand washing. But interestingly 60% respondents mentioned to do hand washing. Study presented that ideal hand washing practice were significantly less common in lower middle-income group with the under aged (<18 years) workers compared to low income group and the elders.

These findings demonstrated that verbal response about hand washing behavior did not merge with the real scenario of practices. The maximum number of respondents didn't have idea about the proper technique of hand washing, but more than half of the respondents used to follow the appropriate timing and materials of hand washing by inheriting this habit from their family.

A similar study conducted among slum dwellers in Bangladesh showed that 67% of the respondents were habituated to washing hand by soap before taking meal.[25]Another similar study revealed that majority (90%) of respondents had knowledge about hand washing with soap before eating and after defecation, but only 21% and 88% respondents reported to do so respectively.[27]A study conducted in China among hospitalized patients showed that majority (94.2%)

of the participants believed that handwashing was important for disease recovery, and almost the same percentage (93.2%) of them believed that handwashing could prevent infection spread among patients.[28]

Some research demonstrated that hand washingpractice declinedrespiratory infections by around 15% to 20%. A studyfound only 5% of Americans wash their hands properly.[29]Although the Communicable Disease Control (CDC) Unit recommends spending 20 seconds for hand-washing to prevent diseases, but people averagely spend only six second to wash their hands.[30]

From many COVID-19 investigative reports from international media and WHO situation analysis reported that hospitalized patients of China were more conscious regarding hand washing compared to the American peoples.[31]

In this study, we found that comparatively more educational qualification had positive influence on the indicators of personal hygiene behavior' among female garment workers. A Similar study among university students showed that the level of higher-grade education of participants had also played a significant impact on handwashing practices compared to that of lower grade education.[35]

Various studies revealed that the majority of the female workers in the garment sector in Bangladesh suffer from the physical and mental health diseases.[8,36-38]In the context of Bangladesh, personal hygiene seeking behaviors and hygiene education might play advantageous role to mitigate and controls of COVID-19 and others communicable diseases. The policy makers and other concern organizations should take necessary steps to maintain good health status of the garment workers in Bangladesh.

Table 1: Demographic characteristics of the participants (n=500)			
Characteristics		**Frequency (n)**	**Percent (%)**
Age	≤18	64	12.8
	>18	436	87.2
Religion	Muslim	485	97
	Non-Muslim	15	3
Education	Up to class 8	451	90.2
	Class 9 or above	49	9.8
Marital Status	Married/separated/divorced/widowed	283	56.6
	Unmarried	217	43.4
Socio-economic Status	Low: BDT ≤5360	263	52.6
	Lower-middle: BDT (5362-21270)	237	47.4
BMI (Body Mass Indexed)	Underweight: <18.5	141	28.2
	Normal weight: 18.5-24.9	291	58.2
	Overweight: 25-29.9	55	11
	Obesity: >30	13	2.6

Table 2: Proportion of respondents according to the knowledge and behaviour on personal hygiene (n=500)					
Sl No	**Item Topic**	**Knowledge**		**Practice**		**χ2/P**
		Yes (%)	**No (%)**	**Yes (%)**	**No (%)**	
1	Taking bath	439 (88)	61 (12)	442 (88)	58 (12)	95.68/0.01s
2	Brushing teeth	485 (97)	15 (3)	500 (100)	0	-
3	Washing feet	469 (94)	31 (6)	468 (94)	32 (6)	1.47/0.01s
4	Washing/changing cloth	424 (84)	76 (15)	409 (82)	91 (18)	88.67/0.01s
5	Washing hair by soap/shampoo	126 (25)	374 (75)	405 (81)	95 (19)	22.20/0.01s
6	Trimming nail	412 (82)	88 (18)	467 (93)	33 (7)	8.58/0.01s
7	Hand washing	15 (3)	485 (97)	301 (60)	199 (40)	10.22/0.01s

*P value was generated through Chi-squire analysis, s=significant

Table 3: Predictors identified for personal hygiene behaviours by the study respondents (n=500)

Variables		Items of Personal hygiene behavior Ideally practiced n (%)	Level of Practice		COR	P value	AOR	P value Lower	95% CI	
			Non-ideally practiced n (%)						Upper	
Age	<18	Taking bath	51 (79.7)	13 (20.3)	2.22	0.02ˢ	1.32	0.46	0.63	2.75
	>18		391 (89.7)	45 (10.3)	Reference category					
Marital status	Married/ separated/ Divorced/ Widowed		264 (93.3)	19 (6.7)	0.32	0.01ˢ	0.37	0.01ˢ	0.19	0.69
	Unmarried		178 (82)	39 (18)	Reference category					
Marital status	Married/ separated/ Divorced/ Widowed	Washing feet	274 (96.8)	9 (3.2)	0.28	0.01ˢ	0.27	0.01ˢ	0.12	0.6
	Unmarried		194 (89.4)	23 (10.6)	Reference category					
Marital status	Married/ separated/ Divorced/ Widowed	Washing/ changing cloth	244 (86.2)	39 (13.8)	0.51	0.01ˢ	0.57	0.02ˢ	0.35	0.92
	Unmarried		165 (76)	52 (24)	Reference category					
Monthly income	Low income	washing hair by soap/ shampoo	204 (77.6)	59 (22.4)	1.62	0.04ˢ	1.67	0.03ˢ	1.05	2.65
	Lower middle income		201 (84.8)	36 (15.2)	Reference category					
Age	<18	Cutting nail	55 (85.9)	9 (14.1)	3.61	0.01ˢ	3.61	0.01ˢ	1.36	9.6
	>18		412 (94.5)	24 (5.5)	Reference category					
Age	<18	Washing hand	34 (53.1)	30 (46.9)	0.53	0.02ˢ	0.57	0.04ˢ	0.33	0.98
	>18		165 (37.8)	271 (62.2)	Reference category					
Monthly income	Low income		120 (45.6)	143 (54.4)	0.6	0.01ˢ	0.62	0.01ˢ	0.43	0.9
	Lower middle income		79 (33.3)	158 (66.7)	Reference category					

*Binary Regression, s=significant

Conclusions

It is encouraging that a large proportion of female garment workers were identified in this study with good knowledge on different personal hygiene behavior, which had a significant impact on their practice. Very least number of respondents in the study were depicted with poor personal hygiene behavior and the significant predictors behind this were mostly underneath the having proper knowledge and socio-demographic situation such as under age (<18 years), unmarried status, low education (<class 8) and low-income level of the workers. These crucial factors need to be addressed by the employers of the garment industries of Bangladesh.

Most important upshot of this study was least knowledge and practice of technique-based hand washing among the female workers which is alarming in this COVID-19 pandemic situation. Successful implementation of comprehensive health and hygiene intervention programs is required to substantially attenuate the transmissible disease borne by female workers in Bangladesh.

Footnote:

Limitations of the study:

The present study has several limitations. This cross-sectional study involved only 4 garment factories with a small sample size; therefore, caution needs to be taken to generalize the data to the wider settings. Lastly, our survey looked at only garment factories at capital city Dhaka; therefore, does not represent the knowledge and practices of garment workers outside Dhaka city.

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A Cross Sectional Study on the Prevalence of Abuse and Self Defence among Female Medical Students in Hubli

Dattatraya Dinna Bant

Professor and Hod, Dept. of Community Medicine, Kims Hubli

Abstract

Background: Female abuse and harassment are burning issues of the present times and has shown increasing trend of late.Harassment at workplace is a violation of Human Right.It degrades a person's privacy and dignity leading to emotional stress,humiliation,anxiety and depression.Hence a study on the prevalence of abuse among female medical students is highly warranted.

Methods: A cross sectional study was conducted for a duration of one month among 100 female medical students in Hubli,providing them with pretested semistructured questionnaire after obtaining informed oral consent.The participants were assured of their confidentiality.The data collected,was entered in excel sheet,tabulated and represented as tables and graphs.

Conclusion: 95% female students felt that they have been harassed atleast once,among which 53% of the abusers were strangers.Verbal abuse was the most common form of abuse .Majority of them failed to inform higher authorities and had deep psycho social impact.Only a meagre of them were trained in self defense technics.

Keywords: *Abuse, Self Defense, Female Medical Students, Hubli*

Introduction

Female abuse is defined as 'intentional and systemic use of tactics to establish and maintain power and control over the thoughts,beliefs and conduct of a woman through the inducement of fear and/or dependency.[1] This definition encompasses aspects of the definition from the United Nations Declaration on the elimination of violence against women(1993)

Harassment is defined as any 'improper and unwelcome conduct that might reasonably be expected or be perceived to cause humiliation to another person. [2] It takes the form of words,gestures,or actions which tend to annoy, alarm, abuse, demean, intimidate, belittle, humiliate or which create an intimidating,hostile or offensive work environment.[3]

Harassment at workplace is a violation of Human Right.It degrades a person's privacy and dignity.

It causes emotional stress to the victim apart from humiliation,anxiety, depression, anger, powerlessness, fatigue and physical illness.

Street harassment refers to verbal comments and physical actions between strangers that are unwelcome or threatening and those that occur in public places.It is an understudied form of violence against women.[4]

Aim

1. To study the prevalence of abuse among femae medical students in Hubli.

2. To study the psycho social impact of abuse in female medical students

3. To study the prevalence of self defense technics among female medical students

Materials and Methods

A cross sectional study was conducted among 100 female medical students- comprising of 2nd yr,3rd yr,interns and postgraduates studying in medical college of Hubli.The sample was selected using covenient sampling and the study was done for a period of one month from 9 Dec 2019 to 8 Jan 2020.A pretested,semi structured questionnaire was handed over to the study participants after obtaining informed oral consent for the study.The participants were assured of their confidentiality.The data thus collected was entered into an Excel sheet,tabulated and represented as tables and graphs.

Result

Among the 100 participants,65 of them were pursing MBBS degree while the rest of them were pursuing postgraduation.90% of them had working shifts of 5-8 hours in a day when compared another 8% having 9-12 hour shifts and 2 of them worked for more than 12 hours a day.The age distribution of the study participants were almost equally distributed,with 54% of them in the age group of 18-22 years and 45 percent of them between 23-26 yrs with one perosn above 26years.Furthermore 98% of the study population had normal BMI while only 2% were undernourished.

74% of them confessed themselves to be modest in appearance whereas 23 of them felt they were beautiful and another 3 felt they were very beautiful. In addition to it,more than half of the study population had friendly attributes as part of their personality(Figure 1).Discomforting looks and stares,embarassing comments and jokes,unwanted physical contact and flirting were what that was considered as 'harassment' by the study population.Shockingly 95% of the study subjects faced with harassment atleast once.89% of the students were abused by males while 7% were abused both by males and females.67% of the study participants wer abused outside their campus.

Apparently, verbal abuse was considered to be the most common form of abuse among others(Table 1). while 22 of them were abused often(figure 2).Saddening to hear is that,54 of them were completely freezed and couldn't even react during abuse.(table2).Furthermore 88 of them reported about the abuse another person-mostly to their friends(Table 3).Among those who failed to report the incident,the reasons identified were:fear of complicated legal procedures,didn't consider the act as important and was unaware as to whom to open up with.

Incidentally majority of the abusers were in the age group between 26-35 years.(fig.3) Altogether about 53% of the abusers were starngers to the study participants,while 16% of them were in campus staffs and other workers,8% were their own classmates and 5% patient and their relatives while others didnt wish to comment.

It is interesting to note that 18 of them were abused by a group of people and another 15 of them were abused both in groups and later individually.On enquired with the reason for abusing,many felt a male dominated society of ours to be the reason(Table 4)

Lastly 83% of the females were not trained in any self defense technics which is a lacunae in our modern society that needs to be addressed.
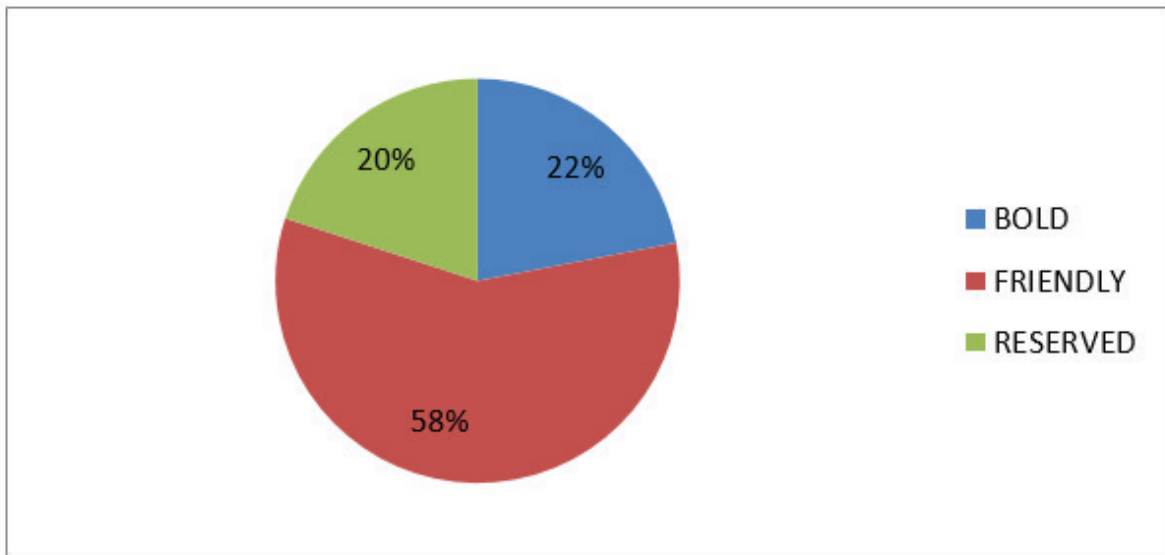
FIGURE 1: FIGURE 1 INDICATES PERSONALITY ATTRIBUTE AMONG STUDY PARTICIPANTS
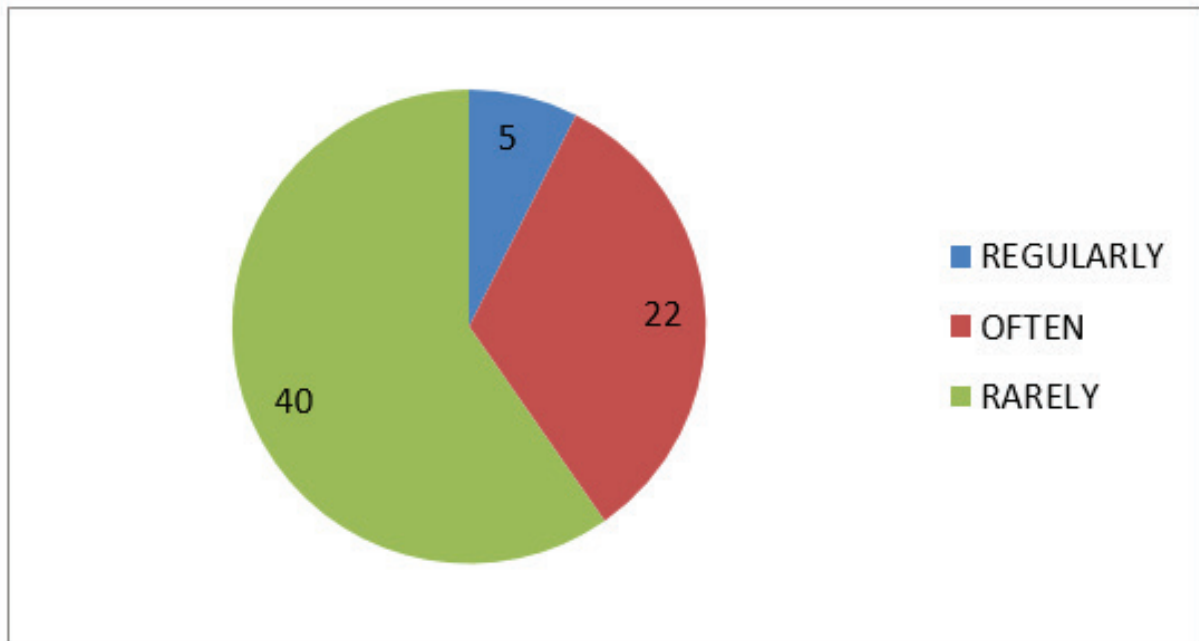
FIGURE 2: FIGURE 2 INDICATES FREQUENCY OF HARASSMENT(N=67)
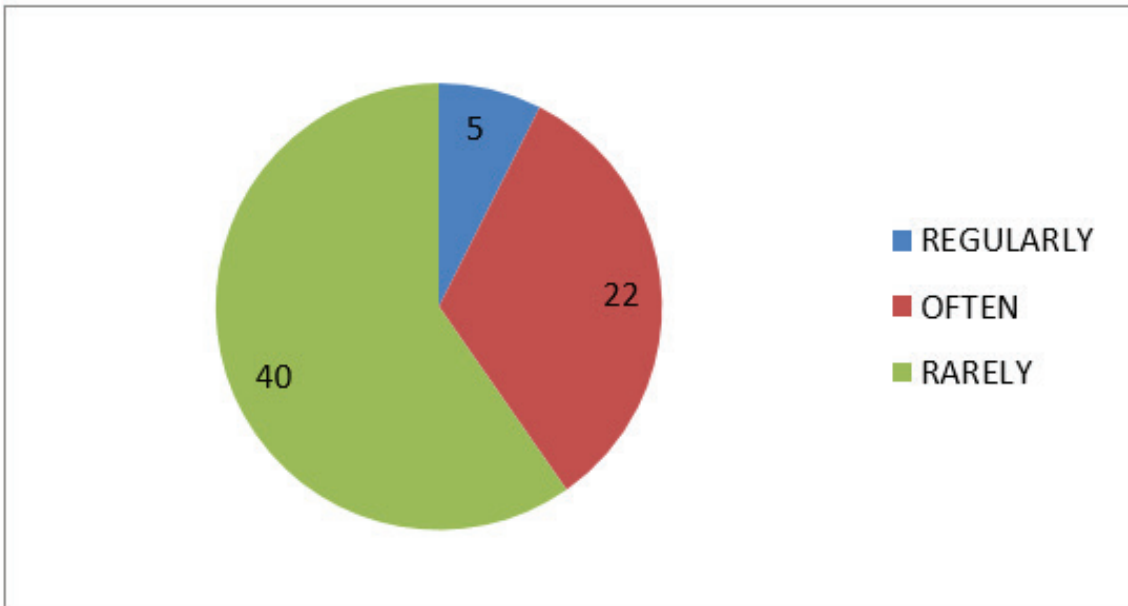
FIGURE 3: FIGURE 3 INDICATES AGE DISTRIBUTION OF THE ABUSERS(N=94)

TABLE 1: TABLE 1 INDICATES THE NATURE OF HARASSMENT

NATURE OF HARASSMENT	NO. OF PARTICIPANTS(N=100)
SEXUALLY PROVOKED LOOKS	24
VERBAL ABUSE	29
UNWANTED PHYSICAL CONTACT	22
RAPE	0
ACADEMIC ABUSE	7
RELIGIOUS DISCRIMINATION	4
LANGUAGE DISCRIMINATION	14

TABLE 2: TABLE 2 INDICATES THE IMMEDIATE RESPONSE OF PATICIPANTS UPON HARASSMENT

REACTION OF PARTICIPANT TO HARASSMENT	NUMBER(N=100)
NONE	56
SHOUTED AND ASKED TO STOP ABUSE	20
THREATEN TO REPORT	6
PHYSICALLY TRIED TO STOP	3
RAN AWAY	15

TABLE 3: INDICATES WITH WHOM THEY HAVE SHARED THE UNTOWARD INCIDENT WITH

SHARING/REPORTING THE INCIDENT TO	NUMBER(N=100)
FRIENDS	58
FAMILY	35
HIGHER AUTHORITY	6
POLICE	1

TABLE 4 INDICATES PROBABLE REASON SUSPECTED BY THE PARTICIPANTS FOR ABUSE

REASON TO BE HARASSED	NUMBER(N=100)
GOOD ACADEMIC PERFORMANCE	7
GOOD LOOKING	17
INNOCENCE	22
MALE DOMINATED SOCIETY	31
DO NOT KNOW	23

Conclusion

95% female students felt that they have been harassed atleast once,among which 53% of the abusers were strangers.Verbal abuse was the most common form of abuse .Majority of them failed to inform higher authorities and had deep psycho social impact.Only a meagre of them were trained in self defense technics.

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Sepsis, a Common Endpoint to Even Non-Infectious Comorbidities, A Single Center Study on 49,107 Patients, at a Tertiary Care Center in India

Dhaval Dalal[1], Girish Rathod[2], Kamalpriya Thiyagarajan[3], Namrata Britto[4], Veda Devakumar[5], Vijaykumar Gawali[6]

[1]*Professor, Internal Medicine, Department of Internal Medicine, Consultant Internal Medicine,* [2]*Professor Head of Orthopedic Department, Consultant Orthopaedician,* [3]*Professor, Gynaecology and Obstetrics, DGO, Consultant Obstetrician & Gynaecologist, Medical Research Department, Bhaktivedanta Hospital and Research Institute, Bhaktivedanta Swami Marg, sector 6, Srishti complex, Mira Road, Thane, Maharashtra, India,* [4]*Research Scholar, Department of Biological Sciences, Sunandan Divatia School of Science, NMIMS, Deemed to be University, Thane, Maharashtra, India,* [5]*Research Scholar, Department of Medical Research,* [6]*Researcher, Medical Research Department, Bhaktivedanta Hospital and Research Institute, Bhaktivedanta Swami Marg, sector 6, Srishti complex, Mira Road, Thane, Maharashtra, India*

Abstract

Background & Objectives- Sepsis, is caused by dysregulated host response that leads to multiple organ dysfunction. Complications of sepsis being so grave, it becomes important to address it in a community setting as sepsis always presents itself as a reason for clinical deterioration of preventable and common diseases.

Methods- Analysis of in-patient records of 49,107 at a tertiary care centre in India were analysed from years 2016-2020, to study correlation of sepsis with various comorbidities such as Diabetes, Hypertension, Coronary artery disease, Cerebrovascular accident and Thyroid; and also, to study the death toll occurring due to sepsis.

Results- Sepsis has a higher prevalence in the vulnerable age groups that is > 60 years followed by < 20 years of age. Sepsis is observed more in males (56.32%) than females (43.68%). Sepsis was found to have a statistically significant association (P<0.0001) with Diabetes, Hypertension, Coronary artery disease and cerebrovascular accident. 38% of total deaths that occurred in the hospital were due to sepsis. 68.9% of patients who died due to sepsis were ICU cases.

Interpretations & Conclusions- Septic patients are 9 times more prone to death than non-septic patients in an Intensive care unit. There is no statistically significant association between thyroid disorder and sepsis (P=0.38). Generally, a researcher would expect diabetes to be a major contributor to sepsis, however our paper reports 70% of total septic cases to be non-diabetic ones. Sepsis itself is caused due to microbial infections but the comorbidities contributing to its prevalence are non-infectious in nature.

Keywords- *Cerebrovascular accident, Coronary artery disease, Diabetes, Hypertension, infection, sepsis, septic shock, Thyroid.*

Corresponding Author:
Dr. Girish Rathod
Email: drgirishrathod@gmail.com,
Phone address: +91 9321996804

Introduction

Sepsis is an increasing cause of morbidity and mortality worldwide. [1] Sepsis, also known

as septicemia, occurs due to bacterial, fungal and viral infections. It could also be life threatening if not treated well. [2] Its symptoms include low blood pressure, difficulty in breathing, chills, mental confusion, skin discoloration, organ dysfunction. In non-medical terms, sepsis is referred to as blood poisoning. Sepsis itself isn't contagious, but its causative pathogens may be one. Sepsis consists of three stages: stage one being sepsis itself, stage two as severe sepsis and stage three being septic shock; this stage is characterized by an escalated microbiological burden. [3] This increase in the microbiological burden, results in the experience of failure of various organs that often leads to death of an individual. Thus, septic shock is known to be one of the most common causes of death worldwide. The leading pathogens involved in neonatal and maternal septic infections include Group B streptococcus and Escherichia coli. [4] The prevalence of sepsis has been high in India too. In January 2020 the results of a Global study published in The Lancet revealed that India stands second highest in death caused due to sepsis in South Asia [5]. Sepsis does remain the leading cause of death in Intensive care units, till date. [6, 7, 8, 9]

In this study we aim to understand the association of septicemia with comorbidities such as diabetes, hypertension, coronary artery disease, cerebrovascular disease and thyroid.

Materials and Method

Post institutional ethics committee approval, the data records of all patients admitted in the hospital from year 2016 to 2020 was retrieved from the Medical records department. Parameters like age group, gender, no. of deaths, association of sepsis with comorbidities such as diabetes mellitus, hypertension, coronary artery disease, cerebrovascular accident and thyroid were studied as shown below in figure 1. A total data of 49,107 patients were analysed for this study. Statistical analysis of the data was performed using SPSS software.

Results

The obvious risk factors for sepsis is infection. The infection could be bacterial, fungal or viral too. The main treatment for sepsis is antibiotics especially via IV. But if the condition becomes severe then severe sepsis is termed as a time critical condition which increases the chances of death of an individual for every delayed response during treatment. But what could be a way to fight against sepsis? The only way is by understanding factors contributing to/leading to sepsis and providing in-time treatment for it.

Subsequent to analysis of data it was observed that Sepsis has a rising trend from 2016-2020. The following are the percentages- 1.74%, 1.81%, 2.08%, 2.07%, 2.86%, 2.1% for 2016, 2017, 2018, 2019, 2020 respectively.

Gender wise, males are more prone to sepsis and age wise aged people (above 60 years) are more prone to sepsis. Sepsis was found to have statistically significant association ($P<0.0001$) with diabetes, hypertension, coronary artery disease and cerebrovascular accident; implying that existence of sepsis with these comorbidities could prove to be fatal for a patient. From the total deaths that occured in the hospital, 38% deaths were due to sepsis. Death due to sepsis was highly found in ICU patients (68.9%) as compared to ward patients (31.09%). Among all ICU cases in the hospital, the number of patients who died due to sepsis were 9 times more than those who died without sepsis indicating the severity of the case.

Discussion

Sepsis, a life-threatening condition of the body that occurs due to microbial infections, eventuates to organ dysfunction in humans. No matter what the origin or cause of infection, sepsis is a result of a mishandled immune response in which inflammation has spread to various organs of the body. [10] If left untreated, it could lead to stage three- septic shock that could result in death of a patient. Despite of best possible treatments, around 50% of sepsis survivors suffer with post-sepsis syndrome (PSS). PSS includes long term effects such as: damaged organs, insomnia, lowered cognitive functioning, fatigue, disabled muscle and joint pain and much more. [11, 12] In short, sepsis does have a huge impact on human lives even if treated or left untreated. Hence it

is incumbent to address this issue and understand what other comorbidities could possibly contribute to this condition; helping us to gain more insights for better treatment of a patient. The discussion part is categorized under the following nine sections.

1. Age

In multiple previous studies, it has been observed that people of age 60 years and above are highly prone to sepsis and mortality due to sepsis. This could be due to the fact that in elderly people, the White Blood Cell counts are slightly low as compared to other age groups, but a rise in the total WBC count is observed during sepsis or an acute infection; some reports do suggest that this increased WBC count could result as a predisposing factor to bacteremia. Thus, contributing to the condition of septicemia. [13] In this study, age groups of 0-20 years, 21-40 years, 41-60 years and 61 & above were observed for having the condition of sepsis and it was observed that the age group of 61 and above (i.e., elderly people) are highly prone to sepsis; followed by younger children (0-20 years). It can thus be concluded that people in the vulnerable age group are found to be more prone to sepsis. In this study, significant association between age group 61 & above and sepsis has been observed. (P<0.0001)

2. Gender

Many studies reveal that males are more prone to sepsis as compared to females. Mortality due to sepsis are higher in males than females. This may be due to the fact that, women exhibit stronger immune responses as compared to males which could favor the clearance of pathogens from the body and could contribute to immune mediated pathologies such as in inflammatory diseases and autoimmune diseases. [14] In this study, 56.32% males and 43.68% females were found to have septicemia.

3. Deaths due to sepsis

Severe sepsis is a common occurrence in India. In a study conducted in 2017 with 4711 patients, it was found that, death occurring due to sepsis was 56.1%. It also inferred that most infections were stemmed from the respiratory tract. [15] In our study there is an increase in the trend of death along with sepsis. Stage 3 septic shock is highly lethal as it often leads to organ failure especially when the pathogen involved in the infection is multi drug resistant. Worldwide mortality due to sepsis is at an all-time high at 85.0% according to WHO. [4] Hence it is imperative to manage sepsis in a hospital setting. In our study it was observed that in the presence of sepsis, the mortality rate was observed to be higher as compared to patients without sepsis. We analysed all death cases (total 430 deaths) from 49,107 in-patient records. Sepsis does prove to contribute to cases becoming severe as 38.13% of total deaths that occured in the hospital from 2016-2020 was due to sepsis.

4. Sepsis with Diabetes mellitus

It is believed that diabetic patients are commonly prone to sepsis, this could be as sepsis causes upregulation of many hormones such as vasopressin, cortisol, insulin and IGF-I. [16] Diabetic patients have an increased risk of developing sepsis that constitutes up to approximately 20 - 22%. [17] This is because diabetes does cause a reduction in a cell's immune function causing immune deficiency; this leads to the display of minimal bacterial clearance by the patients with increased risks to infections and higher mortality rates. [5] In this study, a significant association (P<0.0001) was observed between diabetes and sepsis suggesting that the case of a diabetic patient could turn out to be fatal if sepsis is present. Epidemiology and outcome of stage 2 and 3 of sepsis in a South Indian tertiary care hospital conducted in 2017 suggested that diabetes mellitus was the major comorbidity prevalent in septic patients, that was found to be around 51.2% [18]; whereas in our study it was found to be 29.96%. Prevalence of sepsis along with diabetes is observed in Table I.

Table I: Prevalence of sepsis with diabetes

	diabetic	non-diabetic	Total
septic	308 (29.96%)	720 (70.03%)	1028 (100%)
non-septic	7609 (15.82%)	40470 (84.17%)	48079 (100%)
Total	7917 (16.12%)	41190 (83.87%)	49107 (100%)

(Chi-square = 147.665, P<0.0001)

5. Sepsis with Hypertension

A study conducted in 2014 showed that both systolic and diastolic blood pressure values are higher in patients with sepsis. [19] This can be attributed to the fact that sepsis does endocrinological changes which often leads to progression of this disease. A case report published in May 2014 suggested the prospective study that acute arterial hypertension must be researched in a sepsis setting. [20] As explained earlier that sepsis is caused due to prevailing bacterial infections, these bacteria produce toxins; and the untreated toxins could lead to the damage of tiny blood vessels, causing them to leak out of the tissues they are surrounded by. This could thus affect a person's blood pumping ability and thus causing low blood pressure. [21] In our study that analyzes the cases of 49,107 patients, there was a statistically significant association found between sepsis and hypertension (P<0.0001). Results are documented in Table II.

Table II: Prevalence of sepsis with hypertension

	hypertensive	non-hypertensive	Total
septic	290 (28.21%)	738 (71.78%)	1028 (100%)
non-septic	8094 (16.83%)	39985 (83.16%)	48079 (100%)
Total	8384 (17.07%)	40723 (82.92%)	49107 (100%)

(Chi-square = 91.186, P<0.0001)

6. Sepsis with Coronary artery disease

Many studies show that having sepsis does increase the risk of cardiac dysfunction, this is because as sepsis worsens, the flow of blood to all the vital organs of our body gets impeded. As sepsis may cause abnormal blood clotting that would lead to damage in tissues and blood vessels of all vital organs such as heart, brain, kidneys, etc. Sepsis induced systemic inflammation could also be a factor affecting the cardiovascular system. It has been observed that most people do survive or recover from mild sepsis but the mortality rate for septic shock still remains as high as 40%. [22] In this paper, a statistically significant association (P<0.0001) was found to be present between sepsis and Coronary artery disease as shown in Table III, proposing that septic patients are more prone to cardiac dysfunction that could possibly lead to organ failure.

Table III: Prevalence of sepsis with Coronary artery disease

	coronary artery disease	non- coronary artery disease	Total
septic	168 (16.34%)	860 (83.65%)	1028 (100%)
non-septic	5593 (11.63%)	42486 (88.36%)	48079 (100%)
Total	5761 (11.73%)	43346 (88.26%)	49107 (100%)

(Chi-square = 21.105, P<0.0001)

7. Sepsis with Cerebrovascular accident

Sepsis has also been a concern in patients who have suffered a stroke, due to the immunosuppressed environment and their susceptibility to infections. Studies suggest that infections prior to stroke are not associated with stroke severity suggesting sepsis not to be a predecessor of stroke. [23] Septic shock is often associated with acute brain dysfunction as sepsis causes inflammatory and non-inflammatory processes that leads to alterations in various vulnerable parts of the brain. [24] Table IV tells us that there was a significant association (P<0.0001) observed between sepsis and Cerebrovascular accident which tells us that stage 3 sepsis (septic shock) could lead to brain damage and further systemic failures.

Table IV: Prevalence of sepsis with Cerebrovascular accident

	cerebrovascular accident	non- cerebrovascular accident	Total
septic	64 (6.22%)	964 (93.77%)	1028 (100%)
non-septic	1120 (2.32%)	46959 (97.67%)	48079 (100%)
Total	1184 (2.41%)	47923 (97.58%)	49107 (100%)

(Chi-square = 63.289, P<0.0001)

8. Sepsis with Thyroid

Studies have revealed that sepsis is often accompanied with T_3 syndrome that is caused due to thyroid dysfunction. [25] Sepsis causes downregulation of hormones such as T_3, TSH, Testosterone and estrogen. In an experimental study conducted to understand the role of thyroid hormone in sepsis, it was shown that septic rats showed lower mortality rates when supplemented with the thyroid hormone. [26] It is a known fact that during illnesses, the body does show reduction in levels of the thyroid hormone. Hence one may consider that sepsis has a significant association with thyroid but in our paper, no statistically significant association was observed between sepsis and thyroid (P=0.38). Results for the same are documented in Table V.

Table V: Prevalence of sepsis with Thyroid

	thyroid	non-thyroid	Total
septic	29 (2.82%)	999 (97.17%)	1028 (100%)
non-septic	1133 (2.35%)	46946 (97.64%)	48079 (100%)
Total	1162 (2.36%)	47945 (97.63%)	49107 (100%)

(Chi-square = 0.750, P=0.3866)

9.   Sepsis: a threat to ICU patients

When total deaths in the ICU were analysed, sepsis contributed to 38%. When deaths in septic population was compared with non-septic population in an ICU setting it was observed that 17.33% deaths occurred in septic population and 2.21% deaths occurred in non-septic population. It can thus be inferred that a patient with sepsis is 9 times more prone to death as compared to the one without sepsis. A study conducted in 2016 of around 4209 patients from 124 ICUs across India reported 18.1% mortality rate of septic ICU patients. [27, 28] A recent study also revealed that severe sepsis is common to ICU patients in India [15] implying that mortality rates of septic patients are higher in ICU.

Conclusion

Septic cases analysis in a nutshell - The total septic population of the hospital from 2016-2020 was analysed to study the co-prevalence of septic deaths and non-death cases with various comorbidities. The results obtained in this study suggests that septicemia, which is an infectious disease is prevalent in even those patients with comorbidities that are non-infectious in nature.

Ethical Clearance: Obtained

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Silent Epidemic of Non-communicable diseases- Trend of Diabetes, Coronary Artery Disease, Cerebrovascular Accident, Thyroid and Hypertension at a Tertiary Care Center in India

Dhaval Dalal[1], Vaishali Choudhari[2], Veda Devakumar[3], Namrata Britto[4], Vijaykumar Gawali[5]

[1]Professor, Internal Medicine), Department of Internal Medicine, Consultant Internal Medicine, Bhaktivedanta Hospital and Research Institute, [2]Professor, Gynaecology and Obstetrics, Consultant Obstetrician & Gynaecologist, Bhaktivedanta Hospital and Research Institute, [3]Research Scholar, MSc. Biochemistry, Department of Medical Research, Bhaktivedanta Hospital and Research Institute, Bhaktivedanta Swami Marg, sector 6, Srishti complex, Mira Road, Thane: 401107, Maharashtra, India, [4]Research Scholar, MSc. Biological Sciences, Department of Biological Sciences, Sunandan Divatia School of Science, NMIMS, deemed to be University, Thane, Maharashtra, India, [5]Researcher, Head of Medical Research Department and Academics, Bhaktivedanta Hospital and Research Institute, Bhaktivedanta Swami Marg, Thane, Maharashtra, India

Abstract

Introduction- In a developing country like India, non-communicable diseases are on a rise. Diabetes (DM), Coronary artery disease (CAD), Cerebrovascular accident (CVA), thyroid disorders and hypertension (HTN) are the leading communicable diseases and have become a common occurrence. In this study we aim to study the prevalence of these diseases over the span of five years as well as their association with each other.

Material Methods- In this retrospective study we aim to study trends of non-communicable diseases, in a cohort of 48,966 in-patients for 5 years from 2016-2020. Co-prevalence and association of these comorbidities with each other were also studied.

Result- Non-communicable diseases had an increasing trend from 2016-2020. Association of diabetes and hypertension (Chi-square 12268.54 , $P<0.0001$), diabetes and CVA (Chi-square 864.99, $P<0.0001$), diabetes and CAD (Chi-square 4999.73, $P<0.0001$) diabetes and thyroid (chi-square 583.60, $P<0.0001$), hypertension and CAD (Chi-square 8013.82, $P<0.0001$), hypertension and CVA (Chi-square 2135.881, $P<0.0001$), hypertension and thyroid (Chi-square 1097.278, $P<0.0001$), thyroid and CVA (Chi-square 18.81, $P<0.0001$), thyroid and CAD (Chi-square 1233.501, $P<0.0001$), CAD and CVA (Chi-square 704.662, $P<0.0001$) was found to be very highly significant statistically .

Conclusion- The increase in non-communicable diseases is imminent in developing countries like India and it emphasises the importance of timely clinical investigations and interventions. The increasing trend of non-communicable diseases in India may be attributed to sociological changes towards a more westernised lifestyle.

Keywords- *Diabetes, Hypertension, Coronary artery disease, Cerebrovascular accident, Thyroid, Non-communicable.*

Introduction

Non-communicable diseases account to 70% of deaths worldwide.[1] There is a notable increase in the number of cases of diabetes, hypertension, coronary artery disease, cerebrovascular accident and thyroid disorders in India.[2,3,4,5,6] Although there is a considerable decrease in the cases of CAD and CVA [7,8] in the west, the increase in other comorbidities match

the increase in India.[9, 10, 11] India's rapid change in lifestyle tending more towards a western lifestyle can contribute to the rise. The risks of these diseases are well established, and their occurrence is now considered common. This epidemic of non-communicable diseases is a silent threat and calls for more attention to control and manage this spread.

In this study we aim to study the trends of Diabetes, Hypertension, CAD, CVA and Thyroid disorders in India and the degree of association of these diseases by analysing a cohort of 48,966 patients over the span of five years in a tertiary care hospital.

Materials and Method

Post approval from the ethics committee, patient data records were retrieved from the medical records department. Coded data as per International classification of diseases was analysed by the team of bio-statisticians. A total of 48,966 admitted patients from year 2016 - 2020 were analysed. Parameters such as age, gender, diabetes, hypertension, Coronary Artery Disease, Cerebrovascular accident and Thyroid were analysed using SPSS software. Senior consultants in internal medicine dept interpreted data for its clinical

significance.

Results

Diabetes, CAD, hypertension, CVA and thyroid disorders are in a rising trend from the year 2016-2020. Percentages of hypertension (17.68%), cerebrovascular accident (2.52%), coronary artery disease (12%) and thyroid (2.46%) were found to be in an increasing order for the years 2016, 2017, 2018, 2019 and 2020. Mean age was found out to be 46.64 with a standard deviation of 19.31. Figure 1 shows the trend of diabetes, hypertension, coronary artery disease, cerebrovascular accident and thyroid from 2016-2020.

Association of diabetes and hypertension (Chi-square 12268.54 , P<0.0001), diabetes and CVA (Chi-square 864.99, P<0.0001), diabetes and CAD (Chi-square 4999.73, P<0.0001) diabetes and thyroid (Chi-square 583.60, P<0.0001), hypertension and CAD (Chi-square 8013.82, P<0.0001), hypertension and CVA (Chi-square 2135.881, P<0.0001), hypertension and thyroid (Chi-square 1097.278, P<0.0001), thyroid and CAD (Chi-square 1233.501, P<0.0001), thyroid and CVA (Chi-square 18.81, P<0.0001), CVA and CAD (Chi-square 704.662, P<0.0001) was found to be very highly significant statistically .
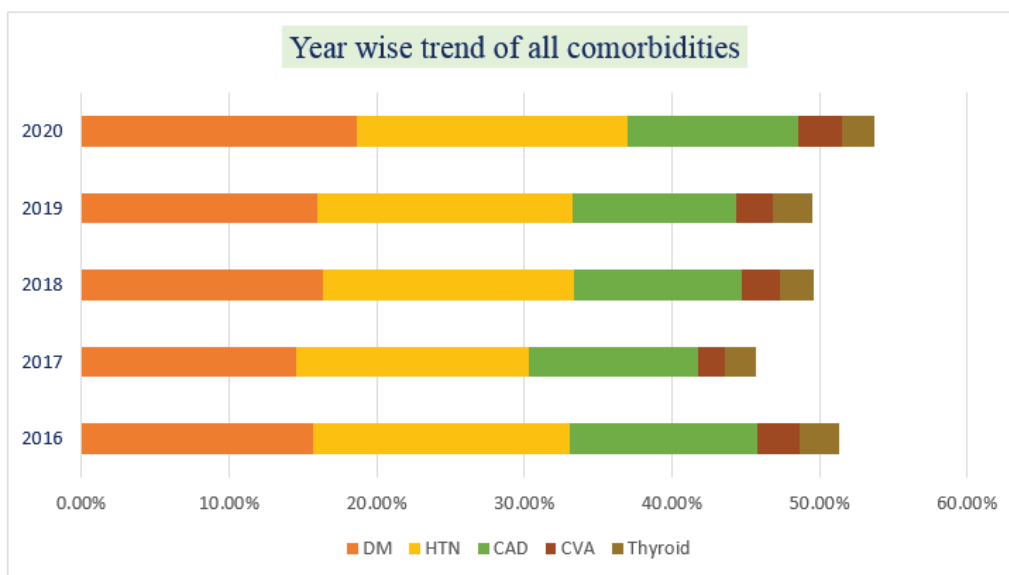
Figure 1: trend of diabetes, hypertension, coronary artery disease, cerebrovascular accident and thyroid from 2016-2020.

Discussion

1. Diabetes and Hypertension:

Type 2 Diabetes and Hypertension are two non-communicable diseases seen in the urban population of India, which can be prevented by leading a healthy lifestyle and thus reducing the risk of other cardiovascular events such as stroke. The association between diabetes mellitus and hypertension can be attributed to their common factors such as hyperinsulinemia, obesity, sedentary lifestyle etc. Both these diseases can either precede or succeed each other. The risk of cardiovascular death in diabetic patients is nearly doubled in the presence of hypertension.[12] Diabetes Mellitus and Hypertension was found to coexist in 50% of patients in a study conducted by Gupta A et al. [13] The association between diabetes and hypertension can be seen in figure 2a.

2. Diabetes mellitus with coronary artery disease:

There is an increase in mortality associated with coronary artery disease in urban populations due to epidemiological transition. [14] The prevalence varies from 2% to 4% in urban populations and 1% to 2% in rural populations. [15] It has been observed that for Type 2 Diabetes mellitus, CAD has been the main cause of death. [16] It has been stated that 2 out of 3 people with diabetes are prone to die from CAD related episodes like a stroke or a heart attack too. [17] In case of increased mortality risks from CAD or heart disease, diabetes mellitus is associated with it: twofold to fourfold. [18] The modifiable risk factors associated with type 2 diabetes and CAD are as follows: Hypertension, obesity, sedentary lifestyle, elevated LDL or low levels of HDL etc can be focussed on to reduce the several risks involved. [19] Here, 48.62% of the total patients were found to have to CAD. From our data, when a patient is suffering from diabetes the risk to develop CAD was found to be 7 times more than when a patient was not suffering from diabetes. Results for the same are documented in figure 2b.

3. Diabetes mellitus with Thyroid:

Thyroid disease and diabetes mellitus are two of the common endocrine disorders in the adult population as it is well known that thyroid hormones and insulin influence each other's actions [20]. For the same, thyroid disorders and diabetes have a propensity to coexist in patients. In a study conducted in 2017, Hypothyroidism was observed in 16% of the diabetic patients while least common was hyperthyroidism that was observed in only 1% diabetic patients. [21] Similarly, in our study the prevalence of hypothyroidism with diabetes was found out to be 11.8% and hyperthyroidism was found out to be only 0.5%. This indicates that it is prudent for clinicians to look for hypothyroidism when the patient presents with diabetes and should call for an HbA1C test and blood sugar fasting when they present with hypothyroidism. This relationship can be attributed to the fact that due to the low metabolic state created due to hypothyroidism can work adjacently with insulin resistance. In this five-year retrospective study, a total of 41.88% of patients were observed to have diabetes mellitus along with thyroid. Association is also highly statistically significant. ($P<0.0001$) as shown in figure 2c.

4. Diabetes mellitus with cerebrovascular accident:

Diabetes has been a prominent risk factor for CVA and is reported by some to be second only to hypertension. [22, 23] Additionally, higher mortality rates and post stroke outcomes are poorer in patients with diabetes and stroke. It has also been shown that the young population having diabetes has a higher risk of stroke. [24] The Framingham study conducted in 1997 had resulted in the inference that, among men and women aged 45 to 74 years; the incidence of atherothrombotic cerebral infarction was 2.5 to 3.5 - fold greater in diabetic than in non-diabetic patients. [25] 47% of patients who suffered a CVA have been noted to have Diabetes and there is a strong association between the two ($P<0.0001$) which is also shown in figure 2d.
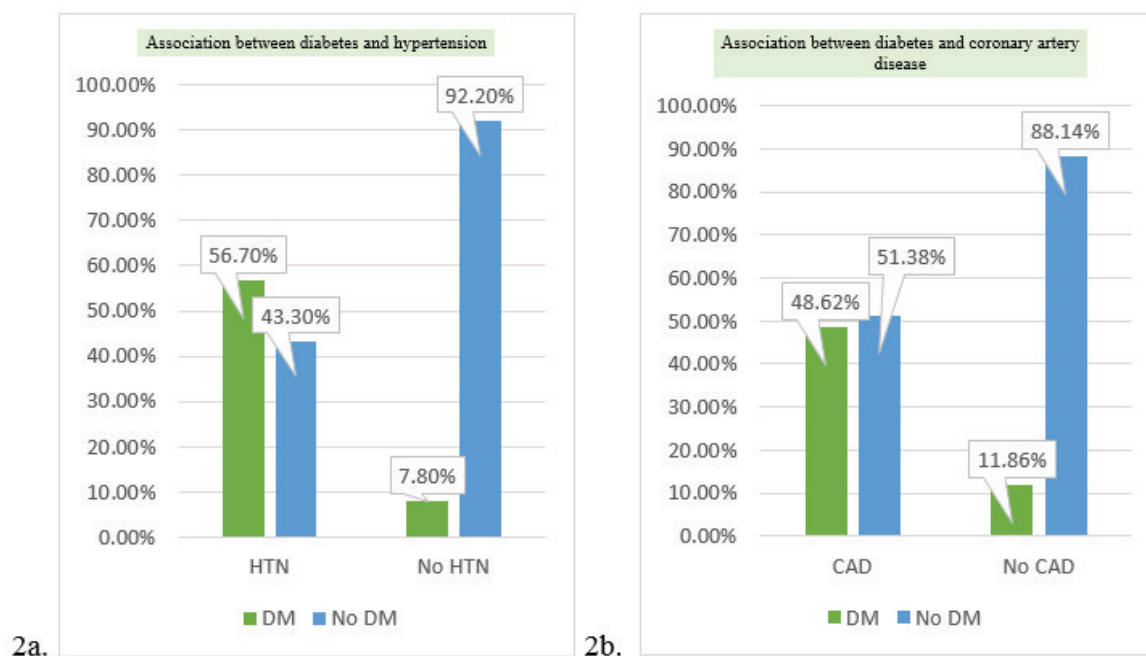
Figure 2: Association of Diabetes mellitus with other comorbidities.

5. Coronary artery disease with cerebrovascular accident:

In a study conducted at University Hospital in Lisbon on 248 patients for understanding the association between heart disease and acute cerebrovascular accident, it was learned that in stroke, heart disease is very frequent. [19] Both Coronary artery diseases (CAD) and cerebrovascular diseases (CVD) are caused by blockage of the blood supply to their respective end organs, thus they have a common pathology. [13] Heart disorders leads to stroke as plaque in the arteries leads to blockage of the flow of oxygen rich blood to the brain. The association between Coronary artery disease and cerebrovascular accident can be seen in figure 3a.

6. Coronary artery disease and Thyroid:

Hypothyroidism has profound effects on cardiac function as it decreases cardiac output due to impaired relaxation of vascular smooth muscle and decreased availability of endothelial nitric oxide which is very essential for relaxing vessels and keeping them flexible

for boosting blood flow. [26] A study conducted in 2009 on 1047 patients for understanding the relation between thyroid dysfunction and coronary artery disease revealed that hypothyroid in particular may lead to CAD, and this may be due to presence of biologically active free triiodothyronine in the serum. [27] Our study has shown a strong association between these two diseases (figure 3b).

7. Coronary artery disease and Hypertension:

The association of hypertension and coronary heart disease is a frequent one and as seen in our study (P<0.0001) which is also documented in figure 3c. There are several pathophysiologic mechanisms which links Hypertension with coronary artery disease. Hypertension induces endothelial dysfunction that exacerbates the process of atherosclerosis and it contributes to making the atherosclerotic plaque more unstable. Treatment should always be aimed to achieve optimal values of blood pressure, and all the strategies to treat coronary heart disease should be considered on an individual basis [28].

3a.

3b.

3c.
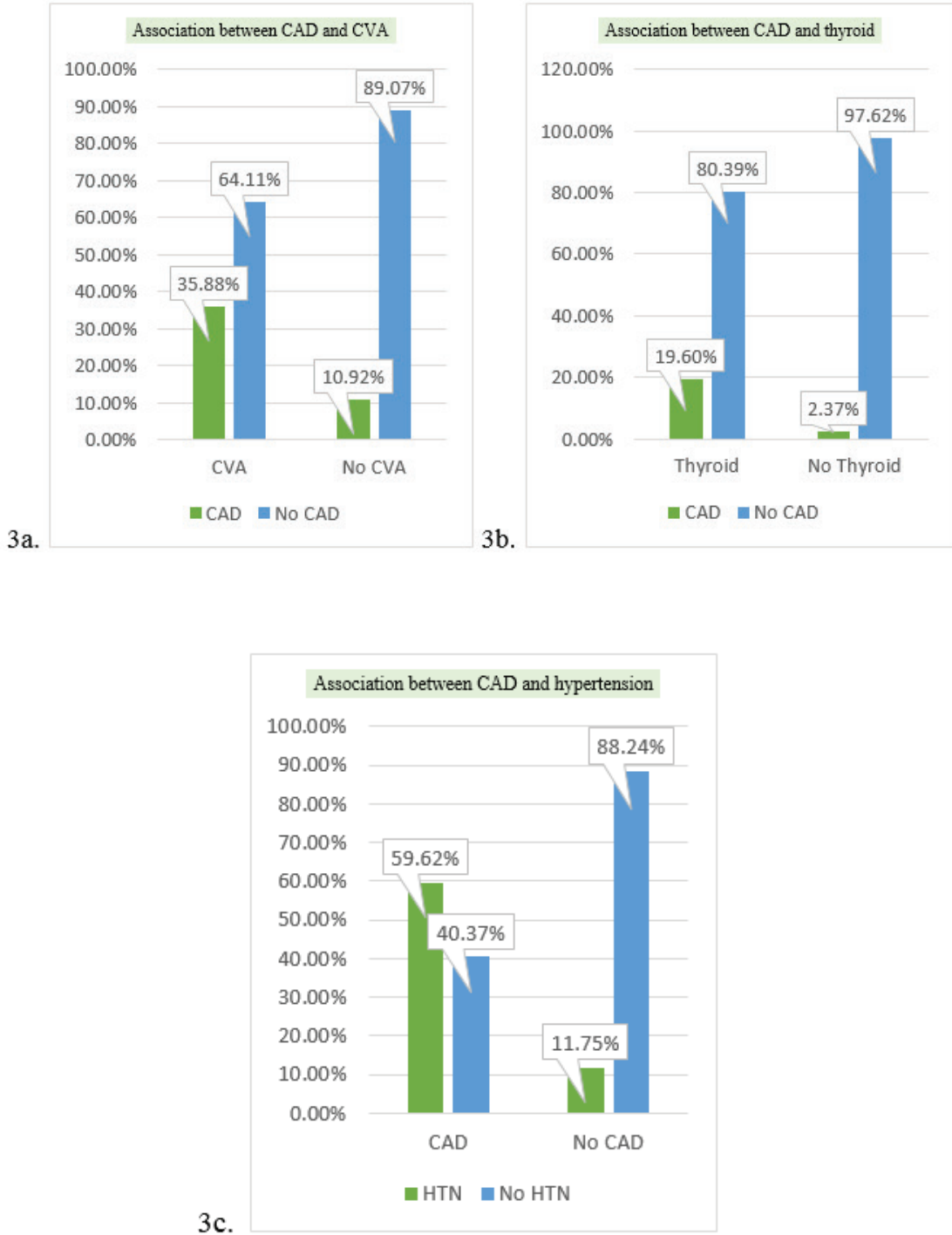
Figure 3: Association between Coronary artery disease with other comorbidities.

8. Hypertension with cerebrovascular accident:

Hypertension is the most prevalent risk factor for stroke. Stroke causes haemodynamic consequences which are heterogeneous in nature that makes the management of blood pressure in stroke patients complex, requiring an accurate diagnosis and precise definition of therapeutic goals.[29] It has been observed that patients having cerebrovascular accident also

have acute rise in blood pressure and this rise in blood pressure is associated with worst outcomes. [30] Significant association between these two comorbidities were observed in this study too, as shown in figure 4.
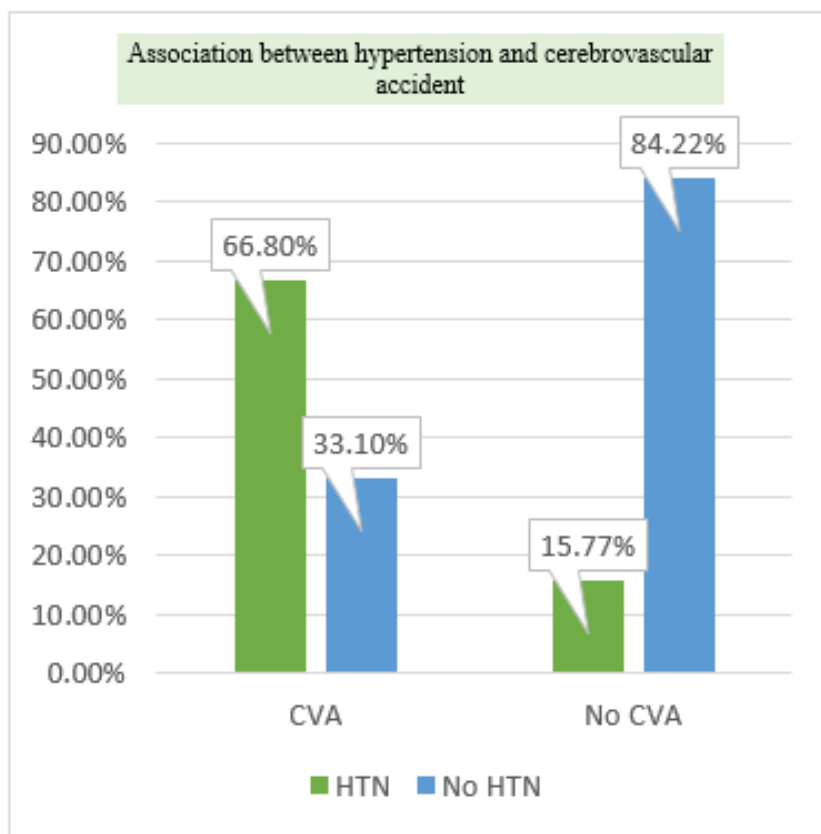
Figure 4: Association between hypertension and cerebrovascular accident

9. Hypertension with thyroid:

Endocrine disorders are common illnesses and some of them may lead to elevated blood pressure, among which thyroid diseases are of high prevalence and often overlooked, especially in mild cases. Overt and subclinical hyper and hypothyroidism can both lead to (mostly mild) hypertension; however, the underlying mechanisms are only partially understood. [31] From our study it is evident that hypothyroidism and hypertension have a strong association which is also observed in figure 5a.

10. Cerebrovascular accident with thyroid: In various thyroid disorders, the presence of acute cerebral ischaemia is observed. It is suggested that hyperthyroidism is more associated with acute cerebral venous thrombosis, but strong research evidence for the same is yet lacking suggesting the need for more study in this area. [32]A case report published in 2016 showed a Hispanic man having the condition of cerebrovascular accident due to thyroid storm. [33]This suggests that a patient with thyroid disorder could possibly be prone to having cerebrovascular accident. Figure 5b shows the correlation between Cerebrovascular accident and thyroid which is actually not much high.
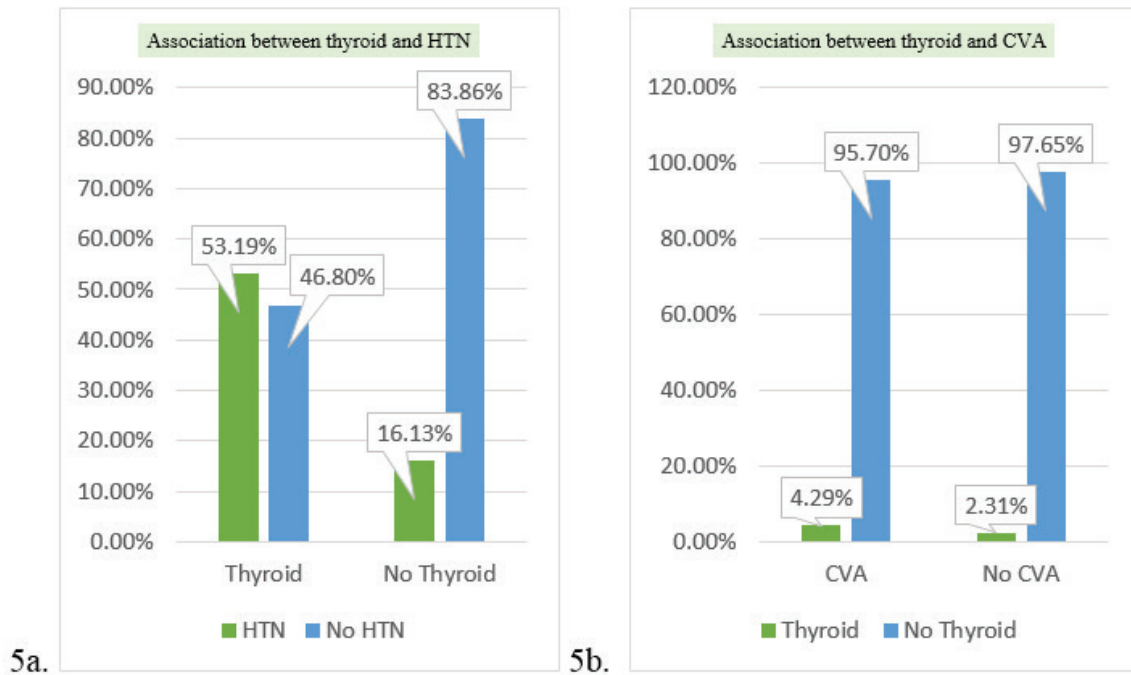
Figure 5: Association between Thyroid with other comorbidities.

Conclusion

The prevalence of non-communicable diseases is increasing worldwide and it is driven by a complicated and cumulative interrelation of multiple factors such as: genetic, lifestyle, environmental, demographic and socioeconomic factors. Of the above factors lifestyle modification probably is the only preventable modifiable variable which can impact disease outcome. As India, more importantly urban India is moving towards a westernized lifestyle it is raising the risks and concern of these preventable diseases. One can consider these diseases to be a silent epidemic as they are now becoming more socially acceptable for their occurrence and often receive patients' focus only when complications arise. The strong association between these diseases also point towards the predilection of developing a secondary disease when a patient is presented with a condition. This study also highlights that clinicians should look for hypothyroidism when the patient presents with diabetes and should call for an HbA1C test and blood sugar fasting when they present with hypothyroidism. It is the need of the hour to emphasize the risk prevalence of non-communicable diseases and spread awareness to prevent them.

Ethical Clearance: Obtained

Conflicting Interest *(If present, give more details):* The authors do not have any conflict of interest.

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Impact of Inhalers in the Management of Asthma/Chronic Obstructive Pulmonary Disease in General Public

Divya B M[1], Ayyar Ajitha Narayanan[1], Monika Sahana Yadav[1], Pushpa G[1], Vineela Nekkanti[2], Srinivasan R[3]

[1]Pharm D Interns, [2]Assistant Professor, [3]Chairperson, Department of Pharmacy Practice, Faculty of Pharmaceutical Sciences(Formerly PES College of Pharmacy), PES University, 50 Feet Main Road, Mysore Bank Colony, Hanumanthnagar, Banashankari Stage I, Bengaluru, Karnataka

Abstract

Background- Appropriate selection and adherence to inhalers is essential in the management of Asthma/ Chronic Obstructive Pulmonary Disease. Even though there are some benefits pertaining to the use of inhalers,the drawbacks have led to poor lung capacity among the patients and therefore poorer management and control of disease conditions. **Objective**s- the objectives are to monitor adherence and satisfaction to the inhalers, counsel the patients about right inhaler technique and consequences of incorrect use and to evaluate lung function. **Methods-** This prospective observational study was conducted in three phases namely Evaluation of Test for the Adherence to Inhalers (TAI-10 questionnaire); Health Education Program; Evaluation of Feeling of Satisfaction with inhaler questionnaire (FSI-10). **Results-** The study included 404 subjects where the inspiratory and expiratory lung capacities were measured using three ball incentive spirometer and peak floor meter respectively. After health education program, the lung capacities of the subjects gradually increased which was initially deprived. The p-value for peak flow meter and spirometer which was interpreted using two-tailed t test indicated that the results were statistically significant. Furthermore, scores for TAI-10 and FSI-10 were assessed and results were analysed. **Conclusions-**Poor adherence to the use of inhalers is a major challenge in the management of asthma/COPD, which occurs due to lack of awareness about the right use of inhalers. Hence, the clinical pharmacist should educate the asthma/ COPD patients on the appropriate use of inhaler for the better management of the disorders.

***Key words** - test for adherence to inhalers, feeling of satisfaction with inhaler, lung functions, right inhaler technique.*

Introduction

Bronchial asthma and COPD (Chronic Obstructive Pulmonary Disease) are the two major respiratory disorders contributing to the increased mortality and morbidity across the world. According to 2016, global statistics 235 million people affected by asthma worldwide, of which 15 to 20 million people are from India.[1] On the other hand, 90 percents of death associated with COPD occur in low to middle-income countries. It is also estimated that by 2030 COPD becomes the third leading cause of death worldwide.[2]

In countries like India people consider asthma as a stigma and fail to seek health care services, as a result, there is no conclusive evidence about the prevalence of asthma. Besides respiratory inhalers are considered to be the best treatment in the management of bronchial asthma and COPD. There are different types of inhalers that are available and are utilized in the management of asthma. People believe that inhalers are strong medications and are also habit-forming because of

Corresponding author:
Divya B M
Pharm D Intern
No.303, Ganga 9th Block, BDA Jnanabharathi Enclave, Valagerahalli, Bangalore-560059
Email Id- divyamanjunath96@gmail.com

which they fail to adhere to the therapy. The increased mortality and morbidity rates associated with these disorders occur mainly either due to poor compliance or due to inappropriate use of inhalers. It was also found that there is a dearth of health education pertaining to the need for the use of inhalers in the management of these respiratory illnesses, among the public. The lack of knowledge to incorporate correct techniques may cause depressive episodes due to limitations in the daily activities, poor management of disease condition, and frequent exacerbations leading to poor quality of life.[3]

One of the most common concerns is the feeling of satisfaction with inhaler use. If the patient is satisfied and has a better understanding why the inhaler is used in their case will help us obtain a good control in their condition. Age, disease control, and training in inhalation technique all play a compelling role than a diagnosis in understanding and explaining satisfaction with the device in patients with asthma and COPD. Hence better training and more active monitoring of inhalation techniques will help improve patient satisfaction and outcomes.[4]

Another aspect with inhaler use is adherence. Most of our population are rarely adherent to inhaler use than oral therapies and this nonadherence leads to poor control of lung function, which in turn causes poor management of the underlying condition. Nonadherence is extremely common across all severities of asthma and also a common reason for "difficult asthma" in adults and youngsters. Also, poor adherence to inhalers may be associated with suboptimal outcomes and disease exacerbation. Studies have shown that adherence to inhaled therapy for asthma and COPD probably reduces the risk of exacerbation by improving both symptoms control and disease outcomes.[5]

Precise use of inhalers in administering the drugs has a direct relationship with the delivery and efficacy of these medications. When the technique of inhalation is poor, the drugs are often not delivered appropriately to the lungs leading to poor treatment outcomes. Poor inhalation technique leads to poor efficacy of medications; the prescription of more or additional medication with a higher probability of side-effects; increased costs; frequent hospitalizations and emergent department visits.[6]

Once the proper inhalational technique is incorporated, the patients' satisfaction with their inhaler use and the level of adherence to the inhalers may yield a positive prognosis and good quality of life.

The purpose of the current study was to monitor the vital steps in the inhaler use so as to avoid treatment failure, interruption of daily activities due to poor management, non-adherence, and recurrent hospital admissions. Hence the current study was designed to assess the compliance of patients with inhaler use by checking the subjects' adherence, counseling the patient about the right use of inhalers, evaluate lung functions, educate the consequences of incorrect inhaler use and estimate satisfaction with inhaler use.

Materials and Methods

A prospective observational, community-based study was carried out for a period of six months in south Bengaluru. The subjects with a self-reported medical history of asthma/COPD and belonging to the age range between 15 and 85 years were recruited into the study. The need for the study was explained and oral consent was obtained from the subjects willing to participate in the study. The data on subject demographics were obtained. The satisfaction and adherence to the inhaler use was assessed using questionnaires such as Feeling of Satisfaction with Inhalers (FSI), and Test for Adherence to Inhalers (TAI) respectively. While the lung functions were measured using a peak flow meter and three ball incentive spirometer. Additionally, Lupihaler, Rotahaler, Metered-dose inhaler, Accuhaler and Zerostat Spacer were used to demonstrate the correct technique of inhaler use.

The study was conducted in three phases:

Phase 1:- Evaluation of Test for the Adherence to Inhalers (TAI-10 questionnaire);

In this phase, the study subjects were interviewed face-to-face, and information regarding their demographic details and current therapy was captured in

the data collection form. In addition, study subjects were asked to answer the TAI questionnaire to assess the level of adherence. Later, the subjects underwent screening for their lung function by performing spirometer and peak expiratory flow meter for 3 consecutive times, and the average of the readings was documented.

Phase 2: Health Education Program by demonstrating the steps to use inhalers

In this phase, the study subjects were asked to demonstrate the steps they followed usually while using an inhaler. If an incorrect technique was observed, the corrections were explained (Health Education Program) and ensured proper use before closing the session by asking the patients to explain the corrections and demonstrate (without giving themselves another dose) how they would now administer their medications. During the Health Education program, the subjects were instructed about the steps to be used while inhaling and importance of each step was discussed

along with the consequences of incorrect inhaler use and their impact on the severity of Asthma/COPD.

Phase 3: Assessing the satisfaction with the current inhaler using Feeling of Satisfaction with inhaler questionnaire

This phase was conducted after an interval of one week where Patient satisfaction with his or her current inhaler was assessed with the specific Feeling of Satisfaction with Inhaler (FSI-10) questionnaire. At the end of this phase, the subjects' lung function was screened similar to that of Phase 1.

Statistical Analysis

The obtained data were analyzed using SPSS Software version 17. The percentage and numbers were used to summarize categorical variables. A two-Tailed t-test was used to analyze the values of the lung function tests that are 3-ball incentive Spirometer and Peak flow meter, keeping the significance as 0.05%.

Results
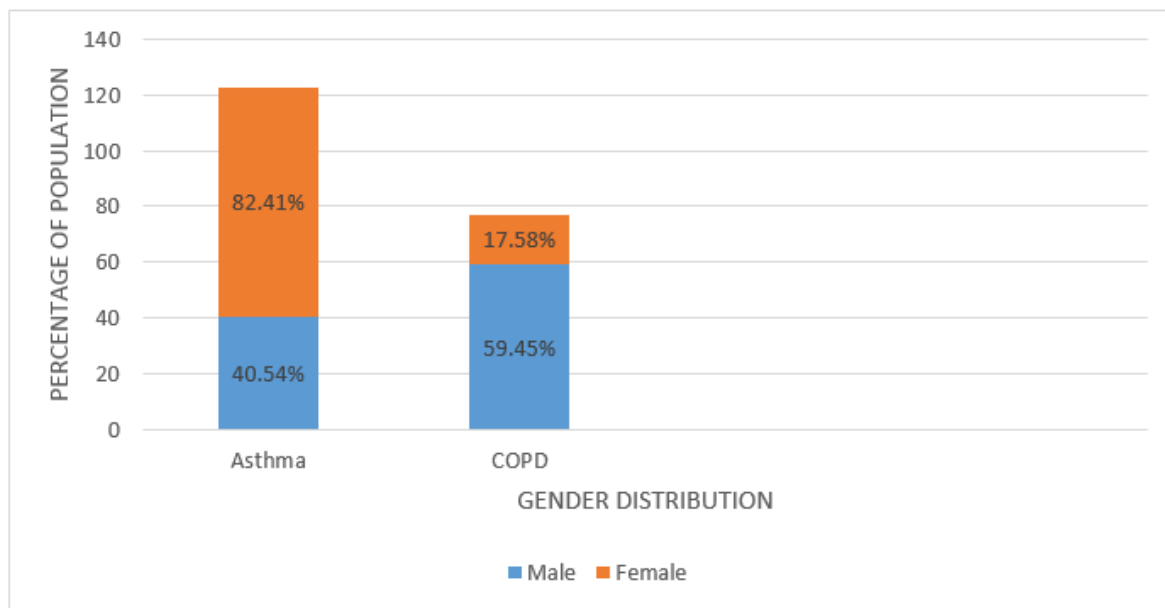
Figure 1: Gender distribution based on asthma and COPD

Figure 1: In the current study, a total of 404 patients with asthma or COPD were enrolled and followed up with an interval of one week. Among the 404 subjects, 182 (45.05%) were females and 222 (54.95%) were males. Also, 240 (59.40%) subjects had asthma and 164 (40.59%) subjects had COPD. The prevalence of asthma was more in females while the prevalence of COPD was more in males.
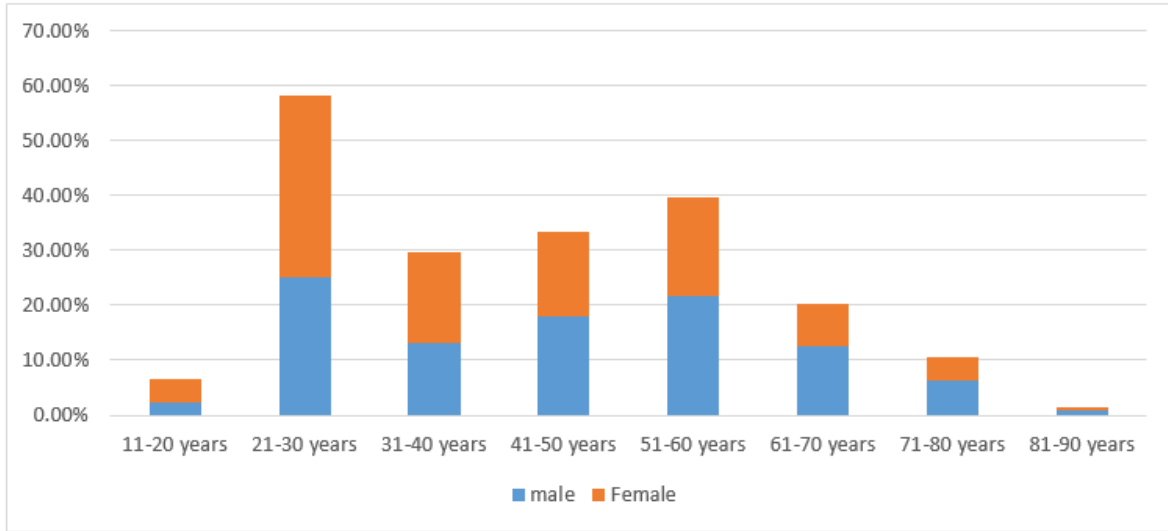
Figure 2: Distribution of patients based on age group:

Figure 2: The overall age group of the subjects ranged from 15 years to 85 years. The maximum number of asthma or COPD patients were in the age group ranging from 21-30 years

Table 1: depicts that 64(15.8%) subjects had poor expiratory lung capacity and 340(84.15%) subjects had average expiratory lung capacity during Phase 1. After one week interval, it was observed that 22(5.44%) subjects had poor expiratory lung capacity, 361(89.35%) subjects had average expiratory lung capacity and 21(5.19%) subjects had good expiratory lung capacity at Phase 3 of the study.

Table 2: revealed 228(56.43%) subjects had poor inspiratory lung capacity and 176(43.56%) subjects had average lung capacity at Phase 1 of the study. After an interval of one week, it was observed that 57(14.10%) subjects had poor inspiratory lung capacity and 347(85.89%) subjects had average inspiratory lung capacity at Phase 3 of the study

Table 3: shows that 13(3.21%) subjects had good adherence to inhalers having the score =50, 44(10.89%) subjects had intermediate adherence with the score ranging from 46-49 and 347(85.89%) subjects had poor adherence with the score ≤45 indicating that more subjects were seen with poor adherence.

Table 4: represents that FSI-10 scores by group and for the whole study population. The asthma group was more satisfied overall having the mean percentage of 94.23% v/s 93.26% and the highest rated item in both the groups was item 1(easy to learn to use an inhaler) which had a positive rate of 98.16% and 97.68% in both Asthma and COPD subjects respectively. Again the second highest item in both subjects was item 10 (overall satisfaction) with a positive rate of 98.12% and 96.34%. In contrast the 2 lowest rated items were the same for both that is item 4(easy to clean inhaler) with a rate of 82.66% and 85.36% and item 5(normal activities) with a rate of 88.5% and 88.17% respectively.

Table 1: Grouping subjects based on peak flow meter before and after follow up:

PFER (L/min)	Before follow up	After follow up
Poor	64 (15.8%)	22 (5.44%)
Average	340 (84.15%)	361 (89.35%)
Good	-	21(5.19%)
Total (N)	404 (100%)	404 (100%)

Table 2: Grouping subjects based on spirometer before and after follow up:

Spirometer (three ball test)	Before follow up	After follow up
Poor	228 (56.43%)	57 (14.10%)
Average	176 (43.56%)	347 (85.89%)
Good	-	-
Total (N)	404 (100%)	404 (100%)

Table 3: TAI adherence level

TAI- 10 item question scores	No. Of responses (N)	Percentage of responses (%)	Interpretation
=50	13	3.21	Good Adherence
46-49	44	10.89	Intermediate Adherence
≤45	347	85.89	Poor Adherence

Table 4: Feeling of Satisfaction with Inhalers

Item (Q.No.) In questionnaire	Asthma total score	Percentage of item the score for asthma(%)	COPD total score	Percentage of item score for COPD (%)
1	1178	98.17	801	97.68
2	1140	95	785	95.73
3	1169	97.42	782	95.36
4	992	82.67	700	85.36
5	1062	88.5	723	88.17
6	1168	97.34	784	95.60
7	1163	96.92	773	94.26
8	1114	92.84	737	89.88
9	1144	95.34	773	94.27
10	1181	98.12	790	96.34

Discussion

Control of the disease is not established in practice even though there are several inhalational therapies to assist in the control of Asthma/COPD. One of the significant reasons is poor inhalational techniques whereas lack of education among the patients and lack of time for the physicians to counsel the appropriate measures to use the inhalers have also contributed to the failure of disease control.

Out of 404 subjects enrolled, 222(54.95%) were males and 182(45.05%) were females. Among 404 subjects enrolled, 240(59.40%) subjects had asthma and 164(40.59%) subjects had COPD. Out of 240 subjects having Asthma 90(37.5%) subjects were male and 150(52.5%) subjects were females. Out of 164 subjects having COPD, 132(80.48%) subjects were males, and 32(19.51%) subjects were females (Figure 1). Most of the Asthma and COPD subjects had ages ranging from 21-30 years (Figure 2).

Out of 404 subjects, it was observed that 64 (15.8%) subjects had poor expiratory lung capacity and 340(84.15%) subjects had average expiratory lung capacity during Phase 1. After one week of health education, it was observed that 22 (5.44%) subjects had poor expiratory lung capacity, 361(89.35%) subjects had average expiratory lung capacity and 21(5.19%) subjects had good expiratory lung capacity at Phase 3 of the study. The health education program on the right use of inhalers showed an improvement in lung function (Table 1). It was found that there was a statistically significant association between the right use of inhalers and improvement in lung capacity at p<0.00001. Therefore, there is an association between good inhaler technique and lung capacity. Similar findings were observed in a study by Bassam Mahboub et al, where PEFR, with or without questionnaire could be used as a simple tool in the primary health care setting to determine the airflow limitation compatible with COPD.[7]

While using the spirometer, it was observed that out of 404 subjects 228(56.43%) subjects had poor inspiratory lung capacity and 176 (43.56%) subjects had average lung capacity at 1st Phase of the study. After an interval of one week, it was observed that 57(14.10%) subjects had poor inspiratory lung capacity and 347(85.89%) subjects had average inspiratory lung capacity at the 3rd Phase of the study (Table 2). This was similar to the study conducted by Tatiana Zacarias Rondinel et al which concluded that Incentive Spirometer provides an improvement in asthma control and quality of life for patients with severe asthma.[8]

Out of 404 subjects, it was observed that 13(3.21%) subjects had good adherence to inhalers having the score =50, 44(10.89%) subjects had intermediate adherence with the score ranging from 46-49 and 347(85.89%) subjects had poor adherence with a score ≤45 (Table 3). Our study concluded that a high proportion of participants had poor lung function before counselling using TAI(Test for Adherence to Inhalers)[9], where similar outcomes were observed in the study conducted by Vincent Plaza et al which inferred that TAI is a reliable and homogenous questionnaire to identify easily non-adherence and to classify from a clinical perspective the barriers related to the use of inhalers in asthma and COPD. [10]

The health Education given in Phase 2 was found to be beneficial as a significant increase was observed in lung function. It was noticed that proper inhaler use/technique also improved lung function. Thereby a reduction was seen in clinical manifestations of Asthma/COPD.

The FSI-10[11] is a self-completed 10-item questionnaire to assess patient opinions regarding ease or difficulty of use, portability, and usability of devices for delivery of inhaled medications. We grouped the patient responses on 5-point scale into positive ("yes "and "frequently") and negative responses ("rarely" and "no"), the highest-rated item in both the groups was item 1(easy to learn to use an inhaler) which had a positive rate of 98.16% and 97.68% in both Asthma and COPD subjects respectively. Again the second highest item in both subjects was item 10 (overall satisfaction) with a positive rate of 98.12% and 96.34%. In contrast, the 2 lowest rated items were the same for both is item 4(easy to clean inhaler) with a rate of 82.66% and 85.36%, and item 5(normal activities) with a rate of 88.5% and 88.17% (Table 4). It is easy to understand, complete and infer the difference in patients' satisfaction with different inhalers. This was similar to the study conducted by Miguel Perpina Tordera et al which concluded that FSI-10 is a useful instrument for assessing the degree of satisfaction of asthmatic patients regarding available inhalation devices which were easy to understand and complete, and was able to identify differences in patient

satisfaction with the different inhalers.[12]

In the current study, poor adherence to the inhaler use (poor adherence value) was identified before the health education session, which was clinically evident with the low lung function (Table 1 & Table 2). During the health education session, the right steps involved in the use of inhalers were demonstrated personally. In the follow-up visit, the lung function values of the study subjects showed an improvement (Table 1 & Table 2), which may indicate an improvement in the adherence to inhaler use. However, the study subjects were found to be satisfied with the use of inhalers (Table 4). The health care team should work to improve patient satisfaction with the use of inhalers because improved satisfaction may increase the adherence rate, which helps in better management of asthma or COPD. This decreases the morbidity and mortality rate, health care costs, and emergency admission to the hospital.

Limitations of The Study

The limitations of our study were the follow-up interval for the lung function tests were of a short period, medications used by the patients were not taken into consideration, the steps missed by the subjects during inhalation was not documented, however, the incorrect steps were corrected by oral communication. Limitations inherent to the FSI-10 scale may also have influenced our results, as no minimum score have been established to determine clinically relevant differences and the cut-off level to distinguish between high and low-level satisfactions was arbitrary.

Future Directions:-

Pharmacist intervention to patients about inhaler technique and medication adherence had improved outcomes in disease control. Hence pharmacists taking part in therapy and management of asthma and COPD can help the patients be more educated about their disease and medications; and improve disease control and therapy outcomes.

Conclusion

Poor adherence to the use of inhalers is a major challenge in the management of asthma/COPD, which occurs due to lack of awareness about the right use of inhalers. Hence, the clinical pharmacist should educate asthma/ COPD patients on the appropriate use of an inhaler for the better management of the disorders.

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Otology and Mobile Phone : A Correlation

Vandana Singh[1], Abhay Kumar Singh[2], Sushil Gaur[3], Raina Rathore[4]

[1]Professor & Head, [2]Assistant Professor, [3]Associate Professor, [4]Senior Resident, Santosh Medical College, Ghaziabad

Abstract

Introduction: The mobile phone is a modern-day invention. Since their introduction in 1980s, mobile phones have gone from being expensive items that were mainly used by the business elite, to being communication tools used by the general population. Since ear is the closest organ to mobile phones receiving higher energy deposition than other organs, the effects of mobile phone radiation on hearing will be a topic debate.

Aims and Objectives: To determine the physical and functional effect of mobile phone use on ear, To assess the hearing pattern in mobile phone users,To ascertain any other self-reported symptoms associated with mobile phone use like headache, tinnitus, hearing loss, vertigo/dizziness, tension anxiety, fatigue and forgetfulness ,To find out possible remedial measures to avoid/reduce ill effects of mobile phones in mobile phone users.

Material and Methods: A study was conducted in the Department of E.N.T., Santosh medical colleg, ghazaiabd, U.P., India which included 350 patients using mobile phones presenting to outpatient clinics. Correlation was done between mobile users and hearing.

Results: We have evaluated that among 350 subjects, 299 subjects had normal hearing,

37 subjects had 5dB hearing loss, 9 subjects had 10dB hearing loss and 5 subjects had

15dB hearing loss irrespective of duration of mobile phone use.

Conclusion: Phone should only be used when necessary and calls should be kept short ,Use of mobile phone should be avoided if the signal strength is low ,Phone should be kept away from the head, eyes, testicles, breasts and internal organs as far as possible. Hands free device should be used,Phone should be switched off when not in use**.**

Keywords: Fine Needle Aspiration Cytology, Cervical Lymphadenopathy

Introduction

The mobile phone is a modern-day invention. Since their introduction in 1980s, mobile phones have gone

Corresponding author:
Dr. Abhay Kumar Singh
Assistant Professor, Department of ENT, Santosh Medical College, Ghaziabad,
Abhaysingh2786@gmail.com

from being expensive items that were mainly used by the business elite, to being communication tools used by the general population.[1] The use of mobile phones has dramatically increased all over the world during the 1990s. Mobile Phones have become a more and more widespread means of communication. They have become a part of everyday life with a growing number of people enjoying the service and extra freedom they provide. The advent of third generation system will extend the use of most novel forms of communication

technologies.

The mobile phone radiations have many side effects:-[2]

- Different forms of cancers (brain tumors, lymphoma)

- Neurological disease (Alzheimer's disease)

- Sleep disturbances.

Since ear is the closest organ to mobile phones receiving higher energy deposition than other organs, the effects of mobile phone radiation on hearing will be a topic debate.[3]

Most of the studies undertaken to observe the effect of mobile phone use on hearing and other associated effect on body have used a smaller sample size. In this study a decent sample size is being used to consider the effect of mobile phone use.

And see for following objectives:[4]

1.To determine the physical and functional effect of mobile phone use on ear.

2. To assess the hearing pattern in mobile phone users.

3. To ascertain any other self-reported symptoms associated with mobile phone use like headache, tinnitus, hearing loss, vertigo/dizziness, tensionanxiety, fatigue and forgetfulness.

4. To find out possible remedial measures to avoid/reduce ill effects of mobile phones in mobile phone users.

Material and Methods

The study was conducted in the Department of Otorhinolaryngology at

Santosh Medical College and Hospital, Ghaziabad, U.P . A total no. of 350 subjects between the age group of 11-40 years using mobile phones for at least 5 years were selected and screened for otological or other physical symptoms.

The Physical and Otoscopic examination was performed in all the patients before testing in order to rule out any external or middle ear pathology that could affect audiometric measurements. The hearing levels of subjects was tested by using different frequencies (250Hz – 8000Hz) by ALPS Pure tone audiometer and Medicaid

System BERA in which latency of the subjects was tested at different intensities. All tests were performed in a sound-treated room.

The hearing status of participants for each ear was measured for both air

(250 Hz to 8 kHz) and bone (250 Hz to 2 kHz) conducted sound stimuli.

The subjects were divided into three groups for final evaluation, as follows:-

Group I:-11 – 20 years of age

Group II:-21 – 30 years of age

Group III:-31 – 40 years of age

A comparative evaluation was done to assess the otological effects of mobile phones in different age groups, sexes, dominant ear and occupation. Associated

symptoms with mobile phone use were also be evaluated to find out other effects of mobile phone use on general health and wellbeing of the subject.

Subjects having conductive or sensorineural hearing loss, tinnitus, vertigo and headache due to any cause, were not be included in this study.

Result

Age Groups:-

In our study we have divided subjects into three different age groups.

Group -I included age groups between 11-20years.

Group -II included age groups between 21-30years.

Group -III included age groups between 31-40years.

110 subjects in Group-I, 145 subjects in Group-II and 95 subjects in Group-III were included in this study.

Symptoms at Presentation:-

Subjects complained of headache, tinnitus, sleep disturbance, tension, anxiety, dizziness, increased lacrimation and forgetfulness on mobile phone use. We found that 18% of subjects complained of headache after prolong mobile phone use, 7% complained of tinnitus, 3% complained of sleep disturbance, 2% complained of tension anxiety/dizziness/increased lacrimation and 1% complained of forgetfulness.

Hours of Exposure:

In our study 129 subjects (37%) used mobile phone for less than 1hour per day, 175 subjects (50%) used mobile phone between 1-2 hours per day, and 46 subjects (13.1%) used mobile phone for more than 2hours per day.

AVERAGE DAILY MOBILE PHONE USE AND HEARING LOSS IN dB:-

In this study we observed that, hours of exposure play an important role in hearing loss on different frequencies. 129 Subjects used mobile phone for less than 1 hour per day had hearing loss of 5dB in 5% of subjects, 175 subjects used mobile phone between 1-2 hours had 5dB loss in 10% of subjects, 10dB loss in 2.1% of subjects & 15dB loss in 1.3% of subjects and 46 subjects used mobile phone for more than 2hours per day had hearing loss of 5dB in 7% of subjects, 10dB loss in 3.8% of subjects & 15dB loss in 1.9% of subjects.

We have evaluated that among 350 subjects, 299 subjects had normal hearing,

37 subjects had 5dB hearing loss, 9 subjects had 10dB hearing loss and 5 subjects had

15dB hearing loss irrespective of duration of mobile phone use.

HEARING STATUS IN THE DOMINANT EAR:-

We observed that out of 350 subjects, 283 (80.85%) subjects were right

handed and used right ear while using mobile phone and 67 (19.14%) subjects were left handed and used left ear while using mobile phone. Hence, in this study right ear was the dominant ear.

GROUP WISE DISTRIBUTION OF HEARING STATUS:-

On observing the group wise distribution of hearing loss, it was seen that out of a total of 110 subjects in Group I, hearing impairment was observed in 13 subjects (11.81%).

In Group II out of 145 subjects, hearing loss was seen in 23 subjects (15.86%).

In Group III out of 95 subjects, hearing loss was seen in 15 subjects (15.79%).

It was observed that hearing loss in different age groups was 11.81% (Group I),

15.86% (Group II) and 15.79% (Group III).

Hearing loss was minimum in 11-20 years of age group, who have been using mobile phone for the same duration as was being used in other groups.

Discussion

The study was conducted in the Department of Otorhinolaryngology at

Santosh Medical College and Hospital, Ghaziabad, U.P (West). A total no. of 350 subjects between the age group of 11-40 years using mobile phones for at least 5years or more were selected and screened for otological or other physical symptoms.

The present study has been undertaken with a view to establish any ill effects of prolonged mobile phone use in healthy young adults.[5] In this study, we have taken a large sample size, to get good representation of results.

Sensorineural deafness in the audiogram is suggested by hearing loss at higher frequencies and no gap between air and bone conduction curve in audiometry.

WHO recommended the following classification on the basis of pure tone audiogram taking the average of thresholds of hearing for frequencies of 500, 1000 and 2000 Hz with reference to ISO:R.389-1970 (international calibration of audiometers).[6]

1. Mild 26-40 dB

2. Moderate 41-55 dB

3. Moderately severe 56-70 dB

4. Severe 71-91 dB

5. Profound >91 dB

We found mild hearing loss in all the cases with hearing impairment using mobile phone. However, the hearing loss was not very significant, as many of the subjects did not report the symptoms and some of them were even not aware of the hearing impairment.[7]

350 healthy subjects of age group of 10-40 years have been included in this study, in different age groups:-[8]

· Group I - 110 subjects of 11-20 years of age.

· Group II - 145 subjects of 21-30 years of age.

· Group III - 95 subjects of 31-40 years of age.

These subjects have been using mobile phone ranging from less than 1 hr/day to more than 2hrs/day up to 5years or more. So, we tried to include a large group of subjects who have been using mobile phone for a considerably long duration of time.

Similar studies have been undertaken by various workers who have included varying number of subjects. Large sample size has been studied by Garcia Callejo11 (323),

Sultan Meo and Abdul M. Al-Drees12 (873), M.Shayani-Nasab et al17 (200), Hutter

HP et al33 (200), Panda NK et al34 (172), Chu MK et al36 (247) and Kucer N andPamukcu T44 (350).

Studies have been conducted with smaller sample size also by various workers

Gabo Stefanics et al17 (30), Kwon MS et al32 (17), GC Sahoo and Honeymol sebastian35 (100), CS Ramya et al38 (50), Hitesh Patel and Rizwan Qureshi46 (30) and G Revanth et al47 (70).[9]

But the results and inferences drawn on a smaller sample size are debatable.

In our study, there were healthy young subjects who were using mobile phone for a longer duration of time. We have included subjects up to the age of 40 years only, so as to avoid the element of presbyacusis in the subjects.

In our study, we have included 225 males and 125 females with a ratio of 1.8:1. In similar studies conducted by various workers, the male female ratio was almost similar.

IngridaUloziene et al10 (18 males & 12 females), Meo and Abdul M.Al-

Dress12 (498 males and 348 females), M.Shayani-Nasab et al14 (160 males and 40 females) and GC Sahoo&Honeymol Sebastian35 (62 males and 38 females).[10]

In this study, we observed decreased hearing, ear ache and increased lacrimation in the subjects using mobile phones. Similar complaints were noticed by

Sultan A Meo and Abdul M. AL-Drees12. Our study is in agreement with this study, as far as such symptoms are concerned.

In our study, we analysed that out of 350 subjects in 283 subjects right ear was dominant ear and 67 subjects had left ear as dominant ear.

Those subjects who used mobile phone predominantly in right ear i.e. 283 subjects, among those 243 subjects were with normal hearing, 29 subjects (10.47%) had 5 dB hearing loss, 7 subjects (2.56%) had 10 dB hearing loss and 4 subjects (1.58%) had 15 dB hearing loss at speech frequencies.

Those subjects who used left ear as dominant ear i.e. 67 subjects, among those 56 subjects were with normal hearing , 8 subjects (11.94%) had 5 dB hearing loss, 2 subjects (2.98%) had 10 dB hearing loss and 1 subject (1.58%) had 15 dB hearing loss at speech frequencies.

In our study, duration of daily mobile phone use was from less than 1hour/day to more than 2hour/day. It was observed that the subjects who used mobile phone for longer duration of time had more hearing loss.

Sultan A.Meo and Abdul M.Al-Drees et al12 also observed that those who used mobile phone for less than 5min/day, 32% had hearing complaints and those who used mobile phone for 5-10min/day, 33% of subjects had hearing complaints.

In this study, those subjects were included, who used mobile phone at least for 5 years. We found increased hearing threshold in these subjects. In similar studies conducted by GC Sahoo&Honeymol Sebastian35, Chu MK et al36, CS Ramya et al38 and G Revanth et al47 it was observed that those mobile phone users who used mobile phone for up to 5 years, had statistically significant altered hearing thresholds.

Conclusion

It is concluded that mobile phone use has detrimental physical and functional effects on the body; including hearing. So following measures are recommended to avoid these effects:-

· Phone should only be used when necessary and calls should be kept short.

· Use of mobile phone should be avoided if the signal strength is low.

· Phone should be kept away from the head, eyes, testicles, breasts and internal organs as far as possible. Hands free device should be used.

· Phone should be switched off when not in use.

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Public Expenditure on Healthcare in India and Tamil Nadu: Five-Year Plans

Elango J. Parimalam[1], V. Sathishkumar[1], R. Rajanbabu[2]

[1]*Assistant Professor, Department of Economics, Loyola College, Chennai, India,* [2]*Assistant Professor, Department of Economics, Manonmaniam Sundaranar University, Tirunelveli, Tamil Nadu, India*

Abstract

Background: Health is both an input and an outcome of broader social and economic development. It is also well known that achievements in health do not simply depend on the health sector, other than arise out of improvements in education, standard of living, social stability, housing, water supply, sanitation and other environmental factors. These are amenable to change by actions taken by households, communities and governments and are typically outside the domain of the health system.

Objective: The present paper attempts to estimate the extent of public health expenditure in India and Tamil Nadu over the period under review with reference to five-year plans.

Methodology: The particulars regarding the total plan investment outlay, health and family welfare expenditures in India and Tamil Nadu have been collected from the published source which is presented beneath the respective table. To carry out the research, straightforward tabular statements were prepared for working out the percentage and average value.

Conclusion: From the analysis, it's evident that the total expenditure on health and family welfare of the central and state government shows a steady increase over the plan periods. It's clear from that the plan outlay on both the health and family welfare has increased from first plan (1951-56) to twelfth plan (2012-17) in absolute terms. However it has been always low sharing to the total plan investment outlay of the country. In Tamil Nadu, almost in all the plan periods, the approved outlay was less than incurred actual expenditure.

Keywords: *Public Expenditure, Health and Family Welfare, Public Expenditure on Health.*

Introduction

The public investment in health and health outcomes often does not exhibit any relationship. However, analysis of differences in health expenditure assumes significance and eventually is the starting point in any attempt to describe the differences in the health outcomes (World Bank, 1993). Health as conceived by WHO (World Health Organization) is a "state of physical, mental and social well-being and not just the absence of disease or infirmity". According to Amartya Sen, health contributes to a person's basic capability to function, to choose the life he/she has reason to value (Sen, 1985), health is not just an attribute of individual; it is also a reflection of the social environment in which an individual experiences life. How a society values and understands health will determine in great part how the individual person experiences life. Even more, it will determine what society and individuals can do

Corresponding Author:
R. Rajanbabu
Assistant Professor, Department of Economics
Manonmaniam Sundaranar University, Tirunelveli
Tamil Nadu, India
E-mail: rajaneco@rediffmail.com; rajeneco@gmail.com

about health– how health will be measure and how the society's medical care services will be evaluated. Health, in other words, is thought to be influenced by relative income suggesting that levels of health can be regarded as a signal of the socio-economic development within which people live, as well as to how rich or poor the society is on average.

Significance of Health

It is now widely recognized that health is both an input and an outcome of broader social and economic development. It is also well known that achievements in health do not simply depend on the health sector, other than arise out of improvements in education, standard of living, social stability, housing, water supply, sanitation and other environmental factors. These are amenable to change by actions taken by households, communities and governments and are typically outside the domain of the health system.

Moreover, good health also improves educational attainment and promotes economic growth and political participation. Yet unhealthy behaviour, sickness, malnutrition and high fertility are also significant causes of poverty. Health and health services have a major influence on the well- being of individuals and societies and are an important part of a nation's politics and economy. Sick health and poor health services are increasingly recognized as major dimensions of poverty in their own right, so that efforts to battle poverty ought to consider the role of health. Good health is universally acknowledged to be of intrinsic value and, therefore, constitutes an integral element of development. One can be rich but sick enough to, not to enjoy any opportunities that wealth opens up and poor health may translate into worsening economic opportunities as well. There are numerous factors that influence health like hereditary factors, environmental factors, life style, adequate housing, basic sanitation and socio-economic conditions including income, education, availability and quality of health infrastructure and per capita health expenditure.

Determination of Health Status Indicators

The health status indicators are as follows: (i) Mortality Indicators (ii) Morbidity Indicators (iii) Delivery Indicators (iv) Indicators of Utilization rate (v) Indicators of Social and Mental Health (vi) Environmental Indicators (vii) Socio-economic Indicators (viii) Health Policy Indicators and Indicators for quality of life.

Mortality Indicators: Mortality indicators are the traditional measure of health status which includes the following. Infant mortality rate (IMR), Child mortality rate 1-4 yrs. (CMR), Maternal Mortality Rate (MMR), Crude Death Rate (CDR) and Disease specific mortality rate.

Morbidity Indicators: Incidence and prevalence of morbidity, Notification rates, Attendance rate at our – patient department health centres etc., Admission, readmission and discharge rates, and Duration of stay in hospital, and absence from work or school.

Health care Delivery Indicators: Doctor–population ratio, Doctor-nurse ratio, Population per health centre/sub-centre, Population–bed ratio and Population per traditional birth attendant.

Indicators of Utilization Rates: Proportion of pregnant women who receive antenatal care, Proportion of infants who are fully immunized against the diseases, Proportion of population using the various method of family planning, Bed-occupancy rate (i.e., average daily inpatient /average number of beds), Average length of stay (i.e. days of care rendered), and Bed turnover ratio that is discharge/average beds.

Indicators of Environment: Population of air, water, radiation and noise, Solid waste, Exposure to toxic substances in food or drink, and having access to safe water and sanitation.

Social Economic Indicators: Per capita GNP, Level of unemployment, Dependency ratio, Literacy rates, (specially, female literacy rate), Family size, Housing (Number of persons in a room), and Per capita calorie availability.

Policy Makers Indicators: This indicator is a political commitment. Which are following as

proportion of GNP spent on health services, Proportion of GNP spent on health related activities (water supply, sanitation, housing, nutrition), and Proportion of total health resources devoted to primary health care.

The main objective of the study is to estimate the extent of public health expenditure in India and Tamil Nadu over the period under review with reference to five-year plans.

Methodology and Data

This study is based on secondary information, which satisfies the objectives chosen for the study. It was mainly related to public health expenditure. The particulars regarding the total plan investment outlay, health and family welfare expenditures in India and Tamil Nadu have been collected from the published source which is presented beneath the respective table. The data on total plan investment outlay, health and family welfare expenditures have been collected for the five-year plan periods (1951-56 to 2012-17). The data have been collected from Annual Financial Statements of various years, budget documents, various reports of Planning Commission of India and Tamil Nadu. Straightforward tabular statements were prepared for working out the percentage and average value.

Five-Year Plan Outlays on Health and Family Welfare

The table 1 depicts that the pattern of central allocation of five year plan outlays on health and family welfare. The First five-year plan where the total plan investment outlay for all heads of development was Rs.1960 crores and the outlay on health and family welfare was just Rs.65.3 crores which was just a meagre (3.3 per cent) of the total plan investment. The Second five-year plan period, the outlay on health increased to Rs.145.8 crores but the outlay on health as a percentage of the total plan investment decreased even further to 3.1 per cent. Third plan where the outlay on health increased to Rs.250.8 crores, but the outlay on health as a percentage of the total plan investment decreased even further to 2.9 per cent. The outlay on health as a per cent age of the total plan investment increased slightly under the annual plans and the fourth five plans where it was 3.2 and 3.9 per cent respectively.

Fifth five-year plan, the outlay on health expenditure increased to Rs.1252.6 crores as the government in an attempt to eradicate poverty and also realising the failure of coercive methods to control population, stressed on health family planning and nutrition as a component of the minimum need programme etc., although the outlay on health as percentage of the total plan investment again declined to 3.2 per cent. The government decided to discontinue the fifth-five year plan in 1978 and brought an annual plan in 1979-80 with new priorities and programme. Yet, under this annual plan where the totally expenditure on health was Rs.341.6 crores, the per cent of outlay on health as a percentage of the total plan investment was the lower (2.8 per cent).

Table 1: Central Allocation of Five-Year Plan Outlays on Health and Family Welfare

(Rs. in Crore)

Sl. No.	Five-Year Plan	Period	Total Plan Investment Outlay (all heads)	Health Sector	Family Welfare	Sub-Total	Percentage of Outlay
1	First Plan	1951-56	1960.0	65.2	0.1	65.3	3.3
2	Second Plan	1956-61	4672.0	140.8	5.0	145.8	3.1
3	Third Plan	1961-66	8576.5	225.9	24.9	250.8	2.9
4	Annual Plans	1966-69	6625.4	140.2	70.4	210.6	3.2
5	Fourth Plan	1969-74	15778.8	335.5	278.0	613.5	3.9
6	Fifth Plan	1974-79	39426.2	760.8	491.8	1252.6	3.2
7	Annual Plan	1979-80	12176.5	223.1	118.5	341.6	2.8

***Cont...* Table 1: Central Allocation of Five-Year Plan Outlays on Health and Family Welfare**

8	Sixth Plan	1980-85	109291.7	2025.2	1387.0	3412.2	3.1
9	Seventh Plan	1985-90	218729.6	3688.6	3120.8	6809.4	3.1
10	Annual Plan	1990-91	61518.1	960.9	784.9	1745.8	2.8
11	Annual Plan	1991-92	65855.8	1042.2	856.6	1898.8	2.9
12	Eighth Plan	1992-97	434100.0	7494.2	6500.0	13994.2	3.2
13	Ninth Plan	1997-02	859200.0	19818.4	15120.2	34938.6	4.1
14	Tenth Plan	2002-07	1484131.3	31020.3	27125.0	58145.3	3.9
15	Eleventh Plan	2007-12	2156571.0	136147.0	3988.0	140135.0	6.5
16	Twelfth Plan	2012-17	7669807.0	75145.3	10044.0	85189.3	1.1

Source: Planning Commission of India.

In the Sixth and Seventh plans the expenditure on health was Rs.3412.2 crores and Rs.6809.4 crores respectively and outlay on health as a percentage of the total plan investment was similar at 3.1 per cent. The eight-five year plan could not take- off due to the fast changing following situation at the centre and it was decided that 1990-91 and 1991-92 would be treated as separate annual plans. Again under both Annual plans the per cent of outlay on health as a percentage of the total plan investment was the low at just 2.9 per cent.

Eighth-five year plan the outlay on health increased to Rs.13994.2 crores, which reflect on the outlay of health as a percentage of the total plan investment increased slightly to 3.2 per cent. There was improvement in outlay of health under the Ninth-five year plan which was increased to Rs.34938.6 crores, still the outlay health as a percentage of the total plan investment was 4.1 per cent.

Health expenditure increased to Rs.58145.3 crores under the Tenth-five year plan but the outlay on health as a percentage of the total plan investment decreased to 3.97 per cent. Later in the Eleventh plan actual plan outlay on health and family welfare were Rs.136147 crores and Rs.3988 crores respectively. Similarly, in the Twelfth plan actual plan outlay on health and family welfare were Rs.75145.29 crores and Rs.10044 crores respectively.

Health and family welfare expenditure by the centre and states, both plan and non plan, will have to be substantially increased by the end of the Twelfth five-year plan. The twelfth-five year plan projections visualize increasing total public funding, both plan and non- plan, on core health from 1.04 per cent of GDP in 2011-12 to 1.87 per cent of GDP by the end of the twelfth five-year plan. From 0.94 per cent of GDP in the tenth-five year plan it has already increased to 1.04 per cent in the eleventh five-year plan. Under the twelfth five-year plan, the principle source of finance for publicly delivered health services would be from the general tax revenues and these are to be supplemented by partnership with private sector, as well as corporate contributions as a part of their corporate social responsibility. In all, the analysis of the data reveals that the central allocation has drastically increased over the plan periods.
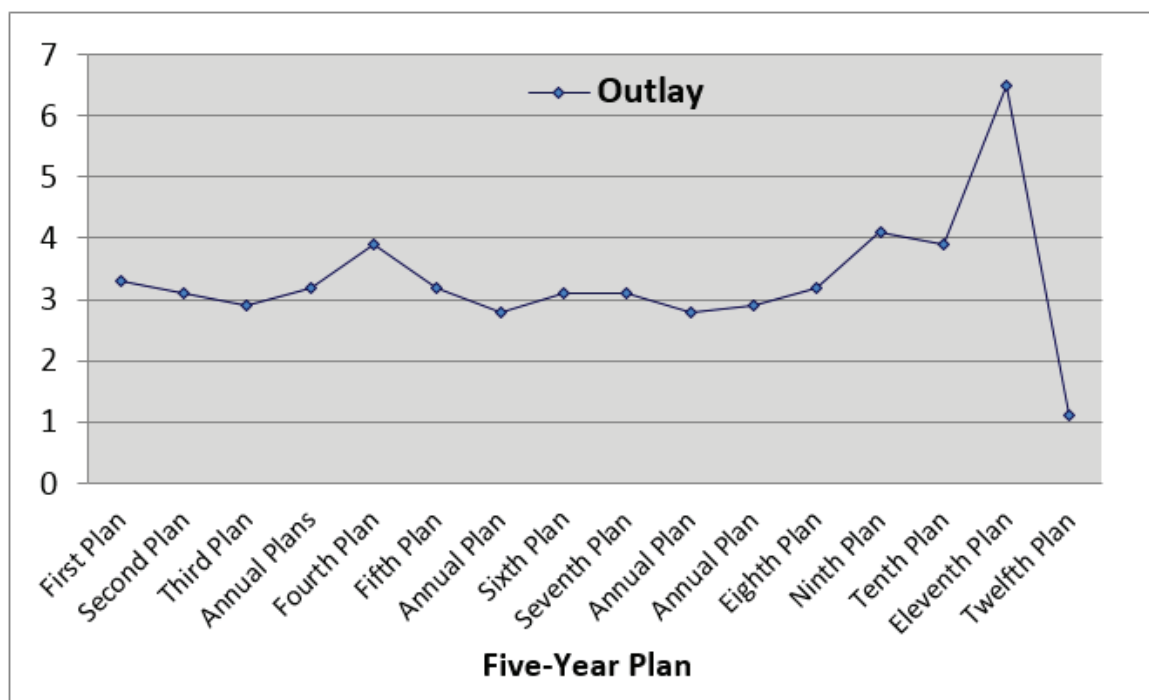
Fig.1: Percentage of outlay to the total plan investment outlay in India

Five-Year Plans in Tamil Nadu

It is very essential to know the plan outlay and its expenditure over the plan period after independence. It will be very helpful to review the health sector status of Tamil Nadu. The power of political leaders and official authorities made to plan and execution of five year plans.

The table 2 portrays that central assistance over the period was varied, which reveals the cooperation / support of central and state for the betterment of Tamil Nadu economy. In the last plan period, the receipt of central assistance was 31.08 per cent which was the lowers over the plan period. The highest central assistance received by Tamil Nadu was in the eight plan period that is 137.49 per cent. Almost in all the five-year plan periods, the grant outlay was not as much of as incurred actual expenditure.

Table 2: Five-Year Plans Total Outlay and Expenditure in Tamil Nadu

(Rs. in Crore)

S. No.	Plan	Period	Approved Outlay	Actual Expenditure	Percentage of Expenditure
1	First Plan	1951-56	86.00	80.00	93.02
2	Second Plan	1956-61	186.19	188	101.08
3	Third Plan	1961-66	342.33	342	101.46
4	Annual Plans	1966-69	266	266	100.00
5	Fourth Plan	1969-74	552	559	101.27
6	Fifth Plan	1974-79	1122.32	1165	103.83
7	Annual Plan	1979-80	343	380	110.79

***Cont...* Table 2: Five-Year Plans Total Outlay and Expenditure in Tamil Nadu**

8	Sixth Plan	1980-85	3150	3645	115.71
9	Seventh Plan	1985-90	5750	6316	109.84
10	Annual Plan	1990-91	1450	1591	109.72
11	Annual Plan	1991-92	1600	1726	107.88
12	Eighth Plan	1992-97	10200	14024	137.49
13	Ninth Plan	1997-02	25000	25036	100.14
14	Tenth Plan	2002-07	40000	43568	108.92
15	Eleventh Plan	2007-12	85344	92655	108.57
16	Twelfth Plan	2012-17	211250	65656*	31.08*

Source: State Planning Commission, Govt. of Tamil Nadu

*Expenditure computed for two years (2012-13 & 2013-14)

The Tamil Nadu government is trying to enhance the health status of people through various health programmes. Health programmes become successful when people's cooperation and participation are solicited and ensured. Meagre incurring huge health expenditure will not bear fruit. Health consciousness has to be created in the minds of the people. Health education has to be important and health habits have to be inculcated. Thus promotional health care delivery indirectly plays an important role in achieving better health status of people in the state.
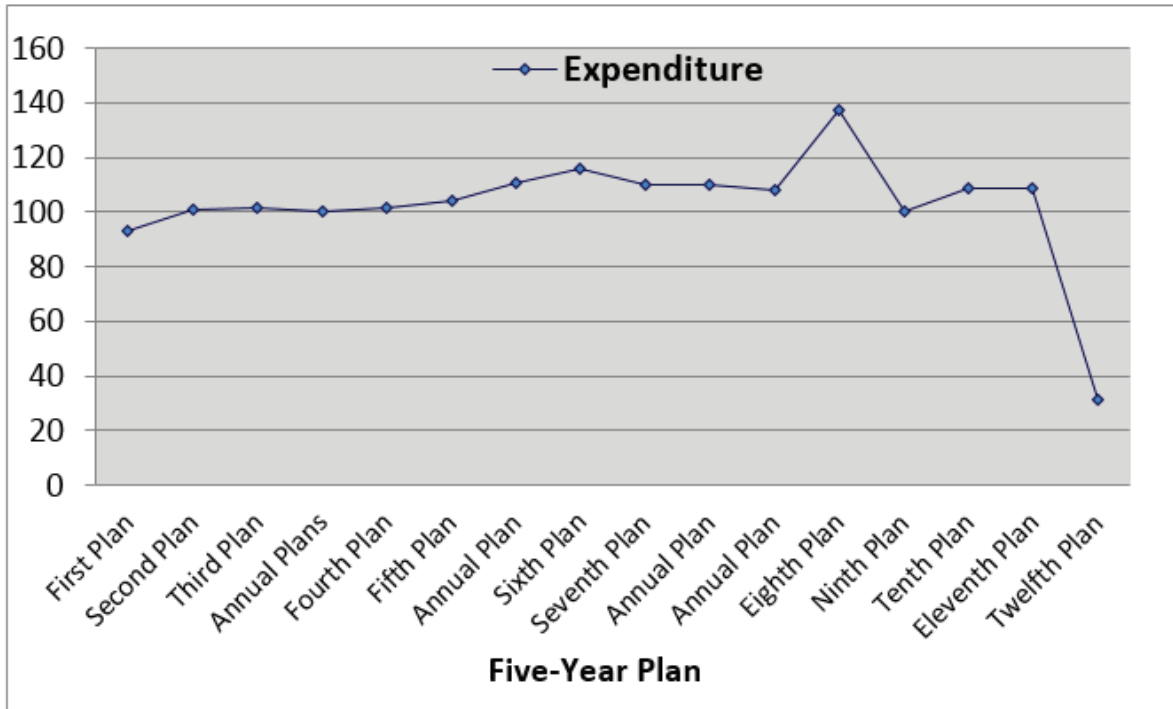
Fig.2: Percentage of expenditure to the approved outlay

Conclusion

From the analysis, it's evident that the total expenditure on health and family welfare of the central and state government shows a steady increase over the plan periods. It's clear from that the plan outlay on both the health and family welfare has increased from first plan (1951-56) to twelfth plan (2012-17) in absolute terms. However it has been always low sharing to the total plan investment outlay of the country. In Tamil Nadu, almost in all the plan periods, the approved outlay was less than incurred actual expenditure.

Ethical Clearance – Secondary dataset, available in public domain.

Source of Funding – Self

Conflict of Interest – Nil

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Assessing Knowledge, Attitude, Practice, and Risk Perception towards COVID-19, among Dental Students in Southern Iran

Elham Ansarifard[1], Maryam Hejazi[2], Zahra Tavallali[3], Mojtaba Fakhrahmad[4]

[1]Assistant Professor, Prosthodontist, Department of Prosthodontics, School of Dentistry, Shiraz University of Medical Sciences, Shiraz, Iran, [2]Assistant professor, Prosthodontist, Department of Prosthodontics, School of Dentistry, Shiraz University of Medical Sciences, Shiraz, Iran. [3]Student, School of Dentistry, Shiraz University of Medical Sciences, Shiraz, Iran, [4] Researcher, Shiraz University, Shiraz, Iran

Abstract

Aims: Coronavirus Disease 2019 (COVID-19), affecting a large number of people worldwide, has been declared as a public health emergency. The goal of this study was to assess the Knowledge, Attitude, Practice (KAP), and risk perception of dental care during the covid-19 among dental students.

Methods: An online questionnaire was sent to 4th- 6th-year dental students. The questionnaire was divided into 5 sections. The first part contained questions regarding demographic information, whereas the other sections each assessed knowledge (18 questions), attitudes (5 questions), practices (7 questions), and risk perception (2 questions) of dental students.

Findings: Among 314 participants, 69.43% were female. The mean scores for Knowledge, Attitude, Practice and Risk Perception were 70.06 ± 8.95 (range: 0-100), 8.86 ± 1.70 (range: 5-15), 5.59 ± 1.86 (range: 0-7) and 4.72 ± 1.92 (range: 2-6), respectively. The mean knowledge score was not significantly different across gender ($P \geq 0.05$), females had a lower attitude score (P= 0.017) while their practice score was significantly higher (P=0.009). Based on the linear regression results, higher scores of risk perception were associated with gender (female vs. male: B=0.653, P=0.001). A significant positive correlation was found between practice and risk perception (r=0.215, p=0.007). Moreover a negative correlation between attitude and risk perception (r= -0.192, p=0.016).

Conclusions: This study revealed that the overall scores of KAP among the dental students were good, however, their knowledge about the extra precautionary measures requires further educations.

Keywords: *Coronavirus, knowledge, attitude, practice, risk perception.*

Introduction

COVID-19 is a newly emerged viral infection that first appeared in Wuhan, China in late 2019 and it has dreadfully spread among people from all over the world ever since. On 11 March 2020, the Director-General of the World Health Organization (WHO) declared the COVID-19 outbreak a pandemic. [1]

The virus responsible for COVID-19 has been named "Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)" by the International Committee on Taxonomy of Viruses, given its genetic relativity to the SARS-CoV which caused an epidemic in 2003. [2, 3] Studies have shown that SARS-CoV-2 is very similar to SARS-CoV-like coronaviruses. Since it can be transmitted from non-human animals to humans,

Corresponding author:
Maryam Hejazi
ORCID ID: 0000-0001-5961-3854,
Tel: +98 9173079581
Email: maryhejazi1366@gmail.com

bats are most likely to be the origin of COVID-19. [4]

The clinical manifestations of COVID-19 may vary from the presence of fever, dry cough, tiredness, or less common symptoms including loss of taste or smell, red eyes, sore throat, headache, skin rash, diarrhea, and nasal congestion to more severe symptoms such as dyspnea, confusion, high temperature above 38°c. [5] This newly discovered disease appears to have a much lower fatality rate than diseases caused by Middle East Respiratory Syndrome Coronavirus (MERS-CoV) and SARS-CoV[6]; however, it is more contagious. [7, 8] Three main ways of the virus transmission in oral health care setting are 1-direct transmission through inhalation of droplets generated through sneezing or coughing; 2- direct transmission via exposure of mucous membranes such as nasal, oral mucosa, or eye to infectious droplets; and 3- indirect transmission via contaminated surfaces such as door handles, chairs, phones, and reception desks. [9]

As COVID-19 is a very recent and rapidly evolving disease, there is yet no definitive treatment. [1] Therefore, adhering to the standard precautions and preventive procedures is of great importance for protecting the individuals from hazardous outcomes of COVID-19. [10] Based on March 2021 updated WHO report, the degree to which the vaccines can protect not only against the disease but also against the infection and the transmission is not clear, so being vaccinated does not mean that people can throw caution to the wind and put themselves and others at risk. [11]

Dentistry is on the list of high-risk jobs due to inevitable close contact, production of a great amount of aerosol and droplets during routine dental procedures, such as using an ultrasonic scaler, and high and low-speed headpiece. Dentists, dental assistants, dental staff, and patients all are at high risk. [12] During the pandemic COVID-19, dental care should be performed while taking the mandatory precautions. It is recommended to minimize aerosol-generating procedures (AGPs), or using high-level evacuation and utilizing a rubber dam throughout AGPs. [13, 14]

Dentists and dental students must follow the practical international guidelines including the World Health Organization (WHO) [15], Center for Disease Control (CDC) [16, 17], and American Dental Association (ADA) [13], to minimize the risk of transmitting this dangerous disease. The amount of adherence to preventive measures during dental care is affected by the knowledge, attitude, and practice (KAP) of dentists. [18]

The purpose of the present study is to determine KAP and risk perception of dental care during the COVID-19 pandemic among dental students from southern Iran.

Methods

A cross-sectional survey was conducted in 2020 on Iranian dental students. An online questionnaire using Google forms was used to collect the data anonymously to maintain confidentiality. The target group was 4th-6th year dental students from different Universities of Medical Sciences from southern provinces of Iran, who have entered the phase of clinical treatments in university dental clinic. The majority of the participants included students from Shiraz, Boushehr, and Yasooj. The link of the questionnaire was posted on several social media platforms such as Instagram, Whatsapp, Telegram, and some relevant forums. The first question was designed to get the students' consent and inform them that participating in this survey was fully voluntary. Among the students who had agreed to participate, only those who had completely filled the questionnaire were selected as reliable and eligible members to be considered in the study. This survey was approved by the Ethics Committee of Shiraz University of Medical Sciences (IR.Sums.Rec1399.600).

Using the information from the websites of WHO, CDC, ADA, and the ministry of health and education (Iran), 35 questions were designed in Farsi. The final questionnaire was divided into 5 sections; the first section was devoted to assessing demographic and general characteristics including gender, age, and years of practice. The second section contained 18 questions regarding the dentists' knowledge of COVID-19. In this section, each correct answer was scored 1 and each incorrect answer was scored 0. Then, the total score which ranged from 0 to 18 was converted into a percentile. The scores above 75% were considered as

high, 50-75% as moderate, and below 50% as low. The third section consisted of 5 questions regarding attitude towards COVID-19. Each question contained 3 choices using a 3-point Likert scale including low, moderate, and high, and once chosen by the participants, they were scored 1,2, and 3 points respectively ranging from 5 to 15 in total. Scores below 8 were regarded as low, 8 to 12 as moderate, and above 12 as high. The fourth section was about assessing practice which contained 7 yes or no questions. As for the scores, choosing yes was scored 1, and choosing no was scored 0. The total score for this section was in the range of 0-7. Afterward, the score was converted into a percentile. A score above 75% was considered as high, 50-75% as moderate, and below 50% as low. Finally, in the fifth section, the participant was asked about risk perception regarding COVID-19 in 2 questions. Using a 3-point Likert spectrum, the options were as follows: a) low which was scored 1, b) moderate which was scored 2, and c) high which was scored 3. The overall score for each participant was calculated which ranged from 2 to 6. A score below 3 was considered as low, 3 to 5 as moderate, and above 5 as high. A pilot study was conducted on 30 students to assess the reliability of the questionnaire and its Cronbach's alpha was obtained 0.79, which represents good levels of internal consistency.

In order to assess the content and the validity of the questionnaire, it was given to four experts in relevant fields (including two epidemiologists, one expert in infection control and one dental public health specialist). They reviewed the questions to ensure they were associated with the topic and added more related questions if necessary. The confusing questions were enhanced based on the reviewers' comments.

Statistical Analysis

The normality of data was assessed using the Kolmogorov-Smirnov test. Means and standard deviations (SDs) were calculated for continuous variables and percentages were used for categorical variables. Independent t-test or one-way analysis of variance (ANOVA) was used to compare the mean values of KAP and risk perception scores between the groups of demographic variables. Multiple linear regression and ordinal logistic regression analyses were conducted to recognize the factors associated with attitude, practice, and risk perception. Moreover, the Pearson correlation test assessed the relationship between major variables. Data were analyzed using the IBM SPSS version23.

Results

A total of 346 dental students participated in the present survey (86.93% response rate); among their responses, 32 subjects were excluded due to incomplete answers to the questionnaire. According to the demographic characteristics of the participants, as shown in Table1, females were 218 (69.43%). The 4th,5th, and 6th graders were 94 (29.94%), 120 (38.22), and 100 (31.84%), respectively. Their mean age was 24.07 years (SD: 2.73, Min:21, Max:43). Their initial source of information was the social network (77.6%) followed by the media (49.1%), standards guidelines (48.4%), family members and friends (29.8 %), and academic courses (4.3 %).

Table 1.Comparison of the major variables between the groups of demographic variables

Variable	n (%)	M ± SD			
		Knowledge (Range: 0-100 %)	Practice (Range: 0-7)	Attitude (Range: 5-15)	Risk perception (Range: 2-6)
Total		70.06 ± 8.95	5.59 ± 1.86	8.86 ± 1.70	4.72 ± 1.92
Gender					
Female	218 (69.43)	70.08 ± 8.55	5.83 ± 1.80	8.68 ± 1.66	4.95 ± 1.09
Male	96 (30.57)	70.02 ± 9.91	5.04 ± 1.91	9.25 ± 1.73	4.21 ± 1.27
P		0.495	0.009	0.017	<0.001
Education level		1.607			
4	94 (29.94)	71.63 ± 9.21	5.19 ± 1.94	8.87 ± 1.71	4.74 ± 1.21
5	120 (38.22)	68.80 ± 9.04	5.92 ± 1.57	8.92 ± 1.66	4.55 ± 1.13
6	100 (31.84)	70.11 ± 8.54	5.58 ± 2.07	8.77 ± 1.76	4.90 ± 1.25
P		0.232	0.236	0.988	0.306
Work to serve the patients					
No	178 (56.69)	69.91 ± 9.01	5.62 ±1.95	8.39 ± 1.49	5.04 ± 1.01
Yes	136 (43.31)	70.26 ± 8.94	5.56 ± 1.76	9.47 ± 1.77	4.29 ± 1.28
P		0.550	0.682	<0.001	<0.001
Work under compulsory rules of the clinic or the university					
No	108 (34.39)	70.68 ± 8.32	5.24 ± 1.78	9.63 ± 1.65	4.20 ± 1.56
Yes	206 (65.61)	69.74 ± 9.29	5.78 ± 1.89	8.45 ± 1.59	4.99 ± 1.12
P		0.918	0.013	<0.001	<0.001
Get news and information regarding COVID-19 through social media					
No	72 (22.93)	72.07 ± 9.25	5.67 ± 1.79	8.46 ± 1.46	4.31 ± 1.21
Yes	242 (77.07)	69.47 ± 8.82	5.57 ± 1.89	8.98 ± 1.75	4.84 ± 1.16
P		0.083	0.549	0.093	0.017

Knowledge

The mean COVID-19 knowledge score of students was 70.06% (SD: 8.95, min: 22.22, max: 88.89) which was not significantly different across gender and level of education (P ≥ 0.05). As shown in Table 2, the vast majority of the students were aware of the modes of transmission (98.1%) and common symptoms of COVID-19 (96.9%). The respondents had low knowledge scores regarding how far the aerosols spread (26.5%) and the standard means of disinfecting the room air (42.4%).

Table 2: Correct answers to the questionnaire (N:158)

Variable	Question				Correct Answer N(%) / Mean ± SD
Knowledge	Sources of information regarding COVID-19			Social network (Instagram, WhatsApp, etc)	242 (77.6%)
		Media (television, radio, newspaper, etc)	152 (48.1%)		
		Family members and friends	94 (29.8%)		
		Guidelines presented by WHO, CDC, ADA, or the ministry of health	152 (48.1%)		
		Academic training courses	14 (0.044%)		
	Common symptoms				306 (96.9%)
	Incubation period				184 (58.2%)
	Modes of transmission				310 (98.1%)
	Social distancing				230 (72.7%)
	Regarding aerosols	The permanence in ambient air			184 (62.0) %
		The length of spreading			84 (26.5%)
		Aerosol generating procedures			170 (53.7%)
		The standard indoor ventilation			134 (42.4%)
	Regarding PPE	About Masks		Protection from different types	238 (75.3%)
		Wearing surgery masks under full-face shields	236 (74.6%)		
		The correct sequence of wearing			226 (71.3%)
		The proper eye protection			300 (94.9 %)
	Prescription of the more preferable:	Radio graph			306 (96.8%)
		Mouthwash prior treatment			160 (50.6%)
	The proper time of disinfecting prosthetic shipments to the laboratory				286 (90.5%)
	Regarding treating a suspected COVID-19 patient	The primary management in a patient enduring pulpal pain			204 (64.5%)
		Prescribing ibuprofen for pain control			204 (64.5%)
	possible duration of the virus presence in the saliva of recovered COVID-19 patients				178 (56.3%)

Cont... **Table 2: Correct answers to the questionnaire (N:158)**

Attitude	Perception of COVID-19	2.667 ± .48
	Willingness to treat a dental emergency for a suspected case	1.252 ± .47
	Confidence confronting a suspected case	1.538 ± .63
	The efficiency of the distancing project and using PPE	1.785 ± .80
	The efficiency of fever assessment and disinfecting hands before entering the room	1.643± .70
	The reason for performing dental treatment during the pandemic 136 (43%) Compulsory rules of the university 204 (64.5%)	
Practice	Tele-screening patients before setting up appointments	254 (80.3%)
	Explaining preventing measures to patients	280 (88.6%)
	Using personal protection equipment (PPE)	278 (87.9%)
	Asking the visitors — Follow the distancing project	260 (82.2%)
	Disinfect their hands before entering the room 240	
	Assessing patients' fever before entering the room	198 (62.6%)
	Using a rubber dam	246 (78.8%)
Risk perception	Perception of the risk of getting infected with COVID-19 as a dentist	2.669±.63
	The degree of fear of getting infected with COVID-19	2.051±.79
Data were presented as N (%) for Knowledge and practice, and Mean ± SD for Attitude and Risk Perception(range 1-3)		

Attitude

The mean score of the attitude of the participants was 8.86 (SD: 1.70, min:6, max:13)(Table2) which was significantly different between males and females (P = 0,017). Females had lower attitude scores. There was no significant difference among the students of different levels of education (p ≥ 0.05). According to linear regression results, higher scores of attitude were associated positively with work to serve the patients (β = 0.818, P = 0.005) and age of respondents (β = 0.100, P = 0.043) and negatively with work under compulsory rules of the university (β = -0.733, P = 0.023) (Table 3). The mean score of the attitude of the students toward the willingness to treat dental emergencies for suspected patients was 1.25.

Table 3. Multiple linear regression results for practice, attitude, and risk perception as dependent variables

Variable	Dependent Variable					
	Practice		Attitude		Risk perception	
	β (SE)	P	β (SE)	P	β (SE)	P
Age			0.100 (0.049)	0.043	0.097 (0.032)	0.003
Gender (female vs. male)					0.653 (0.192)	0.001
Education level (5th grade vs. 4th grade)	0.780 (0.371)	0.038			-0.473 (0.207)	0.024
Education level (6th grade vs. 4th grade)						
Work to serve the patients (Yes vs. No)			0.818 (0.288)	0.005	-0.450 (0.193)	0.021
Work under compulsory rules of the clinic or the university (Yes vs. No)			-0.733 (0.318)	0.023	0.443 (0.215)	0.041
Get news and information regarding COVID-19 through social media (Yes vs. No)			0.694 (0.303)	0.024	0.546 (0.200)	0.007
Knowledge						
Practice					0.126 (0.046)	0.007
Attitude						
Risk perception	0.385 (0.145)	0.009				

SE: Standard error

p: p value (significance level: < 0.05)

According to the ordinal logistic regression results (Table 4), those participants whose reason for treating COVID-19 suspected patients was not compulsory rules of universities were less likely to express greater levels of willingness (β = 0.804, P=0.028). The respondents without a desire to serve their patients reported lower levels of willingness (β =-1.988, P<0.001).

Table 4. Ordinal logistic regression results for the dependent variable (How willing are you to treat a dental emergency for a suspected COVID-19 patient?)

Cumulative intercepts	Model1		Model2	
	β (SE)	P	β (SE)	P
Intercept1 (Not much)	0.267 (0.600)	0.657	0.892 (1.647)	0.588
Intercept2 (To some extent)	3.171 (0.798)	<0.001	3.932 (1.737)	0.024
Independent variables				
Work to serve the patients (ref = Yes)				
No	-1.988 (0.482)	<0.001	-2.045 (0.491)	<0.001
Work under compulsory rules of the clinic or the university (ref = Yes)				
No	0.804 (0.365)	0.028	0.646 (0.375)	0.085
Control variables				
Age			0.051 (0.065)	0.437
Gender (ref = male)				
Female			-1.012 (0.358)	0.005
Education level (ref = 4th grade)				
5th grade			0.072 (0.386)	0.852
6th grade			-1.313 (0.617)	0.033

SE: Standard error

p: p value (significance level: < 0.05)

Model 1: A model that only includes the reason for performing dental treatment during the pandemic as independent variables

Model 2: A complimentary model for model 1 that also includes demographic variables.

In Model 2, all independent and control variables were involved in the regression. The results showed that females compared to males and 6th graders compared to 4th graders expressed higher levels of willingness to treat dental emergencies for suspected patients. After introducing all control variables, serving the patients' reason remained the most effective, whereas the effect

of the reason for the compulsory rules on the dependent variable was no longer significant.

Practice

The mean self-reported preventive behavior score of the students was 5.59 (SD: 1.86, min: 0, max: 7). The practice score was significantly higher in females (P = 0,009). More than 80% of the participants declared that they would use Tele-screen the patients before setting up an appointment, explain preventive measures to the patients, use PPE, and follow social distancing. 78.8% of the students showed their willingness to use a rubber dam during treatments in the COVID-19 pandemic (Table 2).

According to linear regression results, good scores of practice were associated with the education level (5th grade vs. 4th grade) (β =0.780, P = 0.038) and risk perception score (β = 0.385, P = 0.009).

Risk perception

The mean cumulative score of risk perception was 4.72 (SD: 1.92, min:2, max: 6). Based on the linear regression results, higher scores of risk perception were associated with, work under compulsory rules of the university (Yes vs. No) (β =0.443, P=0.041), practice score (β =0.126, P=0.007), age of respondents (β =0.097, P=0.003), and gender (females vs. males: β =0.653, P=0.001). Lower scores of risk perception were associated with the reason of *willingness for dental treatment during the Covid-19 pandemic* (Yes vs. No) (β = -0.450, P = 0.021) and *education level* (5th grade vs. 4th grade: β =0.-473, P=0.024) (Table 3)

According to the Pearson correlation coefficient analysis, a significant and positive correlation was found between practice and risk perception (r=0.215, P = 0.007). Moreover, there was a negative and significant correlation between risk perception and attitude (r = -0.192, P = 0.016).

Discussion

The rapid spread of COVID-19 has affected the lives of people around the world. The long asymptomatic incubation period of COVID-19 (as long as 14 days), makes it harder to minimize the probability of exposure to this new coronavirus. [19] Dentistry is categorized into very high-risk jobs during the pandemic; hence, the dentists and dental health care workers are more likely to get infected and further spread the virus. Based on WHO updated on 3 August 2020, effective prevention of oral problems and self-care remain a high priority during the COVID-19 pandemic. [14] To reduce the risk of transmission of COVID-19 in dental offices and schools, dentists and students must follow valid and reputable guidelines such as CDC, WHO, and ADA.

In the present assessment, the number of students who participated from year 4th-6th was almost equal; however, females (69.43% vs. 30.57% for males) were predominant which could be associated with the higher number of female students in the investigated dental schools.

The initial source of information among students was social networks (78.1%), followed by media (48.1%). These findings are in line with the results of the Kamate et al.' study. [18] However, these sources are always reachable and valuable for increasing public awareness, reliable sources such as reports of international health organizations and scientific health articles are recommended to be the main informative sources.

In the present study, we found out that dental students had relatively good knowledge (70.06±8.95%) toward COVID-19 however it was less than recent similar studies by Kamate et al. (92.7% among multinational dental practitioners) and Zhong et al. (90% among Chinese residents). [18, 20]. This is probably related to different questionnaires (specialized vs general) and also different study populations (students vs. dentist). Since the COVID-19 is an emerging, rapidly evolving situation and also there is a lack of an educational course, it was expected that there would be no difference in the knowledge of different education levels, which was confirmed in this study. Moreover, less than 50% of the students mentioned valid guidelines as their source of information which could affect the results. The vast majority of students had a wealth of knowledge about

the generalities of the COVID-19 pandemic. [14] More than 96% of students were aware of the main symptoms of COVID-19, which is essential for students to screen the patients and, if possible, postpone the dental care of suspected cases. Reportedly, about 80% of COVID-19 patients show only mild symptoms or no symptoms at all, especially during the incubation period of the virus; thus, they might be left undiagnosed. (19) Awareness of the COVID-19 modes of transmission is mandatory for effective infection control, especially against undiagnosed cases. In this study, modes of transmission were identified well (98.1%) which is in agreement with the previous studies. [18, 19, 21] 72.7% of dental students were aware of social distancing in the workplace which is a measure to reduce the risk of infection and is determined 6 feet according to published guidelines [16]. In another study that has similarly assessed the knowledge and attitude of Iranian dental students during the COVID-19 pandemic, a different result has been achieved and reported (43%). [22] This difference can be justified by the fact that our population included only 4th-6th-year students, while their population consisted of a wider range of students with younger average age.

Approximately, half of the students had correct information on the following topics: the probable duration of the virus presence in the saliva of recovered COVID-19 patients and recommended mouthwash before dental treatment. Compared to the study of Imran et al., which had reported that only 38.9% of the students had correct information about the preferred mouthwash to eradicate the COVID-19 virus, the present study revealed a higher knowledge level of the participants (50.6%) in this regard, which is not still a satisfying value [14]. These not high percentages narrate from the dearth of knowledge regarding the best choice of mouthwash, while the clinicians have a wide assortment of mouthwashes with different active ingredients.

Only 64.6% of students were informed of primary management and the controversy about ibuprofen administration in suspected patients. Students should be trained to assess a true emergency and discern how to manage an emergency during the COVID-19 outbreak.

The results showed some gaps in the knowledge about how far aerosols spread in the air (26.5%) and a gold standard for indoor ventilation (42.4%). According to the literature, there is no evidence regarding the transmission of COVID-19 via the generated aerosols in dental practices. However, guidelines have been recommended given the urgency and taken special precautionary measures targeted toward aerosol transmission to prevent and control the spread of this highly contagious disease. [23, 24] Aerosols containing SARS-COV-2 travel over a great distance and could be suspended in the air for many hours, so the importance of good indoor ventilation which is best provided with a negative pressure room to maintain a healthy environment for the patients and the dental team is highlighting. [15, 16]

In the present survey, the level of dental students' attitude was in the moderate range although they had almost good knowledge. Most of the students perceived COVID-19 as a very dangerous disease and were not willing enough to perform dental treatment for a suspected patient (Table 2). These findings are consistent with the findings of the study conducted by Arabian dentists about SARSCOV-2 [25]. The reason for this finding may be related to the high number of patients diagnosed positively for COVID-19, together with local and global reported deaths according to the lack of antiviral treatment or vaccine for the whole population. Moreover, most of the students expressed a high risk of getting infected with COVID-19 as dentists and have considered measures like disinfecting hands, observing social distance, and using PPE, not very much effective in preventing the transmission of the disease. (Table 2) Other probable reasons may be related to their belief that following the protection protocol completely is difficult in dental schools due to a large number of patients and students.

As shown in Table 4, females (compared to males) and 6th graders (compared to 4th graders) were more willing to treat a dental emergency for a suspected COVID-19 patient. Moreover, students who anticipated performing dental treatment for suspected patients with the purpose of "serving the patients" expressed more

desire to treat a dental emergency for a suspicious patient. The ordinal logistic regression coefficients revealed that the reason for serving the patients was the most effective predictor of willingness.

A high level of students' practice was seen in this study. 80% of the students reported they would perform Tele-screening and health triages of patients at the time of scheduling appointments. Based on the latest edition of the CDC guideline, patients should be instructed to call ahead and discuss the need to reschedule their appointment if they have symptoms of COVID-19 on the day they are scheduled to be seen. [22] Most of the students expressed that they ask patients to keep social distance and disinfect their hands in a waiting room. About 88% of the students would wear PPE and explain the risk of COVID-19 and its preventive ways to their patients (Table 2). These findings are in agreement with the previous studies [18, 20, 25]. This good preventive behavior as claimed by the respondents could be related to their good knowledge about COVID-19. Moreover, none of the respondents had considered COVID-19 to be non-dangerous.

The cumulative score of risk perception was 4.72 ±1.92 out of 6 which was in the moderate range. It was significantly associated with gender. Females reportedly had more risk perception scores and better practice scores compared to males; however, their knowledge scores did not differ significantly. Students in the 4th grade showed higher risk perception and lower practice scores than the 5th graders. Students who expressed higher risk perceptions selected "compulsory rules of the university". (Table 4) Improving the proper knowledge of dental students by following reputable guidelines can reduce their stress level and fear of getting infected with COVID-19. They would observe cross-infection control protocols and more precautions against any suspicious patient to decrease the risk of exposure to the virus.

A significant positive relationship was found between risk perception and practice scores. Besides, there was a substantial negative correlation between risk perception and attitude scores, which revealed the role of risk perception in the students' motivation and performance.

Despite the valuable results and the strengths of this study like its questionnaire -regarding COVID-19 considerations in dentistry compared to general questionnaires in similar articles-, some limitations are worth mentioning. This survey could not assess all aspects of KAP related to dental care during the COVID-19 outbreak. Another limitation of this cross-sectional study was the inability to supervise the students' practice; therefore, we ought to trust their statements.

As future work, it is recommended to study a different population of dental health practitioners, including professional dentists and specialists. Moreover, to generalize the results obtained in the studies, future investigations on wider populations of dental students are needed to be performed in future works.

Conclusion

In conclusion, the overall score of the dental students' knowledge was good, however, a particular course seems necessary to be included in the curriculum of the dental students based on the updated guidelines. The mean score of their self-expression practice was at a high level, but their attitudes were in the moderate range. The risk perception score had a significant negative correlation with the attitude score and a significant positive correlation with the practice score. Improving awareness helps reduce the risk perception followed by a higher attitude and better practice of dental students during the COVID-19 outbreak.

Ethical Clearance: This study was approved by the Ethics Committee of Shiraz University of Medical Sciences (IR.Sums.Rec1399.600).

Conflict of Interest: No

Sources of Support: This study was self-supported and did not receive any grant from funding agencies in the public, commercial, or not-for-profit sectors.

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On the Changing Image of Women a Scientific Treatise on the Professional Situation of Women with Children

Friederike Harrich[1], Van Brunschot[1]

[1]Researcher, Institut für Geschichte, Theorie und Ethik der Medizin, Neubau 17.11, Raum 01.32, (Hauspostfach 1114), Moorenstr. 5, 40225 Düsseldorf, Germany

Abstract

In its publication "Guiding principles for complementary feeding of the breastfed child", the WHO propagates that exclusive breastfeeding in the first six months post partum at normal term is essential for the development of the infant. However, the first question that arises is how to breastfeed children when the occupational situation of mothers changes to a large extent due to a change in the image of women in society. Of particular interest here is the possible difference between academic and non-academic women, which has not yet been evaluated, explicitly in a division of women into decades of childbirth in order to show a progression over time.

For this purpose, Dr. med. Friederike Harrich interviewed mothers about their situation and evaluated them in a large-scale study. This study was compared with two other studies in order to pool the data. [1, 2, 3, 4, 6, 7, 8, 9, 10, 11, 12, 13]

The women were interviewed with a questionnaire, followed by an oral interview using the oral history method.

The final analysis shows that women without an academic educational background return to work more often after childbirth than women with an academic educational background. The 1980s are an exception here, where academically educated women work more after childbirth. [4, 6, 7]

Keywords: *Breastfeeding, Breastfeeding behaviour, Breast milk, Mothers, Image of women, Gynaecology, Obstetrics, Paediatrics*

Introduction

The change in the image of women is still a present topic, explicitly with regard to re-entry into the labour market after childbirth, during pregnancy itself and in the context of breastfeeding. Women are still disadvantaged in terms of salary and professional career. This study provides a detailed breakdown of academic and non-academic women. It refers to a previous study (Harrich, F. H. M., Zum Wandel des Stillverhaltens von Müttern im Großraum Düsseldorf zwischen 1951 und 1990 - Eine Oral History Studie, p. 29, Düsseldorf, 2020) and in combination with two other studies forms a quintessence (Heininger, L., On the change in breastfeeding behaviour in the FRG between 1950 and 1990, p. 29, Düsseldorf, 2014., Freiin Teuffel von Birkensee, A. C., The breastfeeding behaviour of female academics in the period from 1950 to 1990, p. 65, Düsseldorf, 2014.).[4, 6, 7]

Material and Methods

The comparable studies are titled as follows in this meta-analysis:

Study A:

"The breastfeeding behaviour of female academics in the period from 1950 to 1990" by Antonia Charlotte Freiin Teuffel von Birkensee. [4]

Study B: "On the change in breastfeeding behaviour in the FRG between 1950 and 1990 - An Orla History study" by Luisa Heininger.[7]

Study C: "On the Change in Breastfeeding Behaviour of Mothers in the Greater Düsseldorf Area between 1951 and 1990 - An Oral History Study" by Friederike Helene Margarethe Harrich. [6]

The three studies A, B and C were conducted as retrospective cohort studies. In studies A and B, a telephone interview was used to collect the data; in study C, a questionnaire was filled out in writing by the study participants alone, followed by a personal interview. Both methods have the advantage that the effect of social desirability in the form of impression management and self-deception is greatly reduced. The questionnaires, which are to be seen as a guide for the interviews, differ slightly, but also contain identical questions. All comparable surveys are compared in this meta-analysis. The study designs of the three studies to be compared are very similar, comparable but not identical. For example, it is noticeable that the time periods studied differ. While studies A and B examined breastfeeding behaviour in the years 1950 to 1990, study C investigated the same

in the years 1951 to 1990.The dissertations by Ms Freiin Teuffel von Birkensee (Study A) and Ms Heninger (Study B) have the problem that the years 1960, 1970, 1980 and 1990 were duplicated in the cohort classification, which is not the case in Ms Harrich's study (Study C). In order to prevent this duplication and still maintain equal time intervals, Study C began with a survey of women who gave birth in 1951. [4, 6, 7]

Furthermore, the studies differ in the number of study participants. Study A and B each involved 100 women, 25 per cohort, while Study C involved 44 women, 11 per cohort. It should be noted with regard to the size of the cohorts that in study C an incomplete completion of the questionnaire or a failure to remember led to exclusion from the study, which was not the case in studies A and B. The number of women participating in study A and B was not significant. [4, 6, 7]

In summary, Study A deals with the breastfeeding behaviour of academic women in the period mentioned, Study B deals with non-academic women in the period mentioned, and Study C shows a mixed study population. This and a closely aligned study design provide optimal opportunities for comparison.[4, 6, 7]

Table 1: Prenatal occupational exposure of mothers.

	Study A	Study B	Study C
Cohort 1	Occupation: 20%	Occupation: 64%	Occupation: 54,5%
	No Occupation: 80%	No Occupation: 36%	No Occupation: 45,5%
Cohort 2	Occupation: 40%	Occupation: 72%	Occupation: 45,5%
	No Occupation: 60%	No Occupation: 8%	No Occupation: 54,5%
Cohort 3	Occupation: 76%	Occupation: 100%	Occupation: 63,7%
	No Occupation: 24%	No Occupation: 0%	No Occupation: 36,3%
Cohort 4	Occupation:92 %	Occupation: 100%	Occupation: 81,8%
	No Occupation: 8%	No Occupation: 0%	No Occupation: 18,2 %

Rounding errors by the sources were compensated for in the decimal point.

With regard to workload in the prenatal phase, there are clear differences in the three studies compared over time, which are shown in Figures 8, 9 and 10. The listing of the percentages in study A shows that the percentage of working women has risen massively over time. While in the 1950s it was only 20%, it rose to 40% in the 1960s, 76% in the 1970s and 92% in the 1980s. A clear increase can thus be observed in the course of the observed period.[4, 6, 7]

When looking at the percentage values of the evaluation from study B, a clearly weaker percentage growth is recorded, but the entry value in cohort 1, i.e. in the 50s, is 44% higher than in study A. It is 64%. In Cohort 2 of Study B, this value is 72%, so it has increased by 8% compared to Cohort 1, but this is a marginal growth considering that it doubled when we jumped from Cohort 1 to Cohort 2 in Study A. In cohort 3 and 4 of study B, the values of this comparison reach a maximum of 100% in both cohorts.[4, 6, 7]

In the evaluation of Study C, there is also a growth in the percentage occupation, but also a much weaker one, than in Study A. While the percentage of women working in cohort 1 of study C was 54.5%, it rose from 45.5% in cohort 2 and 63.7% in cohort 3 to 81.8%.[4, 6, 7]

What is striking in this comparison is the low percentage in Cohort 1 of Study A in the context of the strong growth in this study across cohorts. It should be remembered that Study A looks exclusively at the breastfeeding behaviour of academic women and academic wives. This is a unique feature of this study compared to Studies B and C. Since the values mentioned clearly stand out, the question arises to what extent the growth is related to the academic level of education.[4, 6, 7]

Table 2: Postnatal occupational stress of mothers.

	Study A	**Study B**	**Study C**
Cohort 1	Occupation: 8%	Occupation: 32%	Occupation: 9,1%
Cohort 2	Occupation: 32%	Occupation: 36%	Occupation: 36,4%
Cohort 3	Occupation: 48%	Occupation: 56%	Occupation: 18,2%
Cohort 4	Occupation: 68%	Occupation: 44%	Occupation: 63,6%

The postnatal occupational stress across the cohorts is presented in the comparison of studies A, B and C. The results are similar to the comparison of the prenatal occupational stress of the mothers. With regard to the behaviour of the growth in the evaluation of studies A and C, a similar picture emerges as in the comparison of the prenatal occupational stress of the mothers.

The evaluation of the results from study A shows a growth across the cohorts of 60%.

In the evaluation of the data from study B, this percentage is only 12% across the cohorts. In study C, this value is 54.5%.[4, 6, 7]

It can be seen that Study B, the only study from which female academics were explicitly excluded as study participants, shows a low growth in the percentage described. This suggests the hypothesis that women without an academic degree have returned to work less and with a lower percentage over time in terms of the development of working after childbirth.[4, 6, 7]

Table 3: Occupational sectors of the women interviewed in study B.

	Factory work	Agriculture	Office activity	Housework	Other
Cohort 1	12 %	16 %	28 %	36 %	8 %
Cohort 2	20 %	20 %	16 %	12 %	32 %
Cohort 3	12 %	8 %	40 %	0 %	40 %
Cohort 4	0 %	0 %	45 %	0 %	55 %

No information was given on this in study A. The item "civil servant employment" was not asked about.

It is noticeable that the chosen occupational sectors are diverse in cohorts 1 and 2 of study B, while this is reduced in cohort 3 of that study, which continues in cohort 4. 36% of the women in Cohort 1 of Study B were housewives, 28% had an office job, 16% worked in agriculture, 12% were factory workers and 8% had another occupation. The aforementioned diversity becomes clear, with housewifery and office work making up the largest share.[4, 6, 7]

Table 4: Occupational sectors of the interviewed women from study C (before the first pregnancy).No information was given on this in study A.

	Factory work	Agriculture	Office activity	Housework	Other	Civil servant employment
Cohort 1	20 %	10 %	10 %	40 %	20 %	0 %
Cohort 2	0 %	0 %	45 %	9 %	36 %	9 %
Cohort 3	0 %	0 %	55 %	0 %	36 %	9 %
Cohort 4	0 %	0 %	36 %	0 %	27 %	36 %

When looking at the evaluation of the occupational sectors of the interviewed women from study C, it becomes clear that the mentioned diversity of cohorts 1 and 2 from study B in study C is exclusively shown in cohort 1.[4, 6, 7]

40% of the women interviewed from Cohort 1 of Study C were employed as housewives. 20% were engaged in factory work, 10% worked in agriculture, 10% worked in an office job and another 20% were engaged in another occupation not further defined in the study. In the evaluation of cohort 2 of this study, it is evident that the diversity of occupational sectors is declining. 45% of the women in this cohort work as office workers, 36%

in an occupation not further defined here. This picture continues in similar, though not equal, percentages in the following cohort. The same applies to cohort 4 of study C, although it is noticeable in the evaluation of this cohort that civil servant employment as an occupational sector of the study participants predominates here as the only cohort, with 36% compared to the percentage of civil servant employment in cohorts 1, 2 and 3.[4, 6, 7]

A direct comparison of cohorts 1 of studies B and C reveals how similar the breakdown of occupational sectors still is in the 1950s. Non-academics (Study B) and academics and non-academics (Study C) seem to differ only slightly in their choice of occupational

sectors in the decade indicated, indicated here by the occupational sector "other". The percentages of the occupational sectors differ in the comparison, but by a maximum of 18% in the area of office work.

If the two cohorts 2 of studies B and C are compared with each other, as shown in figure 18, a difference in the percentages of the occupational sectors between non-academics (study B) and academics and non-academics (study C) becomes apparent.Participants in Study B were engaged in agriculture with a percentage of 20, as well as factory workers with 20%. In Study C, 0% were in both sectors. The sectors "other" and "domestic work" differed by study comparison of cohorts 2 with only 4% and 3%. It is noticeable that there is a civil servant employment with a percentage of 9 in cohort 2 of study C, which cannot be explained by the fact that the mentioned sector was not recorded in study B, because the difference of the sectors "other" does not explain this. However, since the mentioned sector "other" is not defined in more detail, this cannot be ruled out with a probability bordering on certainty either, although it seems unlikely.A comparison of the occupational sectors of studies B and C of cohorts 2 shows an approximate homogeneity in the percentages of the results of the evaluation of the sectors "other" and "office work" with differences of 4% and 15%. These two sectors dominate the overall picture of the occupational sectors in both studies and thus represent a common feature of non-academics (Study B) and academics and non-academics. Being a female academic does not seem to be a relevant factor in the evaluation of the 1970s with regard to the occupational sector "office work". The situation is different for other sectors. The non-academic women (Study B) from Cohort 3 were more likely to be factory workers with a rate of 12% and to work in agriculture with a rate of 8%. Neither occurred in the same cohort of Study C, which included female academics. The percentage here was 0. It seems that the selection of the occupations "factory worker" and "farmer" are related to academic status. This is supported when looking at the results of cohort 2, where 9% of the women were employed as civil servants. This is an evaluation of a sector that was not asked about in Study B. The number of different occupational sectors represents the number of women in the cohort.[4, 6, 7]

The number of different occupational sectors is lowest in cohorts 4 of studies B and C in comparison to all cohorts of the two studies. The occupational sector "other" accounted for 55% in cohort 4 of study B, with the remaining 45% stating that they worked in an office. Women in the same cohort of Study C reported having a civil service job at a rate of 36%. The same rate of study participants worked in an office and 27% of women from the said cohort reported "other" as their occupational sector. The 36% rate of civil servants in Cohort 4 of Study 3 can be explained. On the one hand, in Study B this sector was not included in the survey, as only non-academic women were interviewed; on the other hand, in the evaluation of Cohort 4 from Study B, a higher percentage is found in the area of the sector "Other", which is not explained in more detail in Study B, with a difference of 28% to Cohort 4 from Study C.[4, 6, 7]

Conclusion

An ondulating change in the image of women may complicate the conditions to feed an infant according to WHO specifications.[4, 6, 7, 13]

Women without an academic educational background are more likely to return to work after childbirth compared to women with an academic educational background. The 1980s are an exception here, where academically educated women work more after giving birth.

Conflict of Interests:

Friederike Harrich is the lead author

Denise Özdemir - van Brunschot is the second author

Source of Funding: self funded

Ethical Clearance: Ethical clearance was taken from the Ethics Committee of the Heinrich-Heine-University Düsseldorf, Germany

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Peace and Improvement in Iraqi Childhood Nutrition

Huda S. Saeed[1], Besmah M. Ali[2], Jawad K. Al-Diwan[3]

*[1]Researcher, Department of Family and Community Medicine, Collage of Medicine, Baghdad University,
[2]Assistant Professor Ministry of Health, [3]Professor Dept. of Family and Community Medicine, College of
Medicine, Baghdad University*

Abstract

Background: Malnutrition is faulty and bad nutrition. It is a silent invisible emergency that can be easily prevented and managed. High prevalence rates of malnutrition were reported in Iraq since 1996 but started to decline after the change in regimen in 2003.

Objective: To demonstrate the negative effects of conflicts (wars, widespread violence …etc.) on children growth.

Materials and Method: A review of data was done from MICS reports from 1996 till 2018. Under 5 years malnutrition trends were graphically presented.

Results: All malnutrition indicators rates (stunting, wasting, and underweight) in both their moderate and severe forms for under five years children were presented in graphs including north middle, and south regions of Iraq.

Conclusions: Peace is an essential element in preventing malnutrition. Wars and social strife are the main factors that precipitate it. Low prevalence rates of malnutrition reflect good health.

***Keywords:** Malnutrition, MICS, sanction, Iraq, under five children.*

Introduction

Malnutrition is one of the main factors that has an impact on childhood morbidity and mortality. It is the outcome of many factors that are related to inadequate food intake, recurrent and severe infections, poor food quality, or combination of factors. [1]

Undernourished children are at high risk for poor socio-emotional development, impaired mental and physical growth, low IQ level, and high risk of recurrent diseases. The effects expand beyond adulthood life too where it has a considerable role in minimizing adults' productivity and social activities even adulthood life span will be affected enormously. [2] [3]

Iraq was faced many life challenges i.e., wars, civil wars, economic sanctions, environmental changes, and geopolitical instability. [4] [5] The undernutrition indicators (stunting, wasting, and underweight) are greatly affected by these man-made disasters. [6] Many surveys had been carried out to assess the nutritional status of Iraqi children e.g., Multiple Indicator Cluster Survey (MICS) [7], and Comprehensive Food Security and Vulnerability Analysis (CFSVA). [8] None of these surveys draw trends of these indicators over years. So, the aim of the study was to show the impact of geopolitical instability on Iraqi children nutritional status from the north to the south since 1996 till 2018.

Materials and Methods

A review of MICS reports (1996, 2000, 2006, 2010, 2018) was done to draw trends of malnutrition indicators and to show the impact of geopolitical instability on

Corresponding author:
Dr. Huda S. Saeed
Email: dr.hudasabah@gmail.com

these indicators on children nutritional status from the north to the south.

Operational definitions:

Stunting: failure to reach linear growth potential due to suboptimal health and / or chronic inadequate food intake. It is the chronic form of malnutrition.

Wasting: recent weight loss due to acute severe illness or famine. It is the acute form of malnutrition.

Underweight: it represents general malnutrition, describes recent body proportion and linear growth; therefor, reflecting both stunting and wasting.

Moderate malnutrition: children with z score between -2SD and -3SD.

Severe malnutrition: children with z score below -3 SD. [9]

Instruments and tools:

In all MICS, the anthropometric measures were taken using electronic scale and a wooden board. Z distribution was used to identify the prevalence rates of malnutrition indicators (stunting, wasting, and underweight).

Results

Figure (1) shows trends of under 5 children malnutrition indicators in Kurdistan region, while figure (2) shows these trends in the middle and south of Iraq 1996-2018.
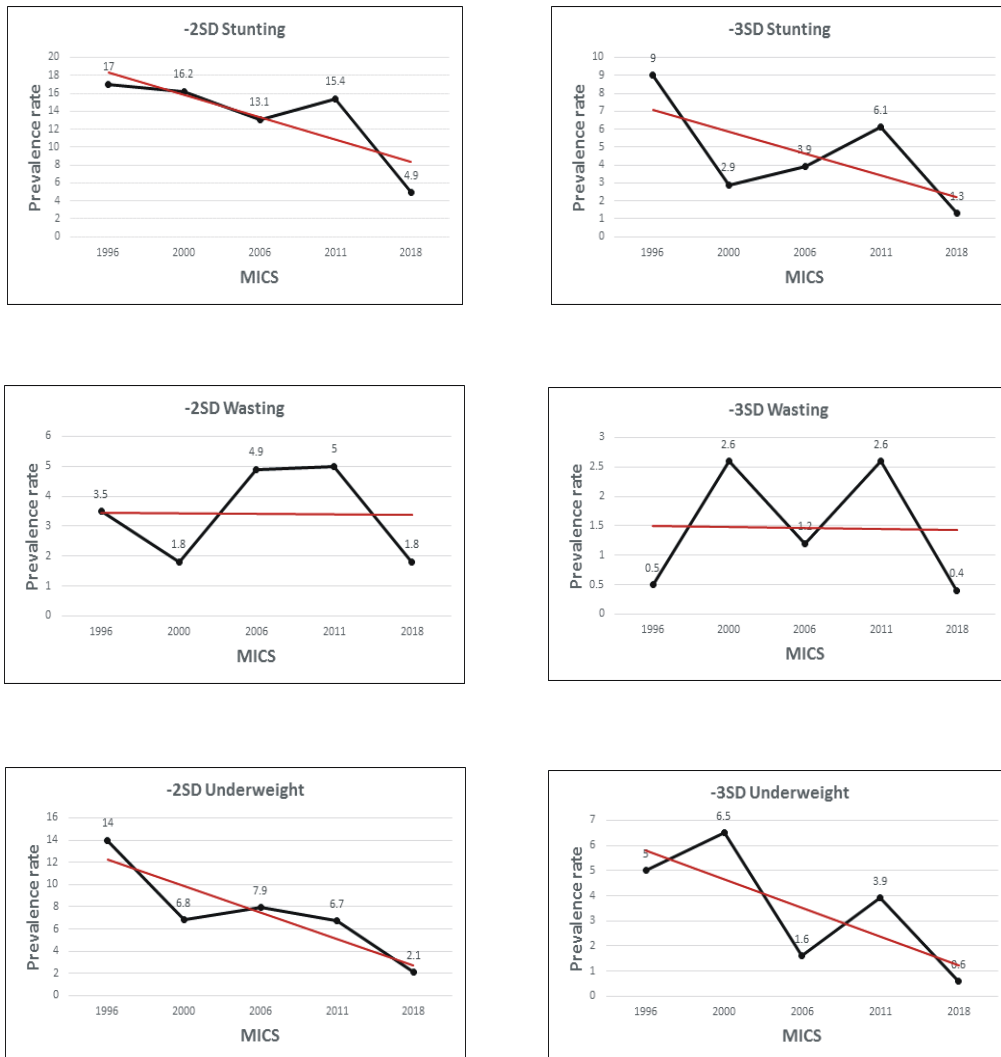
Figure (1): Trends of under 5 years children malnutrition indictors in Kurdistan region 1996- 2018.
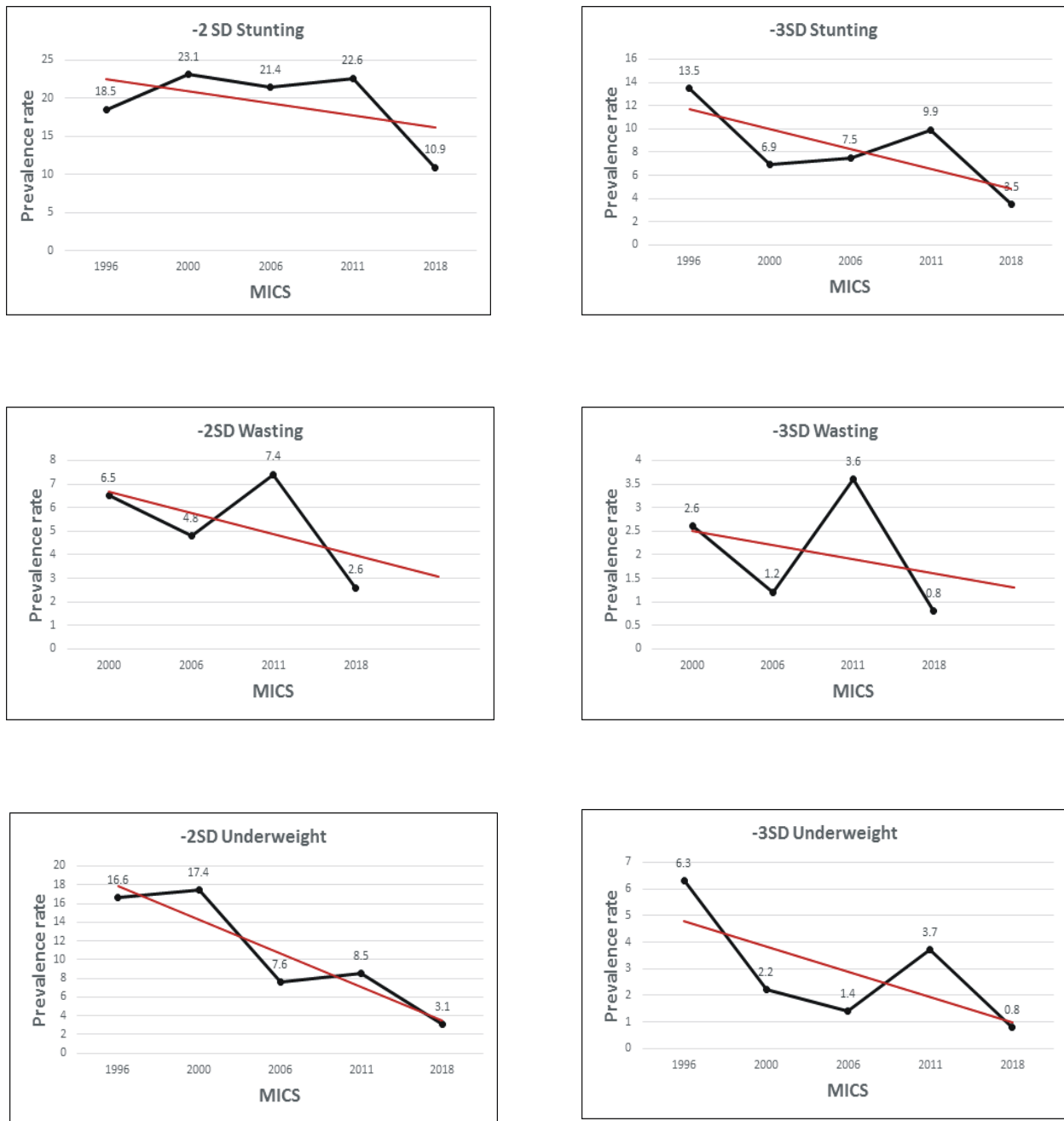
Figure (2): Trends of under 5 years children malnutrition indicators in the middle and south of Iraq 1996 – 2018.

Discussion

High rates of malnutrition indicators in MICS 1 (1996) might be explained by the fact of Iraq wars (1980-1988, and 1991) and economic sanctions. Several articles documented the effects of war on nutritional status of children. [10] MICS 1 showed definitely the effect of six years' sanctions. Because of these high rates, the Security Council was enforced to announce the

Oil For Food Programme (OFFP) on April 1995 which was 1st carried out on May 1997 as Memorandum Of Understanding (MOU). The effect of this memorandum was apparent in MICS 2 (2000), where all the indicators improved. Stunting is a chronic irreversible condition that needs time to get rid of sanction's effect. Besides, it is not related to childhood malnutrition only, it is greatly affected by maternal nutritional status too. MICS 3 (2006) reflected the change in regime and wealth

redistribution.

A peak in malnutrition indicators appeared in MICS 4 (2011). It might be due to financial crisis. A dramatic decline in malnutrition indicators was documented in MICS 6 (2018). Increase awareness about the importance of proper nutrition during pregnancy and early childhood, improved health services and easy access to health facilities, and availability of different food staff with different prices all aid in reduction of malnutrition indicators. This reduction reflects enhancement to good health.

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Assessment of Some Reproductive Hormones and Inflammatory Cytokine Levels in HIV Infected Females on Hormonal Contraceptives in Nnewi, Nigeria

Ifeoma N Monago[1], Nkiruka R Ukibe[2], Victoria O Agu[2], Chinedum C Onyenekwe[2], Ofia Anya Kalu[3], Solomon N Ukibe[4], Ezinne G Ukibe[3]

[1]Chief Medical Director, Medical Center, Federal Polytechnic, Oko, Anambra State, Nigeria, [2]Associate Professor, Post graduate, Senior Professor, Department of Medical Laboratory Science, Faculty of Health Sciences and Technology, Nnamdi Azikiwe University, Nnewi Campus, Anambra State, Nigeria. [3]Senior Lecturer, Medical Student, Department of Medicine, Faculty of Medicine, College of Health Sciences, Nnamdi Azikiwe University, Nnewi Campus, Anambra State, Nigeria, [4]Senior Lecturer, Department of Microbiology, Faculty of Medicine, College of Health Sciences, Nnamdi Azikiwe University, Nnewi Campus, Anambra State, Nigeria

Abstract

Objective: This was a case-controlled retrospective study aimed to assess the effect of hormonal contraceptives (progesterone based) on some reproductive hormones and cytokines in HIV infected females in Nnewi, Nigeria. **Materials and Methods:** A total of 118 premenopausal females on regular menstrual cycle aged (17-49) years were recruited based on their menstrual cycle phase (follicular (7-13th) and luteal (21-23rd day) with aid of questionnaire. 58 were HIV seropositive females [29 on hormonal contraceptive (A), 29 not on hormonal contraceptive (B)], while 60 were HIV seronegative females (controls) [30 on hormonal contraceptives (C) and 30 not on hormonal contraceptive (D)]. Reproductive hormones (FSH, LH, prolactin, progesterone, estradiol) and cytokines (TNF-α, IL-2) were assayed using enzyme-linked immunosorbent assay kits (ELISA). **Results:** TNF-α was significantly increased in HIV seropositive females on contraceptives compared with their counterparts not on contraceptives and controls on/not on contraceptives at both phases of menstrual cycle ($P= 0.000$). IL-2 was significantly decreased in HIV seropositive females on/not on contraceptive compared with control females not on contraceptive but significantly increased in HIV seropositive on contraceptive compared with their corresponding females not on contraceptive at follicular phase of menstrual cycle ($P=0.002$; 0.005 respectively). Progesterone and estradiol were significantly decreased in HIV seropositive females on contraceptives compared with their corresponding females not on contraceptives and controls on/not on contraceptives at both phases of menstrual cycle ($P = 0.000, 0.001$ respectively). **Conclusions:** The significant elevation in TNF-α and IL-2 in HIV infected females on contraceptives indicates active inflammation which was more marked at follicular phase of menstrual cycle. The significant decrease in ovarian hormones suggests hypogonardism and may be linked to exacerbated inflammatory reaction.

Key-words: HIV, contraceptives, fertility hormones, cytokines.

Corresponding author:
Nkiruka Rose Ukibe.
Email address: nr.ukibe@unizik.edu.ng

Introduction

HIV pandemic is a major public health challenge. It has a great impact on humans' life, especially women

and children. [1] This will pose a global threat to human existence if left unchecked. Contraceptive need of HIV infected females if fully met will reduce the global burden of mother-to-child HIV transmission and also prevent pregnancy. [2] However, hormonal contraceptives being a synthetic preparation alter the body physiology; this may interfere with the immune response to HIV virus such as the cytokines that are vital immunomodulators. [3] The effects of these immunomodulators on the reproductive system may subsequently affect the reproductive hormones that are essential for female fertility in the long term.

According to Stringer *et al.,*[3] hormonal contraceptives modulate the immune system in such a way that may affect the immune response to HIV infection. Research has shown that HIV impact negatively on women's reproductive health. [4,5,6] These negative impact ranges from menstrual disorders to outright infertility while some of the disorders result to deranged ovarian function with damaging effects on sex hormones. [6] However, much work has been done on cytokines and reproductive hormones changes in HIV. [6, 7] This work is designed to assess the effect of contraceptive use on some of the female reproductive hormones and cytokines in HIV infected females in Nnewi, southeast Nigeria.

Materials and Methods

Study Design

This research is a case-controlled, observational and retrospective study that assessed the effects of hormonal contraceptive use on some female reproductive hormones (FSH, LH, prolactin, estradiol and progesterone) and cytokines (IL-2 and TNF-alpha) levels in HIV infected females attending Nnamdi Azikiwe University Teaching Hospital Nnewi. The information on the contraceptive use was obtained through questionnaire. The sampling technique used for this research was the purposive sampling technique.

Study Area

The study was carried out at Nnamdi Azikiwe University Teaching Hospital Nnewi. The laboratory investigation was done in the chemical pathology laboratory department of the same hospital. The hospital is the major referral tertiary health facility, established in 1988 and is located in the heart of the commercial city of Nnewi.

Inclusion and exclusion criteria

HIV infected females on HAART aged 18-49 years on/not on hormonal contraceptive (HIV stage I and II) and age matched HIV seronegative females on/not on hormonal contraceptive were included in the study. HIV stage III and IV infected females; HIV co-infected with tuberculosis, Females with diabetes and hypertension, pregnant women and females below 18 years or above 49 years was excluded from the study.

Study population

A total of 118 premenopausal female participants (18-49yrs) were recruited for this study and they were divided into four groups as follows: **Group A:** HIV infected females on hormonal contraceptives (n=29), **Group B:** HIV infected females not on hormonal contraceptive (n=29), **Group C:** HIV seronegative females on hormonal contraceptive (Control 1) (n=30) and **Group D:** HIV seronegative females not on hormonal contraceptive (Control 2) (n=30). All the HIV infected females were on HAART for a minimum period of three years as at the time of sample collection and they were on fixed regimen as follows: Tenofovir/Lamivudine/Efavirenz (TenoLamE) (300/300/600mg) once daily, Tenofovir/Lamivudine/Dolutegravir (TenoLamD) (300/300/50mg) once daily, Lamuvudine/Zidovudine/Nevarapine (Combo pack) (150/300/200mg) twice daily, Abacavir/Lamuvudine (600/300mg) once daily plus a NNRTI, Atazanavir/Ritonavir (300/100mg) twice daily plus a NRTI or NNRTI, Lopinavir/Ritonavir (200/50mg) twice daily plus a NRTI or NNRTI. The Nucleoside Reverse Transcriptase Inhibitors (NRTI) include: Lamivudine, Abacavir and Tenofovir while the Non- Nucleoside Reverse Transcriptase Inhibitors (NNRTI) include: Efavirenz, Nevirapine and Dolutegravir. The Protease inhibitors include: lopinavir, ritonavir, atazanavir.

The participants on hormonal contraceptive has been on it for minimum of three years before sampling, the contraceptive used include; Depo-provera (medroxyprogestrone acetate) - an injectable hormonal contraceptive containing 150 mg of progesterone given once in three months, Jadelle an implantable hormonal contraceptive containing 150 mg of progesterone (levonorgestol) which once implanted last for a period of 5 years, Implanol an implantable hormonal contraceptives containing 68 mg of progesterone (etonogestrol) which once implanted last for a period of 3 years.

Ethical Consideration

The ethical approval for this work was sought and obtained from the ethics committee of Nnamdi Azikiwe University Teaching Hospital Nnewi (NAUTH) in accordance with Helsinki declaration by the World Medical Association (WMA) on the ethical principles for medical research involving human subjects. [8] Informed consent was also obtained from the participants before sampling.

Sample collection

Approximately 5 mls of venous blood was collected aseptically through venepuncture from the participants attending the adult antiretroviral clinic, family planning clinic and prevention of mother-to-child transmission clinic, as well as members of staff of Nnamdi Azikiwe University Teaching Hospital, Nnewi, at both follicular (9-13th day) and luteal (21-23rd day) phase of menstrual cycle on a follow-up. The blood samples were collected between 10.00am-1.00pm into a plain vacutainer tube and allowed to clot, thereafter it was spun for 5 minutes at 1500 revolution per minutes (rpm) using a bench centrifuge. The serum was separated for the analysis of reproductive hormones (progesterone, estradiol, prolactin, follicle stimulating hormone, and luteinizing hormone) and cytokines (IL-2 and TNF alpha) levels. The separated sera were preserved at -80ºc in the retroviral laboratory of Nnamdi Azikiwe University Teaching Hospital prior to assay.

Laboratory analysis

Determination of HIV-1/2 assays was done with Determine manufactured by Alere medical company limited, Japan by the method of Piot et al., [9] HIV-1/2 assay was also done using Stat Pak kit manufactured by Chembio diagnostic systems incorporated as described by Chembio, [10] while, HIV confirmation was done with Uni-Gold manufactured trinity Biotech Plc, Ireland using the method described by Klarkowski et al., [11]

Prolactin was assayed using ELISA method as described by Smith *et al.*, [12] FSH and LH were assayed using ELISA method as described by Baastal *et al.,* [13] while, Progesterone and estradiol were assayed using ELISA method as described by Edward *et al*., [14]

Tumor Necrotic Factor Alpha was assayed using ELISA method as described by Hedeyati *et al*., [15] and Interleukin-**2** by ELISA method as described by Malek *et al*., [16] All the test kits used were produced by Melsin Medical Company limited, Changchun China.

Anthropometric data collection

The blood pressure was obtained using mercury sphygmomanometer. The height (meter) was recorded with the use of a meter ruler and the weight (kg) was taken using a standard weighing scale. The body mass index (BMI) kg/m^2 was obtained using the formula; weight (kg)/height (m^2)

Statistical Analysis

Statistical package for social sciences (SPSS) version 21 was used for the statistical analysis. Student t-test was used to compare two independent variables while ANOVA was used to compare more than two independent variables and the post-hoc was done using Fishers least significance difference (LSD) for group comparison to assess significant mean difference. Pearson correlation was used to correlate the different parameters. Statistical significance between test group and controls was taken at $p<0.05$.

Results

Demographic characteristics

A total of 118 premenopausal female participants were recruited through questionnaire. 58 of the participants

were HIV infected (29 on hormonal contraceptive and 29 not on hormonal contraceptive), while 60 were HIV seronegative (30 on hormonal contraceptives and 30 not on hormonal contraceptives). The study population are predominantly traders 95 (80%), few civil servants 15 (13%) and students 8 (7%). The educational levels are as follows; No formal education 9(8%), primary education 18(15%), secondary education 61(52%) and tertiary education 30(25%) (Table 1).

Levels of TNF-α (pg/ml) and Interleukin-2 (ng/ml) in HIV infected females and control females on/not on hormonal contraceptives.

The mean serum TNF-α was significantly higher in HIV infected females on/not hormonal contraceptives (8.89±4.14, 3.07±0.61) and control females on hormonal contraceptive (2.32±0.78) compared with the control females not on hormonal contraceptives (1.30±0.63) at follicular phase of menstrual cycle (p=0.000 respectively). Similarly, The mean TNF-α was significantly higher in HIV infected females on/not on hormonal contraceptives (5.93±2.48, 3.82±1.22) and control females on hormonal contraceptive (6.76±9.20) compared with control females not on hormonal contraceptives (1.78±0.36) at luteal phase of menstrual cycle (p=0.032 respectively).

A significant increase in the mean serum TNF-α was observed at follicular phase of menstrual cycle in HIV infected females on hormonal contraceptives (8.89±4.14) compared with HIV infected females not on hormonal contraceptives (3. 07±0.61) and control females on/not hormonal contraceptives (2.32±0.78, 1.30±0.63) (p=0.000 respectively). At luteal phase of menstrual cycle, a significantly increase in mean serum TNF-α was observed in HIV infected females on contraceptives (5.93±2.48) and control females on hormonal contraceptives (6.76±9.20) when compared with control females not on hormonal contraceptive (1.78±0.36) (p=0.016, 0.013 respectively).

When the mean serum IL-2 at follicular phase of menstrual cycle was compared between test and control groups, the mean serum IL-2 was significantly lower in HIV infected females on/not hormonal contraceptives (0.38±0.24, 0.12±0.05) and control females on hormonal contraceptive (0.14±0.09) compared with control females not on hormonal contraceptives (0.80±0.08) (p=0.002 respectively). However, there was significant increase in mean serum IL-2 at follicular phase of menstrual cycle in HIV infected females on hormonal contraceptives (0.38±0.24) when compared with HIV infected females not on hormonal contraceptives (0.12±0.05) and control females on hormonal contraceptives (0.14±0.09) (p=0.002, 0.005 respectively). Contrastingly, significantly lower serum IL-2 was observed for HIV infected females on hormonal contraceptives (0.38±0.24) compared with control females not on hormonal contraceptive (0.80±0.08) (p=0.002) (Table 2).

Levels of LH (iu/ml), FSH (iu/ml), prolactin (ng/ml), progesterone (ng/ml), estradiol (pg/ml) in HIV infected females and control females on/not on contraceptive (mean ±std deviation).

A significantly higher mean serum FSH was observed in control females not on hormonal contraceptive at follicular (5.56±1.79) compared with luteal (2.63±0.84) phase of menstrual cycle (p=0.001).

However, a significant decrease was observed in mean serum progesterone value in control females not on contraceptive at follicular (6.02±0.87) compared with luteal (7.21±2.33) phase of menstrual cycle (p=0.002 respectively). When the mean serum progesterone values at follicular phase of menstrual cycle was compared between test and control groups, progesterone level was significantly lower in HIV infected females on hormonal contraceptives (4.73±1.75) compared with HIV infected females not on hormonal contraceptives (7.39±0.57) and control females on/not hormonal contraceptive (6.73±0.79, 6.02±0.87) (p=0.001 respectively). Similarly, at luteal phase of menstrual cycle, when the mean serum progesterone level was compared between test and control groups, the mean serum progesterone was significantly lower in HIV infected females on hormonal contraceptives (4.32±2.65) compared with HIV infected females who were not on hormonal contraceptives (7.42±0.93) and control females on/

not on hormonal contraceptive (7.10±4.09, 7.21±2.33) (p=0.000 respectively).

A significant decrease in the mean serum progesterone value was observed at follicular phase of menstrual cycle in HIV infected females on hormonal contraceptives (4.73±1.75) compared with HIV infected females not on hormonal contraceptives (7.39±0.57) and control females on/not on hormonal contraceptives (6.73±0.79, 6.02±0.87) (p=0.003, 0.027, 0.023 respectively). Similarly, at luteal phase of menstrual cycle, a significant decrease was observed in mean value of serum progesterone in HIV infected females on contraceptives (4.32±1.65) compared with control females on/not on hormonal contraceptive (7.42±0.93, 7.21±2.33) (p = 0.001, 0.000 respectively).

When the mean serum estradiol values at follicular phase of menstrual cycle was compared between test and control groups, the mean serum estradiol value was significantly lower in HIV infected females on hormonal contraceptives (33.19±7.68) compared with HIV infected females not on hormonal contraceptives (57.89±5.50), control females on/not on hormonal contraceptive (61.24±3.55, 62.69±4.67) (p=0.000 respectively). Similarly, at luteal phase of menstrual cycle, when the mean serum estradiol were compared between test and control groups, the mean estradiol value was significantly lower in HIV infected females on hormonal contraceptives (37.52±9.83) compared with HIV infected females not on hormonal contraceptives (58.60±4.86) and control females on/not on hormonal contraceptive (61.07±2.54, 66.06±4.08) (p=0.000 respectively).

There was significant decrease in mean serum estradiol value at follicular phase of menstrual cycle in HIV infected females on hormonal contraceptives (33.19±7.68) when compared with HIV infected females

not on hormonal contraceptives (57.89±5.50) and control females on/not on hormonal contraceptives (61.24±3.55, 62.69±4.67) (p=0.000 respectively). Similarly, at luteal phase of menstrual cycle, a significant decrease in mean serum estradiol value was observed in HIV infected females on contraceptives (37.52±9.83) compared with HIV infected females not on hormonal contraceptive (58.60±4.86) and control females on/not on hormonal contraceptives (61.07±2.54, 66.06±4.08) (p=0.000 respectively). Similarly, a significant decrease in mean serum estradiol level was observed in HIV infected females not on hormonal contraceptive (58.60±4.86) when compared with control females not on hormonal contraceptives (66.06±4.08) (p=0.049) (Table 3).

Correlation of BMI and blood pressure with female reproductive hormones and cytokines in HIV infected females and control females on/not on contraceptives.

Contraceptive use showed a strong positive correlation with age in HIV seronegative females on hormonal contraceptives (r=0.661, p=0.002).

Body mass index showed moderate negative correlation with estradiol in control females on hormonal contraceptives (r= -0.477, p=0.034).

Similarly, progesterone showed a moderate negative correlation with DBP in HIV infected females who were not on hormonal contraceptives (r= -0.435, p=0.030).

Similarly, SBP also showed moderate positive correlation with IL-2 (r=0.422, p=0.036), TNF-α (r=0.479, p=0.015) in HIV infected females on hormonal contraceptives and a strong negative correlation with IL-2 in HIV infected females who were not on hormonal contraceptive(r=-0.481, p=0.015) (Table 4).

Table 1: Levels of TNF α, and IL-2 in HIV infected females and control females on/not on hormonal contraceptive (mean ±std deviation)

Group	TNFa (pg/ml) Follicular	Luteal	P- value	IL-2 (ng/ml) Follicular	Luteal	P - value
A	8.89±4.14	5.93±2.48	0.963	0.38±0.24	0.23±0.10	0.145
B	3.07±0.61	3.82±1.22	0.125	0.12±0.05	0.17±0.07	0.096
C	2.32±0.78	6.76±9.20	0.225	0.14±0.09	0.76±1.31	0.234
D	1.30±0.63	1.78±0.36	0.100	0.80±0.08	0.14±0.05	0.107
F - value	14.518	2.239		6.301	2.429	
P - value	0.000	0.032		0.002	0.082	
A vs B	0.000	0.171		0.002	0.749	
A vs C	0.000	0.678		0.005	0.052	
A vs D	0.000	0.016		0.002	0.654	
B vs C	0.576	0.109		0.827	0.068	
B vs D	0.266	0.155		0.618	0.859	
C vs D	0.525	0.013		0.499	0.058	

Key: A = HIV infected females on hormonal contraceptive (n =29), B = HIV infected females not on hormonal contraceptive (n =29), C = HIV seronegative females on hormonal contraceptive (n =30), D = HIV seronegative females not on hormonal contraceptive (n =30).

Table 2: Levels of LH, FSH, Prolactin, progesterone, estradiol in HIV infected females and control females on/not on hormonal contraceptive (mean±std deviation)

Group	LH (iu/ml) follicular	luteal	p-value	FSH (iu/ml) follicular	luteal	p-value	Prolactin (ng/ml) Follicular	luteal	p-value	Progesterone(ng/ml) follicular	luteal	p-value	Estradiol (pg/ml) follicular	luteal	p-value
A	15.33±29.93	5.91±7.36	0.400	27.58±68.94	8.10±7.35	0.407	15.51±13.13	11.85±6.48	0.483	4.73±1.75	4.32±1.65	0.724	33.19±3.68	37.52±7.83	0.568
B	16.15±13.38	8.12±10.65	0.130	10.18±3.76	11.18±19.79	0.891	17.66±18.38	18.27±14.34	0.931	7.39±0.57	7.42±3.93	0.940	57.89±5.50	58.60±4.86	0.753
C	6.25±3.05	3.52±3.00	0.155	9.58±4.85	5.14±3.52	0.113	15.92±15.93	17.38±18.58	0.887	6.73±0.79	7.10±1.09	0.514	61.24±3.55	61.07±2.54	0.931
D	4.28±4.06	7.68±13.37	0.594	5.56±1.79	2.63±0.84	0.001	17.64±17.80	26.13±20.15	0.440	6.02±0.87	7.21±2.33	0.002	62.69±4.67	66.06±4.08	0.174
F-value	0.709	0.293		0.566	0.902		0.038	1.294		4.24	12.55		20.88	16.44	
p-value	0.555	0.830		0.643	0.450		0.990	0.292		0.001	0.000		0.000	0.000	
A vs B	0.928	0.628		0.340	0.597		0.780	0.352		0.003	0.000		0.000	0.000	
A vs C	0.343	0.687		0.342	0.696		0.958	0.537		0.027	0.001		0.000	0.000	
A vs D	0.300	0.720		0.297	0.388		0.811	0.061		0.023	0.000		0.000	0.000	
B vs C	0.325	0.394		0.976	0.382		0.836	0.912		0.468	0.664		0.475	0.598	
B vs D	0.285	0.917		0.831	0.122		0.998	0.224		0.709	0.179		0.353	0.049	
C vs D	0.861	0.466		0.857	0.730		0.857	0.311		0.779	0.160		0.782	0.317	

Key: A = HIV infected females on hormonal contraceptive (n =29), B = HIV infected females not on hormonal contraceptive (n =29), C = HIV seronegative females on hormonal contraceptive (n =30), D = HIV seronegative females not on hormonal contraceptive (n =30).

Table 3: Correlation of BMI and blood pressure with female reproductive hormones, cytokines and immunoglobulin in HIV infected and control females on/not on contraceptive

Parameters	HIV infected females on contraceptives (n=29)		HIVinfected females not on contraceptives (n=29)		HIV seronegative females on contraceptives (n=30)	
	r	p	r	p	r	p
Contraceptive use vs age	-	-	-	-	0.661	0.002
BMI vs estradiol	-	-	-	-	-0.477	0.034
DBP vs prog	-	-	-0.435	0.030	-	-
IL-2 vs SBP	0.422	0.036	-	-	-	-
TNFα vs SBP	0.479	0.015	0.481	0.015	-	-

Discussion

Since the introduction of HAART, the living conditions of HIV infected persons had greatly improved; including sexuality, with many HIV infected persons desiring to have their biological children which has also resulted to so many unintended pregnancies that need to be checked with contraception to reduce; the spread of HIV infection, birth of HIV infected children and other sexually transmitted diseases. Studies have shown that HIV infected females use hormonal contraceptives less frequently than HIV seronegative females despite their effectiveness and potential benefits. [17] In this study: the effects of hormonal contraceptive on some reproductive hormones, immunoglobulin and cytokines in HIV infected females in Nnewi, Nigeria were evaluated.

This study found no significant difference in the mean serum levels of FSH, LH, prolactin, progesterone and estradiol in HIV infected females on/not on hormonal contraceptives and control females on hormonal contraceptives at both follicular and luteal phases of menstrual cycle. This contrasts the observation of elevated level of FSH at follicular phase and progesterone at luteal phase of menstrual cycle in control females not on hormonal contraceptive. In apparently healthy females, the values of estrogen, FSH and LH are usually higher at the follicular and peak at mid follicular phase to enable ovulation. [18] On the other hand, progesterone predominates at the luteal phase in association with LH; estrogen similarly rose at the mid-luteal phase thus making progesterone, LH and estrogen the hormones of luteal phase in healthy females. The absence of this pattern in HIV infected females on/not on hormonal contraceptives and control females on hormonal contraceptives may cause changes in menstrual cycle which may likely affect reproductive functions in the affected females. In apparently healthy females, FSH together with LH stimulates follicular development and maturation. The stimulated follicle produces estrogen which causes the surge in LH that induces ovulation and subsequent priming of the slugged endometrium. Following ovulation, the empty follicle luteinizes and becomes an endocrine gland that produces progesterone with the aid of LH to prepare the endometrium for implantation and sustenance of pregnancy should pregnancy occur. Otherwise, the endometrium regresses and menstruation ensues. Therefore, significant reduction in estrogen at follicular phase may cause inadequate priming of the uterus and breast and this may affect implantation, lactation and menstruation. Similarly, significant reduction of progesterone at luteal phase may affect the sustenance of pregnancy which may lead to spontaneous abortion. While significant reduction in progesterone and estrogen (hypogonadism) may

cause significant disturbances in menstrual cycle with resultant fertility challenges in the affected females. The significant decrease in the serum level of progesterone and estrogen at both follicular and luteal phases of menstrual cycle observed in HIV infected females on hormonal contraceptives when compared with HIV infected females not on hormonal contraceptives, control females on/not on hormonal contraceptives indicates presence of hypogonadism in HIV infected individuals on hormonal contraceptives. The hypogonadal effect of HIV infection was further shown with significantly reduced level of estradiol in HIV infected females not on hormonal contraceptives compared with control females not on hormonal contraceptive at luteal phase of menstrual cycle. The observation of hypogonadism in HIV infection in this study is in agreement with the works of Ikechebelu *et al.,* [4] Fallahian *et al.,* [5] and Ukibe *et al.,* [6] The hypogonadism observed in HIV infected females on hormonal contraceptive may be as a result of the combined effect of HIV infection and hormonal contraceptive on the gonads. The hormonal variation induced by HIV infection and hormonal contraceptives use may explain the high incidence of menstrual irregularities associated with hormonal contraceptive use and increased infertility associated with HIV infection as previously documented.

Studies have shown that sex hormones play a vital role in immune regulation due to the presence its receptors on the immune cells and through these receptors it interacts with cytokines to cause cytokine release. Cytokines in turn determines proliferation, maturation and differentiation of various immune cells which may result to inflammation as observed in HIV infection and hormonal contraceptive use. [19] The hypogonadism observed in HIV infected females on hormonal contraceptive could be associated with the ovarian regulatory effect of cytokines as documented by Bornstein *et al.,* [20] and Lanchil *et al.,* [21] In HIV infection as with every systemic infection there are increased inflammation which are characterized by high levels of inflammatory cytokines (TNF) and low level of anti-inflammatory cytokines (IL-2) which inhibits ovarian function. [22, 23, 24] This cytokine changes were equally observed in this study. Similarly, hormonal

contraceptives are known immunomodulator [3, 25] hence the altered immune response and hypogonadism observed with hormonal contraceptive use in this study. The link between hypogonadism and inflammation documented by previous author [20, 21] could be related to increase levels of inflammatory marker (TNF) observed at both follicular and luteal phases of menstrual cycles in HIV infected females on hormonal contraceptives. This explains the pronounced effect of hormonal contraceptive and HIV infection on female reproductive system as observed in HIV infected females on hormonal contraceptives in this study. Several authors [6, 26] reported that HIV infection significantly affects ovarian function in women; others [27, 28] reported no significant effect on ovarian function. This study however found that hormonal contraceptive use in HIV infection produced significant effect on ovarian functions possibly through inflammatory process.

This research observed significantly increased level of TNF-α in HIV infected females individuals on/not on hormonal contraceptives and control females on hormonal contraceptive compared with control females not on hormonal contraceptive at both follicular and luteal phases of menstrual cycle. This showed higher degree of inflammation in HIV infected females and hormonal contraceptive users when compared with control females who were not on hormonal contraceptive. Excessive TNF-α has been linked with inflammation, other ailments and ovarian failure. [24, 29] The elevated level of TnF-α observed may account for the inflammation and hypogonadism in HIV infected females on hormonal contraceptives. Similarly, the increased level of TnF-α observed in hormonal contraceptive users may be implicated in the increased risk of cancers of the breast, cervix and ovary. [30] It is well documented that HIV infection is associated with over-expression of TNF at all stages of the infection with increased viral load and depletion of CD4+ T-cells. [6] Cytokines are implicated in ovarian development and atresia, ovulation, steroidogenesis as well as in the formation, development and regression of corpus luteum. Dysregulation of these cytokines causes reduction in ovarian function and cancer of the ovary. [23, 24, 30] Hence, the hypogonadism associated with elevated level

of TNF in HIV infected hormonal contraceptive users evidenced by low levels of estradiol and progesterone as observed in this study**.** Thus the elevated levels of TNF observed in HIV infected females and hormonal contraceptive users in this study may be responsible for the inflammation and hypogonadism associated with hormonal contraceptive use in HIV infection. Similarly, the elevated levels of TNF observed in control females on hormonal contraceptive compared with control females who were not on hormonal contraceptive at luteal phase of menstrual cycle suggest that hormonal contraceptive is associated with inflammatory reaction. This showed that the combined effects of hormonal contraceptive and HIV infection may be responsible for the pronounced increase in TNF observed in HIV infected females on hormonal contraceptive as well as the hypogonadism observed in this study group. The finding of elevated TNF-α in HIV infection from this study is in tandem with the work of Enrique *et al*, [31] and Ukibe *et al*., [6]

Hormonal contraceptives and ARDs interactions can significantly affect the potency of hormonal contraceptives and ARD in HIV infection. It is documented that hormonal contraceptives especially those containing progesterone selectively compromises antiviral activity of Tenofavir and Tenofavir-alafenamide [32] and this may suggests decrease ARD protection in hormonal contraceptive users. Similarly, Efavirenz and Nevirapine significantly reduce the effectiveness of progesterone containing contraceptive [17, 33, 34] thus resulting to contraceptive failures. The interaction of hormonal contraceptives with ARD may account for the pronounced inflammation observed in HIV infected females on hormonal contraceptives in this study.

This study observed significantly decreased levels of IL-2 in HIV infected females on/not on hormonal contraceptive and control females on hormonal contraceptive compared with control females not on hormonal contraceptive at follicular phase of menstrual cycle, these suggest a depressed immunity in HIV infection and hormonal contraceptive use at follicular phase of menstrual cycle in these study groups, this observation is in agreement with decreased IL-2 in HIV infection and hormonal contraceptive as recorded by

Stringer *et al.,* [3] The follicular phase of menstrual cycle (associated with high level of FSH, LH, estrogen and low level of progesterone) coincides with the period of egg development and menstrual bleeding. At this phase, there is less susceptibility to infection due to increased immune response attributed to estrogen that helps to protect the embryo should fertilization occur. However, the luteal phase is associated with depressed immunity and the reduced inflammatory response predisposes to increased susceptibility to infection and it coincides with the period of high level of progesterone in apparently healthy females, [35, 36] the suppressed immune response is vital to accommodate the fertilized embryo should conception occur. The cyclical changes of menstrual cycle caused by changing levels of female sex hormones such as estrogen and progesterone influence the female immune system thus predisposing to increased or reduced risk of infection at different phases of menstrual cycle. This pattern was not observed in HIV infected females on hormonal contraceptive, HIV infected females who were not on hormonal contraceptive and control females on hormonal contraceptive. These observations suggest that HIV infection and hormonal contraceptives alters the immune response to microorganism.

BMI showed moderate negative correlation with estradiol in control females on hormonal contraceptives. This indicates that with increasing BMI in hormonal contraceptive users there is high tendency to decreased level of gonadal (estradiol) hormone which suggest that prolonged contraceptive use associated with raised BMI may predispose the user of hormonal contraceptive to hypogonadism as reflected with the negative correlation in this study. BMI is used to measure body fitness and extreme BMI are associated with reproductive challenges such as anovulation, menstrual irregularities, PCOS, infertility etc. Therefore, raised BMI (obesity) disrupts the hypothalamic-pituitary gonadal axis thus affecting the reproductive health of females. Several studies have established that obesity has a direct link with infertility as manifested by low levels of gonadal hormones. [37, 38]

Studies have shown that cytokines can alter the hemodynamic parameters by binding to angiotensin II type 1 receptors thereby activating T-lymphocyte and

release of proinflammatory cytokine (such as TNF) which may provoke inflammatory response in the vasculature thus causing alterations in blood pressure which overtime may lead to cardiovascular diseases such as atherosclerosis. [39, 40] This study showed moderate negative correlation between DBP and progesterone. The relationship between progesterone and blood pressure is controversial. While some authors associate increase level of progesterone with high blood pressure. [41, 42, 43] Kristianson *et al.,* [43] reported that progesterone lowers blood pressure by binding to mineralocorticoid receptors thus inhibiting aldosterone activity with resultant natriuresis. However, in females with gain-of-function mineralocorticoid receptor mutation; progesterone increases blood pressure and this mutation may be responsible for the sudden death in young women on fourth generation hormonal contraceptive (drosperinone).

Hormonal contraceptive use showed strong positive correlated with age in control females on hormonal contraceptive. Age is an important risk factor for cardiovascular diseases, in healthy females at younger age; there is lower risk of CVD due to protective effect of estrogen but at menopause, the levels of estrogen falls which then predispose women to increased risk of cardiovascular diseases [44, 45] The observation in this study is similar to that in apparently healthy premenopausal females. As the duration of contraceptives increases with age the risk of CVD increases, this may be the reason why as the age of a woman advances an alternate choice of contraceptives are considered.

Conclusion

The decreased level of ovarian hormones (estradiol and progesterone) observed at both phases of menstrual cycle suggests hypogonadism while the changes in the inflammatory markers may result to active inflammation and suppressed immunity. The profound inflammatory impact observed may possibly be due to combined effects of hormonal contraceptives and HIV infection. HIV infected females on hormonal contraceptives should therefore, be closely monitored for inflammation and reproductive changes through routine screening and reproductive education irrespective of contraceptive

use. The drug interaction between ARD and hormonal contraceptive should be critically examined before placing a patient on a particular contraception method.

Conflict of Interests: The authors declare no conflict of interest

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The Role of Il6 in Spontaneous Preterm Labour

Intisar Younis Mohammed Ibrahim

High Diploma in Gynecology and Obestetric /College of Medicin/Univircity of Baghdad M.B.Ch.B. D.G.O Mosul General Hospital

Abstract

Objective: Preterm birth (PTB) and Preterm labour (PTL) (PTL is defined as 'regular uterine contractions, which result in cervical changes before 37 Week of pregnancy. The main cause of neonatal morbidity and mortality with 5-18% of pregnancies was the preterm labour. Interleukin-6 (IL-6) amniotic fluid is an important cytokine used to identify intra-amniotic inflammation and those at risk to imminent premature delivery in patients with elevated AF IL-6. However, results of the traditional measurement method (ELISA) are generally unavailable in time in order to inform care. The aim of this study was to establish if intra-amniotic inflammation and/or infectious patients and those intended to spontaneous pre-term delivery among women with preterm labour and intact membranes can be identified through a point of care (POC) test or lateral-flowimmunoassay for AF IL-6 concentration measurement.

Methods: In this study, one hundred and thirty-six singleton pregnant women who had symptoms of premature labor and amniocentesis were included. At the time of diagnosis, amniocentesis was carried out. In this study, the determination of AF (white blood cells, gram stain) was happened. By the results of AF culture, microbial invasion of the amniotic cavity (MIAC) was defined. Enzyme Linked Immunosorbent Assay (ELISA) and the lateral flow based immunoassay used to determine AF IL-6 concentrations. Define AF ELISA IL-6 as $\geq$ 2600 pg/ml as the primary result for intra- amniotic inflammation

Results: (1) The concentrations of AF IL-6 has been determined by a POC test with a specificity (91%), sensitivity (93%) and a positive likelihood ratio (10) where Intraamniotic inflammation identified with the threshold of 740 pg/ml; (2) The POC test and IL-6's ELISA are also used to identify patients at risk of acute placenta inflammation, MIAC and impending spontaneous preterm delivery.

Conclusion: Intra-amniotic inflammation in women who present subsequently with spontaneous delivery before 34 week of gestation or those who will present with preterm and intact membranes can be identified by POC AF IL-6 test. It can be achieved within 20 minutes – this has important clinical implications and opens up opportunities for early diagnosis and treatment of intra-amniotic infection / inflammation.

Keywords: *Interleukin-6, Preterm birth, Preterm labor, Neonatal mortality, Inflammation.*

Introduction

The leading cause of neonatal morbidity and mortality [2] can be considered preterm birth which affects on 5 – 18 % of pregnancies [1]. In the women who deliver preterm, one in four of them infected with an intraamniotic infection that is largely subclinical [3,4]. Inflammatory processes (that mediated Microbial associated preterm labour) involving production of cytokines such as interleukin IL-6 [5,6], IL-1 [7], IL-10 [8], matrix degrading enzymes [9], chemokines [6], tumor necrosis factor-alpha (TNF-α) [6,10] and other inflammatory-related proteins activate common parturition pathway [1]. Multiple studies showed that IL-6 amniotic fluid (AF) is superior to AF (glucose, Gram stain, white blood cell (WBC) counts) , or equal to proteomic markers for identification of the amniotic cavity intraamniotic and amniotic microbial invasions

(MIAC) [11]. In addition, the elevated concentrations of AF IL-6 , even if the amniotic cavity absence the demonstrable microorganisms, is associated with an increase risk of neonatal outcomes and adverse pregnancy in the context of preterm prelabor rupture of the membranes (preterm PROM) [12], preterm labor [13] and a short cervix [14]. The concentrations of AF IL-6 therefore have both diagnostic and prognostic value.

The determination of AF IL-6 concentrations takes usually hours and results often cannot be made available on time in order to inform clinical decisions. In adult and neonatal sepsis [15] as well as in other inflammation-related conditions [16] , there was widely used a POC (lateral flow- based immunoassay) test. Recently, these tests were applied in obstetrical applications. In the pilot study our group has found that AF IL-6 levels determined through POC tests correlated strongly with those measured through conventional immunosorbent (ELISA) (Spearman's $\rho = 0.92$) [17]. In addition, our group has shown strong correlations. In addition, the POC IL-6 test results may identify preterm PROM patients intended for preterm delivery and/or acute histological chorioamnionitis [18].

In the present study determined by a POC test, we investigate whether AF IL-6 concentrations are able to identify patients (with intact membranes and preterm labour) who deliver spontaneously before term and/ or have intraamniotic infection and or inflammations, relative to the concentrations performance determined by conventional ELISA.

Materials and Methods

Study populations

A retrospective cohort study used to identify patients with intact membranes with a diagnosis of spontaneous preterm labor. If the following criteria were met, the patients could be included: (1) microbiological studies conducted for 20 to 35 weeks of transabdominal amniocentesis (2); available AF for microbiological research performance (3) singleton gestation; and (4) neonatal results known. Patients who had a fetus with structural or chromosomal abnormality or they had

placenta previa, were excluded. Patients diagnosed with preterm labor associated with intact membranes, were told by their treating doctors about the potential value of microorganisms for AF identification. For research reasons outside of the clinical studies, women who agreed to undergo an amniocentesis were asked to donate AF. The doctor in charge of the further treatment of these patients. All patients received informed consent in writing and the use of clinical data and biological specimens were approved.

Samples and biological analyzes

To the clinical laboratory for genital mycoplasma and (anaerobic, aerobic bacteria) and in a syringe with a capped sterile, AF was transported. The centrifuge of AF, that is not required for clinical assessment, was for 15 min at 4 °C and stored at −75 °C until analysis. The assessment was also carried out soon after gram stain, glucose, WBC count and AF were collected. To know if there is intraamniotic inflammations and /or infection, the concentrations of AF IL-6 needed and by ELISA was determined.

Clinical definitions

Preterm labor was diagnosed in patients with cervical changes involving at least two regular uterine contractions every 10 minutes, related to gestational age from 20 to 36 6/7 weeks. Acute histologic chorioamnionitis was diagnosed with the above criteria [19]. Funisitis was diagnosed by the use of previously reported criterion for infiltration by neutrophils in walls of the umbilicus or Wharton jelly [20]. When the AF IL-6 concentration was ≥2600 pg/ml (≥2.6 ng/ml), that determine by ELISA, Intra-amniotic inflammation has been diagnosed [21]. Based on the results of AF culture, MIAC was defined. The combination of intra-amniotic inflammation and MIAC was defined as intra-amniotic infection.

IL-6 concentrations and analyzing it by AF samples

In the case of AF IL-6 concentrations (pg/ml), the Enzyme Linked Immunosorbent Assay and lateral immuno-assay POC tests were both determined. The immunoassays from R&D Systems for ELISA

have been used to determine AF IL-6 concentrations (Minneapolis, MN). A lateral flow- based immunoassay test POC was used to determine AF IL-6 concentrations (pg/ml). ELISA [6,11]and POC immunoassay details and performance have been described previously [17]. For IL-6 POC tests, the intra-assay variation coefficients and inter are 12.1% and 15.5% respectively.

Study outcomes

The main results of this study are intra-amniotic inflammation and positive AF culture. While Spontaneous preterm (24 hour, 48 hour and 7days admission), acute inflammatory placental lesions (acute histologic chorioamnionitis and / or acute funisitis) with spontaneous preterm delivery (<28 week and <34 week of gestation) are considered the secondary results. The relation between acute chorioamnionitis histologically and amniotic fluid IL-6 concentrations were examined in 60 patients administered three days after amniocentesis. In this interval, a significant temporal relation between placental pathology and the amniocentesis results has been maintained.

Statistical Analysis

In order to evaluate normality in arithmetic data distributions, the Kolmogorov–Smirnov test used. Kruskal–Wallis and Mann–Whitney U tests were performed to compare the groups of arithmetic variables. Chi-square or Fisher's exact test was used for comparisons of the categorical variable. SPSS 19 (IBM Corp., Armonk, NY) and SAS 9.4 were used for statistical analysis (Cary, NC). Statistically significant was a p value <0.05.

Results

Characteristics of study populations

In this study, 136 women have been included with preterm labour with intact membranes. In Table 1, The clinical features are listed. The prevalence was nearly 16% (23/136) for MIAC and nearly 44% (60/136) for intra-amniotic inflammation. Spontaneous preterm deliveries were reported in most participants, nearly 22.7% (31/136) for < 28 weeks, 54.1% (74/136) for < 34 weeks and 64.2% (87/136) for < 37 weeks. In 24 hr, 48 hr, and 7 days, spontaneous delivery ratesranged between 33.7% (46/136), 43.5% (59/136) and 47.7% (65/136) respectively. In amniocentesis, the median gestational age was 30.8 weeks (27–32.4). 57.2% (31/54) of the 54 women with an acute histological chorioamnionitis and a large number of funisitis were diagnosed within 3 days after amniocentesis and placenta pathology reports [67.8% (21/31)].

Table 1. ' Study populations' clinical features or characteristics

Table 1. Clinical characteristics of the study population.

Characteristic	Median (interquartile range) or percent ($n = 136$)
Maternal age (years)	24 (20–29)
Nulliparity	33.8% (46/136)
Prior preterm delivery	37.5% (51/136)
Gestational age at amniocentesis (weeks)	30.9 (27–32.4)
Amniotic fluid glucose (mg/dl)	24 (17–30.8)
Amniotic fluid white blood cell (cell/m^3)	1.5 (0–13)
Microbial invasion of the amniotic cavity (%)	16.2% (22/136)
Intra-amniotic inflammation (ELISA IL-6 $\geq$ 2600 pg/ml) (%)	44.1% (60/136)
Gestational age at delivery (weeks)	33.3 (28.2–36.9)
Interval from amniocentesis to delivery (d)	8 (1–36.8)
Spontaneous deliver within one day after amniocentesis (%)	33.8% (46/136)
Spontaneous deliver within two days after amniocentesis (%)	43.4% (59/136)
Spontaneous deliver within seven days after amniocentesis (%)	47.8% (65/136)
Spontaneous delivery at <28 weeks of gestation (%)	22.8% (31/136)
Spontaneous delivery at <34 weeks of gestation (%)	54.4% (74/136)
Spontaneous delivery at <37 weeks of gestation (%)	64% (87/136)
Acute histologic chorioamnionitis (%)*	57.4% (31/54)
Acute funisitis (%)*	38.9% (21/54)
Acute inflammatory lesions of placenta (%)*	57.4% (31/54)

The data presented as % (*n*) or median. Inflammatory lesions of placenta acutely include acute chorioamnionitis histologically and acute funisitis which included only patients who had intervalfrom amniocentesis to delivery < 4 d (n= 58).

In Table 2, the microorganisms identified by culture AF, gestational aging at delivery, IL-6 levels (by ELISA and POC), inflammatory AF and placental lesion type or absence of acute inflammation in MIAC women are listed. Ureaplasma urealyticum, which was found in 18 percent (4/22) of these women, was the most often identified microorganism.

Table 2. Inpatients with microbe invasion of the cavity using cultivation techniques, clinical characteristics, inflammatory amniotic fluid response, and acute placental inflammatory lesions.

Table 2. Clinical characteristics, amniotic fluid inflammatory response and acute inflammatory placental lesions in patients with microbial invasion of the amniotic cavity using cultivation techniques.

No.	Organisms	GA at delivery (weeks)	AF glucose (mg/dl)	AF WBC (cell/mm^3)	ELISA IL-6 (pg/ml)	Point of care IL-6 (pg/ml)	Acute histological chorioamnionitis	Acute funisitis
1.	*Prevotella* spp., *Enterococcus faecalis*	25^{+1}	10	1	52 637	3208	No	No
2.	*Mycoplasma hominis*	33	1	420	172 301	4613	N/A	N/A
3.	*Ureaplasma urealyticum*	28^{+6}	13	180	9433	10 000	Acute chorioamnionitis	No
4.	*Candida albicans*	26^{+3}	10	2160	201 261	4448	Necrotizing chorioamnionitis	No
5.	*Streptococcus agalactiae*	25	10	4	93 638	3575	Necrotizing chorioamnionitis	No
6.	*Candida albicans*, *Lactobacillus* spp.	33^{+1}	10	43	200 626	3554	Acute subchorionitis	No
7.	*Haemophilus influenza*	30^{+6}	10	40	92 063	6467	Necrotizing chorioamnionitis	Necrotizing funisitis
8.	*Fusobacterium* spp., Gram-negative bacilli	21^{+6}	19	1564	317 655	6228	Subchorionic microabscesses	Necrotizing funisitis
9.	Gram-negative bacilli	21^{+1}	20	66	242 699	5934	Subacute chorioamnionitis	Umbilical arteritis
10.	*Streptococcus agalactiae*	25^{+2}	19	5	248 889	8208	Acute chorioamnionitis	Umbilical arteritis
11.	Gram-positive cocci	22^{+5}	10	125	470 626	5540	Necrotizing chorioamnionitis	Umbilical arteritis
12.	*Fusobacterium* spp., Gram-negative bacilli	28^{+1}	1	22	301 426	3996	Acute chorioamnionitis	Umbilical arteritis
13.	*Ureaplasma urealyticum*	33	10	500	85 962	4628	Acute chorioamnionitis	Umbilical phlebitis/chorionic vasculitis
14.	*Streptococcus anginosus*, *Streptococcus mitis*	22^{+6}	10	10	73 254	7246	Acute chorioamnionitis	Umbilical phlebitis/chorionic vasculitis
15.	*Bacteroides* spp., *Mobiluncus* spp., *Clostridium sporogenes*	22^{+4}	10	295	517 846	4748	Necrotizing chorioamnionitis	Umbilical phlebitis/chorionic vasculitis
16.	*Ureaplasma urealyticum*	39^{+2}	19	2	1274	155	No	No
17.	Gram-negative bacilli	26^{+5}	N/A	610	1779	10 000	N/A	N/A
18.	*Streptococcus* spp., *Gemella morbillorum*	31^{+6}	10	1920	741	6796	Necrotizing chorioamnionitis	Umbilical arteritis
19.	*Candida albicans*	32^{+4}	10	1292	96 334	4252	Acute chorioamnionitis	Necrotizing funisitis
20.	*Staphylococcus capitis*	28^{+6}	20	24	360 503	4374	Subacute chorioamnionitis	Umbilical arteritis
21.	*Mobiluncus* spp.	32	10	570	76 888	8144	Acute chorioamnionitis	Umbilical phlebitis/chorionic vasculitis
22.	*Ureaplasma urealyticum*	34^{+3}	24	0	244	60	Acute subchorionitis	No

N/A: results were not available: WBC, white blood cell count; AF, amniotic fluid: acute subchorionitis/chorionitis = acute histologic chorioamnionitis stage 1; acute chorioamnionitis = acute histologic chorioamnionitis stage 2; necrotizing chorioamnionitis and subacute chorioamnionitis = acute histologic chorioamnionitis stage 3: subchorionic microabscesses = severe acute histologic chorioamnionitis; umbilical phlebitis/chorionic vasculitis = acute funisitisstage 1; umbilical arteritis = acute funisitis stage two; necrotizing funisitis = stage three acute funisitis.
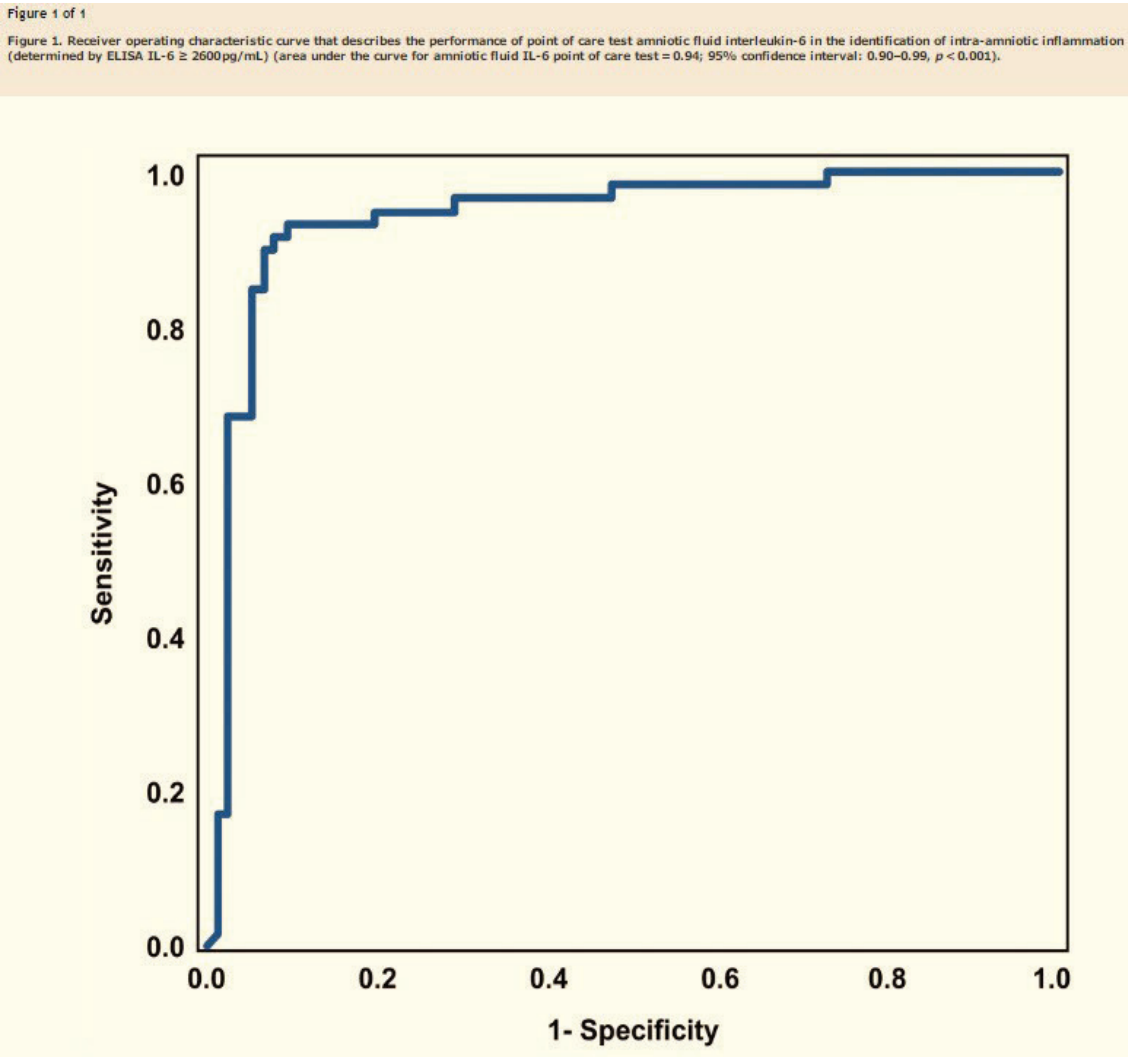
Figure 1. Characteristic curve of the operating receiver describes the performance of an amniotic Fluid Interleukin-6 test in intra-amniotic inflammation identification (the area under curve for amniotic fluid IL-6 point = 0.93; 96% confidence interval: 0.91–0.98, P < 0.002).

The diagnosis of an AF IL-6 POC test to identify the inflammation of the intraamniotic A threshold of = 745 pg/ml was selected for the POC test after inspecting a recipient operational characteristic curve to identify an intraamniotic inflammation [zone of curve = 0.94 (0.90–0.99)]. (Figure 1). The POC test was given a sensitivity of 93% and a specialty of 91% in Table 3 lists.

The diagnostic performance of an AF IL-6 POC test for the identification of MIAC and acute inflammatory lesions of placenta

Table 3 shows that the POC test performance was equivalent to conventional ELISA when identifying MIAC and placental lesion patients in line with acute inflammation. 18.2% (4/22) of MIAC patients showed negative results for ELISA IL-6 (Table 2). In two of these four patients, however, the POC AF IL-6 was raised. One of those patients with acute histological chorioamnionitis and funisitis implies a real intraamniotic infection. A placental pathology report was not provided to the other patient. Note, the potential for a contamination is suggested by one of two patients who had AF IL-6 negatives in both trials (POC and ELISA) delivered at the term of the trial and had not placental lesions consistent with acute inflammation.

The identification of preterm delivery The AF IL-6 POC test

In **Table 3**, the tests for women spontaneously deliveries are presented with Point of care test and Enzyme Linked Immunosorbent Assay AF IL-6. Table 2. Both tests had positive probability equivalents in identifying patients who had spontaneous preterm delivery within one of the days of amniocentesis or patients who spontaneously delivered after a gestation of less than 28 weeks. Each one had marginally a greater sensitivity and specificity than ELISA for the POC test in determining women who would spontaneously deliver within two or seven days of amniocentesis. In comparison with ELISA's results the sensitivity for spontaneous preterm delivery was slightly higher at less than 34 weeks of gestation, while the specificity was slightly less. However, confidence intervals in the assessment of the diagnostic performance of the POC test have overlapped the ELISA test, statistic equivalent performance in the assessment of the risk of spontaneous premature delivery.

Discussion

The main findings from the study: (1) The POC-determined AF-IL-6 concentrations are highly sensitive (93%) and are specific (91%) to identify intra-amniotic inflammation with a 745 pg/mL threshold and (2) IL-6 determination by POC test and ELISA was performed similarly in patients identifications with acute inflammatory lesions of placenta, MIAC and the patient with intact membrane and preterm labour at risk of spontaneous preterm delivery.

AF IL-6 POC test for intra-amniotic inflammation identification and imminent preterm delivery Preterm labor and other adverse effects are at greater risk of intraamniotic inflammation, as demonstrated by compelling evidence without identifiable microorganisms [13]. In patients with preterm labor and intact membranes, sterile intra-amniotic inflammation, an inflammatory process in which neither culture nor molecular methodology can be observed, has previously been demonstrated to be more prevalent than intra-amniotic, microbial inflammation. [22], Preterm PROM and asymptomatic sonographic short cervix [14]. We have also shown that sterile inflammation intraamniotic is connected to unhealthy pregnancy; hence intraamniotic inflammation is important [22, 14].

In this study, we have shown that the point of care AF IL-6 test is highly sensitive and specific to identify spontaneous premature delivery and intraamniotic inflammations. The results of the POC test are compared with AF IL-6 concentrations determined by ELISA in the identification of infection-inflammation-related obstetric outcomes, but they could be determined within 20 minutes. Therefore, contrary to conventional ELISA, the POC AF IL-6 results can be available on time for clinical decisions, similarly to an MMP 8 rapid matrix test which has demonstrated that patients with preterm labor and intact membranes with >80 percent susceptibility and >90 percent specificity have an intraamniotic infection or inflammation [23]. In addition, the MMP-8 test has been shown to be useful in identifying intra-amniotic inflammation in preterm PROM, MIAC in preterm delivery risk patients, and funisitis in preterm delivery patients.

Interestingly, six out of seven patients with POC and ELISA negative results had spontaneous early (<34 weeks) preterm delivery within a period of two days after amniocentesis. This suggests that the POC test provides additional risk information beyond the standard ELISA tests. It should also be noted that two out of four POC negative and ELISA positive which at term delivered, one of whom did not have acute inflammation with placental lesions and the result was positive (2609 pg/ml). In the previous study, we showed that the concentrations of AF IL-6 that determined by POC test were 30 percent less on average than those established by conventional ELISA. Therefore, it is no surprise that the POC selected the lower AF IL-6 cut-off for intra amniotic

inflammation (THI) patients (THI 745 pg/ml) in this study). Kacerovsky and others suggested a higher reduction (1000 pg/ml) to detect MIAC in a study that used the same test for AF IL 6 levels among preterm MIAC women or the combination of MIAC with acute histological chorioamnionitis. Other POC test researchers reported a high negativity of IL-6 detection predictive value in vaginal fluid in women with preterm PROM, comparable to that found in our study (97.6 percent versus

94.4 percent) [23]. However, our study showed more positive predictive value than the concentration of IL-6 vaginal fluid POC test (88.9 percent versus 50 percent). Using POC IL-6 in vaginal fluid for pregnancy results has been reported by Vousden et al. in asymptomatic high risk patients with preterm birth [18]. A cut off of 56 pg/ml had 81 percent sensitivity and 65 percent specificity for the vaginal fluid IL-6 concentration for identifying people who were given under 28 weeks of gestation [18]. The diagnostic performances in this study are somewhat lower than POC AF IL-6. In line with the risk/benefit ratios for specific actions, the optimal cutoff value is to be determined.

Strengths and Limitations

The study strengths include: - (1) Test POC for the purpose of informing treatment was not used and (2) including a group of patients with preterm labour with intact membrane instead of patient with preterm prelabour rupture of membranes who have high prevalence of infection and/or inflammation. One constraint is the use of cultivation techniques to identify amniotic cavity microorganisms, therefore, it may not be possible to detect non-cultural bacteria that could have been identified using molecular microbiological techniques.

Conclusions

Intra-amniotic inflammation can be identified by a POC AF IL-6 test as determined by ELISA in women with premature labour and intact membranes and also by equivalently identifying thosewho deliver spontaneously before the term subsequent to this test. Further studies are necessary to determine whether the results of POC AF IL-6 inform sufficient therapeutic decisions to improve pregnancy results in patients of this type.

Conflict of Interest: There is no conflict of interest among the authors.

Funding: Self

Ethical Clearance: This study is ethically approved by the Institutional ethical Committee.

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Mother's Health Seeking Behavior During Childhood illness in Northeast India: Findings of National Family Health Survey 4 (2015-16)

Jatin Phukan[1], Bipin Gogoi[2]

[1]Ph.D. Scholar, [2]Professor, Department of Statistics, Dibrugarh University, Assam, India

Abstract

The latest National Family Health Survey (NFHS-4) report reflects the current health condition of the country and its states as well as.Based on these findings this review carried out to highlight the mother's health seeking behaviours during childhood illness for the North-eastern states of India along with existing health programs catering to maternal and child health.Overall 60 percent of the children aged under five (U-5) were received any advice or treatment for Acute Respiratory Infection (ARI) from a health provider in Northeast India. Nearly 20 percent of the children with fever were given antibiotic drug and only 1 percent of them were given antimalarial drug. Meghalaya is the only North-eastern state were the maximum incidence (12%) of diarrhoea has been observed while least was seen in Sikkim (2%). The lack of basic amenities is directly or indirectly responsible for the high burden of childhood morbidities in this region. Also, poor and unequal distribution of maternal health seeking behaviours for their children were observed to all the North-eastern states of India. A huge proportion of children are still lagging behind from the adequate advices or treatments due to various reasons like, poor quality of care and the lake of government health facility in the area, health personnel were often absent from government health facilities and the major problem was the distance to a health facility specially in rural areas.

Key-words: *Children U-5, Childhood illness, Health programs, Northeast India.*

Introduction

Despite the economic success over the last two decades, India failed to achieve its millennium development goal targets for child mortality[1]. Globally, one in five deaths in children under the age of 5 yearsoccurs in India[2]. Preschool child population constitute approximately 15 percent of the county's total population and are the most vulnerable group suffers from highest morbidity[3]. Most of the Indian children are affected by various common and easily preventable illness. Infectious diseases like ARI, fever, diarrhoea, malaria and whooping cough have been found to be the leading cause of morbidity and premature death especially in developing countries[4-5].It has been estimated thatthe mortality among children are mostly caused by respiratory infections 6.9%, malaria fever 2.2% and other childhood illness 2.0%[6]. Thus, this

review has been made to highlight the mother's health seeking behaviours during childhood illness base on the current National Family Health Survey (NFHS) report in North-eastern states of India along with existing health programs that catering to maternal and child health. This region comprises eight small states, namely, Assam, Arunachal Pradesh, Manipur, Meghalaya, Mizoram, Nagaland, Sikkim and Tripura. The latest NFHS report shows a little variation across states in all the indicators. While some of the states performing well in some of the indicators, a couple of states show completely deteriorated picture.

Material and Methods

Analysis of data in this study is based on 37,167 Northeastern children included in the fourth round of National Family Health Survey (NFHS-4) conducted during 2015-16. This study considered only children

aged 0-59 months (U-5) and the three basic parameters of childhood illness included, namely acute respiratory infection (ARI), fever and diarrhoea which are collected from a representative sample of 98,702 eligible women aged 15-49 years form 89,992 households in Northeast India.The fourth round of NFHS data[7] has recently released by the government of India after a decade in the previous one in the year 2005-06 (NFHS-3)[8], which was conducted during 2015-16. The survey provides crucial information on reproductive and child health, including socio-economic characteristics of the usual members of household, fertility, family planning, water and sanitation, health insurance, certain non-communicable diseases (NCO), and many other topics. For the first time, in NFHS-4, all 640 districts in the country were covered by adopting a modular approach to arrive at estimates of crucial indicators at the district and state levels and also address the key healthcare challenges facing by the districts and the states.

The NFHS provides a separate section for the common childhood illness where discussed prevalence and treatment of acute respiratory infection, fever, and diarrhoea. Mothers of children born during the five years preceding the survey were asked if their children had suffered from cough, fever, or diarrhoea during the two weeks preceding the survey, and if so, the type of treatment given. Accuracy of all these measures is affected by the reliability of the mother's recall of when the disease episode occurred. But two-week recall period is ideally most suitable for ensuring that there will be an adequate number of cases to analyse and that recall errors will not be too serious.

Graphical representation is used to show the prevalence of childhood illness among the North-eastern children aged U-5.

Findings

Acute Respiratory Infection (ARI)

ARI is one of the leading causes of childhood morbidity and mortality throughout the world[9-10]. Early diagnosis and treatment with antibiotics can prevent a large proportion of deaths caused by ARI. In NFHS-3,

the prevalence of ARI was estimated by asking mothers whether their children under age five years had been ill with a cough accompanied by short, rapid breathing which was chest related in the two weeks preceding the survey. These symptoms are included with ARI which are same for NFHS-4.During last one decade**,** the prevalence of ARI decreased nearly 50% from the level of 5.8% in NFHS-3 (2005-06) to 2.7% in NFHS-4(2015-16) at national level but it was slightly high in Northeast India (3%) (Figure 1). Meghalaya is the only North-eastern state where the prevalence of ARI has increased more than three times (5.8) in NFHS-4 as compared to NFHS-3 (1.9). While lowest prevalence was observed in Sikkim (0.3%) followed by Assam (1%). The percentages of children who received some advice or treatment from a health provider were comparative low in all the North-eastern states of India than the national average (78%) except Sikkim (100%). Only one third of the children aged U-5 in Nagaland received some advice or treatment from a health provider and half of the children in Arunachal Pradesh (51%) and Manipur (46%) are not received any treatment for ARI from a health provider. Form these statistics it is clear evidence that – still, the healthcare facilities are not utilizedby many population in Northeast India.

The ARI Control Programme was started in India during 1990. Since then, various community-based interventions are implemented under ARI control program. Identification of severe respiratory infections by health care worker from rural area, wide access to antibiotics, and its administration by health care workers can prevent and control the burden of ARI. While acute upper respiratory tract infections are very frequent in children, pneumonia is the leading cause of under-five mortality. For children with non-severe pneumonia the ARI control program recommends oral Cotrimoxazole as the first line drug. A number of previous study has revealed that the assessment of various interventions against ARI like breast feeding, zinc prophylaxis, access to clean fuel for cooking, and community/facility-based case management has high impact to combat the burden of ARI[11].

Fever

Fever is a major manifestation of malaria and other acute infections in children. Malaria and fever contribute to high levels of malnutrition and mortality among children in India [8]. In NFHS-3, mothers were asked whether the child took any medicine at any time when ill with fever, and if yes, to give the name of the drug. Overall, the prevalence of children suffered from fever were decreased only one percent from 14% in NFHS-3 to 13% in NFHS-4 at national level. Though, prevalence of childhood fever is low in North-eastern region (10%) (Figure 1) as compared to national level but there exists an unequal distribution among the North-eastern states of India. For instance, nearly one fourth of the children

(23.3%) in Meghalaya had fever in two weeks before the survey while in Sikkim it was only 4 percent followed by Nagaland (7.1%) Manipur (8.2%) and Assam (9%). Twenty percent of children aged who were ill with fever were given antibiotic drugs in NE India during 2015-16 where it was highest in Mizoram (55%) and lowest in Assam (15%) even below at the national average (21%). Almost all of the children in Manipur, Meghalaya and Tripura who were ill with fever are likely to be received advice or treatment from a health provider but half of the children in Arunachal Pradesh (54%) were not received any advice or treatment from a health provider when they were ill with fever. Other hand, nearly 20 percent of the children with fever were given antibiotic drug and only 1 percent of them were given antimalarial drug in Northeast India during 2015-16.
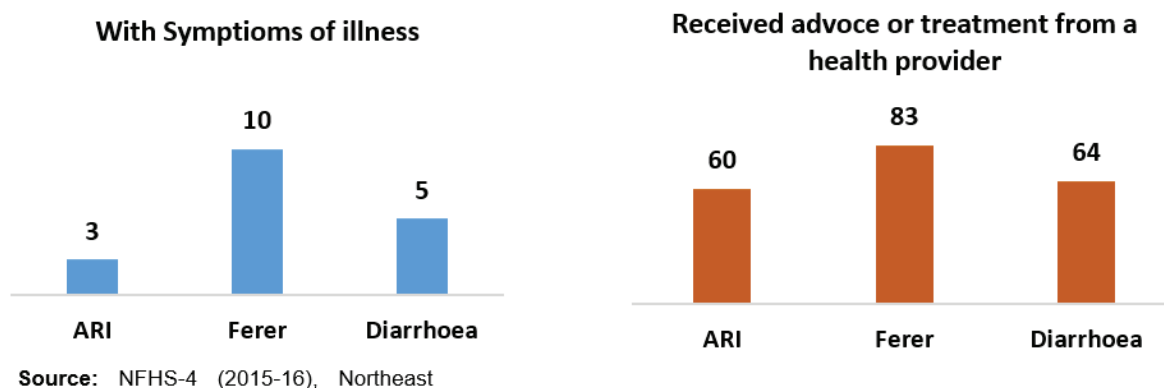
Figure 1: Percentage distribution of children aged U-5 with symptoms of illness (ARI, Fever and Diarrhoea) in two weeks before the survey and percentage of children who were received advice or treatment form a health provider, Northeast India, 2015-16.

Diarrhoea

Diarrhoea is one of the single most common causes of death among children, following acute respiratory infection. Deaths from acute diarrhoea are most often caused by dehydration due to loss of water and electrolytes. Nearly all dehydration-related deaths can be prevented by prompting administration of rehydration solutions. NFHS asked a series of questions to eligible mothers about episodes of diarrhoea suffered by their children in two weeks before the survey, including questions on feeding practices during diarrhoea, the

treatment of diarrhoea, and their knowledge and use of ORS. The incidence of diarrhoea remain the same (9%) between NFHS-3 and NFHS-4 in India. Maximum incidence of diarrhoea has been observed in Meghalaya (12%) among the North-eastern states of India while least was seen in Sikkim (2%) followed by Assam (3%), Mizoram (5%), Nagaland (5%) and Tripura (55). Overall, 36 percent of the children in NE India who had diarrhoea in two weeks before the survey were not received any advice or treatment at all during 2015-16. Maximum advice or treatment were received by the

children of Meghalaya (78%) and Tripura (73%) even above the national average (68%) and the lowest advice or treatment were received by the children of Nagaland (30%).

Oral rehydration therapy (ORT) is a simple and effective way which can reduce the duration and severity of diarrhoea. Eighty-three percent of the children in Meghalaya who were suffer from diarrhoea had received some form of ORT while in Tripura, only 49 percent of the children received ORT followed by Nagaland (54%) and Assam (59%). In order to control deaths due to diarrhoea and generate awareness in the community, an Intensified Diarrhoea Control Fortnight (IDCF) was implemented by the Govt. of India in the year 2014 all over the country with the ultimate aim of "zero child deaths" due to childhood diarrhoea. Also, Govt. of India has launched the Oral Rehydration Therapy Programme as one of its priority activities for child survival. One major goal of this programme is to increase awareness among mothers and communities about the causes and treatment of diarrhoea. Oral rehydration salt (ORS) packets are made widely available and mothers are taught how to use them. To strengthen the child health activities in the country, Government of India has introduced Integrated Management of Neonatal and childhood Illness (IMNCI) for early diagnosis and case management of common ailments of children with special emphasis on pneumonia, diarrhoea and malnutrition is being promoted for care of children at community as well as facility level[12].

Discussion and Conclusion

NFHS surveys is a landmark initiative of Ministry of Health and Family Welfare (MOHFW), Government of India, which conducted periodically with a vast amount of information on reproductive and child health, including socio-economic information for the country and its states as well as. This survey is a proxy remainder for the government to wake up and respond to the urgent issues that have been triggering through decades. Despite the launch of many health related programs between 2005 to 2015, only some improvement has been seen. Global evidence states that, unless a country expends at least 5% of its GDP on health with Government expenditure contributing to a major part, fundamental healthcare needs are hard to meet[13-14]. The Government spending on healthcare in India is only 1.15% of GDP[15]. In contrast, 2.7% of GDP is allocated to military spending[16]. Therefore, a differentiated and more focused strategy is called for. At the same time the new NHP 2017, has set stringent objectives for child health viz. to reduce under-five mortality to at least 23 by 2025, infant mortality rate to at least 28 by 2019; neonatal mortality to at least 16 and still birth rate to "single digit" by 2025[17]. The policy aims at universal health coverage with provision of comprehensive services to all while reducing out of pocket expenditures.

Findings of NFHS-4 reflect that – all the North-eastern states of India comes under poor and unequal distribution of maternal health seeking behaviour for their children. Though, prevalence of childhood illness is low in Northeast region as compared to other parts of the nation, a huge proportion of children aged U-5 are still lagging behind from the adequate advices or treatments due to various reasons like, poor quality of care and the lake of government health facility in the area, health personnel were often absent from government health facilities and the major problem for rural women was the distance to a health facility. Other hand, waiting time was too long in government hospitals and health personal were often absent in the government health centres[18]. Also, this region is not only physically isolated from the rest of the country due to mountainous terrain and poor infrastructure, it also has diverse socio-cultural practices of bringing up children, given that the region is inhabited by numerous tribal and ethnic groups. These indigenous people live in traditional, thatched roof huts, without basic amenities. The lack of basic amenities is directly or indirectly responsible for the prevalence of high burden of childhood morbidities and malnutrition in this region.

shtml. Therefore no ethical issue is involved.

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Assess the Psychological Problem and Coping Strategies Adopted among Post Menopausal Women at Tribal Area of Bhandardara

Kale Kalpana Shivaji

Asst. Professor, Pravara Institute of Medical Sciences (Deemed University), College of Nursing, Loni (Bk), Tal. Rahata, Dist. Ahmednagar – 413736, Maharashtra

Abstract

Background: Menopause is Universal phenomenon and is permanent cessation of menstruation resulting to loss of ovarian follicle development. Menopause is most striking feature during the period of transition from the reproductive to the non-reproductive stage of life due to hormonal changes women experience wide range of physical, psychological and social problem. Psychological symptoms causes effect of daily life and also most often neglected. Stress due to transition includes a adjusting to the changing self, alteration in sexuality caused by hormonal changes. Coping strategies help women to overcome these problems and lead a normal lifes.[1]

Aim of the Study: Assess the psychological problem and coping Strategies adopted among Post menopausal women. **Methods**: A cross sectional survey of 250 post menopausal women, selected by non-probability purposive sampling technique. Survey was conducted by structure questionnaire at tribal area of Bhandardara. **Result**: Majority (30%) women from 45-55 years of age. Overall mean score for psychological problem were (60.26±14.13) whereas for coping strategies mean score was (106.79±22.60). Nearly half (50%) women under study had mild to moderate psychological problems. There is statistical significant correlation between psychological problems and coping strategies adopted by menopausal women at 0.05 level.

Conclusion: Study findings shows most of the women had mild to moderate psychological symptoms and very few women adopted the coping strategies to reduce the psychological problem.

Keywords: *Assess, Psychological problems, coping strategies, Postmenopausal women.*

Introduction

Continuation of the universe is centered on the female gender. Her role keep on changing, she is a daughter, wife, mother and so on. Once mother, she leads the family unit and determines its course. She has the maximum influence on the family. These changing roles constantly change her normal physic. The family support influences the mental and physical development of women. Nowadays woman participate in all activities such as social, cultural, political areas etc. Woman hood starts with menarche and this marks the beginning of

the child bearing period and continues till menopause, when there is no menstrual period for 12 consecutive months without any biological or physiological cause. It is the end of fertility, the end of the childbearing years. Menopause is inevitable for every woman.[2]

One of the most important stages in woman's life is Menopause. Menopause is the permanent shutting down of the female reproductive system, a considerable length of time before the end of life span[2]. The word 'menopause' literally means the end of monthly cessation from the Greek word 'pausis' (cessation) and the root

word 'men' (month), because the word 'menopause' was created to describe the change in human females, where the end of fertility indicated by the permanent stopping of monthly menstruation.[3]

Hormones are important in menstruation and in postmenopausal period, blood level of some of the hormones is decreased. There are physical, physiological, psychological and social effects due to changed hormonal level. In some women psychological changes are more prominent and may affect the mental health and social life of women. Modification in life style and adopting coping strategies during menopausal period are important.[4]

Each woman who deals with menopause may find that her typical stress-coping strategies may need to be adjusted because of the high level stress that may be occurring as a result of physical changes during menopause. It does not automatically require any kind of medical treatment at all except from mental preparation. However in those case where the physical, mental and emotional effect of menopause are strong enough that they significantly disrupt the everyday life of the women.[1]

Many women arrive at their menopause transition years without knowing anything about what they might expect. Very often a woman has informed about this stage of life. So it is necessary to educate the onset and changes happen in this period, so that women should be prepared and easily cope with the situation. Women have many choices in the way menopause symptoms can be treated. Treatment can be approached in two phases, use of hormones, life style changes and use of herbs.[5]

Objectives:

1. To determine the level of Psychological problems among postmenopausal women.

2. To find out the coping strategies adopted for Psychological problem among postmenopausal women.

Material and Methods

A descriptive study with cross sectional survey approach was used for the study. Around 250 post menopausal women above 45 years of age group from tribal area of Bhandardara village of Akole taluka, Ahmednagar, Maharashtra. Non probability; purposive sampling technique was used to select the women. *The inclusion criteria for post menopausal women:* 45 years old and above, Menopause for more than a year, Residing tribal area of Bhandardara, willing to provide written inform consent and available during data collection period. *Tools and Technique:* The structure interview schedule was used to collect the data. **Section A**: sociodemographic data of postmenopausal women (11 Items) like age, education, marital status, occupation, income, religion, type of family, duration of menopause, spend years in menopause, most supportive person in family etc. **Section B**: *Assessment of psychological problem* by using Beck's Anxiety (21 Items), Depression scale (21 Items) and BORN- STEINER Irritability scale (21 Items) **Section C**: *Assessment of coping strategies adoption* :Rating scale for coping strategy Anxiety scale (12 Items), Depression scale (14 Items) and irritability scale (11 Items). The collected data was analyzed by descriptive statistics like frequency, percentage , mean and SD.

Ethical Clearance:

— Approval from the Institutional Ethical/ Research Committee of PIMS (DU),Loni.

— Written permission sought from Sarpanch of Bhandardara village.

— The written informed consent taken from post menopausal women.

Results

Sociodemographic characteristics of post menopausal women:

Majority (30%) of the post menopausal women were from 51-55 years of age. Nearly half (46%) of the women had primary education. Most (46%) of women were housewife. A majority (29%) woman has monthly income of Rs/-6001-9000. Maximum (60%) of the women under study were from Joint family. Majority (90%) of the women under study were married. Most

(82%) of women under study from Hindu religion. Nearly half (49%) women spend 6-10 years in menopause. Majority (70%) women had achieved menopause at 46-50 years of age. Most (49%) women said that the most supportive person in the family was Husband.

Assessment of psychological problems of post menopausal women:
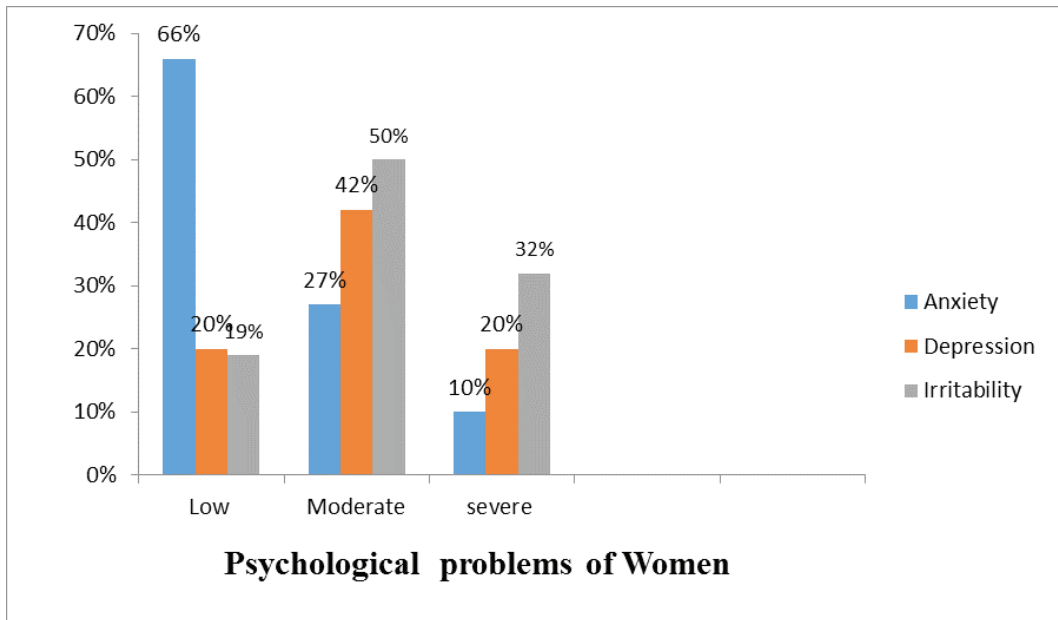
Fig No. 1

Above figure shows that majority (66%), (24%) and (10%) women had High, Moderate and low anxiety score respectively whereas, (42%), (20%) and (18%) women had mild, borderline and moderate Depression respectively and half (50%), (30%) and (20%) women under study had moderate, severe and mild irritability respectively. It shows most of the under study had mild to moderate psychological problems.

Coping strategies adopted by women:
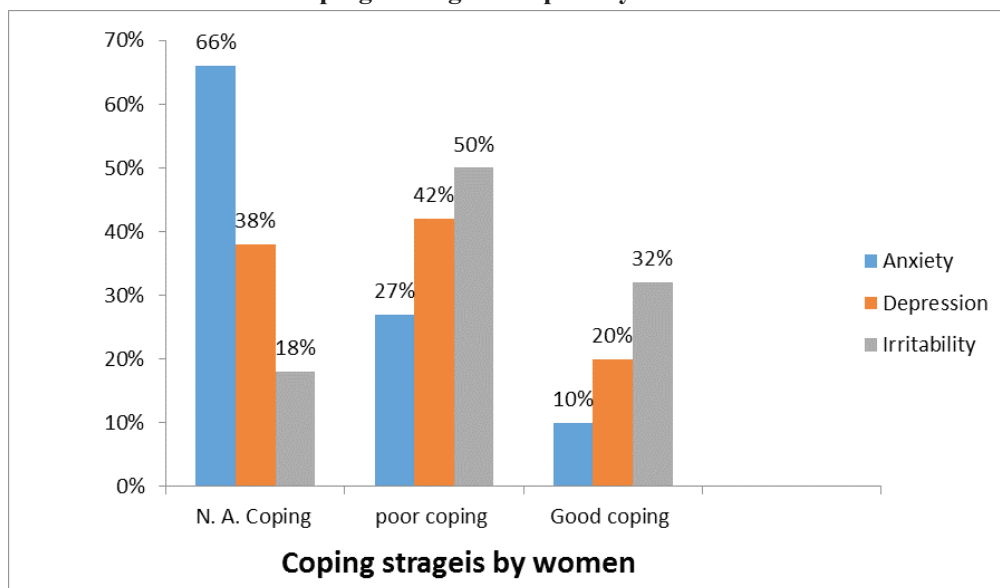
Fig no: 2

Above figure shows that the majority (64%) of women in tribal area were not adopted any coping for anxiety, (26%) of them poor coping and only (10%) of them used good coping for anxiety. Whereas in depression most (42%), (38%) and (20%) of women had poor, good and not adopted any coping respectively. It shows that very few women under study coping strategies and most of them were not adopt any kind of coping strategies for psychological problem.

Table No: I Area wise comparison of mean, SD for psychological problem and coping strategies adopted by Post-Menopausal women

N =250

SN	Area	Psychological problem		Coping strategies	
		Mean	**SD**	**Mean**	**SD**
1	Anxiety	23.42	3.75	15.96	5.64
2	Depression	14.97	5.92	12.92	3.59
3	Irritability	21.86	4.79	13.94	2.76
	Overall	60.26	14.13	42.82	10.60

Above table shows in psychological problems the overall mean score was (60.26±14.13) whereas in coping strategies overall mean score was (42.82± 10.60). In psychological problem the highest mean score (23.42± 3.75) in area of Anxiety and lowest score (14.97± 5.92) in Depression. It depicts that most of women under study were suffering from psychological problem in area with Anxiety whereas, in coping the highest mean score (15.96± 5.64) and lowest mean score in (12.92± 3.59) in area with Anxiety and Depression respectively. It shows that women under study used highest coping in area Anxiety and lowest in Depression.

It interprets that women under study used coping strategies rarely. There is statistical significant correlation between psychological problems and coping strategies adopted by menopausal women at 0.05 levels.

Discussion

Study finding shows in this study (21%) women under study was from 45-50 years of age where as similar findings noted by Mali N and Shinde M (2014)[6] that (22%) women were from 45-49 years of age. In this study (94%) women were married and (8%) women were widow. The study was parallel with study conducted by Kiranpreet K, Manupreet K(2016) reported that (90%) women were married and (10%) women were widow. In this study (82%) of women had Hindu religion similarly Agarwal AK, Kiron N(2018)[7.] Et.al too noted that in their study (82%) of women had Hindu religion. In this study (82%) women achieved menopause at 45-50 years of age and (49%) women told that most supportive person in the family was Husband similarly study by V.M Siji, T Tessy(2011)[1] too noted that (88%) women achieved menopause at 45-50 years of age .(51%) women responded that Husband was most supportive person in the family.

In this study nearly (50%) of women under study had mild to moderate and (30%) women had severe psychological problem and (10%) of them often use coping strategies (17%) of them used coping strategies for psychological problem Similarly the findings study by Karandikar V,Potdar N (2020)[8] that in their study (50%) women had mild to moderate and (23%) of them had severe Psychological problem and (10%) women

adopted coping for Anxiety, (20%) for depression and (10%) for irritability respectively. Similarly Kiranpreet K, Manupreet K(2016)[9] too noted that (26%) women had mild and (74%) women reported moderate psychological problem and (26%) women had adequate coping and (74%) women had inadequate coping respectively.

Most of the women under study adopted coping strategies reported that they sharing their problem with others, crying and relax, some of them told that they are praying to god, visit to temple or keeping busy themselves in religious activity, some of them they told, when any anxiety or tension are not taking meal, some of them keeping busy themselves in work, doing meditation, taking sleep when had anxiety. As all women are staying in tribal area no one take medical help and not taken any medication like anti-depressant or anti-anxiety medication or perform any activity like yoga.

Conclusion:

Study findings shows that the most the women under study had mild to severe psychological problem and most of the women neglect psychological problem. As this study was conducted in tribal area and most of them were not adopted any coping strategies to overcome the problem. considering the importance of mental health of post menopausal women, there is need to help the post menopausal to overcome the problems related to menopause along with emphasis on the importance by policy makers recommended through the use of problem oriented strategies . The role of health professional in field of education use of coping strategies to women in premenopausal women ages is emphasized to prepare them before entering the vulnerable period of menopause and improve QOL of the post menopausal women.

Conflict of Interest: Nil

Source of Funding: self-funded.

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Macrovascular and Microvascular Complications in Newly Diagnosed Type 2 Diabetes Mellitus

Drkumar Satyam[1], Umeshkumar[1]

[1]*Post Graduate, Department of Internal Medicine, SGRRIM&HS, Patel Nagar, Dehradun, U.K*

Abstract

Background and Objectives: India is claimed to be the diabetes capital of the world. Many studies had proven that persistent hyperglycemia and associated metabolic syndrome features like hypertension, dyslipidemia and obesity contribute to the development of vascular complications.

The present study aims to study the prevalence and clinical profile of microvascular and macrovascular complications in newly diagnosed type 2 diabetes mellitus patients.

Methods: The study is a clinical, prospective and observational study of 100 newly detected type 2 diabetics attending medicine department outpatient/ inpatient, SGRRIMHS hospital, dehradun, form the subject for the study August 2018 to July 2020 (24 months) who matched the inclusion criteria**.**

Results: In this, 62 were males and 38 were females and the mean age was 54.05 ± 13.24 years. 44% were detected when they presented with multiple complications due to diabetes. Common complications which they presented were coronary artery disease (15%), infection (12%), stroke (6%), ulcers (4%), neuropathy (4%) and diabetic ketoacidosis (1%). The prevalence of macrovascular complications CAD, CVD and PAD was 26.0%, 8.0% and 11.0% respectively and microvascular complications retinopathy, nephropathy and neuropathy was 20.0%, 34.0% and 16.0% respectively.High incidence of complications especially microvascular and CAD occur with HbA1c of range >6.5. The correlation coefficient of FBS and PPBS in relation to HbA1c was 0.56 and 0.57 respectively.

Conclusion: Smoking, increased BMI and waist circumference is associated with increased prevalence of diabetes.There is high prevalence of coronary artery disease, retinopathy and nephropathy at diagnosis. HbA1c levels predict the prevalence of complications.

Key Words: Type 2 Diabetes mellitus, microvascular, macrovascular, HbA1c, CAD

Introduction

Diabetes mellitus is a common and a serious disease with chronic complications and constitutes a substantial burden for both patient and health care system. In 2011, the global prevalence of diabetes was estimated at 366 million this figure is predicted to reach 552 million by 2030 as a consequence of longer life expectancy, sedentary life style and changing dietary patterns.The prevalence of diabetes for all age-groups worldwide was estimated to be 2.8% in 2000 and 4.4% in 2030.[1, 2]

The onset of type 2 diabetes is often silent and insidious. Pathogenic processes causing type 2 diabetes range from autoimmune destruction of cells of pancreas with consequent insulin deficiency to abnormalities that result in resistance to insulin action. The asymptomatic phase of hyperglycemia accounts for the relatively high prevalence of complications at initial presentation.[3]

This study aims in assessing the prevalence and to study the clinical profile of macrovascular and microvascular complications in newly diagnosed type 2 diabetes mellitus patients. This will highlight the need

for screening for complications at initial presentation irrespective of the presence or absence of symptoms of the complications. Early detection and intervention will reduce the morbidity and mortality due to the complications.

Materials and Method

SOURCE OF DATA

Newly detected patients with type 2 diabetes mellitus attending department of medicine(outpatient/ inpatient), SGRRIMHS , dehradun, form the subjects.

DESIGN OF THE STUDY

Cross-sectional descriptive study

DURATION OF STUDY

August 2018 to July 2020 (24 months).

Inclusion Criteria

Newly diagnosed type 2 diabetes mellitus adult patients greater than 20 years of age were included for the study.

(Laboratory diagnosis of diabetes mellitus was confirmed by latest criteria laid by the American Diabetic Association. Blood glucose levels were checked on two separate occasions before the diagnosis of diabetes mellitus was made.)

Exclusion Criteria

1. Type 1 diabetes mellitus

2. Any other severe illness

3. Patients already diagnosed of diabetes mellitus and on treatment

4. Refusal to be a part of the study

5. Pregnancy

SAMPLE SIZE

Hundred cases of newly diagnosed type 2 diabetes mellitus were included in this study.

METHOD OF COLLECTION OF DATA

Patients newly detected of type 2 diabetes mellitus attending medicine department outpatient/ inpatient, SGRRIMSHS hospital, dehradun were included for the study.

History

• Demographic characteristics such as age and sex were recorded.

• Family history of diabetes was recorded.

• Symptoms suggestive of diabetes or of related complications were noted.

• Past history of hypertension and complications of diabetes was documented. Any previous treatment for these complications taken was recorded.

• Smoking or alcohol history was noted.

• Nutritional history was taken.

Examination

• On general physical examination, the level of consciousness of the patient, vital parameters such as pulse, blood pressure (in sitting and standing position) temperature and respiratory rate was recorded.

• Anthropometric measurements:

a) Weight (in kilograms) and height (in centimetres) was recorded.

b) The body mass index was determined by dividing the weight (in

kilograms) by height (in metres^2).

c) Measurement of waist circumference (cm) - It is measured just above the uppermost lateral border of the right iliac crest, a horizontal mark is drawn, and then crossed with a vertical mark on the midaxillary line. The measuring tape was placed in a horizontal plane around the abdomen at the level of this marked point on the right side of the trunk.

• Presence of skin infections, gangrene and ulcers

was noted.

- Systemic examination was carried out in all patients.

- Presence of sensory neuropathy was defined by symptoms of tingling and numbness over the extremities (bilaterally symmetrical) with or without impaired touch, vibration sense or joint position sense. Presence of motor neuropathy was noted. Autonomic dysfunction in the form of resting tachycardia, orthostatic hypotension, gastroparesis/ diarrhoea or abnormal sweating was noted. 10gm monofilament was used to note any reduced sensation due to neuropathy.

- Dilated pupil fundoscopy was carried out in all patients in conjunction with ophthalmologist and retinopathy was defined and graded as non proliferative diabetic retinopathy and proliferative retinopathy. Proliferative retinopathy was described by the presence of any retinal or optic disc neovascularisation, or the presence of preretinal or vitreous haemorrhage, whereas the presence of microaneurysms, exudates (lipid exudates or ‗cotton-wool spots‗) and/or retinal haemorrhages only was defined as non-proliferative retinopathy.

Laboratory Investigations

- Fasting and postprandial blood sugars (venous blood samples drawn) on two separate occasions using glucose oxidase-peroxidase method.

- Renal function tests included blood urea, serum creatinine and urine analysis.

- Urine was analysed for glucose, ketone bodies and protein.

- Microalbminuria was estimated by nephelometry. Microalbuminuria is defined as a mean urine albumin concentration more than or equal to 25mg/ml by nephelometry on three consecutive days.

- Presence of diabetic ketoacidosis was confirmed by high blood sugars, ketonuria, and metabolic acidosis on arterial blood gas analysis.

- Fasting lipid profile included serum cholesterol, serum triglycerides, serum high density lipoprotein, and serum low density lipoprotein. Patient was termed to have dyslipidemia if LDL was more than 100mg/dl, serum cholesterol>200 mg/dl, serum HDL<40 or serum triglycerides >150mg/dl.

- A 12- Lead electrocardiogram and 2D echocardiography to note the presence of ischemia or infarction.

- Carotid doppler was done to note for presence of stenosis.

- Ankle- brachial index was determined using arterial doppler.

Results

In this present study, 62 % and 38% comprised of males and females respectively and male: female ratio was 1.6:1.

Patients age class were classified based on the mean and SD , as per the result the mean age of the patient was 54.05±13.24 .Age group between 30-40 years mean age was

16 (36.68±3.53years ,p=0.002); 41-51yrs 31(45.61±3.20 ,CI 5%,45.61-46.50,P=0.523); 52-62 years 28(57.28±2.44, CI 95% 56.47-58.08,p=0.880); 63-71 15(67.47±3.24, CI 95%

67.73-69.06,p=0.788) and >72 years the mean age was 10(78.90±6.52, CI 95% 74.4183.38,p=0.698) .The age group between 30-40 years were statistically significant and less prone to express diabetics and its complications.

The mean age of diabetics in this study was 54.05±13.24 years. The youngest was 30 years and oldest was 95 years. The maximum incidence of diabetics was seen in 52-62 years and more chances of developing diabetes in older age group (52-62 years) and incidence were statistically significant p<0.05.

Duration of smoking was analysed by using univariate analysis, the result showed that individuals with longer duration of smoking were more susceptible

for diabetes and its complications . It was expressed that, the mean duration of smoking was 20.20±3.56 years, p=0.02*. We correlated duration of smoking with respect to the different age group of the patients. Between 1-15 years 10(10.9±1.91years, median 8.0 and p=0.65); 10-21 years 09(19.6±1.26 years, median= 16, p=0.03); 22-26 years 03(24.00±3.38, median =22, p=0.08), and more than 26 years was 14 (28.07±2.76years, median=21, p=0.01).

Total 100 diabetics were considered for the study out of which 36 patients were smokers. The prevalence of diabetes among smokers is statistically significant (p<0.05) and positively correlated with duration and its complications (r=0.64).

Patients presented with symptoms suggestive of different complications of diabetes viz., CAD, CVD, PVD, retinopathy, nephropathy and neuropathy. History from the patients was recorded systematically by using structured questionnaires. The patients presented with complaints correlated with diabetics complications of coronary artery disease, cerebrovascular disease, peripheral artery disease, retinopathy, nephropathy and neuropathy. The result being that 15% of cases expressed coronary artery disease, 7% was cerebrovascular disease, 7% peripheral artery disease, 2% was retinopathy and neuropathy 7% respectively .

Hypertension is considered as the one of the determinants for associated complications of diabetics. BP ranges <120/80 was statistically significant and more associated with diabetics p=0.02, followed by BP ranges between 120/80-140/90, p=0.01, 140/90- 160/110, p=0.03 respectively. BP >160/110 was statistically not significantly associated with diabetics. 46 and 19 cases had prehypertension and hypertension respectively.

Body mass index is a profounded parameter for the onset of diabetes and its complications. In India, 65% of the patients suffered from diabetes with associated risk factors .The present study documented that, BMI was considered as one of predictor's for the diagnosis of diabetics. Elevated BMI is more associated with diabetic complications. Study results showed that cases with BMI <18 was 4, p>0.05, 18.1-24.9 was 24, p<0.05, 25-29.90

50, p<0.05 and more than 30 BMI was 22, p<0.05 .

Distribution of waist circumference presented , males and females expressed the variations of waist circumference; between <80cms was 11% (p=0.88), 8090cms was 34.0% (p=0.01), 91-100cms was 38.0% (p=0.02) and >100cms was 17.0% (p=0.56). The waist circumference class interval between 80-90 and 91-100cms was statistically significant and more prevailing for diabetics complications (p<0.05) . Mean in males was 90.14±9.83 and in females was 87.92±8.86cms.

Total cholesterol was raised in 13 cases and rest were within normal range. Significant p value <0.05 was noted in cases with total cholesterol less than 200. Cholesterol is an important hallmark parameter for development of diabetes and its complications. Elevated serum cholesterol level can cause various manifestations in diabetics. Present study documented between 150-200 mg/dl as 45 cases were seen, p=0.002 and it was expressed in both gender followed by 100-150 (27), p=0.023, <100mg /dl was (15), p=0.01. The elevated serum cholesterol level was not statistically significant (p>0.05) with association of diabetes.

Fundus examination was done for all eligible patients, the study revealed that no changes were seen in 80 cases, NPDR was 19 cases and PDR was seen in only one cases .

Laboratory parameters was analysed by standard laboratory procedure, the present study showed microalbuminuria in 34 cases and it was statistically significant (p<0.050) .

ECG expressed different variants myocardial infarction in (3.0 %) ; left bundle branch block (3.0%); left ventricular hypertrophy (3%); old infarction (7.0%) ; ischemic changes (8.0%) and arrhythmias in (2.0%).

ABI scale was recorded by using standard operating guidelines of diabetics patients, the ABI was expressed the range between <0.70 was 7.0% 0.7-0.90 was 12% and > 0.90 was 81.0% respectively. 19% of cases had limb ischemia, out of which 7% had critical ischemia.

Out of the total 100 diabetics, 28 cases were detected on routine investigations, 28 were incidentally detected when they attended the hospital for other illnesses and rest of the 44 cases presented with multiple complications due to diabetes.

Out of 100 cases, patients presenting with complications suggestive of CAD was (15.0%, p=0.014), CVD was (6.0%, p=0.521) PAD was (6.0%, p=0.448). Symptoms of neuropathy seen in 4.0%, p=0.69; infection in 12.0%, p=0.033 and DKA was seen in only one cases p=0.896. The CAD and infection were positively associated with diabetics and statistically significant (p<0.05).

Of 100 cases, macrovascular complications CAD, CVD and PAD were expressed 26.0%, 8.0% and 11.0% respectively and microvascular complications retinopathy, nephropathy and neuropathy was expressed 20.0%, 34.0% and 16.0% respectively. Higher prevalence and statistical significance (p<0.05) of presence of CAD, retinopathy and neuropathy at diagnosis was noted in this study.

The study results determine that CAD is positively associated with smoking (p=0.002). The prolonged duration of smoking >20 years emerged to express CAD. Present study has been compared with non smoking and it was found to be statistically non significant with diabetics associated complications (p<0.05).

The study results revealed that CAD is positively associated with hypertensive patients (p=0.004). More hypertensives express CAD complication than other complications. Present study has been compared with normotensive and it was found to be statistically non significant with diabetics associated complications (p<0.05).

HbA1c is an important predictor for development of complications. High incidence of complications especially microvascular occur with HbA1c of range 6.5-7.5 and also >9.5% .In our study, correlation coefficient of FBS and PPBS in relation to HbA1c was 0.56 and 0.57 respectively.

Discussion

This is a study done over a period of 24 months in cases of newly detected type 2 diabetes mellitus attending the inpatient and outpatient department of SGRRIMSHS hospital.

The mean age of the diabetics in our study was 54.05±13.24 years. The maximum incidence of diabetics was seen between 52-62 years.

In our study, 62 were males and 38 females with a male: female ratio of 1.63:1. In western study, ratio is 1.07:1 and in Sri Lankan study it is 1.63:1. This difference noted is probably due to illiteracy and decreased turnover of females to hospital for routine and treatment purposes.

In our study, 36 cases of the 100 were smokers. In the study conducted by Drivsholm et al, 86% of men and 50% women were smokers.

Family history of Diabetes in our study was 2% and in Nambuya AP et al study was 16%. This variation is probably due to high illiteracy and lack of awareness of diabetes among the people.

In our study, correlation coefficient of FBS and PPBS in relation to HbA1c was 0.56 and 0.57 respectively. In DCCT, it was 0.82 and in a study conducted by Nathan et al it was 0.89. The relative contribution of postprandial PG decreased progressively from the lowest to the highest quintile of HbA1c. By contrast, the relative contribution of fasting PG showed a gradual increase with increasing levels of HbA1c.

Conclusion

• Prevalence of diabetes increases with age and preponderance of males in our study.

• Increased BMI and waist circumference is associated with increased prevalence of diabetes.

• Large proportion of population presented because of complications occurring due to diabetes- a silent killer.

• Screening for CAD, retinopathy and

nephropathy at diagnosis was statistically significant.

• There is high prevalence which is statistically significant (p<0.05) of coronary artery disease (26%), retinopathy (20%) and nephropathy (34%)at diagnosis.

• Prevalence of CVD, PVD and neuropathy is 8%, 11% and 16% which is

statistically insignificant.

• HbA1c levels predict the prevalence of complications.

• There is moderate correlation between HbA1c and blood glucose levels.

• Screening with simple tests such as ECG, ECHO, fundoscopy and urine

microalbuminuria at diagnosis for all cases of diabetes is essential to identify the complications at an early reversible stage.

Ethical Clearance- Taken from institutional committee.

Source of Funding- Self

Conflict of Interest – Nil

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Road Traffic Accidents among the Young-Aged Riders in India

Kumar Sumit

Assistant Professor-Senior scale and PhD Candidate, Prasanna School of Public Health, Manipal Academy of Higher Education, Manipal, Karnataka

Abstract

Road traffic accidents have emerged as the new public health challenge of the 21st century. There has been an unprecedented upsurge in the area of auto mobilization like never before in the post-liberalization era in India. With a population close to 1.37 billion people, India now faces the worst ever road congestion in most of the areas. Indian roads are the most vulnerable road in the world. Road traffic injuries are the sixth leading cause of death in India. It is imperative to comprehensively understand the underlying behavioural factors related to road traffic accidents. Literature related to traffic behaviour is sparse in India. The current paper intends to highlight behaviours & underlying determinants, which cause road traffic accidents (RTA). Drunken riding, cell phone usage & tailgating are some of the risky riding behaviour prominent among the young riders in India. The informed evidence from the current review can provide valuable leads to the policymakers at the local level to initiate targeted interventions.

Keywords- *Low and middle-income countries, Road crashes, Risky riding behaviour*

Introduction

Internationally, road traffic accidents (RTAs) have emerged as the latest public health challenge of the 21st century. Every year more than 1.2 million lose their life due to RTAs making it one of the leading causes of death worldwide[1]. Around 90% of the RTAs occur in low and middle-income countries (LMIC) even though their contribution to the number of vehicles in the world is 54%[1, 3]. Road crashes have been identified as the leading cause of death among young people aged 15-29 years in the (LMIC) [1, 2]. Road traffic injuries result in a loss of 3% of GDP in LMIC[1]. The global plan for a decade (2011-2020) of action for road safety has been drafted to channelize efforts at various levels to reduce the fatalities associated with RTAs globally. To this end, the essential data about RTAs has focused on high-income countries rather than vulnerable road users in LMIC[3, 4].

In India, there has been an unprecedented upsurge in the area of auto mobilization like in the post-liberalization era. The roads which were constructed during the pre-liberalization era are not able to support the ever-increasing traffic load. One other point of concern is the mixing of heavy vehicles with daily commuting vehicles on the road. There has been a construction boom in India due to rapid urbanization, and hence to support the logistics supplies of the site, heavy vehicles move around the city roads, making it much more vulnerable. With a population close to 1.37 billion people, India now faces the worst ever road congestion in most of the areas. The issues related to road safety in India is very diverse. It ranges from individual, environmental, infrastructure, awareness, poor implementation of laws & absence of graduated riding licensing program.

There has been an exponential increase in the number of RTAs in India from the last four decades and an increase of 9.8 times in the fatalities associated with that[3, 4]. According to the report published in the National crime records bureau, around 141,526 people were killed, and 477,731 were injured due to road traffic injuries in India[4]. Motorized two-wheelers consist of 70% of the vehicle population in India, and it is beyond any doubt that motorcyclists are the most vulnerable as far as RTA is concerned. In India, motorized two-wheelers account for the maximum share of RTAs with an increase of 26.3

% in 2013 to 27.3 percent in 2014 and 28.8 % in 2015[6]. The National highways, which run across the length and breadth of India, account for 28.4 % of the total RTAs and share of 35 % mortality associated with it [5, 6]. The young riders in India contribute to maximum cases of mortality and morbidity due to RTAs.

Risky riding behaviour among the young-aged riders

Age and gender are significant predictors of adverse and aggressive riding outcomes. The personality of an individual has been associated with riding behaviour through risk perception. Personality-wise, young males and females are remarkably different. The young male riders are more likely to indulge in risky riding behaviour due to several factors such as reckless riding, drunken riding, mobile phone usage, helmet/seatbelt usage, peer pressure, triple riding in a two-wheeler, non-adherence to traffic rules, and irregular vehicular examination.

Drunken riding

According to the WHO, 3% of India's population consumes alcohol regularly[1]. Alcoholism is always associated with violent crimes. It impairs the social judgment process and thereby promotes the probability of risky riding and violent behaviour. Drinking and riding promptly the predisposing psychological factors which affect individual riding behaviour and their subsequent decision-making process. With risky riding behaviour already evident in young riders, there can be preparedness of having alcohol before riding. To this end, 70 % of RTA in India is due to drunken riding. Drunken riding is reported high among the male riders in India. According to the Delhi based community against drunken riding (CADD), drunken riding is very much persistent in India, even though the persecution of drunken riding has increased in urban India[7, 8]. The states in India where alcohol sale is banned like Gujarat, Lakshadweep, and Nagaland have recorded comparatively less number of accidents as compared to all other states where alcohol sale is not prohibited. Drinking alcohol and subsequent riding behaviours can be attributed to a lack of knowledge about the consequences of it, impulsivity, self-control, and lower

cognitive ability. In India, riders who drink and drive violate the law as they are mostly about it.

Cell Phone Usage

Cell phone usage while riding is a common sight on Indian roads. The use of cell phones while riding can overall impact the performance of the rider, response time to unexpected events, and the necessary situation awareness. Motorcyclists can be easily be spotted using the cell phone by one hand and handling the motorbike with another hand or balancing the cell phone between ears and shoulder blades by leaning on one side. Cell phone usage while riding can create a precarious situation not only for the riders but also for the other commuters on the road. Age and gender are the critical determinants of cell phone usage while riding. Youngsters owing to their advanced mobile literacy rate than the older generations are more likely to use the cell phone for talking and texting while riding. A study conducted by Brusque & Alauzet[9] young men receives or gives more than five calls a day while riding (Figure 1).

Courtesy-The Hindu-January 10, 2010

Helmet usage

The helmet is personal protective equipment (PPE), which is of importance for the motorcyclists against the head injury-related with RTA. Riding without a helmet is one of the quintessential risky riding behaviour observed among the motorcyclists in India, which accounts for most of the RTA injuries and fatality. The determinants associated with non-usage of the helmet by the motorcyclists on Indian roads are inadequate

information about the helmet, young age, lack of education, and failure in believing in its injury reduction value[12, 13]. Despite the evident facts available about the viability of helmet as PPE while riding, the two-wheeler riders abstain from them. It is also observed that many female bike riders in India cover their head with "dupatta" instead of the helmet while riding (Figure 2).

Courtesy-The Times of India, 11ᵗʰ January 2011

Peer passenger influence

Peer passengers or the pillion rider on the motorbike can influence the riding behavior. A study conducted by Morton et al. reported that young and novice riders are more likely to engage in risky riding behaviour in the presence of a risk accepting or risk provoking passenger[17]. The young riders are more likely to be socially influenced by peer groups and friends. The risk of a crash is higher in the young riders carrying passengers as compared to the older riders. Age, sex, and riders related to the passenger effects the impact of influence on the riding behaviour for the passenger. Talking to the peer passenger divert the attention of the rider while riding as he is not fully able to concentrate on riding. The effect is much more profound if the peer passenger is spouse, female friend, or someone closely related[18].

Tailgating

Tailgating is an act of riding on the road too close to the vehicle in front, such that the distance between the two vehicles does not guarantee that stopping to avoid a collision is possible. A study conducted by Central Road Research Institute[17], New Delhi, reported that the leading cause of tailgating is the eagerness to jump a red light, overtaking more heavy vehicles and getting delayed to reach the destination. According to the crash investigation project conducted jointly by the NATRiP and IIT Delhi, 45 % of the road crashes are due to tailgating[4]. Tailgating behaviour is more during peak hours as compared to the non-peak hours. Tailgating is more common among the male riders. Maintaining a safe distance from a vehicle is not considered to be an essential safety measure for many young and novice riders. Riders are not aware of the distance which they should maintain from the other vehicle for safe riding and minimizing the risk of crashes.

Unintentional risky riding behaviour & Antecedent's risky riding behaviour

An ideal riding practice can be disturbed in adolescent depending upon their physical and mental state while riding. Impairment such as colour blindness or poor eyesight, memory loss, mental disturbances like assignments, or work pressure leads to risky riding among them [18]. Negative and positive emotionality can accelerate the rash riding consequences in young adults. Accidents can be the outcome of anger, alienation, stress outburst, achievement, and social potency (influences) [19]. Physically stressed body due to adequate sleep, excessive workload, sedative drug medication, sleep apnea can alter the riding behaviour [18].

The absence of parental monitoring and sensitizing about the ideal road safety practices among adolescents has been a major underlying factor for committing traffic violations [16]. Many studies have shown that parents and family riding practices and lifestyle have a significant role in the risky riding behaviour among their offspring [18]. The rate of risky riding behaviour among the children, irrespective of the gender, was associated with the parents having lower perseverance towards traffic rules and found with substance abuse while riding [19]. Parents play an essential role in the complex structure of risky riding practices in teenagers and the ones who have newly secured the learners' riding license. There is much research that supports the fact that the children of

the parents who are stricter with road safety and rules are less likely to commit traffic violations and have the best road safety practices [15, 16].

Conclusion

There is no doubt that RTA had emerged as one of the significant public health threat of the 21st century. The vehicle population and traffic has witnessed an unprecedented rise in the last two decades. The current Motor vehicles act of 1988 with a slight amendment needs to be tailored to cater to the fastest-growing motorization in the second-most populous country in the world. Road safety and mitigations of the challenges posed by it needs a multidisciplinary approach. Many western countries, the concept of road safety is handled by the rainbow of professionals, which include doctors, engineers, psychologists, public health professionals, and sociologists. In India, by and large, it remains a domain in the realm of civil engineering. Risky riding among young riders is more of behavioural issues. This is the area where there is a scope of the intervention in the form of strict law enforcement, educational and community interventions, and graduated licensing programs. The young riders are mainly students who are frequent commuters on the road. Youths are the most valuable asset of any country, and any loss associated with RTA among the youth is having an immense social and economic impact. A rapidly developing country like India cannot afford to lose its most valuable resource. The concept of road safety needs a significant overhaul in India to meet the dynamic road safety challenges of the 21st century. Intervention can be done in the form of educational and community interventions, strict law enforcement, and graduated driver licensing programs.

Source of Funding- None

Conflict of Interest – Nil

Ethical Clearance- Not required

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Spatial and Temporal Analysis of Vector Borne Disease Epidemics for Mapping the Hotspot Region, Risk Assessment, and Control for Sustainable Health

M.Palaniyandi

ICMR-Vector Control Research Centre, ICMR-VCRC Field Station, Madurai, Tamil Nadu, India

Abstract

Vector borne diseases are having increasing trend in both vertical and horizontal structure of the disease epidemics in India for the recent decades. Filariasis, Japanese Encephalitis, Dengue, Chikungunya, Leishmaniases, and Malaria are the major vector borne diseases in India for several decades. The increasing trend of both spatial distribution and magnitude of the disease makes public health challenging problem in India, especially, for the recent decades. The both spatial extent and magnitude of vector borne disease outbreaks have been increasingly reported and it has been found ubiquitous across the country. The geographical extent of endemic regions, the frequency of outbreaks in both urban and rural, and the spatial and temporal aspects of vector borne disease epidemics were analyzed across the nation for the past 30 years, in order to assess the probability of potential risk of the VBD outbreaks in the country using GIS, accordingly, the appropriate control strategy will be prepared to manage the future epidemic situations in a site specific areas of high risk hotspot regions. Spatial and temporal dynamics of vector-borne disease epidemics across the country have been evidently associated with land use / land cover changes including the agriculture practices, urban dynamics, industrial growths, population movements, manmade environmental transition, etc., and have been acted upon the epidemic scenarios change the indigenous territories, and also intrusion into the non-endemic areas. The concept of control activities of vector borne disease sudden occurrence could not be achieved with no single intervention will be sufficient to control epidemic diseases, and therefore, prevention measures and control strategy must have to be advantageously applied during the intermittent outbreaks situations regularly, so as to move towards the achievement of erratic transmission control and prevent acceleration in epidemic transmission early in advance successfully.

Key words: *vector borne diseases, spatial and temporal analysis, risk assessment, epidemics, malaria, dengue, chikungunya, Japanese encephalitis, leishmaniasis, filariasis*

Introduction

The epidemics of vector borne diseases, viz; Filariasis, malaria, Dengue, Chikungunya, Japanese Encephalitis, and Leishmaniases have been occurred across the nation for several decades[1-45]. Spatial and temporal analysis of vector borne diseases epidemic transmission in India with a retrospective view has shown the accelerated trend for the recent decades[1,2,9,10,16]. The unplanned urban agglomeration, increasing transportation, globalization, irrigation and power projects, and industrial developments are causing the land use /land cover dynamics[6]. Increasing temperature, irregular and uncertainty of rainfall[17,19,20], and the environmental transition[9,10,20] are brought multiplier effect on micro climate change[5], landscape changes[34,39], and change in micro organism including the vector mosquitoes[9]. It has influence on the variations VBD vector mosquitoes (*Aedes, Anopheles and, Culex sp.*) life cycle, particularly, on the fecundity, fertility

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Corresponding author:
M.Palaniyandi
smp.geog@gmail.com

and survival of the vector mosquitoes[3,20,21,23],are created conducing environment for mosquito breeding[3,14,23], and moreover, landscape changes, unplanned developmental activities, lack of knowledge[18], socio-economic factors, are responsible for increase or decrease of vector mosquitoes profusion, administrative breakdown of vector control strategy and disease prevention measures collectively have been permitted for the increase of vector borne diseases both in vertical and horizontal structures in India for the recent decades[1-5,12]. The present study is made for mapping hot spot epidemic regions as well as risk assessment with the geo-environmental variables, and thus, the geographical distribution and the longitudinal spread of VBD transmission risk patterns have been predicted[22,24], using remote sensing and GIS[6,7,34,41,45,48], as a result, the health officials of the national VBD controlling authority could be made the appropriate control strategy in a site specific hotspot high risk region.

Study area: India has awfully diverse with its natural landscapes, viz; mountain ranges, hills, plateaus, deserts, and plains. She has a coastline of over 7,000 km (4,300 miles), most of India lies on a peninsula in Southern Asia. She has the extensive fertile landscape namely, Indo-Gangetic plain occupies most of Central, Northern, and Eastern India, the Deccan Plateau in the Southern India, and the desert in the west of the country. Climate ranges from Tundra in the Himalayan ranges to equatorial in the far south. India has divided into 27 States and 9 Union Territories for the administrative purpose. India is geographically lies between the 8^0 4' N and 37^0 6 'N latitudes, and 68^0 7' E and 97^0 25'E longitude. It is the seventh-largest country in the world, with a total geographical area of 3,287,590 km² (1,269,219 square miles), and has the population about 135.26 Crores (2018).

Materials and Methods

The epidemic data pertains to vector borne diseases (VBD) were collected from various sources including the WHO, 2019, National Vector Borne Disease Control Programme (NVBDCP), India, 2019, research and review reports available in the public domain. MS Excel software was used to develop a database in the Dbase format for analyse the spatial and temporal aspects of vector borne diseases, mapping hotspot epidemic regions, and VBD transmission risk assessment for the past 30 years, using ARC GIS version 10.0. The detailed information on urban landscape dynamics, land use / land cover changes, climate determinant variables (temperature, relative humidity, rainfall, water features, floods) along with vector borne disease epidemics data were analysed using geo-statistical software SPSS 10.0. The geo-climate, landscape, manmade and environmental risk variables associated with the occurrences of epidemic transmissions were critically analyzed to make a conclusion on the dimension of the extension of longitudinal geographical patterns as well as enormity of the periodical transmission across the country.

Results and Discussion

Malaria: Malaria cases were estimated about 251 million, 231 million, 228 million cases, deaths were estimated 585, 000, 416, 000, and 405, 000 caused by malaria globally, during 2010, 2017, and 2018 respectively[1-3]. Children aged below 5 years old are the most susceptible group affected by malaria[2], account to 67% worldwide, during 2018. According to the WHO report 2018, 19 nations in the Sub-Saharan Africa region, and India were affected 85% of the global malaria burden[12]. In Asia, 75% of malaria cases have been reported from India[1,12.] The facts of malaria is the most important public health problem in the country[2], is transmitted by nine *Anopheles species* in diverse geo-ecological paradigms[2], however, *An. culicifacies, An. fluviatilis, An. stephensi, An. minimus, An. dirus, An.Annularis*, are contributing higher level[1], among these mosquitoes, *Anopheles culicifacies* is the main rural malaria vector, followed by *Anopheles stephensi* is the major urban malaria vector, and *Anopheles fluviatilis* is the hilly or tribal region malaria vector of Indian sub-continent[1-3,5,12]. The average confirmed malaria incidence of *P.falciparum* 63 %, *P.vivax* 37 %, and estimated death about 16,700 were reported in India[12], during 2017. The spatial and temporal analysis of malaria clusters were investigated at the country level, the results shows that the high transmissions of malaria

were occurred (>1 *falciparum* cases per 1000 population) across the nation with affected 162.5 million people 12% of the total population, and low transmission (0-1 cases/1000 population) was about 1.1 billion people 81% of total population, and free from malaria is 87.9 million people accounted 7% of total population in India[12], during 2017. The map illustrates that clusters of malaria transmission hotspot regions has been occurred in the Eastern and North Eastern regions[1-3,12], and followed by western part, central and northern regions in India[1-3,12]. The wetland cultivation of irrigated rice fields provides the ideal ground for abundance of malaria vector mosquito's larval habitats[7,10,14], across the country, and remote sensing and GIS were used for mapping the epidemics and risk assessment[9,10] and demarcate the hotspot endemic regions[3-8,11]. Climate factors are completely determined the abundance of *Anopheles species* malaria vector mosquitoes[3], and the mean annual temperature between 20°C to 30°C determine the vector's fecundity, however, the transmission of *Plasmodium vivax* could be sufficient with a minimum mean temperature of 15°C, and transmission of *Pf* is possible with a minimum temperature of 19°C. In India,

the *P.vivax* requires 15 to 25 days to complete its cycle in the vectors, provided, the temperature must be within 15°C to 20°C, the relative humidity (RH) for both parasites between 55 to 80% , and the high incidence of malaria cases were reported 68±5% mainly during the monsoon period[1-3,10], with 95% statistically significant p value <0.001, mostly associated with people those who are occupied in the agriculture activities in the 14 States and Union territories 80% of plain and plateau regions. North Eastern States and other part of hilly tribal regions of India are reported 20 % about 2 million cases, 1000 deaths annually. However, the confirmed malaria cases by Slide Positivity Rate (SPR) method were reduced from 3.50 to 0.26, during in 1995 and 2019 respectively[1]. The *Plasmodium Falciparum* (*Pf*) cases were reduced from 1.14 million in 1995 to 0.16 million cases in 2019. But, the imported cases were gradually increased from 39% in 1995 to 46.55% in 2019, mainly due to the population mass movements on occupations during the period 2001-2010, nevertheless, the both incidence of confirmed malaria cases and deaths rate has been progressively reduced across the country[1-3,12], since 2006 (Fig.1, and 2).
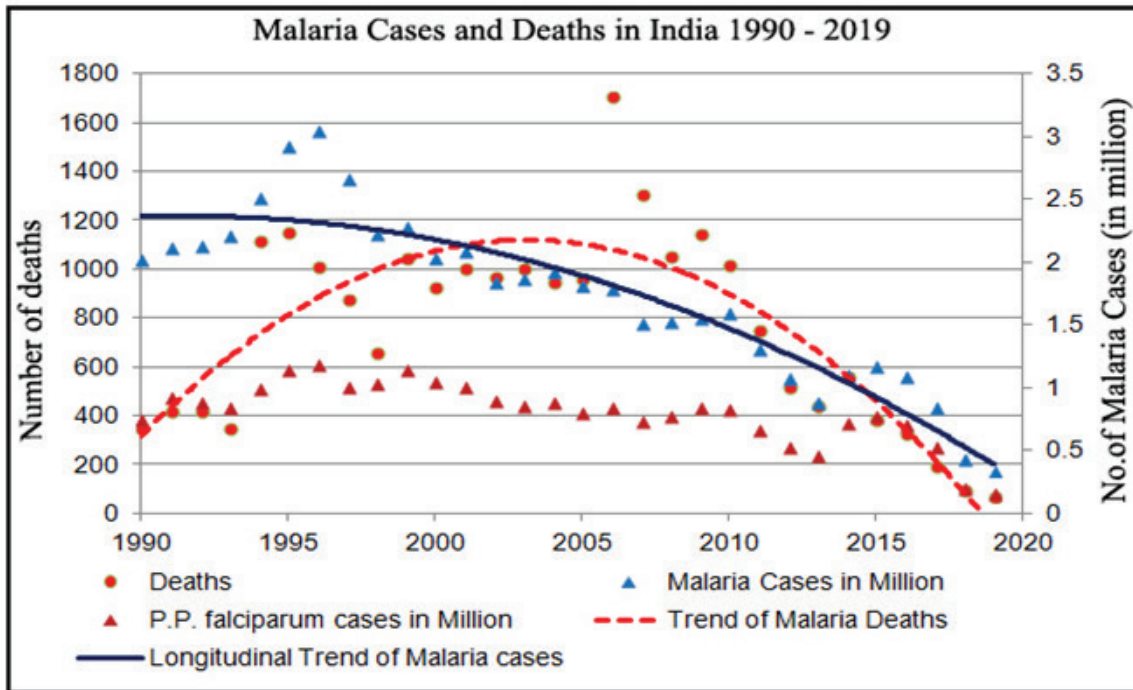
Fig. 1. Malaria cases and deaths reported in India (1990-2019), the trend line shows the longitudinal vertical dimension of cases and death over a period of 30 years
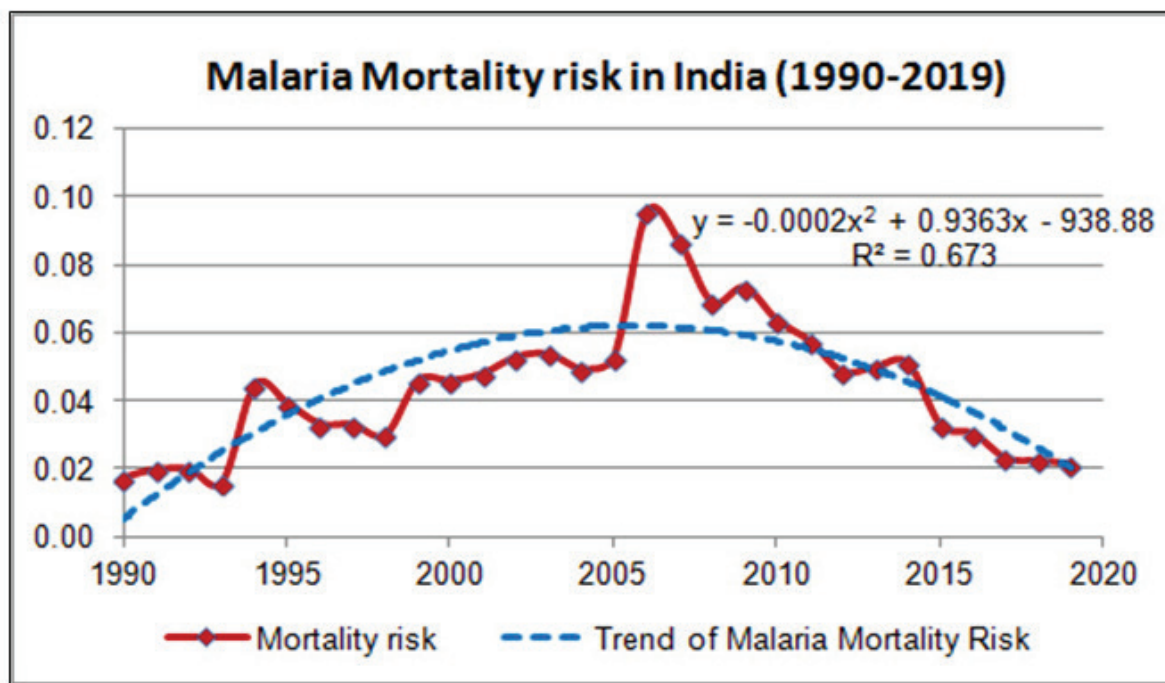
Fig. 2. Malaria Mortality Risk in India (1990-2019), the trend line shows the longitudinal vertical dimension of mortality risk is reduced 67% over a period of 30 years

over all — **Table.1. Vector borne diseases in India (1990-2019)**										
Years	Malaria Cases (in Million)	Malaria Deaths	Malaria Mortality Risk	Dengue Cases	Deaths	Dengue Incidence	Dengue Mortality Risk	Dengue Epidemic Risk	VL Cases	VL Incidence/ 1000
1990	2.02	353	0.02	NA	NA	-	-	-	57742	57.74
1991	2.12	421	0.02	NA	NA	-	-	-	61670	61.67
1992	2.13	422	0.02	NA	NA	-	-	-	77102	77.10
1993	2.21	354	0.02	NA	NA	-	-	-	45459	45.46
1994	2.51	1122	0.04	7494	4	7.494	0.05	0.793	25652	25.65
1995	2.93	1151	0.04	7847	10	7.847	0.13	0.814	22625	22.63
1996	3.04	1010	0.03	16517	545	16.517	3.30	1.681	27049	27.05
1997	2.66	879	0.03	1177	36	1.177	3.06	0.118	17429	17.43
1998	2.22	664	0.03	717	18	0.717	2.51	0.070	13627	13.63
1999	2.28	1048	0.05	944	17	0.944	1.80	0.091	12886	12.89
2000	2.03	932	0.05	650	7	0.65	1.08	0.062	14753	14.75
2001	2.09	1005	0.05	3306	53	3.306	1.60	0.308	12239	12.24
2002	1.84	973	0.05	1926	33	1.926	1.71	0.176	12140	12.14
2003	1.87	1006	0.05	12754	215	12.754	1.69	1.147	18214	18.21
2004	1.92	949	0.05	4153	45	4.153	1.08	0.368	24479	24.48
2005	1.82	963	0.05	11985	157	11.985	1.31	1.044	32803	32.80
2006	1.79	1707	0.10	12317	184	12.317	1.49	1.057	39173	39.17
2007	1.51	1311	0.09	5023	62	5.023	1.23	0.425	44533	44.53

Cont... **Table.1. Vector borne diseases in India (1990-2019)**										
2008	1.53	1055	0.07	12561	80	12.561	0.64	1.046	33598	33.60
2009	1.56	1144	0.07	15535	96	15.535	0.62	1.276	24213	24.21
2010	1.6	1018	0.06	28292	110	28.292	0.39	2.292	28382	28.38
2011	1.31	754	0.06	18860	169	18.86	0.90	1.508	25000	25.00
2012	1.07	519	0.05	50222	242	50.222	0.48	3.968	21000	21.00
2013	0.88	440	0.05	75808	195	75.808	0.26	5.919	13869	13.87
2014	1.1	562	0.05	40571	137	40.571	0.34	3.131	9241	9.24
2015	1.17	384	0.03	99913	220	99.913	0.22	7.626	8500	8.50
2016	1.09	331	0.03	129166	245	129.166	0.19	9.752	6249	6.25
2017	0.84	194	0.02	188401	325	188.401	0.17	14.074	5758	5.76
2018	0.43	96	0.02	101192	172	101.192	0.17	7.481	4380	4.38
2019	0.34	73	0.02	136422	132	136.422	0.10	9.984	3143	3.14

Data Source: WHO – South East Asia, 2019, and 2) NVBDCP, Ministry of Health and Family Welfare, Government of India-2019

NA- Not Available

Dengue: India is known for dengue endemic country and the epidemics are reported from 24 States and 3 Union Territories of 34 States / Union Territories in India[12], and highest report was recorded in 5 major States[13] (Tamil Nadu, Kerala, Karnataka, Punjab and West Bengal) during 2019. *Aedes aegypti* mosquitoes are transmitting the dengue epidemics in India[1,15,18], followed by *Ae.albopictus* is contributed to epidemics in India[12-16]. The First case of dengue virus DENV1 was clinically confirmed in Vellore in Tamil Nadu State of India, during 1956. The geographical extent of occurrences of dengue DENV1 virus epidemics in India during 1963-1964, subsequently, all the four types of DENV1-4 were reported in various parts of the country, followed by major outbreaks were occurred, during 1967-1968, and the epidemics were occurred in major cities of India, during years 1983, 1985, 1990, 2003, 2004, 2005, 2006, 2010. Subsequently, dengue epidemics have been increased in India, since 2010. As the result, dengue epidemic areas has been changed its scenario into endemic situation during the recent decades[12-16]. Dengue epidemics in India (1994-2019), have shown the linear trend of three fold outbreaks across the country[13,18]. The exponential model tend to have the trend of epidemics across the nation with increasing average risk of infection rate 3.75 per 100,000 population, and is the alarming and warning to the public health. However, the mortality risk has been drastically reduced with 1.02 %. The probability of predicted epidemic trend is increasing 68% by the year 2025, and the longitudinal trend of dengue epidemics pattern in India illustrates that the steady increase of dengue epidemics with 68% during 2012–2019 (Fig.3). Drinking water for the domestic purpose was intermittently supplied or once in a week, consequence of that storing water in the big plastic containers / metal vessels and cement containers makes ideal breeding grounds for the *Aedes* mosquito population, was significant with $\chi2$ test, (P value <0.05). The NDVI values of remote sensing data <0.4 was spatially correlated with vector profusion in the presence of actively photosynthesizing vegetation viz., pineapple, rubber plantation, and forest covers. Climate variables viz. temperature, relative humidity, saturation deficiency, and rainfall, are fuelled for conducing environment for the vector abundance and dengue virus incubations[17,19-21] Temperature ranges between > 21 and < 34, and relative humidity >70% and <90% has influence on the impact of variations on

the fecundity, fertility and longevity of female *Aedes species,* and flying capacity and egg laying capacities are reduced with temperature < 10 ^{0}C, and mean temperature >35 ^{0}C, respectively[17,20,21]. The hot spot dengue epidemics patterns are spatially correlated with mean annual rainfall between 300 mm to 1200 mm, and tend to have seasonal patterns, particularly, during and after the monsoon[17,20,21,23].
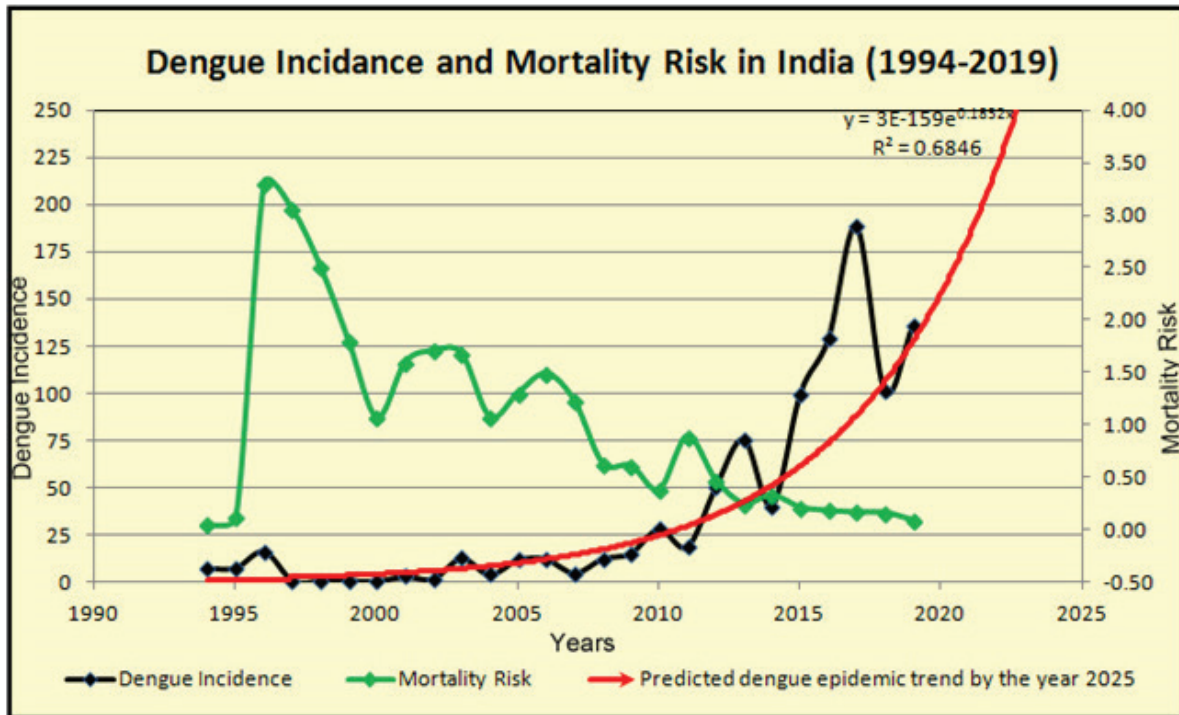
Fig.3. Illustrate the trend of dengue epidemics and mortality risk in India during the period of 1994-2020

Chikungunya:

Chikungunya fever (CHIKF) is caused by a virus belongs to the *Alphavirus* genus of the family *Togaviridae*, transmitted by the infected *Aedes genus* female mosquitoes[1,13,16]. It is deteriorating human soft tissues and weakening bone with joint pain, but non-fatal, however, it causes many behavioural changes in the human body including irritability, attention disorders, and memory issues, febrile seizures, isolated cranial nerve palsies, stroke, and hearing loss, and probably chronic fatigue syndrome[25]. The first confirmed report of chikungunya was recorded in 1963 (Kolkata), and followed by Pondicherry in 1965, Tamil Nadu, Andhra Pradesh, Madhya Pradesh, and Maharashtra[1,18,20] during 1973, and subsequently, sporadic cases were recorded in Maharasthra[1,18,20], during 1983 and 2000. A major outbreak of chikungunya was occurred in the 213 districts from the states of South India viz Maharasthra, Gujarat, Madhya Pradesh, Andhra Pradesh, Karnataka, Tamil Nadu, and Kerala[1,18,20], during 2006, and it was happened after the 25 years period, and subsequently, it has been reported with considerable cases every year[1]. The ecology and climate conditions of the chikungunya vector are the same of dengue vector mosquitoes[20]. But, the occurrences of epidemic cases are drastically reduced after the major outbreaks[1, 12] across the country during, 2006.

Japanese Encephalitis:

Japanese Encephalitis (JE) is a viral disease caused by a *flavivirus* virus affected approximately 50,000 cases, and 10,000 deaths every year all over the epidemic countries in the Asiatic region[1,12], and in India, 1,500 - 4500 cases have been reported in all the year[1,12,26].

Most of the infected JE cases are asymptomatic, but later on, it causes considerable morbidity and mortality in the age group of children below 15 years[1, 12]. The first report of confirmed cases was registered during 1955, subsequently, 6 districts were affected with JE cases during 1956-1965, followed by 6 districts were recorded during 1965-1975, it was highly increased and reported from 81 districts. JE cases were spread across the country with high magnitude in both vertically and horizontally during 1975-1985, magnitude of the cases were reported from 43 districts during 1985-1995, the cases were recorded in 18 districts, it was gradually reduced during 1996-2015 (Fig.4), however, problem is still continued in the 16 districts of 12 states, namely, Assam, Meghalaya, Tripura, Arunachal Pradesh, Bihar, Karnataka, Jharkhand, Uttar Pradesh, Odisha, West Bengal, Telangana, Tamil Nadu[26], since 2013. Totally, 154 districts of 21 States / Union Territories in the country were reported JE outbreaks[26] during 1956-2019, but it was reported in 15 states / UT, during 1998-2019. The most difficulty for the public health department that controlling the outbreaks are challenging problems in the endemic regions where it persist every year due to the complex of phenomenon including nature and man-made. In India, the JE outbreaks have been mostly correlated with construction of mega water resource irrigation projects brings extensive land use / land cover changes in many parts of the nation[10,26]. The change in agriculture cultivation practice from dry land to wet land have been probably creating the conducing environments for fecundity of JE vector mosquitoes i.e. *Culline* mosquitoes mainly *Cx. vishnui* species (*Cx. Vishnui, Cx tritaeniorhynchus, Cx. pseudovishnui, Cx. whitmorei, Cx.epidesmus, Cx.fuscocephala, Cx.gelidus, and Cx. bitaeniorhynchus*). The spatial and temporal analysis shows that the clusters of geographical hotspot region of JE JE epidemics in India for the past 65 years, has significant spatial auto correlation with wet irrigation cultivation and alluvial soil. The profusion of vector mosquito populations are directly changing the epidemiology of disease transmission in the country[26-29], and the results has spatially significance r^2 value 0.63, and p value < 0.05. Remote Sensing and GIS were used for the mapping JE hotspot regions by the researchers for the recent decades, and the similar study was conducted by the author gives the clear pictures of susceptible province of JE epidemics as well as endemic hotspot regions in India, could be used as the datum of baseline for the site specific target for control[47].

Leishmaniases:

Leishmaniasis is a neglected tropical disease which has been spread to humans by the infected female *phlebotomine* 90 species of sand flies[1,12,30]. Leismaniasis are classified in to 4 major groups, namely; Visceral Leishmaniasis (VL), otherwise known as (Kala-azar), Post-Kala-azar Dermal Leishmaniasis (PKDL), Cutaneous Leishmaniasis (CL), and Mucocutaneous Leishmaniasis (MCL), and are caused by a protozoa parasite account to more than 20 *Leishmania* species[12]. The clinical syndromes are characterized by fever, weight loss, splenomegaly, hepatomegaly, and anemia. The incidences of leishmaniasis are reported from 102 countries in the world[12]. The annual incidence of CL is estimated about 1.5 million cases, and VL is estimated 500,000 cases from 98 countries with 310 million people at risk of infection cross the world[12]. The leishmainasis are endemic in the 119 districts/counties of four major countries in South Asia, namely; India, Bhutan, Nepal, and Bangladesh, and 90% of the global burden of VL cases are reported from Brazil, Ethiopia, India, Somalia, South Sudan and Sudan[12].

India is known for endemics of visceral leishmaniases and cutaneous leishmaniases, from very early period, and the first outbreaks of visceral leishmaniasis (VL)/ Kala-azar was occurred during 1824–1825 in Jessore district of India, present day Bangladesh[30-38]. VL is caused by the protozoan Leishmania parasites *L. donovani* are being spread by the bite of infected female *phlebotomine* sandflies, namely; *P. argentipes, P. papatasi* are died before laying eggs at the minimum temperature <15 °C, however, the lifespan of the female adult *P. papatasi* is increased with decreasing temperature within a range of 18–32 °C, and the immature *phlebotomines* are ecologically sensitive insects[34,37-39], and highly abundance in the cool and moist areas with high organic matter that serve as food for larvae[37,38,40]. During the

southwest monsoon (July-October) in India, there was a increasing of irrigation sources leads to extensive areas of cultivation with edible crops and agricultural plants in the alluvial soil regions, is dark coloured alkaline in nature (pH 7.2– 8.5), calcareous with chief inorganic constituents of silicon, iron and aluminium, and its capability of retaining water, and thus, flourishing growth and wealth of edible crops, and agricultural plants[34]. Mostly, the houses in the endemic regions are mud plastered roof tops with crack and crevices on the walls have been supported for the effective day-resting habitats[30-36, 39].

The VL cases are reported from 54 districts of endemic region in India[1,12,34], and the most endemic states are namely; Bihar, West Bengal, Jharkhand, Uttar Pradesh, Gujarat, Kerala, and foothills of the Himalayan mountain range in the North Western sector of India[1,12,34]. Visceral leishmaniasis transmission hotspots clusters were identified using the universal spatial autocorrelation analyses, the result illustrates that Bihar state alone is at the risk of infection account to reported 80 % of the cases in India where 90% of the population lives in extreme poverty[1,12], currently represents 50% of the global burden of VL, and it has the co-incidence with HIV infected cases are increasingly reported among migrant workers[1,12]. CL by *L. tropica* and *L. major* occur in the West and North-western states of India[34-36] viz; Rajasthan, Punjab, and Bikaner district in Rajasthan, and cases reported from other districts are mostly migrants from Bikaner district. It has been affected severely in the poor economic groups who have lack of knowledge and poor access to free treatment, and because of the lack of government hospitals, many of them are focused to use the private hospital for the immediate recovery from the illness. The present analysis shows that it has the declining trend of 48 % (Fig.4) over the period of 30 years (1990 to 2020).

Filariasis:

In India, filariasis is caused by the parasite species namely; *Wuchereria Bancroft* 99.4 % and *Brugia malayi* 0.6%, and are spread by the bites of infected female *Culex quinquefasciatus*, and *Mansonia annulifera/ M.uniformis* species vector mosquitoes respectively[1,12,40-43]. The *Bancroft* vector mosquitoes are found ubiquitous across the country[40-43] throughout the year due to the huge urban agglomeration and settlements growths, whereas the districts are located in the filariasis hotspot endemic regions along the coastal districts, and the districts of major perennial river belts all over the country[40-44], and *Mansonia annulifera/ M.uniformis* species mosquitoes have been densely occurred in the Kerala state of western coastal region[40-43]. India is known for the filariasis endemic country in the world representation for more than 100 years[1,12], and 257 districts are affected with filariasis endemic spatially distributed in the 21 States and Union Territories of India [1,12, 40-43]. India has Filariasis 0 mF prevalence in 50 districts, < 1.0 mF prevalence in the 221 districts, and > 1.0 mF prevalence in the 172 districts across the country, and remaining districts are predicted as free from filariasis[1, 40-43]. The national health policy was aimed to eliminate the filariasis in the country by the year 2015, and it was extended to 2017, and again it was postponed to 2020. In India, the Elimination of Lymphatic Filariasis (ELF) was started in 2004 to cover 202 endemic districts in the 20 states and Union territories[1,43], and subsequently, it was extended to cover 257 endemic districts in the 21 states and UTs with 650 million population[1]. The ELF was started with single drug DEC, and later during 2006, and the main constrain of the NFCP is that it is distributed in the urban areas and does not cover the total population at risk of infection in the rural areas[43-46] combination of DEC and Albendazole was distributed. After 10 years, the validation of drug administration was carried out during 2013. The Global Alliance Elimination of Lymphatic Filariasis (GAELF) was organised during 2018, accordingly, in India, the Integrated Drug Administration (IDA) was launched with combination of 3 drugs (DEC + Albendazole + Ivermectin) [1,12] in 2019. IDA was started in 1 district of Bihar state during 2018, and followed by 16 districts in the 16 endemic states, during 2019, and 21 districts in the 20 endemic states during 2020. The IDA has been implemented in the filariasis endemic districts, and among the endemic districts, all the 257 districts were surveyed in very earlier in different localities at point of

time period[40], and as of now, it is outdated, and therefore, resurvey must be conducted constructively in all the districts all over the country where mF prevalence was positive in the earlier period, make a plan accordingly, and distribute the IDA in the hotspot endemic districts across the nation, otherwise, the elimination of filariasis in the country by 2020 will be a utopian illusion.

Conclusion

India is resourceful country and naturally diverse. On other side, whole country has been suffered from major vector borne diseases and the hundreds of million people at risk of infection. The national health policy of the Government of India has been planned to operate the appropriate control strategy and prevention measures periodically, as the result, the VBD namely; malaria, filariasis, and chikungunya are drastically reduced across the nation, on the contrary, quite a few of the VBD number of cases have been increased for the recent decades. The longitudinal epidemics pictorial representation illustrates that the outbreaks have been upward trend, and have been increased spatially and vertically, paradigm; dengue have been steadily increased in both horizontal and vertical dimension across the nation for the recent decades. Malaria is still highly challenging problems in the Eastern, and North Eastern states, followed by northern, central regions, and western part of India. Japanese encephalitis epidemics are uncontrollable in the wetland rice cultivation regions of India. Leishmaniasis have been challenging public health problem for the very long period, particularly, in Uttar Pradesh, West Bengal, Bihar, Jharkhand, Assam, i.e. Gangetic river plain and Brahmaputra river plain. The public health authority must have to pool the base line information on the VBD hotspot regions across the nation, and accordingly, make a control plan and the prevention measures in a right place and right period.

Conflict of Interest: Nil

Source of Funding: Self

Ethical Clearance: Not applicable

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The Environmental Risk Factors Significant to *Anopheles* Species Vector Mosquito Profusion, *P.falciparum, P.vivax* Parasite Development, and Malaria Transmission, Using Remote Sensing and Gis: Review Article

M.Palaniyandi

ICMR-Vector Control Research Centre, Field Station, Madurai-625002, Tamil Nadu, India

Abstract

The prevalence of spatial distribution and the seasonal variation of malaria epidemics in India have been most significantly determined by the environmental variables including climate, landscape, and the man made factors. The risk factors are acting as decisive factors on the development of *Anopheles* genus mosquitoes. The landscape environments (slope, altitude, land use / land covers), human settlements proximity to permanent water bodies of mosquito breeding habitats (lake, pool, streams, rivers, tanks etc), agricultural wet rice cultivation land, land use dynamics, population density, urbanization, increase of man water resource projects. The coefficient model of climate determinants (rainfall and temperature) with the mosquito abundance are highly associated with the Normalized Difference Vegetation Index (NDVI) value derived from multispectral satellite data, and is useful in the assess the ground situation of *Anopheline* malaria vector mosquito larval abundance 7 days in advance in the wet irrigation rice fields using remotely sensed data. The result of logistic regression model provides the spatial agreement between the observed and predicted values of larval index within buffer zones 2.5 KM around the trap location in the wet cultivation rice fields much appropriate for *Anopheline* vector mosquito breeding. However, transmission of *Plasmodium vivax* requires a minimum average temperature 15.0°C and transmission by *Plasmodium falciparum*, requires a minimum average temperature of 19.0°C. The *P.vivax* vector requires 15 to 25 days to complete the parasite development cycle within the temperature range between 15°C to 20°C, the relative humidity for both species requires range between 55% to 80% and its life cycle may be completed within 6 to 10 days, if the temperature range remains within 25°C to 30°C. Multivariate analysis could be predicted accurately the relative abundance of malaria vectors breeding habitats suitability and epidemics. The malaria cases in the endemic districts and the relative abundance of the malaria vectors are directly controlled by the climate variables with >85 % accuracy.

Key words: Anopheles genus mosquitoes, malaria vector breeding habitats, malaria endemic, environmental variables, climate factors, multivariate analysis, remote sensing, and GIS

Introduction

Malaria has been one of the most potent scourges of human population from time immemorial, and it remains, with tuberculosis and ADIS, one of the three major communicable diseases. Even a century after the discovery of malaria transmission through mosquitoes during 1897, malaria has stubbornly been endemic major public health problem in India, predominantly, in East, North East, Central, and North West India [1-4]. Malaria transmission in the tropical countries has been spatially most significant with poverty, ignorance, lack of knowledge, seasonal huge population movements, and socio-economic deprivation among the community,

For corresponding author:
M.Palaniyandi
E-mail: smp.geog@gmail.com

and the environmental variables including climate, landscape, and the man made factors, and are influenced decisive factors on the development of *Anopheles* genus vector mosquitoes, and are the intermediate host for the transmission of malaria parasites [3-5]. The landscape environments (slope, altitude, land use /land covers), human settlements proximity to permanent water bodies of mosquito breeding habitats (lake, pool, streams, rivers, tanks etc), agricultural wet rice cultivation land use, population density, urbanization, increase of water resource projects are added fueling to the vector abundance [6-9].

The developmental activities including urban growth, urban sprawl, urban agglomerations, and the related urban developments are the important witness of constructive progress of the country. However, the health issues of urban environment concern, the mosquito nuisance and the urban malaria has been a big challenging problem in India. The estimated annual prevalence of malaria was many folds approximately 75 times higher in 1950 than in 2019, and it has been gradually reduced through the national malaria programs [1,2,4]. The health programmers have joint hands with the environmental scientists to apply remote sensing, GIS, and GPS technology for mapping malaria mosquitogenic conditions in both rural and urban setup. Land use / land cover categories and has also been made spatial auto correlation with malaria endemic situation [9], examine the close association between the environmental changes and the malaria prevalence and the determinants of climate variables and malaria epidemics [10,11]. Remote sensing and GIS highbred techniques could be provided the relevant surrogate information relating to the spatial variation of the climate variables (land use / land cover categories, including wet irrigation rice cultivation areas) the malaria mosquito breeding habitats and the probability of malaria transmission risk [3,8,12,13]. It has been potentially used in delineating the mosquitogenic conditions in the urban environment [9], mapping the environmental variables [10], land use / land cover classes [14-16], and mosquito breeding habitats [6,] breeding surfaces areas [11], and correlate with malaria cases [17-21]. The specific aquatic habitats with a particular wet irrigation rice plant communities support malaria

vector mosquito juvenile breeding habitats [7,1318]. The Normalized Difference Vegetation Index (NDVI) values (-1 and +1) derived from the Multispectral Landsat TM satellite data[22-27] and, the Indian remote sensing of IRS LISS-I, LISS-II, LISS-III, and WiFS data were used to study the suitability of malaria mosquitoes vector breeding habitats[7,9].

The spatial distributions of malaria epidemics are not spatially ubiquitous, and have been continuously registered confirmed cases in the tropical regions, particularly, where the environmental variables and climate parameters are constructively supported. The study of land use / land cover changes, climate determinants and landscape ecology of mosquito immature breeding habitats and malaria epidemics, and the environmental determinants of both malaria endemics and epidemics in the developing world including India for the several decades [20,4,26]. Remote sensing and geographical information systems (GIS) has essentially applied in studying the landscape environment, vector ecological, and climate determinants and its influences on the spatial distribution, and seasonal variation of malaria parasitic disease transmission with reference to space and time [7,15,16.23,24,27]. The spatial auto correlation between vectors and malaria epidemics, the environmental factors and vector abundance are the fundamental keys to prevention measure to malaria control. There have been several research studies established that mosquito abundance is highly determined by the climate variables, particularly, the duration, intensity, and amount of rainfall, temperature, and relative humidity, and as a result, the total areas of larval breeding sites are influenced the spatial relationship between larval habitat availability and adult mosquito abundance [28]. Remote sensing data pooled in the spatial database engine was used to mapping and analyzing layers of thematic map information pertaining to immature larval habitats, land use / land cover categories, human settlements, population density, housing structures, water features, and hydrologic schemes were overlaid with adult mosquito abundance [7,13]. The environmental heterogeneity has effected on malaria vector mosquito juvenile larval habitats, and the spatial distribution of *An. gambiae* and *An. funestus* adult

female mosquitoes, the most important malaria vectors [28]. A geo-spatial analysis method has been used to study the spatial autocorrelation between the adult mosquito abundance among houses in the settlement clusters and the malaria epidemics with cross-correlation between adult mosquito abundance and geo-environmental risk factors, statistically significant [7,25].

Rationale of the Study

This study is planned to review the efficacy of remote sensing data utility, GIS techniques for geographical analysis of malaria transmission, and assessing the people at risk of parasitic infection within the endemic regions and the non endemic regions. The results obtained from the study provides information for gaining a better understanding of the spatial distribution of malaria parasitic disease transmission and the disease diffusion with site specifications of different geographical locations at different time points. The significant studies were made to attribute the spatial relationship between the geo-climate variables and the malaria disease transmission [17,18,19,29-31], Land use / land cover changes and increasing the spatial extension of vector breeding habitats, the environmental determinants and the vector abundance / vector density [20,32-35]. The low cost remote sensing and GIS for mapping malaria transmission and gaining the knowledge on the environmental aspects of malaria vector mosquito habitats, vector abundance, and vector density are increasingly important for designing a rapid method of disease surveillance for monitoring and control.

Prevalence of malaria epidemics problem in India

The malaria endemic problem is major concern in the 14 states and the highland areas of north eastern states, central and eastern states, and the eight other states of India have highly public health important. Malaria epidemic has drastically reduced in India 112.5 times for the past 70 years, and the graph illustrate the decline of malaria epidemics in India for the past 30 years, at the same time, India alone has contributed 75 % of the burden of malaria epidemics in the South East Asia [1,2]. The Indian subcontinent has malaria endemic

problems especially in the North-eastern states (Assam, Arunachal Pradesh, Manipur, Meghalaya, Nagaland), Orissa, Chhattisgarh, West Bengal, Rajasthan, Gujarat, Jharkhand, Karnataka, Madhya Pradesh, Uttar Pradesh, Haryana, Maharashtra, Tamil Nadu and Andhra Pradesh. The map explains that malaria prevalence is highest in Odisha (formerly Orissa) state, and followed by Jharkhand, Chhattisgarh, Madhya Pradesh, Gujarat, Maharashtra, West Bengal, Uttar Pradesh, Rajasthan, Assam, Andhra Pradesh, Haryana, Meghalaya, and so on. Based on the malaria occurrences of malaria API index value (Annual Parasite Index) for different states at the district level, the problematic endemic states of was used for the spatial analysis of malaria transmission endemic risk zones.

Geo-Spatial predictive model for analyzing the malaria epidemic transmission trend

The wealth of malaria vectors are influenced by the climate, and environmental variables, immature malaria vectors larvae are mostly presented in the small water pools nearby human activities [34,35,39]. The geo-spatial analyses of malaria epidemic transmission have been provided the trend of future spatial diffusion accurately, and added improved precise result with predictive models, proviso, it needs to improve with refining the existing models with the empirical knowledge of environmental observations, ground truth studies, and laboratory experiments. The GIS was used to construct the thematic maps of different ecological zones, and epidemiological mapping of malaria distribution with respect to space and time. GIS techniques were extended to spatial analysis of vector abundance, vector density, parasite ratio, the community at risk of malaria disease transmission as perennial, seasonal, bi-seasonal, sporadic epidemics etc., it allows the layers of information of different mosquito species, different environmental variables (mosquito habitats, breeding sources, mosquito ecology, site specific location) and climatic variables (Temperature, relative humidity, saturation deficiency and rainfall). The indication of reproduction rate (Ro) of the disease is warning signal for malaria epidemic situation when Ro value is greater than (0), in a Boolean situation, where climate is suitable (1) or unsuitable

(0). The predicted Boolean thresholds value of the combination of temperature–rainfall was considered for mapping the probability of malaria transmission based on the threshold value 1 is suitable and where malaria is expected to occur, and value 0 means, malaria is expected not to occur, would be ignoring climate, landscape, and environmental spatial variations, and natural uncertainty. A fuzzy analysis provides the key elements for mapping the areas of climatic conditions where most suitable, unsuitable, moderately suitable or in between, semi-suitable for malaria vector species (A*nopheles genus)* and the malaria disease transmission. The geo-spatial analysis of superimposed overlay thematic maps of climate variables on the malaria epidemic prevalence map to construct a spatial modeling for prediction of both horizontal and vertical magnitude of malaria transmission risk in the both endemic and non-endemic regions [3,7,1719,29-31,37]. The results of the documents of published research works show that the geographical distribution of malaria transmission and spatial diffusion are greatly influenced by climate determinants, and the environmental variables.

Land Use / Land Cover Transforms and Malaria epidemics

Land use / land cover changes (dry land agriculture to irrigation wet irrigation crop cultivation) and the growth stage of land cover changes of vegetation types may perhaps play an important role in determining vector abundance, irrespective of their association with other variables [7,13,34]. Vegetation is playing important role in the vector potential, which surrounds the environment for breeding sites (and thereby provides potential resting sites, sugar-feeding supplies for adult mosquitoes and protection from climatic conditions) may also be important in determining the abundance of mosquitoes associated with the breeding site [28-39]. The early period of irrigation rice crops wet cultivation 2-6 weeks provide potential breeding sites for *Anopheles mosquitoes*, it has been changed when the rice plants grownup, and form a dense canopy cover over the water protected from larvae breeding (Palaniyandi M, 2014, Wood BL, et al., 1991 and 1992). The regional climate change (temperature, rainfall, and humidity) and land use / land cover changes are fueled

to promoting a new emerging vector borne diseases in many newer areas [3,12,21]. There have been evidenced by growing incidence of malaria epidemics in different parts of our country, and more frequently in the regions where the extended irrigation areas by construction of water resource development projects/ irrigation canals, and as a result, has been fueled for malaria vector mosquito abundance and it has been evidenced that a few classical studies were conducted on malaria and JE epidemic in Thar Desert in India [3,12,21], respectively, the *Anopheles* genus malaria vector mosquitoes and *Culex tritaeniorhynchus* JE vector mosquitoes found heavy breeding in the areas where the introduction of wet irrigation through the Indira Gandhi water resource project in the absolutely dry region/ semi desert areas of Rajasthan state in India. The result shows that water leakage throughout the irrigation canals and drinking water lines, and land use / land cover changes from dry land to wet irrigation rice cultivation land, and thus, the disease outbreak in and around of the buffer zone of 2.5 Km of water resource projects (Irrigation Canals, lake, perennial or semi-perennial river / stream, water pools), and wet irrigation rice cultivation agriculture areas, [3,12,21]. The type of wet irrigation rice crops are the potential breeding sites for *Anopheles* malaria vector mosquitoes, and determining the abundance of mosquitoes associated with the number of breeding sites [13,14].

Weather determinants and Malaria transmission

The climate determinants are most important in limiting transmission and distribution of malaria on a large scale than the micro scale [17,19,20,29-31], and hence, meteorological variables (Temperature, humidity, saturation deficiency, and rainfall) are used for predicting the malaria epidemics in advance. The determinants of malaria transmission are very complex and many, such as, mosquito ecology, mosquito breeding habitats, mosquito abundance and density, human activities, human and vector genetics, proximity of human and vector contact, etc., *Anopheles* malaria vector mosquito breeding found primarily in the pools where rainwater collected during the monsoon. It has also been found in large quantities during the inter-monsoonal period, and semi-permanent

pools supplied water by the irrigation canals, and rainfall during the monsoon season, and permanent water source in the pools have been found the major breeding grounds for wealthy *Anopheles* immature breeding in Sri Lanka [34], and malaria non-endemic regions turn to become endemics in India [3,12,21].

Temperature and precipitation influence on malaria transmission

Temperature has the most significance role in the determinants of the vector survival, parasite development, parasite incubation, and the malaria disease transmission. In India, climate factors, principally, temperature range between 20°C and 30°C most favorable for *Anopheles* malaria vector mosquito species survival and profusion. However, transmission of *Plasmodium vivax* requires a minimum temperature 15°C, and transmission of *Plasmodium falciparum*, requires a minimum temperature of 19°C. The influence of temperature on the transmission cycle of the malaria parasite *Plasmodium falciparum,* and *Plasmodium vivax* are numerous, and has specific impact, and significant effects on the period of parasite development (n) and mosquito survival (p), which are contributing the most important in malaria epidemics [20]. There have several studies been demonstrated that the annual distribution of precipitation, the amount of rainfall, the number of rainy days, duration and intensity of rainfall, and the atmospheric humidity, and degree of soil wetness has significant effects on malaria prevalence.

Relative Humidity and Saturation Deficiency influence on malaria transmission

The rainfall and humidity are important determinants of vector breeding and survival Predictions about the spatial diffusion, direction, magnitude and the suitability specific location for malaria epidemic changes and malaria transmission are drawn largely from temperature dependencies. There were many pioneers carried out studies on the interaction and the influence of climatic conditions with respect to malaria transmission in many of the arid and semi-arid areas [7,12,21]. Rainfall and humidity on vector populations and, the influence of sturdiness of precipitation on malaria transmission current scenarios and the distribution of malaria transmission is most associated with types of landscape environments (rural, high lands and hilly lands). The climatic condition of relative humidity with a particular bandwidth of temperature interval could provide past, present, and the future spatial trends of corresponding spatial movements of malaria occurrence. The life span of the mosquito gets so shortened and the malaria transmission is remarkably diminished where the region has experienced with mean monthly relative humidity is < 55 % and > 80 % [7,12,21].

Table.1. A multivariate geo-statistical model for predicting the malaria transmission

Model Prediction				
Model	**R value**	**R square**	**Adjusted R square**	**Std Error of the Estimate**
1	0.631a	0.398	0.387	5.9753
2	0.683b	0.467	0.456	5.3264
3	0.684c	0.468	0.458	4.5432

a.

Predictors (constant): Temperature, Relative Humidity (RH)

b. Predictors (constant): Temperature, Relative Humidity (RH), Saturation Deficit (SD)

c. Predictors (constant): Temperature, Relative Humidity (RH),Saturation Deficit (SD), Precipitation / Rain Fall (RF)

The cumulative effects of climate risk factors on malaria epidemic transmission

The cumulative effects of climate risk factors on malaria epidemic transmission has significantly increased when include one and above risk factors, result shows that the effect of temperature added with relative humidity on malaria epidemics, and has relatively significant p value <0.05, temperature, relative humidity and saturation deficit has good significant r value = 0.683, p value <0.05, and finally, the temperature, add with relative humidity, saturation deficit and precipitation has perfect fit with spatial agreement and statistically significant, r value = 0.684, p < 0.05, and consequently, concluded that the cumulative effects of the climate variables provides not only the good agreements, but also blindly fueled to both vector abundance and disease epidemics. The malaria cases in the endemic districts and the relative abundance of the malaria vectors are directly controlled by the climate variables and the results show that a spatial agreement between the climate variables (independent) and the malaria cases (dependence) was existed [3]. The four possible geo-climatic variables were included in the analysis, out of four variables and the combined effect of multivariables has statistically significant. Pearson's auto correlation coefficient was applied to analyzing the degree of association between the geo-climatic variables (temperature, rainfall, relative humidity, and saturation deficit) and malaria endemic areas. The rural and highland malaria cases India has the spatially significant with the range of population density, it means the village settlement clusters within the range of population between 100 and 1100 has mostly affected by malaria transmission across the country [3]. Multivariate analysis provides the strong relationship between the geo-climatic variables and malaria transmission [3]. The delimitation, stratification and mapping of malaria transmission risk zones and estimation of disease burden

and the population at the risk of disease transmission in the community is the datum of baseline for decision making and disease control in the country [7,15,16,22-28].

Remote Sensing and GIS for mapping of *Anopheles genus* vector mosquitos' ecology

The multispectral remotely sensed data has been integrated with GIS for mapping malaria vector abundance and the disease epidemics in the rural areas and high land hilly regions for different climate season [3,37]. The normalized differential vegetation index (NDVI) has spatially auto correlated with aquatic environment of *Anopheles genus* vector mosquitoes breading habitats and the model has fitted [7,13,22-28,38]. The *An. culicifacies* – a rural vector, and *An. fluviatilis* a resident of hilly-forested and high lands are causes malaria in the most part of India except the regions at elevations >1800m and in some of the coastal belt (Palaniyandi M, 2013). The the suitable larval habitats are spatially determined by the climate variables (Bhattacharya S, et al., 2006), especially, the amount of rainfall received in the areas, and thus, the adult mosquito abundance was spatially constrained, and has spatially significant [28]. The Normalized Difference Vegetation Index (NDVI) derived from the formula (Infrared band values – red band values / Infrared band values + red band values) and the values of NDVI between (-) 1 and (+) 1. The values are standardized, and are recorded well within these limits for image analysis and interpretation: NDVI value range between 0.0-0.2 appear to bare ground, 0.2-0.7 denotes the presence of actively photosynthesizing plants, and the negative values designates water bodies. The logistic regression model applied to predict the malaria vector mosquitoes immature population in the rice field based on the field collected samples, the result provides the spatial agreement between the observed and predicted values r=0.76 sensitivity, and specificity of 0.78 of larval index [13]. The coefficient model of rainfall and temperature with the mosquito abundance are highly correlated with the normalized difference vegetation index (NDVI) derived from NOAA- AVHRR satellite data, and used to evaluate to project the mosquito larval population profusion 7 days in advance, similarly, a study was conducted to estimate the *Anopheline* malaria

vector mosquito abundance in the mosquito habitats of rice fields using remote sensing spectral signatures. The multispectral and multi-temporal IRS WiFS, Landsat-TM data were critically analyzed to mapping land cover categories of swamp and pasture, was found suitable field for the *An. albimanus,* malaria vector species immature larvae, and GIS buffering technique was applied to ground truth field samples to predict high and low vector abundance areas with 90% accuracy [7,26,27].

The NDVI values derived from red and infrared satellite data have been used for mapping the areas suitable at the early stage of rice growing season 2-6 weeks, usually found likely to have ideal grounds for *Anopheles* species higher immature larval mosquito densities (Palaniyandi, M, 2014). The Indian remote sensing satellites (IRS) Linear Imaging and Self Scanning, IRS LISS I, LISS-II and LISS III data were used for mapping 'mosquitogenic' conditions and mapping malaria vector breeding habitats with high and low larval density fields [9,15,16]. The human dwellings and livestock sheds data location map was overlaid on multispectral remotely sensed data, and a linear multiple discriminant analysis was enabled added advantage of mapping the host availability of *anopheles genus breeding* habitats suitability with 85% accuracy, and 100 % sensitivity [32]. The remote sensing of Landsat TM, IRS LISS-I, LISS-II, LISS-III, and IRS WiFS data were used to analyze the areas suitable for mapping vector breeding habitats, and assessing the vector abundance [9,15,16]. Subsequently, it helps to assess the mosquito abundance for mapping the seasonality and the occurrence of malaria transmission intensity [3-8,17,20,23,30-33]. The integrated remote sensing, GIS and GPS have been used for the delineating, portraying mapping, monitoring, continuous surveillance, and risk assessment of epidemic transmission in advance [3-8,15,16,22-28,39].

Mapping malaria risk zones and Forecasting epidemics

Remotely sensed imagery data was used to understand the spatial distribution and the abundance of mosquitoes, mosquito habitats and mosquito borne diseases from large scale (Block or District level) to small scale regional/ state/ national level and also it helps to predictions of malaria seasonality. In the present decade, the satellite image processing and GIS software are widely useful to research workers in developing countries like India where the malaria challenge is the greatest. The logical step towards developing the malaria epidemics risk model based on the environmental determinants and climate variables guide us for decision making to both malaria vector mosquitoes control and the malaria epidemic control at the national level. Considering the climate determinants governing malaria transmission in India, remote sensing and GIS provides datum of information to assess the probability of spatial extent of malarial transmission associated with projected climate changes. Perhaps, based on the current endemic situation and the spatial nature of malaria in India, GIS is applied for spatial and temporal aspects of ecological modeling of malaria transmission risk with readily available climatic variables, and geographic data (land use / land cover) obtained from aerial and space borne sensors, and the epidemiological data obtained from national health services or hospital records. Thus, remote sensing and GIS assist to produce the constructive maps for highlights the "mosquitogenic condition" using geo-climatic variables and the predicted surface of the disease, provided entomological data as the additional data fueled to classify the areas into four categories of region i.e. 1.stable malaria region, 2.epidemic malaria region, 3.malaria free region, 4.spatial sifting or spatial diffusion of malaria region, and further steps to take action plan for both vector mosquito and malaria epidemic control activities.

Conclusion

Beyond mapping, the utility of remote sensing and GIS are widely appreciated for the geographical analysis of the *Anopheles* immature mosquito breeding habitats, and linking with land use/ land cover changes, water bodies, river/streams, etc., and identifying the range of suitable climate variables (temperature, humidity, and saturation deficiency, rainfall) for delineating the malaria prevalence, and diffusion of malaria transmission. It has been used to obtain the information pertains climate, landscape, and the environmental variables relevant to

Anopheles species vector mosquitoes breeding potential habitats, immature larvae peaks seasons, mosquito abundance, parasite development, epidemics seasons and spatial variations under the GIS spatial engine. The spatial analysis of malaria cases and climate variables providing the decision support tools for prioritizing the areas for vector control, and prevent the possible outbreaks of malaria epidemic as well. Therefore, the following areas were classified into four major categories, and hence, recommended for the control operation, particularly, vector mosquito immature population in the given areas, such as; (i) coastal region with dense human settlements, (ii) dense population in the foothill areas, (iii) marshy areas / Industrial areas with low density population settlements and (iv) semi-urban in the peripherals of the metropolitan, (v), mega water resource projects irrigation wet cultivation areas, (vi) dense settlement areas with high density population and low income areas, (vii) settlements in the newly developed irrigation canals and wet cultivation areas, (viii) dense forest and high land / hilly areas in the country.

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Infant and Young Child Feeding – Importance During COVID-19 Pandemic

Madonna J Dsouza[1], Muhammed Muntazeem G[2], Arun Daniel J[3], B.A Varadaraj Rao[4]

[1]*Assistant Professor, Department of Community Medicine, Mahatma Gandhi Medical College and Research Institute, [2]Assistant Professor, Department of Community Medicine, Navodaya Medical College, Hospital & Research centre, Raichur, Karnataka, [3]Associate Professor, Aarupadai Veedu Medical College and Hospital, Pondicherry, [4]Professor, Department of Community Medicine, SSIMS & RC, Davanagere, Karnataka*

Abstract

According to the "Convention on the Rights of the Child," every baby and child has the right to good nutrition. Dietary practices especially during first thousand days of life from gestation to two years of age have a permanent impact on life. Breast feeding up to first 6 months life exclusively followed by complementary feeding in addition to breast milk is an important aspect in person's physical and mental development. Deficiency or excesses in person's intake lead to malnutrition. The burden of malnutrition in India being high, hence the importance of Breast feeding and IYCF is being highlighted in this perspective during COVID-19 Pandemic.

Key Words: *Breast Feeding, IYCF, Complementary Feeding, COVID-19.*

Introduction

Optimal feeding practises for infants and young children are one of the most successful strategies for improving child wellbeing. Unfortunately, 45 percent of child deaths are linked to malnutrition. In 2019, it was reported that 144 million children under the age of five were stunted (too low for their age), 47 million were wasted (too thin for their height), and 38.3 million were overweight or obese globally. Approximately, only 44% of infants aged 0–6 months receive exclusive breast feeding. Be that as it may, numerous kids are not taken care of in the suggested way. Numerous moms, who start breastfeeding acceptably, regularly start complementary feeds or quit breastfeeding inside a couple of months. In addition, many children, even those who have grown well for the first six months of life, do not receive adequate complementary feeds. Hence there is a need to protect, promote and support breastfeeding and complementary feeding practices especially during COVID-19 pandemic.

Why should Breastfeeding Be Initiated Early after the Birth of the Baby?

Breastfeeding ought to be begun when the child is delivered with in initial an hour after the birth and not later than 60 minutes. In the event that the infant can't be put to breast after ahead of schedule, even skin to skin contact with the mother assists the milk with streaming. The child is alert around this time. The family can see that the child is prepared for breastfeeding when he/she opens the mouth, turns the head as though looking for the areola or sucks on fingers or hands. Beginning breastfeeding early is truly outstanding activity that the mother can do to help her child be strong and has numerous benefits for both infant and the mother.[1]

Corresponding Author:
Dr Arun Daniel J
Associate professor, Aarupadai Veedu Medical College and Hospital, Pondicherry, Manimegalai Street, Anandha Nagar, Puducherry, 605009
drdanfi@yahoo.co.in

The infant gets every one of the advantages of the principal milk which resembles the child's first inoculation and shields the infant from disease. It additionally assists with smooth passage of stools, like a laxative, clears the meconium. It is plentiful in nutrient A which is significant for the eyes [2]

Early suckling aids in the production of more milk, the flow of breast milk, the prevention of early breastfeeding difficulties, and the improvement of overall health. Maintains the baby's warmth and encourages bonding in the relationship between the mother and the child. It comes in a number of different styles. There are many benefits to the mother. It's beneficial in a variety of circumstances. The placenta is pushed out, and bleeding is reduced. Breast engorgement is avoided in the mother[2]

Levels of recommended feeding practices globally

World-wide, short of what one out of two babies are put to the breast inside the principal first hour of birth, and just more than two out of five new-born children under a half year old enough are only breastfed. The World Health Organization (WHO) suggests that breastfeeding proceeds until age 2 and past, yet under two out of three small kids matured 12–23 months are profiting by it.[3]

Worldwide evaluations for taking care of youngsters matured a half year to 2 years show considerable opportunity to get better. Somewhat more than 66% of six–to eight-month-olds are getting any good food whatsoever, and when considering proportions of diet amount and quality, the rates are a lot of lower: just one out of two get a base supper recurrence and short of what one out of three a base eating regimen variety.

Levels of suggested taking care of practices differ generally among locales. While more than two of every three babies in Eastern Europe and Central Asia are put to the breast with in one hour of birth, just one out of three infants in Middle East and North Africa get advantages of early commencement of breastfeeding. Essentially, in the event of kept breastfeeding, more than three out of four kids 12-23 months old enough in South Asia are still breastfed contrasted with short of what one of every two kids in Latin America and the Caribbean. This noticed

example is nonetheless, turned around if there should arise an occurrence of markers surveying diets of babies and small kids like least dietary variety. Contrasted with three out of five youngsters 6–23 months old enough in Latin America and the Caribbean, short of what one of every five kids in South Asia get food varieties from the base number of nutrition classes [3]

Focus on complementary feeding practices

From the age of a half year, a baby's requirement for energy and supplements begins to surpass what is given by breast milk, and corresponding taking care of gets important to fill the energy and supplement deficit gap [4.] On the off chance that correlative food sources are not presented at this age or on the off chance that they are given improperly, a new-born child's development may flounder. In numerous nations, the time of reciprocal taking care of from 6–23 months is the hour of pinnacle rate of development wavering, micronutrient lacks and irresistible sicknesses [5].

Even after integral food sources have been presented, breastfeeding stays a basic wellspring of supplements for the baby and young child. It gives around one portion of a new born child's energy needs up to the age of one year, and up to 33% during the second year of life. Breast milk keeps on providing more excellent supplements than reciprocal food varieties, and furthermore defensive variables. It is consequently suggested that breastfeeding on request proceeds with sufficient integral taking care of as long as 2 years or past [6.]

Complementary food varieties should be healthfully satisfactory, safe, and fittingly taking care to meet the small kid's energy and supplement needs. Nonetheless, integral taking care of is regularly full of issues, with food varieties being too weaken, not took care of frequently enough or in too modest quantities, or supplanting breast milk while being of a second rate quality. Both food and taking care of practices impact the nature of integral taking care of, and moms and families need backing to rehearse the complementary feeding during the pandemic [7]

Breast Feeding and COVID-19

It expresses that ladies with suspected, plausible or affirmed Coronavirus ought to be upheld to have their babies set skin-to-skin with them following birth, start breastfeeding inside an hour of birth, to keep their newborn children close by day and night, and solely breastfeed [8] Close by these practices, moms ought to apply contamination avoidance and control gauges by rehearsing respiratory cleanliness, washing their hands when contact with their newborn children, and guaranteeing that surfaces that they have been in contact with are cleaned and sanitized [8]. Where moms can't breastfeed in light of ailment they are to be helped to communicate milk for their babies [8] On the off chance that this is preposterous, the utilization of benefactor human milk ought to be investigated and if this isn't accessible wet nursing or newborn child recipe might be thought of. Continuous milk articulation and relactation when moms are all around ok is additionally suggested [8].

In any case, concerns have been raised about whether moms with Coronavirus can communicate the SARS-CoV-2 infection to their baby or small kid through breastfeeding. Proposals on mother-newborn child contact and breastfeeding should be founded on a full thought of not just of the possible dangers of Coronavirus contamination of the baby, yet additionally the dangers of horribleness and mortality related with not breastfeeding, the unseemly utilization of baby recipe milks, just as the defensive impacts of skin-to-skin contact. This logical brief looks at the proof to date on the dangers of transmission of Coronavirus from a tainted mother to her infant through breastfeeding just as proof on the dangers to youngster wellbeing from not breastfeeding. [9]

WHO recommends that mothers with suspected or confirmed COVID-19 should be encouraged to initiate or continue to breastfeed? Mothers should be counselled that the benefits of breastfeeding substantially outweigh the potential risks for transmission. Even complementary feeding in addition to breast feeding is of utmost importance. Cleaned utensils and spoons for feeding and usage of masks by the mothers in case of contact with COVID positive case and isolation of mother and child in separate rooms if positive case is present in the house

Recommendations to the mother

Mother is supposed to practice respiratory cleanliness, including during taking care of the child, if there are respiratory symptoms such as being short of breath, a medical mask has to be used when near the child. Ask mother to wash hands completely with cleanser or sanitizer when contact with their kid. Routinely clean and disinfect any surfaces you touch. In case the mother of the child is seriously sick with Coronavirus or experience the ill effects of different entanglements that keep you from really focusing on your baby or proceeding with direct breastfeeding, express milk to securely give breast milk to your new born child [10.]

On the off chance that you are too unwell to even consider breastfeeding or express breast milk, you ought to investigate the chance of relactation (restarting breastfeeding after a hole), wet nursing (another lady breastfeeding or really focusing on your youngster), or utilizing contributor human milk. Which way to deal with use will rely upon social setting, adequacy to her, and administration accessibility [10]

Conflict of Interest – Nil

Source of Funding – Nil

Ethical Clearance – Not Applicable

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Prevalence of Hypertension and its Various Determinants among the Factory Workers in City of Rajasthan, India

Mahendra Khatri[1], Shweta Asthana[2], Anshul Sharma[3]

[1]*Associate Professor, Department of Community Medicine, American International Institute of Medical Sciences, Udaipur, [2]Associate Professor, Department of Anatomy, RNT medical College, Udaipur, [3]Assistant Professor , Department of Physiology, Government Medical College, Bharatpur*

Abstract

Introduction: In modern world Non-communicable diseases (NCDs) is the major killer causes almost 44 million deaths each year, equivalent to 72% of all deaths globally. Cardio-vascular diseases account for most NCD deaths or 17.81 million people annually. Factory workers has been exposed to the most stressful occupations in the world, so these workers are more susceptible to coronary heart disease. **Materials and Methods:** A cross-sectional study was carried out during Jan 2021– March 2021 among 456 Factory workers posted in Udaipur city of Rajasthan selected randomly. The investigator made two measurements of blood pressure. Data were collected using predesigned, pretested, semi-structured interview schedule, and analyzed using the Statistical Package for the Social Sciences version 20.0. **Results:** Among 456 participants, 142 (31.1%) participants were found to be hypertensive. Age of study participants, duration of service, rank, and education are significantly associated with the prevalence of hypertension (HTN) among Factory workers. **Conclusion:** HTN in Factory workers has emerged as an important public health problem. Knowledge of important risk factors for HTN may give tracks for better prevention in this population. Therefore, it is very important to make screening strategy to diagnose HTN among Factory workers and devise a comprehensive strategy for the management of HTN.

Keywords: City, hypertension, Factory workers

Introduction

In today world , the chronic non-communicable diseases (NCDs) are a major global health challenge with numerous deaths and complications on the human body. NCDs kill 44 million people each year, equivalent to 72% of all deaths globally. Each year, 17.81 million people die from a NCD between the ages of 30 and 69 years; over 80% of these premature deaths occur in low- and middle-income countries.[1]

Raised blood pressure (BP) is estimated to have caused 9.47 million deaths and 7.21% of disease burden – as measured in disability-adjusted life years – in 2010. The global prevalence of raised BP (defined as systolic and/or diastolic BP equal to or above 140/90 mmHg) in adults aged 18 years and over was around 22.1% in 2014.[2]

Decreasing the global burden of NCDs is an overriding priority and a necessary condition for sustainable development. Many factors contribute to the high prevalence rates of hypertension (HTN) such as eating food containing too much salt and fat, not eating enough fruits and vegetables, overweight and obesity, harmful use of alcohol, physical inactivity, aging, genetic factors, psychological stress, inadequate access to health care, and socioeconomic determinants.

There is an increasing prevalence of HTN in the Indian population, especially in the urban areas.[3] This global risk factor affects all populations of the world including the special occupational groups, for example, the Factory workers . Factory workers do their shifts to provides continuous service to the civilians. They have to serve 24x7 for timely production for public. Factory

workers has been regarded by some researchers as one of the most stressful occupations in the world.[4]

They are also stressed by job responsibilities, supervisors, irregular sleep schedule, shift work, and citizens at large. Thus, they have inadequate personal time. When individuals are overwhelmed by occupational stress, they suffer from increased chronic stress, HTN, depression, heart disease, gastrointestinal disorders, tobacco, alcohol, and drug use. Irregular lifestyle and work-related stress are responsible for the increased vulnerability of police personnel to many NCDs. Even though studies were available from few states of India, no such study had been conducted in Haryana. Hence, the aim of our study was to determine the prevalence of HTN and its risk factors among factory workers which may help in devising new strategies to bring about a healthy change in their lifestyle.

Various studies have reported significantly high prevalence of stress-related disorders such as HTN, diabetes, and cardiovascular diseases among different field workers. In a study, coronary heart disease has been identified as a major cause of mortality in this population.[5]

Objectives of Study

1. To study the prevalence of Hypertension among Factory workers.

2. To study the important socio-demographic factors associated with HTN.

Materials and Methods Study design and study participants A cross-sectional study was carried out from Jan 2021– March 2021 among 456 Factory workers posted in Udaipur city of Rajasthan which were selected randomly.

Inclusion criteria Serving Factory Workers who have had at least 2 year of service were included in the study.

Exclusion criteria: Those who were not willing to participate were excluded from the study.

Sample size calculation and sampling technique

Udaipur city has mining and other large scale industries where thousands for factory workers provide theri round the clock services. Assuming the prevalence of HTN as 30.5% (as per Ramakrishnan *et al*.[6]) and allowable error of 15% at 95%, level of significance, and using the formula $N = 4pq/L^2$, the calculated sample size was 414. However, considering the 10% attrition a sample size of 464 eligible participants was taken. Among those selected, 8 were excluded from the study as they left the study without any prior information. Hence, the final number of the sample we got 456.

Before conducting the study, a written permission was sought from each factory owner at Udaipur. The complete list of all factory workers was taken. A list of total of 850 factory workers were posted at various factories was taken and out of them, 456 factory workers were selected randomly from list. The investigator visited all factories at a time convenient to the study participants. After explaining, in details, the aims and objectives of the study, a written informed consent was obtained from all the participants. Socio-demographic details were obtained using predesigned, pretested, and semi-structured interview schedule. The investigator made two measurements of BP on each study participant with an aneroid anometer using a standard technique. [7] Persons in the age group of 18–58 years having systolic BP ≥140 mmHg and diastolic BP ≥90 mmHg or any level of BP in patients taking antihypertensive medication were considered as hypertensive.[8]

Statistical Analysis

Appropriate Statistical analysis was done by using latest SPSS version. For all variables, Chi-square test was applied to test the relationship between two categorical variables. *P* value of <0.05 were considered as statistically significant. Pearson's Chi-square test was used to evaluate differences between groups for categorized variables. Binary logistic regression analysis was used to evaluate the independent associations of various factors with the prevalence of HTN among Factory workers.

Results

A total of 142 of 456 participants were found to be hypertensive, so the prevalence of HTN came out to be 31.1% in our study. Among 456 study participants, 74 (16.3%) were already known cases of HTN but among them, only 29 (39.1%) were taking medicines regularly [Table 1].

Status		Table 1: Distribution of the study participants according to hypertension (n=456)	
		Frequency	Percent
HTN	YES	142	31.1%
	NO	314	69.9%
KNOWN CASE OF HTN	YES	74	16.3%
	NO	382	83.7%
REGULARLY TAKING TREATMENT	YES	29	39.1%
	NO	45	60.9

*HTN= Hypertension

[Table 2] shows the independent association of various factors with HTN. It was observed that age was found to be independent significant predictor of HTN. With increase in age, the odds of development of HTN were increasing and this was found to be statistically significant. Among the other factors, it was observed that the odds of development of HTN decreased with increase in educational status. However, this was not found to be statistically significant. Higher odds for the development of HTN were observed among the participants ranked mid level supervisors and above and among those who had more than 20 years of service duration although it was not statistically significant.

Table 2: Logistic regression for independent predictors of hypertension		
Variables		aOR (CI)
AGE		1.049 (1.009-1.101)*
EDUCATION	Matric	Reference
	Senior secondary	1.041 (0.568-1.827)
	Graduate	0.621 (0.313-1.170)
	Postgraduate and above	0.429 (0.081-2.561)

***Cont...* Table 2: Logistic regression for independent predictors of hypertension**

RANK	Unskilled workers	Reference
	Skilled workers	0.781 (0.245-.441)
	Mid level supervisors	0.563 (0.161-1.969)
	Senior supervisors	1.356 (0.517-3.575)
DURATION OF SERVICE (YEARS)	<10	Reference
	10-19	0.656 (0.261-1.679)
	20-29	1.319 (0.430-4.147)
	>30	1.043 (0.278-4.556)

*Statistically significant ($P<0.05$). aOR: Adjusted odds ratio;

CI: Confidence interval

[Table 3] Shows there was an increase in the prevalence of HTN with age, and this association of HTN with age was found to be statistically highly significant ($P = 0.005$). The prevalence of HTN was higher among those who had lower level of education, and this association between HTN and education was found to be statistically highly significant ($P = 0.005$). The prevalence of HTN was increasing with higher rank of workers and was found to be statistically significant ($P = 0.005$). As the duration of service increased, so did the prevalence of HTN with 20% among those with < 10-year service duration to 36.8% among those having service more than 30 years and it was found to be highly significant ($P = 0.002$).

Table 3: Association of hypertension with sociodemographic variables (n=456)				
Variables		**HTN**		**P**
		YES	**NO**	
AGE GROUPS	20-29	2(8.6%)	21(91.4%)	<0.0001*
	30-39	19(24.6%)	58(75.4%)	
	40-49	59(35.1%)	109(64.9%)	
	50 and above	62(32.9%)	126 (67.1%)	
EDUCATION	Matric	89(45.6%)	106 (54.4%)	0.005*
	Senior secondary	27(24.7%)	82(75,3%)	
	Graduate	24 (24.24%)	75 (75.76%)	
	Postgraduate and above	2 (3.7%)	51 (96.3%)	

***Cont...* Table 3: Association of hypertension with sociodemographic variables (n=456)**

RANK	Unskilled workers	15(12.7%)	103 (87.3%)	0.005*
	Skilled workers	51 (36.5%)	87 (64.5%)	
	Mid level supervisors	56 (37.08%)	95 (62.92%)	
	Senior supervisors	21 (42.%)	29 (58%)	
DURATION OF SERVICE (YEARS)	<10	16(20%)	64 (80%)	0.002*
	10-19	29 (29.0%)	71 (71.0%)	
	20-29	76(34.7%)	143 (65%)	
	>30	21 (36.8%)	36 (63.2%)	

HTN: Hypertension. *Statistically significant

Association of HTN with the age group was found to be statistically highly significant in our study (*P* = 0.005). Our study reported that the prevalence of HTN was the highest (32.9%) in the age group of 50 years and above and lowest (8.6%) in the age group of 20–29 years while it was 24.6% in 30–39 years of age group and 35.1% in 40–49 years of age group [Table 3].

Discussion

In our study, the prevalence of HTN among Factory workers came out to be 31.1% [Table 1] which is comparable with studies conducted by Ganesh *et al*.[9] among workers n urban Puducherry, by Prajapati *et al*.[10] among workers in Ahmedabad city, by Jahnavi *et al*.[11] . In another study by Martinez *et al*.[12] among metallurgic and siderurgic company′s workers in 2006 showed prevalence of 24.7% of hypertension and 11.4% for diabetes.[12] The prevalence of HTN was low in a study by Abu-Aisha *et al*.[13] among workers in Khartoum, Sudan, which was 27%. The reason for low prevalence may be due to study conducted in a different geographical area (Sudan) and probably because of difference in dietary pattern.

When modifiable behavioural risk factors like tobacco use, alcohol intake, physical activity, and dietary habits were assessed, it was found that 18.9% of factory workers fell in the category of current smoker/ smokeless tobacco user. This goes in line with another

study by Mou *et al*.[14] among migrant factory workers in China in 2012 where overall smoking prevalence (including occasional, daily, and heavy daily smoking) was 19.1% among factory workers which was less than the rates obtained for national population.[14] However, alcohol usage was more statistically significantly among the factory workers than other group. The obesity was present in 18.9% of factory workers although the results were not statistically significant. A study by Al-Zurba *et al*.[15] among non-Bahraini workers (labor force) in Bahrain in 2003 found that 30.6% of workers had BMI > 25.

For physical activity, it was found that inadequate physical activity was present in 97.3% of the population. This is in contrast to another study by Mehan *et al*.[16] in 2006 where about 17.3% of the subjects were categorized as physically inactive. In this study the tobacco and alcohol usage habit was prevalent in 31.4 and 5% of the study subjects, respectively. Inadequate fruit and vegetable intake was present in 100% of the workers as compared to 83% of the non-factory group. This is in accordance with another study by Mehan *et al*.[17] among chemical industry workers in Baroda in 2007 in which majority (93.2%) of the workers had low intake of fruits and vegetables. In another study by Kishore and Joshi[18] in 2001 among male workers in Delhi showed that prevalence of chronic illnesses like asthma, heart disease, and diabetes in businessmen and professionals

was higher than other categories of workers. Current tobacco, alcohol use and non-vegetarian diet was more prevalent in unskilled (41.61, 36.02, and 61.09%), semiskilled (42.57, 37.62, and 64.34%), and skilled (44.75, 36.96, and 61.09%) workers.

The present study shows that factory workers are not at a greater risk of developing NCDs as compared to non-factory worker with some exceptions like alcohol use, and fruits and vegetable intake. Other possible explanations for the results could be small sample size and healthy worker phenomenon. Healthy worker effect (HWE) is a phenomenon initially observed in studies of occupational diseases. It means that occupationally active people have a more favorable mortality experience than the population at large.[19] HWE phenomenon has also been shown in some other studies.[20] The results could also be influenced by statistically significant difference in educational status and monthly income.

The prevalence of HTN was higher among those who had lower level of education, and this association between HTN and education was found to be statistically highly significant ($P = 0.005$). Similarly education was significantly associated with HTN. This difference in the prevalence of HTN with educational status may be due to lower level of awareness about HTN among those with lower level of education which has an effect on their general attitude toward lifestyle modifications and health-seeking behavior. However, in studies by Prajapati *et al.*,[10] this association was found to be nonsignificant. Majority of our study participants were skilled workers (30.2%) and mid level supervisors (33.1%) followed by semiskilled (25.8%) and upper level supervisors rank (10.2%). The prevalence increased with higher rank, and this association was found to be statistically significant ($P = 0.005$) [Table 3]. Reason for higher prevalence of HTN with increase in rank may be attributed to enhanced work burden and responsibilities besides possibly rising age among the study participants.

As duration of service increased, a higher prevalence of HTN was observed, i.e., 21% in <10-year service duration and 36.8% in those having service more than 30 years and it was found to be statistically highly significant ($P = 0.002$). Putting in more years of service in such a job probably increases the vulnerability to HTN besides increasing age of the study participants along with increasing duration of service.

Conclusion

Hypertension among factory workers has emerged as an important public health problem. Knowledge of risk factors regarding HTN may give proper track for prevention in this population. Therefore, it is the need of hour to devise a sound screening strategy to diagnose HTN among factory workers at an early stage and comprehensive strategy for management of HTN which includes timely diagnosis, appropriate treatment, adoption of healthy lifestyle, and healthy dietary habits.

Recommendations

It is necessary to introduce screening through regular health camps at factory for factory workers to identify HTN at an early stage. Those at risk should be identified so that appropriate interventions can be instituted to prevent further progression of disease.

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Effect of Discoloration of Silver Diamine Fluoride versus Sodium Fluoride Varnish in Treatment of Carious Primary Teeth: ARandomized Clinical Trial

MarwaA. Salamoon[1], Nevine G. Waly[2], Eman S. Elmasry[2], Fatma Abdelgawad[3]

[1]Post graduate Student, Faculty of Dentistry, Cairo University, [2]Professor, Paediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Cairo University, [3]Associate Professor, Paediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Cairo University

Abstract

Background: Identifying successful and affordable method to manage decayed tooth in children with high risk caries or with difficulty to obtain proper dental care is very important to avoid probable complications and to decrease caries subsequent problems. Silver diamine fluoride (SDF) has been identified as an anticaries agent that successfully arrests dental decay and has the potential to address the epidemic of untreated decay in young children.

Aim: Evaluation of discolorationand failure of silver diamine fluoride and comparing it with sodium fluoride varnish.

Methodology: Sample size 62 Children with 298 carious primary teeth were selected following eligibility criteria and randomization was performed 1:1 allocation ratio: Group I: (38%) Silver Diamine Fluoride and group II: (5%) Sodium Fluoride Varnish. All patients recalled after 3,6,9 and 12 months to evaluate discoloration and failure.

Results: Comparison between both groups was performed using Chi square test which revealed that, group I was significantly higher regarding Black discoloration after 12 months, Group II was significantly higher than group I after 6- and 12-months regarding failure. Also, correlation between discoloration and failure revealed significant strong positive correlation in both groups.

Conclusion: Black discoloration is higher in group I, while failure is higher in group II.

Keywords: *Black discoloration, Pain free, Taste acceptability, Silver Diamine Fluoride and Sodium Fluoride Varnish.*

Introduction

Althoughdental caries, responsible for a low mortality rate, but it has a considerable influence on self-confidence. Teeth not only important for appearance but also it plays a great role in speaking and pronoun cation of many sounds.[1].

Teeth problems among children younger than 6 years old is described as Early childhood caries (ECC), which is as great worldwide health problem and considered one of the most predominant diseases in childhood (60% to 90% of children).[2,3].

Progression of untreated caries into the pulp of tooth induce pain and infection as it may spread systemically, in preschool children who are too young to withstandlong

Corresponding author:
Nevine Gamil Waly
Email: Dr_Nevinewaly@hotmail.com
Address: EL-Saraya St. Manial, Cairo, Egypt. Postal code: 11553, Telephone number: +20-101555055

dental treatment visits, its preferred to receive dental treatment under general anesthesia which poses a life-threatening risk to young children.[4].

Conserving a great part of the original, healthy tooth structure is the main goal of "minimally invasive procedures" as natural enamel and dentin are still considered as the best dental materials. Topical application of fluoride varnish considered as the most successful preventive method especially if applied every 3 to 6 months according to caries risk assessment. [9] Fluoride varnish not onlythe most successful topical fluoride agent. but also, it is considered as the only safe and practical topical fluoride agent [5].

Prevention of dental caries or delaying the progress that delay the needed treatment of the child till reach to more cooperative age can be obtained by using SDF as a preventive or therapeutic modality which depends on its combined advantageous effect of both silver and fluoride(3). However, the clinical application of silver fluoride compounds has been restrictedespecially in due to the black staining as silver compounds [6,7]

In spite of the hopeful results of SDF, the American Dental Association's Center for Evidence-Based Dentistry reported restricted evidence of using SDF among children [14]. Further clinical researches are essentialto evaluate patient acceptance, failure, and its relationship with discoloration. Also, they recommended the implementation of long term (more than 3 months) randomized clinical trials.[3]

Methodology

Study design:

This randomized Clinical Trial (RCT NCT03554980) was completed after approval by Research Ethics Committee, Faculty of Dentistry– Cairo University was gained (approval number 18.7.54).

Sample size calculation:

Power calculator for binary outcome superiority trial. was used (https://www.sealedenvelope.com/power/binary-superiority). Which revealed that a total sample size of 52 patients are required to compensate

loss to follow up 20% was increased to 62 and thus 31 per group.

Recruitment strategy:

Patients were recruited from outpatient clinic of Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Cairo University.

Eligibility criteria

All the included children should have onlydeciduous teeth without permanent teeth, high caries risk patients with carious lesions and unhelpful children without access to or with difficulty to obtain dental care.

Randomization and Allocation:

Patients assigned to one of the two experimental groups (1:1 ratio)

Patients grouping:

Group I (Intervention group 31 patients / 175 teeth):application of 38% Silver Diamine Fluoride SDF every 6 months.

Group II (control group 31 patients / 123 teeth): application of 5% Sodium Fluoride Varnish NaF every 3months.

· **Sequence generation:**through using Rondom. org.online software.

· **Allocation concealment:**by assistant supervisor using envelop technique.

· **Clinical procedures:**

1- Diagnosis: personal, medical and dental history were obtained, the intra and extraoral examinations were made. Also, baseline recordswere collected.

2- Clinical intervention:

· Patient preparation:

No operative intervention was initiated to achieve caries arrest, patient was protected with plastic-lined bib and glasses, cotton rolls were used for proper isolation. In group I, plastic dappen dish was used as SDF corrodes

glass and metal, while in group IIthe NaF was placed on the paper pod provided.

· **Application of tested material:**

The child waspositioned in supine position on dental chair, the affected tooth surfaces were dried with a gentle flow of compressed air, the micro sponge brush was bent on the dappen dish side to allow excessliquid removal before application.

In group I, the SDF was directlyapplied to the affected tooth surface only. the excess of SDF was eliminated using cotton roll to prevent systemic absorption. Also, isolation of the site was continued for up to three minutes as possible.

In group II, the NaF Varnish was evenly applied in a thin layer on all teeth surfaces directly, after application, the patient was instructed to close his or her mouth till complete varnish setting varnish.

· **Post-operative instructions:**

Patients of group I instructed to avoid eating or drinking for 30 -60 min., brush with fluoridated toothpaste at night not immediately after SDF application. In group II, parents instructed to don't brush or floss teeth for at least four hours and perfectly up to 24 hours after the treatment, eat soft food for the rest of the day, avoid rinsing or spitting after treatment, the teeth brushing with fluoride toothpaste should resume the following morning and children's parents or guardians were informed that the teeth may appear discolored temporarily.

3- Follow up:

The patients were recalled after 3, 6, 9 and 12 months to evaluate:

· Discoloration using visual examination of a carious lesion color that was performed by 2 assessors. Lesions determined to be successfully arrested when they black in color.

· Failure of treated teeth were assessed by the presence of pain and/or infection and visual observation of yellow color (indicate non arrested lesion).

Results

Regarding discoloration in group I, bothyellow and brown discoloration decreased gradually to 0, 2.9 % after 12 months respectively. On the contrary, black gradually increased to 95.4% after 12 months as presented in table. In group II, both yellow and brown discoloration decreased gradually to 12.2, 47.2 % after 12 months respectively. On the contrary, black gradually increased to30.9 % after 12 months. Comparison between both groups using Chi square test revealed statistical significant difference between both groups during (3, 6, 9, 12 months) except immediately as presented in table (1) and figure (1).

In failure, in group I, the highest failure percentage was at 9 months (4%), then decreased to (0%) at 12 months. While in group II, the highest percentage was at 6 months (5.3 %) then decreased to (4%) at 12 months. Comparison between failure of both groups revealed statistically significant difference after 6 and 12 months as presented in table (2).

Inter observer reliability coefficient (Kappa test) was used to evaluate the agreement between two assessors regarding discoloration and revealed strong agreement (IOC= 0.82) in group I at baseline while revealed almost perfect agreement in both groups regarding different follow up periods as presented in table (3).

In group I regarding failure, brown presented the highest percentage (100%) at 3 months, while at 6 months yellow and brown percentages were equal (50%), and at 9 months yellow revealed the highest percentages (57.1%). In group II, black presented the highest percentage (100 %) at 3 and (80%) at 9 months, while at 6 months, brown revealed highest percentage (87.5%) but yellow and brown were equal after 12 months (50%) as presented in table (4). Spearman`s correlation revealed a statistically significant difference with *P* value ($P = 0.00$)strong (r>0.6) positive correlation between discoloration and failure in both group Iand group II, as presented in table (4).

Table (1): Discoloration in both groups immediately, after 3, 6,9 and 12 months:

Discoloration		Group I		Group II		P value
		N	%	N	%	
Immediately	Yellow	30	17.10	27	22.00	0.24
	Brown	103	58.90	76	61.80	
	Black	42	24.00	20	16.30	
3 M	Yellow	2	1.10	22	17.90	0.001*
	Brown	2	1.10	66	53.70	
	Black	155	88.60	25	20.30	
6 M	Yellow	0	0.00	18	14.60	0.001*
	Brown	4	2.30	62	50.40	
	Black	155	88.60	29	23.60	
9 M	Yellow	0	0.00	16	13.00	0.001*
	Brown	5	2.90	62	50.40	
	Black	164	93.70	30	24.40	
12 M	Yellow	0	0.00	15	12.20	0.001*
	Brown	5	2.90	58	47.20	
	Black	167	95.4	38	30.90	

Group I: 38% Silver Diamine Fluoride SDF.   Group II: 5% Sodium Fluoride Varnish NaF.

*Significant difference

Table (2): Failure of both groups immediately, after 3, 6,9 and 12 months:

Failure	Group I		Group II		P value
	N	%	N	%	
Baseline	0	0.0	0	0.0	1.00
After 3 months	1	0.6	2	1.3	0.56
After 6 months	2	1.1	8	5.3	0.031*
After 9 months	7	4.0	5	3.3	0.71
After 12 months	0	0.0	6	4.0	0.02*

Group I: 38% Silver Diamine Fluoride SDF.   Group II: 5% Sodium Fluoride Varnish NaF.

*Significant difference.

Table (3): Inter observer reliability in both groups regarding discoloration report:

	Group I		Group II	
	IOC	Reliability	IOC	Reliability
Baseline	0.826	Strong	0.971	Almost perfect
3 months	1.00	Almost perfect	1.00	Almost perfect
6 months	1.00	Almost perfect	1.00	Almost perfect
9 months	1.00	Almost perfect	0.957	Almost perfect
12 months	1.00	Almost perfect	0.957	Almost perfect

Group I: 38% Silver Diamine Fluoride SDF.   Group II: 5% Sodium Fluoride Varnish NaF.

*Significant difference.

Table (4): Distribution of failure among discolored teeth and correlation between them:

	Discoloration	Failure										r	P
		Baseline		3 M		6 M		9 M		12 M			
		N	%	N	%	N	%	N	%	N	%		
Group I	Yellow	0	0.0	0	0.0	1	50	4	57.1	0	0.0	0.81	0.00*
	Brown	0	0.0	1	100	1	50	3	42.9	0	0.0		
	Black	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
	Total	0		1		2		7		0			
Group II	Yellow	0	0.0	0	0.0	1	12.5	0	0.0	0	0.0	0.67	0.00*
	Brown	0	0.0	0	0.0	7	87.5	1	20	3	50		
	Black	0	0.0	2	100	0	0.0	4	80	3	50		
	Total	0		2		8		5		6			

Group I: 38% Silver Diamine Fluoride SDF.   Group II: 5% Sodium Fluoride Varnish NaF.

*Significant difference

| a.   Group I discoloration at baseline, after 6month., and after 12 months | b.   Group II discoloration at baseline, after 6month., and after 12 months |

Figure (1): Discoloration of both groups.

Discussion

In the present study, the selected patients were less than 6 years old to ensure that they only have primary teeth. Additional, children in this age range may profit from postponed dental treatment and overall caries arrest. [3] Also, the written informed consent included detailed information in a simpleand understandable language about the research topic, such as possible benefits and harms, treatment procedures because SDF will darken tooth structure, so it is very important that parents understand this fact[8]

Therapy using fluoride application is relatively cheaper and easier treatment. In addition, it can arrest active dental caries because of fluoride ability to inhibit demineralization of enamel. Moreover, it can enhance remineralization of enamel, increasing the remineralization process speed. The incorporation of fluoride also makes the deposited mineral less soluble in acids[9] Also, Fluoride affect the ability of bacteria to produce a greatquantity of acid from carbohydrates [10]

The control group was NaF varnish according to the U.S. Preventive Services Task Force recommends application of fluoride varnish in children starting from age of primary teeth eruption till age of 5 years by primary care health professionals. A 5 % sodium fluoride varnish was considered as control group because the arrestment proportion of caries for sodium fluoride varnish according to [11-13]

Silver diamine fluoride was considered as intervention group. Because the American Academy of Pediatric Dentistry, 2017 stated that Silver diamine fluoride (SDF) is a brush-on liquid that arrest 87.7%

of dental caries lesions. The success rate is similar for restorations placed under general anesthesia[14-15].

A 5 % sodium fluoride varnish was applied every three months as recommended by American Dental Association ADA 2006 , American Academy of Pediatric Dentistry AAPD2018 and American Academy of Pediatric Dentistry 2017,another studies recommend application of 5 % NaF varnish every 3 months for children at high risk. Also, the best results were achieved in the treatment with 5 % NaF fluoride within a 3-month periodicity.[8, 16,17]

Regarding the Clinical procedure of SDF application there are important considerations and recommendations such as applying a protective coating (Vaseline butter) to the lips and skin to prevent temporary black stain, careful application with a micro-brush was adequate and no more than one drop of SDF was used for the entire appointment [8]

Comparison between both groups regarding discoloration revealed statistical significant difference between both groups in all follow up periods.However, discoloration of teeth after application of SDF was mentioned because of caries arrest in many studies [3] Similar to this study, another study reported that all children in SDF group came in their next visit at 3 weeks with all their treated teeth discolored. [4,18]

Regarding Correlation between discoloration and successfully treated teeth:In this study, the highest percentages were black in different follow up periods in both groups. Similar to another study which reported that the clinical success of SDF application in arresting active caries lesion may be absolutelyassociated with the presence of as a black stain appearing over the lesion (a protective layer)· [18]

In addition, other study reported that the arrested caries has a black, smooth, and hard surface when gently explored. However, according to the standards of care, a hard dentin surface and the dark color of an arrested lesion are valid clinical indications for positive outcomes benefitting the patient.[3]

In this study, the highest percentage of failure was observed in group II than group I with statistically significant difference at 6 months and 12 months, while revealed no statistically significant difference at baseline, 3 and 9 months. Despite the NaF caries-preventive effect, NaF varnish is ineffective at arresting coronal dentine caries. [19]

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Applied GIS: Critical Cartography and Geovisualization Methods and Techniques in Public Health Epidemiology, Arthropod Vectors Ecology and Surveillance

Masimalai Palaniyandi

ICMR-Vector Control Research Centre, ICMR-VCRC Field Station, Madurai-625002, Tamil Nadu, India

Abstract

Better understanding by mapping picturesque thematic information, and visualizing the actual burden of arthropod vector borne disease vertically and horizontally, using GIS, analytical cartographic and geo-visualization methods guide to select an appropriate methods for control and management of the disease. Both, the site specific public health epidemiology and entomological reality information on the grounds could be collected with GPS, and could be mapped under the GIS techniques. Different type of field survey methods and techniques could have been functional for the study of arthropod vectors surveillance, especially, mosquitoes, ticks, and mites vector abundance, and ecology, must have been essentially needed revision and updates for the achievements of goal move towards the betterment of vector borne disease control and management. Probability sampling (random sampling, systematic sampling, stratified sampling), and Non-probability sampling (convenience sampling, snowball sampling, quota sampling) existing conventional survey methods have been replaced with GIS scientific methods, used for public health epidemiological studies, and arthropod entomological study as well. Applied GIS contains the methods and techniques used for different field survey, such as; a systematic grid sampling techniques, GIS and GPS based reconnaissance survey methods, cluster sampling, stratified sampling, multistage sampling pilot sampling and random sampling survey with i) physiographic landscapes, ii) climate zones, iii) socio-economic structures, iv) settlement structures, v) land use / land cover categories, and vi) sampling survey in the buffering zones, etc., provides the accurate geo-coordinates site specific approach to portray the diversity and reliability of arthropod vector presents, and geovisualization of the vertical and longitudinal pattern of vector profusion, and thus, researcher and planners could be formed a datum of guidelines for arthropod vectors surveillance, and hence, preparing the indispensable prevention measures to vector borne disease control and management for sustainable health.

Key words: *GIS mapping, vector ecology, public health entomology, survey methods, spatial epidemiology, surveillance, mosquitoes, ticks, mites, arthropod vector borne diseases*

Introduction

Applied GIS is the structured spatial engine to include the range of techniques for amalgamation of collected entomological information, in which analyse vector profusion, diversity and its association with local environmental conditions, using geostatistics, and digital cartography and geovisualization methods [1-7]. Arthropod vectors include mosquitoes, sand flies, ticks, mites, bugs, lice, fleas, and biting midges, and other arthropod vectors which carry the pathogens, and act as an agent to transmit parasites mainly to animal and human host either by injection into the bloodstream directly, or through their salivary glands, or transmit by forcing parasites into a pool of blood which develops when masticating the body skin[8]. The neglected tropical diseases transmitted by arthropod vectors have public health importance, parasites causing fever by transmitted pathogens have obvious records

reported all over the world and significance. Choosing an appropriate sampling technique for field survey to collect vectors, disease ecology, and the epidemiological information has the most important role in visualising the real situation of the ground perfectly, further leads to plan accordingly to make proper choice for both vector and the epidemic control [9,10].

The combined cartography and geo-statistical methods are mandated to bring the information on the health planners table instead of keeping a bulk of records in the file, which provides the burden of epidemics, perpetrator behind in it, and their hidden risk factors including natural and manmade. Cartographic visualisation has been applied to trace the reason for the impulses of the tropical infectious disease epidemics from 18th Century onwards, and arrived to draw a conclusion scientifically [2-4]. The modern GIS techniques have replaced the classical cartographic visualization methods with high accuracy, speed, and comparatively low cost. Beyond mapping techniques, GIS has inbuilt combination of cartography, geo-statistics, cartography, computer science and engineering, mobile online database connectivity (ODBC), geodesy civil engineering (surveying and mapping), web mapping and real time embedded mapping, structured query language (SQL), decision support with spatial analysis and spatial modelling techniques, etc.,[1-16] The modern cartographic visualisation methods has been aid to shape for scientific conclusion on disease epidemics for several decades [3,9,10]. The state /national public health planners have made scientific thought about the vector and vector borne disease epidemics based on the single frame map on their table at a glance. The spatial and temporal aspects of disease prevalence provide guidelines about the disease burden, spatial extent, and diffusion trend. During and after the world war-II, prolonged famine, natural calamities and disasters including floods, tsunami, cyclone, terrific Toronto weather, landslides, monsoon failure and droughts are fuelled to many fold increase of infectious diseases including vector borne diseases. The advanced GIS mapping critical cartographic techniques, and geo-visualization methods aided to plan for the prevention and control in the appropriate manner lead to appreciate level [1-7].

Applied GIS: Cartography and Geovisualization

Geographical Information Systems (GIS) is a modern cartographic technology which could provide the answer to the many of public health or spatial epidemiological questions, such as; what is present (disease or vector)? Where is it (location)? How they are present (spatial patterns, diffusion direction, and vertical trends)? Which magnitude (vector abundance or number of disease)? Why it is there (reasons for vector presence or disease epidemics)? Raw data compiled in a file could not make any sagacity, and incredibly difficult to interpret the actual ground situation [3]. The huge numbers of commercial GIS software are available with comparatively low cost in the public market, and therefore, the GIS user experts have to choose the right software for their needs to accomplish the purpose [9,10]. At a glance, raw data could not provide the details of vectors [11], and vector borne diseases presence with have no site specific location with a particular shape, size (area), diffusion trend, and pattern, whereas, GIS analysis and mapping have fulfil the expectations of researchers and programmers [12-16]. Spatial analysis could be answered to find the disease origin or epic centre, magnitude, direction, trend of its spatial diffusion. As for the environmental pollution concern which affects nature, as a result, imbalance or deteriorating nature leads to human health issues, such as; physical illness, mental health, profusion and propagations of vectors, parasite development, and disease epidemics. Cartographic visualisation and GIS techniques are applied to endow with solutions for the environmental management to vector control, and prevent the vector borne disease epidemics. Cartographic results shows the disease burden of the community visualise the prospect risk of neighbours with infectious disease in a definite time point. The applied GIS has no limit in its applications, and used to conduct a field survey, choosing a sampling techniques, to develop a database information management, answer the structured queries, portray of the vector density, mapping the ecology, disease epidemics, guidelines to public health personnel about the disease magnitudes, spatial disparity or ubiquitous of the health services, beyond all, it could be provided the visual pictures of the epidemics, vector ecology, enlist the causative risk

factors of the diseases (man made causative risk factors, socio-economic inequalities, climate, and environmental determinants), lead to predict the disease transmission in the newer areas, and address the difficulties through map guidelines to use as investigation apparatus to draw the new insights to good public health management. Spatial and temporal analysis of diseases, using GIS has been addressed to standardize the both vertical and horizontal structure of the communicable disease patterns with site specific at a particular time point, and as a result, the public health administrators choose a required control strategy to maintain sustainable health.

Survey Methods and Techniques

For both vector ecology and disease epidemiology, survey methods and techniques are varied with its purpose. Probability sampling (random sampling, systematic sampling, stratified sampling, buffering, multistage sampling, cluster sampling, pilot sampling), and Non-probability sampling (convenience sampling, snowball sampling, quota sampling) are used to collect the field sample primary data relevant to vectors and the patients.

Probability sampling: A systematic grid sampling techniques are applied to collect the fixed number of field data within the lattice boundary limits. Random sampling is used to ascertain the predicted value of vector abundance or risk of epidemic transmission or predicted map value using Kriging spatial interpolation methods (Simple Kriging/ Co-Kriging, Universal Kriging, Indicator Kriging, Probability Kriging, Disjunctive Kriging, Empirical Bayesian Kriging, and Areal Interpolation) used to assign the continuous spatial value for the unknown points in an area or not easy access point or data is not available, using a set of mean tendency of values in neighbouring grid segments or global means, applied within geo-statistical methods [3,15]. Buffering technique has been employed to fix the trap to collect the immature and the adult vectors, as well as the collecting the epidemiological information within the fixed radius boundary limit to assess the spatial agreement between the vector breeding surroundings, vector profusion, and vector borne disease epidemics.

Buffering have made along the rivers, lakes / pools / dams / water reservoirs, rice fields, human settlements, roads, railway lines, forest land covers, , etc., [14]. Multistage sampling is applied to study the disease epidemiology in the different age group at a particular community or conveniently, in different locations / area codes [14,16]. Cluster sampling is employed to collect samples in the different unique clusters (for example- vectors: low density, moderate density, high density or disease- low risk, moderate risk, high risk). Pilot sampling is used to collect samples in a fixed radius, size, and shape boundary limit randomly fixed in number of sample sites in different land use / land cover categories/ different ecosystems/ physiographic landscapes/ different climate zones [14,16].

Non-probability sampling: Convenience sampling methods is not fixed or restricted to collect samples, and it depends upon the researcher / field investigator convenient [16] (for sample: i) Socio-economic inequality and human health based on the field quantum sampling techniques, ii) Knowledge, Aptitude, and Practice of prevention methods and control of vector borne diseases among the different community). Snowball sampling is used to recruit the people for testing the newly developed vaccine or medicine, if the test is proved positive results, the researcher has to keep on increasing the sample test. Quota sampling is a stratified sampling employed to collect the samples within the administrative boundaries (for example: Recruit the patient's quota samples to study the education level and health status in the different community or different age groups of the different districts/ state/ country).

GIS for mapping vector ecology and surveillance

Disease ecology and epidemics have been mapped and spatial autocorrelation was well documented by a physician John Snow who traced the cholera occurrences which claimed 616 deaths toll associated with a selective drinking water pump supplied contaminated drinking water in London, UK, during 1854 [1-5]. Vector borne disease epidemics control and management could be achieved by one of the ways is a systematic regular real time vector surveillance [6,11]. GIS has been used

to mapping vector ecology, and categorize the vector profusion for the purpose of site specific vector control target with right method for the effective vector control and prevention of epidemics transmission in different locations where the probability of arthropod vector borne diseases viz; malaria, dengue, chikungunya, yellow fever, West Nile Virus, Japanese Encephalitis, Zika virus (ZIKV), Lyme disease, filariasis, Leishmaniasis, etc., become high risk [7,9,10]. GIS has been applied to execute spatial analysis and develop an ecological niche modelling to study the spatial relationship among the ecology, vector abundance, and outbreaks. Previous studies were carried out to study the rice agriculture fields and *Anopheles* mosquito's malaria vector abundance, household's access to streams / water pools located within buffer zone 2.5 Km. *Aedes* mosquitoes breed in containers in and around households, rubber and pineapple plantation, dengue vector abundance, dengue epidemics and ZIKV [11]. Japanese Encephalitis and West Nile Virus (WNV) vector habitats are associated with aquatics environment, wild migratory birds, wild animals, mollycoddle animals, and human accessibility, and *Culex quinquefasciatus* vector mosquitoes transmit parasite *Wuchereria bancrofti* causes lymphatic filariasis, avian malaria, and vector abundances are closely associated with coastal belts, river plains, and alluvial soils distributed in the sub-tropical regions, and *Mansonia* mosquitoes causes brugian filariasis which are breeding in a aquatics floating habitats like *Pistia stratiotes* and *water hyacinth* [8,912,14]. The study of public health entomology, vector ecology, spatial topology, and environmental epidemiology has momentous insights to practise appropriate prevention measures to reduce or control outbreaks in the right time. Reveal and ranking the causative risk factors spatially associated with hierarchy of epidemic risk zones, based on the functional categorization of ecosystems, and their suitability for both immature and adult vector survival, and profusion. Global Positioning Systems (GPS) have used to collect the both immature and the adult vector data in the field with exact geographical locations, subsequently imported to the Geographical Information System (GIS) spatial expert engine which allows the collected data to map visualization of the

data for the seasonal investigations [9]. Mapping of vector ecosystems and the vector borne diseases, using GIS accurately classified into endemic, non-endemic, epidemics, chronic suffering, morbidity, disability, and sporadic stigmatization of the infections have been prepared, as a result, both vector control and prevention of outbreaks could be achieved successfully [9,10].

Mapping Techniques in Public Health Epidemiology

Different quantitative mapping techniques were applied to portray the data perfectly [1-5,10]. Each quantitative technique has the significant effect on map illustration and visual impact on a frequency distribution of the vector as well as epidemiological data (equal interval, quantile, equal groups, equal density, log interval, etc.,) , and therefore, choosing a right quantitative method is highly important for mapping and analysing spatial epidemiological data [10]. Fundamentals of critical and analytical cartographic and geo-visualisation knowledge must be chosen to employ for correct pictorial representation of ground reality. Chorochromatic, choroschematic, and choropleth are applied to functionally classifying different themes with different colours, different symbols or pictorial representation on various scales; different colours or line shadings / size and number of dots per inch are used to distinguish the different infectious diseases distribution concentration respectively [10,13]. Digital Terrain Elevation Model (DTEM) in 3D pictures are created to analyse the landscape ecology, slope, vegetation cover, urban land use planning for choosing a sites for hospital, school, markets, residential dwelling, parks, auditorium, health hazard disposals grounds, construction of underground canal / drainage systems for proper discharge of industrial, hospital, and household liquid waste for betterment of environmental safety, and human sustainable health. Critical cartography in public health has main focus on mapping of infectious disease epidemiological data started with map representation, and followed by map generalization, map overlay, map interpolation, map topology, map query, and the rational map generation ready to exercise for the optimum health delivery services, disease epidemic

control, and management of the crucial situations [1-5,10,13]. Mapping techniques have been used in public health over 160 years, and it has been further refined with integral part of multidisciplinary approach, as a result, spatial analyse, and spatial modelling have been used to move the next steps towards the decision making for betterment of human health [1-5]. The mapping concept has been gifted intelligent to fuse public health epidemiological information, and facilitated key elements of components scientifically, and to practice evidence based adequate strategy by collaborating multisectoral and multidisciplinary expert of different public health stakeholders including the researchers, pharmaceuticals investors, and medicine suppliers for better improvement human illness leads to move towards the national sustainable health.

Conclusion

The distribution of vectors and disease outbreaks are determined by complex phenomena, and it is much more difficult to understand the problems and their spatial cognitions with available raw data on the round table discussion. Applied GIS for mapping, spatial analysis, and geospatial modelling aided to visualise the spatial and seasonal variation of the both vector density and disease epidemics to pinpoint, and to appreciate the key risk factors force in functional behind the public health issues. Map prophecy provides the guidelines to understand the key elements of vector ecology, locality of patient's house hold locations, risk of neighbourhoods, hospitals sites, transport networks and health service facilities. Therefore, the public health entomologist, and communicable disease salutary officials have been integrated in course of action arrival to making final decision to plan a choice of operational targets to vector control and surveillance to prevent the outbreaks early in advance successfully.

Conflict of Interest: Nil

Source of Funding: Self

Ethical Clearance: Not applicable

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Single versus Double Umbilical Cord Blood Transplants: A Meta-analysis of Comparative Studies Umbilical Cord Blood Transplants

May AlMoshary

Assistant Professor, Basic science department, College of Medicine, Princess Nourah Bint Abdulrahman University, Riyadh,Saudi Arabia

Abstract

Background: A number of alternatives has been proposed, including umbilical cord blood transplant (UCBT), in patients who do not matched donors for hematopoietic stem cell transplantation (HSCT). However, there are conflicting results regarding the role of the two units UCBT (dUCBT) compared to single unit (sUCBT). The present systematic review and meta-analysis aimed to compare the outcomes of dUCBT versus sUCBT in patients without suitable HLA-matched donor

Material and Methods: We performed an electronic search in the following bibliographic databases: Medline via PubMed, SCOPUS, Web of Science, and Cochrane Central Register of Controlled Trials (CENTRAL). Both prospective and retrospective studies which compared sUBCT and dUBCT were included. Data were analysed using RevMan version 5.3 for windows.

Results: The present review included 12eligible studies. The overall effect estimates did not favour either of the two groups in terms of neutrophil engraftment (OR =0.92, 95% CI [0.71, 1.19]; p =0.52), palatals engraftment (OR = 1.10, 95% CI [0.79, 1.53]; p =0.59), relapse rates (OR = 1.31, 95% CI [0.82, 2.09]; p =0.26) 5-year disease-free survival (OR = 0.87, 95% CI [0.59, 1.28]; p =0.49), and 5-year overall survival (OR Figure.6). However, the overall effect estimates favoured sUCBT group over the dUCBT group in term of the incidence of grade 2-4 GVHD (OR = 0.66, 95% CI [0.45, 0.97]; p =0.03).

Conclusion: In conclusion both sUCBT and dUCBT have comparable results in terms of engraftment success, relapse rates, transplant-related mortality, and overall survival. However, dUCBT is associated with higher risk of acute GVHD which further limit any potential advantages of the dUCBT.

Keywords: Umbilical cord transplants; hematological malignances; Meta-analysis

Introduction

Over the past few decades, the uses and indications of hematopoietic stem cell transplantation (HSCT) have

increased dramatically; HSCT become the cornerstone treatment modality for the management of many hematological disorders and malignancies. Allogenic SCT involves replacement of the immune system of patients with immune dysfunctions or restoration of the bone marrow after total body irradiation for patients with hematological malignancies[1]. However, allogenic-SCT requires the presence of human leukocyte antigen (HLA)-matched siblings as donors in order to be effective and to avoid the hazards of graft rejection[2]; according to previous reports, almost 70% of patientsin

Corresponding author:
May AlMoshary
Affiliation: Basic science department, College of Medicine, Princess Nourah Bint Abdulrahman University, Riyadh, Saudi Arabia.
Mobile: +966 50 312 5551
Email: Hemmai2020@yahoo.com

Western countries, who are indicated for allogenic HSCT, do not have an available HLA-identical sibling [3]. Therefore, a number of alternatives has been proposed including the transplant from unrelated HLA-matched donors,haploidentical donors, and umbilical cord blood transplant (UCBT)[4].Unrelated UCBT are cryopreserved graft source that has emerged as an effective alternative of allogenic-SCT in case of absence of matched-donor; the UCBT are relatively immunologically-free with less risk of immune-mediated complication[5]. Previous retrospective studies have shown that UCBT led to comparable survival to unrelated bone marrow transplants in children with lacking of an acceptable HLA-matched donors[6].

On the other hand, the limited number of T cells in a UCBT product is a major drawback to the technique; it was reported that 10-20% of the UCBT recipients are at increased risk of graft rejection due to low stem cell doses[7,8]. Thus,transplantation of double UCB (dUCBT) units has been proposed in order to increase cell dose, especially in adult patients[9]. Although the dUCBT showed early promising results in terms of graft failure, an increased incidence of graft-versus-graft (GVG) effect was noted among dUCBT recipients, compared to single dose UCBT (sUCBT)[10], which can limit the beneficial role of dUCBT in the case ofinadequate cell dose. In order to compare the effectiveness and safety of both modalities, a growing number of retrospective studies and clinical trials were conducted with conflicting results[11,12].

Therefore, we conducted the present systematic review and meta-analysis to synthesize evidence from the published literature regarding the safety and efficacy of dUCBT versus sUCBT in patients without suitable HLA-matched donor.

Materials and Methods

We confirm that the presentsystematic review and meta-analysis run in concordance with the recommendations of Preferred Reporting Items of Systematic and Meta-analyses (PRISMA) and Meta-analysis Of Observational Studies in Epidemiology (MOOSE) statements[13,14].

Inclusion and Exclusion Criteria

In the present study, we included studies that meet the following criteria: (1) studies that included children or adults, who were indicated for unrelated HSCT, with the absence of suitable HLA-matched donor; and (2) studies that compared the efficacy and safety of dUBCT versus sUBCT in this type of patients. There were no restrictions regarding the type of study designs or the characteristics of the included patients. In the case of multiple reports, we included the most completed report. We excluded non-English studies, reviews, thesis, and conference proceeds.

Search Strategy and Screening

An online bibliographic search of the following databases was conducted from the their inception till December 2018: Medline via PubMed, SCOPUS, Web of Science, and Cochrane Central Register of Controlled Trials (CENTRAL) using different combination of the following keywords:Umbilical cord blood transplant; hematological disorders; and double units. Retrieved citations were imported into EndNote X7 for duplicates removal. Subsequently, unique citations were imported into an Excel sheet and screened by two independent reviewers; the screening was conducted in two steps: title and abstract screening, followed by a full-texts screening of potentially eligible records.

Data Extraction and Efficacy Measures:

Data entry and processing were carried out using a standardized Excel sheet and two reviewers extracted the data from the included studies. The extracted data included the following domains: (1) Population and methodological characteristics of the included studies; (2) Risk of biasof studied populations, and (3) Study outcomes. The reviewers' independently extracted data from the included articles and any discrepancies were solved by discussion. The outcomes measurements, in studies compared dUBCT versus sUBCT, were: transplant-related mortality, primary engraftment failure, incidence of GVG effect, disease-free survival, and overall survival.

Risk of Bias Assessment

The quality of the retrieved randomized controlled trials (RCTs) was assessed according to the Cochrane handbook of systematic reviews of interventions 5.1.0 (updated March 2011 which included the following domains: sequence generation (selection bias), allocation sequence concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective outcome reporting (reporting bias) and other potential sources of bias. The authors' judgments are categorized as 'Low risk', 'High risk' or 'Unclear risk' of bias[15]. On the other hand, the quality assessment of observational study was assessed using new-castle Ottawa scale (NOS) which included the following domains: the selection of the study groups; the comparability of the groups; and the ascertainment of the exposure or outcomes. A sum quality score was calculated for each study (range 1 -9) and the studies were categorized into high (score 1-3), moderate (score 4-6), and low (score 7-9) risk of bias[16].

Data Synthesis

We performed a paired comparisons meta-analysis using Review Manager (RevMan) version 5.3 software for windows. Dichotomous data were pooled as odds ratio (OR) with 95% confidence interval (CI) using Mantel-Hansel method. The heterogeneity of the pooled effect estimates was quantified by the I^2 and the corresponding p-value.The random-effects modelwas applied based on the assumption of the presence of substantial heterogeneity between the included studies. All reported p values were two-sided, and p-value< 0.05 was considered statistically significant.

Results

Literature Search Results

We retrieved 1121 unique citations after the initial bibliographic search. Then, we retained 42 potentially eligiblerecords afterthe initial title and abstract screening for full evaluation. Finally, 25studies

(RCTs=2; Prospective =2; Retrospective =21 studies) were included in the present systematic review and meta-analysis..

Characteristics of studies

The present meta-analysis included 25 studies with 6571 patients (sUBCT =3245 patients; dUBCT =3326 patients). All included were retrospective cohort studies, exceptfour studies; two studies were RCTs[11,17] and the other two studies were prospective studies[18,19]. The sample size of the included studies ranged from 19 to 1494 patients with a median follow-up that ranged from 19 to 57.4 months. Notably, there were substantial variations in the characteristics of the patients who received UBCT among the included studies.In addition, the included studies reported conflicting results regarding the efficacy and safety of dUBCT versus sUBCT.

Risk of Bias Assessment

The two included RCT exhibited low risk of selection bias, high risk of performance bias, and low risk of bias of other domains inthe Cochrane risk of bias tool. With regard to the included observational studies, the risk of bias ranged from moderate to high according to the NOS; all studies had high risk of bias incomparability and follow-up domains**.**

- Outcomes

Graft Failure

Twelve included studies reported the success rate of neutrophils engraftment in sUCBT (N =915 patients) and dUBCT groups (N =1235 patients), the overall effect estimates did not favoureither of the two groups (OR =0.92, 95% CI [0.71, 1.19]; p =0.52); no significant heterogeneity was identified (p =0.43; **Figure.1**). On the other hand, seven studies reported that the effect of UBCT on the success rate ofplatelets engraftment, the overall effect estimates did not favoursUCBT or dUCBT groups (OR =1.10, 95% CI [0.79, 1.53]; p =0.59); however, significant heterogeneity was identified (p =0.05; I^2 =52%).
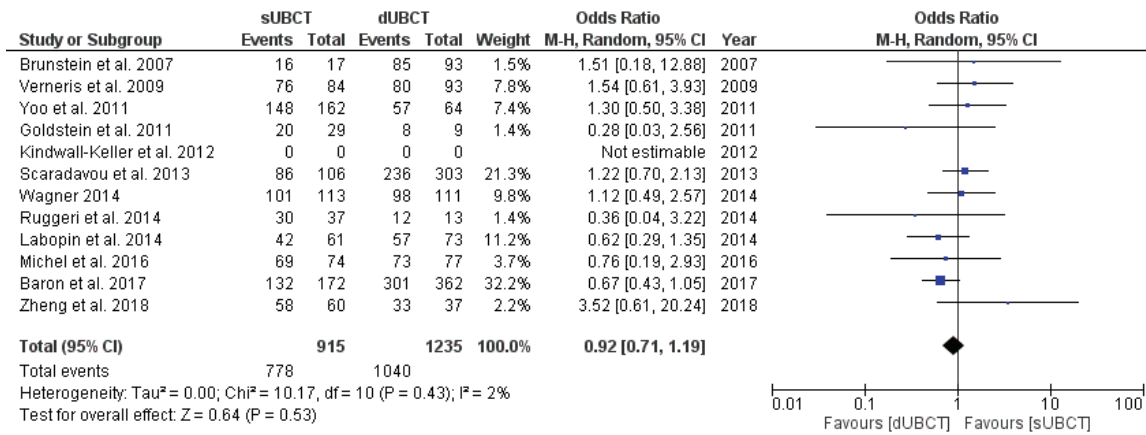
Figure .1: Forest plots shows the difference in the neutrophil engraftment success rates between sUCBT and dUCBT groups

Relapse and Survival

Eight included studies reported the rate of relapse in sUCBT (N =849 patients) and dUBCT groups (N =1435 patients), the overall effect estimates did not favour either of the two groups (OR =1.31, 95% CI [0.82, 2.09]; p =0.26); there was a statistically significant heterogeneity (p <0.001, I^2 =78%; **Figure.2)**. In addition the 5-year disease-free survival (OR =0.87, 95% CI [0.59, 1.28]; p =0.49; **Figure 3**) and 5-year overall survival were no significantly different between both groups.
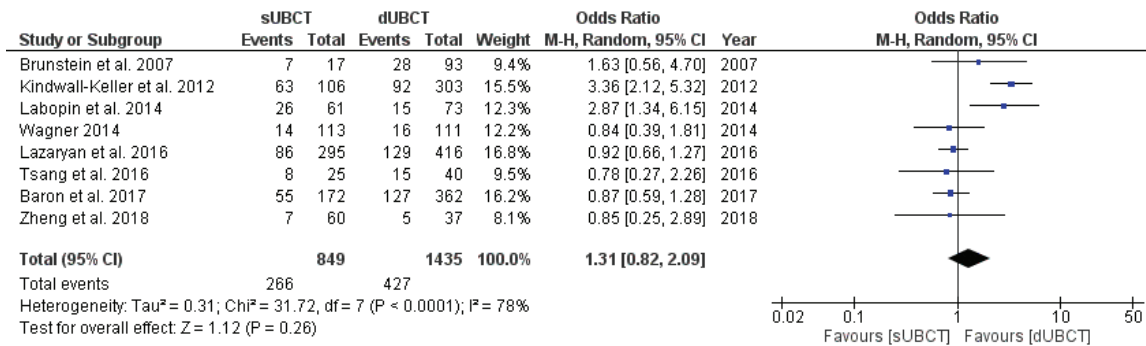
Figure 2:: Forest plots shows the difference in the relapse rates between sUCBT and dUCBT groups
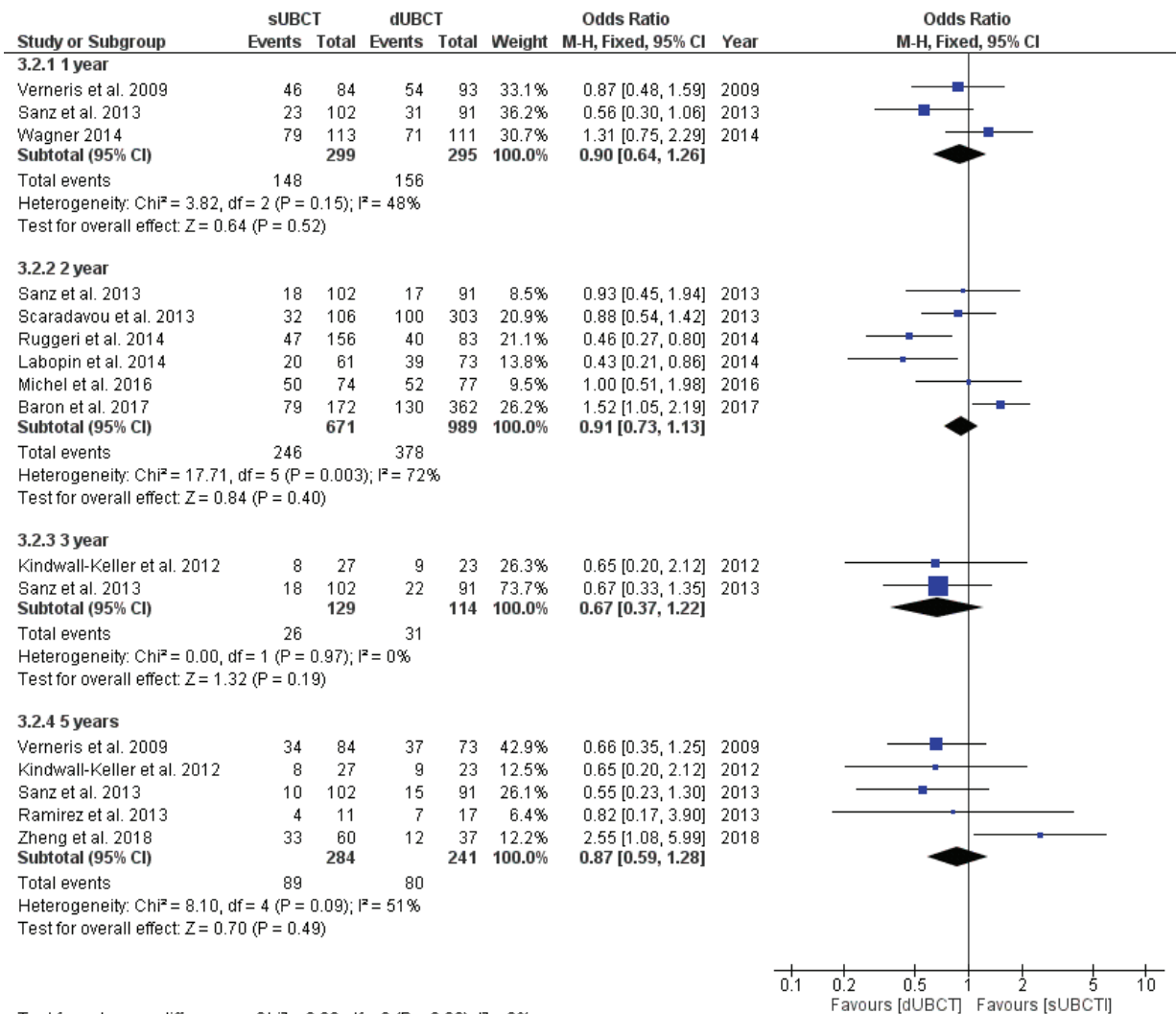
Figure 3: **Forest plots shows the difference in the disease-free survival between sUCBT and dUCBT groups**

GVHD

On the other hand, 11 included studies reported the differences in the incidence of grade 2-4 acute GVHD between sUCBT (N =1866 patients) and dUCBT groups (N =1932 patients), the overall effect estimates favoured sUCBT group over the dUCBT group (OR =0.66, 95% CI [0.45, 0.97]; p =0.03); there was a significant heterogeneity in the pooled effect estimate (p <0.001; I^2 =82%. Similarly, 12 studies reported the incidence of grade 3-4 acute GVHD in sUCBT (N =1949 patients) and dUCBT groups (N =2052 patients), the overall effect estimates favoured sUCBT group over the dUCBT group (OR =0.73, 95% CI [0.53, 1.00]; p =0.05); there was a statisticallysignificant heterogeneity (p =0.007; I^2

=57%). In contrary, the overall effect estimate did not favour any og the two groups in terms of the incidence of chronic GVHD(OR =0.76, 95% CI [0.54, 1.08]; p =0.12) and any extensive GVHD.

Discussion

There is no consensus in the published literature regarding the role of administration of two units of UCBT on the engraftment success and survival rates. The present systematic review and meta-analysis showed that there were no statistically significant differences between sUCBT and dUCBT in terms of neutrophils and platelets engraftment. In addition, the 5-year disease-free survival and the overall survival were no significantly comparable between both groups. On the

other hand, the results showed that patients receiving dUCBT are at increased risk of developing grade 2-4 acute GVHD; while the overall effect estimate did not favour any of the two groups in term of the incidence of chronic GVHD. Notably, there were statistically significant heterogeneities in the most of the pooled effect estimates.

Graft failure is a devastating condition that may complicate stem cell transplantation, the failure mainly occurs as a result of graft rejection or severe septicemia and may be manifested by lack or slow engraftment of donor cells[20]. As the UCBT contains limited total nucleated cell and CD34+ cell dose, it carries a higher risk of graft failure than the expected from other transplant options[21]. Therefore, the dUCBT was proposed as a potential guard against graft failure by increasing the cell dose. Our results showed that there were no statistically significant differences between sUCBT and dUBCT groups in terms of success rates of neutrophils and platelets engraftment. In concordance with our findings, a recent systematic review showed that the majority of the published literature reported comparable rates of neutrophil and platelet engraftments after sUCBT and dUBCT[22]. This finding was similar to the results of the only two published RCTs that compared dUCBT with sUCBT[11,17]. Another study reported no difference in engraftment rate between different types conditioning[23]. Nevertheless, other retrospective studies reported higher engraftment rates after sUCBT, compared to dUCBT[24].

The current body of evidence shows that UCBT is associated with lower risk of relapse compared mismatched transplants and haploidentical transplant[25,26]. Moreover, UCBT was reported to have higher 3-years survival than HLA-mismatched unrelated donor transplants[27]. However, there are conflicting results regarding the effect of the number of UCBT units on relapse ratesand overall survival. In the present meta-analysis, there were no statistically significant differences between sUCBT and dUCBT in terms of relapse rates, disease-free survival, and overall survival. Similarly, Wang and colleagues[22] more than half of the published literature showed comparable relapse rates and overall survival between the two groups. In contrary, a previous prospective study reported a lower relapse risk after infusion of dUCBT.

The present systematic review and meta-analysis has a number of strength points. The review run in concordance with the recommendation of the Cochrane handbook and PRISMA, and MOOSE statements. However, we acknowledged the presence of some limitations. The majority of the included studies were retrospective cohorts which may lead to the introduction of many methodological biases including recall bias and misclassification. In addition, there were statistically significant inconsistencies in the pooled effect estimates which may be due to wide variations in the characteristics of studies' population, designs, and transfusion protocols. Moreover, the methodological quality of the included studies was from low-to-moderate which may affect the quality of the present evidence.

In conclusion, the present meta-analysis showed that both sUCBT and dUCBT have comparable results in terms of engraftment success, relapse rates, transplant-related mortality, and overall survival. However, dUCBT is associated with higher risk of acute GVHD which further limit any potential advantages of the dUCBT. However, it should be noted that there were substantial variations in the methodology of the included studies, which led to substantial statistical heterogeneity in the pooled effect estimates. Moreover, only one two RCTs assessed the role of dUCBT, while the rest of included studies were retrospective cohort studies. Thus, it appears that the current evidence is insufficient to support the clinical decision and further well-design studies are still needed.

Conflict of Interest: All authors confirm no financial or personal relationship with a third party whose interests could be positively or negatively influenced by the article's content.

Ethical Clearance: As the present study is a systematic review of the literature, the need for ethical

approval from the local ethics committee of Princess Nourah Bint Abdulrahman University was waived.

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Original Article:

Hepatitis B Vaccinationstatus and Status of Vaccine Non-Responders among Healthcare Workers in a Tertiary Care Hospital of Western Uttar Pradesh

MehakManro [1], Anita Pandey[2], Priyanka Chaturvedi[3], Kaynat Naseer[4]

[1]Resident PG, [2]Professor & Head,[3]Tutor Post PG , Post Graduate, Department of Microbiology,
[4]Assistant professor Department of Community Medicine , Subharti Medical College and Associated
ChhatrapatiShivajiSubharti Hospital, Meerut, (U.P.), India

Abstract

Background and Aims: Health care workers (HCWs) are at risk of acquiring Hepatitis B Virus infection (HBVI). Despite being a vaccine preventable disease, the vaccine "non-responders" are at a constant risk of acquiring infectiondue to lack of seroconversion. The current study aims to evaluate theHepatitis B vaccination coverage and status of vaccine non-responders among HCWs in a tertiary care hospital.

Methods: Among the 183 participating HCWs, 11(6.01%) who were Hepatitis B surface antigen (HBsAg) positive were excluded from the study. Estimation of anti-HBs titre was determined in HBsAg negative individuals. The HCWs with antibody titre <10mIU/ml (non-response) were identified and revaccinated. Post-vaccination titre in these individuals was reassessed 1-2 months after the last dose of both the vaccination series to look for sero-conversion and finally identify the vaccine non- responders.Individuals who did not seroconvert even after the 2nd series of vaccination were thus labelled as "non-responders".

Result: Overall, 72.67 % HCWs were immune (anti HBs titre ≥10mIU/ml). Male population, age ≥50 years, smokers, history of hospitalisation, previous operations and dental procedures in the past were the predisposing factors identified in non-response HCWs. Sero-conversion was seen in 96% of non- responsive HCWs. A total of 4% HCWs were vaccine "non-responders".

Conclusion: Complete vaccination coverage was low among health care workers. The vaccine non-responders were identified,counselled and posted at low risk area for their safety. Every health care organizationshould have a mandatory policy to vaccinateall the HCWsirrespective of their vaccination status at the commencement of their joband monitor their post vaccination antibody titre.

Keywords: *Health Care Worker, Hepatitis B Virus, anti- HBs titre, vaccine non-responders*

Corresponding Author:
Dr.Anita Pandey,
Professor & Head, Post Graduate Department
of Microbiology, Subharti Medical College and
Associated ChhatrapatiShivajiSubharti Hospital,
Meerut, (U.P.), India, Phone number: 9837717720
E-mail address: anipanmicro@gmail.com

Introduction

Hepatitis B virus (HBV) is a highly contagious blood-borne infection which can lead to the development of liver disease.[1] It is the most important occupational health hazard among the Health Care Workers (HCWs).[2] Due to frequent handling of blood and body fluids of patients,HCWs are four times more at risk of contracting

HBV infection as compared to the general population.[3] Immunization with Hepatitis B vaccine remains the most effective way of prevention of HBV infection (HBVI).[4] Following complete series of vaccination in an individual, an anti- HBs titre of ≥10mIU/ml is immune (protective antibody titre), titre between 10 and 100 mIU/ml is considered as hypo-response, titre of >100mIU/ml is high level of immunity and titre of < 10mIU/ml is considered as non-response.It has been shown that even after complete vaccination series (3 doses), the prevalence of non-response ranges between 10 - 15% , thus highlighting the importance of estimation of post-vaccination anti-HBs titres.[5]Some individuals fail to get protective antibody titre even after two complete series of vaccination and are labelled as "non-responder".[6] It has been shown that age, gender, obesity, smoking, immunity, and genetic predisposition might be factors responsible for reduced immune response to vaccination in some individuals. [7]

To the best of our knowledge this is the first study carried out from this geographical area which aims to evaluate the Hepatitis B vaccine statusand status of vaccine non-responders among the HCWs in a tertiary care hospital. An attempt has also been made to identify various factors responsible for reduced immune response.

Methods

A cross-sectional study was conducted among 183 participating HCWs in a tertiary care hospital. The participation was voluntary and informed consent was duly obtained from all the participants before conducting the study. The participants included doctors, post graduate (PG) students, nursing staff, technicians (OT & Lab technicians) and housekeeping staffs (cleaning staff and attendants). HCWs irrespective of age, both genders and Hepatitis B surface antigen (HBsAg) negative were included. Those with past history of jaundice or other chronic liver disease, pregnant women and who were HBsAg screen positive were excluded. The demographic data such as age, gender, designation, department, personal health information and vaccination detail was noted in a self-structured questionnaire (Table 1) distributed to all the participants.

According to the vaccination history given by the participants in the questionnairethey were grouped into 5 subgroups: i) completely vaccinated: participants who had received all 3 doses of HB vaccine. ii) incomplete/partially vaccinated: participants who had received only one or two doses of vaccine. iii) non-vaccinated: participants who had not received any dose of vaccine. iv) unknown: participants who were unaware of neither their vaccination status nor the number of doses received. v) booster dose vaccinated: participants who had taken complete vaccination followed by booster dose after 5 years .

All the serum samples collected were first screened for HBsAg by rapid immune-chromatographic test (Standard Q HBsAg test, SD Biosensor Healthcare Pvt. Ltd). The HBsAgscreen negative serum samples were then subjected for estimation of anti-HBs titre by ELISA (DIA.PRO, Diagnostic BioprobesSrl; San Giovanni, Milano Italy) as per manufacturer's instructions to look for presence of protective immunity (titre ≥10mIU/ml). The non-immune (non-response) individuals (titre <10mIU/ml) were identified and motivated for complete 3-dose series vaccine irrespective of their previous vaccination status. These non-response HCWs were subjected for serologic testing 1–2 months after the last dose of vaccine to look for sero-conversion as per the recommendation of Advisory Committee on Immunization Practices (ACIP).[4] Those who did not sero-convert after the first dose were given the second vaccine series to finally identify the vaccine non-responders. However after 2 series no further routine doses or testing wasindicated in these individuals.[6]

Statistical Analysis

SPSS software version 25 (IBM, SPSS statistics) was used for statistical analysis. Chi-square test was performed for data analysis. The p values below 0.005 were considered to be significant.

Results

A total of 49.72% HCWs gave history of being completely vaccinatedfollowed by (15.84%) who were partially vaccinated and (10.38%) who had taken

a booster dose vaccination. However, a significant number of HCWs (16.93%) were unaware about their vaccination status and 7.10% disclosed that they were non-vaccinated (Table2)]. Among the different groups of HCWs ,maximum (75%) of OT technicians were completely vaccinated followed by doctors (66.66%), attendants (63.33%), nurses' (62.5 %) and cleaning staff (54.55%). However, 18.18 % of the cleaning staff, 15% of the PG students and 6.67% attendants were non-vaccinated. (χ^2-value=103.5214,p-value=0.000). Among the participants, 58% were males and 42% were females.

A fairly high number (6.01%) of HCWs, were HBsAg positive.An estimation of anti-HBs titres in negative group showed high level of immunity (titre of > 100mIU/ml) in 52.32%, hypo-response (titre 10-100mIU/ml) in 20.35% and non-response (titre <10mIU/ml) in 27.33%. (Table 3) On correlation of level of immunity with age, non- response to vaccination was seen in ≥50 year's (64 %)age group. (χ^2-value=8.315,p-value=0.015). The non- response to vaccination was maximum (91.66%) in the non-vaccinated category followed by unknown status category (35.5%), showing the direct relation between vaccination and production of antibodies. (Table 4) High level of immunity (100%)

was seen in booster dose vaccinated individuals followed by completely vaccinated (56.47%) and partially vaccinated (40%) individuals. However, 38.70% of the unknown status category individuals and 8.33% of the non-vaccinated individuals also had presence of high level of immunity. The latter may have been due to the presence of natural immunity in these HCWs. The association was statistically significant (χ^2-value=48.6991, p-value=0.000).

Overall in our setup, 125 (72.67%) HCWs had a protective antibody titres (10-100mIU/ml) as compared to 47 (27.32%) with non-protective titres (<10mIU/ml). Smoking, alcoholism, history of hospitalisation, previous operation, dental procedure, and obesity were the major associated factors identified comparatively more in HCWs with non-protective titres (non-response) as compared to those with protective anti HBs titres (Table 5) .(χ^2- value=4.338, p-value=0.888). Among the 27.34% non-responsive individuals, 96% seroconverted (titre >10mIU/ml) after 2nd complete series of vaccination. However, 4% showed non-response. As these non-response individuals belonged to the completely vaccinated category, as per the CDC definition they were termed as vaccine "non-responders".[6]

Table 1: Structured questionnaire distributed among the HCWs for demographic, personal and vaccination details

Name: Age/Sex:, Designation :Department:, Relevant details:

S.No.	History	Yes	No
1.	Received Hepatitis B vaccination		
2.	Received all three doses of Hepatitis B vaccination		
3.	Received single or two doses of Hepatitis B vaccination		
4.	Do not know the status/ dose of vaccination received		
5.	Received booster dose of Hepatitis B vaccination in the last 5 years		
6.	Known HBs antigen positive status		
7.	Jaundice or any other chronic liver disease		
8.	Prolonged steroid therapy/ immunosuppressive drugs		
9.	Smoker		
10.	Diabetic		

Cont... **Table 1: Structured questionnaire distributed among the HCWs for demographic, personal and vaccination details**

11.	Alcoholic		
12.	Family history of hepatitis B		
13.	History of hospitalization		
14.	History of previous operation		
15.	History of blood transfusion		
16.	History of any dental procedure			
17.	Current Pregnancy status			
18.	Obesity			

Table 2: Overall assessment of vaccination status among the participating groups of Health Care Workers as per the questionnaire (n=183)

Designation	Completely vaccinated	Partially vaccinated	Booster dose vaccinated	Non-vaccinated	Unknown status of Vaccination	Total	χ^2-value, p-value
PG students (n=60)	19 (31.66%)	12(20%)	4(6.66%)	9(15%)	16(26.66%)	60	
Doctors (n=12)	8(66.66%)	1(1.66%)	2(3.33%)	0(0%)	1(1.66%)	12	
Nurses (n=48)	30(62.5%)	7(14.58%)	2(4.17%)	0(0%)	9(18.75%)	48	
Lab technicians (n=10)	0(0%)	1(10%)	9(90%)	0(0%)	0(0%)	10	
OT technicians (n=12)	9(75%)	1(8.33%)	0(0%)	0(0%)	2(16.67%)	12	χ^2-value=103.5214, p-value=0.000
Attendants (n=30)	19(63.33%)	5(16.67%)	2(6.67%)	2(6.67%)	2(6.67%)	30	
Cleaning staff (n=11)	6(54.55%)	2(18.18%)	0(0%)	2(18.18%)	1(9.09%)	11	
Total	91 (49.72%)	29 (15.84)	19 (10.38%)	13 (7.10)	31 (16.93%)	183	

Table 3 : Correlation of level of immunity of HCWs with age (n=172)

Age group (in years)	Anti HBs Titre : <10mIU/ml (non-response)	Anti HBs Titre : 10-100mIU/ml (hypo-response)	Anti HBs Titre : >100mIU/ml (high level immunity)	Total	χ^2-value, p-value
18-49 (n=161)	40 (25%)	33 (20%)	88 (55%)	161 (93.60%)	
≥50 (n=11)	7 (64%)	2 (18%)	2 (18%)	11 (6.40%)	χ^2-value=8.315, p-value=0.015
Total	47 (27.33%)	35 (20.34 %)	90 (52.32%)	172 (100%)	

Table 4: Correlation of vaccination status with immune response (n=172)

Vaccination status	<10mIU/ml (non-response)	10-100mIU/ml (hypo-response)	>100mIU/ml (high level of immunity)	Total	χ^2-value, p-value
Completely vaccinated (n=85)	18 (21.17%)	19 (22.35%)	**48 (56.47%)**	85	
Partially vaccinated (n=25)	7 (28%)	**8 (32%)**	10 (40%)	25	
Booster dose vaccinated (n=19)	0 (0%)	0 (0%)	**19 (100%)**	19	
Non vaccinated (n=12)	**11 (91.66%)**	0 (0%)	1 (8.33%)	12	χ^2-value=48.6991, p-value=0.000
Unknown status (n=31)	**11 (35.5%)**	8 (25.80%)	12 (38.70%)	31	
Total	47 (27.32%)	35 (20.34%)	90 (52.32%)	172	

Table 5: Comparison of the associated factors affecting immune response identified in HCWs with protective and non-protective antibody titre (n=172)

Factor	HCWs with protective titres (10-100mIU/ml) (n=125)	HCWs with non-protective titres. (<10mIU/ml) (n=47)	Total n=172	$\chi2$-value, p-value
History of hospitalisation	32 (25.6%)	19 (40.42%)	51 (29.65%)	
History of previous operation	20 (16%)	16 (34.04%)	36 (20.93%)	
History of dental procedure	21 (16.8%)	8 (17.02%)	29 (16.86%)	
Alcoholic	16 (12.8%)	8 (17.02%)	24 (13.95%)	
Smoker	15 (12%)	7 (14.89%)	22 (12.79%)	$\chi2$- value=4.338, p-value=0.888
Obesity	8 (6.4%)	5 (10.64%)	13 (7.56%)	
Prolonged steroid therapy	8 (6.4%)	3 (6.38%)	11 (6.39%)	
Diabetic	1 (0.8%)	2 (4.26%)	3 (1.74%)	
History of blood transfusion	6 (4.8%)	2 (4.25%)	8 (4.65%)	
Family history of Hepatitis B	2 (1.6%)	1 (2.12%)	3 (1.74%)	

Discussion

HCWs are always at risk of contracting hepatitis B infection due to frequent handling of blood and body fluids of patients.[3] Vaccination against HBV is the most effective way to prevent HBVI.[4] Despite being a vaccine preventable disease, due to lack of sero-conversion, some individuals fail to develop protective level of antibody even after two complete series of vaccination. The vaccine "non-responders" have a false sense of security and are at a constant risk of acquiring infection. Therefore along with immunization of HCWs, testing for evidence of protective immunity becomes essential in any health care setting.

A study conducted by Singhal*et al.*,[8] from AIIMS New Delhi, showed only 50.2% of HCWs was completely vaccinated, 6.3% were partially vaccinated and 43.5% were non-vaccinated. The vaccination coverage in our institution was coherent to apex institute like AIIMS. Another similar study from G.B. Pant Hospital, Delhi, also showed only 55.4% of HCWs being completely vaccinated against Hepatitis B.[9] The percentage of completely vaccinated HCWs ranged from 40% to 49.6% across various Hospitals in India.[10-12]

Two groups of HCWs were identified, first were those who were either partially vaccinated, non-vaccinated or had unknown status thus emphasizing an urgent need to implement a proactive Hepatitis B immunisation programme to improve protection against this infection and to achieve target of 90% vaccination coverage.[13] The second group included significant numbers of HCWs in booster dose vaccination category showing

relatively good vaccination awareness and vaccination coverage in our hospital. (p-value<0.05) Overall the vaccination coverage rate among the doctors, nurses, OT technicians, attendants and housekeeping staffs was fairly good in our hospital as compared to other institutions. Previous studies carried out by Batra*et al*.,[10] and Singhal*et al*.[8] showed highest vaccination coverage rate in doctors and lowest among grade IV/laundry staff/ housekeeping staff. We observed the lowest vaccination coverage among the PG residents. This emphasizes a need of a mandatory policy to vaccinate all the residents & HCWs irrespective of their vaccination status at the commencement of their course or job in an organization. Simultaneously, regular screening for HBsAg should be part of immunization programme to prevent the spread and transmission of this infection.

As per CDC criteria(titre ≥10mIU/ml), [4] 72.67% HCWs were immune and 27.33% were non-immune in our hospital (p-value=0.000). However, some researchers have identified anti-HBs titre of >100mIU/ml as protective for sero-conversion to immune status.[14] Taking this latter criteria, 52.32% in our setup had high level of immunity (titer>100mIU/ml) and 20.35% had hypo-response (titer of 10-100mIU/ml). Different levels of antibody response in HCWs have been shown by various workers in the past.[15,16]

The non–response was observed maximum in the non- vaccinated category (91.66%) of individuals. Similar findings have been reported.[15] The non-response was also seen in (35.5%) unknown status category and 21.17% incompletely vaccinated category, showing the direct relation between Hepatitis B vaccination and production of antibody in vivo. (p-value=0.000) High level of immunity was seen in the booster dose vaccinated category individuals followed by completely vaccinated category. However, protective level of antibody titres was also seen in unknown status category and non-vaccinated category individuals. This may be due to the presence of natural immunity through previous contact with HBV. Similar observations have been reported previously by other workers.[8]

Increase in age (≥50 years) was identified as a major factor responsible for low immune response irrespective of the vaccination status (p-value=0.015). Similar observation has been reported. [2] It maybe because advancing age proves to be a big factor for low antibody response and could be due to a decrease in lymphocyte proliferation activity. The other factors identified for non-response was male gender (56%) as compared to the females (44%) which is coherent to a previous study.[17] The effect of gender could be explained by the greater weight of men.[18]Smoking was another factors identified in non-responsive HCWs, which is in concurrence with study done in the past.[19] This may be because of 1st lower number of immunoglobulin in smokers than in non-smokers [20] and 2nd impaired dendritic cell function in smokers.[21] History of hospitalisation, previous operation, dental procedure in the past, alcoholism and obesity were other associated factors identified more in non-responsive HCWs. (p-value=0.888)

Sero-conversion was seen in 96% of non- responsive HCWs however, 4% were vaccine "non-responders"[6](no seroconversion).The **"non-responders"**are at a constant risk for being infected as they tend to have a false sense of security of being immune but are not. There are no regulations and guidelines that demand removal of these non-responders from the job; moreover each organization needs to develop a policy concerning non-responders. Infact, the vaccine non-responders should first be identified then counselled as to what non-response to the vaccination series means for him/her that is, they are susceptible to HBVI and the treatment modality for post exposure prophylaxis for any known or likely exposure to a positive sourceis to use HBIG.[22]

There are limited literatures that address the issue of non-responsive HCWs. An old study involving about 2000 HCWs, showed cumulative response rate to three re-vaccination doses of 69%.[23] Another study showed 85.7% sero-conversion rate after 3 repeat dose of HBV vaccination in non- responsive HCWs and 73.2% sero-conversion rate with a single booster dose of the same vaccination.[24]

The Occupational Safety and Health Administration (OSHA) mandate that employers offer Hepatitis B vaccination to all employees who are at occupational risk, [25] along with provision of adequate personal protective equipment . Adequate documentation in the employee record regarding nonresponse to vaccination is required. Simultaneously, HBsAg testing should be recommended in these individuals as it is possible that these employees maybe chronically infected with HBV.[6]

Conclusion

Complete vaccination coverage was low among health care workers. We could identify the vaccine non-responders in our setting thus emphasizing the importance of this study. However , the study has few limitations like not able to enrol all the HCWs in a setup plus those on long leave and maternity leave were missed. In future studies may be carried out by following up the non-responders to determine the long term outcome.Finally, we recommend that every health care organization should have a mandatory policy to vaccinate all the HCWs irrespective of their vaccination status at the commencement of their job and monitor their post vaccination antibody titreto identify these HBV vaccine non-responders, counsel them and post them at low risk area for their safety.

Financial Disclosure: Nil

Conflict of Interest: None declared.

Ethical Clearance: Approved by the Institutional Ethical and Research Committee.

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First Aid Management: Effectiveness of Training Program among School Children

Mehev Khanam[1], Prema Bausamy[2]

[1]Ph.D. Scholar, [2]Asst. Professor, Faculty of nursing, Bareilly International University, Bareilly India

Abstract

Accidents may happen anyplace at any time. First aid knowledge is the ways and techniques that are used to perform practices associated with prevention and immediate response to health emergencies. The main objectives of the study were to assess the knowledge, attitude, and practice regarding First Aid Management among school children for experimental group and control group, to assess the effectiveness of training programs regarding first aid management among school children for the experimental group and control group, to associate the pre-test knowledge score with demographic variables for the experimental group**.** The research approach selected for the study was the quantitative (quasi-experimental nonequivalent control group pre-test -post-test only design) approach. A sample of 140 school children (70 experimental group and70 control group) was selected by purposive sampling from selected school of Bareilly. The major findings of the study showed that themean post-test knowledge scores (37.67) of school children regarding first aid management was higher than their mean pre –test knowledge scores (21.67) with a mean difference of 15.88 themean post-test attitude level (22.07) of school children regarding first aid management was higher than their mean pre –test attitude level (21.02) with a mean difference of 1.05 themean post-test practice scores (6.17) of school children regarding first aid management was higher than their mean pre –test practice scores (0.41) with a mean difference of 5.76.The Training programe was effective in enhancing the knowledge, attitude and practice of school children on first aid management. No significant association between post-test knowledge scores and demographic variables. The findings indicate that the training Programme on first aid management developed by the researcher was effective in enhancing the knowledge, attitude and practice of school children.

Keywords: *First Aid Management.Knowledge, Attitude, Practice, Training Program, School Children, Burns, Drowning, fall, Fracture, Accidents*

Introduction

The life-saving care or first aid is an assessment and intervention that may be administered by a person with nominal or without medical equipment[1]. Therefore, this makes it necessary to have basic information about first aid. The ultimate goal of first aid is to prevent or reverse the possible damage at a given time before reaching the suitable health care center[2]. First aid knowledge is the ways and techniques that are used to perform practices associated with prevention and immediate response to health emergencies. Basic knowledge and understanding of first aid may be valuable for people to be able to give emergency care in the event of an accident, probably saving lives and minimizing injury. The goal of first aid is to save a life, prevent an injury or illness from worsening, or help a speedy recovery. First aid and basic life support are so important that teaching basic first aid should be compulsory in all schools[3]. Building skills in first aid with vulnerable individuals will facilitate creating safer and healthier communitiesThe main objectives of the study were to assess the knowledge, attitude, and practice regarding First Aid Management among school children for experimental group and control group, to assess the effectiveness of training programs

regarding First Aid Management among school children for the experimental group and control group, to associate the pre-test knowledge score with demographic variables for the experimental group. Asnurse educator, has a bigger role to educate the school children relating to numerous aspect of health like prevention of accidents, safety needs, first aid etc. Since the investigator is also one of them. therefore has to contribute little portion to this life saving measures through this minor study. This study can improve the knowledge of school children relating to first aid management.

Material and Method

The research approach selected for the study was the quantitative (quasi-experimental nonequivalent control group pre-test -post-test only design) approach. A sample of 140 school children (70 experimental group and70 control group) was selected by purposive sampling from selected school of Bareilly. The current study was conducted at selected schools of Bareilly U.P. Data was collected from both the experimental and control group through structured knowledge questionnaire attitude scale and check list. First aid training programe introduced to the experimental group in order to increase knowledge attitude and practice and same will be withheld from the control group. Finally post-test was conducted among both groups.

Finding

The major findings of the study showed that themean post-test knowledge scores (37.67) of school children regarding first aid management was higher than their mean pre –test knowledge scores (21.67) with a mean difference of 15.88 themean post-test attitude level (22.07) of school children regarding first aid management was higher than their mean pre –test attitude level (21.02) with a mean difference of 1.05 themean post-test practice scores (6.17) of school children regarding first aid management was higher than their mean pre –test practice scores (0.41) with a mean difference of 5.7.The Training programe was effective in enhancing the knowledge, attitude and practice of school children on first aid management.

No significant association between post-test knowledge scores and demographic variables. The findings indicate that the training Programme on first aid management developed by the researcher was effective in enhancing the knowledge, attitude and practice of school children.

Discussion

In the present study post-test knowledge, attitude and practice scores of school children were significantly higher than pre-test knowledge, attitude, and practice scores after the training program. The training program was found to be an effective strategy in increasing the knowledge,attitude, and practice of school children. Thus it was suggested that the training program was beneficial to the school children in enhancing their knowledge, attitude, and practice regarding first aid management.

Conclusion

The following conclusions were drawn from the findings of the study: The training program was effective in enhancing the knowledge, attitude, and practice of school children on first aid management. No significant association between pre-test knowledge scores and demographic variables.The findings indicate that the training Programme on first aid management developed by the researcher was effective in enhancing the knowledge of school children.

Conflict of Interest: Informed to all participant regarding procedure of study. No potential risks and discomforts to study subject. We hope that this training programme will help to improve stress level as beneficial for study subject. It was declared that participants will not be entitled to any compensation for participation in this study and participation in this study is completely voluntary. The name and other details will be kept confidential.

Source of Funding- Self

Ethical Clearance : Permission to conduct the study was taken from competent authorities. Theresearch committee of Bareilly international university. Formal administrative approval from the Principals, of selected schools of Bareilly The informed consent form for

school children in the study. The informed consent form for parents of school children.

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A Comparative Study on Effect of IFT and Conventional Exercises Versus ICT And Conventional Exercises in Cervical Spondylosis

Minal Dhairya Bhavsar

Tutor cum Physiotherapist/ Incharge Lecturer in Government spine institute and Physiotherapy College, Civil Hospital, Ahmedabad

Abstract

Background And Purpose:-Cervical spondylosis is a chronic degenerative condition of the cervical spine that affects the vertebral bodies and intervertebral discs of the neck. IFT and ICT are used in patients with cervical spondylosis. The purpose of this study is to compare the effects of IFT and ICT in patients with cervical spondylosis.

Methods:-30 patients with cervical spondylosis were divided into group A and group B.

Group A patients were given IFT plus conventional exercises while group B patients were given ICT plus conventional exercises. Pain (visual analogue scale) were recorded before and after the treatment

Conclusion:-When the results were analyzed using "T- test" it shows that there is significant effect of IFT plus conventional exercises on pain compared to ICT plus conventional exercises.

Keywords:- *IFT, ICT, Cervical spondylosis, Visual analogue scale*

Introduction

Cervical spondylosis is a common and occasionally disabling condition, occurring as a natural Consequence of aging in the vast majority of the adult population.[1]The goal of treatment is to relieve pain and prevent permanent injury to the spinal cord and nerves.

Various treatments for cervical spondylosis available are:-[2]

Treatment of mild cases: - Neck brace

- Nonsteroidal anti-inflammatory drugs (Advil, Motrin, others)

- Exercises

Treatment of more serious cases: - bed rest and traction

- Muscle relaxants (methocarbamol)

- Injecting corticosteroid medications into the joint

If conservative treatment fails or if your neurological signs and symptoms, such as weakness in your arms or legs, are getting worse, you may need surgery. Indications for surgery include intractable pain, progressive neurologic deficits, and documented compression of nerve roots or of the spinal cord that leads to progressive symptoms.[3]

Many treatments are available to patients and accepted as standard forms of practice, including such common conservative strategies as medication, physical medicine methods, manual treatments, and education of patients. There is little evidence, however, for their accepted use.[4,5]

Common physical therapy treatments for cervical spondylosis are: [6]

1. Physical agents &Massage: - hydro collator packs and infrared

   - Short wave diathermy, microwave and ultrasound

   - Ice- massage, Ice packs, TENS, IFT

      - Effleurage, Circular Kneading & Friction

2. Exercises – Isometric Neck Exercises and Shoulder Scapular Exercises to Strengthen the Muscles.

3. Cervical Traction: - Various studies have shown that cervical traction may relieve the symptoms of spondylosis. Traction on the spine can be applied manually or mechanically.

4. Manipulation: - Reduction of intra-articular displacement in cervical Spondylosis by Manipulation is very effective.

5. Cervical Collar

6. Postural and ergonomic advice.

Effects of traction: Various studies have reported the benefits of traction. (Cailliet, 1988; Harris, 1977; Matthews, 1972: pellechia, 1994; saunders, 1985)

Traction has the mechanical benefits of temporarily separating the vertebrae and causing mechanical sliding of the facet joints in the spine. If done intermittently, this motion may help reduce circulatory congestion and relieve pressure on the dura, blood vessels, and nerve roots in the intervertebral foramina. Improving circulation of noxious chemical irritants from swelling and inflammation. Traction has been demonstrated to widen the intervertebral foramina. Traction may relieve symptoms from a disc protrusion

Positioning the spine in flexion prior to the application of traction provides the greatest increased space.(Cailliet, 1988; Harris, 1977; Matthews, 1972; pellechia, 1994)

Effect of IFT:-Various studies have reported the benefits of IFT. (Hans Nemec, Kloth 1987) A good number of recentstudies (e.g. Hurley et al 2004, Johnson and Tabasam 2003, Walkeret al 2006, McManus et al 2006, Jorge et al 2006) provide substantive evidence for a pain relief effect of IFT.

It is the form of electric current in which 2 medium frequency currents with slight change in frequency willinterference with each other produces current which have low frequency and effect like medium Frequency. This medium frequency current will pass more easily than low frequency because lower skin resistance is offered, to medium frequency current.

Mechanism of action of IFT

Higher frequencies (100-130H2) close the pain gate mechanisms and thereby reduce the painPerception. IFT may act directly on peripheral nerves by slowing the conduction, which in turn reduces the volume of nociceptor traffic. Electrical Stimulation also reaches the cerebral cortex in the sense that the patient is aware of a prickling or tingling sensation. This may contribute to the placebo effect.

There are 4 main clinical applications for which IFT appears to be used: Pain relief, Muscle stimulation, increased local blood flow and Reduction of edema

There is little information available from randomized clinical trials to support various approaches for treating neck pain.[7, 8]

So the purpose of the present study is:-

-   To study the effects of IFT and Conventional Exercises on Pain in patients with Cervical Spondylosis

-   To study the effect of ICT and Conventional Exercises on Pain in patients with Cervical Spondylosis.

-   To compare the effect of IFT and Conventional Exercises Versus ICT and Conventional Exercises on Pain in patients with Cervical Spondylosis.

Methodology

Ø   **Study design**: - Comparative Study design.

Ø   **Duration of study:-** 6 months

Ø **Duration of treatment**:- 10 days

Ø **Study setting**: - This study was conducted at Govt. Physiotherapy College, Paraplegia Hospital Civil Hospital Campus, Ahmedabad. All the patients were referred from Orthopedic outpatient Department, Civil Hospital, Ahmedabad.

Ø **Sample size**:- Group A 15

  - Group B 15

Ø **Study sampling: -**30 patients of Cervical Spondylosis were selected by simple, purposive Random sampling on the basis of inclusion and exclusion criteria.

Group A- IFT and Conventional Exercises.

Group B- ICT and Conventional Exercises.

Ø **Inclusion criteria:**

- Patients Diagnosed with Cervical Spondylosis by medically qualified orthopedic doctors

- Age:-25 to 50 years

- Willingness to participate

Ø **Exclusion Criteria:-**

- Patients with cord compressions

- Patients with spinal tumors, infection

- Previous spinal surgery

- Very old age

- Patients with spondylolisthesis, PIVD

- Recent motor vehicle accident involving cervical spine

- History of psychological or psychiatric illness

Ø **Materials:**

- Examination table

- Consent form

- Visual Analogous Scale sheet

- Pencil, papers and recording sheets, assessment charts.

- ICT machine

- IFT machine

- Chair

Ø **Procedures**

- Selection of subjects has done by simple purposive random sampling. A total of 30 subjects were selected for the study and assigned to either control or study group. All subjects who matched the inclusion criteria were selected after giving informed consent to the study. Standardized evaluation protocol is used and management given.

- Group A was treated with IFT & conventional exercises, ergonomic advice. Group B was treated with ICT & conventional exercises. Both groups were recorded for their pain intensity by Visual analogue scale. Then the gathered data is tabulated and interpreted.

Ø **Protocol:-**

Group-A – IFT

  - Isometric Neck Exercises

  - Shoulder Scapular Exercises

  - Neck Care

Group-B- ICT

  - Isometric Neck Exercises

  - Shoulder Scapular Exercises

  - Neck Care

Ø **Technique of IFT**

- Position of Patient: - Comfortable sitting Position

- 4 carbon rubber electrodes are used with conducting gel

- Placement of Electrodes – 2 electrodes at

the shoulder girdle level & 2 electrodes at the area of radiating pain.

Parameters: - 4 pole 90 vector

- Spectrum – 80-120 Hz

- Base – 80

- Sweep- 40

- Intensity- as tolerable

- Duration – 15 minutes for 10 days

Precautions:-

- Skin resistance must be decreased by washing skin before treatment

- Skin sensation should be checked.

- Bare metal electrode or their connection should not touch the skin

- SWD can interfere with delicate balance of IFT machine hence the machine is operated well away from diathermy at least at a distance of 6 meters.

Ø   Technique of ICT:

Position of patient: Supine or sitting. Traction in supine produces better relaxation, greater intervertebral separation, decreased muscle guarding and increased stability

Traction force: vary between 1/10 and 1/7 of the patient's body weight At least 10-15b force is required initially for vertebral separation

Duration of traction: 10-15 minutes for 10 days

Angle of pull of traction

Traction in flexion: - maximum pull and vertebral separationoccurs at lower cervical spine. Studies shows that vertical diameter of C5-C6 vertebral foramen increased by 1.5 mm at 20 degrees if flexion

Traction in neutral: - maximum pull and vertebral separation occurs at mid cervical spine

Traction in hyperextension: - maximum pull and vertebral separation occurs at upper cervical spine

Exercises -isometric neck exercises and shoulder scapular exercises. 10 repetitions per one session with 10 sec hold for 10 days.

OUTCOME MEASURES

Pre & post Visual Analogue Scale were assessed before the treatment and after 10 days of the treatment.

Results

In this study 30 patients of cervical spondylosis were taken.

Results of the study are as under.

TABLE- 1 PAIRED t- TEST:

Comparison of pretreatment and post treatment values of pain within GROUP A and GROUP B

		Mean	SD	t- Value	P value and level of significance
GROUP A	Pre test	7.54	1.00	19.38	p>0.05
	Post test	2.54			
GROUP B	Pre test	7.67	1.24	13.71	p>0.05
	Post test	3.27			

(A) PAIRED TEST

GROUP-A:

When the pre-treatment and post treatment values of pain within GROUP A are analyzed by paired "t test at 5% level of significance. The calculated value is 19.38, which is greater than the table value of 2.15 for 14 degrees of freedom Thus NULL HYPOTHESES is rejected.

GROUP B:

When the pretreatment and post treatment values of pain with in GROUP are analyzed by paired test at 5% level of significance. The calculated value is 13.71, which is greater than the table value of 2.15 for 14 degrees of freedom. ThusNULL HYPOTHESES is rejected.

INTERPRETATION:

There is significance difference of pretreatment and post treatment values of pain in patients receiving IFT andCONVENTIONAL EXERCISES.

There is significance difference of pretreatment and post treatment values of pain in patients receiving ICT and CONVENTIONAL EXERCISES.

TABLE- 2 UNPAIRED t- TEST

Comparison of mean values of pain between GROUP A and GROUP B

GROUP	Mean	SD	t- Value	P value and level of significance
A	5	0.71	2.06	p>0.05
B	4.4	0.88		

(B) UNPAIRED t TEST:

When the difference of pre-treatment & post treatment values of pain within GROUP A & GROUP B are analyzed by independent t-test at 5% level of significance. The calculated value is 2.06 which is greater than the table value of 2.05 at 28 degrees of freedom. Thus NULL HYPOTHESES is rejected.

Interpretation:

There is significance difference of pretest& post values of pain existing between the individual receiving IFT and CONVENTIONAL EXERCISES and the individual receiving ICT & CONVENTIONAL EXERCISES.

Discussion

Cervical spondylosis is a progressive degenerative disorder exacerbated by a history of poor lifestyle or health. It is now common for many people to work at a computer or watch TV for too long with resulting damage to the muscles, tendons and bones, leading to this disease.

Schmori and junghanns report upon finding in autopsies of 4253 spines found evidence of spondylosis in 60% of women and 80% of men by the age of 49 years. He found 95% incidence in both sexes at age 70 years. Significant structural changes in the disk have been reported in most studies of pathologic disks in patients past the age of 30-35 years.[9]

Spondylosis is a term applied to changes noted in the spine of radio logically significant (1) narrowing of the disk height (2) presence of osteophytes arising from the disk margin (3) osteoarthritis changes in the posterior Zygapophysical joints.[9]

In this study sample size is 30. Group A were treated with IFT & Conventional Exercises. Group B were treated with ICT & Conventional Exercises.IFT

and ICT both are effective in the treatment of cervical spondylosis.While comparing the mean values of group A and group B (Mean-group A- 5, group B- 44) there is significant difference existing between the two groups. Thus, making the mean values into consideration it can be concluded that Interferential therapy shows more significant improvement than intermittent cervical traction.

It is important to find the most effective treatment programs to treat cervical spondylosis.IFT is the form of electric current in which 2 medium frequency currents with slight change in frequency will interference with each other produces current which have low frequency, and effect likemedium frequency.[10, 11]

A good number of numerous studies (e.g. Hurley et al 2004, Johnson and Tabasam 2003, Walker et al 2006, McManus et al 2006, Jorge et al 2006, Partan et al 1953, Scott and purves, 1991, Stephenson and Johnson 1995) provide substantive evidence for a pain relief effect of IFT.

Higher frequencies (100-130H) close the pain gate mechanisms (Meizack and Wall) and thereby redace the pain perception. It may act directly on peripheral nerves by slowing the conduction, which in tum reduces the volume of nociceptor traffic. Electrical Stimulation also reaches the cerebral cortex in the sense that the patient is aware of a prickling or tingling sensation This may contribute to the placebo effect.

Various studies have reported the benefits of traction. (Cailliet, 1988, Ham, 1977; Matthew 1972 pellechia, 1994; Saunders, 1998)

1. Cervical traction cause gentle mobilization of the Zygoapophyseal joints and may cause analgesic effect by stimulating mechanoreceptors. Mechanoreceptor impulses arriving in theSpinal cord may tend to inhibit recognition of nociceptive impulses, resulting in some degree of analgesis.

2. Cervical traction causes stretching of the small neck muscles and this increases relaxation and reduces pain.Isometric exercises are equally important in both the methods of treatment Alternating isometric contractions

between antagonists also enhance stability.[12]

The Benefits of Neck isometric exercises, which helps in cervical spondylosis.

- Improvement in the static strength.

- Relaxation of the muscles, which provides better posture to work

IFT was more effective in pain reduction due to radicular pain than cervical traction As we have used 4pole 90 vector, it will cover large area so it will be more beneficial in patients because pain will radiate to the hand.IFT directly stimulate the mechanoreceptors so according to the pain gate theory it relieves pain faster than cervical traction.

Most of the authors says that electrotherapeutic modalities like IFT & ICT are effective only temporarily. Exercises are the main reason for the improvement and will provide long term effect. Neck care and ergonomic advice is also a useful tool to reduce the recurrence rate of neck pain. A small pillow under the neck enhances relaxation and thus reduces pain.

Conclusion

IFT along with conventional exercises & ICT along with conventional exercises both are highly efficient in relieving symptoms of cervical spondylosis on VASScores on individual basis.

But comparatively IFT along with conventional exercises is more effective than ICT & Conventional exercises as there is significant difference found between the results of these two treatments.

Limitation Of The Study

- The small sample size of 15 in each group (group A & group B) may limit generalization the results of this study to all the patients with cervical spondylosis.

- Long term follow up was not done

- Isometric neck exercise at home was not supervised.

- Cervical range of motion was not taken.

SUGGESSION

- It can also be done with larger sample size in both the groups to find out the effectiveness of IFT & ICT

- I would like to recommend that the future study to conduct and find out how long IFT &ICT effect lasts for and whether it is relieving pain or not.

Ethical Clearance: - Taken from Ethical committee

Source of Funding: - Self

Conflict of Interest: - Nil

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Lower Extremities Fractures in Alnajaf/Iraq

Mohammed Hasan Razoki[1], Hmamdalla Hadi Albosaisi[2], Ahmed Mohammed Hasan[3]

[1]Head of Department of Orthopaedics/College of Medicine/University of Kufa/ Professor Consultant Orthopaedic Surgeon/ Alsader Medical City/Alnajaf /Iraq, [2]Professor consultant orthopaedic surgeon /Department of Orthopaedics/College of Medicine/University of Kufa/Iraq, [3]SHO(Surgery)/ Department of Surgery/Alsader Medical City/Iraq

Abstract

Purpose: To take an idea about the size of an important socioeconomically public health problem and to put solutions.

Material and Methods: All the patients who sustained lower extremities fractures in one year (between 1st Jan. till 31st Dec. 2018)included in this study. Data collected from the documents of Alsader medical city in Alnajaf, it included the types of fractures, ages , gender, side of fracture ,and causes. Analysis of these data was done and the results were demonstrated in tables.

Results : The total number of the patients was (2466),males (1655) and females(811).The types of the fractures include: hip fracture 350, fracture femure 738, patellar fracture 49, leg fracture 831, ankle fracture 220 and foot fracture 278. People in the 1st decade were the most 697 followed by the 3rd decade 446, 2nd decade 440 , 4th decade 287 , 7th decade 193, 5th decade 155, 6th decade 142 , and above 70 (106) patient. The most common cause of the fractures was RTA in 800 patient followed by fall 727, fall from height 594 ,and fall of heavy object 123 patients.

Conclusion: Children and adolescent are mostly affected. People below thirty represent more than 50% of the cases. Planes from all the government administrations showed be more effective to decrease the occurrence of such injuries by learning programs to avoid fractures in all ages , in order to decrease the socioeconomically burden on the community.

***Key words:** lower extremity, fractures , lower limb, Alnajaf*

Introduction

Lower limb fractures are common injuries . It account for about one third of all fractures. It may result in high rate of morbidity and mortality which can be reduced by early appropriate management.[1,2,] Fractures, mostly arising from injury , are a big public health problem .

In china injuries is the 5th most common cause of death, and resulting in more fatalities than DM and infectious diseases. [3,4]

In general males had significantly higher fracture prevalence than females in every age group except in old people where the prevalence is more in women.[4,5,6]

The high incidence of lower limb fractures in women is related to hip fracture, due to osteoporosis which affects women more frequently. In US the number of osteoporosis –related fractures was estimated to exceed 2 million in 2005. With time it causes increasing economic burden on the health care system. [5,6,7,8]

For our knowledge there are no updated papers which discuss this important issue in Iraq.

This paper is to discuss this problem from all sides regarding types of fractures, age groups and the causes .Hoping that the administrations will start putting planes to decrease the rate of occurrence of these fractures and to put solutions and improve the methods of early

management to decrease morbidity among population.

Material and Method

This paper was conducted on patients attended the main hospital in Alnajaf (Alsader teaching hospital) in the period between the 1st of January 2018 to the 31st of December 2018.The data was collected from the documents of the outpatient clinic and from the emergency ward. The data include the age, gender, type of fracture, and the cause. For the age the patients were grouped according to the decades from one year old up to above 70 years old.

Regarding the types of fractures we started proximally from hip fracture, fracture femure, fracture patella, leg fracture, ankle fracture and foot fractures. Hip (proximal femure)fracture includes intra and extracapsular fractures. Fracture femure include all types of femoral shaft fractures including distal fractures. Leg fractures include isolated fractures of tibia or fibula or both of them. Ankle fractures include all fractures of distal tibia and fibula. Foot fractures include the tarsals , metatarsals, and fracture phalanges.

The causes of fractures include fall during walking or playing, fall from height (FFH), road traffic accidents (RTA), fall of heavy object (FHO), direct hit, sport mainly foot ball (FB), bullet injury, injury due to explosions, and machine injuries.

Statistical Analysis

Statistical analysis was done by using SPSS (statistical package for social sciences) version 20, in which we use frequency and percentage, mean and standard deviation as descriptive statistics. Chi square test used for analytic statistics. P value <=0.05 regarded significant.

Results

The total number of the patients was 2466 in one year. The number of the males was 1655(67.11%) and the number of females was 811(32.88%).

Table one shows details of gender, age range, mean age, and the side of the fractures.

Table (1): types of fractures, gender, age, side

Fracture Type	Male No.&%	Female No.&%	Age: rang	Mean age	Right side	Left side	Total
Hip	149 42.57%	201 57.42%	3-90	55.90	174 49.71%	176 50.28%	350 14.19%
Femure	516 69.91%	222 29.94%	1-88	17.40	379 51.35%	359 48.64%	738 29.92%
Patella	29 59.18%	20 40.81%	6-70	37.56	25 51.02%	24 48.97%	49 1.98%
Leg fractures	649 78.09%	182 21.90%	1-85	21.70	420 50.54%	411 49.45%	831 33.69%
Ankle	135 61.36%	85 38.64%	6-70	31.01	112 50.90%	108 49.09%	220 8.92%
Foot	177 63.66%	101 36.33%	3-75	30.67	136 48.92%	142 51.07%	278 11.27%
Total	1655 67.11%	811 32.88%	1-90	27.86	1246 50.52%	1220 49.47%	2466

The table show that the most common fracture was leg fractures (33.69%),followed by fracture femure(29.92%) . It also shoes that males affected more than females (67.11%) and (32.88%) respectively, ratio of(2.04:1). The mean age of the patients was (27.86) years. The right sides affected almost equally as the left sides in all fractures .

The table show that there was significant association (P<0.05) between hip fracture and female gender while all other fractures occur more in males.

Foot fractures include hind foot, mid foot and forefoot fractures. The hind foot fractures are those of calcaneum which constitute about 16% of all foot fractures , and the other 84% are those of mid and forefoot fractures. All affect males more than females.

Table (2) lower limb fractures/age groups

Fracture Type	Age group/No. &%								Total NO.
	1-10	11-20	21-30	31-40	41-50	51-60	61-70	>70	
Hip	18 5.14%	7 2%	14 45%	17 4.85%	18 5.14%	67 19.14%	138 39.42%	71 20.28%	350 14.19%
Femure	375 38.23%	122 16.53%	102 13.82%	60 8.13%	14 1.89%	27 3.65%	14 1.89%	24 3.25%	738 29.92%
Patella	---	3 6.12%	21 42.85%	5 10.20%	11 22.44%	3 6.12%	6 12.24%	____	49 1.98%
Leg fracture	278 33.45%	177 21.29%	178 21.41%	98 11.79%	51 6.13%	24 2.88%	14 1.68%	11 1.32%	831 33.69%
Ankle	5 2.27%	75 34.09%	42 19.09%	40 18.18%	28 12.72%	12 5.45%	18 8.18%	---	220 8.92%
Foot	21 7.55%	56 20.14%	89 32.01%	67 24.10%	33 11.87%	9 3.23%	3 1.08%	____	278 11.27%
Total	697 28.26%	440 17.84%	446 18.08%	287 11.63%	155 6.28%	142 5.75%	193 7.82%	106 4.29%	2466

Table (2) shows the type of the fracture in relation to age groups in decades. It is obvious that children up to ten years are mostly affected (28.26%) , and patient up to 30 years of age constitute about (64.18%) of the whole group It show significant association (P<0.05)between type of fracture and the age where fracture hip occur in old ages while all other fractures are more common in young people.

Table (3):causes of lower limb fractures

Fracture type	Cause of fracture/No.& %									Total
	Fall	Fall from height	Road Traffic Accident	Fall of heavy object	Direct hit	Foot ball	Bullet	Expl-osion	Machine	
Hip	246 70.28%	65 18.57%	35 10%	----	1 0.29%	----	3 0.85%	---	---	350 14.19%
Femure	161 21.18%	175 23.71%	324 43.90%	25 3.38%	1 0.13%	7 0.94%	25 3.38%	11 1.49%	9 1.21%	738 29.92%
Patella	17 34.69%	5 10.20%	27 55.10%	---	---	---	---	---	---	49 1.98%
Leg fractures	164 19.75%	200 24.09%	317 38.19%	38 4.57%	35 4.21%	32 3.85%	18 2.16%	27 3.25%	---	830 33.69%
Ankle	59 26.81%	71 32.27%	52 23.63%	---	18 8.18%	17 7.72%	3 1.36%	---	---	220 8.92%
Foot	80 28.77%	78 28.05%	45 16.18%	60 21.58%	5 1.79%	2 0.71%	7 2.51%	1 0.35%	---	278 %
Total	727 29.48%	594 24.08%	800 32.44%	123 4.98%	60 2.43%	58 2.35%	56 2.27%	39 1.58%	9 0.36%	2466

Table (3) show that the most common cause of neck femure fractures were fall(70.28%) ,while RTA was the most common cause of fracture femure(43.9%) , fracture patella (55.1%) and fracture leg (38.19%). Regarding ankle fractures the most common cause of fractures was fall from height(32.27%). For foot fractures the most common causes were fall(28.77%) and fall from height (28.05).

Discussion

Hip fracture(proximal femur)

The number of hip fracture expected to reach to 6.2 million by the year 2050 ,while it was 1.66 million in 1990. [8,9] It is more common in elderly people especially femals.The most common cause is fall. Osteoporosis is the main risk factor, it represents a major health problem because of its association with low energy trauma or fragility fractures

Hip fracture has been recognized as the most serious consequences of osteoporosis because of its complications . [10]

In our series hip fracture represent 14.2%of lower limb fracture , while JA Kaye et al found that it represent 16.7%. [2]

A.Moayyer et.al. found that the most common cause of hip fracture was fall . Female affected more than male

and the percentage was 56.4% and 43.6% respectively. [11]

These figures are comparable to our figures where more than 70% of hip fractures were due to fall , and females represent 57.4% while males were 42.6%. with mean age of more than(55) year.

Fracture femure

Worldwide RTA injuries cause over 1.3 million deaths and many more disabilities annually. Approximately one in ten RTA injuries involve a femoral shaft fracture.[12]

The annual rate in children up to 18 years was 19.15 per 100.000.The primary cause include fall in children less than 6 years old, pedestrian RT in 6-9 years old ,and motor vehicle for teenager. [13] JA Kaye et. al. found that it represent 8.1% of lower limb fracture , while we found that it represent(29.92%) of lower limb fracture. In our study the mean age of patients was 17.4 years and about 38% were in the 1st decade and 16% in the 2nd decade which indicate that this fracture is more common in children. Also the most common cause was RTA(43.9%) followed by fall from height(23.7%) and fall in about (21.2%) .

Fracture patella

Peter Larson et al founded that the mean age was 54 years for all patients , it was 46year for males and 61year for females. Females affected more than males;56% for females and 44% for males.

They found that males have higher incidence than females in the 2nd decade of life , while females have higher incidence during the 6th and 7th decades.[14]

These results are not comparable with our study where the mean age in our study was 37 years and males affected more than females ,59% and 41% respectively. People in the 3rd and 5th decades affected more commonly, 43% and 22% respectively.

Leg fracture (tibia and fibula)

Diaphyseal tibial fractures are the most common long bone fracture.[15]

Mario Serotorio et al found that the age range between 14 and 83 years with average (32) years. Males affected more than females ,73.74% and 26.26% respectively. The most common cause was RTA (80%). Right side affected more than left. [16]

The mean age in our study was 21.7 years ranging from 1-85 years. Males represent 78% and females 22% which is comparable to other studies. People in the 1st decade affected more(33%), followed by people in the 3rd decade (21.4%) and 2nd decade(21.3%). Leg fracture was the most common fracture of lower limb in this study represents 33.69% of the whole group. The most common cause of this fracture was RTA (38%) followed by fall from height(24%) and fall(19%).

Ankle fracture

Ankle fracture is one of the most common fractures increasing in aging population.[17]

Rasmus Elsoe et al found that the mean age of patients was 41.4 years , males represent 53% and females 47%. The peak incidence was among adolescent with male predominance. The cause of fracture was fall in 61% and sports in 22%. [18]

In our study the patients were younger with mean age of 31 years ,males represent 61.36% and females 38.64% .Peak incidence was among people in the 2nd decade (34%). The main cause of the fracture was fall from height 32.3% followed by fall 26.8% and RTA 23.6%.

Foot fracture

Christian G.et al found that the mean age of patients was 36.1 year (females 41.3 years and males 31.3 years). Males represent 54.3% and females 45.7%.The peak incidence of the fracture was in the 2nd decade. People under age of 30 years represent 43.9%.

The main cause of the fractures was low energy trauma (98.7%).Hind foot fracture occur in 8.3% of patient while mid and fore foot fractures occur in 91.7%. [19]

In our study patients with foot fracture were younger with mean age of 31 years. Males represent. 63.7% while females represent 36.3% . The peak incidence was among people in the 3rd decade of life. The cause of the fractures is low energy trauma in more than 78% of the cases. RTA was the cause in 16% of the cases. Hind foot fractures occur in 16% while mid and fore foot fractures occur in 84% of the cases.

Conclusion

Lower extremity fractures in general are more common in young people below 30 years except for hip fracture which is more common in old people. The most common cause is RTA. The most common type is leg fracture. Respect ion of regulation regarding road traffic is very important to decrease accidents. Also protection of children by family and school are most important. Regarding old people application of (fall prevention program) may be effective to decrease osteoporotic related fractures.

Conflict of Interest: No conflict of interest

Funding: Self Funding

Ethical Clearance: Compliance with ethical

Standerds: this study was approved by the ethical

Committee of Alsader medical city /Alnajaf/Iraq

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The Impact of WIFA Program on Haemoglobin Concentration of Stunted and Non-Stunted Female Students and Factors Affecting Haemoglobin Concentrationin Cianjur Regency, West Java Province, Indonesia

Nadhea Alriessyanne Hindarta[1], Hadi Riyadi[2], Ali Khomsan[2]

[1]Graduate Student of Nutrition Science, Faculty of Human Ecology, IPB University, Bogor, Indonesia, [2]Lecturer, Department of Community Nutrition, Faculty of Human Ecology, IPB University, Bogor, Indonesia

Abstract

Background: Stunting is a nutritional problem occurs on adolescents that have risk to develop into anemia. This is known as co-occurrence anemia-stunting (CAS). Stunted adolescents have significantly lower haemoglobin level than non-stunted adolescents. The Weekly Iron Folid Acid Supplementation (WIFA) is one of government programs to resolve stunting problem by preventing anemia and/or CAS. This study aimed to analyze impact ofWIFA supplementation on haemoglobin concentrationfrom stunted and non-stunted female students as well as factors affecting haemoglobin concentration.

Methods: This study applied a cross sectional design. The subjectswere 66 female studentsdivided intostunted group and non-stunted group. Subjects were selected using a simple random sampling technique. The data takenwerebody weight and height, anemia and WIFA knowledge, compliance of WIFA consumption,dietary diversity, andhaemoglobin concentration. Dietary diversity was obtained by 2x24 hours recall by employingWDDS questionnaire. Thedifference and correlation test were used to analyse the data.

Conclusions: There was no significant different haemoglobin concentration of both group and there wereno correlation between affected factors with haemoglobin concentrationwhich could be caused by haemoglobin concentration on normalcategory at the beginning of WIFA program and good quality diet that could promote haemoglobin production.

Keywords: stunted;anemia; co-occurrence anemia-stunting; WIFA supplementation

Introduction

Stunting is one of the chronic malnutrition problems in Indonesia that has not been resolved. Z-score height for age of stunted individual is< -2SD.[1]A stunting condition has a negative impact such as suppressing linear growth and causing cognitive development disorders. In the long term, a stunting problem is capable to reduce work capacity, increasing the risk of developing metabolic syndrome and non-communicable diseases in their adulthood.[2]

Indonesia's stunting prevalence rate reaches 30.8%.[3] Among all Indonesia provinces, West Java province also has stunting problems with prevalence rate reaches 29.2% for toddler,stretching out into 29 districts. The Cianjur regency reported a higher stunting prevalence for toddler (35.7%) comparing to its province.[4]

A stunting is not only a nutritional problem for children but also becomes a prolong problem into their adolescents time. Stunted children will tend to grow into stunted adolescents or stunted adults.[5] In Indonesia, for West Java in particular, the prevalence stunting for 13-15 years old reached 33.8%, while the stuntingfor 16-18 years old reached 29.7%.[6]

Anemia is one of many contributing factors to the formation of the stunting generation. Anemic women in their reproductive age are at risk of giving preterm birth, low birth weight (LBW), and small-for-gestational-age (SGA) babies. Moreover, the LBW, preterm birth, and SGA are exposed to 3.2 times higher risk to develop into stunted children.[7]

Apart as a contribution factor to the creation of the stunting generation, anemia also becomes significant risk to happen in stunted individual.[8] The study of Puristasari et al. (2016) stated that stunted adolescents had significantly lower haemoglobin levels than non-stuntedadolescents.[9] The micronutrients deficiency occurred in stunted individuals contributes to low haemoglobin formation.[10] The condition of anemia and stunting incidence that occurs simultaneously is known as co-occurrence anemia-stunting (CAS). Hence,a prevention of anemia or CAS is needed to avoid the birth of children with risk of stunting and anemia.[11]

Weekly Iron-Folic Acid Supplementation (WIFA) is one of the Indonesia government programs to prevent and overcome iron deficiency anemia in order to reduce stunting. The program of improvement and prevention of anemia is considered as one of the modifying factors that have a major effect on the birth of children with a stunting potential.[11] One of the targets of this program is adolescent girl. The dosage contained in one tablet of WIFA is 182mg offerro fumarate and 0.4 mg of folic acid.[12] WIFA is consumed once per week. The expected effect of the WIFA consumption is the improvement of iron status and haemoglobin concentration.[13]

The haemoglobin concentration of WIFA recipients can be affected by several factors such as the anemia and WIFA knowledge, compliance of WIFA consumption, and dietary diversity. Knowledge plays a role in guiding individuals to make various efforts to meet their nutritional needs.[14] Adolescent girls with less knowledge of anemia have 14.4 times higher risk of developing anemia.[15] Compliance is one of the most influential factors in the success of the WIFA program. The WIFAsupplementation can increase haemoglobin concentration when accompanied by compliance with consumption.[16] Dietary diversity is an indicator that can be used to assess dietary adequacy that affects blood formation.[17] An increase in one dietary diversity score can increase haemoglobin levels by 0.714 g/dL.[18]

Researches on the haemoglobin concentration of stunting adolescent girls as recipients of WIFA program which especially conducted in Cianjurregency as one of the areas that has a high prevalence of stunting are still limited. The factors affectinghaemoglobin concentration also need to be explored for evaluation the next implementation of the WIFA program. The aims of this study are to determine the impact WIFA program on stunted and non-stuntedfemale students as well as factor affecting the haemoglobin concentration in Cianjur regency, West Java province, Indonesia.

Materials and Method

This study applied a cross sectional design and was a part of the research of Khomsan et al. (2020) funded by the Neys-van Hoogstraten Foundation, The Netherlands. This study was conducted from June 2019 to June 2020. It has met the requirements the ethical review of the Medical/Health Research Bioethics Commission under acceptance letter of 004/I/2020/ Bioethics Commission from Sultan Agung Islamic University Semarang, Indonesia.

The population target in this study was female students with age ranging from 15-18 years old in Cianjur regency. This study involved 66 samples which divided into two groups;stunted group and non-stunted group. Sampling was carried out by simple random sampling technique in 12 Senior High Schools. The inclusion criteria were female students who recipient the WIFA program, have HAZ < -2SD for stunted group and ≥ -2SD for non-stunted group, haveBMI for age on normal category for both groups, and willing to attend all series of research. Meanwhile, the exclusion criteria were female students who had an infectious disease in the past one year, and taking supplements or drugs with substances that could inhibit or increase iron absorption.

The data collections were included subject identity,anthropometric data (weight and height),

anemia and WIFA knowledge, compliance of WIFA consumption, dietary diversity, and haemoglobin concentration. Anthropometric data were obtained by taking a direct measurement twice by employing a digital scale for weight with accuracy of 0.1 kg and microtoise for height with accuracy of 0.1 cm. Data on level of knowledge and compliance of WIFA consumption were obtained through direct interviews using a questionnaire. Subjects are considered to have knowledge if they are able to choose at least one correct answer in every aspect of the question. Data of food consumption were obtained through 2x24 hours recall interviews on non-consecutive days. Food consumption data was then processed to determine individual food diversity by using the Women's Dietary Diversity Score (WDDS) questionnaire.[19] Haemoglobin concentration was obtained by direct measurement using the Hemocue 301 device. Haemoglobin concentrationwas categorized as anemia (haemoglobin concentration<12 g/dl) and non anemia (haemoglobin concentration ≥ 12 g/dl).[20] All data analyzed by SPSS 23.0 software. The test used in this study are Independent T test and the Mann-Whitney test to determine difference in haemoglobin concentration between groups, as well as the Pearson correlation test and Spearman correlation test to determine the relationship between variables.

Results and Discussion

Characteristics of Research Subjects

Table 1 shows that there were 12.12% had anemia and 9.09% experienced CAS. The conditions of anemia and CAS in adolescents girls require serious handling. Anemia condition in adolescent girls that is not treated properly leads to the potential problems during pregnancy, such as low birth weight (LBW)[21], preterm birth[21], and small-for-gestational-age(SGA)[7]. This condition will be exacerbated in anemicadolescents with stunting problem. Moreover,stunting problems have a transgenerational effect, a stunted woman tends to deliver stunted offspring.[2] Stunted women also have a similar risk of experiencing pregnancy problems as anemic women.[22,23] The poor quality of pregnancy that occurs in anemic and stunted individuals will lead to give birth of children with stunting and anemia problems.[7,10]

Table 1. The Characteristics of Research Subjects

Category	Stunted n(%)	Non-stunted n(%)
Age		
Middle adolescents (14-16 years)	16 (48.48)	24 (72.73)
Late adolescents (17-20 years)	17 (51.52)	9 (27.27)
Anemia status		
Anemia	3 (9.09)	4 (12.12)
Normal	30 (90.91)	29 (87.88)
Haemoglobin concentration (g/dl), mean±SD	13.52±1.21	13.47±1.68

Knowledge about Anemia and WIFA Supplementation

Table 2 shows that subjects of both groups had a knowledge score of ≥60 with the largest percentage in the moderate category.Subjects in the both groups relatively had almost the same answer choices. The eminent cause of anemia that widely known was lack of iron intake (60.61%). Iron deficiency becomes a factor that contributes to the incidence of anemia. However, there are deficiencies of other nutrients that also cause anemia, including folic acid, B12, and protein. Folic acid and B12 play a role in the DNA and haemoglobin synthesis during the RBC formation[23], while protein facilitates the absorption and mobilization of iron, and the synthesis of haemoglobin[24]. The incidence of infections such as worms and malaria are also associated with anemia which worms cause iron loss, and malaria causes metabolic and iron distribution disorder through hemolysis and decreased iron absorption.[25]The anemia effect that extensively recognized is having difficulty in concentrating. The WHO states that anemia that occurs during adolescence can affect physical and cognitive growth, work performance,and reproduction quality.[26]

The subject's knowledge about WIFA was dominated by a score of≥60. Table 3 illustrates side effect that most recognized in both groups was nausea. Subjects in both groups knew about how to reduce side effectsby consuming WIFA tablets after meal. 90.91 % subjects in both groups chose the benefit of consuming WIFA tablets was to preventanemia.

Table 2. Knowledge and Compliance of WIFAof Research Subjects

Subject Knowledge About Anemia		
Aspects	Stunted n(%)	Non-stuntedn(%)
Scores of knowlegde about anemia		
1. Low (score <60)	0 (0.00)	0 (0.00)
2. Moderate (score 60-80)	18 (54.50)	18 (54.50)
3. Good (score>80)	15 (45.50)	15 (45.50)
Causes of anemia		
1. Blood loss due to menstruation or accidents	19 (57.58)	18 (54.55)
2. Deficiency iron intake	20 (60.61)	20 (60.61)
3. Deficiency folic acid intake	5 (15.15)	2 (6.06)
4. Deficiency vitamin B12 intake	5 (15.15)	4 (12.12)
5. Infections (worms and malaria)	5 (15.15)	1 (3.03)
6. Vegetarian	2 (6.06)	1 (3.03)
7. Deficiency protein intake	7 (21.21)	15 (45.45)
8. Lack of fruits consumption	10 (30.30)	17 (51.52)
General signs		
1. Palecolor of eyes, nails, and palms	18 (54.55)	20 (60.61)
2. Dizzy	27 (81.82)	28 (84.85)
3. Weak	19 (57.58)	21 (63.64)
4. Fatigue	16 (48.48)	15 (45.45)
5. Lethargic	20 (60.61)	22 (66.67)
Effects of anemia		

Cont... **Table 2. Knowledge and Compliance of WIFAof Research Subjects**

1.	Decrease academic achievement	12 (36.36)	12 (36.36)
2.	Difficulty concentrating	23 (69.70)	30 (90.91)
3.	Decrease work performance	10 (30.30)	10 (30.30)
4.	Low birth weight offspring	7 (21.21)	9 (27.27)
5.	Susceptibility to infection	2 (6.06)	1 (3.03)
	How to prevent anemia		
1.	Consumption of weekly iron- folic acid supplementation	28 (84.85)	30 (90.91)
2.	Consumption of dark green leafy vegetables	22 (66.67)	24 (72.73)
3.	Consumption of vitamin C rich vegetables and fruits	17 (51.52)	19 (57.58)
4.	Consumption of meat and chicken's liver	14 (42.42)	20 (60.61)
5.	Taking worms medicine once for 6 months	5 (15.15)	1 (3.03)
6.	Getting enough rest	16 (48.48)	18 (54.55)
	Detection of anemia		
	Haemoglobin level	17 (51.52)	15 (45.55)

Table 2. Knowledge and Compliance of WIFA of Research Subjects (Continue)

Knowledge About WIFA Supplementation		
Aspects	**Stunted n(%)**	**Non-stunted n(%)**
Scores of knowlegde about WIFA supplementation		
1. Low (score <60)	6 (18.20)	7 (21.20)
2. Moderate (score 60-80)	12 (36.40)	13 (39.40)
3. Good (score>80)	15 (45.50)	13 (39.40)
Frequency consumption (once a week)	28 (84.85)	31 (93.94)
Duration of taking WIFA supplementation in a year (52 weeks)	20 (60.61)	13 (39.39)
WIFA supplementation content (iron and folic acid)	11 (33.33)	10 (30.30)
Side effect of WIFA consumption		
1. Nausea	27 (81.82)	24 (72.73)
2. Difficulty defecating	0 (0.00)	0 (0.00)
3. Blackish stool	6 (18.18)	6 (18.18)
4. Rust sensation	4 (12.12)	6 (18.18)
5. Dizzy	12 (36.36)	20 (60.61)
How to prevent or reduce the side effects		
1. Consumption WIFA after meal	20 (60.61)	18 (54.55)
2. Consumption with fruits	7 (21.21)	12 (36.36)
Benefit		
1. Increase concentration	18 (54.55)	19 (57.58)
2. Not easy fatigue	17 (51.52)	20 (60.61)
3. Increase work productivity	9 (27.27)	7 (21.21)

Cont... **Table 2. Knowledge and Compliance of WIFA of Research Subjects (Continue)**

4.	Increase work capacity	5 (15.15)	9 (27.27)
5.	Prevent anemia	30 (90.91)	30 (90.91)
Compliance of WIFA Consumption			
Aspects		Stunted n(%)	Non-stuntedn(%)
Compliance of WIFA consumption			
Not comply		20 (60.60)	12 (36.36)
Comply		13 (39.40)	21 (63.64)
Reason for compliance :			
Asked by the teacher		4 (12.12)	6 (18.18)
Asked by the health center staff		4 (12.12)	1 (3.03)
Prevent anemia		13 (39.39)	14 (42.42)
Reason for not compliance :			
Taste of tablet is bad		9 (27.27)	6 (18.18)
Already feel healthy		1 (3.03)	1 (3.03)
Worrying about side effect (nausea, vomiting, dizzy)		12 (36.36)	7 (21.21)
Worrying about unwanted health problems		0 (0.00)	0 (0.00)
Not attending at school		1 (3.03)	2 (6.06)
Forget		8 (24.24)	7 (21.21)
Reason for not compliance :			
Unnecessary		2 (6.06)	0 (0.00)
Blackish stool		0 (0.00)	1 (3.03)
Family do not allow		0 (0.00)	0 (0.00)

Compliance of WIFA Consumption

Table 2 shows that the subjects in the stunted group was more likely to not comply to consume the WIFA tablets (60.60%) compare to the non-stunted group (36.36%). The most reason subjects obeyed the consumption of WIFA was preventing anemia. This result is similar to a study conducted inEthiopia.[27] The reasons for the subjects not adhering to the consumption of WIFA were worry about side effects (nausea/ vomiting, headache), bad taste of the tablets, and forgetfulness. It also similar to researches conducted in Indonesia and Iran.[28,29] Providing information about side effects, the right time for consumption, its benefits and complications of WIFA consumption needs to be carried out by health personnel through nutritional counselling to improve subject compliance.[30]

Dietary Diversity

Dietary diversity becomes an indicator that strongly correlated with micronutrient adequacy such as vitamin A and heme iron. Table 3 shows that only 27.37% of the stunted group and 30.30% of the non-stunted group had adequate food diversity. Table 4 shows that the food groups with a low percentage of consumption are dark green leafy vegetables, vegetables and fruits rich in vitamin A, milk and its processed products, and organ meat. These food groups are rich in vitamin A content. Vitamin A plays an important role in the formation of RBC through the modulation mechanism of erythropoietin synthesis[25], and acts as cell-mediated immunity, thereby reducing the risk of anemia due to infection[31]. This study shows difference in the consumption of milk and milk products group on the

first and second recall day (p=0.014). This result could be due to a special day that provides these food products which coinciding with the second recall day. The result of this study is similar to a study of Savyet al.(2007) which states that market day is one of the special days that causes changingfood groups consumption. The changing in consumption of food groups had impacted on the increasing score of food diversity.[32]

Table 3. Dietary Diversity of Research Subject

Categorization	Stuntedn (%)	Non- stuntedn (%)
Inadequate (consumption <5 food groups)	24 (72.73)	23 (69.70)
Adequate (consumption ≥ 5 food groups)	9 (27.37)	10 (30.30)
Total score, mean±SD	4.24±1.15	4.27±1.03

Table4. Dietary Diversity Based Food Group

Food group	Recall day -1n (%)	Recall day -2n (%)	p
Strachy staples			
No consumption	0 (0.00)	0 (0.00)	1.0001)
Consumption	66 (100.00)	66 (100.00)	
Dark green leafy vegetables			
No consumption	46 (69.70)	44 (66.67)	0.7101)
Consumption	20 (30.30)	22 (33.33)	
Other vitamin A rich fruits and vegetables			
No consumption	47 (71.21)	56 (84.85)	0.0591)
Consumption	19 (28.79)	10 (15.15)	
Other fruits and vegetables			
No consumption	26 (39.39)	25 (37.87)	0.8591)
Consumption	40 (60.61)	41 (62.12)	
Organ meat/ Offals			
No consumption	58 (87.88)	62 (93.94)	0.2281)
Consumption	8 (12.12)	4 (6.06)	
Meat and fish			
No consumption	17 (25.76)	16 (24.24)	0.0762)
Consumption	49 (74.24)	50 (75.76)	
Eggs			
No consumption	33 (50.00)	29 (43.94)	0.4892)
Consumption	33 (50.00)	37 (56.06)	
Legumes, nuts, and seeds			
No consumption	28 (42.42)	22 (33.33)	0.0852)
Consumption	38 (57.58)	44 (66.67)	
Milk and milk products			
No consumption	63 (95.45)	54 (81.82)	0.0141)
Consumption	3 (4.55)	12 (18.18)	
Total score of food diversity, mean±SD	4.18±1.37	4.33±1.26	0.2992)

[1] Mann-Whitney test; [2] Independent T test; p<0,05

Difference Variables Between Stunted and Non-Stunted Groups

Table 5 shows no difference in haemoglobin concentration of both groups (p=0.887). That is expected to be the effect of WIFA supplementation because there is no literature stating that iron metabolism and haemoglobin production mechanisms differ between both groups. Interventions to improve haemoglobin concentration must be carried out immediately for stunted individuals to prevent low haemoglobin levels and the negative impact on rapid growth process of the adolescent period.[33]

Table 5. Bivariate Analysis

Difference Variables Between Stunted and Non-Stunted Group			
Variables	**Mean**		**p**
	Stunted	**Non stunted**	
Score of knowledge about anemia	86.06±14.56	88.48±11.21	0.451[1]
Score of knowledge about WIFA supplementation	74.75±17.24	72.73±17.09	0.634[1]
Dietary diversity	4.24±1.15	4.27±1.03	0.911[1]
Haemoglobin concentration	13.52±1.21	13.47±1.68	0.887[1]
Compliance of WIFA consumption	56.89±37.76	75.25±31.59	0.036[1]
Correlation Variables with Haemoglobin concentration			
Variables	r		p
Score of knowledge about anemia	-0.078		0.534[2]
Score of knowledge about WIFA supplementation	0.044		0.727[2]
Consumption of WIFA	-0.135		0.279[3]
Compliance of WIFA consumption	0.068		0.589[2]
Dietary diversity	-0.095		0.447[2]

[1] *Independent T test*; [2] *Pearson Correlation*; [3] *Spearman Correlation*; p< 0,05

Correlation of Affected Factors to Haemoglobin Concentration

Table 5 shows that there were no significant correlation all variables with haemoglobin concentration. The intervention research conducted by Allen et al.(2000) states that the absence of a significant variable with haemoglobin concentration can be caused by the level of haemoglobin in a normal category at the beginning of WIFA program and a good quality diet that can support the formation of haemoglobin.[34] The causal relationship cannot be clearly illustrated in this study because of the use of a cross sectional design.

Conclusion

There was no significant difference the haemoglobin

concentrationofboth groups and there were no correlation between affected factors with haemoglobin concentration. The absence of a significant variable with haemoglobin concentration can be caused by the level of haemoglobin in normal category at the beginning of the WIFA program and a good quality diet that is able to support the formation of haemoglobin. As a final remarks, the causal relationship cannot be described clearly because of the use of a cross sectional study design in this study.

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A Study of Duration of Oxygen Therapy and Severity of Respiratory Distress in New Born

Navaney Hiru[1], Anjali Ahuja[2]

[1]Associate Professor, [2]PG 1st year Student, Department of Pediatrics, Saraswathi Institute of Medical Sciences, Pilkhuwa, Hapur

Abstract

Objective: This prospective study was conducted:

1. To study the duration of oxygen therapy and severity of respiratory distress in newborn.

2. To establish that with increase in severity of distress (Downe's score) there is increase in duration of oxygen requirement.

Methods: This study was carried out on a total number of 100 newborns including preterm and term newborn with respiratory distress.

Spearman Rank Correlation:

Cofficient was used to assess the correlation between Downe's score and number of days oxygen required. Data analysis was done using statistical package for social sciences(SPSS) Version 22.0.

Result: The study shows that 24% the newborn with respiratory distress required O2 treatment for less than 24 hours, as compared to the 76% of newborns with respiratory distress (42% for 2 days, 10% for 3 days, 3% for 4 days, 21% for 5 days) required O2 treatment for >24 hours. There was no newborn with respiratory distress that did not required O2 therapy. None of the newborn with TTN required O2 for more than 2 days, 7 out of 14 newborn with RDS (50%) and 3 out of 13 newborns with MAS(23.07%) had severe distress and required oxygen for more than 24 hours. Bhutta ZA et al studied 81 neonate with respiratory distress and it was seen that these babies required supplemental oxygen while in NICU, but unlike our study, the above study has not analyzed O2 requirement depending on the cause of respiratory distress which should help to determine clinical outcome.

Conclusion: A total of 100 newborns with respiratory distress including term and preterm delivered either by vaginal or cesarean section, outborn or inborn were studied. The study showed that 24% newborn with respiratory distress required oxygen treatment for less than 24 hours as compared to 76% of the newborn with respiratory distress.

Keyword: *TTN, MAS, RDS,NICU, O2, INSURE,TOF*

Introduction

Respiratory distress in newborn is a common problem accounting for large number of NICU admission with considerable mortality. The causes of respiratory distress in a newborn are diverse and multisystemic disorders like intracranial injury, cardiac failure, metabolic disorders, septicemia and congenital malformation can also manifest clinically with respiratory distress. Newborn respiratory distress presents a diagnostic and management challenge. Newborns with respiratory distress commonly exhibit tachypnea with a respiratory

rate of more than 60 respirations per minute. They may present with grunting, retractions, nasal flaring, and cyanosis. Common causes include transient tachypnea of the newborn, respiratory distress syndrome, meconium aspiration syndrome, pneumonia, sepsis, pneumothorax, persistent pulmonary hypertension of the newborn, and delayed transition. Congenital heart defects, airway malformations, and inborn errors of metabolism are less common etiologies. Clinicians should be familiar with updated neonatal resuscitation guidelines. Initial evaluation includes a detailed history and physical examination. The clinician should monitor vital signs and measure oxygen saturation with pulse oximetry, and blood gas measurement may be considered. Chest radiography is helpful in the diagnosis. Blood cultures, serial complete blood counts, and C-reactive protein measurement are useful for the evaluation of sepsis. Most neonates with respiratory distress can be treated with respiratory support and noninvasive methods. Oxygen can be provided via bag/mask, nasal cannula, oxygen hood, and nasal continuous positive airway pressure. Ventilator support may be used in more severe cases.

Surfactant is increasingly used for respiratory distress syndrome. Using the INSURE technique, the newborn is intubated, given surfactant, and quickly extubated to nasal continuous positive airway pressure. Newborns should be screened for critical congenital heart defects via pulse oximetry after 24 hours but before hospital discharge. Neonatology consultation is recommended if the illness exceeds the clinician's expertise and comfort level or when the diagnosis is unclear in a critically ill newborn.[7]

Material and Method

The study was carried out on patient being admitted in NICU, department of Pediatrics, Saraswathi institute of Medical Sciences, Hapur (Uttar Pradesh). A total number of 100 newborns, include preterm and term newborn delivered either by vaginally or by cesarean section, inborn or outborn admitted in NICU with respiratory distress were selected by applying the inclusion criteria of present working proforma designed for the study.

DOWNE's SCORE:

SCORE	RESPIRATORY RATE	CYANOSIS	AIR ENTRY	GRUNT	RETRACTION
0	<60/min	None in room air	Normal	None	Nil
1	60-80/min	No cyanosis with O2 support	Decreased	Audible with stethoscope	Mild
2	>80/min	Cyanosis inspite of O2 support	Barely audible	Audible without stethoscope	Moderate to severe

SCORE 0-3 = Mild respiratory distress

SCORE 4-6 = Moderaterespiratory distress

SCORE>6 = Impendingrespiratory distress

Respiratory distress scoring was done according to DOWNE's scoring and graph 1 depicts correlation between DOWNE's score and oxygen required:

Correlation bw DOWNE's score and Oxygen required
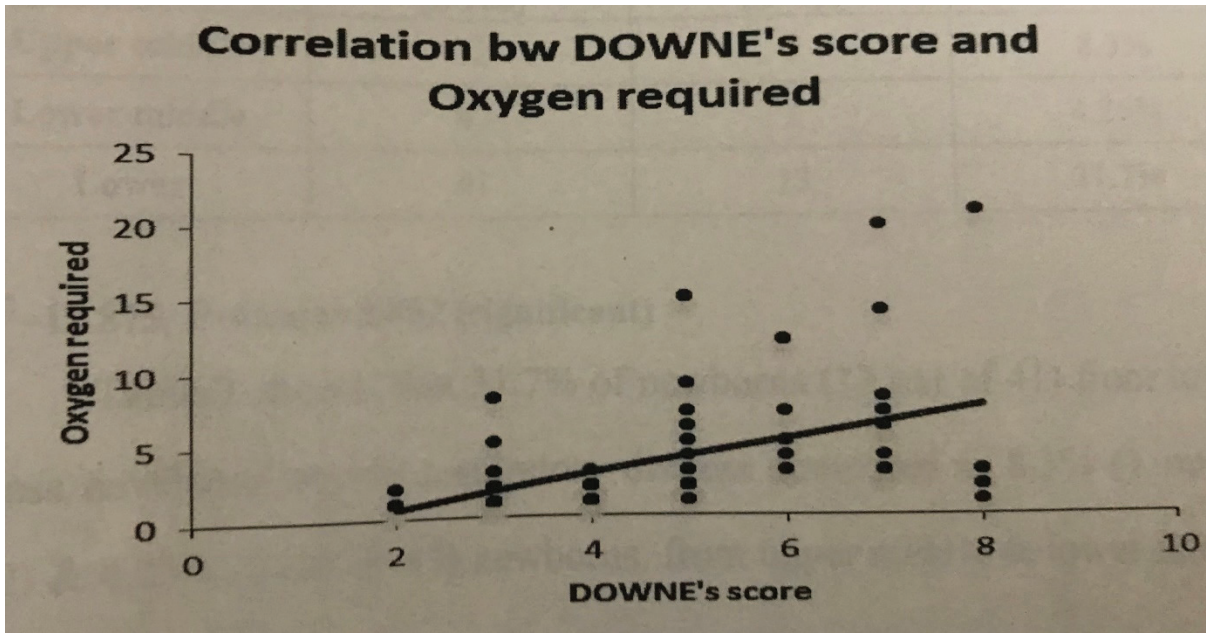
Criteria For Patients Selection:

Inclusion Criteria:

Both inborn and outborn neonate admitted to NICU of Saraswathi medical college, Hapur with respiratory distress within 72 hours of life defined clinically by presence of atleast 2 of the following criteria:

1. Tachypnoea (RR of 60/min or more).

2. Increased work of breathing (subcoastal indrawing, xiphoid retraction, suprasternal indrawing, flaring of alar nasi, expiratory grunt).

3. Cyanosis in room air(sp02<90%).

Exclusion Criteria:

1. Babies more than 72 hour of life.

2. Babies with congenital anomalies(TOF, Diaphragmatic hernia etc.)

3. Babies with gestational age less than 28 completed week.

4. ELBW (babies weight<1000 gm)

SPEARMAN RANK CORRELATION:

Cofficient was used to assess the correlation between Downe's score and number of days oxygen required. Data analysis was done using statistical package for social sciences(SPSS) Version 22.0.

Result:

Duration of O2 therapy v/s severity of respiratory distress.

TABLE-1:

Diagnosis	Frequency (n=100)	Severe distress (n=16)	No. of days of O2 Therapy					
			0	1	2	3	4	>4
TTN	60	00	0	23	37	0	0	0
MAS	13	03	0	0	01	5	1	6
RDS	14	07	0	01	03	1	1	8
HIE	08	04	0	0	01	3	1	3
SEPSIS	04	02	0	0	0	1	0	3
CHD	01	00	0	0	0	0	0	1

Table –1 shows that 24% of the newborns with respiratory distress required O2 treatment for less than 24 hours as compared to 76% of newborn with respiratory distress(42% for day 2, 10% for day 3 , 3% for day 4 and 21% for day 5) required O2 treatment for more than 24 hours. There were no newborn with respiratory distress that did not require O2 therapy. None of the newborn required oxygen for more than 2 days, 7 out of 14 newborn with RDS (50%), 3 out of 13 newborn with MAS (23.07%) had severe distress and required O2 for more than 24 hours.

TABLE-2:

No. of day oxygen required	Frequency (n=100)	Severe Distress =16	Mean	Standard deviation	Min.	Max.
1	24	1	3.292	1.3015	2	8
2	42	2	4.19	1.1943	2	8
3	10	4	5.6	1.8974	3	8
4	03	1	6	1	5	7
>4	21	8	5.857	1.3148	3	8
TOTAL	100	16	4.52	1.6298	2	8

DURATION	O2 Days
1	0.625
p-value	<0.0001
TOTAL	100

V – COEFFICIENT FACTOR

P- VALUE -<.0001 , highly significant

TABLE -2 shows that about 42% of neonates with respiratory distress required O2 for 48 hours along with other treatment. It was observed that the more the days the child was on oxygen the more severe is the distress.

Discussion

The study shows that 24% the newborn with respiratory distress required O2 treatment for less than 24 hours, as compared to the 76% of newborns with respiratory distress (42% for 2 days, 10% for 3 days, 3% for 4 days, 21% for 5 days) required O2 treatment for >24 hours. There was no newborn with respiratory distress that did not required O2 therapy. None of the newborn with TTN required O2 for more than 2 days, 7 out of 14 newborn with RDS (50%) and 3 out of 13 newborns with MAS(23.07%) had severe distress and required oxygen for more than 24 hours. Bhutta ZA et al studied 81 neonate with respiratory distress and it was seen that these babies required supplemental oxygen while in NICU, but unlike our study, the above study has not analyzed O2 requirement depending on the cause of respiratory distress which should help to determine clinical outcome.

Conclusion

A total of 100 newborns with respiratory distress including term and preterm delivered either by vaginal or cesarean section, outborn or inborn were studied. The study showed that 24% newborn with respiratory distress required oxygen treatment for less than 24 hours as compared to 76% of the newborn with respiratory distress.

Compliance with Ethical standard

Conflict of interest – None

Source of funding – None

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Analysis of N-Terminal Fragment B Type Natriuretic Peptide Serum In Chronic Kidney Disease

Nelly Tolla[1,2], Rachmawati A. Muhiddin[1], Fitriani Mangarengi[1]

[1]Department of Clinical Pathology, Faculty of Medicine, Hasanuddin University-Dr.Wahidin Sudirohusodo Hospital Makassar, Indonesia. Jl. Perintis Kemerdekaan Tamalanrea, Makassar, Telp. (0411)581226. Department of Physiology, Faculty of Medicine, Unismuh University Makassar, Indonesia. Jl. Sultan Alauddin No.259 Makassar

Abstract

Chronic kidney disease (CKD) is a condition of decreased kidney function due to chronic and irreversible renal parenchymal damage. Chronic kidney disease is one of the world's health problems due to its high prevalence of the disease, increasing morbidity and mortality rates and expensive treatment costs. Cardiovascular complications have been recognized as the leading cause of death in CKD. Left ventricular hypertrophy (LVH), systolic and diastolic dysfunction are the most common cardiovascular complications found in CKD. NTproBNP is an early diagnostic and prognostic biomarker of cardiovascular diseases, hence it can distinguish between acute and chronic cardiovascular diseases. Therefore, this examination is recommended to monitor patient treatment. NTproBNP levels circulating in the circulations of cardiovascular patients are about six times higher than other biomarkers including BNP. This study aims to assess serum NTproBNP levels in various degrees of CKD. This research is an observational analytic study with cross sectional approach. It was conducted between June and August 2019 at Dr. Wahidin Sudirohusodo hospital with total sample of 86 patients diagnosed with CKD who met the inclusion and exclusion criteria. Based on the Kruskal Wallis test, which were used due to abnormal data distribution, a significant difference was found in serum NTProBNP levels based on the degree of CKD with the initial increase occured in grade III CKD with mean value of 4,653 ng/L. Serum NTproBNP levels were not significantly different based on the degree of hypertension. Serum NTProBNP levels were significantly correlated with urea and creatinin levels and GFR value based on the Rho Spearman correlation test with a p value <0.05.

Keyword: *Chronic Kidney Disease, NTProBNP, Glomerular Filtration Rate, Hypertension*

Introduction

Chronic kidney disease is a condition of decreased kidney function that is chronic and irreversible. A person is diagnosed with CKD if there is an abnormality and damage to his the kidneys for approximately 3 months which is characterized by a decrease in kidney function with or without an abnormality of the kidneys. Chronic kidney disease is one of the world's health problems due to its high prevalence, increased morbidity and mortality rates and it requires expensive treatment costs. The increased prevalence of CKD is in line with the increased incidence of obesity, diabetes mellitus (DM), dyslipidemia and high blood pressure as the risk factors for CKD.[1,2]

About 20 million (10.8%) of the population of the United States experience CKD and 400,000 (0.1%) of them are categorized as ESRD which must be treated with dialysis (hemodialysis or periotenal dialysis) or kidney transplantation. Based on the data compiled from the 9th Annual Report of the Indonesian Renal Registry, the number of deaths of CKD patients in 2016 in Indonesia was 2,221 with cardiovascular complications

as the highest cause of death with the prevalence of left ventricular hypertrophy (49%) and coronary heart disease was 40%.[3]

Over the past decade, cardiovascular complications have been recognized as the leading cause of death in CKD. Left ventricular hypertrophy (LVH), systolic and diastolic dysfunction are the most common cardiovascular complications found in CKD. Most researchers report cardiovascular complications starting at the onset of decreased LFG. For CKD patients, especially at grade V, the decrease in LFG causes the disruption of water, electrolyte, and urea regulation. This leads to an increase in extracellular volume and vascular volume due to the retention of sodium and water by the kidneys. Increased vascular volume causes cardiac burden and strain increase resulting in cardiovascular diseases.[4]

Clinical manifestations experienced by CKD patients such as anemia, hyperkalemia, malnutrition, inflammation and impaired calcium and folate metabolism are involved in accelerating the process of heart damage. Hemodialysis is a therapy commonly experienced by CKD patients to control uremia, excess of fluid, and maintain electrolyte balance. Actions of hemodialysis repeatedly cause new problems with the emergence of various kinds of comorbidities, especially cardiovascular disease (68.4%). The slow identification of asymptomatic cardiovascular complications is a major cause of death in patients with CKD.[5,6,7]

Various biomarkers have been recommended as markers of cardiovascular diseases such as troponin, natriuretic peptides (BNP), N-terminal fragments of B-type natriuretic peptide (NTproBNP), C-reactive protein (CRP), Creatin Kinase (CK), Lactate dehydrogenase (LDH), homocysteine and plasminogen activator inhibitor 1 (PAI-1). Biomarkers that are considered to be clinically useful should have high sensitivity and specificity for detecting diseases with coefficient of low enough variation so that small changes in biomarkers reflect actual changes in the patient's clinical condition. N-terminal fragment B-type natriuretic peptide is an early diagnostic and prognostic biomarker of cardiovascular diseases, is able to differentiate between acute and chronic cardiovascular disease and is recommended for examination in follow-up therapy. NTproBNP levels circulating in the circulation of cardiovascular patients are about six times higher than other biomarkers including BNP. NT-proBNP levels increase along with increasing severity of heart failure and serve as a screening test for heart failure and asymptomatic left ventricular dysfunction.[8,9]

Methods

This study is an observational analytic study with cross sectional approach analyzing NTproBNP as an early diagnostic and prognostic biomarker of cardiovascular disease. The study was conducted during Juny until August 2019 at Clinical Pathology Laboratory of Dr. Wahidin Sudirohusodo Hospital Makassar. The study sample was all CKD patients diagnosed by Internists based on Glomerular Filtration Rate (GFR) by using cockroft-Gault formula. Patients who have been diagnosed with heart disease, obesity and patients who have undergone HD for more than 3x were excluded. All subjects were tested for serum NTproBNP, ureum, creatinine levels in Hasanuddin University Faculty of Medicine Research Unit/Hasanuddin University Hospital. NTproBNP assay was carried out with the Cat. No E-EL-H090296T ELISA kit.

Data were analyzed statistically by Kruskal Wallis test to determine the differences in NTproBNP levels of CKD in various degrees and hypertension. Spearman correlation tests was performed to analyze the correlation of NTproBNP levels with ureum creatinine levels and GFR. The results were considered significant if $p < 0.05$.

Results

The study samples obtained were 86 CKD patients who met the inclusion criteria. The characteristics of the study samples can be seen in table 1 that shows male subjects were more than female. Most study subjects were found in the 36-59 years-old group. Most of the study subjects had a history of hypertension and DM with a percentage of 44.2% and 22.1%, respectively.

Table 1. Sample characteristics

Sample characteristics	N (%)	Mean ± SD	p
Gender			
Male	57 (66.3)		
Female	29 (33.7)		
Age (years)		47.19 ± 11.88	0.036
NTProBNP (ng/L)		7.57 ± 8.29	0.013
Ureum (mg/dL)		89.01 ± 47.69	0.200*
Creatinine (mg/ dL)		3.51 ± 2.37	0.010
GFR (mm/menit/1.73 m2)		32 ± 22.7	0.200*
Platelet (x103/mm3)		273.65 ± 123.16	0.077*
Haemoglobin (gr/dL)		10.32 ± 2.19	0.083*
Blood Pressure			
Pre Hypertension	44 (51.2)		
Hypertension I	29 (33.7)		
Hypertension II	13 (15.1)		
Basic Diseases			
Hypertension	38 (44.2)		
Diabetes Mellitus	19 (22.1)		
Other diseases	19 (22.1)		
More than one diseases	10 (11.6)		

<div align="center">

Table 2. Comparison of NTproBNP levels based on various degrees of CKD

</div>

*Kruskall Wallis Test

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Table 2 showed the comparison of NTproBNP levels in various degrees of CKD patients. This study showed a significant difference NTproBNP levels in various degrees of CKD patients with p=0.000.

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Degree	NTproBNP Levels (ng/L)		
	N	Median (Min – Max)	P value
I	4	0.68 (0,58- 0.95)	
II	8	0.67 (0.36- 1.99)	
III	28	2.72 (0.34 – 30.45)	0.000*
IV	24	7.5 (0.60 – 34.93)	
V	22	9.67 (0.60 – 35.28)	

As shown on graph 1, the average level of NTproBNP began to increase at degree III with a mean of 4.65 ng / L and reached the highest level at degree V (mean = 12.05 ng / L).

<div align="center">
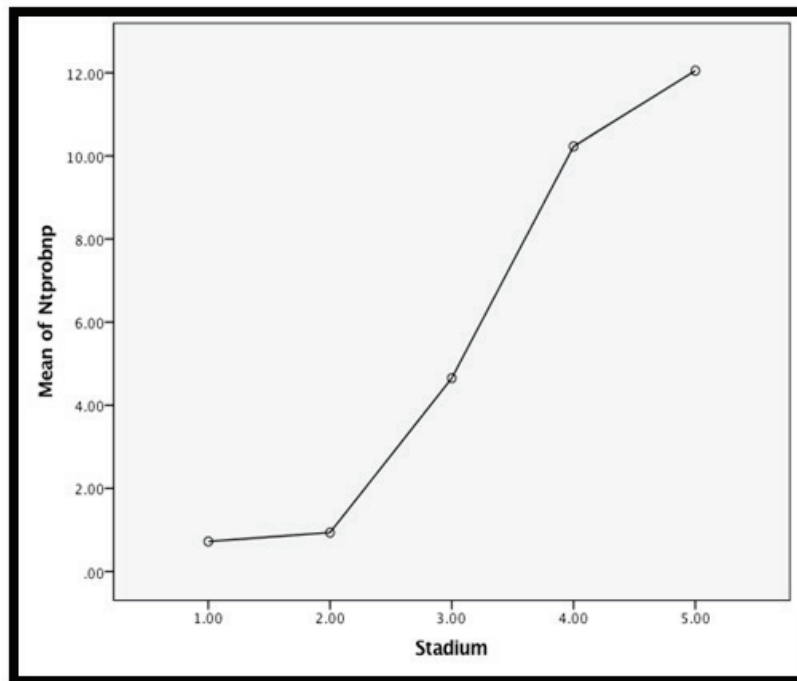
Graph 1. Average Ntprobnp Levels Based on PGK Degrees

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Table 3. Comparison of NTproBNP levels based on the degree of hypertension

Degree	NTproBNP Levels		
	N	Median (Min – Max)	P value
Pre Hypertension	44	3.79 (0,36- 35.28)	
Hypertension I	29	7.67 (0.34- 23.95)	0.708
Hypertension II	13	2.72 (0.58 – 15.53)	

*Kruskal Wallis Test

Table 3 showed the majority of the subjects was in the pre hypertension group, counted for 44 subjects. There was no significant difference in NTproBNP level at various degrees of hypertension (p = 0.708) based on the results of the Kruskall Wallis test.

Table 4. Correlation of NTproBNP levels with serum urea and creatinine levels

		Ureum	Creatinine
NTproBNP	N	86	86
	p	*0.019	*0.007
	r	0.253	0.289

*Correlation Spearman Rho test

Statistical analysis showed a positive correlation of NTproBNP levels with the ureum and creatinine levels with a weak correlation (r=0.50) as shown in Table 4

Table 5. Correlation of NTproBNP levels with GFR degrees

		GFR degrees
NTproBNP	N	86
	p	0.000
	r	-0. 579

*Correlation Spearman Rho test

Statistical analysis showed a negative correlation of NTproBNP levels with the GFR degrees levels with a medium correlation (r=-0.579) as shown in Table 5

Discussion

This study was conducted at Dr. Wahidin Sudirohusodo Hospital Makassar during the June-August 2019 period, involving 86 patients, including male (66.7%) and female (33.7%). Most patients with CKD were found in the average age of 47 years-old with the most common underlying disease is hypertension (38%). This is in line with the Indonesian Renal Registry (IRR) data (2016), showing that the highest prevalence of kidney failure found in male (0.5%) and female (0.2%) of all patients who are generally caused by diabetic nephropathy (52%), hypertension (24%), kidney stones, ureteric stones (6%), gout (1%), lupus disease (1%) and others (IRR, 2016). This result is dissimilar with what has been described by Kamelia that the number of CKD is not different between male and female.

NTproBNP levels were found to differ at each CKD levels and began to increase in the third grade CKD with a decrease in LFG <60 mm / min / 1.73 m2 with a median value and a minimum-maximum value of 2.72 (0.34 - 30.45). This study is in line with research conducted by Horii et al in Japan, BNP and NTproBNP levels were associated with cardiomyocyte damage in patients with CKD grade IV and V compared to the grade with the I-III grade. In a Chinese study, NTproBNP was the cause of death in patients with LFG <60 ml / min per 1.73 m2. In addition, the limit of NTproBNP associated with mortality is higher in patients with CKD (2584 pg / ml) than in people without CKD (370 pg / ml).[10,11]

Several studies conducted in the United States concluded that an increase in NTproBNP had a four times higher risk of cardiovascular complications than patients without CKD. The increasing prevalence of CKD is one of the main problems related to the incidence of heart failure as a complication which is 56% asymptomatic. Therefore, new parameters are needed to help in the identification and early detection of heart failure in CKD. The NTproBNP parameter is one of the molecules synthesized in cardiac myocytes in response to stress by stretching the left ventricular wall. Apart from being more stable in shape, a longer half-life is a better biomarker for chronic volume expansion or stress than BNP.[12,13]

The results of this study showed no significant difference between blood pressure (TD) and serum NTproBNP levels based on the degree of hypertension. This is not in line with research conducted by Supriati W, 2018 who found the opposite, showed that there is a significant difference in NTproBNP levels in the degree of BP increase associated with the duration of hypertension. [14]This study uses research samples with various causes of CKD such as HT, DM, ureteric stones, pyelonephritis and other diseases so that the blood pressure in patients varies greatly and is influenced by several factors such as therapy, duration of disease and etiology of more than 2 diseases.

Hypertension is one of the main risk factors for cardiovascular diseases, such as heart failure, acute myocardial infarction and even sudden death. Patients with hypertension can experience cardiac arrhythmias and abnormalities such as left ventricular hypertrophy (LVH) and left ventricular systolic dysfunction (LVSD), due to the induction effect by the left ventricular hypertrophic response to increase post cardiac load. Detection of this condition is very important in the management of hypertensive patients. Therefore, NTproBNP is used as a marker for the detection of heart failure.[15,16]

This study found a significant correlation between serum NTproBNP levels with urea levels (p = 0.019) and creatinine (p = 0.007) with a weak correlation. This is in line with research conducted by Astor BC in 2008, concluding that there is a significantly stronger correlation in CKD patients with proteinuria associated with impaired renal filtration function with a p value = 0.05. This study is different with research conducted by Fabio et al, 2011 NTproBNP levels is correlated with urea and creatinine and GFR with a p value> 0.05. Patients with CKD who undergo HD, have a higher cardiovascular risk of suffering from heart disease than non-HD patients. Left ventricular hypertrophy and left ventricular dysfunction are currently considered the strongest predictors of cardiovascular diseases and total mortality in the dialysis population. Left ventricular hypertrophy is a widespread complication of end-stage renal disease with prevalence rates ranging from 60 to

80%. [12,17]

This study found higher levels of NTproBNP in HD patients compared to patients without HD even though the patients were asymptomatic. NTproBNP levels are going to increase as a result of decreased renal excretion and fluid volume and due to several other factors such as uremic syndrome, blood contact with the dialysis membrane and progression to decrease LFG. NTproBNP can routinely be used as a diagnostic tool to detect LVD in CKD patients.

This study has several limitations, This study did not analyze the length of continuation of the underlying disease and the given treatment, the history of other risk factors causing cardiovascular disease such as smoking and not evaluating the cardiovascular diseases by echocardiography.

Conclusion and Suggestion

This study concluded that there were differences in NTproBNP levels in various degree of CKD and begin to increase in the third stage. There was no difference in NTproBNP levels in the degree of hypertension. There was a weak positive correlation between NTproBNP levels and ureum creatinine levels and medium negative correlation with GFR. Patients with CKD, it can be considered NTproBNP examination to prevent further cardiovascular complications. Beside that, further researches that measures NTproBNP levels in CKD by considering echocardiography examination to establish a definitive diagnosis of cardiovascular complications.

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The Effect of Health Education on the Level of Knowledge and Behavior in Diabetes Mellitus Management

Noor Diani[1], Alfian Nur[2], Dhemes Alin[3]

[1]Lecturer, Department of Medical Surgical Nursing, Nursing School, Faculty of Medicine, Lambung Mangkurat University, [2]Lecturer, Department of Community, Nursing School, Faculty of Medicine, Lambung Mangkurat University, [3]Education Staff, Nursing School, Faculty of Medicine, Lambung Mangkurat University

Abstract

Diabetes mellitus is a metabolic disease characterized by glucose levels in the blood that are more than normal or hyperglycemia, this is due to a decrease in the body's ability to react with insulin, or it could be impaired insulin secretion.Riskesdas 2013 shows that diabetes mellitus sufferers in Indonesia are around 6.9% or around 12 million people with 1.4% of diabetes sufferers in South Kalimantan or around 38,113 people diagnosed with diabetes mellitus, especially type 2 diabetes mellitus which is related to lifestyle.One of the efforts made is health education. This research is an experimental research using pre-experimental method with one group pretest-postest design. The sampling technique used consecutive sampling of 50 people.The results of the effect of health education on the behavior of diabetes mellitus sufferers obtained p-value = 0.011<0.05, this indicates that Ho is rejected, which means that there is an effect of health education on the behavior of diabetes mellitus sufferers in handling diabetes mellitus.The results of the effect of health education on the knowledge level of diabetes mellitus sufferers obtained p-value = 0.421> 0.05, this indicates that Ho is accepted, which means that there is no effect of health education on increasing knowledge of diabetes mellitus sufferers in handling diabetes mellitus. These results were obtained from the pre and post-test scores of the respondents which indicated that there was an influence before and after health education to the public.

Keywords: *Diabetes Mellitus, Health Education, Knowledge, Behavior*

Introduction

Diabetes mellitus is a metabolic disease that has a collection of symptoms due to an increase in blood glucose levels above normal values (hyperglycemia) due to a decrease in the body's ability to react with insulin, impaired insulin secretion, or both[1,2].

There was an increase to 422 million people in 2014[3]. Indonesia is ranked seventh in the world with 10 million people with diabetes mellitus in 2015[4]. The increase in the prevalence of diabetes mellitus globally is mainly due to a lack of knowledge about diabetesmanagement and lifestyle changes such as unhealthy behavior, obesity and lack of exercise[5]. Diabetes mellitus has complications that can occur in patients such as complications in the heart, kidneys, blindness, atherosclerosis and even limbs that can be amputated due to the death of rotting tissue[6].

Knowledge of diabetics is means that can help sufferers undergo diabetes management during their life so that sufferers understand how to behave in dealing with their disease. The behavior of diabetics is very much influenced by knowledge, in this case knowledge is very important to determine behavior that can reduce the risk of complications[5].

The results showed that 83.3% of respondents had inappropriate behavior in managing diabetes mellitus[7]. According to other research, it shows that 23.3% of respondents have less knowledge about diabetes mellitus foot care[8]. Other research shows that 68.3% of respondents do not comply with physical exercise[9].

Management of diabetes mellitus that is understood by people with diabetes mellitus in the community needs to be identified and analyzed as the basis for to develop diabetes mellitus prevention efforts in the community.There has never been a comprehensive health education on the management of diabetes mellitus in the community.

Based on the phenomena and results of previous studies, researchers are interested in conducting research on the effect of health education on the level of knowledge and behavior in diabetes mellitus management.

Method

This research is an experimental research using pre experimental method with one group pretest-postest design. The population in this study were patients with diabetes mellitus in Cempaka Village. The sampling technique used consecutive sampling and a sampling size of 50 samples based on inclusion criteria.

The instrument used was a questionnaire consisting of three parts: demographic questionnaire, diabetes mellitus knowledge questionnaire, and diabetes mellitus management behavior questionnaire.

Results and Discussion

RespondentCharacteristics

Table 1. Characteristics of Respondents

Respondent of Characteristics	Quantity	Percentage
Age		
36-45 tahun	3	6,0
46-55 tahun	27	54,0
56-65 tahun	16	32,0
> 65 tahun	4	8,0
Total	50	100,0
Gender		
Male	14	28,0
Female	36	72,0
Total	50	100,0
Education		
Notcompleted in primary school/ not elementaryschool	36	72,0
Junior highschool Senior high school	11	22,0
College	3	6,0
Total	50	100,0

Respondent of Characteristics	Quantity	Percentage
Profession		
Government Employees	0	0,0
Private	0	0,0
Farmer	2	4,0
Traders	7	14,0
Others	41	82,0
Total	50	100,0
Long suffered Diabetes Mellitus		
0-5 years	38	76,0
6-10 years	8	16,0
11-15 years	3	6,0
16-20 years	0	0,0
> 20 years	1	2,0
Total	50	100,0
Comorbidities		
Have	39	78,0
Do not have	11	22,0
Total	50	100,0

In table 1.The characteristics of respondents obtained the most data based on age at the age of 46-55 years, namely 54%, the most gender is female, 72%. another 82% which includes housewives, retired and not working. The longest duration of diabetes mellitus sufferers was at 0-5 years, namely 76%, respondents who had the most comorbidities with diabetes mellitus were 78%.

This age range is included in the range of middle adulthood (Middle Adulthood)[10]. Age over 40 years is also a risk factor for diabetes mellitus[11]. This is in accordance with other research that old age affects diabetes because physiological body function decreases and there is a decrease in insulin secretion or resistance so that the body's ability to function to control high blood glucose is less than optimal[12,13].

The results of the same study werealso stated that the female respondents who suffered from diabetes mellitus were 84% [14]. This is in accordance with research which states that women have a higher risk of developing diabetes than men. The number of female sufferers compared to male sufferers is caused by risk

factors from the Body Mass Index (BMI) between women and men[15].

In the study, it was stated that there was no significant effect between education level and blood glucose levels in diabetes mellitus patients. The level of education may only affect the perspective of the disease. Patients with a high level of education also have a high awareness of a disease[3].

Work can affect knowledge. Reviewedfrom its type, jobs that often interact with other people are more exposed to information or those without any interaction with other people. Work is also related to the physical activity of people with diabetes mellitus. People who do physical activity will burn body fat. This body fat has the potential to increase blood sugar levels in the body if there is no burning[16].

The longer the respondent suffers from the disease, the better the respondent responds to the disease, such as adhering to the treatment[17]. This is in accordance with other studies, which state that the duration of suffering from diabetes mellitus affects knowledge of the disease[18].

High levels of glucose in the blood, glucose metabolites or high levels of fatty acids in the blood can cause damage to the endothelial cell lining of the arteries[19].Some of the vascularcomplications, including cardiovascular, cerebrovascular and peripheral vascular[20].This can be seen from the respondent's comorbidities, which include high blood pressure, cholesterol, heart disease and stroke. Diabetes mellitus can also reduce the body's immune system. Uncontrolled high blood sugar levels can also result in susceptibility to infection. This can be seen from the respondent's comorbidities related to infection, including the presence of respondents with a history of TBC[21].

Knowledge Levels of Diabetes Mellitus Patients in the Management of Diabetes Mellitus Before and After Health Education Treatment

Table 2. Knowledge Levels of Diabetes Mellitus Patients in Diabetes Mellitus Management Before Health Education Treatment

Knowledge Level	Pre Test		PostTest	
	Quan-tity	Persen-tage	Quan-tity	Persen-tage
Good	38	76,0	41	82,0
Sufficient	9	18,0	7	14,0
Less	3	6,0	2	4,0
Total	50	100,0	50	100,0

In table 2. Knowledge Level of Diabetes Mellitus Patients in Management of Diabetes Mellitus Before Health Education Treatment is given the pre-test results at the level of knowledge before being given health education in the good category, namely 76%.

The results of the post test at the level of knowledge after being given health education were in the good category but increased from the time of the pre-test, namely 82%. The increase occurred by 6% (from 76% to 82%).Thisincrease also shows the effectiveness of health education that has been provided to respondents.

The level of knowledge in the management of diabetes mellitus is related to the duration of suffering from the disease. Most respondents have suffered from diabetes mellitus for five years. This five year period allows respondents to get a lot of information about diabetes mellitus. This is in accordance with other studies, which stated that the duration of suffering from diabetes mellitus affects knowledge of the disease[18].

Knowledge about diabetes mellitus is very important for DM patients, in order to avoid complications. Most of human knowledge is acquired through the eyes and ears[22]. An intervention is needed to increase knowledge about the disease, the management process or treatment therapy[6]. The intervention carried out in this study was by means of health education.

The evaluation in this study was seen from the post test scores that have been carried out. The category of knowledge level in diabetes mellitus sufferers in diabetes

mellitus management before being given health education treatment is in good category. The researcher then provided an intervention in the form of health education to the respondents. As a result, the respondent's level of knowledge increases. This good knowledge is obtained from several factors. Factors that support this

include the length of time the respondent suffer from diabetes mellitus respondents who on average of five years. The increase in respondents' knowledge was then obtained after receiving health education. Respondents returned to get new knowledge about the disease.

Behavior in Diabetes Mellitus Patients in Diabetes Mellitus Management Before and After Health Education Treatment

Table 3. Behavior of Diabetes Mellitus Patients in Diabetes Mellitus Management before and after Health Education Treatment

Behavior	Pre Test		PostTest	
	Quantity	Persen-tage	Quantity	Persen-tage
Good	7	14,0	9	18,0
Sufficient	34	68,0	37	74,0
Less	9	18,0	4	8,0
Total	50	100,0	50	100,0

Table 3. Behavior in Diabetes Mellitus Patients in Diabetes Mellitus Management before and after being given Health Education Treatment, the pre-test result on behavior before being given health education is in the sufficient category, namely 68%. The results of the post-test on behavior after being given health education were in the sufficient category but increased from the initial test, namely 74%. This increase also shows the effectiveness of health education that has been provided to respondents, even though it is in the sufficient category. The increase occurred by 6% (from 68% to 74%).

Behavior is influenced by knowledge. Knowledge is the basis for taking an action[22]. Health behavior is a person's response to stimuli related to illness and disease[23]. The most important thing in health behavior is the problem of behavior formation and change. Behavior

change is the goal of health education or promotion to support other health programs[22].

Knowledge has six levels which were included in the cognitive domain. These levels are knowing, understanding, application, analysis, synthesis and evaluation[22]. This is one of the factors of respondent behavior in the sufficient category. Behavior in the management of diabetes mellitus is in the moderate category. The researcher then provided an intervention

in the form of health education to the respondents. The results remain in the adequate category, but the value of the respondent's level of behavior increases. Another study stated that it took 5 weeks to carry out health education before there was a change in the respondent's lifestyle[24].

The Effect of Health Education on Knowledge Levels of Diabetes Mellitus Patients in Handling Diabetes Mellitus

Table 4. The Effect of Health Education on Knowledge Levels of Diabetes Mellitus Patients in Handling Diabetes Mellitus

Knowledge level	Mean	StandardDevia-tion	DifferenceMean	p-value
Pre	11,14	2,523		
Post	11,44	2,196	0,30	0,421

In table 4.Effect of Health Education on Knowledge Levels of Diabetes Mellitus Patients in Handling Diabetes Mellitus, the p-value = 0.421> 0.05, this indicates that Ho is accepted, meaning that there is no effect of health education on increasing knowledge of diabetes mellitus sufferers in handling diabetes mellitus. These results are obtained from the pre and post test scores of the respondents.

The results of this study are different from other studies, which show that health education has a significant effect on increasing knowledge about DM. This is influenced by one factor is the level of education. The dominant education level of respondents in other studies. The dominant education level of the respondents in this study was that they did not complete elementary school, even not elementary school. The distribution of the education level of the respondents in other studies was 37.9%. This 37.9% figure shows that the distribution of education levels is almost evenly divided into the classifications ofelementary school, junior high school, seniorhigh school and college.

The figure of 72% in this studyshows that the distribution of education levels is dominant in those who do not complete primary school/do not attend school[25].

Health education affects the level of knowledge of respondents which can be influenced by several factors. This factor is the level of respondent's knowledge which was classified as less prior to the intervention as much as 56.6%. The value of the respondent's level of knowledge then improved after the intervention was carried out, namely 93.8%. The category of knowledge level in this study is divided into 3, namely, good, enough and less[26]. This is different from the level of knowledge of the respondents carried out by the researcher. The level of knowledge of respondents before the intervention was in the good category, as well as after the intervention.

The Effect of Health Education on the Behavior of Diabetes Mellitus Patients in Handling Diabetes Mellitus

Table 5. The Effect of Health Education on the Behavior of Diabetes Mellitus Patients in Handling Diabetes Mellitus

Behavior	Mean	StandardDevia-tion	DifferenceMean	p-value
Pre	10,22	2,873	1,16	0,011
Post	11,38	2,276		

In table 5. The effect of health education on the behavior of diabetes mellitus sufferers in the treatment of diabetes mellitus, the p-value = 0.011 <0.05this indicates that Ho is rejected.

It can be concluded that there is an effect of health education on the behavior of diabetes mellitus sufferers in handling diabetes mellitus. These results are obtained from the pre and post test scores of the respondents.

These results are obtained from the pre and post test scores of the respondents. There are five principles for managing diabetes mellitus in general. The five principles are education, diet, exercise (physical exercise), drug therapy and monitoring of blood sugar levels and preventing complications. The five principles are included in the form of diabetes mellitus patient behavior. Health education is a learning effort for people who are willing to take actions to maintain and improve their health, prevent disease, maintain existing health standards, maximize the function and role of patients during illness and help patients and families overcome health problems[22].

The results of this study are in line with other studies, which state that there is an effect of providing health education on the level of dietary compliance in diabetes mellitus sufferers[27]. A diabetes mellitus diet is highly recommended to maintain near normal blood glucose levels, achieve optimal serum lipid levels, and manage acute complications and improve overall health[28]. Another study stated that there was an effect between physical activity on blood sugar levels in patients with diabetes mellitus[16]. Physical activity at least 30 minutes every day, both done in an effort to cure diabetes mellitus.

Sports such as swimming, cycling, jogging and brisk walking are the types of sports that are recommended for sufferers of the disease[29].

Conclusions and Recommendations

There are still many people who do not realize the risk factors for disease to maintain blood sugar stability for people with diabetes mellitus. The community's need for health education is related to the factors that influence disease and the emergence of diabetes mellitus so that people have a healthy quality of life.

This research is expected to be able to contribute to the reading audience to be able to develop research with different methods and to provide related health educationdiabetes mellitus.

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Package of Essential Noncommunicable Disease Services at Peri-Urban Community Setting in Chandigarh, India- An Implementation Research Study

Pal S[1], Thakur JS[2], Suri V[3], Singh G[4], Goyal A[5], Rajwanshi A[6]

[1]Junior Resident, [2]Professor, Community Medicine & School of Public Health, [3]Professor & Head, Obstetrics and Gynecology, [4]Professor & Head, General Surgery, [5]Professor, Pedodontics & Preventive Dentistry, [6]Professor & Head, Cytology & Gynecological Pathology, PGIMER, Chandigarh

Abstract

Background: The National Programme for prevention and control of cancer, diabetes, cardiovasculardisease, and stroke **(**NPCDCS) has been launched since 2011-2012 but there is paucity of information on progress and implementation of this program.

Method: The objective was to do situational analysis for assessing the current implementation of NCD programs in peri-urban area and to implement the package of essential NCD services by capacity building of existing staff through routine health care delivery for effective coverage. After training of ANMs implementation was started. Baseline assessment was performed through pre-tested questionnaire among subjects (n=1026) who were aged> 30 years and residing in that area for >6 months.

Result: About 37% (n= 406) of the people were screened for hypertension, 34% (n=352) were screened for diabetes in the last one year. Post intervention screening coverage was increased to 96.9%, 97.5% for blood sugar and blood pressure respectively and 95.4%, 93.4% and 54.8% for oral, breast and cervical cancer. After implementation 23(2.4%) new cases of diabetes and 132 (13.2%) new cases of hypertension were diagnosed.

Conclusion: Screening coverage at baseline analysis was found to be 37.1% and 34% for blood pressure and blood sugar measurement respectively and 0.5%, 0.2%, 0.3% for oral, breast and cervical cancer screening, respectively. This highlights the poor implementation of the programme. After implementation, screening coverage for measurement of blood pressure and blood sugar improved by about 60% and by about 90% for three common cancers.

Key words: Non-Communicable diseases, quasi experimental study, PEN, India

Corresponding author:
Dr. Swarnika Pal
4/298 Subhash Nagar, Shuklaganj, Unnao. 209861
Swarnikapal19@gmail.com
Paraswarnika19@gmail.com   9915785281
E-mail   Telephone number

Introduction

NCDs are chronic diseases which are slowly progressive and last for long period of time. It is also called as "lifestyle" disease because the majority are preventable diseases.[1] Mortality from communicable diseases have decreased while those from NCDs have increased. NCDs account for 63% of the global deaths,

60% of death in South-East Asian region and 62% of death in India.[2] In Chandigarh deaths due to different NCDs in 2013, circulatory system 10.6%, endocrine nutrition and metabolic diseases is 6.6%, disease of respiratory system 13.9%, neoplasm 8.6%. In Chandigarh prevalence of cardiovascular diseases is 12.3 as per DLHS 4, diabetes 15 as per CUDS study, COPD- 4. Incidence rate of breast cancer 37.5 and cervical is 10.3 which are leading cancer among women.[3] India's economic burden of disease according to WHO associated with NCDs is $3.55 trillion and mental health is $1.03 trillion and overall, of $4.58 trillion for the 18-year period (2012-2030). Total health expenditure over past 19 years is less than six times the estimated losses (roughly $4.5 trillion) over the entire period in India.[4]

Government of India had reinforced the States in management of non-communicable diseases through various vertical programs. National Multisectoral Action Plan for prevention and control of Non communicable diseases**,** in solidarity with Ministry of Health and Family Welfare, GOI, WHO Country Office for India. India was the first country to develop National Monitoring Framework and set targets and indicators as per country perspective.[5] The National Programme on Prevention and Control of Cancer, Diabetes, Cardiovascular diseases, and Stroke (NPCDCS) during 2010-11 was launched to contain the rising burden of Non-Communicable Diseases by Ministry of Health and Family welfare, Government of India. The operational guidelines on prevention and control for non- communicable diseases launched (2013-17).[6] The Government of India and the States have made continuous efforts but have not been able to control the rising burden of NCDs because of the operational issues. We really need a study to understand the implementation issues to ensure comprehensive primary health care and prevent the growing burden of non-communicable diseases. Therefore, this study is done as a step forward to implement the services based on operational guidelines for Prevention, Early detection, and Control for Non-communicable diseases: Hypertension, Diabetes and Common Cancers (2017).

Methodology

The study design was quasi-experimental study conducted over one year period 2016-2017 at an Urban Health Training Centre in Chandigarh. Operational guidelines for Prevention, Early detection, and Control for Non-communicable diseases: Hypertension, Diabetes and Common Cancers (2017),[6] which provides a framework for risk assessment and packages of services for population-based screening of non-communicable diseases, was adapted for this study. The intent of the study was to assess the current situation and progress of the NPCDCS programme in the study area, to implement the packages of services as per operational guidelines (2017) and to assess the feasibility of CBAC (community-based assessment checklist) form as educational tool by health workers.

The population catered by urban health training centre (UHTC), Indira Colony was considered for the purpose of this study which was 28,972. As per the NCD program adults above 30yrs were included in the study, which constitutes 38% of the total population (28,972) and came around 11,009. Sample size was calculated based on mean change in blood pressure of 2.5mm Hg via study done by KR Thankappan.[7] Sample size for the study was total 1026 people considering 8% of non-response rate. Five health workers (1 male and 5 females) working in UHTC Indira Colony were included in the study after taking their informed consent. To complete the required sample size, 205 individuals were selected from the household list available with each of the health workers by systematic random sampling, keeping in view the limited period of study. Anyone residing in the area for more than six months, Age of beneficiary- more than or equal to 30 years for screening for diabetes and hypertension, 30-64 years for the three common cancers, oral, breast and cervical. The workers will continue further implementation till the coverage of entire population is achieved.

Investigator selected sub sample from the study group by systematic random sampling, 34 people (20%) of the sample size of each health worker, total of 205, initially at baseline and then at the end of 5 month in the intervention area for assessment.

For situational analysis of NPCDCS programme pre-designed and pre-tested questionnaire (few components of questionnaire are taken from STEPS questionnaire) was used. Facility based survey was done by the investigator using a pre-designed and pre-tested questionnaire, pre and post-intervention. Capacity assessment of the health staff was done using a pre-designed and pre-tested questionnaire, pre and post-training program.

For Implementation of services- Training of health staff was done in two-day module with hands on training of 7 days each in Post Graduate Institute of Medical and Research, Chandigarh, India, under respective facility.

Under package of services was anthropometric measurements- height, weight, waist circumference. Screening for hypertension using sphygmomanometer, diabetes mellitus by random blood sugar and fasting blood sugar using glucometers, oral cancer by oral visual examination, breast cancer by Clinical Breast examination and cervical cancer by Visual Inspection with Acetic acid.

Services were implemented by the ANMs on every Friday. Population based screening was done for Diabetes Mellitus, Hypertension, Oral cancer & anthropometric measurements. Clinical Breast examination and Visual Inspection with Acetic acid was done at UHTC by motivating women in the community. Referred cases from the field were sent to UHTC for doctor's consultation and further to PGIMER/CHC-Manimajra if needed. The suspected/positive cases found on screening for the three cancers were referred to PGIMER. For referral to PGIMER, the patients were provided with a referral slips for their easier access to higher level health service without much delay. For referral to CHC, the patients were provided with an OPD slip with reason for referral.

The ANM/MPHW followed up with the individual and ensured confirmation of diagnosis for individuals diagnosed with any of the NCDs, initiation of treatment or referral to the next level. Home based NCD screening were provided for high-risk cases unable – or unwilling – to access the health care on screening day.

Feasibility of implementation of risk assessment tool by Health worker was assessed based on visit frequency made by the health worker for reassessment of the patients in the field, regularity of follow up visit, completeness of the forms, whether they were able to complete the whole form in time. Forms filled by the health worker were cross-checked and % of error found in form was noted. Action taken for the people in contact in terms of counselling done and referral rate to urban health centre, secondary and tertiary level centre.

Data Analysis

Percentage and frequency counts were used to calculate distribution of diabetes, hypertension and risk factors associated with non-communicable disease. Wilcoxon sign rank test was used to assess significant change in capacity assessment, pre and post training level of health workers. Paired t test was used to assess mean change in blood pressure and glucose level, chi-square test was used to assess change in number of controlled hypertension and diabetic patient, pre and post intervention. Kappa statistic was used to assess agreement level between health workers and investigator during baseline and endline situational analysis. SPSS 22.0 was used to assess data management and analysis.

Results

The study included 1026 people with 716 (69.8%) females and 310 (30.2%) males, of age 30 years and above.

Facility based assessment.

The baseline and post intervention assessment of the facility in terms of logistics given in table 1, showed non-availability/non-functional of supplies and equipment's. Functional equipment's were not adequate in number to conduct population-based screening. It was strengthened with adequate amount of logistics. The medicines required for NCDs as per IPHS standard guidelines were generally available, but tablet Aspirin and tablet atorvastatin were sometimes available.

Table 1: Availability of logistics at baseline and Post intervention strengthening at UHTC, Indira Colony, Chandigarh.

	Baseline		Post intervention	
EQUIPMENT and SUPPLIES	**Yes/ No**	**Number**	**Yes / No**	**Number**
Functional weighing scale	Yes	1	Yes	2
Stadiometer/ wall markings for height	Yes	1	Yes	1
Functional Glucometer	Yes	1	Yes	3
Glucose Strips	Yes	100	Yes	200
Lancets	Yes	150	Yes	250
Functional B.P apparatus	Yes	1	Yes	3
Functional Nebulizer	No	-	No	-
Non-stretchable measuring tape	Yes	1	Yes	4
Functional Stethoscopes	Yes	1	Yes	1
Functional torch	No	0	Yes	1
Functional autoclave	Yes	1	Yes	1
Functional Health education materials	Yes	-	Yes	-
Cusco's speculum	Yes	5	Yes	15
Acetic acid	No	-	Yes	-
Distil water	No	-	Yes	-
Hypochloric acid	No	-	Yes	-
Cotton tipped swabs	No	-	Yes	-

Capacity assessment of health setting

The Levels of the health workers' capacity determinants pre- and post-training shows that baseline mean score of health workers based on their perception about NPCDCS programme was 3.1 and post training it improved to 3.7. The levels of knowledge and skill of health workers for prevention and control of NCDs pre and post training shows mean score of pre-training observational findings were highest i.e., 1.5 and 1.2 for health promotion, measuring blood pressure and blood sugar and lowest i.e. 1 for cancer screening, referral, data reporting and recording and follow up of patients.

The overall mean score of observational findings were 1, 2.7 and 3 at pre-training, post training (on the same day) and post training/endline(after 5 months) respectively. The improvement between pre and post (on the same day); pre and post/endline (after 5 months).

Implementation of service package

The distribution of Non-communicable disease risk factors in the study participants showed that 82% of the participants had central obesity, 78.7% were physically inactive, 67.8% were overweight, and 38.96% were not compliant to anti hypertensives and oral hypoglycaemic drugs as prescribed by the physician. Current tobacco

and alcohol use was 15.4% and 8.8% respectively. The coverage of package of services, pre and post intervention is given in table 2. Maximum coverage was for blood pressure and blood sugar i.e. 34% and 37.1% respectively and 0.5%, 0.2% and 0.3% for oral breast and cervical cancer respectively at baseline. After implementation was started our coverage increased to 96.9%, 97.5% for blood sugar and blood pressure respectively and 95.4%, 93.4% and 54.8% for oral, breast and cervical cancer respectively. The prevalence among study participants in Pre intervention phase was hypertensive and diabetic patients were 147 (14.7%) and 135 (14.1%) respectively. After implementation 23 (2.4%) new cases of diabetes and 132 (13.2%) new cases of hypertension were diagnosed. Previous records of pre-diabetes were not present and after the intervention 74 (7.7%) cases were found. Thus, overall prevalence was 7.7%, 16.5% and 28% for pre-diabetes, diabetes, and hypertension, respectively. The distribution of outcome of screening for three common cancers, out of total screened, the screened positive cases, 2 for oral cancer were found negative by oral visual examination, 2 for breast cancer were found to have fibroadenoma by clinical breast examination and Mammography, and 6 for cervical cancer were found negative for cancer by Pap smear on further follow up to higher facility.

Table 2: Coverage of package of services, pre and post intervention at UHTC, Indira colony, Chandigarh.

Screening Procedure	Number of eligible study participant	Coverage pre intervention (%)	Coverage post intervention (%)	p-value
Blood sugar (RBS/FBS)	1026	348 (34%)a	994 (96.9%)	
Blood pressure	1026	380 (37.1%) a	1000 (97.5%)	
Oral visual examination	1026	5 (0.5%) b	979 (95.4%)	0.0001
Clinical breast examination	716	2 (0.3%) b	668 (93.4%)	
Visual inspection with acetic acid	428	3 (0.5%)b	235 (54.8%)	

aExamination within1 year before the start of this study. **b** Examination within 5 years before the start of this study.

The change in risk factor for 3 months follow up period is given in table 3. It shows reduction of 13.08 mm Hg in systolic blood pressure, 5.19 mm Hg in diastolic blood pressure and 29.23 mg/dl in blood sugar checked by random blood sugar method. There was increase in number of control cases of hypertension (old cases by 10.2%, new cases by 50.8%) and diabetes (35.8% for old cases and 69.6% for new cases).

Table 3: Change in risk factor during, 3 month follow up period of the study participants at UHTC, Indira colony, Chandigarh.

Characteristics	No. of cases	Baseline	Post intervention	Mean change	p-value*
Mean systolic blood pressure (mm Hg)	251**	141.84	128.75	13.09	
Mean diastolic blood pressure (mm Hg)	251**	86.91	81.71	5.19	
Mean RBS(mg/dl)	135**	167.18	137.94	29.23	
Controlled hypertension					
Old cases	147	89 (60.5%)	134** (91.2%)	45 (50.5%)	<0.05
New cases	132	0	101** (76.5%)	101 (76.5%)	
Controlled blood sugar					
Old cases	135	81 (55.1%)	119** (80.9%)	38 (46.9%)	
New cases	23	0	16** (69.6%)	16 (69.6%)	

* t-test for comparing means and Chi-square test comparing proportions.

** Number of cases followed up after 3 months, excluding loss to follow up cases.
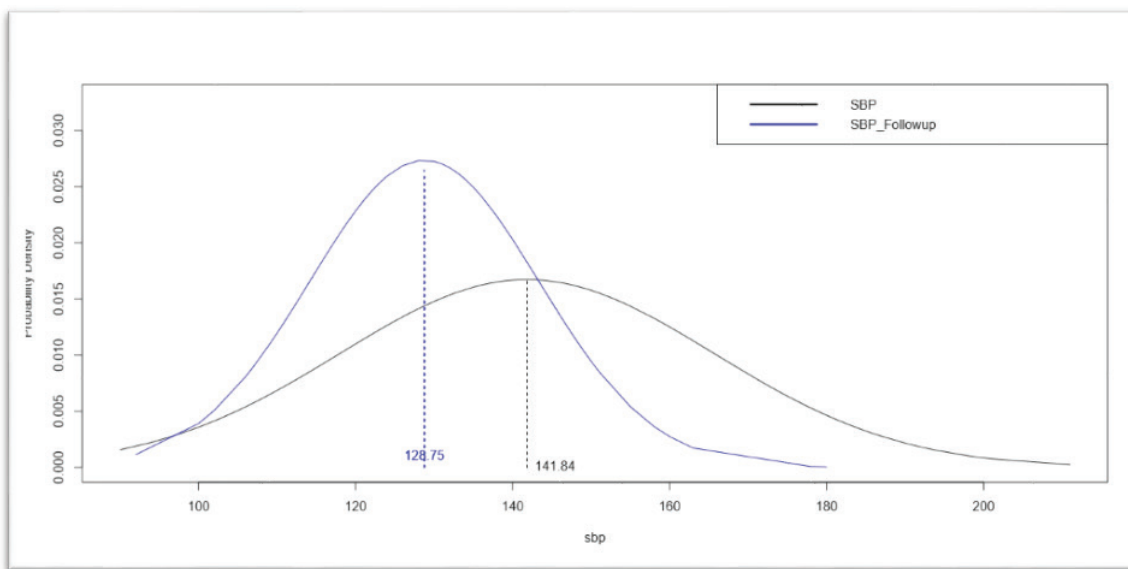
Figure 1: Normal curves, showing shift in mean systolic blood pressure,during 3 month follow up period of the study participants at UHTC, Indira colony, Chandigarh.

*SBP- systolic blood pressure; SBP_follow up- systolic blood pressure after 3 months follow up.

The assessment of feasibility of implementation of community-based assessment checklist form (CBAC) as educational tool by health worker shows that ANMs could complete 98% of the information asked in the forms, except in few cases where aadharcard (identity card) information was missing. During the baseline assessment and implementation at least one visit was made to all the allotted houses. In case of locked houses or if the person was absent at the time of visit, two more visits were made. On population- based screening every individual meeting the ANMs of age 30 years and above was being made aware of benefits of screening. Counselling was done for all pre diabetics, diabetic and hypertension patients. There was total 345 patients whom ANM found at high risk and referred from the field to medical officer at UHTC, Indira colony for further management. Out of these 345 patients, 301 patients visited UHTC. Ten patients were referred to higher facility out of which 9 patients went for further evaluation. At least 1 follow up visit was made for all the high-risk patients. Reason for loss to follow up were, relocation of the family, absent at the time of visit and death in old age group people.

Level of agreement between data reported by health worker and investigator.

The level of agreement between data reported by health worker and investigator was seen for 20% (205) of the study participants, of situational analysis before intervention is given in table 4. It shows disagreement of 2% in assessing family history of DM/HTN/CVD, 1.5% for compliance to prescribed treatment for DM/HTN and if they undertake any physical activity and 0.5% for history of alcohol use and tobacco smoking. Rest other questions shows 100% agreement. Kappa statistics is more than 0.94 for all the question thus showing excellent agreement.

Table 4: Level of agreementbetween data reported by health worker and investigator of situational analysis before implementation of services at UHTC, Indira colony, Chandigarh.

Questions	Response of health worker		Response of Investigator		Agreement	Disagreement	Kappa statistic
	Positive	Negative	Positive	Negative			
*Are you taking medicine as prescribed? (for HTN/DM)	51	5	48	8	202 (98.5%)	3 (1.5%)	0.96
History of tobacco smoking	46	159	45	160	204 (99.5%)	1 (0.5%)	0.99
Do you undertake any physical activity	81	124	78	127	202 (98.5%)	3 (1.5%)	0.96
Family history of DM/HTN/CVD	40	165	44	161	201 (98%)	4 (2%)	0.94
History of alcohol use	36	169	37	168	204 (99.5%)	1 (0.5%)	0.99
Treatment started for HTN	32	173	32	173	205 (100%)	0	1

Cont... **Table 4: Level of agreementbetween data reported by health worker and investigator of situational analysis before implementation of services at UHTC, Indira colony, Chandigarh.**

Treatment started for DM	24	181	24	181	205 (100%)	0	1
Shortness of breath	0	205	0	205	125 (100%)	0	1
Coughing more than 2 weeks	0	205	0	205	125(100%)	0	1
Blood In sputum	0	205	0	205	125 (100%)	0	1
History of fits	0	205	0	205	125 (100%)	0	1
Difficulty In opening mouth	0	205	0	205	125 (100%)	0	1
Ulcers /patch / growth in the mouth	0	205	0	205	125 (100%)	0	1
Any change in the tone of your voice	0	205	0	205	125 (100%)	0	1
Palpable lump in the breast	0	205	0	205	125 (100%)	0	1
Blood stained discharge from nipple	0	205	0	205	125 (100%)	0	1
Change in shape and size of the breast	0	205	0	205	125 (100%)	0	1
Bleeding between periods	0	205	0	205	125 (100%)	0	1
Bleeding after menopause	0	205	0	205	125 (100%)	0	1
Bleeding after inter-course	0	205	0	205	125 (100%)	0	1
Foul smelling vaginal discharge	0	205	0	205	125 (100%)	0	1

*no of study participants on ant-hypertensive and/or oral hypoglycaemic drugs. Out of 205, 155 were not on treatment, pre-intervention phase.

In case of hypertensive patients follow up blood pressure taken by ANMs was considered for comparison with the measurement done by the investigator and was taken after 5 months of intervention. For comparison for measurement of blood pressure range of + 5 mm Hg for systolic blood pressure and + 2mm Hg for diastolic blood pressure was considered. It shows good agreement for measurement of blood pressure and excellent agreement for Oral Visual Examination and Clinical Breast Examination, given in table 5.

Table 5: Level of agreement between data reported by health worker and investigator of post intervention at UHTC, Indira colony, Chandigarh.

Screening Procedure	Agreement (n=205)	Disagreement (n=205)	Kappa statistic
Measurement of Blood Pressure	205	26	0.67
Oral Visual Examination	205	0	1
Clinical Breast Examination	125	0	1

Discussion

The package of essential NCD services is comprehensive in which different kinds of practicable activities are joint to produce a collaborative effect. The effects of components cannot be singled out. The intervention components in the form of health promotion, health services and community participation, all play prominent role in community-based intervention programme. Therefore, this study was done using an integrated approach where the major NCDs were focused based on operational guidelines services for Prevention, Early detection, and Control for Non-communicable diseases (2017) at urban PHC level.

There is paucity of literature. For that reason, available literature on Package of essential Non-Communicable Disease services at community settings is used.

Lack of technical skills by health workers and poor screening coverage highlights the poor implementation of the programme. This component needed strengthening.

The study provides the prospect for strengthening the baseline capacity of health facility for prevention and management of NCDs. The result of post intervention assessment shows, there was upgrading of services in the health facility, it was strengthened with adequate quantity of basic equipment, with contribution from community participation, investigator and constant efforts made by Medical Officer for procurement from PGIMER and National Health Mission office. There was improvement in the knowledge and skills of health worker it was almost double from pre-training level (40% to 81%). The health workers gained confidence in counselling. Population based screening was implemented by the health workers in real life condition. The result showed post intervention screening coverage increased by more than 90% for all screening procedures except VIA which was 54.8%. Intervention led to identification of new NCDs cases, diabetes (2.4%) and hypertension patients (13.2%). The intervention led to early detection and further reduction in complications and co-morbidities associated with NCDs. High screening coverage shows acceptability of screening procedure among the community. This study focused on strong capacity with optimal care. It is essential to note that the capacity of the facilities may change over time. Thus, there is the need for periodic assessment of the

facility and the impact of intervention on NCDs control. The screening result of three common cancers showed that oral, breast and cervical cancer screened positive cases were 2, 2 and 3 respectively, by the ANMs among the study participants. The screened positive cases were followed up by the investigator and further referred to Civil hospital/ PGIMER. All the cases were reported as cancer negative but found to have COPD, cervicitis and fibroadenoma and were recommended to get annual check-up done. Thus, the false positive detection rate was more in case of VIA. At the start, more false positive cases were expected. Looking at the individuals referred, positive point is ANMs were able to pick up high-risk cases. In our study, after 3 months of follow up during intervention of hypertension and diabetic patients, showed significant reduction of SBP and DBP by 13mm Hg and 5.2 mm Hg respectively, there was significant improvement in number of controlled hypertension (70%) and controlled blood sugar (81%) patient both old and newly detected with increased compliance to treatment. It shows that non-physician health workers can effectively deliver services. The results of feasibility assessment of implementation of CBAC form (NCD risk score) as educational tool by health workers showed that it is feasible and can be used for educating the population. The level of agreement between the health worker and the investigator in assessing baseline situational analysis and end-line analysis was more than 95% which is excellent agreement level and was statistically significant. Thus, proving that health workers can efficiently and effectively carry out the programme with supportive supervision and monitoring. As the study involved health service delivery by ANMs, they have good understanding and have a grip on pulse of the community. UHTC also has close collaboration with various community organizations.

Health promotion also played a major role as the health information diffused in the community, enabled the people to take their own health decisions, as was seen by increase in number of people attending the NCD clinic day at UHTC and demanding their screening who otherwise were not amongst the study participants.

Referral linkages were established between UHTC and higher health facilities including PGI. For easy facilitation of patients, referral slips were used. Patient's response after referral visit was good.

The effect of programme intervention may not be entirely reflected by the changes that are measured by a before-after type of study design. A control group in form of other health facilities or comparing their data would have given better estimates of the effect, but it would be unethical to collect data without provision of services and paucity of time.

Challenges: The study faced several challenges, especially during the initial months. Most important challenges faced were related to logistics, motivation of manpower and migration at community level. Inadequate number of basic and vital equipment's for NCDs screening and lack of supplies for VIA were key barriers observed under NPCDCS. Human resources - Initial resistance was faced from the health worker. They felt they will be overburdened and will have more responsibilities. They had hesitations in screening for cancer. These challenges were overcome by making a practical and feasible work plan. Regular supportive supervision of their work in the facility as well as field and constant motivation and appreciating their efforts. Data recording and reporting- ANMs are burdened with preparing additional reports. Along with NPCDCS there are other programmes to be implemented. Under NPCDCS for reporting facility-based screening register is different and CBAC forms are different at field level to be filled by the ANMs. It doubles the work.

Recommendations: Capacity building of health workers and Medical Officers should be strengthened. In addition to the existing training module, refresher trainings should be organized at least annually to maintain and improve health workers skills. Training for colposcopy of Medical Officers, so that for all the suspected cases screened by Visual inspection with acetic acid, colposcopy can be performed immediately at the health facility to reduce the loss to follow up. The data entry for recording relevant history & clinical information, to monitor outcomes and to track for further

follow up of the patients, should be digitalized.

Conflict of Interest: Nil.

Ethical Clearance: Taken from Institute of ethics committee, PGIMER, Chandigarh.

Source of Funding: Self.

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Spanish Flu to COVID-19: Healthcare Challenges and Evolution

Pooja Sachdeva[1], Rohit[2]

[1]Consultant, Department of General Medicine, Sengkang General Hospital, Singapore,
[2]AdjProfessor, Department of Diagnostic Radiology, NgTeng Fong General Hospital, Singapore

Abstract

Spanish Flu (1918-1919) is considered the deadliest Pandemic of the twentieth century, with worldwide mortality of about 50 million people. One hundred years after this Pandemic, WHO had released a pandemic preparedness plan in March 2018 and urged all countries to have planned their response to future pandemics threats. This plan is a guide to building the capacity to face healthcare and economic challenges encountered during any pandemic. Today, in 2020, the world is witnessing Pandemic by another virus called COVID-19. This infection originated in China and has traveled globally to affect almost all countries. Healthcare worldwide in this Pandemic faces many challenges as expected, but the response and resilience in meeting these challenges have been exemplary. HealthCare technological and laboratory advancement has enabled full genomic sequencing within two weeks and the manufacture of trial vaccines within eight weeks. From creating makeshift hospitals and community isolation facilities, manufacturing medical equipment to providing accessible, affordable public health and information are depicting strong political will and motivation to fight this pandemic. This pandemic has also highlighted the gaps in pandemic preparedness among countries and provided them the opportunity to reflect on their healthcare needs and policies.

Key Words: - *COVID-19, Spanish Flu, Healthcare Challenges, Pandemic, Healthcare Evolution*

Introduction

COVID -19 isa respiratory illness caused by Coronavirus, also known as SARS -COV 2 that has affected almost 100 million people worldwide with more than 2.5 million deaths [21] since its first origin in Wuhan, China, in December 2019[22]. It has been declared a pandemic by WHO [36]in March 2020 after acknowledging its fast spread globally.

Corresponding Author :
Dr Pooja Sachdeva,
Consultant, Department of General Medicine. Address : Medical centre level 9, SengkangGeneral Hospital, 110 Sengkang East way, Singapore 544886 Tel No.+65 69302907, Email : dr.poojasachdeva@gmail.com; pooja.sachdeva@singhealth.com.sg.

COVID-19 is being compared with Spanish Flu; the deadliest Pandemic witnessed in the early 20th century (1918-1919) that had affected about 500 million people worldwide with estimated at least 50 million deaths[23.] There has not been any pandemic before and after 1918 that had comparable death rate so far [23.]There are similarities in two diseases in terms of their spread, pathogenesis, management, and challenges these have posed to healthcare worldwide. It is almost a century since the world has witnessed devastating Influenza pandemic, and measures are expected to be in place to prevent another such further pandemic.On May 07, 2018, a one-day symposium [1,2,23] was hosted for the 100th anniversary of the 1918 Influenza pandemic by Rollins School of Public Health at Emory University with Centres for Disease Control and Prevention (USA), to discuss future pandemic threats, its prevention,

control, and preparedness. Global experts acknowledged that challenges would be faced by healthcare in future pandemics despite advancement and readiness and the only way forward would be accepting and confronting them with the rest of the world. This article aims to discuss these challenges in pandemics and the strategies worldwide to meet these challenges.The expedited responses by countries worldwide have shown the rapid evolution of healthcare over the last century.

History

The H1N1 Influenzavirus with avian genes[23]virus caused Spanish Flu. It was first detected in the United States in March 1918 in a military camp wherewith flu-like symptoms [23]were reported in 100 soldiers. It spread rampantly in crowded and poorly maintained military fields, and mortality surfaced as reported by Public health reports in their weekly issue in April 1918. The soldiers were deployed toWorld War Iand required to cross Atlantic every month hence leading to the disease spread through the USA, Europe, and Asia over the next six months. A second wave reported in September 1918 in anothercamp was highly fatal and affected 14000 soldiers with 757 deaths. New York City's Board of health made this Flu reportable and required affected patients to isolate at home or hospitals. There was the third wave in Winters in January 1919 when another surge of cases emerged and continued till Summer before subsiding. It is believed that Flu was eradicated in April 1919.[23]

Spanish Flu had spread like COVID -19 through "Nasal droplets." It caused respiratory illness with cough and breathing abnormalities secondary to pneumonia. This Virus notably affected healthy individuals between 15 to 44 years old [23]. By October 1918, Spanish Flu had spread over a significant part of the world, and challenge in front of healthcare was *inadequate nursing and medical staff* to look after patients as former deployed

to military camps in-country and abroad. There was a call made to recruit volunteers to look after the ill. After its eradication, a bill was passed to provide a one-year training course to become "practical nurse" to address the shortage of healthcare staff.

The other challenge that was with *inadequate testing*. The diagnosis was mainly clinical, and the virus was not isolated or cultured in a laboratory. It was postulated that the third wave of Influenza was fuelled by inadequate reporting and management of the cases. There were no available treatments or vaccines; hence the management mainly consisted of nonpharmacological measures such as isolation, quarantines, good personal hygiene, use of disinfectants, and avoidance of public gatherings. Cold storages were used as temporary morgues as corpses waited to be buried for more than a week.

Public health units had issued recommendations of wearing masks in public about six months after the first case and prohibited all public gatherings and closing of schools, movie houses, and theatres. People were encouraged to walk to work and avoid public transport. They businesses were suggested to stagger working hours to avoid overcrowding. There were an estimated 195000 patients were killed by this pandemic in October 1918 alone.[23.] Public health authorities issued education guidance people to dispose of their nasal discharges properly and maintain social distance.

By the end of World War,I, the U.S. military grew from 378,000 soldiers in April 1918 to 4.7 million soldiers. Another challenge was*insufficient fund*s to study about Influenza. Trustees of Boston City hospital had asked Mayor for a special appropriation of $3000 to research treatment of Influenza. There was a question on *political outlook and motivation* on channelizing the funds to healthcare. There was no central or federal government control over measures to prevent spread. There was a substantial economic loss in the War, and not many funds were available for medical research.

Pic 1: Boston Red cross Volunteers Guage assembled influenza masks for use at hard-hit camp Devens at Massachusetts, (taken from CDC image gallery)

Pic 2: -Soldiers from Fort Riley, Kansas, ill with Spanish Flu at a hospital ward at Camp Funston (Otis Historical Archives, National Museum of Health and Medicine)

COVID -19

The first case of COVID-19 was reported on December 31, 2019.[22.] Much has been studied about this Virus since then. It hadoriginated in Wuhan, China [22]and continued to spread globally, resulting from urbanization, tourism, and enhanced world connectivity[4.]The world had been a spectator of strategies that were used by China to diagnose, manage, and contain it in the early months of 2020. As the spread was fast and rampant, it was paramount to diagnose the illness early and isolation of the organism from the tissues. The understanding of human-to-human transmission was the basis of most of the recommended strategies for its containment.[4,5]The disease hastravelledinternationally, and about 213 countries and territories [21]around the world has been affected by COVID -19. It is predicted that disease will continue to spread and will last for few years.

The world and the healthcare have been fighting with this pandemic for almost a year now. The World Health Organization (WHO) has been actively providing necessary unrestricted information including latest statistics, diagnostic policies, guidelines on management on their website and diagnostic kits, and Personal Protective Equipment (PPE) to the underdeveloped and low-income countries. There are challenges faced by healthcare in all the pandemics, however response to this pandemic has been exceptional. The early lockdown and travel ban by all major countries have been the most significant factor to contain the spread internationally. Almost all countries have developed their own local and state strategies to deal with this disease's challenges.

Healthcare challenges during COVID-19 pandemic

1. Viral isolation and testing

Viral isolation in a laboratory is the first step to diagnose the symptomatic patient. Once an infected patient is identified, he can be isolated from the community to contain the disease's spread. Two kinds of tests[25]can identify the infection, viral testing by RT-PCR (Reverse transcriptase -Polymerase chain reaction) in respiratory secretions and blood antibody testing of infected patients. Scientists from China released the information of the COVID -19 genome on January 11, 2020[1]followed by the Malaysian Institute for medical research (IMR), producing the primers specific to SARS-CoV-2[26]China developed the first testing kits and reagents for respiratory samples taken from nasopharyngeal swabs, sputum, or bronchoalveolar lavage of affected patients.

Within two months of this pandemic, many countries like United Kingdom, Germany, France, Korea, Japan, and Singapore had developed their local tests to identify the virus and infected individuals[26.] Most of the countries had slowly built up the laboratory capacity to test as many patients and individuals as possible.[26]WHO had urged countries to ramp up the testing capacities to slow down the pandemic advancement in news release in March,2020. Most of the countries had targeted their daily testing from 10,000 to 100,000 per day.[26] Currently, antibody testing is being used to identify asymptomatic carriers and past exposure of the disease under active surveillance [26,27.]CDC,however, has suggested using the antibody test cautiously [25]due to its less specificity and sensitivity.

2. Contact tracing and Active surveillance

The next step to slow down the spread of the virus is to actively identify the contacts of the diagnosed patients to break the chain of transmission. Infectious control departments define the close contacts as any individual within 6 feet of an infected or probable patient for 15 minutes.[27]These contacts need to be tested regardless of their symptoms. Negative tested contacts must stay in quarantine for at least two weeks.[27]. It is a fundamental public health measure for countries to do contact tracing and quarantine actively. WHO had emphasized on that contact tracing and active surveillance as strong elements of response as control measures on 03rd] June 2020. Setting up regional centres to swab high-risk asymptomatic carriers actively utilizes considerable workforce and resources.

The ministries in various countries had developed Task forces to trace positive patients' contact and isolate them early.Staff in task forces helps to discover

the contacts and their symptoms via texts, calls, or videos. Various policies are in place for people and contacts to reduce mobilization and spread. Country wide lockdowns, travel ban are public health measures adopted to mitigate spread of the disease.Digital tools like Bluetooth, GPS-related trackers, Safe entry, Trace Together Apps on the phone can provide the mobility history of patients and help identify unrelated contacts. Smartphones and proximity tracking digital[37]sensors that can detect proximity and exposure to COVID-19 positive patients. These measures help to people to identify themselves if they have been in contact and self-isolate and seek medical attention if they have symptoms.

3. Economic burden, resource allocation, and workforce mobilization

There has been an overwhelming surge in patients with COVID -19 since the pandemic, and it has stretched healthcare resources worldwide. Hospital beds in both general wards and ICU (Intensive Care Unit) are limited andrapidly taken up by patients. Resources and supplies are required to manage both COVID-19 and non-COVID patients. The human-to-human transmission also requires that COVID affected patients areadmitted in isolation rooms or separate wards to prevent transmission to other patients and healthcare workers. It was a challenge for that each hospital in every country faced to allocate manpower in teams to avoidcross transmission at workplace.

Splitting the workforce, extra working hours, opening new wards are just the measures taken during desperate needs in any pandemic. China has been exemplary in opening two hospitals, A 1000 bedded hospital with prefabricated wards and isolation rooms and 1500 beddedLeishenshan hospital to accommodate the rising number of patients within two months of pandemic.[38]Almost every country has opened makeshifthospitals at their sports centres, exhibition halls, and public spaces, including airports[39] or central parks.[40]Guidelines regarding patients' management are being updated as disease pathophysiology, and the spectrum is understood gradually. The resources were allocated to admit patients with moderately severe disease[29]while patients with mild disease are isolated in temporary quarantine and community isolation sites or at their homes. Various firms had taken up building more ventilators and medical equipmentto meet the requirements for sick patients.

Teams of healthcare workers are moved from lower affected regions to higher affected areas in big countries to cover the gaps in human workforce.[41]Retired nurses[41,42]and doctors [43]are resuming practices to meet this demand of healthcare providers. Volunteers[44]are recruited to be trained and work in swab teams to channelize medically trained workforce in clinical areas. The response from community and volunteers showing solidarity has been exceptionally motivating and inspiring for healthcare workers worldwide.

4. Medical Education and Research

COVID-19 is a novel, unknown pathogen, and much research was required to understand its pathogenesis, spread, symptoms presentation, management, and outcome. There have been numerous publications since the pandemic that has educated medical fraternity about this virus. Much of the current knowledge about it is a collective effort of healthcare providers worldwide that have submitted their experiences with this pathogen in various medical journals or forums. It provides necessary crucial information about its clinical presentation, laboratory derangements, and radiological pointers, which helps to detect and diagnose early. There has been much data about disease spectrum and outcome. Many studies are going on to understand risk factors leading to severe disease, including mortality. The challenge is to develop an anti-viral treatment for affected patients and a vaccine to prevent the unaffected. Transfusion of convalescentPlasma [8]from affected patients with antibodies against the virus has shown some evidence of providing passive immunity and early recovery in sick patients. Many drugs have been in trials with positive effects such as Remdesivir[9]Hydroxychrlolquine[10] EIDD- 2801[11], Favipiravir[45,] tocilizumab[46,]lopinavir-ritonavir combination[12](Kaletra)however side effects profile, availability and limited evidencehavebeen

holding their widespread use. In a pandemic, desperate cross-sectional observations provide much of the clinical evidence instead of properly conducted randomized trials. However, many Phase III global, randomized trials are going on for anti-viral drugs, and results are awaited. The viral genome sequencing is complete, and a vaccine has been manufactured[30,31] within two months and currently being administered world-wide. Various vaccines based on different viral components have been developed by pharmaceuticals companies such as Pfizer-BioNtech and Moderna's mRNA vaccines[15], Bharat Biotech's Covaxin (whole killed Virus) [16],Russia's Sputnik V (adenoviral vector vaccine)[18] , China's Sinovac(whole Killed Virus)[17],Oxford-AstraZeneca Covishield (adenovirus vector)[19]and Johnsons and Johnsons one shot vaccine [20] are highly efficacious in preventing the disease spread and studies are underway for their long term effects and efficacies.

5. Healthcare workers wellbeingand leadership

Healthcare workers treating and managing positive patients must be provided with adequate personal protective equipment (PPE)[47]to avoid transmission. The droplet mode of transmission requires patients to be placed in separate wards or isolation rooms to prevent cross-transmission. It requires an impermeable apron, face mask, face shield, spectacles, gloves, shoe covers, and headcovers for one visit in a patient room. The demand for these PPE has risen with a surge in affected patients. Almost all the countries faceda shortage of adequate PPE for healthcare staff and the public. On February 27, 2020, WHO[48,49] issued guidance suggesting the "rational "use of PPE citing the disruption of global supply and the insufficient stockpile of PPE that resulted fromgrowing number of patients, misinformation and panic buying. WHO also called upon industries and governments to increase local manufacturing at least by 40 percent to meet therising demand. Nonetheless, there have been hundreds of medical doctors and nurses who have acquired the disease from their patients and have lost lives to this deadly virus[50]Countries since the beginning of pandemic have been manufacturing,securing, and exporting PPE to other countries. Many manufacturing firms[51], fashion firms, and skincare firms have been

building up the PPE supply to meet the requirement.

Like in a war situation, there must be the constant motivation of healthcare workers and the public. Prolonged work and exposure, uncertainties about disease do affect mental health apart from causing physical exhaustion. The limited human interaction and scarcity of support systems during the lockdown period have surfaced many mental health conditions such as anxiety, insomnia, and Major depression [32,33]in healthcare workers and public. The psychiatry departments in hospitals have opened many local helplines [32,33]to provide support and counselling. Ministers and leaders must be transparent about the disease to the public to allay apprehension and to clear misinformation. Many leaders worldwide have been seen speaking to their countrymen about this pandemic on various media channels. Likewise, the hospital administration is actively involved in setting up policies for a smooth workflow, getting feedback from workers, and encourage and inspire them for continued hard work and efforts.

6. Political motivation and support

In any pandemic management, political involvement in healthcare is essential and crucial. Obtaining diagnostic test kits and reagents, running, and setting up laboratories, new hospitals, or placement areas, procuring and manufacturing PPE, recruiting workforce to swab and trace results, contact tracing, active surveillance, and Medical research requires a substantial healthcare budget. While hospitals play their part in healthcare human workforcemobilization, political will and strategies are needed to tackle a pandemic at the state and national levels. Travel & tourism ban, nationwide lockdowns have imposed a substantial financial challenge on economy affecting jobs and small businesses. It requires strong political will and budget from finance ministries to continue providing needed support during this lockdown for its success. Leadership in countries like New Zealand, Taiwan, and Germany have been praised and considered as role models for their responses to this pandemic.

Discussion

CDC talked about 1918'sDeadliest Flu[23]discovery and researchas JohanHultin, a Swedish microbiologist in 1951, requested permission to excavate Brevig Mission, a small oceanside village in Alaska.[23.] A mass grave site marked only by white crosses was created near this village during the 1918 pandemic.Hultin could successfully obtain the samples of the virus from buried bodies' lungs but could not culture them in chicken eggs. In 1997, Dr.Taubenberger, a molecular pathologist working for the Armed Forces Institute of Pathology in Washington, D.C., could do a partial genomic sequencing of this virus by studying a preserved lung tissue sample of a soldier from South Carolina who had died in the pandemic. The Brevig Mission was re excavated to obtain samples of this virus and only in 1999, the scientists succeeded in full sequencing of Spanish flu[13],The Deadly Influenza virus.

Since 1918, the world has witnessed three flu pandemics in 1957 with Asian Flu (H2N2 Influenza), 1968 with Influenza A (H3N2 Influenza) Virus and 2009 with Swine Flu (H1N1 Influenza) virus with much lesser mortalities.[43,44]We are currently amid pandemic, and it is hard to estimate the total burden of disease and its mortalities. However, WHO has mentioned in their news release that COVID -19 is almost ten times deadlier than Swine flu. It has been accelerating extremely fast with slow deceleration. Data suggest about 4 to 11% Case Fatality Rate but vary according to age, geographical location, and healthcare resources. There is enough evidence to suggest that the virus is highly transmissible and has higher mortality than Influenza but lesser than Middle East Respiratory Syndrome (MERS), virus.[14]

Spanish Flu had high genetic virulence, yet there were additional environmental factors that had led to its spread and consequent mortality[23]. During World War I, the movement of troops across the countries placed soldiers in overcrowded closed living spaces. Healthcare services were limited in bothhealthcare workers as they deployed in militaries and medical technology and countermeasures. There were no antibiotics, anti-viral drugs, or Influenza vaccines that could prevent mortality. Mechanical ventilation and ICU support were not available either; hence physicians had options of mainly supportive care [23]for affected patients.

The laboratory services were not developed enough to culture the Spanish flu virus until 80 years of the pandemic.[23]For the longest time, the 1918 pandemic was thought to be caused by a bacteria Pfeiffer bacillus[23]but having full genomic sequencing of COVID -19 within a month of this pandemic is a result of successful modernization of laboratories and healthcare evolution. This exceptional achievement of genomic sequencing has not only permitted the manufacture of rapid diagnostic kits but also opened the doors for trials for anti-viral drugs and vaccines. Setting up temporary labs, recruiting workforce to swab the patients and their contacts actively, and reducing turnaround time for the investigation has been the definite steptowards controlling the transmission of the disease.

New hospitals, isolation, and quarantine facilities are made available to house patients, contacts, and suspected cases. Healthcare workers from various paraclinical specialties, community hospitals, primary care clinics, and nursing homes are getting adequate training to involve them in a bigger workforce pool for allocation at clinical care centres. There is funding made available to research laboratories to work on anti-viral drugs and vaccine manufacturing. Most remarkable in this pandemic has been a timeline for developing the vaccine. It took 42 days[24] for Moderna therapeutics to manufacture a vaccine for human trials from time Viral Genome sequencing on January 11,2020. This timeline is much shorter than the latest H1N1 pandemic(2009), where the vaccine was available 26 weeks after the manufacture.[23]The pharmaceutical companies are prepared to manufacture and distribute the drugs and vaccines to meet the global demand.

In COVID -19 pandemic, various National and state-level policies are set up early. The central governments in the respective countries have been actively planning and initiating interventions such as isolation, quarantine, and stay at home (SAH) orders. Chinese authorities stopped the movement in and out of Wuhan and Hubei Provinces by suspending trains and flights and blocking roads[4,5]

in late Jan 2020 to reduce the spread. Many countries, including India, Singapore, Korea, China, Germany, Spain, France, UK, USA, Australia, New Zealand and Canada, have implemented community mitigation measures such as early nationwide lockdowns to prevent public gatherings and spread. The international and domestic travel ban, and advisories are issued to avoid movement of the virus

There is increased communication and networking in the digital world. Information is made available and accessible for medical professionals, as many esteemed medical journals have provided their free of charge access during this pandemic. Many websites, including WHO, CDC, local Ministry of Health sites, are providing the statistics with numbers of patients diagnosed, quarantined, recovered & discharged, or demised. These are the portals of authentic information about measures to prevent the disease, seek medical attention, contact numbers of involved public health authorities, helplines to reach out. The COVID -19 pandemic has united the world. Numerous international collaborations with teams of doctors and nurses are working together to learn more about the disease and its management. Scientists and researchers worldwide havecollaborated to makesuccessful vaccines and anti-viral drugs. Previous pandemics have prepared nations with medical and societal advancements for an expedited and early response to current and future outbreaks.

Conclusion

There is much to learn about COVID -19 for the medical fraternity. Only the future will tell how this pandemic would be controlled with its final statistics. Nonetheless, this will be a historical landmark in medical history that had embarked upon the best of medical technology and public health. It has provided the world with an opportunity to reflect upon its healthcare, its shortcomings, and needed improvement. Healthcare should be a priority for any country. The author has tried to highlight challenges in healthcare that are faced during any pandemic and have assured that it is being dealt with a much better response compared to a century ago.

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Correction of the Anxiety Level of Students at the Physical Training Classes Using a Complex of Health-Improving Practices

Postol Olga[1], Shchadilova Irina[1]

[1]*Assistant Professor, Candidate of Sciences in Pedagogy, Department "Physical Culture and Sports" Russian University of Transport (RUT (MIIT), Moscow, Russia*

Abstract

Background: Modern life realities in the developed countries presuppose an attentive attitude to human health, and the success of the dynamic development of society greatly depends on the health of young people. It is them who will have to identify and solve global issues regarding transformation and development of the state and society in the future. Great difficulties can arise with a change in the teaching time and regime for students of higher educational institutions. During the COVID-19 pandemic, having moved from classrooms to isolated flats or houses, students were left without a direct, open opportunity to communicate with their peer sand teachers. They had to spend a lot of time at a computer and lead a passive lifestyle, having dramatically changed their usual conditions to self-isolation.

Methodology: The current study has been conducted using methods of pedagogical observation, a questionnaire and an online testing. The experimental platform for the study was the physical training (PT) classes at the Russian University of Transport in Moscow. The pedagogical experiment was conducted from September 2019 till May 2020.

Results: The conducted online testing has shown a significant decline in the indicators of anxiety in the experimental group (P <0.01) compared with the control group. The results of the current study showed that the students of the experimental group, being trained according to the methodology developed by the authors of the current paper, significantly reduced the indicators of situational anxiety on 32.3%, and personal anxiety on 33.3%. The indicators of situational and personal anxiety among students of the control group were moderate (mean).

Conclusions: The effect of the combination of volleyball and oriental health-improving practices on the psycho-emotional state of a person allowed students to reduce the indicators of their situational and general anxiety, which has confirmed a positive effect of oriental health-improving practices combined with sports games on health.

Keywords: *university students, physical training (PT), general anxiety, situational anxiety, personal anxiety, health-improving practices.*

Corresponding Author:
Postol Olga
Candidate of Sciences in Pedagogy, Assistant Professor, Department "Physical Culture and Sports" Russian University of Transport (RUT (MIIT), Moscow, Russia Phone: +79166240759
E-mail: olp1881@yandex.ru

Introduction

Life in megacities, unfavorable climatic and ecological conditions, inappropriate diet, physical hypodynamia, short sleepingand emotional struggles constitute the sources of psychological stress. All this

results in an increased level of anxiety among young people.[1,2] The unusual conditions of the COVID-19 pandemic, which the world has faced and still faces throughout the years of 2020 and a part of 2021, online learning and self-isolation are also linked to elevated distress levels.

Constant emotional stresses and anxiety contribute to the development of many cardiovascular and digestive diseases. This situation is quite predictable and understandable, since such a mental state arises against the background of conditions unusual for the psyche, requiring changes and adaptation of all body systems[3, 4] During the period of intensive formation of a personality, development of their own style of behavior in the society, young people experience anxiety and mental tension more often because the student age is the final stage of progressive age development. All of the listed circumstances combined can give a negative effect.[5, 6]

One of the urgent issues of psychology, medicine and pedagogy is the analysis of mental states and levels of anxiety of the youth. Anxiety is the emotional state of an individual, his emotional reaction to a stressful, unfavorable situation. This phenomenon has been thoroughly studied by such outstanding scientists as Sigmund Freud, Charles Spielberger, Karen Horney, Alfred Adler, Yuri Khanin and others. For the all-round development of a personality, the presence of anxiety is one of the main factors which directly affects the processes of adaptation of the organism to the environment.[7]

A wide range of physiological reactions accompanying anxiety explains the emergence of various psychosomatic disorders on the background of a long state of anxiety, especially in conditions of self-isolation.[8, 9]

In modern reality, the researchers have come to the conclusion that anxiety is a complex personality trait based on the physiological and mental components of a personality, and constantly increased anxiety is an attribute of a weak nervous system.[12, 13] A sufficiently pronounced anxiety includes two components, such as awareness of physiological sensations (palpitations, sweating, nausea, etc.) and awareness of the very fact of anxiety.[10, 11]

The mechanism of anxiety, from the point of view of physiology, causes a reactive response of the body, preparing it for struggle, resistance, and attack. Because of anxiety, the cardiovascular system is excited. Finding themselves in non-standard learning conditions, students experience stress because of leaving their comfort zone.[14, 15]

Materials and Methods

One of the non-drug means and a recognized method in the regulation of mental stress and increased anxiety are regular exercise, sports, any physical activity. The conditions of social self-isolation forced to reconsider a number of approaches to physical education.[16]

It is common knowledge that sports games allow participants closely communicate, interact with each other and a coach, and discharge emotionally due to the ability to move freely around the workspace. Unfortunately, students are deprived of such an opportunity at other educational classes.[17]

The human resources' policy of a progressive employer is based on the principles of preserving the labor potential, health and longevity of its employees. It is undoubtedly important to involve and introduce students as future specialists to a healthy lifestyle, and the Russian University of Transport does its best for it. The university has all possible tools for interaction and communication between teachers and students when switching to a distance learning format (e-learning). The physical education process was not interrupted even during the general quarantine.

The study **methods** were selected in accordance with the purpose and objectives of the research: pedagogical observation, a questionnaire and an online testing.

The experimental platform for the study was the physical training classes at the Russian University of Transport (Moscow) in the 2019-2020 academic year. There were formed two groups of students: one

experimental group (EG) with 27 first-year students and one control group (CG) with 27 first-year students (n = 54).

The pedagogical experiment was conducted from September 2019 till May 2020. The students taking part in the experiment did not have any problems with their health. All were allowed to attend PT lessons. All students, according to the medical examination, had the main health group.

Since the students are faced with very large psycho-emotional and intellectual stress, **the purpose** of the current study was to analyze the possibilities to use combined physical training technologies at PT classes and estimate their effect on the psycho-emotional state of the students.

In the control group (CG), the PT lessons were conducted according to the curriculum of the department of Physical Culture and Sports of the Russian University of Transport. In the experimental group (EG), the PT lessons were conducted according to the methodology developed by the authors for the integrated use of oriental health-improving practices (breathing exercises of yogis, Chinese health-improving gymnastics 'Baduanjing', hatha-yoga exercises) with sports games (volleyball).

The **objective** of the current paper was to study the effect of sport games (volleyball) in combination with the use of a complex of oriental health-improving practices on the level of psychological stress of the first-year students. The basis of the proposed pedagogical technology was the introduction of students in the active environment, such as teaching the elements of volleyball, that objectively affect lowering the level of anxiety and emotional tension, and additionally a use of a set of oriental health-improving practices.

The complex methodology consisted of theoretical and practical sections. The theoretical material was presented both in theoretical and practical lessons in the form of conversations, individual communication with students, lectures, video materials. Health-improving practices were used after playing volleyball at the end of lessons. The duration of the complexes of health-improving gymnastics was 10-15 minutes.

Complexes of breathing exercises of yogis were used to prevent colds, accelerate the body's recovery processes after exercising, relieve tension, relax, improve the functional preparedness of the respiratory and cardiovascular systems, and increase the overall body resistance.

Oriental health-improving gymnastics 'Baduanjing' was used mainly for the improvement and strengthening of the body of students. Attention was focused on smooth stretching of ligaments, tendons and muscles. The movements should be alternated with deep breathing. When performing movements of Baduanjing, there is an effect on biologically active points (BAP) of the body. Due to it, a powerful healing effect occurs, which has a very good effect on the respiratory, cardiovascular and nervous systems. There is a relief of mental and nervous tension, fatigue, improvement of the mood of the trainees.

The duration of the complex of Chinese health-improving gymnastics was 10 - 12 minutes. The complex consisted of 8 exercises, the number of repetitions was 5-8 times. The main structure of the experimental PT lesson included 3 parts: the preparatory part was a volleyball player's warm-up, comprised of a set of exercises that prepared all muscle groups (lasted 15 min); than the main part, that was built depending on the goals and objectives of the lesson (60-65 min); and the final part, which included exercises with the use of health-improving practices, such as a complex of hatha yoga gymnastics for relaxation, relieving nervous tension, lowering the level of anxiety (12 min) or a complex of Chinese health-improving gymnastics Baduanjing (12 min).

The main objectives of the oriental health-improving practices at the experimental PT lessons were:

- strengthening of health, physical and mental conditions;

- increasing mental and physical performance:

- improvement of immunological reactivity and

resistance of the body;

- training in rational breathing;

- acquaintance with oriental health-improving gymnastics and the issues of psychological training and meditation;

- the formation and consolidation of the skills of doing basic exercises that are part of the oriental health-improving practices for further use in the form of individual self-study;

- initiating interest and motivation for independent physical education;

- increasing the resistance of the body of students to negative external effects;

- mastering the techniques of meditation, psychoregulation, relaxation.

In the EG (experimental group) the PT program corresponded to the plan of the CG (control group), but in the final part it ended with exercises from oriental health-improving practices. For determining the level of students' anxiety, there was used the test of Charles Spielberger (State-Trait Anxiety Inventory (STAI)), adapted by Yu.L. Khanin and recommended for practical use by M.A. Kharchenko.[18] The test was conducted at the beginning of the school year and before the exams at the end of the school year.

The STAI measures an individual's situational anxiety and personal anxiety.

Situational anxiety is a psycho-emotional state of a person at the moment, and is expressed by an increased emotional response to stress. Personal anxiety reflects a person's predisposition to anxiety and is characterized by a response to most situations with intense excitement.

A person with increased personal anxiety perceives most of the situations that arise as extremely threatening.

The test consisted of 40 questions. The first 20 questions were intended for assessing the level of situational anxiety, the remaining 20 were for assessing personal anxiety. For quick processing of test results, students took the test online. At the beginning of the pedagogical experiment, the students of the experimental and control groups did not have significant differences.

Results and Discussion

In order to overcome psychological stress, students need to develop the ability to see the reasons for the barrier and adapt to a situation that causes discomfort. In physical culture, the adaptive effect to a competitive situation is carried out in the process of improving the personality traits and mental states, which determine the success and stability of results. Most often, psychological preparation is either correction, elimination of such features as emotional excitability, anxiety, diffidence on the one hand, or the improvement and development of such features as calmness, composure, self-confidence on the other.

Testing of the levels of anxiety (situational anxiety and personal anxiety) among the first-year students of control and experimental groups of the Russian University of Transport was carried out in September 2019 and in May 2020. In order to assess the level of anxiety, we used the State-Trait Anxiety Inventory (STAI) by Ch. Spielberger and Yu.L. Khanin.

The conducted testing of the level of anxiety in September 2019 (the beginning of the experiment) showed that the results of the control and experimental groups did not have significant differences (P> 0.01) (Table 1).

Table 1. Changes in anxiety level indicators (test by Ch.D. Spielberger - Yu. L. Khanin) of the students of control and experimental groups

Indicators		Control group		Experimental group	
		September	May	September	May
Characteristics	Symbols	Units	Units	Units	Units
Situational anxiety (SA)	$\overline{X}$	60.11	52.78	61.07	41.3
	+m	1.89	1.22	1.93	1.7
	P	< 0.01		< 0.01	
Personal anxiety (PA)	$\overline{X}$	59.3	51.22	59.93	39.93
	+m	1.7	1.22	0.93	2.07
	P	< 0.01		< 0.01	

The online testing, conducted at the end of May 2020, identified a significant increase in the indicators of the experimental group (P <0.01) in comparison with the control group. .Both the control and the experimental groups showed a significant improvement in indicators (P <0.01):

- the level of situational anxiety in the control group decreased on 7.33 points, the state of anxiety decreased on 12.2%; the level of situational anxiety in the experimental group reduced on 19.77 points, the state of anxiety decreased on 32.3%;

- the level of personal anxiety in the experimental group decreased on 20 points, the increase was 33.3%; the level of personal anxiety in the control group decreased on 8.08 points, the increase was 13.6%.

The students of the control and experimental groups were found to have high levels of both situational and personal anxiety at the beginning of the pedagogical experiment. The results of the study, conducted in May 2020 (at the end of the experiment), showed that the students of the experimental group, being trained according to the methodology developed by the authors, significantly reduced the indicators of anxiety. The levels of their situational and personal anxiety were moderate (mean). The students of the control group, on the other hand, still had increased levels of situational

and personal anxiety.

Based on the results of testing of the levels of anxiety, we can conclude about the effectiveness of the training complex developed by the authors.

Conclusion

Students, especially freshmen, are subject to fatigue and overwork as a result of active participation in the educational and cognitive process. The methods and organization of teaching at the university differs from the school one. Freshmen are faced with a large amount of educational and scientific information, a lack of time to master it and achieve their social and life maturity, they desire to express themselves and assert themselves in the team.

Providing an individual with the possibility of long and productive physical activity is the main condition for successful economic growth and the main issue of any nation.

The analysis of the testing results, carried out in May 2020, showed that the levels of situational and personal anxiety of students who study according to the experimental method developed by the authors significantly decreased. At the end of the experiment, they had moderate (mean) levels of anxiety. The students of the control group, despite the decrease in

anxiety levels, still showed the high levels of situational and personal anxiety.

The proposed methodology of PT lessons for student allowed reducing their levels of situational and general anxiety, which proves the effectiveness of the combination of a team sport game, such as volleyball, and oriental health-improving practices on the psycho-emotional state of a person which was suggested by the authors.

Conflict of Interest: No

Sources of Support: This research was conducted at the authors' expenses.

Ethical Clearance: The study was approved by the local ethics committee of the Russian University of Transport on September, 12, 2019 (Protocol No 9)

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Creating a green university in Thailand: a case study of Srinakharinwirot University

Prat Intarasaksit[1], Jitjira Chaiyarit[1]

Department of Public Health, Faculty of Physical Education, Srinakharinwirot University and Department of Statistics, Faculty of Science, Khon Kaen University

Abstract

Green development is a challenge at the global level as well as for institutions of higher education. Srinakharinwirot University aims to transform itself into a sustainable university by using UI GreenMetrics Tools to make achieve environmental benefits. Data in all categories were obtained via field observations, in a report from the Sustainable University Working Group. The overall possible score is 10,000, while SWU achieved 4,475; based on 6 categories comprising 39 a total of indicators. The strongest category score for SWU Ongkharak was for Setting and Infrastructure (68.3%), while weakest was Water (25%).Becoming a sustainable university is more than having a strategic plan. Being sustainable must be made a reality. This is achieved as everyone in society (i.e., the target population) is empowered to reflect and enhance the collective well-being by investment from/in the university.

Keywords: *Green university; Sustainable development, Environmental management, Thailand*

Introduction

The goal of sustainable societies is a worldwide challenge. In the past few decades, the world's development has emphasized economic development based on a sustainable development model[1]. Sustainable development is an enormous challenge because of the underlying current dependence on older, non-sustainable, cheap energy/resource paradigms. Human society has exceeded sustainable limits in terms of greenhouse gases emissions, climate change, water depletion, and waste disposal[2]. Definitions of sustainable development as "development which meets the needs of the present without compromising the ability of future generations to meet their own needs"[3]. Thailand attaches great importance to the concept of sustainable

development thanks in large part to recommendations from His Majesty the King Bhumipol who ceaselessly advocated for personal and societal self-sufficiency throughout his 60-year reign. "Thailand 4.0" is a new model for sustainable development. This model has four objectives for developing countries: economic prosperity; social well-being; improving the quality of human but not at the expense of other life; and, valuing environmental enhancement and protection. The meaning of environmental enhancement is that where there has been contamination or degradation, there needs to be reclamation and/or remediation so that the prior land use has been recovered. The meaning of environmental protection is that every activity in every sector should not adversely affect the environment, particularly the climate. By definition then this would mean aiming for a low carbon society, including in the education sector. In 2012, United Nations Conference on Sustainable Development agreed to the Climate Change Convention and Indigenous people Rio + 20. Higher education—especially at the university level—has been involved in sustainable development as they play roles

Corresponding Author:
Prat Intarasaksit,
Department of Public Health, Faculty of Physical Education, Srinakharinwirot University, 26120, Thailand Phone +66 (0) 8958 55779
Email: prat@g.swu.ac.th

in teaching, learning, research, and other academic work related to socio-economic and environmental enhancement. As a consequence, higher educations is affected and must confront these changes proactively[4-6]. Sustainable development in higher education is thus a major focus for university leaders. The three dimensions—social, economic, and environmental—have been conceptualized along with the long-term effects of university activities[7-13]. Several top world class universities have been taking steps to improve their sustainability (viz., University of Oxford, University of North Carolina at Chapel Hill, Massachusetts Institute of Technology and Harvard University). Srinakharinwirot University (SWU) is among this forward-acting group.

SWU was founded in 1949 by King Bhumibol Adulyadej. It is a public university in Bangkok with 15 faculties, 3 colleges, 1 graduate school, 2 research institutes, 7 centres, and 4 demonstration schools. There are 2 campuses, one at Prasarnmit in Bangkok and the other at Ongkharak, Nakhon Nayok Province.

Ongkharak campus requires a significant amount of energy and water to support its academic mission and research functions. The waste generated and air pollution (greenhouse gas emission and dust particles) emitted is significant. Efficiently managing the energy supply and demand will be considered in the future. SWU considered transforming itself into a sustainable university in an effort to minimize environmental impact, especially at the Ongkharak campus.

In 2010, the University of Indonesia developed a tool—UI GreenMetrics—for helping universities transform themselves into sustainable institutions. UI Green Metric focuses on 6 categories: academics & research, setting & infrastructure, energy & climate change, waste management, water management, and transportation. Each category is scored and the total score of all categories is 10000. In 2018, SWU committed to start to be a sustainable university by using UI GreenMetrics and aim. The purpose of the current study was to determine the feasibility of boosting SWU Ongkharak campus to the next step of being a green university using the criteria of UI GreenMetrics.

Methods and materials

Study area: Srinakharinwirot university has five campuses, but the study focused on Ongkharak campus in Nakhon Nayok province. Nakhon Nayok is in eastern region of Thailand (latitude 14°12'16.67" N; longitude 101°12'46.62" E).

Data collection: The data in each category were obtained by (a) field observations at Ongkharak campus, and (b) through reports prepared by the sustainable university working group. The data collection and analysis were done between June 2018 and November 2018

Results

The score to evaluate the sustainability of the university was calculated using the UI GreenMetrics Guideline. The data set comprised six categories and 39 indicators. The six categories included: 1) Setting and infrastructure; 2) Energy and Climate Change; 3) Waste; 4) Water; 5) Transportation; and, 6) Education. The total possible score for the 6 categories is 10,000 points while the calculated score for SWU was 4,475.

Table 1 Total score based on the six categories

Category	Score	Score allocation
1. Setting and Infrastructure (SI)	1,025	1,500
2. Energy and Climate Change (EC)	750	2,100
3. Waste (WS)	525	1,800
4. Water (WR)	250	1,000
5. Transportation (TR)	1,175	1,800
6. Education (ED)	750	1,800
Total	4,475	10,000

Setting and infrastructure (SI)

This category aims to motivate the university to provide more green space for greenery and in safeguarding the environment, through the development of sustainable energy. This category comprises 6 indicators (SI 1 to SI6), and the total possible score is 1500; the total calculated score for SWU was 1025 (68.3%).

Table 2: Setting and infrastructure score

Indicator	Score	Score allocation
SI1: Ratio of open space area to total area	225	300
SI2: Total area on campus covered in forest vegetation	50	200
SI3: Total area on campus covered in planted vegetation	225	300
SI4: Total area on campus for water absorption besides forest and planted vegetation	150	200
SI5: Total open space area divided by total campus population	225	300
SI6: Percentage of university budget for sustainability efforts within a year	150	200
Total	1,025	1,500

Energy and climate change (EC)

UI GreenMetrics requires a university to increase its efforts in energy efficiency vis-à-vis their buildings and to conserve nature and energy resources. The score in this category is the largest number compared with all categories. This category comprises 8 indicators (EC1 to EC8) for a total score of 2100. The total score from per our calculations was 750 (35.7%).

Table 3: Energy and Climate Change score

Indicator	Score	Score allocation
EC1: Energy efficient appliances usage	50	200
EC2: Smart building implementation	0	300
EC3: Number of renewable energy sources on campus	75	300
EC4: Total electricity usage divided by total campus population	150	300
EC5: Ratio of renewable energy production divided by total energy usage per year	0	200
EC6: Elements of green building implementation reflected in construction and renovation policies	225	300

Cont... **Table 3: Energy and Climate Change score**

Indicator	Score	Score allocation
EC7: Greenhouse gas emission reduction program	100	200
EC8: Ratio of total carbon footprint divided by total campus population	150	300
Total	750	2,100

Waste (WS)

Waste recycle and treatment activities are important in creating a sustainable environment. The activities of university students and staff produce waste, so a university needs a program to manage waste such as a recycling program, waste treatment, and/or reduction of single use plastics. This category comprises 6 indicators (WS1 to WS6) and the total score is 1800. The total score per our calculations was 525 (29.1%).

Table 4 Waste score

Indicator	Score	Score allocation
WS1: Recycling program for university waste	75	300
WS2: Program to reduce the use of paper and plastic on campus	225	300
WS3: Organic waste treatment	75	300
WS4: Inorganic waste treatment	75	300
WS5: Toxic waste treatment	75	300
WS6: Sewerage disposal	0	300
Total	525	1,800

Water (WR)

Water use is a further critical element for a sustainable university. The aim is to increase the efficiency of water use at the university by decreasing ground water usage, increasing conservation, and protecting habitats. This category comprises 4 indicators (WR1 to WR4) and the total score is 1000. The total score per our calculations was 250 (25%).

Table 5 Water score

Indicator	Score	Score allocation
WR1: Water conservation program implementation	75	300
WR2: Water recycling program implementation	75	300
WR3: Water efficient appliances usage	50	200
WR4: Treated water consumed	50	200
Total	250	1,000

Transportation (TR)

The transportation system is associated with carbon dioxide emissions, the cause of global warming. The use of environmentally friendly public transportation will decrease the carbon footprint around the campus. This category comprises 6 indicators (TR1 to TR6) and the total potential score is 1,800. The score per our calculations was 1,175 (65.3%).

Table 6 Transportationscore

Indicator	Score	Score allocation
TR 1: Total number of vehicles (cars and motorcycles) divided by total campus population	100	200
TR 2: Shuttle services	225	300
TR 3: Zero Emission Vehicles (ZEV) policy on campus	150	200
TR 4: The total number of Zero Emission Vehicles (ZEV) divided by total campus population	100	200
TR 5: Ratio of parking area to total campus area	150	200
TR 6: Transportation program designed to limit or decrease parking area on campus for last 3 years (2016 to 2018)	50	200
TR 7: Number of transportation initiatives to decrease private vehicles on campus	100	200
TR 8: Pedestrian path policy on campus	300	300
Total	1,175	1,800

Education and research (ED)

This category represents the number of courses or subjects; the contents of which are related to sustainability offered by the respective university. This category comprises 7 indicators (ED1 to ED7) and the total potential score is 1800. The score per our calculations was 750 (41.2%).

Table 7 Education and research score

Indicator	Score	Score allocation
ED 1: Ratio of sustainability courses to total courses/subjects	75	300
ED 2: Ratio of sustainability research funding to total research funding	150	300
ED 3: Number of scholarly publications on sustainability	150	300
ED 4: Number of events related to sustainability	150	300
ED 5: Number of student organizations related to sustainability	150	300
ED 6: University-run sustainability website	50	200
ED 7: Sustainability report	25	100
Total	750	1,800

Discussion

The following discussion is a synthesis of the results per the 6 categories and 39 associated indicators.

Setting and infrastructure category

In this category, the lowest score is the SI 2 indicator—the campus area covered in forest. The calculated score was only 6.9% (50 from 200 points) because Ongkharak campus has proportionally less forested area than the total campus area (124,632 and 1,802,847 square meters, respectively). To improve these score 50 points, Ongkharak campus needs to plant 38,000 m^2 of trees.

Energy and climate change category

In this category, there were 2 indicators that scored 0 points. Ongkharak campus does not have a smart building because most buildings are old, so the EC2 indicator got 0 points. Likewise, the ratio of renewable energy production divided by total energy usage per year (EC5) scored zero points as the ratio of renewable energy production was < 1%. Improving the smart building score is limited due to budgetary constraints but administrative and engineering controls can help to reduce the energy, lighting, and water used. Buildings could undergo simple renovations of various equipment like changing fluorescent tubes to LED lights, and changing manual faucets to auto faucets[14-16].

Waste category

This category comprises 6 indicators. The sewage disposal indicator (WS6) is the only indicator that got a zero. Based on the guidelines, 0 points indicates are mean sewage is untreated before draining into waterways, resulting in serious water pollution.

The sewerage system includes the network of pipes, pumps, and force mains for the collection of wastewaters (sewage). It serves a critical role in sanitation and disease prevention. Wastewater can contaminate the local environment and drinking water supply, thereby increasing the risk of disease transmission[17, 18]. In order to improve health outcomes for both the campus and nearby communities, the University administrators

should construct a sewerage system[19].

Water category

This category comprises 4 indicators. Based on our survey, the score seems good but it not. The score includes indicators WR1, WR2, and WR3 (score: 75, 75, and 50, respectively). Based on the guideline, this means that all three programs are preparatory. University administrators should thus expedite the programs to the action stage. As for the WR4 indicator, treated water consumed, from data we found that score is 50 it means Ongkharak campus use only 1 - 25% treated water consumed. This result in turn suggests that if the university were able to increase the volume of treated water used, it could reduce tap waste consumption from the reservoir[20]. Water is an increasingly scarce resource in Nakhon Nayok province: especially in Ongkharak campus due to the increasing population of students and drought. Ongkharak campus thus set a goal to reduce water use by all faculties and departments.

Transportation category

This category comprises 8 indicators. The lowest score was indicator 6—the Transportation program (score: 50 from 200). The latter was designed to limit or decrease parking on campus over the last 3 years.

The reason for the low score is that indicator requires 3 years of data, but Ongkharak campus had just collected data for 1 year. In addition, the university actually increased parking space. In 2019, parking space at Ongkharak campus was 37,751 square meters, which is larger than Tulane University (33,444 square meters)

Ongkharak campus offers a sustainable transportation program in order to reduce traffic and parking demands. The program offers a free electric shuttle bus for travel around campus, free parking area, and inexpensive bicycle rentals. Ongkharak campus is also constructing new walkways to cut greenhouse gas emissions.

Education category

This category comprises 7 indicators and 3 indicators with the lowest score but two of three indicators—

sustainable website (ED6) and sustainability report (ED7)—are in progress and under construction. Once the website and report are updated, the scores for both indicators should automatically increase.

As for the ratio of sustainability courses to total courses/subjects (ED1), improvement is needed but is achievable as the ED1 indicator only counted courses that included details on sustainability. Accordingly, were all curricula revised to include subject material on sustainability, the score would be improved. Note that sustainable courses can be in any field including environmental science, social science, art, or economics.

Conclusion

Ongkharak campus is part of a larger, interconnected ecosystem. Several activities have negative effects upon the natural environment, so the university needs to tackle these problems first. Our findings reveal that Srinakharinwirot University has a vision to become a sustainable university and could make incremental steps to achieving this objective by a) adopting sustainable designs for green spaces and buildings, b) upgrading to energy saving equipment, c) endorsing environmental policies, and d) gaining the support of university administrators. Collectively these efforts will help the University to reach its environmental goals.

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A Webinar Training on Digitally Transforming the Future of Global Public Health

Priyakanta Naya^k, Anil Purohit^2, Ayushi Shrivastava^3, Mathew Samuel^4, Jagdish Harsh^5, Rahul Singhi^6

^{1}Associate Professor, ^{2}Founder & Chairperson, ^{3}Intern, ^{4}Visiting Professor, ^{5}Associate Professor, Jodhpur School of Public Health (JSPH), ^{6}Co-founder, Poornima University, Jaipur, Rajasthan

Abstract

Background : Poornima University, in collaboration with Jodhpur School of Public Health, hosted an insightful and interactive live global webinar on the topic of "Digitally Transforming the Future of Global Public Health" on July 20, 2020.

Findings: This report gives a brief awareness on the global public health transformation to digital platforms and understand the technical uses of artificial intelligence (AI). During COVID-19, use of Telemedicine has increased, as a tool that reaches patient's home. In the current situation, where social distancing and quarantine have been adopted as effective method to reduce the spread of COVID, telemedicine and virtual software platforms gained more importance to provide health service.

Conclusion: The findings show that telemedicine and virtual software will minimize emergency department visits, protect healthcare resources and reduce the spread of COVID-19 by remotely treating patients during and after the COVID-19 pandemic. Telemedicine has continued to increase in uptake and shows tremendous promise in expanding access to health care, promoting patient disease management, and facilitating in-between health care visit monitoring. Although the future is bright, more research is needed to determine optimal ways to integrate telemedicine, especially remote monitoringinto routine clinical care.

Key words: *Artificial Intelligence, Digital Health, Telemedicine*

Introduction

Digital transformation (DT) refers to "a process that aims to improve an entity by triggering significant changes to its properties through combinations of information, computing, communication, and connectivity technologies". The COVID-19 pandemic has demonstrated the strong potential of various digital health solutions that have been tested during the crisis. Since February 2020, telemedicine grew from less than 1% of primary care visits to nearly 43.5% in April 2020. With telemedicine's current trajectory and rapid adoption rate, it has the potential to disrupt and redefine the way health systems operate, deliver care and manage costs, setting the stage for a vastly different healthcare experience in the future.

Overview and Findings

As COVID 19 continues to spread across the countries, the need for innovative measures to provide high-quality patient care and manage its spread has become more important. Software-based systems such as medical software applications could provide valuable suggestion on health-related information to physicians towards improving quality of life, especially for outpatients. Digital health has a transformative impact on health services, changing the balance of power between provider and patient, encourages new modes of treatment, and moves the focus of health systems to client-centered health[1]. Even though many of these changes are just being felt due to resistance by organizations and individuals reluctant to change the status quo, the explosive growth of digital technology

globally means that these changes are inevitable.

Healthcare organizations aim to deliver better care through a combination of medical, operational and institutional methods, sometimes encouraged and often induced by emerging technology. Important improvements have been made considering tightening budget restrictions and rising operating demand. A range of effects can be observed at several levels and with intended and unintended benefits and consequences. During 2020, the world had to face a global health crisis, a pandemic related with COVID-19. The COVID crisis has pushed even more healthcare ecosystems around the globe to reconsider their global strategies, moving from resilience to anti-fragility. The unpredictable and rapid adoption of digital technology will help the response and management of global health challenges and, at the same time, build new strategic and innovation frameworks for the healthcare ecosystem.

For instance, telemedicine leading to a better outcome for all the stakeholders, from the patient to the operator (surgeon), from the hospital or clinic to the whole society[2]. Due to COVID about 76% of consumers are now interested in using telehealth going forward. When looking at data from a leading hospital in Bangalore, it is seen many cancer patients were spending an average of 12 hours of travel time since many were coming from rural parts of India.

Increased use of telemedicine for remote diagnostics and treatment, protocol-driven healthcare to increase quality of care, and increased access to products and services through improvements in the organisation of transport and delivery services[3,4]. Data will become central to health systems. This will include big data and artificial intelligence tools for surveillance, planning, and management or "personalized data" in the form of universal electronic record systems and customized treatment protocols. As with any disruptive innovation, the growth of digital health will also bring new challenges, including who owns, controls, and manages the data being collected and how to maintain privacy and confidentiality in this data-rich world[5].

Telemedicine also proves useful, to help conserve personal protective equipment and provide isolated patients connection to friends and family. Accordingly, few medical centers have resorted adopting virtual software platforms such as Microsoft Teams, Zoom, Google Hangouts, Skype, Facebook Messenger, Apple Facetime, and others to facilitate telemedicine care during the pandemic[6]. This increase use of telemedicine results in the following:

·   Decrease the time required to get diagnosis and initiate treatment, stabilize, or quarantine a patient.

·   Facilitates close follow-up with patients. Also, the patients can be monitored from their home by doctors to avoid oversaturation of health facilities.

·   Reducing the movement of patients and minimizing the risk of infection which they can get from hospitals.

·   Supports co-ordination of medical resources utilized in distant locations.

·   Prevent the risk of infection from medical practitioner, who are the key asset.

·   Aids in informing the general public

·   Saves costs on disposable robes, gloves, antiseptic material etc.

·   Allows clinicians and students to sharpen their clinical skills in patient interaction

Applications of Tele-medicine

1.   Educational

·   Tele-education: a flexible and engaging long-distance learning platform that offers easier training and updates on new developments in more precise and efficient treatment methods.

·   Tele-Conferencing: Discussion and interaction between doctors during workshop, conferences, seminar or continual medical education programs in a virtual room environment.

2.   Healthcare delivery

·   School-Based Health Centers: Helps manage chronic conditions like bronchial asthma, diabetes and obesity. Telemedicine allows a school nurse, remote access to specialist medical opinion.

·   Correctional Facilities: Cater to the healthcare needs of the inmates without the expense and dangers of inmate transportation or the need for a specialist doctor to enter.

·   Mobile Health Clinics: Provides quick access to a remote physician or medical specialist.

·   Shipping and Transportation: Helps avoid evacuations and unscheduled diversions during a medical emergency.

·   Industrial Health: Provides medical management and triage advice on-site.

3.   Healthcare management

·   Tele-health care: Use of ICTs for preventive and promotive healthcare; it is further divided into teleconsultation and tele-follow up.

·   Tele-home health care: Monitor patients from a central station (Remote patient monitoring) with the help of a Computer Telephone Integrated (CTI) system for 24-hour vitals monitoring.

·   Specialties like tele-ophthalmology, tele-psychiatry, tele-cardiology, and tele-surgery.

·   Diagnostic services like tele-radiology and tele-endoscopy.

4.   Screening of diseases

·   Diabetic screening project by MDRF: The Chunampet Rural Diabetes Prevention Project.

·   Ophthalmology screening by Aravind Hospitals at Andipatti village.

5.   Disaster management:

·   A mobile and portable telemedicine system with satellite connectivity and customized telemedicine software is ideal for a disaster-stricken region where all other modes of connectivity are disrupted.

·   NASA tele-medicine services provided during 1985 Mexico City earthquake and 1988 Soviet Armenia earthquake.

·   Amrita hospital tele-medicine services provided during 2004 Tsunami disaster.

Challenges

Though the use of digital technology has the potential to transform and improve the delivery of health care in low-income countries, it also raises many concerns, including how individual privacy and confidentiality will be maintained, who will control both the technology and the data, who will pay for the technology, and how to deal with the inevitable resistance to the changes discussed by those who benefit from the status quo[7].

Any discussion of electronic health records quickly leads to a discussion of privacy and confidentiality[8]. Though this is not a new concern, because the same issues arise with paper records, the ease of analyzing and reproducing digital data is cause for concern. Recent data breaches by numerous commercial and government enterprises have made it clear that these concerns are real and that data breaches or abuses will become a reality of the digital age. Although we can wish to go back to an era or more privacy and confidentiality, the reality of surveillance cameras on each street corner, tracking location through mobile phone networks, and monitoring credit or debit card transactions has made it nearly impossible to maintain privacy[9]. And as the use of digital cash transfers and Internet purchases grows, control of privacy will become less possible and it is unlikely that we will ever again be able to protect all of our data as was done in the past.Benefits may serve as a basis to initiate the adoption of telemedicine practices in healthcare organization. However, individual hospitals and industry as a whole are facing certain challenges that inhibit the development process[10]. The major ones are:

·   **Data privacy and interoperability rules compliance:** Telemedicine utilizes a lot of confidential

data of patient. As we're talking about collecting, storing, and transmitting the information, we also need to take into account specific requirements in this field.

· **Accessibility:**Telemedicine focuses on out-of-reach patients, the lack of internet connection in remote areas only aggravates the problem, as healthcare providers won't be able to transmit data. But the problem doesn't have a solution in sight since broadband coverage develops over years.

· **Training burden:**Any technology requires both clinicians and patients receive proper training on how to use it. Telemedicine devices and applications are no exception. This burden falls on the healthcare provider, as they will need to establish training and information broadcast for different groups of users, involving additional costs, excluding the telemedicine platform itself.

Conclusion

Telehealth provides an opportunity to provide care that is convenient, accessible and patient-centric, overcoming many of the barriers inherent in traditional health care delivery systems[11]. Although, widespread implementation will require attention to systems engineering approaches to health care design so that it can address incentives, technical and human requirements, work processes, and payment issues. To demonstrate and realize added value to health outcomes, telehealth implementation is not simply a feature to be added to existing health care delivery. It must be integrated into innovation at the system level. Integration involves examining the current flow of care for targeted subpopulations and revising the overall approach to care, integrating telehealth, and changing traditional elements. For example, using telehealth to manage chronic disease might incorporate interprofessional involvement, with nurses, pharmacists, or dietitians coaching the patient through telehealth between visits for primary care. Integration may require challenging adjustments in the current delivery of care. For example, the number of planned primary care visits may be reduced as telehealth is used to augment care.

For telehealth to be fully integrated into global health systems, a number of items that support system transformation will be needed. Given that telehealth often includes patient-generated data, significant changes will be needed to insure accurate, efficient, and timely monitoring of health parameters that are useful for guiding clinical decision making[12]. Integration and interpretation of these data are essential to optimizing telehealth, yet many EHR systems do not have the capacity to incorporate patient-generated data nor are they not able to make it available in a time-sensitive fashion. Similarly, new competencies will be required for health care professionals in telehealth and systems engineering to improve health. Finally, telehealth research needs to promote approaches to care that are amenable for adoption in practice. The age-old challenge is to translate research findings into practice to facilitate adoption of new knowledge to telehealth. The challenges are to reinforce the urgency with which evidence is needed to drive policy and provide greater incentive for researchers and practitioners to collaborate.

Conflict of Interest: Nil

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A Webinar Training on From AIDS to COVID: The Rocky Road of Public Health

Priyakanta Nayak[1], Anil Purohit[2], Nikita Joshi[3], Bhawna Sati[4]

[1]Associate Professor, [2]Founder & Chairperson, Jodhpur School of Public Health (JSPH), [3]Intern, Prin. L. N. Welingkar Institute of Management Development & Research, Mumbai, [4]Head of the Department, Jodhpur School of Public Health (JSPH)

Abstract

Background : Poornima University, in collaboration with Jodhpur School of Public Health, hosted an insightful and interactive live global webinar on the topic of "From AIDS to COVID: The Rocky road of Public Health" on August 8, 2020.

Findings: This report provides information about the coronavirus, the good and bad impact of COVID-19, and some of the major challenges that were faced all across the globe. Many questions are it the origin of the virus or the route of transmission of the virus remains unclear. But the good thing is that there were many innovations in the field of testing, repurposing of drugs, and rapid development of vaccines to reduce the spread of the pandemic.

Conclusion: The findings show that a lot of questions are yet to be answered and that there is a need of focusing on public health. There were many learnings from this pandemic and one of the most important lessons was that the involvement of communities is a key step to face such global challenges. The pandemic is not going anywhere soon, and therefore, it becomes necessary to bring in change and sustain it for the future. The challenges faced during this pandemic have served as valuable lessons and it is vital to focus on the shortcomings to avoid such negative impacts around the world.

Keywords: COVID-19, Coronavirus, Challenges

Background

The COVID-19 was declared a pandemic on 11 March 2020, by the World Health Organization[1]. The COVID-19 jammed the world unprepared with no medical preparedness. At the end of 2019, emerging from Wuhan, China, the novel coronavirus was diagnosed across eight other countries: Nepal, Japan, South Korea, Thailand, Taiwan, Singapore, the United States, and Vietnam by the end of January 2020. Many countries adopted measures such as geographical border closer, preparation of isolation centres, nation-wide lockdown except for medicines, foods, and essential services, promotion of basic hygiene and social distancing practices, and arrangement of welfare packages for the vulnerable population. The WHO supported the pandemic battle by issuing patient monitoring guidance, coordinating for the development of diagnostics, treatment, providing COVID-19 updates, and collection of specimens[2].

Procedure:

Coronavirus is single-stranded RNA containing enveloped viruses that have the potential to infect a wide range of animals and humans. Their morphology is spherical virions that have a core-shell and projections on their surface which resembles a solar corona. The genome size varies between 26 kb to 32 kb. There are four subfamilies, i.e. alpha☐, beta☐, gamma☐ and delta☐coronaviruses. The alpha- and beta- coronaviruses seemingly originate from mammals, especially from

bats, while the origin of gamma- and delta- coronaviruses is from birds and pigs. The alpha-coronaviruses cause asymptomatic or mild symptomatic infection, while beta-coronaviruses might cause severe complications. SARS-CoV-2 is from the B lineage of the beta-coronaviruses and at the whole-genome level is 96% identical to a bat coronavirus. SARS-CoV-2 has seemingly succeeded in transmission from animals to humans in Wuhan, China but the exact route of transmission is still not clear.

Based on the intensity and time of occurrence of symptoms, the infection has been classified as a mild, severe, and critical stage. At a mild stage, the symptoms such as mild fever, sore throat, malaise, nasal congestion, mild/no pneumonia, muscle pain, and headache are observed. In the case of severely affected individuals, symptoms such as cough, oxygen saturation below 93% (hypoxia), and tachypnea (shortness of breath) are observed. At the critical stage, there is severe pneumonia, respiratory failure, septic shock, multiple organ failure, and/or cardiac arrest, which might lead to patient death. Also, research studies have shown that individuals with comorbidities such as severe obesity, diabetes mellitus, and hypertension are at a higher risk of complications and death from COVID-19 infection[3].

The development of specific, sensitive, rapid, and accurate diagnostic tests was one of the important steps to curb the pandemic. The conventional testing methods were replaced by the molecular RT-PCR assays, which were specific, rapid, and highly sensitive. There were breakthrough innovations such as the Xpert® Xpress SARS-CoV-2 test (an RT-qPCR test), Abbott ID NOW. COVID-19 test, IgM–IgG-combined antibody test (developed by Biomedomics), a CRISPR-based Specific High Sensitivity Enzymatic Reporter Unlocking (SHERLOCK) technique, etc. in the field of testing. As per the data by the Foundation for Innovative New Diagnostics (FIND), one of the WHO's associates for the evaluation of diagnostics, there are at least 143 COVID-19 molecular diagnostic kits that are commercially used across the globe[4]. Also, technology such as Artificial Intelligence (AI) has been implemented for the preliminary screening of early infections of SARS-CoV-2. AI is an important tool that can help in understanding the risk involved and transmission dynamics between the diverse population groups. Similarly, the use of telehealth was seen to rise in several regions of the world[5,6].

Another interesting surprise was the rapid development of vaccines. Around 200 vaccines were present in different stages of clinical trials. The vaccines were developed by using different methods such as viral vector vaccine, mRNA vaccine, DNA vaccine, peptide-based, recombinant protein-based vaccine, virus-like particles, live-attenuated vaccine, and killed vaccine[7]. Until the availability of licensed vaccines and antiviral drugs, the most promising option was the repurposing of the available drugs. Favilavir, the first drug tested, by the National Medical Products Administration of China, is used for the treatment of influenza infection. Other drugs such as remdisivir, a combination of lopinavir and ritonavir, hydroxychloroquine in combination with azithromycin, are also some of the repurposed drugs used for the treatment of COVID-19 patients.

With the increasing risk of the spread of the COVID-19 pandemic, many measures were implemented to control the spread of infection. The measures were as follows:

· **Control of cross-country travel and international trade:** The refusal of visa, restrain the entry of selected foreign country individuals based on health status, nationality, or travel history. The unexpected spread of the virus had provided a reality check on the availability of resources and there was a huge demand for personal protective equipment, active pharmaceutical ingredients for drug manufacturing, and ventilators. During these challenging times, it is also important to understand the social, legal, ethical, and economic impact the cross-border measures can have if not given sufficient attention. The cross-border measures could restrict the movement of health professionals and essential supplies and can also cause economic stress and poor health outcomes in some affected nations.

· **Implementing entry and exit controls at the country border:** There was a strong focus on things such as filling the questionnaire, body temperature

check, testing, health certifications, and vector control while traveling to another country. Travelers from other affected countries were quarantined.

· **Use of sanitizers or soaps:** There was a drastic increase in the demand for sanitizers. Sanitizers made up of 70% isopropanol or 60–70% ethanol are effective against SARS-CoV-2. Several health organizations and governments had been focusing on spreading awareness regarding the importance of hand hygiene among the public. The use of sanitizers to clean hands while the use of soap and water for 20 s were important measures promoted to limit COVID-19.

· **Use of masks and spread of awareness:** Another important area of focus was the implementation of the use of masks and creating awareness. The WHO had recommended the use of N95 masks at all times for the infected patients and healthcare professionals only when in close proximity of the infected patients. Bringing in awareness about the routes of transmission, symptoms, and preventive strategies such as social distancing were necessary.

Challenges

With the widespread of COVID-19, multiple challenges were faced by nations across the globe[8]. The danger was not limited to the contraction of the virus but had its indirect impact on various industrial sectors. Be it logistics or healthcare, every sector had to hold back and think of new ways to survive the ongoing pandemic. Some of the challenges caused by the COVID-19 pandemic are as follows:

· **Restrictions on Basic Human Rights:** Soon with the spread of COVID-19, a lockdown was implemented in many countries. This caused restriction on movement, closing of educational institutes, social distancing, ban on visiting religious places, etc. The visit to restaurants, clubs, cinemas, weddings, etc. was also prohibited. Also, many developing countries faced unemployment and hunger issues.

· **Mental Health:** The future uncertainty, a severe shortage of resources for diagnosis and treatment, restrictions on personal freedom, rising economic problems, and ambiguity in the information provided by the authorities are some of the major reasons that have affected mental health. Such public health emergencies affect safety and health at both individuals as well as at the community level[9]. The feeling of insecurity, emotional isolation, confusion, and stigma might arise and also may translate into unhealthy behaviours, a variety of emotional reactions, and noncompliance with public health professionals.

· **Healthcare System:** The lack of healthcare infrastructure, healthcare professionals, and medical resources was evident during the pandemic across various countries across the world. The front-line healthcare workers were at a very high risk of infection and death[10]. The shortage of healthcare professionals coupled with increasing COVD-19 cases caused a lot of stress on the workforce. Further, the shortage of personal protective equipment in many nations increased the problems of the health service providers. Also, the intense focus on COVID-19 impacted the prevention, monitoring, and treatment of other diseases, which lead to increased complications related to diabetes, cardiovascular diseases, HIV, TB, malaria, etc.

· **Social-Economic:** There was an intense socio-economic impact across the globe. The pandemic caused the closing of schools and universities, cancellation of sports events, decline in the stock market and crude oil prices, restrictions on tourism and entertainment industry, etc. The pandemic severely affected to lower socio-economic stratum[11]. In India, there were distressing visuals of migrant laborers walking from cities to their hometowns during the lockdown. The global GDP loss is estimated to be in the range of 1.0 to 2.7 trillion US dollars. It was a big challenge for various countries across the globe to revive the GDP and improve the economic status of the communities.

Conclusion

With the emergence of the pandemic, a lot of gaps were identified be it the knowledge about transmission of the virus from animals to humans, or the preparedness to deal with such pandemic. The knowledge about factors causing the virus to cross the species barriers, the exact

origin of the virus, mutation differences, recurrence of infection in few individuals, and reasons for some remaining asymptomatic while some having severe complications remains unclear. Several questions were raised on implementing effective safety measures and fulfilment of vaccines and other resources to such a large population across the globe. One of the good things that this pandemic has given is the breakthrough innovations in testing. Many companies came up with rapid, sensitive, and specific COVID-19 molecular diagnostic kits. Also, scientists are working hard on vaccines and therapies for the treatment of COVID-19 infection. The use of technology and social media platforms have also played an important role in science and communication.

Starting from Wuhan, China the outbreak had reached around 85 countries/areas/territories as of 5 March 2020. An extensive study was done by the scientists on the characterization of the novel coronavirus and repurposing of available drugs. The pandemic has caused many direct as well indirect impacts on the healthcare ecosystem. With the increasing focus on the prevention and treatment of COVID-19 patients, the care of other patients with non-communicable diseases such as hypertension, diabetes, etc. was neglected. People had the fear to visit the hospitals, and thus, avoided going for detection and treatment. All these factors have increased the complications of diseases and raised the burden of healthcare professionals. Though there has been a rise in telehealth still the utilization has been disproportionate and will require time to gain global acceptance. The pandemic also had a negative impact on the supply chain, social life, economy, mental health, etc. It taught us that community involvement is essential to deal with such global challenges.

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Establishing a Chronic Kidney Disease (CKD) Surveillance in Cuttack District, Odisha, India

Priyakanta Nayak[1], Nikita Raula[2], Basanta Kumar Swain[3], Bikas Patnaik[4], Kailash Chandra Dash[5], Deepak Kumar[6]

[1]EIS Officer, National Centre for Disease Control, New Delhi, India, [2]MPH Intern, Directorate of Public Health, Odisha, India, [3]Epidemiologist, Directorate of Public Health, Odisha, India, [4]Joint Director, Directorate of Public Health, Odisha, India, [5]Director (Public Health), Directorate of Public Health, Odisha, India, [6]Consultant, World Health organization

Abstract

Background: Chronic kidney disease (CKD) is a globalpriority public health concern that accounts for significant morbidity and mortality. Unusual occurrence of CKD was reported from Cuttack district of Odisha. We aim to establish a CKD surveillance system in Cuttack district to estimate the burden of disease and help decision-makers through future epidemiological assessments.

Method: We focused on CKD patients enrolled in the Narsingpur community health clinics and attending the clinics from January to June 2016. We defined a suspected CKD as patientpresenting with any symptoms of loss of appetite, fatigue &weakness, change in urine output, swelling of feet & ankles and blood in urine. A confirmed CKD was defined as a CKD suspect with elevated Serum creatinine (>1.5 mg/dL) and Serum Urea (>40 mg/dL).Besides, we collected relevant data on demography, clinical, laboratory, occupational and family history of patients.

Results: The CKDsurveillance presented over 320 suspected CKD cases, of which 35 cases were laboratory confirmed. The median age was 57 years ranging from 35 -75 years (Mean +SD= 56+9.1), 71% of cases were males and agriculture was the commonest occupation. Laboratory finding shows fasting blood glucose of 147.4 mg/dl (Range 84-249), Serum Creatinine 3.59 mg/dl (Range 2.2-7.9), Serum Urea 76.6 mg/dl (Range 14.1-137), Urine Creatinine 6.0 mg/24 hrs (Range, 4.4-7.3) and Urine Albumin 7.6 mg/dl (Range 7.2-8.4). The majority of patients (57%, 20/35) were in CKD stage 3 (GFR, between 60 and 89 ml/min/1.73m2).

Conclusion: The CKD surveillance system supported CKD patient's analysis by age, gender, geographical distribution and socio-demographic profile. Further, the analysis involved analysing patient's clinical characteristics, CKD staging, associated co-morbidities and treatment modalities.The surveillance system established a scientific platform for primary prevention, early detection, and treatment strategies implementation. The platform eventuallyhelped the decision-makers increase awareness, decrease CKD morbidity & mortality throughmore efficient resource utilization.

Key Words: *CKD, Odisha, Cuttack*

Background

The CKD is a global health challenge. Almost a third of CKD patients live in two countries: India and China. In rural Indian sub-continent, the disease disproportionally affect poor, male farmers, particularly in hot climates. Several countries are undergoing an increased disease prevalence over the past two decades. The countries include El Salvador, Nicaragua, Costa Rica, Egypt, Sri Lanka, and India. As the CKD'saetiology remained unexplained in past decades, the literature mentioned the term "chronic kidney disease of unknown aetiology" since the early 2000s[1].

Compared to 5.21 million projected deaths due to CKD in India in 2008, the estimated deaths in the year 2000 is 7.63 million in 2020 (66.7% of all deaths)[2,3]. In many community-based studies, the CKD prevalence is found between 0.16% and 0.79%. However, these studies mainly focused on stage 3 CKD or worse, and therefore, the real prevalence of CKD is much higher than what these studies noted[4,5,6,7].

Most CKD cases without an exact aetiology (CKDu) are found in adult men aged <60 years from rural areas, especially in those cultivating rice in paddies (in Sri Lanka), vegetables (in Egypt and India) and sugar cane and other crops in Central America[8,9]. In India, epidemics of CKDu affect sharply defined geographic areas that are fertile and swelteringly hot. The victims mostly conduct heavy manual labour, have little formal education, and lack easy medical care access.

A report available from Srikakulam reveals high serum level of Cadmium (Cd) and Molybdenum (Mo) in patients suspected of CKD. CKDu has emerged in in India, and Sri Lanka's geographic pockets, with an estimated more than 20,000 patients diagnosed with late-stage kidney disease. The Countries with large numbers of CKDu patients contributes for major social and economic burden[10]. Multiple factors cause CKDu, likely linked to a combination of environmental factors, diet and nutritional practices, and genetics.

Cuttack district of Odisha, India observed unusual occurrence of CKD since 2010 with clustering of cases in two blocks: Narsingpur and Baramba. Narsingpur reported 780 cases (29% deaths) from 158 villages and Baramba block reported 201 cases (4% deaths) from 20 villages. However, challenges such as inconsistent case definition, poor laboratory capacity, and lack of systematic reporting hindered CKD surveillance system development.

A surveillance system comprehensively captures and tracks all critical manifestations of a disease, providing essential information on disease activity, including persons affected, timing, magnitude, severity and location to guide implementation of medical and public health measures to control or contain the disease[11]. What is highly significant for overall CKDdisease control, in addition to the enumeration of cases, is to track information on the disease burden, its complications and outcomes of the disease management.

We aim to establish and demonstrate a robust CKD surveillance system in Cuttack district to estimate the burden of disease and help decision-makers through future epidemiological assessments. The specific elements of the CKD Surveillance System were to establish a standardized case definition, an algorithm for testing and reporting, a standardized case reporting form, a systematic approach to reporting and data collection and regular analysis of surveillance data to stakeholders.

Methodology

Setting: Narsingpur and Baramba blocks in Cuttack district, Odisha

Target population: All suspect CKD cases in Narsignpur, expectedly, visited the community health clinic for urinalysis and serum creatinine. When elevated serum creatinine (>1.5 mg/dL) and serum urea (>40 mg/dL) level with urine proteinuria the patient weredetected, the concerned patient was registered under the surveillance system. These tests were repeated every month for the next three months. The mentioned abnormalities in the serum creatinine and urine formed the basis to declare patient with CKD. Such confirmed CKDs were then referred to the Nephrology Department of SCB Medical College, Cuttack for registration and clinical management.

Period: January to June 2016.

Case Definition:

Suspect CKD: Any patient residing in CKD endemic area presents with any of the following symptoms:loss of appetite, fatigue andweakness, change in urine output, swelling of feet and ankles, and blood in urine.

Confirmed CKD: A CKD suspect with elevated Serum creatinine (>1.5 mg/dL) and Serum Urea (>40 mg/dL) level with urine proteinuria and three repeated tests in consecutive month with the elevated urine parameter.

Data Collection: The patient data was collected in the CKD registry at Narsingpur CHC laboratory. A line-list was prepared by the trained Supervisor for all confirmed CKD patients. The trained health worker visited the patient house and collected detailed data of the patients in a pre-designed data collection tool. The collected data were compiled at CHC Narsingpur and CHC Baramba by the trained data entry operator identified for the purpose.

Data Validation: The supervisor cross-checked the CHC laboratory register to compare the number of CKD suspects examined in the laboratory and the number of confirmed CKD patients recorded in the line-list. The validation further detailedthe line-list in the SCB medical college and the patient treatment card at block program management unit. The principal investigator conducted triangulation of the data available in laboratory register, line list and treatment card, and ensured correctness of data entered in the electronic database.

Data-entry & Analysis: Trained data entry operators entered the data. Epi Info 7.1.4 software was used for data entry.All discrepancies in data entry were resolved, referringto the original data collection formats, and the database was finalized. The surveillance team securely locked the final database for safety. After removing personal identifiers, a duplicate version of the finalized database wasstatistically analysis using Epi Info 7.1.4 software.

Consent and Data Confidentiality: Informed consent was taken from the participants in a prescribed format after providing accurate information through patient information form. Patients' confidentiality was maintained, and only the study investigators and the field staff of the programme had accessto the data. Names of the patients were not included in the electronic database. Each of the concerned staff wereguided to maintain confidentiality. Simultaneously, the electronic data file was password secured, and only those on the data team had an access to open the file and enter data. While disseminating the study findings to the external audience, only pooled results are shared. No references were made to any individual study participant.

CKD Patient Identification & Referral: A one-day training of medical and paramedical staff including, the field staffs, wasconducted in both Narsingpur and Baramba blocks. Any suspected CKD patients attending the Government or private clinic, with the defined symptoms, was referred to the CHC laboratory, Narsingpur to evaluate CKD. The confirmed CKD patients furtherwere referred to the SCB medical college, Cuttack,Department of Nephrology. The department assessed every patient for GFR after which the patient wereregistered as the CKD patients. A treatment card was opened for each registered patient at the BPMU of the respective blocks

Indicators: The CKD surveillance system will estimate the burden of CKD (both incidence and prevalence)

Health Institutes Involved:

1. CHC, Narsingpur and CHC Baramba of Cuttack district

2. Directorate of Health Services. Odisha

3. SCB Medical College Cuttack, Dept. of Nephrology

4. Centre for Disease control & Prevention, India

5. National Centre for Disease Control, New Delhi, India

Laboratory:

1. CHC, Narsingpur Laboratory (Routine urine and serum Creatinine/ Urea)

2. SCB Medical College Cuttack, Dept. of Pathology (Confirmation for CKD

3. Regional Medical & Research Centre, Bhubaneswar, Odisha (For Human Specimen)

4. Institute of Mineral & Material Technology, Bhubaneswar, Odisha (For Heavy Metals)

Core-committee for CKD Surveillance: As part of the study process, a core committee was formed which comprised comprising of the principal investigator (EIS

Officer, NCDC, Delhi) , Members from Directorate Health Services & Directorate of Medical Education, Odisha, Nephrologist from SCB medical college , Chief District Medical Officer, Cuttack and the Block Medical Officer. An advisory group further supported the core committee from National Centre for Disease Control, Delhi and Centre for Disease Control and Prevention, India. The core committee members met every month to share information, discuss options, gather input, and make decisions. The Principal Investigator was connected to the advisory group weekly by teleconference. The role of the Advisory Group was to provide input on various issues, including the importance of individual topics and measures and the evaluation of data sources.

Ethics considerations: The protocol was reviewed and approved by the core committee, Directorate of Health Services, Government of Odisha who agreed to collaborate for the establishment of CKD surveillance system. Every patient participated and provided an informed consent before collecting the data.

Results

During March 1- June 30, 35 CKD cases were reported from 21 villages in Baramba and Narsingpur blocks of Cuttack district, Odisha. The median age was 57 years ranging from 35 -75 years (Mean +SD= 56+9.1), 71% of cases were males. All patients were enrolled in the surveillance system, and initiated with treatment at SCB medical college, Cuttack and no deathwerereported.

Geographical Location: Twenty-one villages from both the blocks reported CKD cases. Three villages (Godibandha, Jhajia & Jodum) reported 12 cases, each reporting 4 cases. Mahurakhia village reported 3 cases, Paikapadapatna and Balijhari villages reported 2 cases each and rest of the villages reported 1 case each.

Clinical Feature: The most common clinical presentation was fatigue and illness (71%) followed by swelling of foot and ankle (54%), loss of appetite (43%), recurrent urinary symptoms (40%) and change in urine output (30%) **(Table 2).** Out of 35 reported CKD patients, 46% (16/35) has history of chronic illness (arthritis, kidney stone, hypertension, and diabetes) and of them, 63% (10/16) were under medication for the illness **(Table 3).**

Occupational History: Agriculture was the most common occupation (34%) among the cases, and of them, 75% (9/12) has cultivated rice. We found that 23% (8/35) of cases have used pesticides (Jailo & Sabin) and of them only 25% (2/8) have used personal protection during pesticide use. Agrochemical usage (DAF & Urea) was reported in 20% (7/28) of cases and of them, only 14 % (1/7) reported use of personal protection **(Table 4).**

Deep bore well water (54%) was found as the common drinking water source among the reported cases. Among the cases, 14% (5/35) reported alcohol consumption, 26% (9/35) were smokers, and 23 % (8/35) reported chewing tobacco products. Non-steroid anti-inflammatory drugs (NSAID) usage was reported among 43% (15/35) of cases and of them, 27% (4/15) reported daily usage of NSAID**(Table 5).**

Laboratory Analysis: The median blood pressure was reported 141.1 mm of Hg (Range 100-220 mm of Hg). The fasting blood glucose was 147.4 mg/dl (Range 84-249 mg/dl), Serum Creatinine 3.59 mg/dl (Range 2.2-7.9 mg/dl), Serum Urea 76.6 mg/dl (Range 14.1-137mg/dl), Urine Creatinine 6.0 mg/24 hrs (Range, 4.4-7.3mg/24 hrs) and Urine Albumin 7.6 mg/dl (Range 7.2-8.4mg/dl)**(Table 6).**
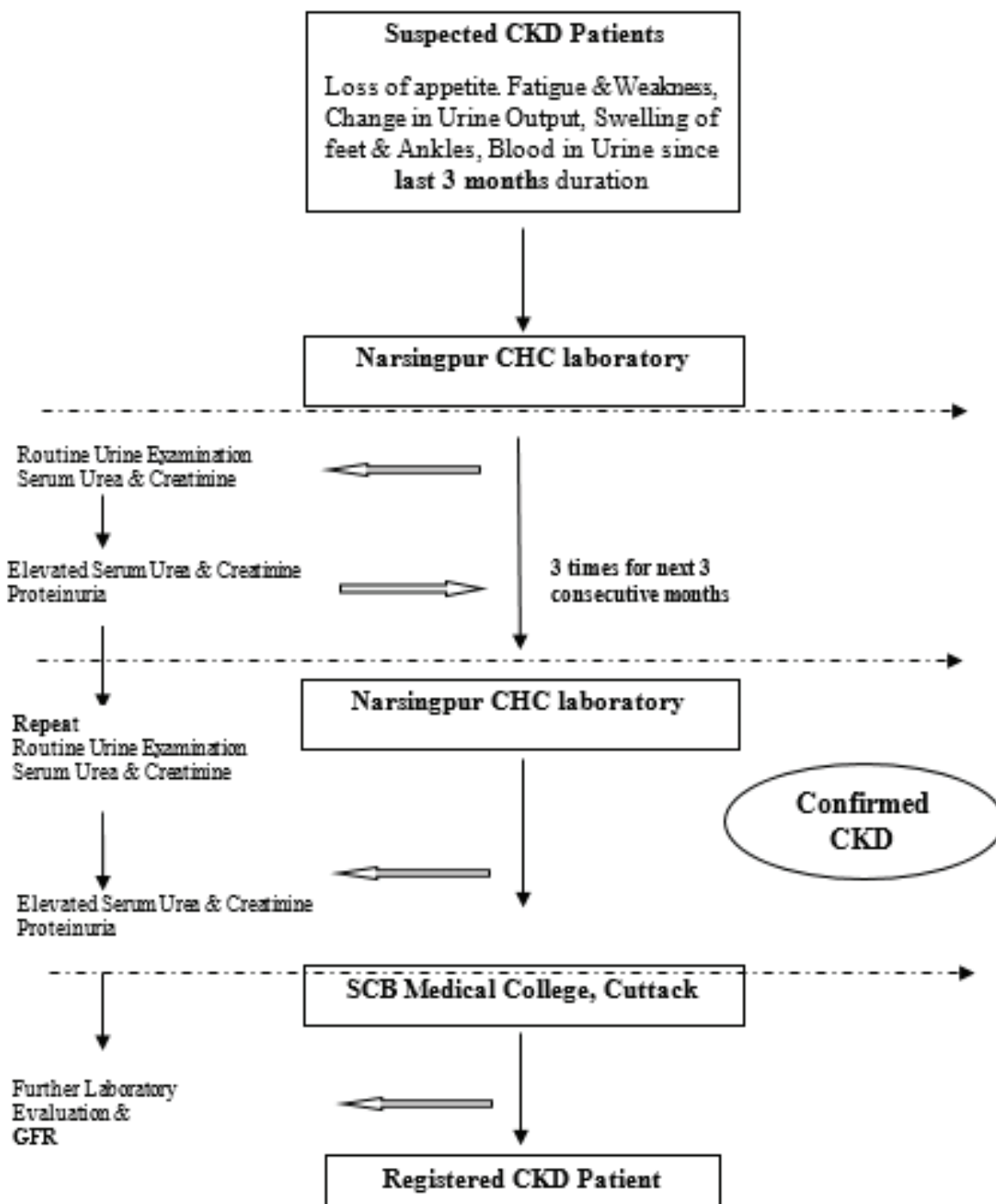
Figure 1; Flow Chart for CKDu Suspects in Cuttack district, Odisha
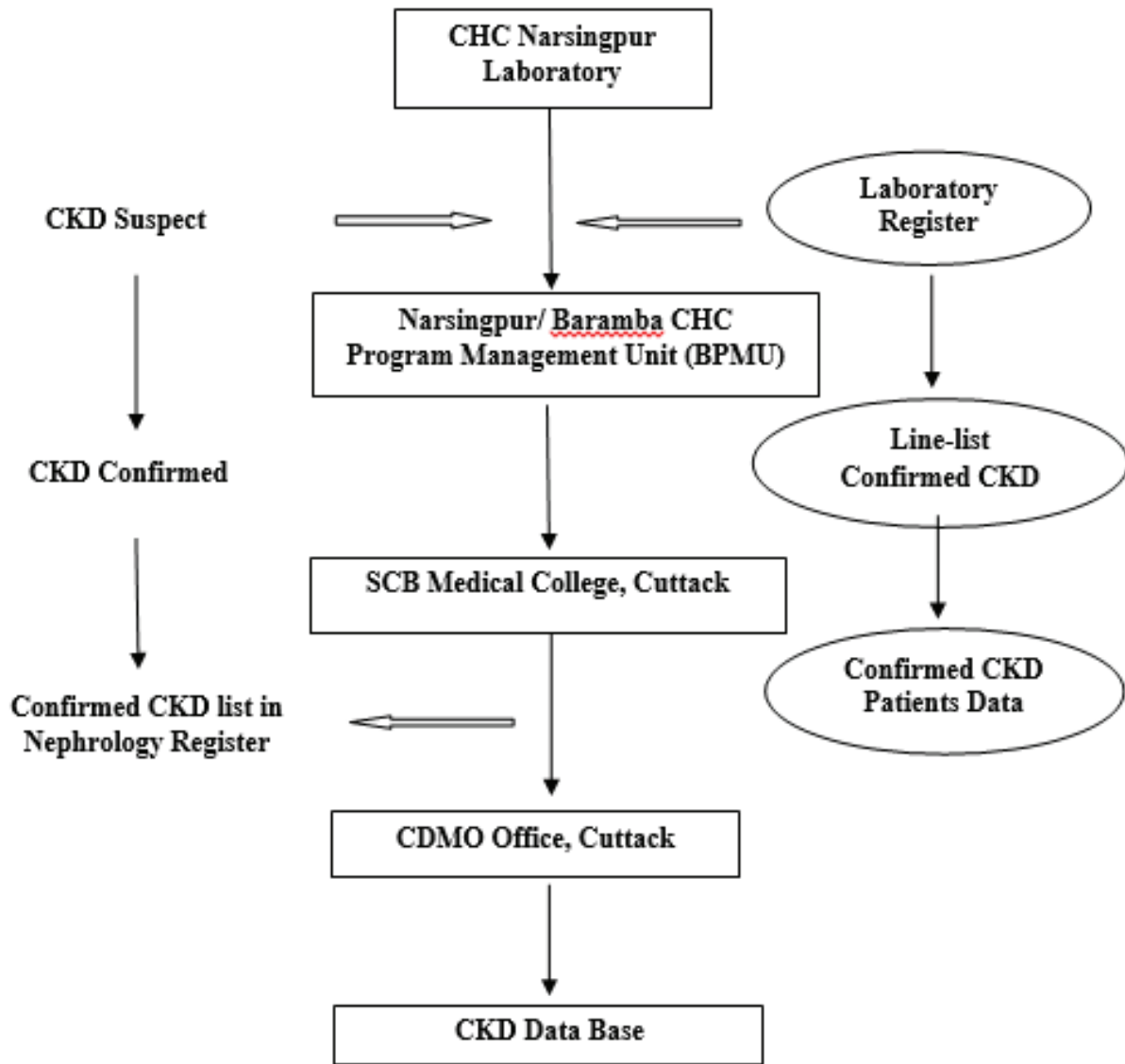
Figure 2: Data Flow in CKD Surveillance System
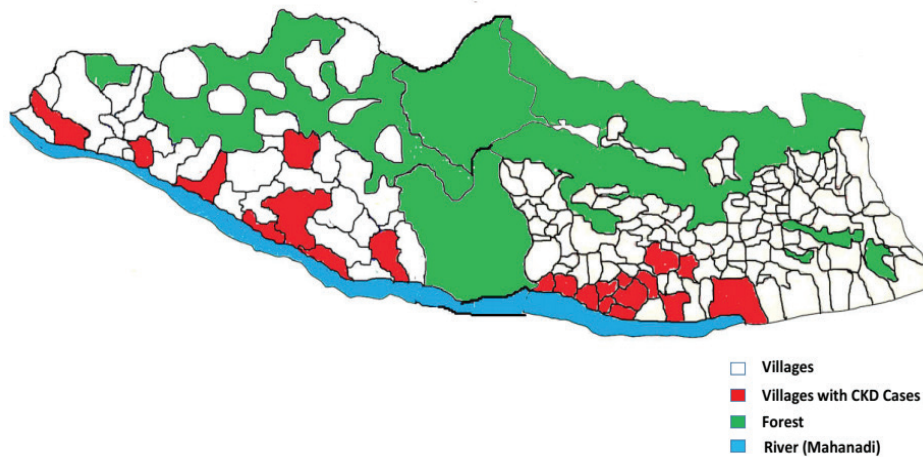
Figure 3: Geographical distribution of villages with CKDu cases in Cuttack district, Odisha

Table 1: CKDu Staging

Stage	Description	GFR (ml/min//1.73 mt^2)
Stage 1	Kidney damaged with Normal or increased GFR	≥ 90
Stage 2	Kidney damaged with mild decreased GFR	60-89
Stage 3	Kidney damaged with moderate decreased GFR	30-59
Stage 4	Kidney damaged with severe decreased GFR	15-29
Stage 5	Kidney Failure	< 15

Table 2: Clinical features of CKDu cases in Cuttack district, Odisha

Clinical Features	Number	Percentage
Loss of Appetite	15	42.8
Recurrent Urinary Symptoms	14	40
Fatigue & Weakness	25	71.4
Change in Urine Output	10	28.6
Swelling Feet & Ankle	19	54.3

Table 3: Chronic Illness History of CKDu cases in Cuttack district, Odisha

Variable	Type	Number	Percentage
Any Chronic Illness	Yes	16	45.7
	No	29	54.3
Type of Chronic Illness (16)	Arthritis	6	37.5
	Kidney Stone	5	31.3
	Hypertension	3	18.7
	Diabetes	2	12.5
Taking medicine for Chronic Illness	Yes	10	62.5
	No	6	37.5

Table 4: Occupational history of CKDu cases in Cuttack district, Odisha

Variable	Type	Number	Percentage
Occupation	Agriculture	12	34.3
	Housewife	9	25.7
	Daily Labourers	10	28.6
	Office Worker	4	11.4
Type of Agriculture (12)	Rice	9	75
	other	3	25
Pesticide Use (Jailo & Sebin)	Yes	8	22.9
	No	27	77.1
Use of Personal Protection during Pesticide use (8)	Yes	2	25
	No	6	75
Use other Agrochemicals (DAF & Urea)	Yes	7	20
	No	28	80
Use of Personal Protection during Agrochemical Use (7)	Yes	1	14.2
	No	6	85.8

Table 5: Habit & Customs of CKDu cases in Cuttack district, Odisha

Variable	Type	Number	Percentage
Drinking Water Source	Deep bore Well	19	54.3
	Community Well	7	20
	Pipe Water	5	14.3
	Private Well	4	11.4
Drinks water / Day	<5 glass	12	34.3
	>5 glass	13	38.5
	>10 glass	10	28.6
Consume Alcohol	Yes	5	14.3
	No	30	85.7

Cont... **Table 5: Habit & Customs of CKDu cases in Cuttack district, Odisha**

Currently Consume Alcohol (5)	Yes	1	20
	No	4	80
Do you Smoke	Yes	9	25.7
	No	26	74.3
Currently Smoke(9)	Yes	5	55.5
	No	4	44.5
Consume Tobacco product	Yes	8	22.9
	No	27	77.1
Consume NSAID	Yes	15	42.9
	No	20	57.1
Use of NSAID (15)	Daily	4	26.6
	Weekly	3	20
	Occasionally	8	53.4

Table 6: Laboratory Analysis of CKDu cases in Cuttack district, Odisha

Variable	Month 1	Month 2	Month 3
Blood Pressure (mm of Hg)	141.1 (100-220)	138.7 (110-180)	151 (118-190)
Fasting Glucose (mg/dl)	147.4 (84-249)	103.8 (43-141)	110 (100-120)
Serum Creatinine (mg/dl)	3.59 (2.2-7.9)	4.05 (1.4-10.5)	3.58 (1.6-6.7)
Serum Urea (mg/dl)	76.6 (14.1-137)	65.3 (14.0-136)	58.3 (14.1-126)
Urine Creatinine (mg/24 hrs)	6.0 (4.4-7.3)	5.8 (4.4-6.2)	6.6 (4.9-7.4)
Urine Albumin (mg/dl)	7.6 (7.2-8.4)	7.4 (7-8.2)	7.4 (7-8.2)

Discussions

The impact of CKDu is growing, and its prevalence is underestimated. Absence of a functional surveillance system is the bottleneck for gaps in data collection, diagnosis and recording & reporting of CKD cases. The symptoms of CKDu appear very slow, and only appears in stage 3 and 4, which accounts for not being diagnosed

at early stages. With the absence of a mechanism to capture early-stage patients, CKDu grossly remained underdiagnosed. Studies from high- income countries such as the U.S[12], Spain[13], and Japan[14] the prevalence of CKD generally between 10 and 13% of the adult population.

Our CKD surveillance system has established CKDu cases with most cases having agricultural occupation and exposure to pesticides and fertilizers. It was also found that deep bore wellswere the commonest drinking water sources indicating possible heavy metal (cadmium, Arsenic and mercury) contamination of water. Several studies from Sri Lanka has explained environmental risk factors as potential triggers for CKDu. The WHO study has hypothesized that chronic exposure to cadmium and Arsenic from pesticides and phosphate fertilizers is a potential risk factor to develop CKDu. Besides, elevated levels of minerals (hard water), fluoride, or heavy metals (e.g., cadmium, uranium, and lead) in groundwater wells were also suspected environmental risk factors for CKD[15].

Expanded CKDu education access and coverage is needed to address fears and aid in early detection. Programs to reach high-risk and endemic communities are now under-resourced, and far too many patients are unable to access care and treatment. Global health research collaborations are needed to exchange data across countries impacted by CKDu. In India, CKDu is a growing problem, and efforts needed to establish commonalities and prevent CKDu(10). A robust surveillance system will address the burden, geographical distribution, and time trends of CKDu in India. The surveillance system should be linked to monitoring potential toxins in food, water and the environmentand providing a platform for long-term research to understand the role of potential risk factors and document the usefulness of ongoing interventions[1].

The major challenge identified to integrating the CKD Surveillance System with IDSP and allowing the long-term monitoring of CKD patients. The system also seeks to be sensitive and flexible to new advances in the field being adaptive to developing newer evidence-based surveillance strategies. CKDu is a complex disease, and there is a need for sharing expertise across disciplines and countries to accelerate knowledge dissemination, guide the research agenda and help solve the mystery of "u" (unknown) in CKDu. Strengthen the early detection and management of CKDu in the early stages, and dialysis in the late stages will prevent CKD morbidity and mortality. Besides, prioritizing safe drinking water and food in the affected areas and ensuring sustainable agricultural practices evidence will certainly help.

Dissemination of the findings: This surveillance system's finding is intended to increase awareness of CKD and its importance as a major public health problem. It will also stimulate multiple stakeholders to develop a comprehensive action plan for health improvement. Data on incidence, prevalence, and risk factors collected by the CKD Surveillance System will prompt the health care providers to screen those at risk for CKD This information will be useful to evaluate the risk factors for CKD and to make appropriate recommendations for primary and secondary prevention.

Conclusion

We have established a CKD surveillance system in the Cuttack district of Odisha. The signficant component including the prevalence and the risk factors for CKD was prioritized for CKD surveillance. ThisCKD Surveillance System was found to be a readily available and useful resource for health care providers, public health authorities, and policymakers alike. In the future, this passive surveillance can be strengthened and replicated in other CKD endemic regions.

Advances in health information technology are very likely to have a major impact on the future surveillance system. We believe that this CKD Surveillance System will be vital for an ongoing assessment of the CKD burden in the district and its impact on the population and the health care system. We hope that it will lay the foundation for widespread efforts toward primary prevention, earlier detection, and implementation of optimal disease management strategies, with resultant decreased rates of CKD progression and lowered morbidity and mortality.

Ethical Clearance: Taken from State Ethics Committee

Source of Funding: Self-Funded

Conflict of Interest: Nil

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Gallbladder Perforation During Elective Laparoscopic Cholecystectomy Incidence, Risk Factors and Outcomes

Rafa'a Sami Mahmood Al- Hayali

Specialist Surgeon, Fellow of Arab Board of Health Specialization, AI-Jumhori Teaching Hospital, Mosul, Iraq

Abstract

Objective: The goal of this study was to discover the risk factors for perforation of the gallbladder during laparoscopic cholecystectomy, as well as the outcomes.

Methods: All patients who had an elective cholecystectomy at our department had their videotapes reviewed retrospectively, and the patients were separated into two groups based on whether or not they had GP. The potential risk factors as well as the early results were investigated.

Results: 664 patients were totally examined [524 (78.9%) females, 49.7±13.4 years old] were observed, and GP (Gallbladder Perforation) occurred in 240 (36.1%) of them, usually during dissecting the gallbladder from its bed (n=197, 82.1%). In 177 (73.8%) of the cases, the GP was not documented in the surgery notes. There was no significant risk factor for GP among the studied parameters, with the exception of a preoperatively high alanine transaminase level (p=0.005), which had 14.2 % sensitivity and 7.4 % specificity in predicting GP. The two groups had comparable results; however, the GP group had a longer operation time (35.4±17.5 vs 41.4±18.7 min, p=0.000) and a higher rate of drain usage (25 % vs 45.8%, p=0.000).

Conclusion: According to the current study, GP occurs in 36.1 % of patients who have a laparoscopic elective cholecystectomy; however, it is not always reported. We were unable to identify any reliable risk factors that enhance the likelihood of GP. The use of GP lengthens the surgery and increases the likelihood of drain usage; nevertheless, the other results were found to be equivalent in patients with and without GP.

Keywords: *Alanine transaminase; gallbladder perforation; laparoscopic cholecystectomy.*

Introduction

Cholecystectomy is the second most frequent abdominal procedure in general surgical practice [1,2]. The advantages of laparoscopic cholecystectomy over traditional cholecystectomy include better aesthetic outcomes, less postoperative discomfort, a shorter hospital stay, and a quicker return to normal activities [3]. Furthermore, cholecystectomy is a risky treatment that might result in serious consequences such as bile duct damage, hemorrhage, abscess, and pancreatitis. Gallbladder perforation (GP), a frequent intraoperative complication during cholecystectomy, has been found to occur at a high rate of 10% to 33% [4]. The causes and consequences of GP have also been investigated

[4-9]. Male sex, a history of acute cholecystitis or previous laparotomies, the use of a laser, an inflamed or nonvisualized gallbladder, and a difficult surgery have all been suggested as factors that enhance the risk of GP [5-7]. Furthermore, bile and stone spillage are infrequent and have been connected to a variety of major health problems [10-15].

Although GP does not affect the procedure's results, it has been suggested that lost stones following GP may induce secondary problems such as discomfort, fever, or intraabdominal abscesses since they are a possible source of infection, and bile spilling can induce chemical peritonitis [4, 10-16]. However, much of the data in the literature may be deceptive because it is primarily based

on retrospective data, and it is likely that GPs were not documented in the operation documentation because GPs are often thought to be safe, with no negative implications in most cases. As a result, we set out to examine compact disc films of the procedures in order to better understand the occurrence, risk factors, and effects of GP.

Materials and Methods

The study's design and substance were approved by the Institutional Review Board. (Reference number: B104ISM4340029/1009/20). Between March 2011 and March 2015, all patients who had an elective cholecystectomy at our clinic were retrospectively evaluated. One of our department's six surgeons conducted or oversaw the surgeries, which were carried out utilizing a four-trocar approach as previously described [17]. Free bile was aspirated, the soiled regions were irrigated with physiological saline until clear, and dropped stones were collected wherever feasible in the event of GP during the surgery. In most cases, these patients were given antibiotics intravenously and orally for a week. The operating surgeon determined whether a drain should be placed and if open surgery should be performed. Patients were usually discharged from the hospital the same day, although extended stays were occasionally required.

The main goals of this study were to find out how often intraoperative GP is, what causes it, and what the effects are during elective laparoscopic surgery. The patients whose procedure was converted to open surgery were excluded from further analysis, however the reasons for the change were disclosed. The operation recordings filmed on compact discs (CD) of all the included patients were watched by an experienced surgeon who was blinded to the patients, operators, and outcomes of the surgeries. The patients were divided into two groups based on whether or not a general practitioner was present at the time of surgery (Perforation or No perforation groups). If the surgery CDs were not accessible or were faulty, the patients were ruled out. During this inspection, the degree of difficulty was determined using Cuschieri's scale, which categorizes the procedure's complexity into four levels [18]. Grade 1 refers to a simple

cholecystectomy with no complications. The presence of mild peri-cholecystitis, adherences, or fatty tissue obscuring the cystic pedicle or mucocele is classified as Grade 2. Grade 3 cholecystectomies in patients with gangrenous cholecystitis, shrunken fibrotic gallbladders, extreme pericholecystitis, subhepatic abscesses, or advanced hepatic disorders such as cirrhosis or portal hypertension are defined by this scale. Because of the accompanying issue of adhesion of Hartman's pouch across the common bile duct, dissections of the cystic pedicle or the body gallbladder from the hepatic bed are difficult or impossible in some cases. Patients with a score of 4 difficulty were omitted since it leads to open surgery conversion [18].

Perforation occurred at the following times: During gallbladder traction, adhesions and bands are dissected, the Calot's triangle is dissected prior to cystic duct cutting, the Calot's triangle is dissected again after cystic duct cutting, the gallbladder is dissected from the hepatic fossa, and the gallbladder is extracted from the abdominal cavity. All patients' charts were reviewed, and computerized data was examined for the following information as risk factors for and outcomes of intraoperative GP. The presence or lack of previous hospitalization for acute cholecystitis, biliary pancreatitis, or cholangitis; demographics; BMI; the presence or lack of prior hospitalization for acute cholecystitis, biliary pancreatitis, or cholangitis; American Anesthesiological Score, laboratory findings [alanine transaminase (ALT), aspartate transaminase (AST), gamma-glutamyl transaminase (GGT), albumin, white blood cell (WBC), hemoglobin, total bilirubin, amylase]; need and evidence of MRCP and/or endoscopic retrograde cholangiography (ERCP) magnetic resonance imaging, ultrasonic findings; Previous procedures (include appendectomy, section, or gynecological); operators (employee or resident) experience; degree of difficulty in the operation stated by Cuschieri; time of surgery; drainage presence or omission; term of hospitalization; and complications and reasons of the rehospitalization, pathological results and mortality. Lastly, two investigators (EG and MH), who blinded to the information and operational CDs of the patients, examined the operation notes, and judged whether they had or had not been reported in the

operation notes. Patients got a cholecystectomy interval between 6 and 8 weeks following the initial presentation during a prior hospitalization, owing to gallbladder blocks. When the operation and hospitalization time is inconvenient in our usual practice, patients are seen after surgery on day 7. Further follow-up is not given in the event of no complaints.

Statistical Analysis

SPSS 17.0 for Windows was used to analyze the data (SPSS Inc., Chicago, IL, USA). Percentages, mean and standard deviations, or median and ranges were used to present the findings. The Student's t-test and the chi-square (Pearson's or Fischer's exact) test were used to compare quantitative and qualitative variables, respectively. When an anomalous distribution of samples was verified by the Kolmogorov– Smirnov test, a Mann–Whitney U test was selected. A p value of less than 0.05 was considered significant.

Results

737 patients [575 (78.0 %) females with a mean (SD) age of 49.1±13.3 years] received an elective cholecystectomy at our department throughout the study period. However, 60 (8.1 %) of the operation CDs were unavailable or damaged, leaving 677 instances for further investigations. Due to severe adhesions (n=9, 1.3%), failure to identify anatomical structures (n=2, 0.3 %), significant bleeding (n=1, 0.1 %), and damage to the transverse colon (n=1, 0.1 %), 13 (1.9 %) required conversion to open surgery. As a result, the present data comprise 664 cases [524 (78.9%) females with a mean (SD) age of 49.7±13.4 years]. 240 (36.1%) of the 664 patients (Perforation group) had an intraoperative GP during gallbladder traction (n=15, 6.3%), adhesions and bands dissection (n=2, 0.8%), and other procedures. Calot's triangle dissection before cystic duct clipping (n=9, 3.8 %), Calot's triangle dissection after cystic duct clipping (n=6, 2.5 %), gallbladder dissection from its bed (n=197, 82.1 %), and gallbladder extraction from the abdominal cavity (n=11, 4.6%).

The remaining patients (n=424) were in the No perforation group. The GP was not included in the operation data for 177 (73.8 %) of the 240 patients.

Almost none of the examined characteristics, including patient-related elements, pre-operative laboratory or other diagnostic results, and operating characteristics, were shown to enhance intraoperative GP during elective laparoscopic cholecystectomy in this study (Table 1). Preoperative ALT level was the sole risk factor that enhanced the likelihood of GP (p <0.05). Although 33 (52.4%) of the 63 individuals with high ALT levels developed GP, the sensitivity and specificity of higher ALT in predicting GP were 14.2% and 7.4%, respectively. Apart from ALP, there were no variations across the blood tests. Although several patients required MRCP or ERCP due to increased bilirubin levels or choledocholithiasis, no patients in the current research required intraoperative cholangiography, common bile duct exploration, or laparoscopic ultrasonography.

The results of the procedures were also examined. There were no statistically significant differences between the groups in terms of postoperative hospitalization time, complications, or re-hospitalizations, according to the findings (Table 2). In addition to the median (range) operation duration [32 (10-120) vs 36.5 (11-120), patients with GP had a substantially higher rate of drain usage (p less than

1.01   for both). As a result of the problems, no patients required reoperation. Pathological examinations, on the other hand, indicated gallbladder cancer in two patients (0.8 %), both in the Perforation group. Both patients required further treatments, however they were alive 5 and 9 months following the operations with no signs of tumor recurrence.

TABLE 1. The risk factors for gallbladder perforation during elective cholecystectomy

	No perforation (n=424)	Perforation (n=240)	p
Demographics			
Age	49.8±13.2	49.7±13.8	0.914
Gender			0.143
Females	342 (80.7)	182 (75.8)	
Males	82 (19.3)	58 (24.2)	
Body mass index	28.5±5.1	29.6±5.5	0.053
Previous hospitalization for	18 (4.2)	8 (3.3)	0.561
Acute cholecystitis	8 (1.9)	2 (0.8)	0.343
Biliary pancreatitis	7 (1.7)	5 (2.1)	0.764
Cholangitis	3 (0.7)	1 (0.4)	0.999
ASA score			
I	83 (20.2)	62 (26.7)	
II	262 (63.9)	129 (55.6)	0.104
III	63 (15.4)	41 (17.7)	
IV	2 (0.5)	0	
Laboratory Findings			
ALT	20 (6-548)	18 (7-671)	
	(n=408)	(n=232)	0.176
Elevated ALT	30 (7.4)	33 (14.2)	0.005
MRCP findings	(n=25)	(n=12)	
Cholelithiasis	21 (84.0)	11 (91.7)	0.999
+ Choledocholithiasis	4 (16.0)	1 (8.3)	
ERCP findings	(n=14)	(n=4)	
Sphincterotomy only	9 (64.3)	2 (50.0)	
+ stone extraction ± stent application	5 (35.7)	2 (50.0)	0.999
USG findings	n=338	n=207	
Stone	322 (95.3)	200 (96.6)	
Polyp	8 (2.4)	4 (1.9)	0.930
Sludge	7 (2.1)	3 (1.4)	

Residue gallbladder	1 (0.3)	0	
Stone size (>1 cm/ < 1cm)	153/169 (63.2/60.4)	89/111 (36.8/39.6)	0.502
Single/multiple	86/236 (62.8/61.3)	51/149 (37.2/38.7)	0.760
Previous operation/laparotomy			
Operations to gallbladder or gastroduodenal region	4 (0.9)	3 (1.3)	0.708
Regional laparotomy	5 (1.2)	5 (2.1)	0.508
Overall laparotomy	41 (9.7)	31 (12.9)	0.196
Experience of the Surgeon Staff/Resident	42 (58.3) / 382 (64.5)	30 (41.7) / 210 (35.5)	0.302
Degree of difficulty			0.136
I	321 (75.7)	165 (68.8)	
II	57 (13.4)	39 (16.3)	
III	46 (10.8)	36 (15.0)	

(Data are presented as either median [range] or mean [±standard deviation]. Information in the parentheses indicates the percentages).

*The levels of Hgb are presented separately in male and female patients; t: Data are presented according to Cuschieri's scale, which defines the complexity of the procedure in 4 grades; however, patients with grade 4 difficulties were excluded since it refers to conversion to open surgery [18].

ASA: American Society of Anesthesiology score; AST: Alanine transaminase; ALT: Aspartate transaminase; GGT: Gamma-glutamyl transaminase; WBC: White blood cell; Ilbg: Hemoglobin; MRCP: Magnetic resonance imaging cholangiography; ERCP: Endoscopic retrograde cholangiography; USG: Ultrasonography.

TABLE 2. Outcomes after gallbladder perforation

	No perforation (n=424)	Perforation (n=240)	p
Operation time (minutes)	**35.4±17.5**	**41.4±18.7**	**0.000**
Drain use	106 (25.0)	110 (45.8)	0.000
Hospitalization period (days)	1.3±1.0	1.3±0.9	0.664
Complications			
Bile drainage	0	2 (0.8)	0.130
Evisceration	0	1 (0.4)	0.361
Abscess	3 (0.7)	3 (1.3)	0.673
Cholangitis	4 (0.9)	1 (0.4)	0.659
Respiratory	2 (0.5)	0	0.538
Overall	9 (2.1)	7 (2.9)	0.522
Re-hospitalization	6 (1.4)	5 (2.1)	0.538

Discussion

Cholecystectomy is one of the most popular surgical procedures performed in the world [1]. Furthermore, GP is common during laparoscopic cholecystectomy. According to a recent assessment of 18.280 patients, the prevalence of GP is 18.3% [19]. In another study, the risk of GP was found to be 29% in 1059 successive laparoscopic cholecystectomies [20]. However, given prospective data has indicated that the frequency of GP following laparoscopic cholecystectomy can reach up to 33%, it's probable that even this higher rate isn't the true incidence of GP [9]. As a result, because most perforations may not be captured in operation records, it may be more appropriate to consider the highest reported rates in the literature.

The debate is likely sparked by the fact that some surgeons fail to include GP in their operation notes, which are used as data sources in retrospective studies. In some cases, GP with or without bile and stone spilling was not documented, according to a recent review of operational notes [21]. As a result, we feel that the GP rate provided in this study is more accurate, as the data was gathered from operation videos. As a result, our findings suggest that GP is more prevalent than previously thought, occurring in at least a third of all patients undergoing laparoscopic cholecystectomy. Furthermore, the current study found that GP is not recorded in nearly three-quarters of surgery records, most likely because most surgeons do not consider GP to be a serious complication and feel it is harmless, thus they do not mention it.

Several researches have looked at the possible causes of GP after a laparoscopic cholecystectomy. Male sex, a history of acute cholecystitis, the use of a laser, and the presence of a highly inflamed gallbladder were identified as independent variables in a multivariant logistic regression analysis and as risk factors for GP [5]. Other studies have found that age, preoperative ultrasound abnormalities such as a thicker gallbladder wall and hydrops, the existence of a prior laparotomy, the form of the stone (pigment stones), and the surgeon's experience all influence the frequency of GP [5, 7, 9, 22]. These studies, however, may be criticized for include patients who underwent both emergency and elective treatments, which are likely two different types of surgeries. As a result, individuals who had emergency cholecystectomies were not included in this research. Furthermore, patients who had conversion to open surgery were excluded since it was difficult to identify if the unfavorable effects in these circumstances were attributable to the GP or the conversion itself. As a result, the current study focuses on a more specific condition: elective non-problematic laparoscopic cholecystectomy, which is the situation in the vast majority of cases.

Although the current study found that a pre-operatively high ALT level may be a signal for a possible GP at the time of the surgery, we are not sure if this is a major factor or an accident because the risk for GP was only 52.4 % in patients with increased ALT levels, which was less than two-fold that of individuals with normal ALT levels. As a result, because the sensitivity and specificity were unacceptably low, the preoperative ALT level, in our opinion, cannot be regarded a predictor of GP. Surprisingly, no association between GP and the cholecystectomy difficulty scale was found in the current data. Although there was no change in the statistical analysis, the p value of 0.136 might indicate a trend. There was no other risk factor that we discovered that enhanced the likelihood of GP. As a result, we feel that GP in the event of an elective cholecystectomy may be unpredictable.

According to a recent study, 69 of 131 gallbladder perforations (52.7 %) died when dissecting the gall bladder from the hepatic fossa [6]. We may infer that separating the gallbladder from its bed is the most dangerous stage of cholecystectomy for a potential GP because we had the same result. This knowledge, we feel, is crucial, and it may alert surgeons to this particular concern. Furthermore, the above-mentioned principle should be stressed during surgeons' training.

The effects of GP have been thoroughly studied in the past. In animal models, GP and the resulting overflow of bile and/or stones have been demonstrated to be safe and do not induce infection or death during the follow-up period [23, 24]. The results of human investigations, on the other hand, are still debatable. Although GP, at least theoretically, causes bile, calculi, and germs to contaminate the peritoneal cavity, some experts feel that the negative effects of spillage following GP during laparoscopic cholecystectomy can be mitigated by rapid recovery of as many spilled stones as feasible, enough peritoneal cavity irrigation, and enough antibiotic treatment [6]. Most studies have found that GP did not increase the risk of complications, reoperations, or hospital stay [6, 25]. According to a recent prospective research, GP and retained gallstones had no negative effects on respiratory mechanics or post-operative discomfort [9]. Furthermore, because bile is usually polluted in the presence of gall stones, several investigations have revealed negative implications of bile spilling owing to GP [26]. In an analysis of 1059 consecutive laparoscopic cholecystectomies, increased incidence of fever and intraabdominal abscesses were discovered if GP occurred at the time of surgery. [20]. Retained gallstones and bile leakage have also been linked to infection, abscesses, fibrosis, adhesions, cutaneous sinuses, small-bowel blockages, and widespread septicemia in some case reports [27, 28]. Finally, in a study of individuals with a loss of numerous or large pigment stones that cannot be recovered by laparoscopy, conversion to open surgery was advised [4]. However, we think that the negative implications of spilling after GP during laparoscopic cholecystectomy can be avoided by retrieving as many of the spilled stones as feasible as soon as feasible, enough irrigation of the peritoneal cavity, and enough preventive antimicrobial prophylaxis [6], as previously noted. We discovered that GP and subsequent intraabdominal

contamination do not enhance the risk of complications or change the results in the early postoperative period using this method. As a result, the current study finds that GP increases the usage of drains and lengthens the operation duration, both of which are likely side effects of GP because stone removal and peritoneal irrigation are necessary in these circumstances. The current study, on the other hand, showed no other negative effects of GP in patients who had laparoscopic cholecystectomies. Similar short- term problems in individuals with GP, on the other hand, may be linked to the therapeutic technique used. Furthermore, many of the recognized complications associated with split gallstones are long-term, occurring often beyond a year. As a result, we are unable to speculate on potential long-term consequences based on the findings of this study. As a result, we conclude that GP should be avoided wherever feasible, but that the outcomes are unaffected if specific standards for minimizing contamination are followed. Finally, the outcomes of two patients with gallbladder cancer in the current investigation must be detailed. Because their pathology results ruled out early T1 tumors, these individuals had further surgeries, including partial hepatic resections and lymph node dissection in the hepatic hilum. However, in one case, bile overflow resulted in tumor implantation on the stomach's front wall, necessitating a distal gastrectomy. Tumor leakage, we feel, is the most serious adverse effect of GP, but it is also a rare complication since incidental gallbladder cancer is uncommon in individuals undergoing elective cholecystectomy.

Because of its retrospective character, the current study has several limitations. The significance of the current data is limited due to missing information, including the lack of operation CDs for 60 patients. Furthermore, the study's conclusions may be questioned from a variety of perspectives. First, despite the statistical significance of the difference, we do not know if a 6-minute increase in operating time reflects importance in everyday practice. Furthermore, the increasing usage of drains in the Perforation group might be due to a lack of clear- cut criteria for when a drain should be installed. This might be due to the study's retrospective character. Furthermore, though GP may

not have caused the increase in operation time or the need for drain utilization, all three endpoints happened as a result of the operation's difficulties. Because all staff surgeons do not have the same skill, the current study results addressing the experiences of the surgeons may be questioned. Furthermore, because the surgeons are aware that their actions are being filmed, they may be more careful, which might affect our results.

Finally, the current study found that GP occurs in 36.1 % of patients undergoing laparoscopic elective cholecystectomy, but is less frequently mentioned in the operation notes. GP is unexpected since there are likely no risk factors that enhance the chance of GP, with the exception of a preoperatively evaluated increased ALT level, which has a low sensitivity and specificity. Patients with GP had comparable early postoperative outcomes as those without, although the operation duration is longer and the use of drains is more common in patients with GP.

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Impact of Mergers and Acquisitions on the Mental Health and Overall Wellbeing of the Employees Involved – A Literature Review

Roopa Shree Rao

Associate Professor, Som Lalit Institute of Management Studies

Strategic Alliances, like mergers and acquisitions are one of the options organizations undertake to grow. A merger involves merging or coming together of two organizations and acquisition is a process when one organization acquires another of its interest.[1] Organizations enter into strategic alliances to compete in the associated market and expand their share in the market, to enter into new geographical areas, to add new product profiles, to capitalize the newer technologies available and also add to their financial competencies. This research paper reviews various literature available on the effect of mergers and acquisitions on the mental wellbeing and overall wellbeing of the employees associated with the organizations undergoing these major changes. Mergers and acquisitions follow three stages and each stage flows into the other, there are various factors which play a very critical role for enabling the mergers and acquisitions to achieve what they set to achieve at each stage. There are various hard factors like the financial parameters, adequate planning for financial and operational integration by capitalizing on the previous experience, assessment of risks and strengths, eliminating excess payments, and various soft issues ,like the cultural issues, ensuring extended assurance from the leadership, facilitating proper and timely communication to avoid unwanted dissemination of information, ensuring adequate speed for the implementation plans , ensuring visible and accountable steps like designating an integration manger to handle all the dilemmas in context to the human resources, implementing various reporting structures and facilitating the combined ways to deal with critical issues, collaborating with the critical teams in the process of integration, efficiently managing the various issues pertaining to human resources to ensure employee motivation and sustainability and implementing various plans to enable and ensure the proper amalgamation of the cultures of the organizations involved to minimize and eliminate the negative effects on the mental wellbeing and ensure the overall wellbeing of the employees involved in the process.[1]

Key Words: *Mental well Being, Overall Well Being, Mergers and Acquisitions, Employees.*

Introduction

Organizations exploring various routes to expand their horizons consider strategic alliances as one of the options. These routes of inorganic growth may be explored to add to their advantage to compete in the associated market, to add to their financial competencies, to open up newer avenues by entering into untapped geographical areas and also getting access to ever changing technological competencies which prove to be very advantageous.[1]

Theoretically a merger can be viewed as a process which results when organizations merge their strengths to represent one entity where as an acquisition is a

Corresponding Author:
Dr. Roopashree Rao,
Associate Professor, Som Lalit Institute of Management Studies, Ahmedabad, Gujarat,
mail id: roopa.rrao@yahoo.co.in, Ph. 9824268352

process which occurs when one entity acquires another entity of its interest.[1]

The merger and acquisition process follows various stages and appropriate strategies during each stage is very important for these life changing events in an organization lifecycle to proceed without major pitfalls. As organizations are predominantly dependent on human beings for their survival managing these important resources in the context of their mental well being and overall well being during these testing times despite making efforts to achieve the objectives intended is of at most importance.[1]

Methodology (Source Selection Criteria):

Various research papers published, dealing with the effects of mergers and acquisition process on the mental and overall wellbeing of the employees involved in the organizations undergoing the merger and acquisition were studied and literature dealing with deals involving both domestic and cross border mergers and acquisitions were also looked into. An attempt is made to review the literature available on the effect of mergers and acquisitions on the mental and over all wellbeing of the employees during all the stages of the merger and acquisition process. Various databases like Google scholar, research gate and other well known databases were explored. [1]

Results

Effect of mergers and acquisition on the mental and overall wellbeing of the employees during the pre merger and acquisition phase and the actual merger and acquisition process:

The stress faced by the employees of the bank of Rajasthan when merged with ICICI bank was determined by the method of paired sample t – test and also by employing the weighted average method and various factors like uncertainty, insecurity, changes in the job and fear of losing the job were identified as the prominent psychological factors which were responsible to initiate stress among the employees. In addition to the above various cultural perspectives in the working environment like reporting structure, the hours of

working, the interpersonal relationship with the superiors were also identified as contributors to the inducement of stress among the employees. The study highlighted the necessity of efficient management of these factors at the appropriate phase of the mergers to facilitate adequate integration process.[2]

The factors which encompasses culture related to work and various psychological factors equaling to thirteen and eleven respectively were studied to identify the predominant stressors causing stress among the 60 bank employees of the Bank of Rajasthan in the city of Udaipur was conducted at the juncture of merging of the above said bank with the ICICI bank.[2]

On employing the factor analysis on the above sample, the absence of excellent fit of culture among the two merging organizations and the conducive human resource policies were identified as the major factors responsible for stress and dissatisfaction among the employees among the merging organizations. The study emphasizes the adequate and timely management of these factors to enable the effective management of stress among the employees.[3]

The relevance of continuous motivation of the morale of the employees of the organizations involved in the merger and acquisition process is highlighted for the efficient performance. The changes ensuing as a result of the process like downsizing, increased workload calls for consistent boosting up of morale to imbibe the changes which volunteers thorough planned communication strategies.[4] The necessity of suitable strategic plan encompassing the required flexibility and creativity parameters to combat the issues of job changes and the ensuing requirement of appropriate development and training are also highlighted. The need for efficient communication strategies during all the stages of the merger process which affirms the efficiency of the ensuing organization which should concentrate on the improvement of the morale and motivating of the employees is also predominantly highlighted.[4]

Employee emotions have received little attention in the literature on M&A outcomes. As acquisitions are highly emotional events for the employees of the

acquired organization, strong affective reactions may emerge resulting in positive or negative work-related outcomes, contributing to the success or failure of an M&A.[5] The extent of the association between the intentions, emotions and behaviors of the employees and the cooperation extended by the managers associated, the extent of communication and the various determinants of the culture are determined by a study on the cross country study on 158 sample of employees involved in the associated three organizations being acquired by a single organization. It is very well observed that the emotions and well being is actively affected by the support the managers extend, wherein the communication of the managers associated had very little effect on the emotional wellbeing and the inclinations of the employees involved to continue in the same organization.[5] Strategic alliances, acquisitions in particular being associated with the feelings and emotions of the employees associated calls for matured and timely handling of the same, failing which resulting in unwanted outcomes in the work scenario and adversely affecting the outcomes, and on the other hand deft handling of the same resulting in the positive and fruitful outcomes.[5]

A multistage and multilevel procedure is implemented to delve into the performance of the mergers and acquisition processes concentrating on the difficulties the human resources encounter, to enable the researchers to identify and explain the gap in the context of the effects of the differences in the culture of the organizations on the performance of the organizations involved.[6] It is observed that the level of identification also plays a major influencing effect on the attitudes and behavior on the organizations involved, playing a crucial role on the performance of the organizations associated in the merger[6].

The effect of the team and task   mental models which were formulated in the pre acquisition phase are analyzed with respect to various functions in the post acquisition phase and an attempt is also made to develop a relation with respect to the size of the acquisition, is observed in a sample size of one hundred and one acquirer transactions in Europe and it is observed that shared team

and task mental models have a positive influence on the activities concerning exploitation which deals with after acquisition.[7] It is also noted that exploration activities are benefitted by team mental models which are shared. It is also observed that these activities contribute to various innovation pursuits as well. This research also emphasizes on the need for exploring the sensitivity of the perspective of benefits of the task mental model on the size parameter.[7]

The case study method is used to observe and study the changes in relation to job, returns from the job in the context of leadership in the preview of the various mergers and acquisitions movements in the cross border context of multi national organizations is studied in relation to Indian and Chinese organizations. It is observed that prominence of leadership having a little impact and whereas the factor of trust having a favorable impact and in addition, the condition of the deal also having a moderating impact on the prominence on the leadership status too.[8] This research also notes the effects of the differences in the nations targeted also.[8] The research stresses the importance and relevance of the adequate and positive psychological safety of the employees involved and also the emphasis that is to be given to affirm and trust building mechanisms of the leaders involved which in turn leads to the acceptance of the style of the management leading to increased productivity after the execution of the merger process. [8]

The effect on the health, both mental and physical and the overall feeling of well being on the employees involved in organizations facing various types of inorganic growth like mergers and acquisitions is an area which remains relatively untapped despite increase in the number of organizations opting for various routes of inorganic growth with motives to obtain an improvement in the profitability despite opening up themselves for facing an array of risks.[9] The research conducted on the managers who are in the middle of the managerial cadre working in U.K.[9] subjected to the merger experienced and acknowledged the process of merger as an event full of stress post the event despite witnessing an excellent match between the organizations involved in the merger. [9] [10]

This research aims at identifying the application of a model which deals with coping or adjusting to stress of the employees who are facing a major change. This study is formulated on the framework that the factors which control and determine the adjustment of the employees involved should be well studied and attention to the knowledge and knowhow of the employees with respect to the change happening and its features and the various mechanisms and support available for the employees are to be dealt in a detailed manner.[11] The research collected the data from staff involved in the fleet side comprising predominantly of pilots who belonged to recently merged organization in the aviation industry. By utilizing the outlook of intergroup, an attempt was made to correlate the appraisals in context to situations, responses of the various adjusting strategies of the two organizations before the merger involving one domestic and another an international airline.[11] In tandem to the social identity theory, the employees involved with the premerger domestic organization demonstrated the highest possible positive reactions to the event notably as this event opened up avenues to add to their social identity.[11]

Effect of mergers and acquisition on the mental and overall wellbeing of the employees during the post acquisition stage of the merger and acquisition process

A study which categorizes the factors which impact the human aspects of the organization in relation to merger and acquisitions are categorized as individual, organizational and as managerial factors.[12] The limitation of the available research wherein the prevalent gap of available studies on post acquisition outcomes is also very well emphasized. Various qualitative studies conducted focuses on the contribution of human resources, of the employees both during and after the merging process, various factors concerned with the individuals like the effect these moves have on the mental well being, the various movement of the employees inside the organization, various factors associated with the organization, namely the differences in the culture and the process associated in the transfer of knowledge and the various factors associated with the managers, like the various processes associated with the

policy of integration during the process. The gap is very well highlighted which calls for the coordination of the effects of the human factors on the performance of the organization.[12]

Akin to various syndromes, the merger syndrome is explained as an observance which is seen in the post merger scenario which normally encompasses the negative effects on the attitude and behavior of the employees of the involved organizations.[13] Despite these events are viewed as effecting the emotions of the people involved, it is an untapped domain particularly in relation to cross border events. This research on the foundations of logic based on various theories and interpreting various data makes an attempt to explore the factor of emotions by applying the theory of cognitive appraisal and affective events and by the aid of qualitative in depth interviews of the employees involved attempts to develop an framework based on analytics to explore the role of emotions in various international mergers and acquisitions.[13] This analysis concentrates on the effect the communication of the managers involved has on the emotions, the way the employees behave and also the behavior of the employees involved.[13]

Among the various moves or changes that takes place in the corporate scenario, strategic alliances and mergers and acquisitions are considered as the changes which results in greater stress and discomfort and the resilience among the employees involved in the process during the integration that happens post the activity.[14] This process of resistance can be attempted to be understood by the thought of psychological capital. The research attempts to review the available literature and attempts to propose a theoretical model which would aid in depleting or decreasing the resistance which eventually gets its validation by an expert panel. This research suggests to improve upon the psychological capital of the employees involved by various interventions that can be tailored to suit the various employees.[14]

Discussions and Recommendations:

The performance of the various strategic alliances can be evaluated on the basis of various determinants like the financial determinants, or by the achievement

of the various strategic objectives of the organizations involved , the strategic management perspective uses the achievement of the strategic objectives as the measure, the economic functions uses the measures based on accounting principles, the financial lens uses the parameters based on the stock market, if we look at the organizational research perspective, it concentrates on the integration process that happens post the merger and acquisition process.[15,16]

This research attempts to review the various research available which highlights the effect of these mergers and acquisitions on the mental and overall wellbeing of the employees who are involved in the process. It is very well evident that these events being major change events have a deep standing effects on the mental health and over all well being of the employees involved in the process. [17]

On detailed review it is been observed that the mergers and acquisition processes follow three stages and each stage flows into the other, there are various factors which play a very critical role for enabling the mergers and acquisitions to achieve what they set to achieve. [18,19.]

During the pre merger phase, efficient assessment of the various parameters and the fit with respect to strategy, proper evaluation of all hard issues like the financial parameters and the soft issues like the cultural issues, adequate planning for integrating the financial and operational domains, utilizing the previous experience in the same arena, good assessment of the various risks involved and also adequate evaluation of the strengths of the organizations involved should be focused upon.[20,21.]

During the merger phase, eliminating paying in excess, ensuring extended assurance from the leadership, facilitating proper and timely communication to avoid unwanted dissemination of information, post the mergers and acquisition, ensuring adequate speed for the implementation plans, ensuring visible and accountable steps like designating an integration manger to handle all the dilemmas in context to the human resources, implementing various reporting structures and facilitating the combined ways to deal with critical

issues, collaborating with the critical teams in the process of integration, efficiently managing the various issues pertaining to human resources to ensure employee motivation and sustainability and implementing various plans to enable and ensure the proper amalgamation of the cultures of the organizations involved to minimize and eliminate the negative effects on the mental wellbeing and ensure the overall wellbeing of the employees involved in the process. [20,21,22]

Ethical Clearance : Not Applicable.

Conflict of Interest : Not Applicable.

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Hospital-based Analysis of the Effects of Mental Health Disorders on Asthma and Nutrition Disorder Admissions and the Cost Saving by Investing in Mental Health in Bhutan

Sacha C. Hauc[1], Agata M.P Atayde[2], Dolley Tshering[3], Dil Kumar Subba[4], Samten[5], Kaveh Khoshnood[6]

[1]Yale School of Medicine, Department of Epidemiology of Microbal Disease, USA; Connecticut, New Haven, [2]Boston College, Department of Public Health, USA, Massachusetts, Chestnut Hill, [3]National HIV/ AIDS and STIs Control Program, Department of Public Health, Ministry of Health, Bhutan, Kawajangsa, Thimphu, [4]National Mental Health Program, Department of Public Health, Ministry of Health, Bhutan, Kawajangsa, Thimphu, [5]District Health Sector, District Administration, Haa District, Bhutan, Haa Town, [6]Yale School of Public Health, Department of Microbial Disease, USA, Connecticut, New Haven

Abstract

Purposes: Aims to explicate the relationship between mental health and disease morbidity in Bhutan and the association between mental health and these two major public health concerns. Furthermore, we evaluated the added economic cost-savings benefit.

Methodology: Univariate linear regression was initially utilized and calculated and ran a Shapiro-Wilk W test and a Lagrange multiplier test.

Findings: It was indicated that for every one-unit increase in the number of admittances categorized as a mental health disorder within Bhutan, there is a significant average increase in health center admissions for asthma by 0.3601 and for nutritional disorders. It was estimated that the increase in the reduction of mental health disorders would increase the number of averted cases and the cost-saving to the Bhutanese healthcare systems to a significant level.

Research limitation: We were unable to infer whether there was an increase in health center admissions due to new disease development or to higher occurrences of existing symptoms caused by these diseases.

Practical implications: In order to decrease the burden of comorbidities associated with mental health disorders, proper dispersal of accessible resources in addition to investment in mental healthcare is necessary.

Social implications: Findings reinforce the need to properly invest in mental health services not only for its own sake but also for the significant morbidities associated with other diseases.

Originality: All data presented in this manuscript are true and valid and no data from the study has been or will be published separately.

Key Words: *mental health, asthma, nutritional disorders, Bhutan, cost-savings*

Introduction

The relationship between mental health disorders and disease morbidity and mortality has been well documented in a variety of settings[1-3]. Research has demonstrated that individuals with severe mental disorders have a life-expectancy 10 to 20 years lower than the general population[4]. In 2010, the Global Burden of Disease study revealed that 10.4% of total global disability-adjusted life years (DALYs), 2.3% of global years of life lost (YLLs), and 28.5% of global years lost

due to disability (YLD), were related to mental health disorders[5]. Despite mounting evidence, low-and-middle income countries spend less than $1 per capita on mental health services[6]. These figures highlight not only a need for greater attention and investment into mental health resources but also the multifaceted interplay between mental health disorders and physical health. While the effects of disease morbidity on mental health, such as on diabetes or heart disease, may be facile to understand, the effects that mental health disorders have on the development of physiological disorders are more obscure. A growing body of evidence has shown that mental health disorders can lead to the development of a variety of diseases[7-9]. Mechanistically, individuals who suffer from mental health issues may be less likely to consume a balanced diet or engage in other health promoting activities[10,11]. The cause of such actions can lead to higher disease morbidities within populations which experience increased rates of mental health disorders. However, within a larger macro context it is often difficult to assess the effect mental health disorders have on disease incidence and prevalence. As such, our team chose to investigate health center admission rates within the Kingdom of Bhutan as a proxy for disease morbidity at the population level. We examined the effect that mental health disorders have on health center admissions for two disease categories – asthma and nutritional disorders. This study offers the first assessment of the effect mental health disorders have on health center admissions onto an entire healthcare system for our disease categories.

Materials and Methods

Our data set was provided by the Bhutan Ministry of Health and was analyzed at the health center level for every major hospital and health center within the Kingdom of Bhutan. It included over 1,600,000 health center admissions from 2018. We specifically examined the effect that mental health disorders (classified as: depression, anxiety, and other mental health disorders) had on the health center admission rates for asthma and nutritional disorders (nutritional anemia, malnourishment, vitamin deficiencies). The classification of these diseases was diagnosed by a Bhutanese

healthcare provider and the data were subsequently aggregated by the Ministry of Health. More specifically, an asthma health admission was classified as such if a health worker recorded that either the primary cause of admission was due to asthma-related reasons or if the patient presented with asthma-like symptoms, likewise for nutritional disorders and mental health disorders. A univariate linear regression was initially utilized to identify which variables were necessary to control for, these variables were subsequently used within our multiple linear regression models. Since the nation of Bhutan affords its citizens free access to universal health coverage, the usage of health center admission rates is a powerful tool for investigating disease morbidity, as there are comparatively few barriers to accessing care within health centers. Within all our models we controlled for the age of the patients (0-15,15-49, 49+), health center admission rates, population per hospital catchment, differences in disease morbidity among hospital catchment (using monthly reported sickness as a proxy for variances in health), hospital differences in mortality, and mental health discrepancies among regions (using health center admissions for mental health disorders across hospitals).

Using the 2011 "A Costing of Healthcare Services in Bhutan," report released by the Bhutanese Policy and Planning Division[12], and our results from our multiple linear regression model, our team calculated the economic savings related to a reduction in mental health disorders on admissions related to asthma and nutritional disorders. We used the average unit cost of admission in each healthcare facility type to find the average estimated cost-savings associated with a decrease in mental health disorders. In order to ensure accurate economic values, we stratified the total number of admissions for the two-specific illnesses we modeled by the three types of Bhutanese healthcare facilities (Primary Health Centers, District Hospitals, and Referral Hospitals) – which each have vastly different costs for admission.

In order to properly model our dependent variable, we ensured that each variable analyzed in our investigation was significantly correlated with the variable "Mental Health Disorders." Additionally, we ran a Shapiro-Wilk

W test to ensure that the variables were all normally distributed. We also checked for the requirement of homoscedasticity within our examined variables by running a Lagrange multiplier test. Lastly, we checked for the effects of multicollinearity within each of our models by ensuring that the variance inflation factor was below the accepted threshold of five. To assess the fit of our models, we report adjusted R^2 values as well as Pearson's R^2 values. SAS version 9.4 was utilized in conducting all of the statistical analysis for this study.

Results

Table 1: The results from our multiple linear regression model indicate that for every one-unit increase in the number of admittances categorized as a mental health disorder within Bhutan, there is a significant average increase in health center admissions for asthma by 0.3601 (95%CI: 0.2052, 0.5167) and for nutritional disorders by 2.049 (95%CI: 1.385, 2.714) the adjusted R^2 and Pearson's R^2 are displayed for each disease model as indicated in the table 1.

Disease Model Mental Health Disorder)	Parameter Estimates	95%CI	P-Value	Adj-R Value	Pearson's R2
Asthma	0.3601	(0.2052, 0.5167)	<0.001	0.6195	0.6871
Nutritional Disorders	2.049	(1.385, 2.714)	<0.001	0.8535	0.8765

Table 2: Estimated number of averted cases along with their associated savings onto the Bhutanese healthcare system with the respective percentage reduction in mental health disorders.

5% Decrease in Mental Health Disorders	Number of Averted Cases	Cost Saved in USD
Nutritional Disorders	2,697	$ 13,400
Asthma	947	$ 4,819
Mental Health Disorders	160	$ 3,412
Totals	3,804	$ 21,631
10% Decrease in Mental Health Disorders	Number of Averted Cases	Cost Saved in USD
Nutritional Disorders	5,394	$ 26,800
Asthma	1,894	$ 9,639
Mental Health Disorders	321	$ 6,824
Totals	7,609	$ 43,263
15% Decrease in Mental Health Disorders	Number of Averted Cases	Cost Saved in USD
Nutritional Disorders	8,091	$ 40,200
Asthma	2,840	$ 14,459
Mental Health Disorders	481	$ 10,236
Totals	11,412	$ 64,895

It was estimated that with the increase in the reduction of mental health disorders would increase the number of averted cases and the cost saving to the Bhutanese healthcare systems to a significant level as shown in the table 2.

Discussion

Our investigations within the Kingdom of Bhutan reveal the impact that mental health disorders have on increasing health center admissions for asthma and nutritional disorders. Additionally, our analysis shows that a decrease in rates of mental health disorders would result in a cost-savings onto the Bhutanese healthcare system. A 15% reduction in mental health disorders can lead to an annual savings close to $65,000 and 11,000 fewer health center admission rates. While these savings may not seem notable, it is important to realize that Bhutan has a particularly low cost of health center admittance; as low as $2.32 per health center admittance. Neighboring nations would likely experience similar if not greater cost-savings. Countries like Nepal and India have significantly higher average cost of health center admittance, with costs of $6.58 and $18.90, respectively[13,14].

The relationship between asthma and mental health, although not well understood, has been studied extensively. Asthma remains a major public health concern, particularly in low-and middle-income countries, and has often been associated with mental health disorders[15]. Although the direction of causality remains unclear, evidence from one group found that depression more often leads to incident asthma than vice versa[16,17]. It does remain clear, however, that there have been no studies fully recognizing the extent to which each contributes independently[18]. Our own research demonstrates a significant linkage between mental health cases and asthma hospital admissions in Bhutan. More specifically, on average, for an increase in 100 mental health disorder admissions, 36 more people were found to be admitted to a health center due to asthma related concerns. In past literature, asthma and mental health disorders have been shown to co-occur at higher rates than expected, supporting a link between the two disorders[16,19]. Whether the coexistence of these co-morbidities has underlying pathophysiological mechanisms or is due to socio-environmental influences has yet to be further studied. However, the impact of psychological factors on asthma has been well described, specifically in the domains of affect, behavior, and cognition[20]. One systematic review of existing literature found that psychological factors play a role in as many as 80-90% of asthma deaths[20]. It is conceivable that negative thoughts or life experiences could play a role in poor breathing functions, such as dyspnea, and other disease activity. In fact, stress-induced or emotionally triggered asthma attacks are no rare occurrence. In an 18-month prospective study of children with asthma, those who had experienced a negative life event had an increased risk of an asthma attack by nearly 2-fold[21]. Additionally, a Patient Health Questionnaire (PHQ-9) developed to examine the impact of depression and anxiety on reduced bronchodilator response (BDR) found that major depression was more prevalent in participants with asthma (8.9%) than those without (2.5%)[17]. While much research is left to be investigated, current literature highlights the association that mental health disorders have on increasing rates of asthma related symptoms as well as new disease cases.

Despite myriad pharmacologic treatments and asthma education worldwide, asthma control can be not only difficult to implement but also hard to maintain. Triggers can be inescapable, whether they be genetic or environmental, and psychological stresses can impede proper medication adherence. In a 2013 review of psychological dysfunction in asthma, it was found that maladaptive breathing behaviors and dysfunctional beliefs about the disease were associated with poor disease control and asthma deaths[20]. Much like mental health, asthma does not have a one size fits all treatment, and varying social determinants can result in profound effects on people's health status. Social pressures, poor housing environments, exposure to pollution, urbanization, and a multitude of other factors are precursors to this multifactorial disease. Unsurprisingly these social determinants have also shown to increase incidence of mental health disorders. These factors increase differential exposure to asthma pathogens, contributing to the experience of psychological stress, which is increasingly linked to asthma expression[22].

Similar to the illness of asthma, nutritional disorders are a significant public health issue in developed and developing countries[23]. The connection between mental

illness and nutrition is one which is multifaceted and has been well reported in literature. The bulk of research done has been conducted on the influence of poor diet and nutritional deficiencies resulting in mental health issues. However, the converse has also been considered in a variety of settings. A 2015 cross-sectional study of 378 patients found that the prevalence of anemia among chronic psychiatry patients was more frequent than the general population[23]. Correspondingly, our results indicated that on average for an increase in 100 mental health disorder admissions, 201 more Bhutanese were admitted to health centers for nutritional related disorders. Understandably, mental health illnesses can have adverse effects on individuals' physical well-being in a variety of manners. Increasingly there is evidence showing that depression has a significant effect on the diet of those suffering from a mental health disorder[24]. A study conducted in 2019, found that depressive symptoms among foreign-born Latinas were associated with lower Healthy Eating Index scores, an increased intake of nutrient poor foods, and decreased fruit and vegetable consumption[24]. From both a scientific and an intuitive perspective, there are many ways poor mental health can negatively affect nutrition consumption and lead to increased rates of nutritional disorders and anemia.

It is also important to note that domestic violence can lead to an increase in depression, anxiety, substance abuse, post-traumatic stress disorder, and other mental health conditions [25]. This is worth mentioning in the context of Bhutan, as acceptance of domestic violence is particularly high in this nation, with about 70 percent of women accepting violence from their husbands[26]. According to an analysis conducted by the World Bank on Bhutan, when results of domestic violence were compared with district levels of anemia, the association was significantly high[26]. Lastly, poor diet is used as a coping mechanism for various mental health illnesses. For example, binge eating disorder (BED) and anorexia nervosa (AN) have been linked to psychological triggers including low self-esteem, traumatic events, and sexual abuse[27,28]. Patients will often find themselves coping with social pressures or past traumas through eating dysregulation, creating a vicious cycle that can lead to a

slew of nutritional insufficiencies and disorders[27]. These findings provide a clear mechanism to understanding how high prevalence of mental health disorders can lead to increases in a variety of nutritional disorders.

Like many resources limited countries, Bhutan struggles to properly invest in mental health services – investing only 1% of their health budget in this category[26]. Due to the few mental health resources available, many individuals could find themselves unable to receive the proper help they require. As inhabitants are predominantly widespread throughout rural regions and have diverse cultural practices, organizing mental health services has resulted to be challenging[18]. Lack of funding, mental healthcare resources, and psychiatrists, in addition to the absence of mental health legislation, remain key issues in adequately addressing mental health and its apparent linkages at hand.

Limitations

While our analysis specifically controlled for discrepancies in mental health disorders across regions, we were unable to infer whether there was an increase in health center admissions due to new disease development or to higher occurrences of existing symptoms caused by these diseases. In other words, we could not delineate whether there was an increase in asthma and nutritional disorders due to new disease cases arising or due to increased symptoms of existing cases. However, research has indicated that both avenues have been linked to mental health disorders – an increase in both symptoms of existing diseases and the creation of new disease cases due to mental health disorders. Additionally, the majority of cost figures were derived from the averages of each specific health center category. Due to this, it is possible that the average cost of admittance at a specific health center is not reflective of the actual cost of admittance for the specific disease modeled.

Conclusion

Our study outlines the specific impact that mental health disorders have on asthma and nutritional disorder admissions in Bhutan. In order to decrease the burden of

comorbidities associated with mental health disorders, proper dispersal of accessible resources in addition to investment in mental healthcare is necessary. This research also reveals the added economic benefit which may be incurred when resource limited nations invest in mental health resources for their citizens. Our findings reinforce the need to properly invest in mental health services not only for its own sake but also for the significant morbidities associated with other diseases. In this regard, to decrease the burden of comorbidities associated with mental health disorders, proper dispersal of accessible resources in addition to investment in mental healthcare is essential.

Declarations:

Ethical approval and consent to participate: Data usage agreement has been drawn with the Health Information and Management System, Ministry of Health.

Consent for publication: All authors unanimously agreed and consented to send the manuscript to Journal of Health Research for publication.

Availability of data and materials: All data generated or analyzed during this review were as prescribed in the data usage agreement

Competing interests: No competing interest

Authors' contribution: The author and co-authors read and approved the final manuscript before the final submission.

Funding: Not applicable

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Nutritional Transition in Unindustrialized Countries: Causes and Consequences on Public Health

Md Shahedul Islam[1], Nusrat Jahan Jhily[1], Rakibul Hasan[2], Nusrat Parvin[1], Mohammad Ariful Islam[3], Imam Hossain[4], Khalesa Akter[5]

[1]Student of M. Sc., [2]Student of B. Sc., Food Technology and Nutrition Science Department, [3]Student of B. Sc., Biochemistry and Molecular Biology Department, [4]Student of M. Sc., Applied Chemistry and Chemical Engineering Department, Noakhali Science and Technology University, Sonapur, Noakhali-3814, Bangladesh, [5]Student of M. Sc, Chemistry Department, Tejgao College, Dhaka, Bangladesh

Abstract

Background: Unlike the double burden of malnutrition, which has had severe consequences for countries all over the world, the triple burden of malnutrition is also causing problems. As a consequence, almost all human behaviours, such as the degree of human physical activity, dietary patterns, physical characteristics and disorder are evolving day after day.

Methods: We analyzed more than 60 articles and included data and information from 26 corresponding sources. These studies have been carried out in voluminous developed and underdeveloped countries of Asia, Africa, America and Europe's.

Results: The findings of these studies showed that in underdeveloped countries, human attitudes, dietary practices, and disease status have been rapidly evolving. In comparison to the previous period, the people of these countries are leading more sedentary lifestyles in the present and consume a high-fat, high-sugar, and high-salt diet. As a result, they've developed a variety of non-communicable diseases, such as obesity, diabetes, and chronic heart disease.

Conclusion: Along with the adverse consequences of nutrition transition in underdeveloped countries, many others have been suffering from malnutrition, causing these countries to endure a double burden. That's why; all responsible authorities should take and apply necessary steps to tackle this burden as early as possible.

Keywords: *Communicable disease, Demographic transition, Double burden,Epidemiologic transition, Globalization, Non-communicable disease,Nutrition transition,unindustrialized countries.*

Introduction

The shift in disease type and prevalence mainly occurred due to shifts in nutrition transition and lifestyle changes that have been regarded in many unindustrialized countries in the world which is closely related to rapid urbanization, economic growth, and technological advances [1].

Increasing globalization in the food system and rapid economic growth, the population shift from minimally processed diets rich in staple foods of vegetable origin to diets high in meat, vegetable oils and processed foods high in refined sugars, sodium, and saturated and trans-fats and the excessive consumption of these nutrients is associated with obesity and diet-related NCDs [2]. Many changes in diet and physical activity are co-occurring in unindustrialized countries [3]. While it is evident that this transition from natural foods and high physical activity to highly processed food and low physical activity is more in the industrialized countries, it must be noted that

the unindustrialized countries are following suit [4].

Nutrition transition cannot be completely discussed without mentioning two well-known transitions in public health. They are "Epidemiologic transition" and "Demographic transition." The shift from a pattern of prevalent of infectious diseases linked to starvation, intermittent drought, and inadequate environmental sanitation to a pattern of prevalent non-communicable, chronic, and degenerative diseases linked to the urban industrial lifestyle is referred to as epidemiologic. Presently most developing countries are experiencing this epidemiologic transition as reflected in the growing burden of non-communicable diseases [5]. On the other hand, the demographic transition is the switch from a pattern of high fertility and high mortality to low fertility and low mortality. The developing countries are having this transition but at a slower rate. There is an improvement in child survival, an increase in life expectancy at birth, and decreasing fertility in developing countries [6].

Non-communicable diseases disproportionately affect more people in developing countries and account for 80% of all NCDs-related death annually [7]. In low-income countries, infectious diseases are now replaced by nutrition-related non-communicable diseases (NCDs) and about 80% of the mortality occurs due to CVDs in most low and lower-middle-income countries [1]. Overweight and obesity are the important risk factor of CVDs, type-2 diabetes, certain cancers, etc. and globally around 2.8 million peoples are dying annually due to having overweight and obesity and about 35.8 million disability-adjusted life-years occurs due to overweight and obesity [8]. World Health Organization exclaimed that eight of the world's ten most obese nations are from Pacific Island Countries where 33% of adults are living with overweight and obesity. In the Pacific region, NCDs are responsible for around 70% of all death, and also life expectancy has fallen [9]. Rapid urbanization and technological advancements in South Asian countries such as India, Bangladesh, and Pakistan reduce the need for and scope for physical activity, resulting in a rise in obesity and overweight prevalence.On the other hand, more than half of the underweight child lives

in South Asia and in this region malnutrition is the major cause of child mortality. Thus the dual burden of diseases is arising in South Asian countries due to the underdeveloped healthcare system [10].

This review aims to focus on the causes of nutritional transition in developing countries and also focuses on the consequences that are occurring due to this transition on public health.

Methods: Literature Search and Study Selection Strategy

In view of writing the paper, reviewed more than 60 articles, and after careful review, data and information from 26 relevant reference sources were included in the research paper. From peer-reviewed indexed journals, a systematic search of national and international literature, especially from developing countries, was conducted. Most relevant data and information on various published papers have been included in this paper, which was collected from the Cochrane Library and Google Scholar using different keywords. The most recent data is used to assess the current situation.

Numerous Causes of Nutrition Transition in Unindustrialized Countries

The nutrition transition is fueled by several factors, including urbanization, economic growth, technological changes in work and leisure, food processing, mass media growth, excessive intake of caloric beverages, excessive snacking. The rise in urbanization translates to the rise in sedentary white-collar jobs as against the previous labor-intensive jobs. With urbanization, the previous modes of transportation that are labor-intensive are replaced by sedentary modes of transportation, e.g., buses and trains[5, 11]. Urbanization is also associated with increased income, with increased spending on food[12].

With increased economic growth, there is higher per capita income; hence the greater population can afford to spend more on edibles leading to excessive consumption, which leads to obesity and nutrition-related non-of communicable diseases. Research has shown that increased income per capita for a country is

linked with increased intake of animal products and fat [13].

Technological changes also pushed the nutrition transition because chores that were previously manually done are now done by machines. Examples include the utilization of washing machines for laundry as against hand wash, use of vacuum cleaners rather than manual sweeping. Technology has also affected recreation, as children who used to run around and play now sit in front of the television or play video games. In addition to inactivity, there is a rise in snacking and soda consumption when watching television [5, 11, 12].

Food processing and increased intake of animal source foods also are factors influencing nutrition transition. Increased food processing leads to the production of high fat and high sugar foods and increased availability of caloric beverages. Research has shown that the diet that increases the risk of chronic diseases is relatively high in total fat, sugar, salt, alcohol, refined grains, and foods of animal origin [13].

Social media growth was noted as another factor accelerating the nutrition transition. There is aggressive marketing by food companies. The adverse is designed to convince people to consume processed foods and calorie beverages. Some of these observe especially in developing countries, are misleading. They give false information about the contents of their products [14].

Various Consequences of Nutrition Transition on Public Health in Unindustrialized Countries

Unindustrialized countries are undergoing various types of transitions. The epidemiological transition allows them to face a dual burden of communicable diseases that cannot be transmitted. Similarly, demographic and socioeconomic are also occurring in these countries. Formerly developing countries had a high appearance of undernutrition, but this era of transition has also brought a dual burden of undernutrition and overnutrition in these countries. The existence of a dual burden poses a challenge for intervention. Overweight and obesity make people prone to non-communicable and degenerative diseases, whereas undernutrition may make them prone

to communicable diseases and reduce productivity [15].

Nutrition transition has led to an increase in the prevalence of nutrition-related non-communicable diseases, including obesity, childhood obesity, cardiovascular disease, cancers, etc. [12-14, 16-18].

Obesity is a major outcome of nutrition transition. It is also a predisposing factor to many other nutrition-related non-communicable diseases, including cardiovascular diseases, diabetes, and cancers. There has been a reported increase in obesity prevalence inunindustrialized countries as depicted by a study in sub-Saharan Africa, which reported that 10 to15 % of adults are overweight [12]. Also, there is an increase in the prevalence of overweight among poor developing countries [19]. The Nigeria Demographic and Health Survey (NDHS) 2008 reveals that nearly 1 in 4 women in Nigeria is either overweight or obese (16% overweight and 6% obese). The NDHS also repeated that more urban women (31%) than rural women (17%) are overweight or obese. It also revealed that overweight and obesity increase with increasing wealth [20]. A meta-analysis of the prevalence of and time trend in obesity in West Africa conducted in 2007 reported thatthe prevalence of obesity in urban West Africa more than doubled (114%) over 15years [3]. Some studies in Thailand have revealed that the prevalence of childhood obesity is increasing in developing countries [21].

Cardiovascular diseases are among nutrition-related non-communicable diseases that are on the rise in developing countries. In Tanzania, the prevalence of hypertension among top executives is as high as 48.9% [22]. The prevalence of cardiovascular diseases has increased to 10 fold in sub-Saharan Africa in the last 20 years [4]. In 1990, developed countries had 5.3 million deaths due to cardiovascular diseases, while developing countries had 8 to 9 million deaths, a 70 percent difference [23].

Diabetes mellitus is another nutrition-related non-communicable disease that is on the increase in developing countries. Eighty percent of diabetes death occurs in low and middle-income countries [12]. The World Health Organization (WHO) predicted that the

most rapid increase in the prevalence of diabetes mellitus would be in India, where a rise is projected from 1997 estimated of 20.8 million cases to 57.2 million in 2025 [24].

The other nutrition-related non-communicable disease that itisappearance is increasing in developing countries is cancer. Dietary factors are estimated to account for approximately 30% of cancers in western countries and 20% in developing countries and are projected to increase [12]. In 1970, approximately 15% of newly reported cancers were in developing countries. The figure increased to 56% in 2008 and is estimated to rise by 70% by 2030 [25]. Also, Dr. Margaret Chan, ex director-general of the World Health Organization (WHO), stated that around 70% of cancer deaths occur in developing countries [25].

Addressing the HIV/AIDS burden as a primary goal has wide-ranging benefits, and failure to do so not only increases the health burden and decreases the lifespan, but has direct economic consequences, as most of those affected comprise the workforce in developing countries [26].

Conclusion

With the advancement of science and technology food production process, food processing techniques and food preservation techniques are changing day by day throughout the world. At the same time human lifestyle and behavioral practices are also fluctuating. As a result, nutrition transition would become very typical. But, to protect the public health, the nutrition transition is an issue that must be considered into. The citizens, parents, families, communities, non-governmental organizations, and the government must be carried along to tackle this. Investing in reversing the transition's tide would undoubtedly pay off, as the latest trend indicates that the strain would be devastating in the future if nothing is done now.

Ethical clearance

As it was a review article, consent for publication and ethical approval was not necessary for this article.

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Effect of Reciprocating versus Rotary Instrumentation on Post-endodontic Pain and Endotoxins Level in Infected Root Canals: A Randomised Clinical Trial

Shaimaa I. Bakry[1], Randa El Boghdadi[2], Geraldine M. Ahmed[3], Olfat Shaker[4]

[1]Assistant Lecturer, [2]Professor and Head, [3]Professor, Endodontic Department, Faculty of Dentistry, Cairo University, Egypt, [4]Professor and Head of Biochemistry Department, Faculty of Medicine, Cairo University, Egypt

Abstract

Background: This randomised, prospective, controlled trial aimed to assess the effect of reciprocating single-file and rotary instrumentation on the intensity of postoperative pain and the amount of endotoxins in primarily infected root canals.

Methodology: Forty participants were randomly assigned into two equal groups according to root canal instrumentation technique (n = 20), control group: root canals were instrumented using ProTaper Next rotary system and intervention group: canals were instrumented using WaveOne Gold reciprocating instrumentation system. Root canal treatment was carried out on two visits and postoperative pain of participants was measured using a numerical rating scale (NRS) at predetermined time intervals 6, 12, 24, 48 hours after instrumentation and obturation appointments. Quantification of endotoxins was done using the Sandwich-ELISA method at predetermined time intervals (after access cavity preparation and after completion of instrumentation). Pain score data were summarised as mean and standard deviation.

Results: No statistically significant difference was noted between the single-file reciprocating system (WaveOne Gold) and the multiple-file rotary system (ProTaper Next) regarding postoperative pain and reduction in the amount of endotoxins (P > 0.05).

Conclusion: Both single-file reciprocating instruments and multi-file rotary instruments resulted in mild to moderate postoperative pain and comparable reduction of endotoxins level.

Keywords: endotoxins, post-endodontic pain, primary endodontic infection, ProTaper Next, WaveOne Gold.

Introduction

Post-endodontic pain is defined as the pain of any degree that occurs after initiation of root canal treatment and it remains to be a significant problem in the dental profession.[1]

Post-endodontic pain is caused by a multitude of factors, one of which is the apical extrusion of debris during root canal treatment both with manual stainless steel and nickel-titanium rotary instrumentation techniques.[2] However, reciprocating instrumentation techniques claimed to significantly increase the amount of debris extruded beyond the apex and, consequently,

the risk of postoperative pain.[3,4]

It is well known that one of the main goals of root canal treatment is to reduce the amount of bacteria and their by-products, all contributing to the perpetuation of apical periodontitis.[5,6] Lipopolysaccharides (LPS), generally referred to as endotoxins, can egress into periapical tissue contributing to the initiation and perpetuation of an inflammatory process, therefore endodontic treatment should not only rely on bacterial elimination but also the reduction or elimination of endotoxins.[7]

The concept of using single-file systems to shape

the root canals completely from start to finish has been questioned for achieving proper cleaning and disinfection.[8]

In this study, root canal preparation was done using ProTaper Next (PTN) and WaveOne Gold (WOG) NiTi Systems. PTN is manufactured from M-Wire nickel titanium alloy to enhance flexibility and cyclic fatigue resistance. It is designed with progressive and regressive percentage tapers, and an off-centered rectangular cross section for superior strength to improve canal shaping efficiency.[9]

WaveOne Gold is characterized by a new thermally treated nickel-titanium alloy named "Gold". The gold process is a post-manufacturing procedure in which the ground NiTi files are heat-treated and slowly cooled. This process results in a distinctive gold finish that improves its resistance and flexibility far in excess of its predecessor.[10]

So the objective of the current study was to test the null hypothesis whether the use of a reciprocating single-file system (WaveOne Gold) for cleaning and shaping of primarily infected root canals differ from rotary instrumentation (ProTaper Next) in the intensity of postoperative pain and level of endotoxins.

Materials and Methods

Study design and setting: The study protocol was registered on pactr.org and the registration number is PACTR201808614861015. The protocol was approved by theResearch Ethics Committee (approval # 14-10-15). Participants were asked to sign a printed informed consent that explained the study aim, benefits, and possible side effects of the treatment, and the investigator's instructions.

Sample size calculation: Prior data[11] indicated that a minimal clinical difference of 1 in pain score between test and control groups would be clinically relevant. Using a power of 80%, a level of significance of 5%, and considering a standard deviation of 1.0, 17 participants per group would be necessary. The number had to be increased to a total sample size of 20 per group to allow for losses during follow up.

Participants and eligibility criteria: After enrollment of 56 patients, only 40 medically-free participantswith an age range of 13-60 years who met the inclusion criteria and diagnosed with non-vital permanent mandibular molars and pain on palpation or tenderness to percussion were enrolled from the outpatient clinic of the Department of Endodontics(Figure 1).

Exclusion criteria comprised of a history of medicine intake including corticosteroids, opioids, and nonsteroidal anti-inflammatory drugs (NSAIDs) in the past 12 h or antibiotic treatment during the last 3 months, patients with a history of intolerance of nonsteroidal anti-inflammatory drugs, or those with systemic disorders or pregnant females; teeth with periodontal pockets deeper than 4 mm, previous endodontic treatment, grade II or III mobility. Before treatment, a list of information regarding age, gender, type of tooth was gathered from each patient, and the treatment was performed on two visits.

Treatment procedures: Endodontic procedures were accomplished by one trained postgraduate student. An electrical pulp tester (Denjoy DY310 Dental Pulp Tester; Denjoy, Henan, China) was used to determine pulp sensibility. Radiographic examination was done using the bisecting angle technique with a photostimulable phosphor plate wireless sensor (SOREDEX, DIGORA). A final diagnosis of necrotic mandibular permanent molar teeth with symptomatic apical periodontitis was confirmed before enrollment in the study.

Preoperative pain was recorded using NRS where 0 indicates no pain and 10 indicates pain as terrible as it could be. Pain intensity was categorised into either: none (0); mild (1–3); moderate (4–6); and severe (7–10).[12]

The tooth was anaesthetised using inferior alveolar nerve block by local anaesthesia (Mepivacaine HCl 2% with Levonordefrin 1:20,000) (Mepivacaine, Alexandria Co. for pharmaceuticals & chemical industries, Alex., Egypt). The tooth was properly isolated with a rubber dam and its external surface was disinfected. Access cavity preparation was performed and the first endotoxin sample (S1) was taken by introducing sterile paper points #15 (DentsplyMaillefer, Ballaigues, Switzerland) into

the largest canal or the one related to apical periodontitis. [13]

Establishing a glide path to all root canals was done and coronal flaring was performed. The working length was determined using an electronic apex locator (Denta Port Zx J. Morita, Kyoto, Japan) and confirmed radiographically.

Randomisation and allocation concealment: At this step, the participants were divided randomly into two groups by an investigator not involved in participant enrollment usinga computer software (http://www.random.org/). Numbers from 1 to 40 were written on 40 pieces of paper folded eight-times. Each paper was placed separately in a closed opaque envelope. Each participant was asked to pick one of the envelopes and the participant was assigned to the groups based on the number in the envelope.

For the control group, canals were instrumented using ProTaper Next (PTN) rotary system (DentsplyMaillefer, Ballaigues, Switzerland) according to the manufacturers' instructions. In the presence of NaOCl, X1 file was used in one or more passesuntil the working length was reached. X2 file was exactly used as described for the X1 file until the working length was passively reached. Afterward, the canal was gauged with a size 25 K-file and, if this file was snug at length, the preparation was considered adequate. If the size 25 K-file was loose at length, canal shaping was continued with X3 and, when necessary, with X4 gauging after each instrument with the 30 or 40 hand files, respectively.

For the intervention group, canals were instrumented using WaveOne Gold (WOG) reciprocating instrumentation system (Dentsply Maillefer, Ballaigues, Switzerland) according to the manufacturers' instructions. In the presence of NaOCl, the canal shaping procedure was initiated with the Wave One Gold primary file using 3 mm amplitude strokes in a gentle inward motion to passively advance the file to the full working length. If the primary file didn't progress, the small file was advanced to the working length followed by the primary file to optimize the shape.If the primary file was loose at length with no dentinal debris in the apical flutes, shaping was continued with the medium or the large file.

Canal irrigation was performed with 5 ml of 2.5% NaOCl solution (Clorox, 10th of Ramadan, Egypt) using a side vented 27-gauge needle (C-K Dental Ind. Co, Ltd, Korea) after each file use. After completion of instrumentation, the root canals were thoroughly flushed using 5 ml of sterile saline solution.

A continuous rinse with 5 ml of 17% EDTA solution (MD-Cleanser, Meta Biomed Co, Ltd, Korea) for 3 minutes followed by a final rinse with 5 ml of sterile saline solution was performed before taking the second endotoxin sample (S2).

At the second appointment, 1 week after the first appointment, the temporary filling was removed and the root canals were irrigated using 5ml saline followed by 1ml of 17% EDTA to remove the smear layer, and then obturation of the root canals was done.

In both groups, root canals were obturated using matching gutta-percha points and a resin-based root canal sealer (Adseal, Meta Biomed CO, LTD, Korea). Finally, the tooth was sealed by a reinforced zinc oxide-eugenol cement.

Endotoxin sampling procedures: The first endotoxin sample (S1) was taken after access cavity preparation by introducing the paper point into the full length of the canal and retained in position for 60 seconds. This procedure was repeated with 3 paper points. Immediately afterward, the samples were placed in a sterile plastic epindorff and stored at -20^0C.[14]

The second endotoxin sample (S2) was taken just after completion of instrumentation and irrigation with saline solution using the same protocol.

Outcomes: Primary outcome: Postoperative pain was measured using NRS at predetermined time intervals 6, 12, 24, 48 hours after the end of each appointment. Secondary outcome: Quantification of endotoxins was done using the Sandwich-ELISA method at predetermined time intervals (after access cavity preparation and after completion of instrumentation).

Statistical analysis: All the data was collected and tabulated. Statistical analysis was performed by Microsoft Office 2013 (Excel) and statistical package SPSS version 22. Pain score data were summarised as mean and standard deviation. Comparisons between the two groups were done using Mann-Whitney test for analysis of the intensity of pain. Unpaired t-test was used when comparing variables between the two groups while paired t-test was used when comparing variables within the same group. The significance level was set at p-value < 0.05.

Results

Demographic data for gender distribution, age of participants, and tooth type showed no statistically significant difference between the two tested groups (Table 1).

Regarding the intensity of post-instrumentation pain at the predetermined time intervals, the control group (PTN) showed the highest mean score of post-instrumentation pain intensity at 6 hours which decreased gradually to reach the least value at 48 hours postoperatively. While the intervention group (WOG) showed the highest mean score at 6 and 12 hours postoperatively which decreased gradually to reach the least value at 48 hours postoperatively. The control group showed less mean pain scores at all time intervals than the intervention group but didn't reach the level of statistical significance. Also, the intensity of post-obturation pain was not significantly different between the two groups at the predetermined time intervals (Table 2). Intragroup data analysis revealed that the intensity of post-instrumentation and post-obturation pain significantly decreased at different time intervals within each group at different follow up periods (p < 0.05; Graph 1).

The comparison between the first (S1) and second (S2) endotoxin samples within each group revealed a statistically significant decrease in the mean value of endotoxin level from S1 to S2. Root canal instrumentation using the ProTaper Next system was able to decrease endotoxin level by approximately 33% while 31% reduction in the endotoxin level was achieved using WaveOne Gold instrumentation system. Regarding the mean values of different endotoxin samples, the comparison between the control and intervention groups showed no statistically significant difference between the two groups at S1 and S2 mean scores (p > 0.05; Table 3).
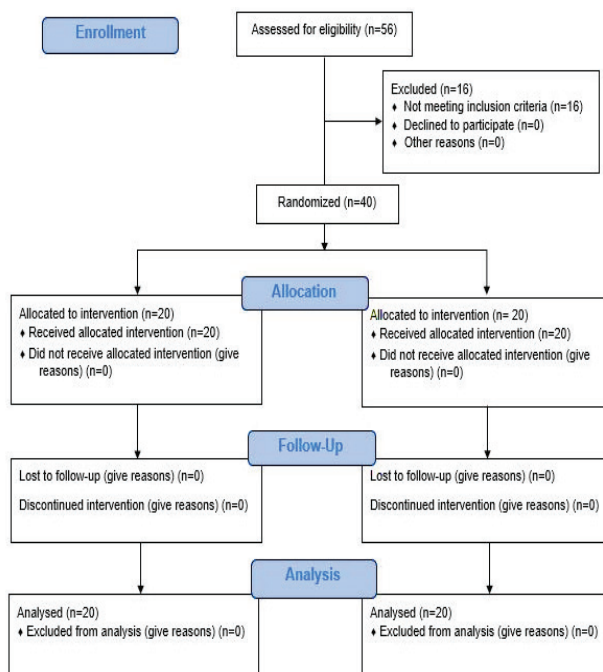
Figure 1: CONSORT flow chart showing the flow of participants along the study
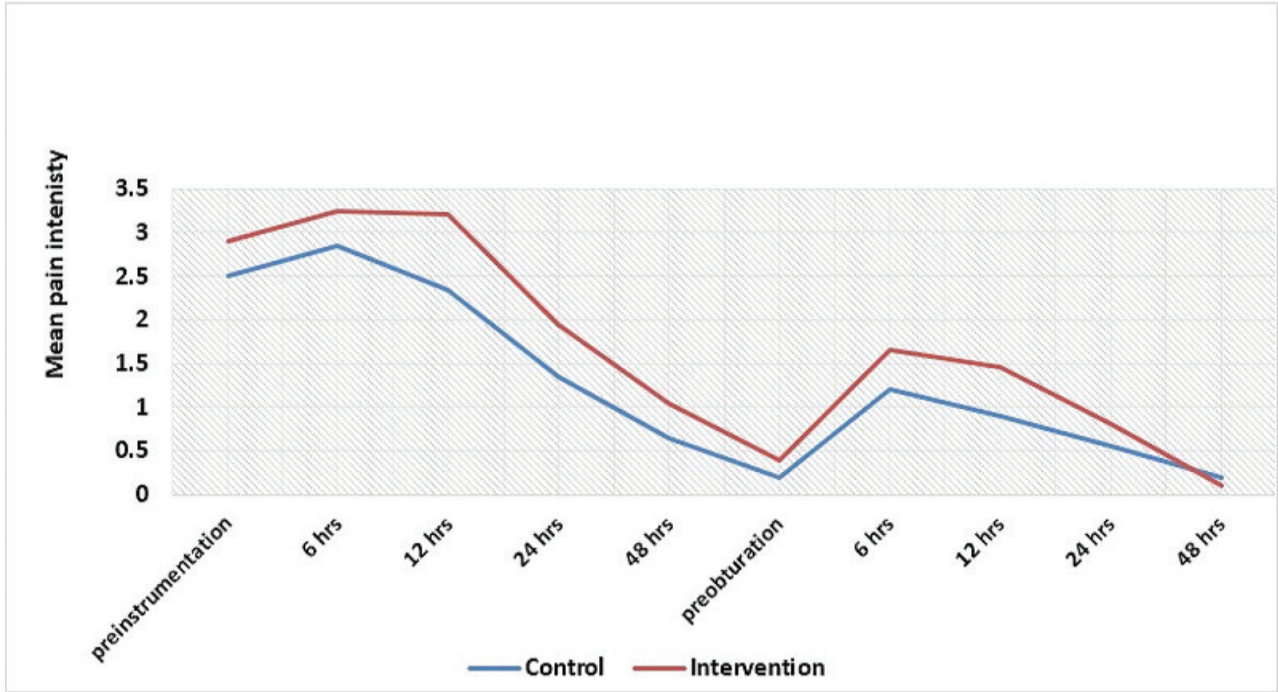
Graph1: Line chart representing the changes in the intensity of pain at different time intervals for each group

Table 1: Baseline characteristics of the included study participants

Variables		Control (PTN) (n=20)	Intervention (WOG) (n=20)	P-value
Gender [n (%)]	Female Male	10 (50%) 10 (50%)	10 (50%) 10 (50%)	1
Age (Mean+ SD)		36.9+13.3	30.9+11.3	0.135
Tooth type [n (%)]	Lower 6 Lower 7	14 (70%) 6 (30%)	13 (65%) 7 (35%)	0.87

SD, standard deviation

Table 2: Intensity of pain (mean±SD) of the two groups at predetermined time intervals using Mann-Whitney test

Time-point	Control (PTN) (n=20)	Intervention (WOG) (n=20)	P-value
Preinstrumentation	2.5±1.4	2.9±1.16	0.42
After 6 hrs	2.85±1.63	3.25±1.29	0.353
After 12 hrs	2.35±1.63	3.2±1.5	0.058
After 24 hrs	1.35±1.42	1.95±1.5	0.151
After 48 hrs	0.65±1.03	1.05±1.31	0.257
Preobturation	0.2±0.52	0.4±0.68	0.429
After 6 hrs	1.2±1.1	1.65±0.98	0.187
After 12 hrs	0.9±0.91	1.45±0.94	0.062
After 24 hrs	0.55±0.75	0.8±0.83	0.292
After 48 hrs	0.2±0.52	0.1±0.3	0.604

Table 3: Endotoxin levels (mean±SD) in the two tested groups

	S1	S2	Percentage of reduction
PTN group Mean+ SD	376.6+150a	252+130b	33%
WOG group Mean+ SD	451+140a	311+120b	31%

[Different lower-case letters represent a significant difference]

Discussion

During chemo-mechanical preparation of the root canals, all instrumentation techniques can produce apical extrusion of debris. However, some studies have stated that full-sequence rotary instrumentation was associated with less debris extrusion compared with the use of reciprocating single-file systems and suggested that this factor could be associated with less postoperative pain.

(15,16)

Bacterial lipopolysaccharides produced by gram-negative bacteria, which were predominantly involved in root canal infections, have been shown to enhance the sensation of postoperative pain.[13,17] Single-file instrumentation systems have been developed with the advantage of cleaning and shaping root canals in a shorter time, however, their ability to properly remove bacteria and bacterial by-products from infected root canals is questionable.

In the present study, postoperative pain was recorded using NRS which was considered a consensus-based, standardised assessment measure, and reported better compliance when compared to other scales.[12]

The time of assessment of postoperative pain intensity in this study was 6, 12, 24, 48 hours after instrumentation and obturation as the exudative process begins within 6 hours, where polymorphonuclear leukocytes (PMNs) begin to enter the injured site and increases steadily, peaking at about 24 to 48 hours after the injury increasing the release of inflammatory mediators and neuropeptides. Then, the proliferative process begins after 48 to 96 hours, which is characterised by declining the PMN population, and the beginning of macrophages to enter the wound site.[18]

In the current study, the intensity of post-instrumentation and post-obturation pain did not differ statistically to a significant level between the two tested groups. This finding resembles the results ofÇIÇEK et al.[9], Relvas et al.[19],Farhad et al.[20] and Saha et al.[21] who found no significant difference in postoperative pain between the rotary and reciprocating instrumentation techniques during endodontic treatment.However, our results were in contrast to those of Krithikadatta et al.[22] and Mehdi et al.[23]who found that reciprocation techniques produced a more significant postoperative pain when compared to rotary instrumentation techniques.

On the other hand, Neelakantan et al.[24]and Shokraneh et al.[25]reported that postoperative pain was significantly lower in patients treated with reciprocating instrumentation techniques in comparison to rotary instruments.

The wide contrast in the results of the different studies might be attributed to differences in sample size, periapical condition, tooth type, preoperative pain score, and discrepancies of instrumentation techniques and systems used for instrumentation of the root canals.[26]

Quantification of bacterial endotoxins was performed with human endotoxin ELISA kit using the Sandwich-ELISA method. The key advantage of a Sandwich-ELISA is its high sensitivity; as it is 2-5 times more sensitive than direct or indirect ELISAs. In addition to this, it delivers high specificity as two antibodies were used to detect the antigen.[27]

Regarding the comparison between different samples of endotoxins (S1 and S2) within the same group of the present study, both groups showed a statistically significant decrease in the mean value of endotoxin between every two samples.

Root canal preparation with both instrumentation techniques in the present study was able to reduce LPS content by about 31-33%. Endotoxin reduction after chemo-mechanical preparation was previously reported to be 60%by Martinho et al.[14], 44% by Vianna et al.[28] using manual instruments for apical preparation, and 29%by Adl et al.[29]using rotary ProTaper instruments.

According to the current study, no statistically significant difference was found between both groups regarding the ability to reduce the amount of endotoxins in primarily infected root canals. Similar findings were reported in other studies conducted by Martinho et al.[13], Marinho et al.[17]and Cavalli et al.[30]

Interestingly, these findings support the efficacy of root canal preparation with a single file for the removal of endotoxins. Therefore, it seems reasonable to assume that the mechanical action of endodontic instruments on dentine together with copious irrigation is more relevant for endotoxin removal than the number of files included in an instrumentation system.[17]

Conclusion

Within the limitation of this randomised clinical study, it could be concluded that; the use of single-file reciprocating instruments or multi-file rotary instruments in primarily infected teeth resulted in a comparable level of postoperative pain and comparable ability of root canal disinfection. However, neither of them rendered the root canals free of endotoxins.

Ethical Clearance: Ethical approval was taken from the Research Ethics Committee of the Faculty of Dentistry, Cairo University, Egypt.

Source of Funding: Self-funded research.

Conflict of Interest: The authors deny any conflicts of interest related to this study.

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The type of manuscript: Original article

Comparative Effect of Lower Limb and Abdominal Isometric Exercises and Yoga Poses on Primary Dysmenorrhea

Sharayu Agre[1], Ronika Agrawal[2], Azaz M. Zehra[3]

[1]Associate Professor, [2]Principal and Professor, [3]Clinical Therapist, MME&RC's M.A. Rangoonwala College of Physiotherapy, Azam Campus, Pune

Abstract

The aim of the study was to analyze comparative effect of lower limb and abdominal isometric exercises v/s yogasana on primary dysmenorrhea. Materials and Methods: Total 75 females were recruited out of which 60 subjects were selected based on inclusion criteria. The samples were divided into two groups: Group A (Isometric exercises) and Group B (Yogasana). The outcome measure used was Moos Menstrual Distress Questionnaire (MDQ) , Score was taken for both groups pre-intervention and post-intervention at the end of 8th week of their intervention programme. Data was analyzed using Microsoft Excel. The results were expressed as proportions after the normalization of the data and p value (<0.05) was considered significant.

Results: The significant difference was noticed in intra group comparison in group A and group B in MDQ score ($p<0.05$). And difference in Group B was greater than Group A in inter group comparison ($p<0.05$).

Conclusion: Study concluded that both lower limb and abdominal isometric exercises and asanas help in reducing distress related to primary dysmenorrhea. However, Yoga intervention is more effective in treatment of primary dysmenorrhea than lower limb and abdominal isometric exercises.

Keywords: *Primary Dysmenorrhea, Yogasana, Isometric exercise, Moos Menstrual Distress Questionnaire*

Introduction

Dysmenorrhea is characterized by menstrual pain [1]. It can be classified as Primary (absence of pelvic pathology) and Secondary (presence of pelvic pathology) dysmenorrhea. [2]. The prevalence of dysmenorrhea was found to be 79.67% in adolescent girls [3]. The risk factors are age <20 years, nulliparity, heavy menstrual flow, early menarche (<12years), longer cycles, smoking, upper socioeconomic status, physical

Corresponding contributor:
Dr. Sharayu Agre,
SIU Ph.D. Scholar, M.PT (Master of Physiotherapy), Associate Professor MME& RC's M.A. Rangoonwala College of Physiotherapy Azam Campus, Pune.

inactivity, sterilization , sexual abuse , attempts to lose weight, disruption from social networks, depression and anxiety[4-7]. The etiology of primary dysmenorrhea is due to release of uterine prostaglandins, particularly $PGF_{2\alpha}$ as this stimulates myometrial contraction, ischemia and sensitization of nerve endings and thus causing pain [6,8].

Exercises such as isometric and yogasanas have been proved to reduce pain as well as other distress related to dysmenorrhea [1,8]. Isometric exercises work on muscle in static position and generates muscle tension without actual movement. Moreover , it is localized to area or joint[8].Whereas, Yoga includes relaxation, control of breathing and various asanas .These asanas can be practiced in both isotonic and isometric way , adding to, it establishes generalized feeling of well being[1,9]. Therefore the purpose of this study is to find

the most effective intervention of the two in preventing or reducing pain and distress related to menstruation.

Materials and Methods

• After approval from the institute from ethics committee, written informed consent from total 75 females were obtained. 60 subjects were selected based on inclusion and exclusion criteria. The samples were allocated into two groups: Group A (Isometric exercise) and Group B (Yogasana). Inclusion criteria for study was age 15-25 years, pain during menses intensity 5 or more on VAS (visual analogue scale), regular menstrual cycle, nulliparous, knowing English language. Exclusion criteria being suffering from any systemic/reproductive or cardiovascular disease, recent orthopedic injuries which will restrain them from doing exercises, on oral contraceptive pills or any other fertility treatment. The study intervention was carried out for 8 weeks [1, 8, 9]. Duration of each session was 25 min.

• The outcome measure used was Moos Menstrual Distress Questionnaire (MDQ), it has reliability of 0.81 and validity (0.88) [11, 12]. MDQ has 8 components and subcomponents counting to total of 47 symptoms. MDQ score was taken for both groups pre- value and at 8th week of their intervention programme.

• Interventions

1. Group A: (lower limb and abdominal isometric exercises)

Group A performed exercises after 5th day of their 1st menstrual cycle 5 days a week and 10 times per session for 8 weeks. All exercises were in supine position and were continued during 2nd cycle menses days as well. In each stage patient had to hold position for 5 second and then relax [5,8].

1. Static hip adductor exercises.

2. Static hip abductors exercise.

3. Static back muscles.

4. Static abdominals.

5. Statics right oblique abdominals.

6. Statics left oblique abdominals.

Group B (Yoga group):

Group B performed- Yogasana after 5th day of their menstrual and were continued during second cycle menses 5 days a week, for 8 weeks. The asanas were performed 5 times each and hold the position for 15 to 30 seconds as per individual's ability to hold it. The Yogasana that they practiced were as bellow.[1,9,10]:

1.Bhujangasana	
2.Bidalasana	

Cont...

3.Setu Bandhasana	
4.Pawanmuktasana	
5 .Baddha konasana	

Results

The data collected were analyzed using SPSS (17) and Microsoft excel. Level of significance was set as 95% thus (p <0.05) was considered significant. Normalization of data was done .The intra – group comparison was done using paired t- test and inter –group analysis was done using unpaired t-test.

TABLE 1 Between group comparisons of Age

Age	Group A	Group B	T value	P value
Mean (SD)	20.3 (±1.6)	20.7 (±2.5)	-0.18	0.42

The mean age for group A (Isometric exercise) was 20.63(±1.6) and 20.73 (±2.5) in Group B (yoga group). Unpaired t test was performed and p value was not significant (p = 0.42). This indicates that the data was comparable at base line (as shown in table 1).

Table 2- Intra group comparison of group A for pre and post 8 weeks MDQ questionnaire score.

	Mean difference	p value	INTERPRETATION OF p value
PAIN	4.13	P < 0.001	SIGNIFICANT
CONCENTARION	2.03	P < 0.001	SIGNIFICANT
BEHAVIOURAL CHANGES	2.43	P < 0.001	SIGNIFICANT
AUTONOMIC REACTIONS	0.56	P < 0.001	SIGNIFICANT
WATER RETENSION	1	P < 0.001	SIGNIFICANT
NEGATIVE EFFECTS	2.73	P < 0.001	SIGNIFICANT
AROUSAL	1	P < 0.001	SIGNIFICANT
CONTROL	0.83	P < 0.001	SIGNIFICANT
TOTAL	15.3	P < 0.001	SIGNIFICANT

Interpretation: Intra-group comparison of mean score of MDQ pre and post intervention in group A(Isometric exercise group). There was significant difference observed in all subcomponents. This suggests that group A intervention showed significant improvement in all subcomponents of MDQ post intervention at 8 weeks.

Table 3 Showing The intra-group comparison of group B showing mean values at pre and post 8 weeks

	Mean difference	p value	INTERPRETATION OF p value
PAIN	5.76	P < 0.001	SIGNIFICANT
CONCENTRATION	4.43	P < 0.001	SIGNIFICANT
BEHAVIOURAL CHANGES	3.6	P < 0.001	SIGNIFICANT
AUTONOMIC REACTIONS	0.8	P < 0.001	SIGNIFICANT
WATER RETENSION	1.56	P < 0.001	SIGNIFICANT
NEGATIVE EFFECTS	7.3	P < 0.001	SIGNIFICANT
AROUSAL	2.23	P < 0.001	SIGNIFICANT
CONTROL	0.86	P < 0.001	SIGNIFICANT
TOTAL	27.6	P < 0.001	SIGNIFICANT

Interpretation: Intra-group comparison of mean score of MDQ pre and post intervention in group B (Yogasana). There was significant difference observed in all subcomponents. This suggests that group B intervention showed significant improvement in all subcomponents of MDQ post intervention at 8 weeks.

Table 4, shows intergroup comparison of the mean difference of group A and Grop B using unpaired t test .

	GROUP A	GROUP B	p value	INTERPRETATION OF p value
PAIN	4.13	5.76	P < 0.001	SIGNIFICANT
CONCENTRATION	2.03	4.43	P < 0.001	SIGNIFICANT
BEHAVIOURAL CHANGES	2.43	3.6	P < 0.001	SIGNIFICANT
AUTONOMIC REACTIONS	0.56	0.8	P < 0.001	SIGNIFICANT
WATER RETENSION	1	1.56	P < 0.001	SIGNIFICANT
NEGATIVE EFFECTS	2.73	7.3	P < 0.001	SIGNIFICANT
AROUSAL	1	2.23	P < 0.001	SIGNIFICANT
CONTROL	0.83	0.86	P < 0.001	INSIGNIFICANT
TOTAL	15.3	27.6	P < 0.001	SIGNIFICANT

Interpretation: Shows comparison of mean difference in group A and group B at end of 8 weeks. Data were analyzed using unpaired t test. Results suggest that improvement in group B (Yogasana) was more than group A and difference was statistically significant. (p < 0.05)

Discussion

Primary dysmenorrhea (PD) is described as pain during the first days of menstruation cycle beginning with the onset of the ovulatory cycle (usually 6 to 12 months after menarche) in the absence of pelvic pathology. Based on current scientific knowledge in primary dysmenorrhea progesterone withdrawal prior to menstruation leads to release of arachidonic acid. Archidonic acid triggers inflammatory response and vasoconstriction via release of prostaglandins (PGs) and leukotrienes (LTs)[11,12].PGs cause contraction of uterus frequently and arrythmically. Uterine contractions lead to vasoconstriction resulting increased sensitivity of peripheral nerves. All this process results in primary dysmenorrhea [6, 13]. Exercises increases release of anti-inflammatory cytokines such as IL-10 and IL-1ra and inhibits pro-inflammatory cytokines IL-1 beta and TNF-alpha 20 or metabolic factors i.e. promotes substrate utilization (a shift from anaerobic glycolysis to aerobic respiration), reduces secretion of lactate ultimately leading to reduction in pain. [14]

The improvement in pain component in group A could be due to isometric exercises of targeted muscle. Contraction of these muscles facilitates bleeding and excretion of waste containing prostaglandins relieving

pain, as prostaglandin were primary source of painful contraction[8]. It also controls pelvic movement by reducing muscular imbalance and reduces the activity of sympathetic system which causes contraction and pain in uterine muscles[5]. A study done by Sara Azim et al investigated effect of isometric exercises as a primary treatment of dysmenorrhea. The study concluded that 8 weeks of isometric exercise reduced the intensity and duration of primary dysmenorrhea.[8]

The significant difference in breast tenderness, weight gain and skin disorders in subcomponent of water retention could be probably due to correction of electrolyte imbalance caused by fluctuation in hormonal levels. Exercise training has been shown to decrease rennin and increase estrogen and progesterone levels leading to improvement of symptoms of water retention and swelling [15].

Mechanism behind physical activity may help in faster transfer of waste products and prostaglandins as root of menstruation pain in uterine muscle[6]. Light to moderate intensity exercises reduce stress, anxiety , depression and improve mental health ,as the negative effects on the body seem to be exaggerated in people who are inactive, a phenomenon called stress-induced/ exercise deficient . Exercise, a natural remedy for negative effects because it releases powerful endorphin chemicals in the brain, which act like the body's built-in painkillers and mood-lifters[16].

Yoga doesn't only target any particular organ or system, it treats individual as whole bringing harmony to body and mind. A study done by Usha Nag and Madhavi Kodali explored Yoga and pranayam as alternative therapy for primary dysmenorrhea. Asanas not only strengthen muscles around pelvis and lower abdomen but also work on muscle flexibility, cramps, mobility of joints as well. Controlled and regulated breathing pattern practiced during yogasan is reported to induce not only local relaxation but also general sense of well being. In current study yoga group had significant reduction in muscle stiffness, headache, cramps , backache and other symptoms of Pain [9]. The Bhujangasan and Setubandhasan stretch anterior abdominal wall. These

positions have seen to have increased blood supply to peritoneal cavity. This increased blood flow helps in washout of inflammatory mediators like PGs leading to relief of pain. [10]

The significant reduction in anxiety, depression, mood swings and other components were noticed. Significant reduction in insomnia, distraction and other component in Concentration subcomponent were seen. Correlation of mind to body is a circle in dysmenorrhea. It's a vicious circle i.e. pain perceived by body leads to stress and stress increases secretion of inflammatory mediators to increase pain. Yogasana helps in breaking this cycle by locally reducing the pain at musculoskeletal system and corrected breathing pattern leading to central relaxation [17]. A study done by Dianne Groll,a Danielle Charbonneau suggests that yogasan has higher influence on sympathetic and parasympathetic system modulating GABAergic activity hence is helpful in reducing negative emotions like anxiety [18]. Yogasan is also seen to have effect on vagus nerve activity and adrenal gland leading to decreased cortisol secretion. These parasympathetic activities leads to better undisturbed sleep pattern. [17].

This study had significant reduction in Control, Behavioural changes and Arousal subcomponents post 8 weeks intervention. Behavioural changes are under influence of autonomous nervous system. Since yogasan has inhibitory effect on sympathetic system leading to change in neurotransmitters and hormone levels; it results in reduction of these components. [19].

In this study, in intergroup comparison group B (yoga group) showed greater decrease in total score of Moos Menstrual Distress Questionnaire than group A (Isometric exercise) which is significant (p <0.05).

Stress has potentiality to increase sympathetic activity and can enhance dysmenorrhea through increase of sympathetic system stimulation. Exercise is crucial stress moderator. Intervention studies have established that practice of exercise is seen to help in release of endorphins and enkephalins which modulates pain threshold. This whole process results in reduction in pain perception [6].

A study done by Ratna Sharma*, Nidhi Gupta and R. L. Bijlan explored effect of Yoga on feeling of well being. This study suggested that combined practice of yoga and pranayam has significantly good results on subjective feeling of well being in merely 10 days. Feeling of well being is related to reduction of stress, anxiety and depression. So besides musculoskeletal benefits of yogasan it also induces sense of well being and reduction in negative emotions like anxiety and depression. [20]. Studies have demonstrated reduction of stress can be improving symptoms of dysmenorrhea [8].

Present study shows significant reduction in distress related to dysmenorrhea in yoga group than isometric exercise group. Yoga also has advantage of being safe and doesn't need fancy props neither bigger area to perform and is extremely efficient in pain reduction.[21] Therefore, yoga can be effectively used as an alternative therapy for primary dysmenorrhea.

Conclusion

It is concluded that both lower limb and abdominal isometric exercises and yoga asanas help in reducing distress related to primary dysmenorrhea according to Moos Menstrual distress questionnaire. However, yoga group was more effective in reducing distress related to primary dysmenorrhea than isometric exercise group.

Financial Assistance: Nil

Conflict of Interest: Nil

Ethics committee Clearance: Ethics clearance was availed from Institutional ethics committee of M.A. Rangoonwala College of Physiotherapy And Research, Pune.

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Effectiveness of Model based Training on Self-Breast Examination among Reproductive Age Group Women in the Community

Shivani Rao[1], Nidhi Budh[2], Abdul Ajees Abdul Salam[3] , Ciraj Ali Mohammed[4], Archita Jain[5], Ajay Raj Sethuraman[6], Mongjam Meghachandra Singh[7]

[1]Assistant Professor, Department of Community Medicine, Maulana Azad Medical College, New Delhi, India, [2]Assistant Professor, Department of Community Medicine, Army College of Medical Sciences, New Delhi, India, [3]Associate Professor, Department of Atomic and Molecular Physics, Manipal Academy of Higher Education, Manipal, India, [4]Director, MAHE-FAIMER, Manipal Academy of Higher Education, Manipal, India, [5]Senior Resident, Department of Community Medicine, Maulana Azad Medical College, New Delhi, India, [6]Associate Professor, Department of Community Medicine, Andaman and Nicobar Islands Institute of Medical Sciences, Port Blair, India, [7]Director Professor, Department of Community Medicine, Maulana Azad Medical College, New Delhi, India

Abstract

Introduction: Breast cancer (BC) is a global disease and is second leading cause of cancer death among women. Timely diagnosis with quick initiation of treatment reduces breast cancer mortality. Therefore, skill development on Self Breast Examination among the community women is essential.

Objectives: To disseminate information about screening method among reproductive age group women in community and to provide the skills on breast self-examination.

Methods: A descriptive cross-sectional study conducted in Urban Health Centre in New Delhi in which 104 women participants of age between 15 to 45 years were included in study. Data was collected with the help of a predesigned, pre-validated and pretested questionnaire. Participants were educated on breast self-examination and technique by using dummy breast model. Pre-Test and Post Test evaluation was done to assess skills on SBE.

Result: Two third of participants had never performed SBE. There was improvement in skill acquired by participants which revealed a mean Pre-test score of 1.91 ± 2.25 which improved to 6.10 ± 0.33 in Post test score and it was found to be statistically significant with $p<0.001$.

Conclusion: This study results confirms that there is general lack of knowledge about Self Breast Examination (SBE) among women in the community and also had poor skills on self-breast examination .Hence Self Breast Examination Module and demonstration of SBE was effective in enabling women in the community with knowledge and skills of Self-evaluation of Breast regardless of their level of education.

Keywords: Breast Cancer, Breast Self-Examination, Skills

Corresponding Author:
Ajay Raj Sethuraman
Address: Department of Community Medicine, Andaman and Nicobar Islands Institute of Medical Sciences, Port Blair, India.
Email: ajay.rms@gmail.com

Introduction

Breast cancer is an alarming public health problem in both developed and developing countries. Globally in 2018 there were approximately 2 million new cases of cancer breast and major cause of cancer deaths among women [1, 2]. Across the globe incidence rates of

breast cancer vary from 19.3 per 100,000 women in Eastern Africa to 89.7 per 100,000 women in Western Europe[3]. In India among all cancers found in women, cancer breast is most common form of cancer and has overtaken cancer cervix[4]. As per GLOBOCAN 2018 about 1,62,468 new cases of cancer breast and 87,090 deaths resulted from breast cancer in India[5].

As most of the risk factors are non-modifiable risk nothing much can be done therefore regular screening for cancer breast is recommended to allow early case detection and thereby prevent death from breast cancer.

Though mammography is the most effective screening method there is limited availability of this service in health centers in India. It is also a very costly investigation procedure available therefore self-breast self-examination (SBE) is considered the most cost-effective method[6] for early detection of breast lump.

The fact that it can be done by the women herself at home provided she should know the correct method of doing Self Breast Examination. It has been observed that there is general lack of knowledge about Self Breast Examination among women in India. Inhibition among women to learn and discuss about SBE is another factor seen among women in Indian community.

Various studies have been published regarding awareness of Breast self-examination but there is paucity of data related to skill development on BSE technique. With this aim the present study was done to focus on skill development of community women on breast self-examination.

Aims and Objectives

Aim:

To administer Self Breast Examination skill to women in the community and evaluate its effectiveness

Objectives:

a. To assess the knowledge and practice about self-Breast examination among reproductive age group women in the community.

b. To study the change in awareness on self-Breast examination after teaching session.

Materials and Methods

Study Design: Community-based Cross-sectional study.

Study Area: The study was carried out at Urban Health Centre, Gokulpuri which is the field practice area of Department of Community Medicine, Maulana Azad Medical College, New Delhi.

Study subjects: Reproductive age group women aged between 15 to 45 years who are residents of the study area were included.

Study period - 6 months

Inclusion Criteria : All women between the age of 15 to 45 years residing in the study area for last one year and who gave consent to participate.

Exclusion Criteria: Participants unable to understand Hindi/English and associated with severe debilitating illness or mental health problem.

Sample size: At 95% confidence interval and according to Madhukumar's[7] study 18% having some knowledge about breast cancer/breast self-examination, and 20% increase in knowledge after lecture and demonstration. So estimated sample size was 161 by using the formula $n = (Z\alpha/2 + Z\beta)^2 (p_1 q_{1+} p_2)/(p_{1-}p_2)$. Due to Covid-19 restrictions, a convenient sample of 104 reproductive age group women was taken by systemic random sampling.

Study Instrument: Data was collected through detailed interview with the help of a predesigned, pre-validated and pretested questionnaire which included questions regarding socio-demography, knowledge, and self-Breast examination technique. About 5 to 7 women were asked to come to Urban Health Centre to attend the health education session for 30 minutes. The session included administration of Pre test followed by power point presentation and video which covered various aspects related to breast self-examination as well as demonstration of breast self-examination on dummy

breast model for 15 minutes followed by post-test which included assessment of their skill to do self breast examination on dummy breast model.

The dummy breast model has been acquired from Mamma Care Foundation based in USA which is an organization which provides a validated and standardized model for teaching and training on clinical breast examination. This model was used to deliver training to participants. The model has been approved and supported by National Cancer Institute USA. This model has been extensively used globally for skill-based training on clinical/self-breast examination including Vardhaman Mahavir Medical College and Safdarjung Hospital, New Delhi.

Statistical Analysis

The data was cleaned and entered in MS Excel spread sheet and analyzed using IBM SPSS Statistics Version 21.0 software (Chicago). Data was expressed in percentage and proportions and were displayed in appropriate tables and figures. Appropriate statistics was applied to achieve desired results (Mcnemar's and Chi square test for pre and post-test comparison). The level of significance was set at 5%. All P-values less than 0.05 were treated as significant.

Ethical Clearance: Written and informed consent were taken from all study subjects. The study was initiated and conducted after obtaining Ethical approval from the Institutional Ethics Board of Maulana Azad Medical College. Confidentiality of the data collected was maintained and data was used only for the study purpose.

Results

A total of 104 participants underwent Model Based learning of Breast Self-Examination. Age of participants in this study ranged from 15 years to 45 years. According to the present study, majority of women 29.8% belonged to age group between 25 years to 30 years. Out of total 104 participants about 12.5% were uneducated and more than 50% were educated beyond high school and more than 90% were employed. As per modified Kuppuswamy's scale, women belonged to various socio economic status as depicted in (Table 1).

Analysis of scores obtained in assessment of Skill acquired by participants revealed that a mean Pre-test score of 1.91±2.25 which was improved to 6.10±0.33 in Post test score (Figure 1). This improvement in scores for skill acquisition was found to be statistically significant with p<0.001. Range of Pre and Post test score was 0-6 and 6-8 respectively.

Analysis was done on responses given by Participants on practices of Self Breast examination prior to attending Self Breast Examination session. Two third of participants have never performed Self Breast examination prior to participating in this study. Appropriate time for breast self-examination i.e. 5 days after menstruation was known to only 12 (11.54%) women which increased to 94.24% in post-test. Only 24 women (23.08%) knew that self-breast examination should be done once in a month which increased in post-test to 90.38 %. Only 18.27 % responded that self-breast examination should be performed after 20 years of age which increased to 92.30% after training session. (Table 2)

On checking their skill before training session, it was observed that only 30.77% used palmar aspect of pulp of middle three fingers to palpate the breast which increased to 97.12% in post-test observation (Figure 2). Only about 34.62% palpated all quadrants of the breast which increased to 97.12% after the training session. Similarly, only 30.77% checked for nipple discharge in pre-test which increased to 98.08% in post-test. Only 30.62% of the participants correctly palpated the lumps in the given model which increased by 98.24% after giving skills. (Table 2) About 85% were aware that they should visit a doctor if they notice any breast abnormality.
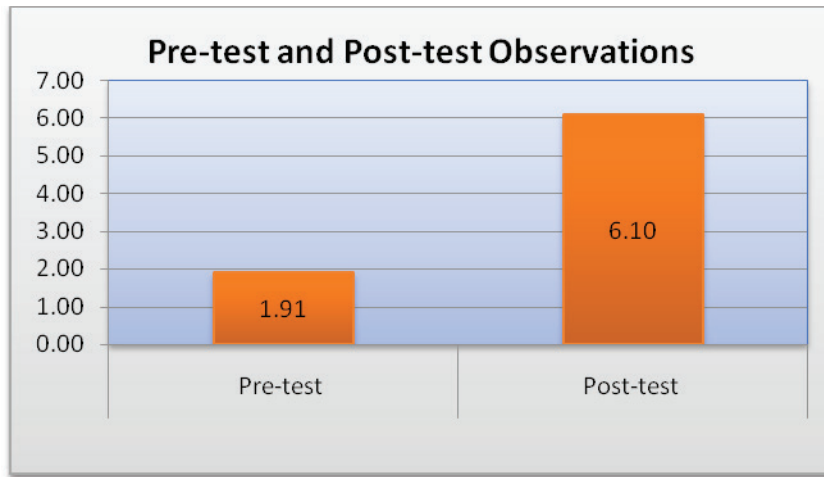
Figure 1: Comparison of pre and post test scores on SBE practice & Skills acquisition by participants (n=104)

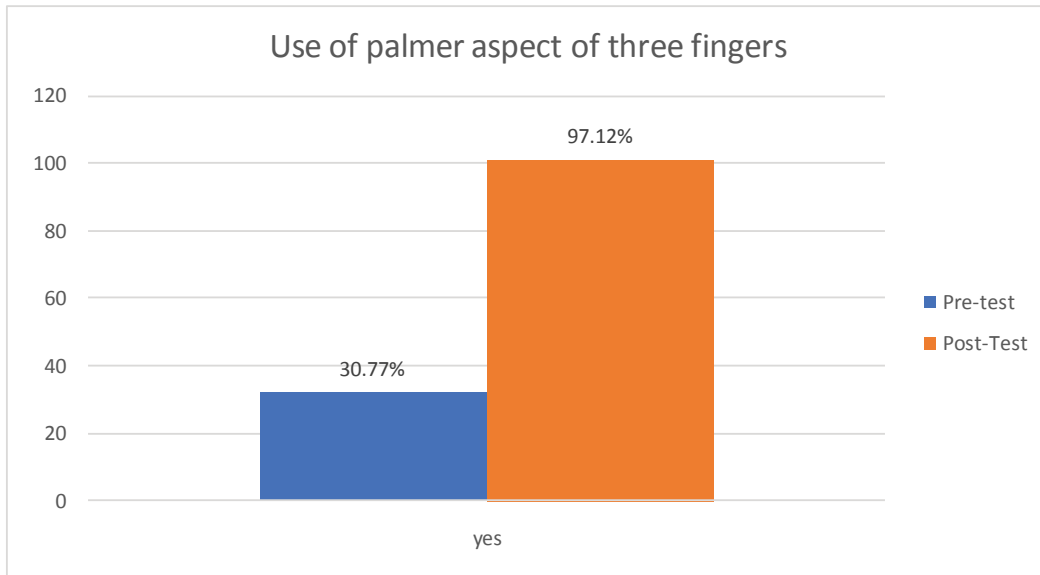**Figure 2: Use of Palmer aspect of middle three fingers by study Participant in pre-test and post-test (n=104)**

Table 1: Socioeconomic status of participants (n=104)

Socioeconomic status (Modified Kuppuswamy Scale)		
	Frequency	**Percent**
Upper	4	3.8
Upper Middle	31	29.8
Lower Middle	34	32.7
Upper Lower	33	31.7
Lower	2	1.9
Total	104	100.0

Table 2: Comparison of pre and post test scores on Self Breast Examination practice & Skills acquisition by participants (n=104)

Assessment	Pretest	Posttest	P value
Knowledge / Practice	%	%	
Appropriate time for breast self-examination?	11.54	94.24	<0.0001
Periodicity of SBE being done?	23.08	90.38	<0.0001
Age to start performing SBE	18.27	92.30	<0.0001
Skill	%	%	
Used palmer aspect of 3 fingers	30.77	97.12	<0.0001
Palpated all quadrants of breast	34.62	97.12	<0.0001
Checked for nipple discharge	30.77	98.08	<0.0001

Discussion

It has been observed that among all the screening methods, breast Self-Examination is the best method for screening of breast Cancer, which is also the cheapest and convenient method. This can be practiced by woman herself. Appropriately practice of Breast self-examination (BSE) will enable a woman with knowledge; skills will empower her in evaluation of breast herself resulting in early reporting of breast cancer to a heath centre and thereby result in their early treatment which will in turn increase their chances of survival.

A total of 104 participants underwent Model Based learning of Breast Self-Examination, majority of women 29.8% belonged to age group between 25 years to 30 years. More than 50% of the women were educated and most of them were employed (more than 90%). As per modified Kuppuswamy scale, women participants mainly belonged to lower middle (32.7%) and upper lower (31.7%) socio-economic status. Regarding the skill on self breast examination present study revealed that the mean Pre-test score was 1.91±2.25 which improved to 6.10±0.33 in Post test score. This improvement in scores for skill acquisition was found to be statistically significant with p<0.001. This finding is consistent with the finding of John Molly et al study[10].Practice about Breast Self-Examination are very low in the present study, two third of participants have never performed Self Breast examination prior to participating in this study this finding is consistent with what was seen in a study done by Rakesh Singh et al.[11]A similar study was done in Andhra Pradesh which revealed that only 2.4% of the participants were practicing BSE[12]. This finding was less than what was observed in our study.

The finding suggests that the importance of self-breast examination is very low among our community women and therefore proper training and health education programmes should be initiated at grass root level to spread the awareness about cancer breast and self-breast examination. The fact that early diagnosis and treatment of cancer breast can increase the cure and chances of survival needs to be emphasized among community women.

Appropriate time for breast self-examination i.e. 5 days after menstruation was known to only 11.54% women which increased to 94.24% in post-test. A study done by Khokhar A[9]revealed that only 1.36% of participants knew correct time of self-breast

examination which was low as compared to our study. Only 23.08% women knew that breast self-examination should be done once in a month which increased in post-test to 90.38 %. A study done by Chaudhary et al[13] and Khokhar A[9] revealed that only 12% and 13.4% of the participants practiced self-breast examination once a month which was low as compared to present study. Only 18.27 % responded that breast self-examination should be performed after 20 years of age which increased to 92.30% after training session. The results in our study is comparatively better than other studies which could be due to a different study setting and also due to the fact that more than 50% of our study participants were educated beyond high school.

We have observed in present study that though results in pretest were poor there was substantial improvement in post test which was done after the training session which indicates that there is definitely a need to create awareness about self-breast examination in the community.

On checking their skill before training session, it was observed that only 30.77% used palmar aspect of middle three fingers to palpate the breast which increased to 97.12% after demonstration of self-breast examination. Only about 34.62% palpated all quadrants of the breast which increased to 97.12% in post-test observation. The pre test results shows that correct method of performing self-breast examination among women in the community were minimum; this finding was also consistent with studies done by Shaista et al[12] and another study done by Puri et al[14] in which 8% of women correctly performed self-breast examination. Present study shows only 30.62% of the participants correctly palpated the lumps in the given model which increased by 98.24% after providing skills on dummy breast model. A study done by Apeksha P et al[15] also revealed that less than half participants (37.86%) correctly identified the lumps. Post intervention about 85% were aware that they should go to doctor if they notice breast abnormality. This finding was coherent with a study done by Syed Arman Rabbani et al[16] which revealed that women were more positive towards medical help-seeking after post-test. Present study reveals that there was better ability to

perform breast examination after demonstration in post test. The study also exposes the fact that irrespective of level of education women can be trained on self breast examination.

Conclusion

The present study shows that practice of breast self- examination among women were very less in the community women. Thus, structured and planned teaching or training programme on self breast examination was found to be effective in creating awareness and development of skill in community women in India. Therefore it is necessary for health personnel to intensify health education on cancer breast and also provide skill regarding technique of doing breast self- examination. Early detection of cancer breast will also reduce financial burden on health sector and thus it will help in improvement of economy of our country.

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Efficacy of Virtual Reality Induced Environmental and Habitual Navigation on Psychological, Cognitive Function that Impacts on Physical Recovery in Patients with Stroke

Shubham Prakash Kamble[1], R.M Singaravelan[2], Tejas Pradeep Borkar[2]

[1]MPT, Department of Neuro Physiotherapy, [2]Associate Professor, [3]Assistant Professor, Dr. APJ Abdul Kalam College of Physiotherapy, Pravara Institute of Medical Sciences (Deemed to be University), Loni 413736, Ahmednagar, Maharashtra, India

Abstract

[Background] Cognitive dysfunction after a stroke is normal, but it is underdiagnosed and has a bad prognosis. In 40-70 percent of stroke survivors, there is a degree of cognitive dysfunction. Similarly, psychometric issues such as anxiety and depression are normal following stroke but are mostly untreated, resulting in a patient's poor quality of life. Whereas it also has an effect on a person's rehabilitation. The use of traditional methodology has certain beneficial effects, but it is not necessarily handled with the individual's own interests in mind. Virtual reality, on the other hand, seems to play a role in dealing with such issues, especially where they are linked to neurological disorders. Virtual reality navigation has the potential to enhance basic cognitive functions such as visuo-spatial perception, executive performance, and attention, both of which can affect one's psychological state and aid in functional rehabilitation. Cognitive deficits and social issues must be addressed because they have a detrimental impact on functional abilities and quality of life.

[Methodology] Twenty-three participants between the ages of 40 and 60 with a stroke diagnosis were chosen. Participants were split into two groups: Group A, which received Virtual Reality induced environmental and habitual navigation as well as Conventional Physiotherapy, and Group B, which received Conventional Physiotherapy as well as cognitive training and relaxation for 4 weeks of duration. The Montreal Cognitive Assessment (MoCA), Hamilton Anxiety Rating Scale (HARS), Hamilton Depression Rating Scale (HDRS), and Functional Independence Measure (FIM) were used to conduct pre and post intervention evaluations.

[Conclusion] The study found that combining virtual reality-induced environmental and habitual navigation with conventional physiotherapy improves cognitive control, psychological function, and functional recovery in stroke patients more effectively than treating them with conventional physiotherapy alone.

Key Words: *Anxiety, Cognitive Impairment, Depression, Environmental Navigation, Functional Recovery, Habitual Navigation, Stroke, Virtual Reality.*

Introduction

Stroke is the most popular classic problem. In the past, ancient Indian physician "Sushrutha," also known as the "Father of Surgery," referred to stroke as

"pakshavada." Around the time of Pericles, around 400 B.C., the Greek physician Hippocrates, also known as the Father of Medicine, coined the term "apoplexy." [1]

William Cole invented the word "STROKE" in the late 17th century, specifically in the year 1689. As a result, stroke has been around for a long time, and many doctors have struggled to describe stroke in its history. Stroke was identified as "rapidly developing clinical

Corresponding author:
Dr. Shubham Prakash Kamble
E-mail: shubhamkamble91@gmail.com

symptoms of focal or global disruption of cerebral function, lasting more than 24 hours or leading to death" by the World Health Organization in 1970. [2]

Stroke is a significant cause of disability and death worldwide; Stroke are classified on the basis of its etiologies as either ischemic (85%) or hemorrhagic (15%). Ischemic stroke is the most common form, and it is caused by a blockage of blood flow to a specific region of the brain. Four subtypes have been identified (atherosclerosis, lacunar infarcts, cardioembolic, cryptogenic). Hemorrhagic strokes, which are caused by the bursting of a blood vessel. Intracerebral haemorrhage (ICH) and subarachnoid haemorrhage, which account for around 5% of all strokes, are the two major forms of haemorrhagic strokes. [3]

In 2010, the global prevalence was 33 million. Despite the fact that the death rate of stroke has decreased by 35.8% in the last decade, nearly 795000 people in the United States still suffer from a stroke. [5] 4 According to recent population-based reports, the incidence rate is 119-145/100,000. Every year, 800,000 new strokes occur in the United States. According to an epidemiological survey, the incidence of stroke in China ranged from 116 to 229 per 100,000 person-years, leaving around 75% of people with motor impairment and 40% with serious disability. India, like many other developing nations, is dealing with a double burden of communicable and non-communicable diseases. The median adjusted prevalence rate of stroke in rural areas seems to be 84-262/100,000, although in urban areas it is 334-424/ 100,000. Every 40 seconds, a new stroke is rendered. [4][5]

The neurological signs and symptoms of an ischemic stroke typically arise immediately, but they can also appear gradually. The most common symptom is sudden onset of hemiparesis in an elderly person. Symptoms and symptoms differ depending on where the occlusion is located and how much collateral flow is present. [9] Neurological symptoms such as limb paralysis, trouble communicating, vision impairment, or a sudden unexplained headache may occur prior to a haemorrhage caused by an enlarging aneurysm putting pressure on the surrounding tissue or a blood leak into the subarachnoid space. [9][10]

Cognitive dysfunction after a stroke is usual, but it is underdiagnosed and has a poor prognosis. In 40-70 percent of stroke patients, there is some degree of cognitive disability. Cognitive impairments are classified into many categories, including: concentration, memory, and executive function (Focus attention, sustained attention, selective attention, and divided attention), recollection (Visual memory, auditory memory, working memory, episodic memory, semantic memory, working memory, and procedural memory), Role of the Executive (Initiation, processing speed, problem solving, planning), Perception and application (Visuo-spatial, visuo-perceptual, Unilateral neglect, inattention, apraxia, agnosia, prosopagnosia), Language impairment like Broca's, Wernicke's, transcortical motor/sensory or mixed, conductive, global aphasia. [13] According to current research, if patients are examined during the stroke phase, up to two-thirds of them will have cognitive impairment. Patients with post-stroke cognitive dysfunction have diminished performance, are more distressed, and have a higher mortality rate. It's a hidden expense and it's easy to overlook if you're not looking for it.[14]

More so when we consider all of this impairment after a stroke, which makes it more difficult for a person to have a successful physical recovery, affecting the patient's coping capacity to recover with regard to social support and a positive attitude about his progress, causing the patient to become irritated, give up, and negatively impacting his overall health. [15] In contrast, following a stroke, particularly in the right hemisphere, a variety of psychological changes can occur, the most common of which are depression and anxiety. [19] Furthermore, previous research suggests that post-stroke anxiety is widespread and long-lasting, and that this is due to a sense of powerlessness and confusion about the future. [20] As a result, the mainstay of post-stroke patient care should be a proper psychometric assessment. There is a connection between cognitive processes, emotions, and anxiety, according to evidence. [18]

Physiotherapy can be considered a good approach to overcome the determining problems, the use of the more active extremities in a functional training strategy promotes synaptic reorganization in the brain. Low-intensity recovery will begin as soon as the patient is medically stable, which is usually within 72 hours. Early on, popular traditional therapy focuses on physical aspects such as stretching, AROM, and PROM exercises to enhance flexibility and joint integrity, tonal management, and positioning techniques. Rolling, supine to sit and sit to supine, bridging, sitting, sit to stand and sit-down transitions, standing, and modifies are all examples of functional training exercises to enhance postural balance and functional mobility. Depending on the severity of the stroke, plantigrade can also recommend interventions to enhance upper and lower extremity functions, as well as balance training. Although relaxation technique may be considered a useful tool determining a positive emotional and psychological wellbeing. [17]

Virtual reality (VR) and immersive video games have emerged as promising therapeutic approaches in stroke recovery in recent years, both for cognitive rehabilitation and the treatment of mood and anxiety disorders. Several writers have used Virtual reality-based therapy for stroke rehabilitation, utilizing the features of the technology. [21] Virtual Reality is the use of immersive stimuli generated by computer hardware and software to allow users to communicate with a virtual world that looks and feels natural. VR has been shown to relieve stress and improve mood in those who live in isolated cramped environments by providing exposure to nature. [20] With recent advancements in interactive technologies, a lively virtual space interface could be developed where the world attracts the participant patient's interest as a ground-breaking way to overcome the challenges of conventional therapeutic stroke therapy. [23] [20]

The aim of this research is to test the results of a hybrid rehabilitative technique, using virtual reality induced environmental and habitual navigation in various environments with the skill of self and automatic navigation and relaxing in the virtual reality, which is accomplished by a head mounted virtual reality interface to provide a 360-degree live immersive experience for a stroke patient. [20][23][24] This could allow for improvements in psychometric parameters such as anxiety and depression, which could help enhance the impaired cognitive realm as well as the physical rehabilitation of the affected patient in stroke patients. [20]

Materials and Methodology

Study was conducted in the In-patient department (IPD) Of Medicine Pravara Rural Hospital and Department of Neuro physiotherapy, Dr. APJ Abdul Kalam College of physiotherapy, PIMS, LONI. The sample was collected from Department of Medicine, Pravara Rural Hospital Loni. The Duration of the study was 2 Years. Study design of the study was Pre-post experimental study. Sample size for the study was calculated and was 20 participants, which were divided into two groups, 10 participants in group A and 10 participants in group B. Sampling method used was simple random sampling. Study population which was included in the study was Acute Stroke population. Participants admitted under condition of stroke, acute in condition at Pravara Rural Hospital, PIMS, Loni. were allowed to participate for the study.

EQUIPMENT USED: - Virtual Reality Device (Type: Headset, Head mounted device)

Fig.1

Control the Virtual World

Bluetooth versions: Bluetooth V3.0, that can be used for VR headsets and also for normal remote functionalities as shown in the manual.

The effective distance: 2 – 10m
Battery: 2pc AAA 1.5V (Battery Not Included)
Compatible with iOS, Android system and PC

360° JoyStick
For Navigation & movement while playing games

On/Off Button & Toggle Button
Press to On/Off & to go Back

Ok Or Conformation Button
Press Ok Button to Select & Press mouse button to get a cursor

Selection Criteria: -

Inclusion criteria: -

1) Both male and female participant. 2) Participant age group above 40 to 60 yrs. 3) First episode of unilateral stroke with hemiparesis. 4) Patient who are diagnosed with investigating reports of Acute stroke on computed tomography (CT) or Magnetic Resonance Imaging (MRI) 5) Ability to follow instructions and perform the exercise programs. 6) Patients who are willing to participate.

Exclusion criteria: -

1) Patients with any Visual Impairment viz. Hemianopia, Neglect, Diplopia, Reduced Visual acuity, ptosis, Anisocoria and Nystagmus. 2) Patients with Significant musculoskeletal abnormalities or pain, cardiovascular disease, or respiratory disease that would interfere with study procedure or affects safety. 3)Patient with severe cognitive impairment.

Procedure

The study received ethical clearance from the Institutional Ethical Committee (PIMS/CPT/IEC/2020/72). All the participants referred were screened according to the inclusion and exclusion criteria. The informed written consent was obtained from the participant regarding the procedure prior to the

study. 23 participants with acute stage of stroke were screed included in the study. The participants were screened and after finding suitability according to the inclusion and exclusion criteria, they were requested to participate in the study. They were explained about the study and the intervention. The participants were briefed about the nature of the study, duration of intervention and the intervention being used and were explained in the language best understood by the participants. The demographic data was obtained and the detailed assessment was done. The sample size of the study was 23 participants. Where 23 participants participated in which the patients were divided into 2 groups. Group A and Group B.

Where experimental Group was given Conventional Rehabilitation and VR induced program with Environmental and Habitual training – 4 wk. (45 min/d, 4 days/wk.) Which included Environmental Navigation and Habitual Navigation i.e., at the first week of training the navigation was performed using joystick by the therapist and navigating in different environment viz. Park and under water scene, further when the patient was comfortable navigation was automated with the normal walking speed where patient has to focus on the environment and remember the environment and the place and get familiar with it in which environment like FARM walk, Village walk and Temple scene where used to navigate in the virtual space. Lastly when the patient was comfortable after a week self-navigation in sitting standing and walking where the patient was himself supposed to move with the environment in control, where the environmental scene was Temple, Village and a traffic spot. Task like active exercises of UE and LE were added with navigation when the patient was easily able to navigate by self. After each navigation a virtual relaxation environment was presented where the patient has to relax in the soothing relaxing environment with calming sound.

Group B was given Conventional rehabilitation and program which includes for -4 wk. (45 min/d, 4 days/wk.) The patients were asked to sit or lie comfortably on a bed, with the therapist standing on the affected side. The movement was driven by cueing (verbal and

motor). Passive range of motion, Active Assisted range of motion, and Active Assisted range of motion were used in the physical activities for the upper and lower limbs, respectively. For enhancing postural control and functional mobility strategies such as rolling, pelvic bridging, supine to sit, sit to supine, sit to stand, standing, transfers, and assisted walking, facilitation techniques such as short stretches, heavy joint compressions, and Proprioceptive Neuromuscular Facilitation (PNF) were used. Mat activities included prone on elbow, prone on side, and quadripod. Language training (alphabet, sentences, and numerical), colours recognition, picture and number identification, and drawing figures were all part of the cognitive training. As the patient's condition improved, gait and locomotor retraining, as well as balance retraining, were provided. Each patient received 45 minutes of counselling, with rest periods in between.

Before treatment pre assessment was done and after 4 weeks post assessment was done. Then all the participate were tested with, Hamilton Depression Rating Scale, Hamilton Anxiety Rating Scale for Psychological status. Montreal cognitive assessment Scale (MOCA) for the Cognitive functions and Functional Independence Measure (FIM) for Physical Recovery.

Outcome Measures: -

Participants are assessed by using scales which was calculated before and after the interventions:

1) Montreal Cognitive assessment Scale.

2) Hamilton Anxiety Rating Scale.

3) Hamilton Depression Rating Scale.

4) Functional Independence Measure

DATA ANALYSIS AND RESULT

Age distribution in group A and B

The average age of Group A (Virtual Reality + Conventional Physiotherapy) was 54.2 ± 6.25 years and in Group B (Conventional Physiotherapy) was 52.7 ± 6.89 years.

Gender distribution in group A and B

There were 7 male and 3 females in Group A and, receiving Virtual Reality and Conventional Physiotherapy and in Group B, there were 5 males and 5 females receiving Conventional Physiotherapy. The duration of treatment in both the groups was for 4 weeks.

Comparison of post-intervention and post-intervention values of Montreal Cognitive Assessment Scale in group A and B

Table no 1: Comparison of post-intervention and post-intervention values of Montreal Cognitive Assessment Scale in group A and B

Post Intervention	Group A		Group B		Unpaired „t" test value	„p" value	Result
	Mean	SD	Mean	SD			
MOCA	10.1	4.533	7.6	3.627	1.362	0.1901	Not significant

Post intervention MOCA score for Group A and Group B were 10.1 ± 4.533 and 7.6 ± 4.4 respectively. On comparison of Post-intervention MOCA mean scores between Group A and Group B by using unpaired „t" test, it is observed that this difference is Not significant. With the reference of Table 1, Group A shows more scores

in MOCA after 4weeks of duration than the Group B. ($p < 0.1901$ and $t = 1.362$ with df = 18).

Comparison of post-intervention and post-intervention values of Hamilton Anxiety Rating Scale in group A and B

Table no 2: Comparison of post-intervention and post-intervention values of Hamilton Anxiety Rating Scale in group A and B

Post Intervention	Group A		Group B		Unpaired „t" test value	„p" value	Result
	Mean	SD	Mean	SD			
HARS	7.9	3.315	8	2.390	0.07827	0.9385	Not significant

Post intervention HARS score for Group A and Group B were 7.9 ± 3.315 and 8± 4.4 respectively. On comparison of Post-intervention HARS mean scores between Group A andGroup B by using unpaired „t" test, it is observed that this difference is Not significant.With the reference of Table 2, Group A shows less scores in HARS after 4weeks of duration than the Group B. (p<0.9385 and t=0.07827 with df= 18).

Comparison of post-intervention and post-intervention values of Hamilton Depression Rating Scale in group A and B

Table no 3: Comparison of post-intervention and post-intervention values of Hamilton Depression Rating Scale in group A and B

Post Intervention	Group A		Group B		Unpaired "t" test value	"p" value	Result
	Mean	SD	Mean	SD			
HDRS	7.6	3.026	7.7	3.335	0.07022	0.9448	Not significant

Post intervention HDRS score for Group A and Group B were 7.6 ± 3.026 and 7.7± 2.39 respectively. On comparison of Post-intervention HDRS mean scores between Group A andGroup B by using unpaired „t" test, it is observed that this difference is Not significant.With the reference of Table 3, (p<0.9448 and t=0.07022 with df= 18).

Comparison of post-intervention and post-intervention values of Functional independence measure Scale in group A and B

Table no 4: Comparison of post-intervention and post-intervention values of Functional independence measure Scale in group A and B

Post Intervention	Group A		Group B		Unpaired „t" test value	„p" value	Result
	Mean	SD	Mean	SD			
FIM	88.6	8.501	74	10.165	3.484	0.0026	Very significant

Post intervention FIM score for Group A and Group B were 88.6 ± 8.501 and 74± 4.4 respectively. On comparison of Post-intervention FIM mean scores between Group A and Group B by using unpaired „t‟ test, it is observed that this difference is Very significant. With the reference of Table 4, Group A shows more scores in FIM after 4weeks of duration than the Group B. (p<0.0026 and t=3.484 with df= 18).

Discussion

This study was conducted to find out the effects of Virtual reality induced environmental and habitual navigation and conventional physiotherapy in between the groups on psychological, cognitive function and functional recovery in patients with stroke.

In the present study, MOCA, HARS, HDRS and FIM were obtained from the patients with stroke in both group A and group B. Before intervention data was obtained. Treatment was given to the patients according to their group and again after 4 weeks, data was collected in data sheet and comparison within the group and between these two groups was done.

The result of this study showed that MOCA score was increased in Group A significantly than Group B, HARS and HDRS score were decreased in both Group A and B, while FIM score were significantly increased in group A, after 4 weeks of intervention after comparing these scores with pre intervention scores by using paired‚ t'' test. It also revealed that after receiving the treatment patients showed more improvement in group A after 4 weeks of intervention.

Improvement in Montreal cognitive Assessment (MoCA):

The Montreal Cognitive Assessment was used in this analysis. It was founded in 1996 by Ziad Nasreddine in Montreal, Quebec. It was validated in the context of minor cognitive dysfunction and has since been clinically adopted in a variety of other environments. [32][33]

Rosaria De Luca et al. investigated the impact of virtual reality on neuropsychiatric conditions after stroke, where psychological parameters such as anxiety and depression were measured in relation to cognitive function. The study found a slight increase in cognitive performance, especially attention, and the author stated that "nonetheless, only at the end of the training in immersive simulated world that is in the CAREN system, they observed substantial improvement in cognitive and behavioural functioning." While the simulated virtual world was just a minor aspect of the research, the patient's concentration systems, visuo-spatial skills, and executive functioning improved significantly. In addition, the report proposed that further trials be conducted to validate the therapeutic feasibility of these interventions in patient populations. [20]

In this study, virtual reality consists of Augmented three-dimensional universes with different landscapes i.e., different environments. Virtual reality is thought to enhance neuroplasticity and motor learning following stroke by activating brain areas involved in motor planning, learning, and execution. The study concentrates on stroke patients who had cognitive dysfunction and neuropsychiatric issues such as anxiety and depression which is tackled with Immersive environmental and habitual virtual reality navigation. [34]

Improvement in Hamilton Anxiety Rating Scale:

The Hamilton Anxiety Rating Scale (HAM-A) is a psychiatric assessment that physicians use to assess the level of anxiety in their patients. It was first published in 1959 by Max Hamilton. Clinicians often use the scale. For medicinal use only. The scale is regarded as a psychological rating of the extent of anxiety, where anxiety may refer to "an emotional condition, a drive, a reaction to a specific situation, a personality trait, and a psychiatric illness. Since it was one of the first anxiety rating scales to be issued, it was used to measure the psychiatric state of the patients in this report. [36]

Anxiety, according to Hoehn-Saric et al, is a biological alert mechanism that prepares us for action. During acute stress, anxiety is marked by a series of hormonal shifts in the body, autobiographical memory, the patient's past, and the social condition. According to certain research, relaxation and breathing techniques have a soothing and stabilizing impact on the autonomic

nervous system. While it is regarded as one of the most successful and beneficial approaches for stress and anxiety relief, there are no findings in the literature that show its efficacy in patients with stroke and neuropsychiatric symptoms. [20]

Calabro et al. have demonstrated that robot-assisted movement training with a robotic avatar would improve not only motor control (such as gait, posture, and muscle force), but also mood, perception, and coping strategies. Indeed, enhanced input during robot-assisted gait appears to be a promising method of not only promoting gait and physical activity, but also of improving psychological and cognitive status, especially in the executive phase. [20]

Similarly, De Luca et al. reported in their study that training in the immersive simulated world, i.e., the "CAREN System," resulted in a substantial change in cognitive and behavioural functioning. Indeed, when the psychometric tests were compared at the conclusion of the integrated method the patient showed significant change in concentration systems, visuo-spatial skills, and executive functioning. Furthermore, the result of De Luca analysis supports the use of the anxiety scale among people with stroke. Thus, the psychometric parameters are affected in consideration of stroke and also could be tackled through the virtual reality training, however, further research is needed to confirm these findings and examine the sensitivity of improvement in Anxiety Level. [20]

Improvement in Hamilton Depression Rating Scale:

The Hamilton Depression Rating Scale (HDRS) is a multi-item assessment used to assess depression and as a tool to measure rehabilitation. Max Hamilton first published the scale in 1960, and it was updated in 1966, 1967, 1969, and 1980. The questionnaire is intended for adults and is used to assess the seriousness of their depression by probing mood, remorse, suicidal ideation, insomnia, frustration or retardation, fear, weight loss, and somatic symptoms. [37]

Illness or accident can have an impact on your physical health, but it can also have an impact on your mental health. When people have a stroke, it causes a variety of signs and symptoms that result in the individual experiencing a series of impairments in later life. This reduces activity, makes the individual dependent on others for necessities, and lowers the quality of life, while also limiting people's occupational and social involvement. These ramifications will have a significant effect on social well-being. [42] Depression and anxiety are the most prominent mental health issues for stroke survivors. The person with stroke's key aim is to preserve a healthy quality of life and improve physical functional freedom.

Chang Hyung Lee et al. researched the association between stroke, cognitive tests, and depression in a paper, where they educated the patient with virtual reality, which supported the results of the current research, where depression scale was taken into account. This resulted in less depression in stroke patients, which improved their mood. [34]

Martina Maier et al. discovered that virtual reality experience decreased depression levels in the samples. That was attributed to the reduction of rumination, a recognized symptom of depression, according to the focus regeneration theory proposes, occurs when a patient effectively breaks away from repetitive physical and mental activities and moves from an effortful, directed concentration to an interest-driven attention, all of which was accomplished by creating an enjoyable environment that was sensory rich, coherently arranged, and allowed for exploration. Training-induced improvements in attention or memory may have resulted in a decrease in depressive levels in the study. Alternatively, the conditioning caused a mood shift, which led to functional development. [34]

Improvement in Functional Independence Measure:

The Functional Independence Measure (FIM) is a widely used functional measure in inpatient therapy that has been thoroughly researched and tested in this setting. It is one of the most commonly used devices in recovery

medicine for assessing disease and dependency. As a result, it was used in this study to measure the patients' functional rehabilitation. [39]

Inouye et al. used functional independence test ratings to assess factors influencing functional outcomes in stroke patients following inpatient care. Total FIM scores at discharge correlated positively with total FIM scores at admission and were negatively correlated with age and onset-to-admission interval, according to Spearman's rank correlation system (OAI). Total FIM scores at the time of admission were the best predictors of total FIM scores at discharge. The type of the stroke, gender, duration of hospital stays, and OAI, on the other hand, were not linked to total FIM scores at the time of discharge. Since the combined scores at admission and discharge is heavily correlated, the scores at admission will be used to establish a recovery regimen, notify the patient and family of the likelihood of success, and evaluate the volume and level of treatment provided in the home or discharge placement. [39]

Heruti et al. looked at improvements in Functional Independence Test scores in 315 stroke patients. a favourable relationship was found between increasing functional and cognitive FIM scores. A similar research looked at the relationship between neurological and motor defects and found that following a stroke, patients encounter deficits in a variety of tasks, from movement to speech and self-care. These restrictions have a detrimental impact on travel as well as the social and vocational facets of training. [41]

According to Arsic et.al, study on Functional Independence and Executive Functions, there is a correlation between mild cognitive dysfunction and functional independence. Stroke patients with cognitive disability have slightly lower degrees of mental freedom in all FIM domains than patients without cognitive impairment. [42]

According to the findings of the study, stroke patients with good executive functions have a higher level of functional independence in all tested realms, especially self-care and socialization. [41][42]

Thus, the current research shows that virtual reality training caused by environmental and habitual navigation improved cognitive change in the experimental group rather than the control group. This research found that therapeutic and cognitive rehabilitation therapy had a good short-term effect in terms of functional recovery for stroke survivors.

Conclusion

The said study revealed that virtual reality induced environmental and habitual navigation training along with conventional therapy is more successful as compared with conventional therapy alone for the management of cognitive impairment especially Attention, Visuo-Spatial Execution, Conceptual Thinking and orientation which further enhances the impact on the psychological condition, it reduced psychological effects increased individuals coping ability which resulted in improved functional recovery during this time of Acute stroke condition, where a stroke patient normally experiences, i.e., Anxiety and Depression.

Limitation of Study

1. The study was conducted on patients with Acute Stroke Patients.

2. The study was conducted on acute stroke patients with the incidence up to 1 week-6 months.

3. The study included smaller sample study

4. The study was conducted on limited age group (40-65 years)

5. The intervention was done only for 4 weeks i.e., a short-term study

6. The study was limited to Pravara Rural Hospital.

study is self.

Conflict of Interest: None

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Adherence to Multidose Hepatitis B vaccination in a Tertiary Care Centre: A Retrospective Cohort Study

Swarup Kumar Patnaik[1], Manoj Kumar Sahu[2], Trilochan Sahu[3], Kanishka Uthansingh[4], Sambedana Mohanty[5]

[1]DM Resident, [2]Professor and HOD, Department of Gastroenterology, [3]Professor, Department of Community Medicine, [4]P.h d Scholar, Department of Gastroenterology, [5]Assistant Professor, Department of Community Medicine, Institute of Medical Sciences and SUM Hospital

Abstract

Background: Globally out of 200 crore population who are getting exposed to the hepatitis B virus (HBV), about 350 million are chronically carrying it resulting in 0.5 to 1.2 million deaths each year . These mortalities are due to chronic hepatitis, cirrhosis, and hepatocellular carcinoma (HCC). Horizontal transmission in early childhood and parental transmission at any age are the important routes of transmission. This study was conducted with following objectives.

(a) To assess the prevalence of adherence to Hepatitis vaccination.

(b) To associate this adherence with demographic factors.

Methodology: After receiving approval from the Institutional Ethics Committee a record based retrospective cohort study was conducted at Gastroenterology and Hepatology OPD of IMS and SUM Hospital, Bhubaneswar. Data regarding all the patients who have received First dose of Hepatitis Vaccine from January 2019 to December 2019 were followed up till June 2020 to find out how many of them have revisited to obtain second dose as well as third dose of vaccine. Their demographic characteristics collected from the immunisation register. Data was entered and analysed using SPSS vs 21 using appropriate statistics.

Results and conclusion: Total 1134 subjects have received the first dose of Hepatitis B vaccine. Mean age of the participants is 36±15yrs. First dose taken by 453(39.9%) people, 324(28.6%) had completed the schedule by taking the final dose of vaccine. Hardly one third of the patients adheres to the schedule and completes it. Inadequate vaccination makes the patients vulnerable to risks of Hepatitis B and its morbidities.

***Kew-words**- Hepatitis B Virus (HBV), Vaccination, Health care workers (HCW), Hepato-cellular Carcinoma (HCC)*

Introduction and Problem Statement:

HBV DNA virus that belongs to Hepa-dna-viridae family causes Hepatitis B infection .It is both acute and chronic in nature. Acute hepatitis B results in acute inflammation and hepatocellular necrosis. Due to persistent stay of hepatitis B surface antigen [Hbs Ag] in the blood or serum for more than six months, chronic hepatitis B results which may or may not be associated with active viral replication and hepatocellular injury. Among neonates young children the risk of chronicity is (90%) and (20-60%) respectively as compared to (5%) among adults.[1,2] Hepatitis B infection can result in liver cirrhosis and cancer which are most of the times fatal.[3,4]

Corresponding Author:
Dr Sambedana Mohanty
Assistant Professor, Department of Community Medicine, Institute of Medical Sciences and SUM Hospital
Email i.d-sambedana87@gmail.com

It accounts for (15 to 40)% of infected cases.[4]

Burden in World: Hepatitis B Virus (HBV) infection is a global public health problem and the tenth leading cause of deaths globally. It has been estimated, nearly 2 billion of the population is infected with HBV worldwide that results in 350million chronic cases and 2 million annual deaths.[2-3,5-10]

According to WHO around 257 million people are living with hepatitis B surface antigen positive.[11,12] From a meta-analysis, the prevalence of HBV among general population was reported to be 2.4% and among tribal population 15.9%.[13]

Globally, Chronic viral hepatitis is responsible for almost 1 million deaths .[4] Hepatitis of all types in toto contributes as seventh leading cause of worldwide mortality. According to The 2015 WHO Global hepatitis report about 3.5% of the general population i. e 257 million population are infected with Hepatitis B virus out of which 68% of the persons live in sub- Saharan African and Western Pacific regions (4)At the other hand The 2016 Polaris Observatory study found that around 3.9% of the World's population i. e 292 million persons are suffering from Hepatitis B infection. It was further estimated by the collaborators that out of total infected persons only 10% (29 million) were detected to be infected and among them only 1.4% (1.8 million) were in children who aged less than 5 years. African, Western Pacific, and Southeast Asia regions contribute to about 80% of the cases worldwide.[4]

HBV infection resulting in cancer attributes to million deaths worldwide annually.[10]

In 2015, 887,000 deaths occurred worldwide due to complications related to chronic HB virus infection.[12]

Burden In India:

In India, HBsAg prevalence among the general population ranges from 2 to 8%, which places India in an intermediate HBV endemicity zone and India with 50 million cases, is also the second largest global pool of chronic HBV infections. [6,7,9]

India falls in the intermediate endemicity zone with an average prevalence of 4%. Pockets of higher endemicity are found in tribal areas where the high burden is maintained through intra-caste marriages, tribal customs, illiteracy and poor exposure to health care resources.[7] In India it is estimated that 2 to 10% of the population are infected with Hepatitis B virus which accounts to 40 million .[1,8] Annually over 100,000 Indians die because of disease related with HBV infection.[8]

Next to Hepatitis E, HBV is the most common cause for acute hepatitis in India being responsible for nearly one-third of acute viral hepatitis patients.[9]

Viral hepatitis is one of major public health problems in India. On an average about (3-4) % of the population carry Hepatitis B virus antigen. In India, 40% of Hepato-cellular Carcinoma (HCC) and 20-30% cases of cirrhosis are due to chronic HBV infection. About 4.7% population i. e 56.5 million are carrier for Hepatitis B carrier rate in India.[1]

Risk factors:

Blood to blood contact, mother to child transmission, unprotected sexual intercourse and sharing salon equipments are the most important routes of transmission of Hepatitis B from one individual to another.[8]

Sexually active heterosexual adults with more than one sex partner in the prior 6 months ,man or woman having history of sexually transmitted disease; men having sex with men; illicit injection drug users, haemodialysis patients and persons at occupational risk of infection are vulnerable to get infected with Hepatitis B.[1,5]

Similarly, recipients of multiple blood/ blood products transfusion, prisoners, migrants and truckers and first degree relatives and family members like mother, siblings, spouse and children, of persons affected with viral hepatitis are also at risk of acquiring the infection.[1]

Horizontal transmission in early childhood (mostly from family contacts) and to lesser extent by perinatal transmission are most common modes of transmission

in India. Due to contact of non-intact skin or mucous membranes with tears, saliva or blood containing HBV-infected secretions or through sharing of toothbrushes horizontal transmission occurs.[14]

There is even chance that patients remain asymptomatic for years and unknowingly may transmit the infection to others via perinatally, percutaneously, sexually , or through close person-to-person contact (e.g., open cuts and sores).[4]

Health care workers (HCW):

Health care workers (HCW) are defined as persons whose activities involve contact with patients or with blood or other body fluids from patients in health care or laboratory settings. They are at occupational risk of exposure to blood borne pathogens like Hepatitis B virus (HBV). In developing countries only 40-60% HBV infections in HCW are attributed to percutaneous occupational exposure due to sharp injuries .[10,15] Healthcare workers always have a high risk of getting exposed to many blood-borne pathogens like HIV, Hepatitis B, and Hepatitis C.[6] There is severe risk of infection among HCWs because of too many virus carriers in the surrounding population, frequent exposure to blood and other body fluids as well as high contagious nature of HBV. Performance of invasive procedures, mucocutaneous exposure while examining the patients physically as well as accidental exposures due to improper disposal of sharps makes HCWs vulnerable to Hepatitis B infection.[9]

Amongst all the body fluids blood has the highest amount of HBV titres and hence is the major vehicle for transmission in the healthcare setting. [6,11]

Due to inadequate sterilisation process and improper hospital waste management there has been rise and spread of hepatitis B as 10 to 20% health care waste is generated to cause hazards.[8] There has been rise and There is (6 to 30)% risk of acquisition of HBV infection in non- vaccinated person after single exposure .[11]

Health-care delivery is responsible for transmission of hepatitis B virus (HBV) to both health-care staff as well as patients. The risk of transmission is dependent on frequency of exposure as well as to how much extent an individual has come in direct contact with human blood and body fluids. HCWs are susceptible to acquire infections from the patients as well as vice versa. The prevalence of HBV infections among HCWs is 14.4%. Dentists, physicians nursing staff, dialysis, and laboratory staff are at highest risk of getting infected.[10]

Needlestick injuries (NSIs) have been defined by The National Institute for Occupational Safety and Health, Centres for disease control and prevention(CDC), as "those injuries caused by needles such as hypodermic needles, blood collection needles, intravenous (IV) stylets, and needles used to connect parts of IV delivery systems." Out of 35 million health-care workers (HCWs) around 2million sustain NSIs every year, as a result of which they are at risk of exposure to blood-borne infectious agents including HBV.[14]

Through NSIs risk of transmission of HBV is (6%–30%).[5,14]

As compared to adult general population, HCWs are four fold more at risk of acquiring the Hepatitis B infection.[3,5,11]

After percutaneous exposure to blood the risk of infection with hepatitis B is about 30%. [5]

The risk of HBV infection is determined by the degree of contact with blood in the workplace and also HBsAg to the hepatitis B-e antigen (HB-e Ag) status of the source person. There is evidence that HBV is able to survive in dried blood, at room temperature, on environmental surfaces, for a long time. It is found in several other body fluids, including breast milk, bile, cerebrospinal fluid, faeces, nasopharyngeal washings, saliva, semen, sweat, and synovial fluid. Degree of exposure to the infected body fluids or blood-contaminated sharps such as needles and other medical instruments, and the duration of employment in an occupational risk category are important determining factors.[6]

It has been estimated that about a million HCWs are suffering from cut and puncture injuries per year. As

per the report of The Department of Health and Human Services, Centres for Disease Control and Prevention (CDC) United States "the risk of infection is depends on the no. of HBV carriers prevalent ,how frequently the HCWs are exposed to blood and body fluids and how infective is the virus".[3]

Vaccination:

A vaccine against hepatitis B has been available since 1982 with the efficacy 85-90% in preventing infection.[8] Routine immunization against hepatitis B has led to a significant reduction in the prevalence of chronic HBV infection among many countries. Based on the global experience, it is liable that an effective childhood immunization program will reduce the burden of infection in this country.[9]

Immunisation along with strict adherence to infection control protocol is one of the most effective prevention strategies for the protection against hepatitis B infection, especially in high-risk groups including the HCWs.[6,10]

As it indirectly helps in the prevention of hepatocellular carcinoma it is considered as the first anticancer vaccine.[8,10]

As per the standard schedule vaccine has to be administered in three doses at 0-, 1-, and 6-month interval. There should be at least 4weeks gap between 1st and 2nd dose and 8weeks gap between 2nd and 3rd dose respectively. It has to be injected through intramuscular route in the deltoid region with a 1–1.5-inch long needle.[10]

Compulsory availability of hepatitis B vaccination services at all hospitals along with postexposure prophylaxis (PEP) can only prevent HCW from getting infected with hepatitis on occupational exposure.[10] The above strategy has infact drastically reduced the occupationally acquired HBV infection in many countries.[10,12]

World Health Assembly in 2016 through its The Global Health Sector Strategy on viral hepatitis called for the elimination of viral hepatitis by 2030. WHO recommends that Hepatitis B vaccine to be administered at birth followed by two or three doses .[12]

In India Hepatitis B vaccine was introduced in the Universal Immunization Program (UIP). It was initially started in 2002-2003 on a pilot basis in 14 cities and 33 districts.

In Phase I it was expanded to ten states in 2007–2008. In Phase 2 i. e 2011–2012 is then extended to the entire country. Vaccine coverage in India has thus increased from 28.9% in 2007–2008 to 62.8% in 2015–2016.[7,12] Self-reported hepatitis B vaccination coverage among adults at risk for HBV infection which was 30% in 1981 increased to 45% in 2002-2004 . It has probably resulted in 35% reduction (from 3.7 to 2.4 per 100,000 populations) in acute hepatitis B incidence during this period. This justifies the need of people at risk of getting infected with Hepatitis B to get vaccinated.

Sero- protection i. e (Anti-HBs level \$10 m IU/ml) has been determined to be 20-30%, 75-80%, and 90-95%, following first, second and third dose respectively.[6]

Policy of administration of Hepatitis B vaccine to at risk individuals has been widely implemented in countries such as UK, USA, and Israel .[3]

Almost all of the children and adults who are receiving the three dose schedule of the vaccine are developing protective antibodies. It has been recommended by the Advisory Committee on Immunization Practices (ACIP) that hepatitis B vaccine should be administered to every individual below 18 years as well as to those above 18 years who are at risk of getting infected.[5]

As per estimates of WHO, in developing countries, on an average (18-39) % of HCWs are vaccinated against Hepatitis as compared to (67-79%) in developed nations.[15]

Objectives:

1. To assess the prevalence of adherence to Hepatitis vaccination.

2. To associate this adherence with demographic factors.

Methodology

After receiving approval from the Institutional Ethics Committee a record based retrospective cohort study was conducted at Gastroenterology and Hepatology OPD of IMS and SUM Hospital, Bhubaneswar. Data regarding all the patients who have received First dose of Hepatitis Vaccine from January 2019 to December 2019 were followed up till June 2020 to find out how many of them have revisited to obtain second dose as well as third dose of vaccine as per the schedule. During their visit to the immunization unit, they were explained about the disease and the benefit of completion of three doses of vaccination, and on the day they received the first dose, a vaccination card mentioning the dates was provided to them. Their demographic characteristics i.e age and gender was also collected from the immunisation register.

Data was entered and analysed using SPSS vs 21 using appropriate statistics.

Results

Total 1134 persons have got vaccinated with the first dose of Hepatitis B vaccine from January 2019 to December 2019.

Table I Illustrates the demographic profile. Among them, 729(64.3%) are males. Mean age of the participants is 36±15yrs.Half of the participants aged from 20 to 40yrs.

Table II indicates the month wise distribution of beneficiaries of first dose of Hepatitis vaccine (n=1134). Most of the beneficiaries had taken their first dose in February (13.8%), March (11.5%), April (11.6%) and November (11.5%).

Table III indicates the distribution of patients according to receipt of the three doses of vaccine. Out of the 1134 first time vaccines 453(39.9%) had taken second dose and 324(28.6%) had completed the schedule by taking the final dose of vaccine

According to Table IV, Out of 1134 candidates, only 324(28.6%) completed the three dose schedule.

Table V infers that No significant association was found with age groups with completion of schedule. Table VI shows that No significant association was found with gender with completion of schedule.

Table-I Demographic profile of beneficiaries(n=1134)

Gender wise distribution	
Male	729(64.3%)
Female	405(35.7%)
Mean Age= 36.4+-15.3years	
Age group wise distribution	
0-9 yrs	10(0.9%)
10-19 yrs	129(11.4%)
20-40 yrs	569(50.2%)
41-60 yrs	347(30.6%)
61-75 yrs	71(6.3%)
>76 yrs	8(0.7%)

Table II Month-wise distribution of vaccination(n=1134)

Jan	103(9.1%)
Feb	156(13.8%)
March	130(11.5%)
April	132(11.6%)
May	42(3.7%)
June	51(4.5%)
July	58(5.1%)
Aug	94(8.3%)
Sept	54(4.8%)
Oct	108(9.5%)
Nov	130(11.5%)
Dec	76(6.7%)

Table-III Distribution of beneficiaries according to receipt of vaccines (n=1134)

Dose	Taken	Not taken
I	1134(100%)	0(0%)
II	453(39.9%)	681(60.1%)
III	324(28.6%)	810(71.4%)

Table-IV Status of three dose schedule(n=1134)

Schedule completed	324(28.6%)
Schedule not completed	810(71.4%)

Table -V Association of age groups with status of completion of vaccination schedule

Age groups	Not completed	completed	X2	P
0-9years	7(70%)	3(30%)		
10-19 years	88(68.2%)	41(31.8%)		
20-40years	410(72.1%)	159(27.9%)	8.132	0.149
41-60years	258(74.4%)	89(25.6%)		
61-75 years	43(60.6%)	28(39.4%)		
³ 76 years	4(50%)	4(50%)		

Table VI- Association of gender with status of completion of vaccination schedule

Gender	Not completed	completed	X2	P
Male	518(71.1%)	211(28.9%)		
Female	292(72.1%)	113(27.9%)	0.139	0.382

Discussion

No studies have been yet done to assess the compliance of general population to multidose Hepatitis B Vaccination. Most of the studies discuss the adherence of healthcare workers to the vaccination schedule.

In a study by Choudhry et al it was found that out of 254 HCWs recruited for the study, 48 (18.9%)were doctors, 93 (36.6%)were nursing staff, 104 (40.9%) were paramedics and rest 9(3.5%) were housekeeping professionals. Among them, 146 i.e 57.5% HCW had received vaccination against HBV. It was analysed that 77% of medical professionals and 43% of the paramedics were compliant towards vaccine. On the contrary housekeeping personnel were not compliant to vaccine .Adherence to vaccine was present among 77(51%) males and 69 (67%) females. Study subjects aged from 19 to 54 years. The mean age at which medical professionals got vaccinated was 30.5 ± 7.3 years whereas that for nursing professionals was 24.7 ± 6.1years.[15]

Siraj et al in their study found that, among 150 cases 69 were medical professionals and 81 were Para-Medical workers. Out of 55(79.7%) medical staff who were vaccinated, 29 (42.02%) had taken 3 doses whereas 26(47%) had taken only 2 doses. Among the 48(59.25%) paramedical staff who were vaccinated 24(50%) and 18(37.5%) had taken 3 doses and 2doses respectively.[8]

In a study by Mangaiyarkarasi et al, out of the 83 HCWs, 37(44.5%) had completed the schedule of HBV vaccine, 15(18.1%) were incompletely vaccinated whereas 31(37.3%) were completely unvaccinated. Out of the 15 who were partially vaccinated, 9(60%) have

received two doses whereas and 6(40%) were vaccinated with only one dose.[14]

Kumar S et al in their study found that 46.2%, 12%, 41% HCW fully vaccinated, partially vaccinated, not vaccinated respectively. [16] Hussain S et al had complete immunization rate of 57.6%, partial 18.5% and non vaccinated 24% respectively.[17] Chandra S et al revealed that 48.5% had got completely vaccinated, 21.8% incompletely vaccinated and 29.7% unvaccinated with hepatitis B vaccine.[18]

Conclusion: Hardly one third of the patients adheres to the schedule and completes it. Failure to complete the schedule makes the patients vulnerable to risks of Hepatitis B associated consequences like Chronic Hepatitis B, Cirrhosis, and Hepatocellular Carcinoma. There is need to raise awareness among public regarding the fact that these adverse events are preventable through three dose vaccination. It has to be supplemented by well organised and clear policies for screening of Hepatitis B and vaccination against it among at risk population.

Limitations-As it is a record based study, hence much information could not be collected. There is scope of Prospective cohort studies in which we can proceed along time and follow up the vaccine recipients to explore the associations of outcomes of Chronic Hepatitis B and its complications with the vaccination status of the patients.

Conflicts of Interest- None

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A Comparative Study to Check Awareness of Food Labeling between Nutrition and Non-Nutrition Undergraduate Students

Tanveer unisa Hyder[1], Avanti Rao[2]

[1]*Postgraduate student Madina Degree and PG College for women,* [2]*Head of the Department of Nutrition of Madina Degree and PG College for women, Himayath Nagar, Hyderabad, Telangana, India*

Abstract

Background: Food labeling can be a very important public health tool in providing consumers with information which may help them to make informed decisions towards choosing good nutrition and health. **Objective:** The main objectives were to assess the awareness and importance of food labeling among students of nutrition and non-nutrition groups and to study the type of information students generally look on the food label while buying a product. **Methods**: A cross-sectional study was conducted at St. Francis College for Women in which 240 undergraduate college girls aged between 18-21 years of age were selected. The questionnaire was used to assess knowledge of the participants towards food labeling. **Results:** The results showed that 89.16% of nutrition and 57.5% of non-nutrition students were aware of FSSAI,78.33% of nutrition and 60.83 % of non-nutrition students were aware of ISI, 80.8% of nutrition and only 12.5% of non-nutrition students were aware of FPO,100% of nutrition and 32.5% of non-nutrition students were aware of trans fat,98.3% of nutrition and 86.66% of non-nutrition students reported that food additives and preservatives affect the state of health, 85.8% of nutrition and 38.33% of non-nutrition students reported that MSG has harmful impact on human health,91.66% of nutrition and 92.5% of non-nutrition students were aware of QR codes. **Conclusion:** The study concluded that those pursuing a degree in nutrition appear to be more capable of interpreting food label information and incorporating that information into a healthy diet than non-nutrition students. Hence, nutrition education can be a powerful tool to create awareness on food label usage.

Key words: Food label, Consumer awareness, Knowledge, Nutrition information.

Introduction

A food label refers to the legally required nutritional or consumer safety information about the food product. The significance of reading food label receives scant attention most of the time. Every educated consumer who cares to enjoy good health should know how to decipher food labels. There is an urgent need for an in depth study to sensitize the population to look into the food labels for wise purchase of foods.[1]

According to the World Health Organization (WHO), food labelling includes "any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal". In general, food labels inform consumers about the composition and nature of products to avoid confusion and protect the consumer against misuse, risk and abuse. Nutrition labelling is the section of information on a food label that specifically declares nutrient content. According to the *Codex Alimentarius,* nutrition labeling is effective when it provides the consumer with information about a food to help him or her to make healthy food choices.

Consumer awareness refers to the individual understanding of their rights as a consumer concerning available products and services being marketed or sold. There is a need of consumer awareness to protect against exploitation, to control over consumption of harmful goods and to construct a healthy society.

Food labels are found to be very important public health tool that is used to promote a balanced diet and enhance the public health and well being. Food labels information assists consumers to better understand the nutritional value of food choices and enables them to compare the nutritional values of similar food products and to make healthy informed food choices based on the relevant nutrition information.[2] As consumers are becoming increasingly aware the relationship between diet and disease, demand for nutrition information increases.[3]

Therefore a small study was conducted to assess awareness among college going students on food labels. Specifically, the study attempts ;

1. To assess the awareness of food labeling among undergraduate students of nutrition and non-nutrition groups.

2. To assess the knowledge of food labeling among undergraduate students of nutrition and non-nutrition groups.

3. To study the type of information students generally look on the food label while buying a product.

Materials and Methods

Selection of area: A survey based study was carried out at "St. Francis Degree College for Women" Begumpet, Hyderabad with the purpose to assess the knowledge and awareness of food labeling among the undergraduate students of different courses.

Sample size: A random sample of 240 participants was selected for the survey. The participants selected for the study were undergraduates. The data was collected among 50% of the students pursuing a degree in nutrition and the rest of the 50% were pursuing a degree in commerce or humanities.

Tools of study: The questionnaire was designed to address the frequency of purchasing packaged foods and the knowledge, awareness, importance and preferences about information on food labels among the students. The questionnaire was pre-tested to check if there was any ambiguity or if the students did not understand the questions. Based on the answers, the questions were then modified. The questionnaire consists of several questions pertaining to the - frequency of purchasing packaged foods, shopping habits of the students, nutrition information, influence of labeling on them. The participant's awareness on-food additives, preservatives and Monosodium glutamate (MSG), manufacturing date, expiry date and best before, FSSAI, ISI and FPO, vegetarian and non-vegeterian mark, trans fat, Unique Selling Propositions (USP) and Quick Response (QR) Codes.

Data analysis: The data was compiled, it was analysed by taking out the percentages of all the samples and bar graphs were used to project the results. Some of the questions were tested by the chi-square test at 5% level of significance *(p= 0.05)* to check if there were any significant differences in the responses of students from the nutrition and non-nutrition background.

Results and Discussion

A total of 240 respondents took part in the study, among them 120 students were pursuing an undergraduate degree in nutrition and 120 students were pursuing an undergraduate degree in commerce and humanities. This study was conducted at St. Francis College for Women, Begumpet, Hyderabad.

Students were asked about the factors that influence them when they purchase a food product. Among the students, 45% of nutrition 52.5% of non-nutrition students were influenced by the brand name and 2.5% of nutrition and 10% of non-nutrition students by the colour of the product. While 28.3% of nutrition and 20% of the non-nutrition students by the price and 24.16 % of nutrition 17.5% of non-nutrition students were influenced by the nutritional information on the food label while selecting a food product.

When the students were asked whether Unique Selling Propositions (USP) influence their choice while purchasing a food product, 88.33% of nutrition and 68.33% of non-nutrition students responded fairly that USP does influence their choice.

Table-1: Level of importance of nutrition information (1=very important) according to nutrition and non-nutrition students

	Nutrition students	Non-nutrition students
	Very important	Very important
Total calories	91.66%	52.50%
Calories from fat	36.45%	40.00%
Total fat	89.16%	42.50%
Saturated fat	63.33%	34.16%
Cholesterol	68.33%	39.16%

Students were asked to assign the level of importance to nutrition information on food labels. Table-1 indicates that 91.66% and 89.16% of nutrition students marked total calories and total fat as very important respectively. While the percentages for other nutrition information such as the calories from fat, saturated fat and cholesterol as marked by the students were almost in the same range.

Table-2: Awareness of students on certified food labels

	Nutrition students	Non-nutrition students
Awareness of FSSAI	89.16%	57.50%
Awareness on the meaning of FSSAI	58.30%	8.33%
Awareness of ISI	78.33%	60.83%
Awareness on the meaning of ISI	-	-
Awareness of FPO	80.80%	12.50%
Awareness on the meaning of FPO	-	-

Table-2 indicates that the majority of nutrition students were more aware of the certified food labels than non-nutrition students. It was also tested statistically, using chi-square test where the results indicated that the nutrition and non-nutrition students differ significantly in terms of the awareness of FSSAI ($\chi^2=25.4$), ISI ($\chi^2=6.81$) and FPO ($\chi^2=93.68$) at 5% level of significance ($p=0.05$).

A similar study was conducted by Premakumari S. and Annapriya R. (2012) which concluded that more number of people checked ISI and AGMARK symbols in food labels when compared to FPO and PFA symbol.[1]

Students were asked about the certified stamped on food products indicated good quality and whether they looked for these labels while purchasing foods. 98.3% of nutrition and 74.16% of non-nutrition students agreed that the certification stamped food products are of good quality. 40% of nutrition and 23.33% of non-nutrition students agreed that they look for these labels while purchasing foods.

Table-3: Order of list of ingredients according to students

	Nutrition students	Non-nutrition students
Ascending order of ingredients	20.8 %	20 %
Randomly	14.16 %	30 %
Descending order of ingredients	31.6 %	9.16 %
Order of nutrient weight	33.33 %	40.83 %

Table-3 indicates the the order of list of ingredients in prepackaged foods according to the students. As per FSSAI, the order of list of ingredients to be followed is the descending order of ingredients and when tested statistically using chi-square test it was concluded that the nutrition students differ significantly from the non-nutrition students in terms of the order of list of ingredients ($\chi^2=19.60, p=0.05$) even though the number who answered correctly was small.

98.3% of nutrition and 86.66% of non-nutrition students reported that they know the symbol for vegetarian and non-vegeterian foods.

When students were asked to what extent reading nutrition labels helped them to make informed food choices, 80.83% nutrition and 20.83% non-nutrition students totally agreed to this statement, whereas 19.16% nutrition and 79.16% non-nutrition partially agreed to this statement.

Table-4: Frequency of use (always) of nutrition information on food packages

	Nutrition students	Non-nutrition students
Brand to buy	91.66 %	44.16 %
Compare types of food	61.66 %	35 %
Checked calorie content	43.33 %	10 %
Determined suitability for family consumption	20.83 %	36.66 %
Help in meal planning	35 %	25.83 %
Determined serving size	68.33 %	19.16 %
Checked storage instructions	34.16 %	21.66 %
Checked cooking instructions	80 %	32.5 %

Table-4 indicates how often students used the nutrition information on food packages. More number of students 'always' checked the brand to buy when compared with other information on food packages while purchasing a product.

A cross-sectional study was conducted by Vemula S. *et al* (2013) which showed similar observations. The study reported that (81%) looked only for the manufacturing date or expiry/best before use. Brand name (85%) was the aspect most commonly checked by

consumers followed by date of expiry (80%). The least checked was the list of ingredients (20%) and less than 40% of consumers across age groups reported that they checked nutritional information on food labels.[4]

Students were also questioned about the function of food labels. 94.16% of nutrition and only 54.16% of non-nutrition students agreed that it helps consumers better understand what is in the foods they eat. When tested statistically using chi-square test, it was concluded that the nutrition students differ significantly from the non-nutrition students in terms of the function of food label ($\chi^2=41.58, p=0.05$).

95% of nutrition and 64.16% of non-nutrition students agreed that the appearance of the food label affects their choice. When tested statistically using chi-square test, it was concluded that the nutrition students differ significantly from the non-nutrition students in terms of the appearance of food labels which influence them while purchasing the foods ($\chi^2=29.48, p=0.05$).

Table-5: Information on manufacturing date and expiry date

	Nutrition students	**Non-nutrition students**
Manufacturing date	1.66 %	1.66 %
Expiry date	4.16 %	47.50 %
Both	94.16 %	50.83 %

Table-5 indicates that students from both the groups look for both manufacturing date and expiry date while selecting a food product.

100% of nutrition and only 32.5% of non-nutrition students responded that they knew about trans fat. 67.5% of non-nutrition responded that they did not know about trans fat. 40% of nutrition and only 5.83% of non-nutrition students were aware of the meaning of trans fat. 17.5% of nutrition and 44.16% of non-nutrition students believe that the amount of trans fat present on the food labels is true.

89.16% of nutrition 81.66% of non-nutrition students reported that in some food products, food additives and preservatives were added but not mentioned on the food label. When tested statistically using chi-square test, it was concluded that the nutrition students differ significantly from the non-nutrition students in terms of whether they think that the food additives and preservatives are added but not mentioned on the food label ($\chi^2=1.97, p=0.05$).

98.3% of nutrition 86.66% of non-nutrition students reported that food additives and preservatives affect the state of health. When this was tested statistically using chi-square test, it was concluded that the nutrition students differ significantly from the non-nutrition students with respect to the food additives and preservatives affecting the state of health ($\chi^2=8.72, p=0.05$).

85.8% of nutrition 38.3% of non-nutrition students agreed with the statement that MSG has a harmful impact on health, while 14.16% of nutrition 61.66% of non-nutrition students disagreed with this.

When students were asked if they check for allergy advice if they are allergic to certain substances before purchasing food, 66.66% of nutrition 39.16% of non-nutrition students agreed to this statement.

A cross-sectional study was conducted by SubbaRao M. *et al* (2016) among adolescents in Kolkata which reported that only 10% always read allergen information.[5]

Students were questioned whether they believed in the claims of milk based malted health drinks, that their

products would 'increase height' and 'make the kids more intelligent', only 10% of nutrition and 20.83% of non-nutrition students believed that to be true. When this was tested statistically using chi-square test, it was concluded that the nutrition students differ significantly from the non-nutrition students in terms of the claims of milk based malted health drinks, that their products would 'increase height' and 'make the kids more intelligent' were true ($\chi^2=4.61, p=0.05$).

91.66% of nutrition 92.5% of non-nutrition students were aware of QR codes, while 8.33% of nutrition 7.5% of non-nutrition students were not aware of QR codes. When tested statistically using chi-square test, it was concluded that the nutrition students do not differ significantly from the non-nutrition students in terms of awareness of QR codes   ($\chi^2=0.0004, p=0.05$).

Summary and Conclusion

Food labels information assists consumers to better understand the nutritional value of food and to select suitable foods for their health conditions. As consumers are becoming increasingly aware of the relationship between diet and disease; their demand for nutrition information increases. Efforts were made to conduct an in depth study to understand the impact of the nutrition education on the usage of food labeling among nutrition and non-nutrition students.

Food labels communicate the relevant information that a consumer needs to know about the product, although it is underutilized by the students. In terms of education, nutrition background students had better awareness compared to the non-nutrition group. They have a better understanding of the information provided in nutrition labeling, thus may interpret it well. People with nutrition background generally reported better food label use and checking behaviours compared with those

without this knowledge. Nutrition students were able to better recognize the essential nutrients required to be mentioned in the food label and assign the importance to them.

Therefore, increasing consumer awareness and enhancing access to nutrition information on labels is very important to help consumers in making right decisions about food purchases. This study adds to the understanding of the use of label information in both groups.

Conflicts of Interest: There are no conflicts of interest.

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Refraction Outcome after Phacoemulsification in High Myopia with and without a Capsular Tension Ring

Vidyapati Mangunkusumo [1,2], Denny Agustiningsih[3], Suhardjo SU[1],Wasisdi Gunawan [1], Wahyu Srigutomo [4], Tjahjono D Gondhowiardjo[2]

[1]*Department of Ophthalmology, Faculty of Medicine Public Health and Nursing Universitas Gadjah Mada, Yogyakarta, Indonesia,* [2]*JEC Eye Hospitals & Clinics, Jakarta, Indonesia,* [3] *Department of Physiology, Faculty of Medicine Public Health and Nursing Universitas Gadjah Mada, Yogyakarta, Indonesia,* [4]*Physics Department, Faculty of Mathematics and Natural Sciences, Bandung Institute of Technology, Bandung, Indonesia*

Abstract

Purpose: To compare the refraction outcomes after phacoemulsification in high myopia implanted with and without a capsular tension ring. **Material and methods:** This retrospective study reviewed all patients with an axial length of 26 mm or more and had phacoemulsification with an intraocular lens (IOL) between January to December 2019. Pre-surgery biometric measurement and IOL power calculation were performed by the Barret Universal II formula. The chosen IOL power to be implanted with the predictive refractive outcome (PRO) was recorded. One month post-surgery, auto-refractive objective refraction in Spherical Equivalent (SE) was measured and compared to the PRO. **Results:** Fifty four eyes from 38 patients had a mean age of 57.15 ± 9.73 (SD). In the non-CTR group, significant statistical difference between the pre to post-surgery outcomes of objective refraction was observed ($p = 0.007$), while in the CTR group there was no significant statistical difference ($p = 0.830$). The CTR achieved an accuracy of $0.01\ D \pm 0.32$ ($p = 0.010$) against $-0.36\ D \pm 0.55$ in the non-CTR group. The CTR group, also reached 88.5% PRO for far vision compared to 53.6% in non-CTR group ($p=0.005$). **Conclusion:** Phacoemulsification with CTR in high myopia resulted in better predictive outcomes.

Keywords: Predictive Refractive Outcome (PRO),Capsular Tension Ring (CTR), Intraocular Lens (IOL), Spherical Equivalent (SE)

Introduction

A Capsular Tension Ring (CTR) is a C-shaped device made of polymethyl methacrylate (PMMA), used to stabilize the capsular bag of crystalline lens during cataract surgery in eyes with zonular weakness. Zonular weakness can occur in post-traumatic cataracts, pseudoexfoliation syndrome, connective tissue disorders (Marfan's syndrome, Ehler Danlos syndrome), eyes that had had vitreoretinal intervention and high myopia.[1,2] The CTR was introduced in 1991 by Hara et al.[1] and for the first time implanted in the human eye in 1993 by Witschel and Legle.[3] Currently, it has evolved into various designs such as Cionni Rings for Scleral Fixation and Ahmed Capsular Tension Segments.[4]

One significant intraoperative observation that led to the idea to implant a CTR in high myopic eyes was the extreme deepening of the anterior chamber that immediately followed after insertion of the phacoemulsfication tip at the start of cataract surgery. This finding was associated with an excessive laxity at the zonules and around the capsular bag.[3]

Implantation of Intraocular Lens (IOL) in the capsular bag could temporarily restore the laxity around and at the capsular bag zonule junction as it was observed in eyes with normal and short axial length.[5] In highly myopic eyes with an Axial Length (AL) of more than 26mm, a standard procedure of intra ocular lens implantation can leads a different course in the forthcoming years. It is hypothesized that in these kinds of preexisting very

elongated eyeballs, lack of resistances in the capsular bag and surrounding tissue combined with the onset of fibrosis can displace the implanted intraocular lens resulting in undesired refractive outcomes. The capsular bag shrinkage produces uneven distribution of forces at the zonule-capsular bag junction leading to an imbalance of biomechanical forces within the capsular bag.[5,6]

The rationale for routine CTR implant during cataract surgery and IOL implantation in myopic eyes is to preserve the capsular bag's circumference after evacuation of the lens material.[7] The ring is aimed to withhold centripetal mechanical forces and is expected to resist capsular bag collapse and related deformations.[8]

The proposed addition of a Capsular bag Tension Ring to the cataract surgery routines in high myopic eyes has two main objectives which are long-term centralization of IOL along the axis of the eyeball and provide intracapsular bag resistance against shrinkage and maintain its circumference.[9]

Even though instruments provide precise biometric measurements, empirical formulae, advanced surgical techniques, and sophisticated IOL designs, unexpected visual complaints after cataract surgery are still occurring.[10] This is often observed in eyes with long axial lengths. Hence, this calls for further evaluation of mathematical formulation for long-term stable IOL positioning. High myopic eyes have generated our curiosity due to the growing incidence of nuclear sclerosis cataracts and the increase of refractive lens exchange as its remedy.[11] Also, this group of patients is being intervened at an earlier age, often at their productive period. Hence this device could maintain good visual quality in the long term.

Since not all surgeons agree to implant a CTR in myopic eyes, we had to make a comparison of the pre-surgical with post-surgical outcomes between the CTR and non-CTR eyes one month after surgery.

Material and Methods

Ethical Approval

The study performed following the principles of the Declaration of Helsinki. Participation in the study was anonymous *and approved by the Ethics Committee for Medical and Health Research, Faculty of Medicine Public Health and Nursing, Gadjah Mada University.* (KE/FK/0093/EC/2019).

Subjects

This study design was an observational study with a retrospective cohort. The data were collected using consecutive sampling on cases without complication from the cataract surgery records performed by three surgeons (JH, UP, VM) who had equal experience and qualifications as cataract and refractive surgeons, between January 2019 to December 2019 at JEC Eye hospitals & clinics, Jakarta, Indonesia.

Inclusion criteria were data from patients with a minimum age of 18 years ; patient's Axial Length of 26 mm or more, underwent uncomplicated phacoemulsification and IOL implant surgery and had accomplished the one-month post-op follow-up in our hospital. Exclusion criteria included history of previous refractive surgery, corneal ectasia and dystrophy, glaucoma, optic nerve, and retinal disease. This was assigned to obtain an accurate pre- and post-surgery refraction and biometric assessment for this study.

In this study, the subjectswere 54 eyes from 38 patients, which matched the eligibility criteria.

Methods

The subjects were divided into two groups, patients who did not get CTR implantation and patients with CTR implantation in their cataract surgery.

All of our patients underwent the mandatory pre-surgery examinations consisting of subjective and objective refraction, non-contact intraocular pressure (IOP) and Biometric examination using IOL Master© 700 (Zeiss Meditec) to measure axial length (AL), anterior chamber depth (ACD), lens thickness (LT) delta corneal astigmatism (Ä K) and white to white (WTW) parameters. These data were fed into the Barret Universal II formula to obtain a series of IOL powers with the corresponding refractive outcome prediction

(PRO). These measurements were performed by a JEC Hospital qualified technician and nursing team.

The IOL implanted was a *plate haptic* ZEISS Asphina® 409M with an optical diameter of 6 mm and total diameter of 11mm and the CTR implanted was NeoEye® corresponding to Morcher type 14C. One month post-surgery, auto-refractive examination was performed using Nidek® ARK500 to obtain the objective refraction and recorded as spherical equivalent (SE).

The accuracy of achievement reaching PRO is defined as the difference between post-surgery objective refractive outcome and the predicted refractive error based on the chosen IOL (PRO) by the surgeon as listed on the Biometric normogram. The smaller the difference the better the accuracy.

Our range of dioptric power to define as an ideal outcome was when the differences between the PRO pre surgery and objective refraction 1 month post-surgery were within +0.25D to -0.5D range.

Statistical Analysis

Statistical data analysis was performed using SPSS 20.0 (SPSS Chicago, Illinois, EEUU) statistical package for Windows. All data were tested with Shaphiro Wilk for normality test, Data with normal distribution were analyzed with paired t-test, abnormal distribution data were analyzed using Wilcoxon test, the difference between the outcomes were analyzed with independent sample T-test. A *p* value less than 0.05 were considered significant. Categorical analyses were tested with chi-square.

Results

In this study, the subjectswere 54 eyes from 38 patients, with the mean age of 57.15 ± 9.73 (SD). The youngest was 34 years, and the oldest was 74 years old at the surgery time. Patient baseline characteristics are shown in Table 1.

Table1. Demographic characteristic of subjects.

Characteristics	Non – CTR (n = 28)	CTR (n = 26)	p
Age (years) Mean ± SD	56.64 ± 9.50	57.69 ± 10.13	0.697*
Sex Male Female	15 (53.6%) 13 (46.4%)	10 (38.5%) 15 (61.5%)	0.266**
Eye OD OS	18 (64.3%) 10 (35.7%)	16 (61.5%) 10 (38.5%)	0.835**

OD: Ocular Dextra, OS: Ocular Sinistra *Independent sample test. **Chi-Square

There was equal distribution between the non-CTR and CTR groups in patients' characteristics, as there was no significant statistical difference between both groups within each category.

Table 2. Pre surgical biometric measurement between non-CTR and CTR group.

Parameters	Non – CTR (n = 28) Mean + SD	CTR (n = 26) Mean + SD	p
AXL (mm)	27.61 ± 1.18	27.44 ± 1.04	0.595*
ACD (mm)	3.55 ±0.31	3.52 ± 0.40	0.705*
Δ K (D)	-1.07 ± 0.76	-0.91 ± 0.56	0.377*
LT (mm)	4.12 ± 0.40	4.40 ± 0.42	0.066*
WTW (mm)	12.01 ± 0.42	12.13 ± 0.36	0.283*
IOP (mmHg)	13.66 ± 2.43	14.93 ± 2.48	0.064*

AXL = axial length; ACD = anterior chamber depth; Δk = delta keratometry; D= diopters; LT = lens thickness; WTW = white to white; IOP = intraocular lens pressure; *independent T-test

There was no significant statistical difference seen within patients' clinical parameters (AL, ACD, Δ K,LT, WTW, IOP); hence distribution were equal.

Table 3 showed a comparison between PRO and the objective spherical equivalent measured one month post-surgery within each group.

Table 3. Predictive refractive outcomes and objective SE outcomes within each group

Group	Predictive Refractive Outcomes Median (min-max)	Spherical Equivalent Objective post-surgery Median (min-max)	p
Non-CTR (n=28)	-0.27 (-2.50 - 0.69)	-0.56 (-3.00 – 0.00)	0.002*
CTR (n=26)	-0.48 (-1.10 – -0.13)	-0.50 (-1.50 – 0.25)	0.830*

*Wilcoxon test

There was a significant statistical difference between the PRO and objective refraction after surgery within the non-CTR group (p = 0.002). In contrast, there was no significant statistical difference in the CTR groups (p = 0.830).

Figure 1 showed the accuracy of achievement reaching PRO which was calculated as the subtraction between achieved post-surgery objective refractive outcome and the PRO.
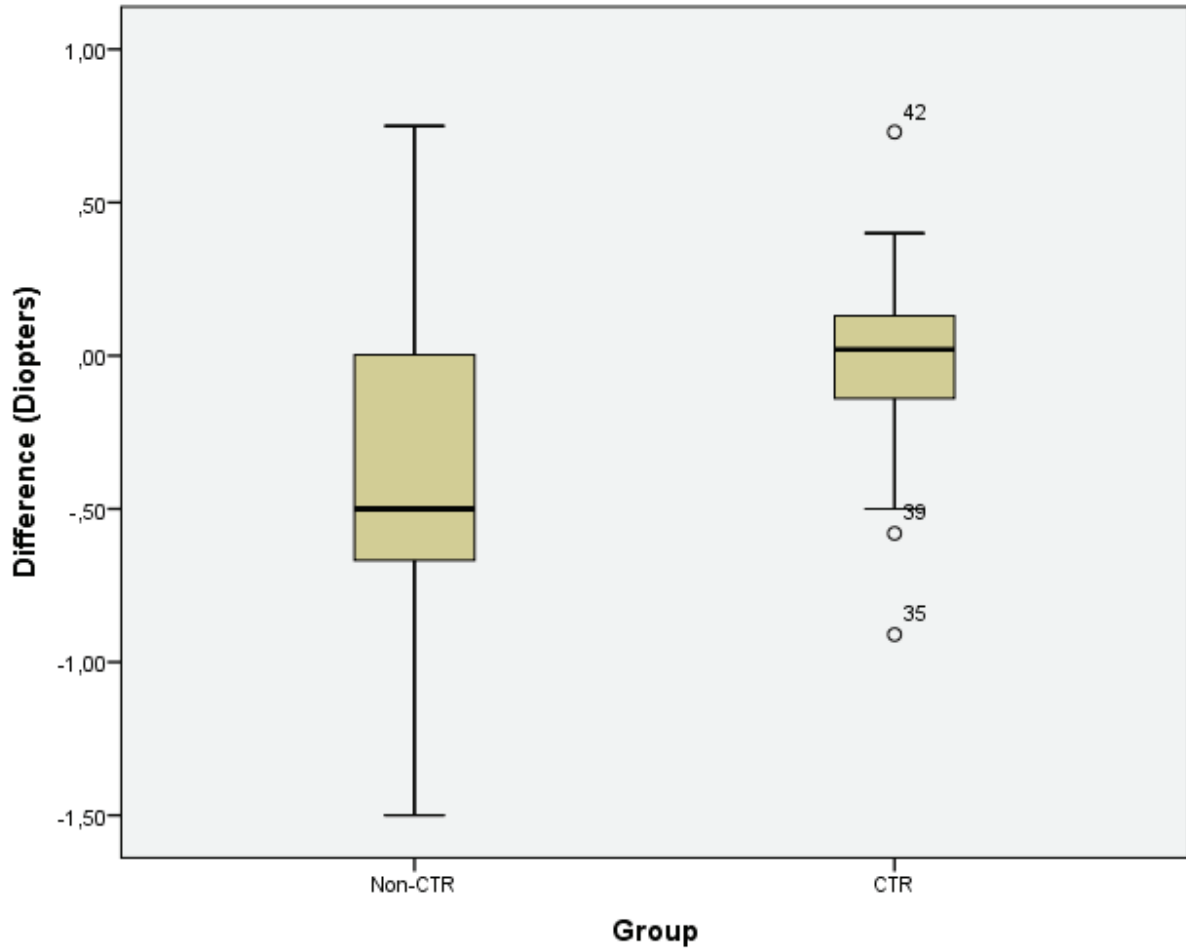

Figure 1. Boxplot of the accuracy of achievement reaching PRO.

The difference in non-CTR group was -0.36 ± 0.55, whilst the CTR group achieved 0.01 ± 0.32. This assured a significant difference between the outcomes in those two groups (p = 0.010).

In table 4, the difference between objective refractive outcome after surgery and the PRO were categorized as follows. Values that were within +0.25D to -0.5 D were categorized as the most prognosticate and values categorized as less accurate when found > -0.5 D.

Table 4. Achievement of accuracy limits (+0.25 to -0.5D) between non-CTR and CTR.

Differences	Non- CTR (n=28)	CTR (n=26)	p
+0.25 to -0.5D	15 (53.6%)	23 (88.5%)	0.005*
> -0.5 D	13 (46.4%)	3 (11.5%)	

D = Diopters; *chi-square

Table 4 showed the distribution of values non-CTR group and CTR group. Slightly more than half of the patients in non-CTR group (n =15) had measurement difference +0.25D to 0.5D, and the rest (n =13) had > 0.5D change. In CTR group most subject (n = 23) had measurement difference +0.25D to 0.5D and only a few (n = 3) had > 0.5D change. There was a significant difference between those two groups (p=0.005).

Discussion

Among epidemiologic studies in South East Asia, The Singapore of eye disease study stated that the average age of cataract surgery patients was 64.6 $\pm$ 8.3.[12] Our study presents participants at a younger age (57.15 $\pm$ 9.73). However, there was no difference in the baseline characteristic between the non-CTR and CTR groups. The sooner onset of cataracts and increase of life expectancy attracted us to raise awareness on the long-term stability of the IOL position in the myopic eye.

The anterior capsule contraction syndrome (ACCS) is a common phenomenon that follows cataract surgery as a result of the myofibroblastic transformation of the capsular bag on the IOL, and results in IOL displacement.[13] In myopic eyes implanted with relatively thinner IOLs, the shrinkage resulting from ACCS is more likely to affect the positioning of the IOL in the bag. Faulty prediction of refractive outcomes after surgery in these kinds of eyes is mainly due to the displacement of the IOL in the bag along the axis of the eyeball.

Stable objective refraction post-surgery depends on the IOL position along the axis of the eyeball. The CTR provides sustainable and evenly distributed circumferential force on the posterior capsule and capsular bag in the long term. The role of CTR placement in the bag is to resist capsular shrinkage and withhold an evenly 360 degrees distributed circumferential force within the capsular bag. In our study, biometric PRO and objective SE outcome of non-CTR and CTR showed a different outcome which suggests a stable position of the IOL along the axis of the eyeball as a biomechanical support by the CTR.

In this study, the refractive outcome with CTR was more predictable. Most high myopic patients expected a spectacle free outcome after their surgery, where as 88.5% of our patients reached PRO accuracy compared to 53.6% in the non CTR group. The magnitude of the difference in refraction between the two groups proved that CTR played a prominent role in predictability. Zhao et al.[14] found the postoperative UCVA among his patients which were implanted with Toric IOLs for high myopia had better results with the CTR compared to the non-CTR.

The CTR implanted was a PMMA open-ring device with blunt tipped eyelets at its ends. The eyelets protrude 0.25mm forward from the ring of the CTR and sit anterior to the anterior capsule.[15] The capsular bag has the characteristics of a membrane shell, it does not have any bending stiffness and thus bends almost without any resistance.[16]

At this point the CTR counteracts the centripetal force of constriction induced by metaplasia and fibrosis of residual epithelial cells at the remaining anterior capsule and the capsulorhexis edge.[17]

The implantation of a 11 mm CTR combined with a Plate Haptic IOL that measured a total diameter of 11mm, was compatible and showed to be effective to hold the IOL in place, by this combination of sizes. It kept the edge of the haptics away from the capsular bag, therefore the implantation of a CTR could prevent distortion of an IOL when the bag tends to shrink.

Earlier publication reported no statistically significant difference in the mean absolute refractive error prediction between the CTR and the control group in myopic eyes.[18] The outcome of our study was different since the objectives for IOL implantation in our hospital followed a uniform standard design (Plate Haptic, 11 mm overall diameter) calculated by the Barret Universal II formula.

This study reviewed the refractive outcomes after the implantation of a single lens design, which would be different if various designs were implanted. However, conducting a study that involved a number of variables

could be difficult to perform; therefore, the result of this preliminary study is expected to be favorable for cataract surgeons.

In conclusion, the implantation of the Capsular Tension Ring together with the IOL showed benefit regarding the predictive clinical outcome, stability of IOL positioning, and spectacle free expectations of the patient.

Authors Contribution

VM conceptualized the manuscript, and edited manuscript; DA supervised, and critically reviewed the manuscript; S supervised, and methodological review; WG supervised, and methodological review; TDG supervised, analyzed data and critically reviewed the manuscript; WS contributed to discussion, and critically reviewed the manuscript. All authors read and approved the final manuscript.

Disclosures

None of the authors has a financial or proprietary interest in any material and device mentioned in this paper

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Study of the Epidemiological factors of Tubercular meningitis among children attending R.T.H.C Kanti and Pediatrics Department of S.K.M.C.H., Muzaffarpur

Vijay Kumar Yadawa[1], KumariSushma Saroj[2], Ravindra Prasad[3]

[1]Tutor, Department of Community Medicine, Sri Krishna Medical College, Muzaffarpur, Bihar, [2]Assistant Professor, Department of Zoology, Dr. L.K.V.D. College, Tajpur, Samastipur, Bihar, [3]Associate Professor &HoD, Department of Community Medicine, Sri Krishna Medical College, Muzaffarpur, Bihar

Abstract

Background: Childhood tuberculosis is a major public health problem in developing countries with tubercular meningitis being a serious complication with high mortality and morbidity. India has one of the highest burdens of tuberculosis (TB) globally, accounting for around 20% of all new TB cases annually.

Aims and Objectives: To investigate the epidemiological and clinical characteristics of tubercular meningitis in children aged 0–14 years at R.T.H.C Kanti and Pediatrics Department of S.K.M.C.H, Muzaffarpur, Bihar.

Methodology: This was a case control study in the Pediatric patients with Meningitis and diagnosed as the TB meningitis by CSF examination at R.T.H.C Kanti and Pediatrics Department of S.K.M.C.H, Muzaffarpur, Bihar during the one year period i.e., from June 2019 to June 2020. There were total 80 patients were included into the study.

Results: The majority of the Patients were in the age group of 0-2 i.e., 28.75%, 2-5 were 33.75 %, 5-8 were 18.75 %, 8-12 were 11.25%, and 12-14 were 7.5 % respectively. Majority of the patients were Male i.e. 58.75% and 41.25% were Female. The most common associated risk factors were Low SES in 85.5%, Malnutrition in 60.5%, Un-immunized patients were 35.5%, H/o Corticosteroid use were in 25.5%, Diabetes in 20.5%, Rural /Slum dwelling in 15.5% and H/o Migration were 13% respectively.

Conclusion: It can be concluded from our present analysis that the majority of the Patients were in the age group of 2-5 i.e., 33.75%. The most common associated factors were Low SES, Malnutrition, Un-immunized patients, H/o Corticosteroid use, Diabetes, Rural /Slum dwelling and H/o Migration.

Key Words: *Tubercular meningitis in Children, Corticosteroid, Diabetes*

Introduction

Tuberculosis remains the major public health problem in India. The overall prevalence of infection (Based on Tuberculin Positivity) is 22.8 to 30.4 %

Corresponding author:
Dr. Vijay Kumar Yadawa, Tutor, Department of Community Medicine, Sri Krishna Medical College, Muzaffarpur, Bihar
Email:drssarojzoo@gmail.com

in the age group of 0-14 years. The prevalence of bacteriological confirmed cases is 4 per 1000 population. A conservative estimate shows that currently the rate of infection in India is 1% to 2% and annual risk of infection among unvaccinated children 0-9 year's age group range from 0.6% to 2.3%[1]. In India 40% children by the age of 6 years, and 80% children by the age of 16 years are labeled as highly infected group. Out of estimated globally prevalence of 15 to 20 million cases, Indian alone accounts for 4.5 to 6 million cases. According to Government of India (2000) the death rates have been

declined from 400 per 100000 populations in 1920-21 to 53 in 1993.

Tuberculosis is caused by Mycobacteria that belong to the family Mycobacteriaceae and the order Actinomycetales. Most frequent and important cause of human disease is Mycobacterium tuberculosis [2]. Closely related organisms that also infect human include Mycobacterium bovis (the bovine tubercle bacilli, once an important cause of tuberculosis of a small percentage of cases in developing countries) and Mycobacterium africanum (isolated in small proportion of cases in West and central Africa.

Mycobacterium tuberculosis is a straight or a slightly curved rod, non-spore forming, acid fast, thin aerobic bacterium measuring 1-4 micron 0.2 to 0.8 micron, occur singly, in pairs, or in clump. Most of the cases of Tubercular meningitis are caused by mycobacterium bacilli. M.bovis infection has become rare now a days, comprising less than 5% of cases of tubercular meningitis due to wide spread use of pasteurized milk .

India has one of the highest burdens of tuberculosis (TB) globally, accounting for around 20% of the all new TB cases annually [3]. It is estimated that childhood TB constitutes 10–20% of all TB cases in high burden countries[4], accounting for 8–20% of TB-related deaths [5]. Approximately, 25% of pediatric TB cases are extra pulmonary, with tuberculous meningitis (TBM) being the most severe form. Worldwide, TBM accounts for majority of the deaths due to TB.

According to WHO, TB is a worldwide pandemic. Among the 15 countries with the highest estimated TB incidence rates, 13 are in Africa, while half of all new cases are in six Asian countries, viz., Bangladesh, China, India, Indonesia, Pakistan and Philippines. A WHO fact sheet dated March 2010 on tuberculosis stated that overall one third of the world's population (over 2 billion) is currently infected with the TB bacillus [6].

The reasons are likely to be multifactorial: inherent not just to the individual person, but to their given population and environment. In populations with high TB prevalence TBM differs from pulmonary and other extra pulmonary tuberculosis, in that the peak age is from 0–4 years [7]. In populations with lower TB prevalence, most cases of TBM are in adults. Risk factors identified for these people are alcoholism, diabetes mellitus, malignancy, and recent corticosteroid use [8].

Materials & Methods

This was a case control study in the Pediatric patients with Meningitis and diagnosed as the TB meningitis by CSF examination at R.T.H.C Kanti and Pediatrics Department of S.K.M.C.H, Muzaffarpur, Bihar during the one year period i.e. from June 2019 to June 2020. There were total 80 patients were included into the study. The detailed history like age, sex, Nutritional status was calculated by WHO's Growth chart and various associated factors like Socio Economic Status was assessed by BG Prasad's Classification, immunization status was checked by immunization card and BCG vaccination was assessed by Scar mark on Left hand and immunization record, H/o Corticosteroid use, H/o Diabetes, Rural /Slum dwellingetc.

Results

Table 1: Age wise Distribution of the Patients

Agegroup	No. of Patients	Percentage (%)
0-2	23	28.75
2-5	27	33.75
5-8	15	18.75
8-12	9	11.25
12-14	6	7.5
Total	80	100

The majority of the patients were in the age group of 0-2 i.e., 28.75%, 2-5 were 33.75%, 5-8

were 18.75%, 8-12 were 11.25% and 12-14 were 7.5%respectively.

Table 2: Distribution as per theSex

Sex	No. of Patients	Percentage
Male	47	58.75
Female	33	41.25
Total	80	100

Majority of the patients were Male i.e. 58.75% and 41.25% wereFemale.

Table 3: As per the associated riskfactors*

Associatedfactors	No.	Percentage (%)
Low SES	35	85.5
Malnutrition	25	60.5
Un-immunized	15	35.5
H/o Corticosteroid use	11	25.5
Diabetes	9	20.5
Rural /Slum dwelling	7	15.5
H/o Migration	6	13

(*Total may be more than 80 as more than one risk factors were associated with the patients)

The most common associated risk factors were Low SES in 85.5%, Malnutrition in 60.5%, Un-immunized patients were 35.5%, H/o Corticosteroid use were in 25.5%, Diabetes in 20.5%, Rural /Slum dwelling in 15.5%, and H/o Migration were 13% respectively.

Discussion

Human migration plays a large role in the epidemiology of TB. The risk factors are Poor SES, Malnutrition; Un- immunized specially BCG immunization, Corticosteroid use and Diabetes Rural/ Slum dwelling[9]. PEM(Malnutrition) is having decreased cell mediated immunity may predispose to Meningitis, BCG vaccination seems to protect from TB specially TB meningitis; also unnecessary use of corticosteroid in pediatric and diabetes are associated with decreased immunity may cause TB Meningitis. The rural or slum area dwellers are exposed to overcrowding and exposure to communicable diseases specially ARI and TB and also there is full of Indoor air pollution causing Pneumonia and its complications like TB Meningitis[10].

In our study we have found that the majority of the Patients were in the age group of 2-5 i.e., 33.75%followedby0-2 were28.75%, 5-8were18.75%,

8-12 were 11.25%, 12-14 were 7.5% respectively. These findings are found in populations with high TB prevalence TBM divers from pulmonary, and other extra pulmonary tuberculosis, in that the peak age is from 0–4 years [11]. Majority of the patients were male i.e. 58.75% and 41.25% were female. Confirmation with *G Thwaites* females were more than Males. The most common associated risk factors were Low SES in 85.5%, Malnutrition in 60.5%, Un-immunized patients were 35.5%, H/o Corticosteroid use were in 25.5%, Diabetes in 20.5%, Rural /Slum dwelling in 15.5% and H/o Migration were 13%, these findings similar to *Tarakad S Ramachandran* and *G Thwaites.*

Conclusion

It can be concluded from our present analysis that the majority of the patients were in the age group of 2-5 i.e., 33.75%. The most common associated factors were Low SES, Malnutrition, Un-immunized patients, H/o Corticosteroid use, Diabetes, Rural /Slum dwelling and H/o Migration.

Ethical Clearance: Taken from Institutional Ethics Committee,Sri Krishna Medical College, Muzaffarpur, Bihar

Source of Funding: Self

Conflicts of Interest: Nil

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Effects of Task-Oriented Exercises on Improving the Balance, Minimizing the Risk of Fall in Patients with Diabetic Neuropathy- A Comparative Study

Yashasree Patil[1], R. M. Singaravelan[2], Tejas Pradeep Borkar[3]

[1]MPT Student, [2]Associate Professor, [3]Assistant Professor, Dr. A.P.J. Abdul Kalam College of Physiotherapy, Pravara Institute of Medical Sciences, Loni, Maharashtra, India

Abstract

Background: Diabetic peripheral neuropathy often demonstrates impairments in balance and thus an increased risk for falls. This affects the both static balance and dynamic balance, but static balance is more affected. Balance training is considered to be a very important tool for prevention of falls in older population. It has been shown to produce improvements in different aspects of balance.

Objective: To find out the effect of task-oriented exercises on improving the balance and minimizing the risk of fall in patients with diabetic neuropathy- a comparative study.

Methodology: 18 patients meeting the inclusion and exclusion criteria were allocated into 2 groups. Group A (n=8) received conventional Physiotherapy & Group B (n=10) received task-oriented exercises along with conventional Physiotherapy.

Result: Result of this study showed that there is significant difference in pre and post values for both FFABQ and BBS scales except for BBS the scores of group A no significant changes. On comparison between Group A and Group B, the group B showed more improvement in FFABQ and BBS score than group A.

Conclusion: This study concluded that the Task-oriented exercises with Conventional Physiotherapy were more effective in improving balance and reducing the fear of fall than with only conventional physiotherapy in diabetic neuropathy patients after 3 weeks of duration.

Key Words*: diabetic neuropathy, risk of fall, conventional physiotherapy, task- oriented exercises, balance.*

Introduction

Diabetes is a common metabolic disorder with severe health consequences, and its prevalence is on the rise [1]. Retinopathy, nephropathy, neuropathy, arteriosclerosis, and other complications of long-term diabetes may occur[2]. Diabetic peripheral neuropathy

Corresponding Author:
Dr. Yashasree Ajit Patil,
MPT Student, Dr. A.P.J. Abdul Kalam College of Physiotherapy, Pravara Institute of Medical Sciences, Loni, Maharashtra, India.

(DPN) is a diabetes mellitus complication described as "the occurrence of signs or indications of peripheral"[3]. Diabetics with mild to severe nervous system disruption make up 60 to 70% of the population. [4] Diabetic peripheral neuropathy is one of the most severe documented microvascular complications of both type 1 and type 2 diabetes mellitus [5-7], with 20-50 percent of the diabetic population suffering from it. [8–12]

Falls cause significant morbidity, immobility, and mortality in the elderly. Every year, nearly 35 to 40 percent of the community-dwelling population over the age of 65 dies. The ratios are higher for people over the

age of 75[39]. Breaks can occur for a variety of reasons; however, falls of diabetics are a big issue, resulting in feelings of unsteadiness, subsequent psychosocial effects, and immediate physical repercussions. Sensory and motor neuropathy of the foot and lower limb are significant contributors of gait impairments, resulting unsteadiness, and elevated risk of falling. Along with vestibular dysfunction and diabetic retinopathy, diabetic peripheral neuropathy is a major contributing factor for the likelihood of dropping in diabetic patients. In particular, patients with DPN have a 2–3 times higher chance of falling [38]. This has an effect on both static and dynamic equilibrium, but static balance is more influenced. [24] Formalized paraphrase As a result, diabetic peripheral neuropathy affects gait characteristics [25]. They did not, however, consider balancing exercises as an action. Furthermore, Liu and Frank [26] and Streckman et al. [27] provide reports on the effectiveness of activities in improving balancing characteristics in older patients and patients with peripheral neuropathy, respectively. Balance teaching is regarded as a critical method for the reduction of crashes in the elderly community. It has been shown to enhance various facets of posture and gait. Previous studies have investigated balancing exercises as an intervention in diabetic peripheral neuropathy patients and found them to be effective whether used alone or in conjunction with other treatments. Weight exercise directly improved balance sway index [28-31], static balance such as one leg stance [30-32-34], tandem stance, and dynamic balance such as forward reached measure [30,32,33], walk over beam [29], and five times sit to stand [33].

Following posture exercise, there was a significant improvement in gait parameters such as gait pace [29], stride length [33], and cadence [35], as well as 10 minute walk time [30] and 6 minute walk distance [36]. Functional and agility tasks, such as time up and go tests or performance-oriented agility, increased post-balance testing [30, 31, 33, 34]. Balance exercises have aided in decreasing response time [37], lowering the chance of falling. [30-37].

Materials and Method

This was a comparative study which was conducted

to evaluate the effects of task-oriented exercises along with conventional therapy on improving balance and reducing the risk of fall in diabetic neuropathy patients. The subjects who meet the inclusion and exclusion criteria and willing to participate in the study were included. We had approached about 20 participants out of which 18 patients completed the protocol. They participants and relatives were explained about the study and the evaluation procedure. The informed written consent form was collected from the participants. Inclusion criteria:- Both male and female participants Medically diagnosed with diabetic neuropathy, Patients with impaired balance. Patients having risk of fall, and Patients who were willing to participate. The exclusion criteria of the study was: - Severe retinopathy and nephropathy, Patient with musculoskeletal deformity in lower limb Eg. Arthritis, fractures, Patient with cognitive impairments or with psychiatric disorders or seizures or with visual impairment or tremors influence balance, Patients with balance impairment i.e. berg balance scale score more than 0-20, Patients with maximum or complete sensory loss.

Procedure

The study received ethical approval from the Institutional Ethical Committee (IEC) of PIMS, Loni. The patients were screened according to the inclusion and exclusion criteria. The patients who were willing to participate in the study were briefly explained about the study in the language best understood by them. They were encouraged to clarify queries regarding the study, if any. An informed written consent form, previously approved by the IEC was then obtained from the patients. The demographic data was obtained and detailed assessment was done.

Twenty patients diagnosed with diabetic neuropathy and admitted to Pravara Rural Hospital (PRH) loni were randomly divided into two groups (Group A and Group B) of 8 patients in Group A and 10 patients in Group B. Among those 20 patients, there were 2 dropouts in group A as the intervention period was not completed due to Covid-19 situation. The variables like Balance and Risk of fall were assessed using the berg balance scale and

fear of fall avoidance behavior scale. The conventional therapy session for group A was given for 30 minutes and the conventional therapy along with task-oriented session for group B was given for 50 minutes. The intervention was given for 3 days in a week for 3 weeks. The data was entered in the excel spread sheet tabulated and subjected to statistical analysis. Data was analyzed using Graph Pad Instat Trial Version 13.3. Descriptive statistics for all outcome measures were expressed as mean, standard deviations and test of significance such as unpaired t test and ANOVA parametric test was

done. The confidence interval was set at 95% and data was considered statistically significant with p <0.05 and highly or considerably significant with p <0.001.

Outcome Measures

1. Berg balance scale

2. Michigan Neuropathy disability symptoms scale

3. Fear of Falling Avoidance Behavior Questionnaire

Data Analysis and Result

Table 1: Age distribution

Groups	Mean Of Age In Years	Standard Deviation (Sd) Of Age In Years
group a	53.12	6.28
group b	54.8	8.61

The average age of Group A (Conventional Physiotherapy) was 53.12 ± 6.28 years and in Group B (Conventional Physiotherapy and task-oriented exercises) was 54.8 ± 8.61 years.

Table 2: Comparison of pre-post intervention of Michigan neuropathy screening instrument in group A

MNSI	Intervention	Mean	Standard deviation (sd)	t value	p value	Result
Group A	Pre	1.25	0.46	0.000	<0.0001	not significant
	Post	1.25	0.46			

Michigan neuropathy screening instrument was used for physical evaluation of the lower limb in patients with diabetic neuropathy. In group A the mean score for pre assessment was 1.25 ± 0.46 and the same was for post assessment as there was no significant changes in the pre-post assessment hence the unpaired 't test = 0.000 (with DF=18)

Table 3: Comparison of pre-post intervention of Michigan neuropathy screening instrument in group B

MNSI	Intervention	Mean	Standard deviation (sd)	T Value	P Value	Result
Group B	Pre	1.2	0.42	0.000	<0.0001	not significant
	Post	1.2	0.42			

In group B the mean score for pre assessment was 1.2 ± 0.42 and the same was for post assessment as there was no significant changes in the pre-post assessment hence the unpaired 't test = 0.000 (with DF=18)

Table 4: Comparison of post intervention of fear of falling avoidance behaviour questionnaire scale in group A and B

FFABQ	Intervention	Mean	Standard deviation (sd)	T Value	P Value	Result
Group A	Post	31.75	3.28	2.067	0.0553	significant
Group B	Post	27.3	5.31			

Post intervention FFABQ mean score for Group A and Group B were 31.75 ± 3.28, 27.3 ± 5.31 respectively. On comparison of Post-intervention FFABQ mean scores between Group A and Group B by using unpaired t test, it is observed that this difference is significant. Group B shows improvement in FFABQ after 3 weeks of duration than the Group A and showed reduced fear of fall. (p= 0.0553 and t=2.067 for part A and B with DF=14).

Table 5: Comparison of post intervention of berg balance scale in group A and B

BBS	Intervention	Mean	Standard deviation (sd)	T Value	P Value	Result
Group A	Post	40	5.01	3.880	0.0013	extremely significant
Group B	post	48.2	3.97			

Post intervention BBS mean score for Group A and Group B were 40 ± 5.01 and 48.2 ± 3.97 respectively. On comparison of Post-intervention BBS mean scores between Group A and Group B by using unpaired't,, test, it is observed that the difference observed is highly significant and shows increase in BBS after 3 weeks of duration than the Group A. (p=0.0013; t= 3.880 for group A and group B with DF=16).

Result of this study showed that there is significant difference in pre and post values for both FFABQ and BBS scales except for BBS the scores of group A no significant changes. On comparison between Group A and Group B, the group B showed more improvement in FFABQ and BBS score than group A.

Discussion

The results of this study revealed a greater increase in the BBS score and a reduction in fear of fall scale which showed that the patient now has lower risk of fall following a task-oriented exercise program in comparison with conventional physiotherapy in patients with diabetic neuropathy. It showed that balance control has significant improvement using task oriented approach for balance training. Scores of berg balance scale suggested a remarkable improvement in dynamic balance between tasks oriented balance training group and traditional balance training group. The results of this study suggested that dynamic balance and fear of fall is improved and reduced respectively in task oriented training group than traditional balance training group [39]

The current study's findings were confirmed by Ghazal et al., who demonstrated that balance deficiency is normal in the diabetic community. In his research, the complex and anticipatory equilibrium of diabetic neuropathic patients was measured, and aimed at task-oriented training and conventional training were extended to the patients for 8 weeks. According to the findings, there was a significant change in the score

during the therapy session in both the participant and the task oriented group. The task-oriented approach yielded a better outcome in terms of decreasing fall probability and improving equilibrium. To avoid more complications and improve quality of life, adequate and proper task-oriented preparation must be included as part of diabetic management. The task-oriented equilibrium training group was found to have a lower chance of falling. [39] Furthermore, Laufer et al. backed the current study's findings. They hypothesised that there was a substantial gap between the impact of task-oriented instruction and traditional physical therapy activities on diabetic neuropathy patients' equilibrium disruption. [40] Sisupadol et al. performed a double blind RCT in 2009 to compare the impact of single task vs dual task balance training on balance performance. The study's participants were randomly assigned to one of three groups: single task, dual task, or dual task with variable priority. After four weeks, the Berg Balance Scale and Activity Balance Confidence scores were tested. They concluded that both single task and dual task testing improved BBS scores, and that gait speed was faster in the dual task group than in the single task group.[41] Refay et al found that combining lower extremity range of motion (ROM) exercises, muscle building exercises for toe flexor/extensor and foot intrinsic muscle, posture training, and gait training exercises increased walking pace, cadence, and ankle range of motion with a substantial decrease in step time, while no significant improvement was found in the control group.[42] This may be attributed to fitness therapy, which has been shown to enhance macro and microvascular factors in diabetics. [43,44] As a result, vascular adaptations induced by exercise can boost blood flow to peripheral nerves while also improving balance and gait function. Similarly, Allet et al found that gait and balance exercises along with function-oriented strengthening strengthened diabetic patients' gait functions as compared to a control group that received no care. [45]

The task oriented training has significant effect on balance improvement and fall risk reduction because such approach has specific goal oriented and focus activities which directly linked with the performance of daily tasks.

Conclusion

This study concluded that the Task-oriented exercises with Conventional Physiotherapy were more effective in improving balance and reducing the fear of fall than with only conventional physiotherapy in diabetic neuropathy patients after 3 weeks of duration.

Limitation of Study

è   Short duration Intervention period

è   No follow up after 3 weeks, so long term effect of intervention could not be suggested.

è   The study was limited to Pravara Rural Hospital.

è   The sample size was small due to Covid 19 situation.

Conflict of Interest: None

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Fracture Stregnth of Endodontically Treated Teeth with Minimally Invasive Access Cvaity Desgins Versus Conventional One (An In Vitro Study)

Mai Mohamed Ibrahim Abo Shadi[1], Nihal Ezzat Sabet[2], Fatma M. Abu Naeem[3]

[1]Master Degree Student Department of Endodontics, [2]Professor of Endodontics Department of Endodontics, Faculty of Dentistry, [3]Lecturer of Endodontics Department of Endodontics, Faculty of Dentistry, Cairo University, Giza, Egypt

Abstract

Aim: Assess the fracture strength of endodntically treated teeth with minimally invasive access cavity design versus conventional one.

Methods: Forty four extracted molars were assigned to 4 groups. Conservative Access Cavity, Ninja Access Cavity, Truss Access Cavity, Traditional Access Cavity (n = 11/group/type). Teeth in the Traditional group were prepared following the principles of traditional endodontic cavities. Conservative access prepared by using 2 periapical radiographs to determine canals location. Ninja access scans were plotted on cone beam computed tomographic images for localization of root canal orifices and Truss group were scanned, and merged with cone beam computed tomography, for fabrication of an endodontic guide.The 44 specimens were loaded to fracture in a universal material testing machine. The maximum load at which the teeth fractured and fracture pattern (restorable or unrestorable) were recorded.

Results: Regarding the fracture strength, results showed that there was a significant difference between Ninja, Conservative,Truss and traditional access groups with ($p < 0.001$) and no significant difference between Conservative and Truss groups. Regarding restorability, there was no statistical difference observed between the four groups with ($p < 0.001$).

Conclusion: Teeth with traditional access showed lower fracture strength than the ones prepared with Conservative, Ninja and Truss.

Keywords: *conservative access ,fracture resistance, ninja, traditional access ,truss.*

Introduction

One of the most important steps for successful endodontic treatment is access cavity preparation which may influence the quantity of the residual dental substance thus affecting its resistance to fracture under functional loads [1,2] .

In traditional endodontic cavity (TEC) preparation, the controlled removal of the tooth structure was thought to prevent complications that can occur during endodontic treatment [3]. However, the removal of tooth structure needed for access cavity preparation decreased the resistance of the tooth to fracture under functional loads [1].

Minimally invasive endodontics is a concept that is adopted recently, comprising smaller access cavities.

Corresponding author:
Fatma Abu Naeem
Lecturer of Endodontics, Faculty of Dentistry, Cairo University, +201001324224
11, Saray AL- Manial st., Faculty of Dentistry, Cairo University

Conservative endodontic cavity (CEC) preparation is a minimally invasive procedure that can preserve tooth structures, such as pericervical dentin which can improve the fracture strength of endodontically treated teeth [1,3].

An extreme conservative approach known as ''Ninja'' tooth can be outlined on cone-beam computed tomographic (CBCT) images by plotting the trajectory toward each canal. In ultraconservative access cavity ''Ninja'' Access was proposed in order to improve the fracture strength of endodontically treated teeth in comparison to both TEC & CEC techniques [1].

Minimal access cavities have been presented as an alternative to traditional endodontic access cavity (TEC), and have been supported to preserve as much tooth structure as possible and thus, theoretically preserve the fracture resistance of root filled teeth [4]. The more conservative access design is mainly supported by the preservation of a greater amount of tooth structure on the occlusal surface, seeking to increase its fracture strength [5].

Hence, the aim of the present study was to assess the influence of minimally invasive access cavity designs on the fracture resistance of endodontically treated teeth.

Materials and Methods

This is an in-vitro study. Conducted in a faculty of dentistry-cairo university, Egypt from September 2018 to October 2021.

Sample size calculation:

Forty four mandibular first molars were randomly assigned to four equal groups according to the required access cavity design where each group comprise 11 samples. Group I: comprise 11 samples where each undergo conservative access cavity design. Group II: comprise 11 samples where each undergo ninja access cavity design. Group III: comprise 11 samples where each undergo truss access cavity design. Group IV: comprise 11 samples where each undergo traditional access cavity design.

· Teeth were inspected, cleaned from blood and tissue debris then root surfaces were scraped with a curette to remove calculus or attached periodontal ligament fibers. Teeth were inspected with a dental operative microscope for cracks then stored in normal saline solution at room temperature till use.

· To simulate the periodontal ligament space, roots were covered with a uniformly thin 0.2-mm layer of silicone impression material.

· Using the analyzing rod of the dental surveyor, each tooth was positioned vertically in a brass ring of self-cured acrylic resin, then teeth were embedded up to 2 mm below the cementoenamel junction.

· In the CAC group, in order to determine the outlines of the access cavity and locate the pulp chamber and canals, we used 2 periapical radiographs made from buccal and mesial aspects as a guide. Then, starting from thecentral fossa, cavities were extended only as necessary to visualize and locate canal orifices while taking care to preserve pericervical dentin. Fig (1).

· In the NAC group, the access cavity was prepared by a size 856 diamond burs in a high-speed hand piece with a sufficient water coolant directed towards the central fossa perpendicularly at the deepest point of the occlusal surface till a drop was felt. Then, when the pulp chamber was reached the cavity was slightly expanded. The mesiodistal length of the cavity was set to 2 mm; meanwhile, the buccolingual length of the cavity was 3 mm Fig (1).

· In TRAC the endodontic guide was printed by a form 3 flawless printer and using dental LT clear resin 3d printing material and a Carbide surgical bur size 2 with a diameter of 1.5 mm with a maximum working length of 13 mm from the top of the sleeve till each orifice opening of each canal in each tooth. The truss access was done by the surgical bur directed towards the access points through the metal sleeves in the endodontic guide exposing each canal orifice Fig (1).

· In the TAC group, traditional endodontic access cavities were prepared following conventional guidelines. In order to obtain straight-line access to all canal orifices, outlines of the cavity and pericervical dentin were removed or modified where necessary Fig (1).
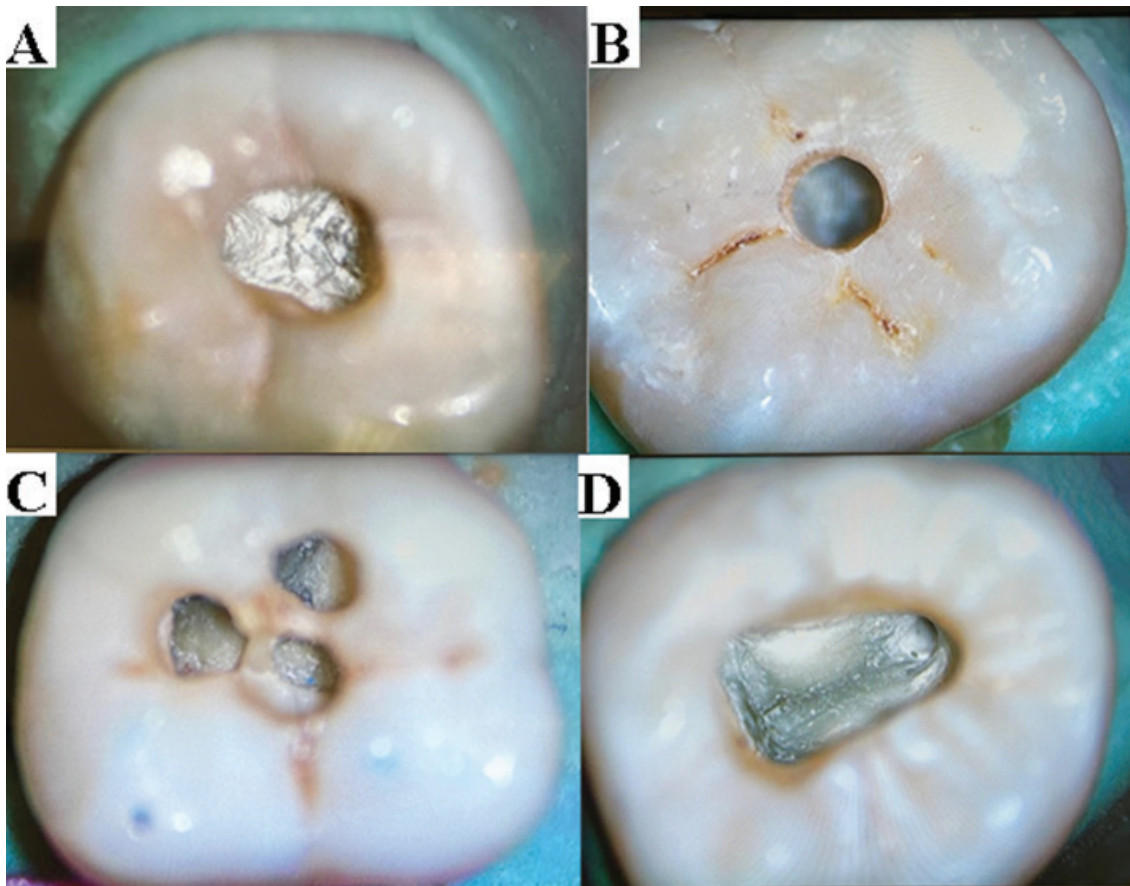

Figure 1. (A–D) photographs showing lower molars prepared with different access cavity designs. (A) Conservative access cavity, (B) Ninja access cavity, (C) Truss access cavity and (D) A traditional access cavity.

Loading of the specimens

1) All the accessed teeth in each group were subjected to the fracture resistance test using the Universal Testing Machine. The testing machine allows an error of 0.04% for a maximal load of 10,000 kg, 0.01% for a repetitive maximal load of 10,000 kg, resolution of displacement of 0.01 mm (10 mm), and an accurate speed of 0.01% of full scale.

2) All the specimens were placed in a custom-made water bath and mounted in the universal testing machine.

Teeth were loaded at their central fossa with an axial angle from the long axis of the tooth. A continuous compressive force at a crosshead speed of 1 mm/min was applied using a 6 mm-diameter ball-ended steel compressive head till fracture occurs.

Primary outcome (Fracture strength): The loads, at which the teeth were fractured, indicated by the software (BlueHill Instron) of the load testing machine, were recorded in newtons.

Secondary outcome (Fracture restorability): The fractured specimens were examined under a stereomicroscope at 17 X to determine the fracture pattern according to.

Fracture patterns were classified into: Favorable: when the failures were above the level of acrylic resin level which signifies that the site of fracture was above

the bone level and was restorable. Unfavorable: when the failures were extended below the level of the acrylic resin level which signifies that the site of fracture was below the bone level and was difficult to restore or totally non restorable.

Results

Comparison between the fracture resistance of the different access cavity designs

Group II showed the highest mean and standard deviation values of fracture resistance (1086.68 ± 262.43) followed by group I with a mean and standard deviation of (725.91 ± 232.22) then group III with a mean and standard deviation of (656.62 ± 445.64), and finally group IV presented the least mean and standard deviation of (242.49 ± 50.55).

Applying Kruskal Wallis test, a significant difference was observed between the four groups with ($p < 0.001$). Using Mann – Whitney U test a statistically non-significant difference was observed between group I and group III

Table (1) Mean, standard deviation values and the results of Kruskal Wallis test for the comparison of the compressive strength between the four test groups

	Group I	Group II	Group III	Group IV	P - Value
Mean	725.91b	1086.68a	656.62b	242.49c	
SD	232.22	262.43	445.64	50.55	
Median	796.82	983.42	619.69	231.41	< 0.001*
Min	364.48	858.60	262.71	171.41	
Max	988.13	1601.00	1479.69	343.41	

Comparison between the fracture patterns of the different access cavity designs:

Group II showed the highest frequency of the restorable fractures (63.6%) in comparison to the non-restorable ones (36.4%) within the same group followed by the group I with a frequency of the restorable fractures (54.5%) in comparison to non- restorable fractures (45.5%) within the same group then group III with a frequency of the restorable fractures (36.4%) which was less than the non-restorable fractures frequency (63.6%) within the same group , and finally group IV presented the least frequency of the restorable fractures (18.2%). Using chi square test, a statistically non-significant difference was observed between the four groups with ($p = 0.14$).

	Group I		Group II		Group III		Group IV		P - Value
	N	%	N	%	N	%	N	%	
Favourable	6	54.5%	7	63.6%	4	36.4%	2	18.2%	0.14
Unfavourable	5	45.5%	4	36.4%	7	63.6%	9	81.8%	

Table (2): Frequencies (N), percentages (%) and the result of chi square test for the comparison of the patterns of fracture between the four tested groups

Discussion

One of the most important causes of fractures in root-filled teeth is the loss of tooth structure during the preparation of the traditional access cavity designs. Thus, a proper and more conservative endodontic access cavity designs are suggested to improve the prognosis for an endodontically treated tooth [1,6.]

Mandibular molars were used in the present study as these teeth are more susceptible to fracture due to its wider occlusal tables subjected to high occlusal stresses. These teeth are also the most commonly endodontically treated posterior teeth and often require cuspal protection [7.]

In the present study, simulation of the periodontal ligament around the teeth was done with polyvinyl siloxane, an elastomeric material that to prevent concentration of stresses in the cervical region of the tooth, since the method of root embedment may affect the fracture resistance significantly [8.]

Cone beam computed tomography (CBCT) was used in ninja access cavity for localization of all root canal orifices. Moreover, truss access cavity was guided by CBCT to design a 3D print for fabrication of endodontic guide template to control the drill path and the needed depth of the drill to the root canal orifices [1, 9, 10,11.]

The fracture resistance was tested using a static compressive loading in a universal testing machine, guided by a sphere head with 5-6 mm diameter to allow adequate contact with cuspal inclines during testing. [7, 12.]

The results showed a statistically significant difference between the four groups accessed with different cavity designs. The fracture strength of the traditional access cavity (control group) was significantly lower than that of the conservative access cavity (CAC), ninja access cavity (NAC) and truss access cavity (TRAC) groups. This could be explained by the fact that access cavity preparation by itself reduces the fracture resistance of the tooth as a result of removal of strategic internal architecture at the center of the tooth during complete deerofing of the pulp chamber [7, 13]

The results of this study were in agreement with Panitvisai et al. 1995, Clark et al. 2010, Krishan et al. 2014, Reddy et al. 2020, who found that the fracture resistance of (CAC) is higher than (TAC). Similar findings were observed in a study conducted by Plotino et al. 2017 who found that the fracture resistance of TAC was lower than CAC. However, these results were in contrast to those found by Moore et al. 2016, Rover et al. 2017, Sabeti et al. 2018 who found that there was no statistical difference between TAC and CAC in maxillary molars. A possible explanation for these differences could be due to the difference in study design as the use of a different type of teeth or due to canal instrumentation. Moreover, Moore et al. 2016 and Rover et al. 2017 restored the cavities with composite bonded restorations.

In the current study, all tested minimally invasive cavity designs (CAC), (NAC), (TRAC) resisted a fracture load significantly higher than (TAC). This could be attributed to the dentin preservation that occurred due to cavity size reduction which improved the fracture resistance of these teeth [14, 15, 17]. Also, in CAC preparation, there was an emphasis on preserving the pericervical dentin by maintaining the soffit dentin which plays an important role in providing a ferrule effect thus increasing the fracture resistance of the tooth [19, 20.] In the same time, it was reported that the removal of cervical dentin, as in TAC, could increase the cuspal deflection and enhance the potential for fracture [14,15.]

Teeth in the NAC group showed significantly higher fracture resistance values than those observed in the control TAC, CAC and TRAC groups, this could be attributed to the minimally invasive access cavity designs of NAC [1] .This was confirmed by Reddy et al. 2020 who calculated the volume percentage of coronal enamel and dentin lost by TAC, CAC, and NAC access cavities and subtracted it from the total enamel and dentin crown volume for each tooth type using CBCT and declared that NAC group contained the least amount of hard tissue removal which resulted in

significantly higher fracture resistance for the tested teeth. Moreover, Plotino et al.2017, Schroeder et al. 2002 and Saygili et al. 2018 found that the fracture strength values of teeth prepared with NAC was higher than that of teeth prepared with CAC and TAC.

In the present study a significant difference was found in the fracture resistance between NAC and CAC groups which is in contrast to Reddy et al. 2020 and Plotino et al. 2017 who found that there was a non-significant difference in fracture resistance between NAC and CAC groups. This might be attributed to the difference in tooth type as Plotino et al. 2017 used a maxillary molars while Reddy et al. 2020 used an unerupted impacted lower third molar with sectioned apex to simulate immature teeth, the second difference was in the test used as Reddy et al. 2020 used Insert On Demand 3D™ software which calculated the volume percentage of coronal enamel and dentin lost by TAC, CAC and NAC access cavities by subtracting the new enamel and dentin crown volume from the total enamel and dentin crown volume for each tooth type. However, no significant difference between the fracture resistance of the CAC and TRAC cavity groups was detected which was in agreement with Plotino et al. 2017 and Corestino et al. 2018. This result might be explained by the fact, that both are minimally invasive access cavity designs with minimal hard tissue removal.

A higher number of restorable fracture patterns in NAC and CAC, TRAC teeth than those in the ones prepared with TAC was presented in this study. This might be due to the preservation of the pulpal chamber roof and precervical dentin [3]. Furthermore, the majority of the teeth prepared with TAC showed unrestorable fracture patterns with no significant difference among the different access cavity designs which may be attributed to the positive correlation between the remaining coronal dentin surface area and the fracture strength; as TRAC access cavity involves separate individual cavities in multirooted teeth which maximizes the dentine preservation between the cavities than in the TAC group which scarifies a much coronal dentin [2,19]. In addition, Plotino et al. 2017 observed that the mean volume of pericervical dentin lost was greater in TEC (14.8%)

group, followed by CEC (8.3%) group and then NEC (6.8%) group which was in agreement with Platino et al. 2017, Özyürek et al. 2018, Abou-Elnaga et al. 2019 and Barbosa et al. 2020. Hence, conservative variation from traditional access cavity design might preserve more sound teeth structure increasing the fracture resistance of endodontically treated teeth.

Conclusion

Within the limitations of this study, it could be concluded that: Minimally invasive access cavity designs improved the fracture strength of endodontically treated teeth. Ninja access cavity design presented the highest fracture resistance when compared to other conservative access cavity designs. Fracture patterns doesn't lean toward any of the conservative access cavity designs nor to the traditional one.

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Temporomandibular Disorders and Its Management in Dentistry: A Review

Vishal. S. Kudagi[1], H. P. Jaishankar[2], Raghunath N[3], Shruti Shivakumar[4], Prasanna S Deshpande[5], Bhagyalakshmi A[6], Nitin V Murlidhar[6]

[1]Lecturer, Department of Orthodontics, [2]Reader, Department of Oral Medicine and Radiology, [3]Professor and HOD, Department of Orthodontics, [4]Lecturer, Department of Pedodontics, [5]Lecturer, Department of Oral Medicine and Radiology, [6]Reader, Department of Orthodontics, JSS Dental College and Hospital, Mysore

Abstract

Temporomandibular disorders (TMD) is a collective term for a group of musculoskeletal conditions involving pain and/or dysfunction in the masticatory muscles, temporomandibular joints (TMJ) and associated structures. It is the most common type of non-odontogenic orofacial pain and patients can present with pain affecting the face/head, TMJ and/or teeth, limitations in jaw movement and sounds in the TMJ during jaw movements. Comorbid painful and non-painful conditions are also common among individuals with TMD. The diagnosis of TMD have significantly improved over time with the recent Diagnostic Criteria for TMD (DC/TMD) being reliable and valid for most common diagnoses, and an efficient way to communicate in multidisciplinary settings. This classification covers 12 most common TMD, including painful (myalgia, arthralgia and headache attributed to TMD) as well as the non-painful (disc displacements, degenerative joint disease and subluxation) TMD diagnoses. Recent studies have demonstrated that the pathophysiology of common painful TMD is biopsychosocial and multifactorial, where no one factor is responsible for its development.

Importantly, research has suggested different predisposing, initiating and perpetuating factors, including both peripheral and central mechanisms. This is an active field of investigation and future studies will not only seek to clarify specific causal pathways but translate this knowledge into mechanism-directed diagnosis and treatment. In accordance with this complex aetiology, current evidence supports primarily conservative multidisciplinary treatment including self-management strategies, behavioural therapy, physical therapy and pharmacotherapy. The aim of this review is to present an overview of most recent developments in aetiology, pathophysiology, diagnosis and management of TMD.

Key words: *TMD, Etiology, Diagnosis, Management.*

Introduction:

Temporomandibular disorders (TMD) is a collective term for a group of musculoskeletal conditions involving pain and/or dysfunction in the masticatory muscles, temporomandibular joints (TMJ) and associated structures. Temporomandibular disorders (TMD) are characterized by craniofacial pain involving the joint, masticatory muscles, or muscle innervations of the head and neck[1]. TMD is a major cause of non-dental pain in the orofacial region. Up to 70% of TMD patients suffer from pathology or malpositioning of the TMJ disc, termed "internal derangement" (ID).

Corresponding author:
Dr. Shruti Shivakumar
Lecturer, Department of Pedodontics
JSS Dental College and hospital, Mysore-15.
drvishalsk@yahoo.com

Incidence of TMD:

Population-based studies show that TMD affects 10% to 15% of adults, but only 5% seek treatment[2,3]. A large multisite prospective cohort study in the USA (OPPERA study) estimated that each year 4% of TMD-free adults aged 18–44 years develop clinically confirmed first-onset painful TMD, and that annual incidence increases with age (18–25 years = 2.5%; 25–34 years = 3.7% and 35–44 years = 4.5%)[4]. Some studies also indicate the percentage of population affected by temporomandibular disorders (TMD) to be as high as 56% to 87.7% of the world population [5,6]. The incidence of TMD peaks from 20 to 40 years of age and symptoms occur disproportionately between the sexes, TMD is twice as common in women than in men and carries a significant financial burden from loss of work[7,8].

Etiology and predisposing factors for TMD:

Factors predisposing to the development of TMD can be systemic, psychological (personality and behavior), and structural (malocclusion and other types of occlusal discrepancies, joint laxity, and others)[9,10]. The etiology of TMD is multifactorial and can also include biologic, environmental, social, emotional, and cognitive triggers. Factors consistently associated with TMD include other pain conditions (e.g., chronic headaches), fibromyalgia, autoimmune disorders, sleep apnea, and psychiatric illness. A prospective cohort study with more than 6,000 participants showed a twofold increase in TMD in persons with depression (rate ratio = 2.1; 95% confidence interval, 1.5 to 3; $P < .001$) and a 1.8-fold increase in myofascial pain in persons with anxiety (rate ratio = 1.8; 95% confidence interval, 1.2 to 2.6; $P < .001$).5 Smoking is associated with an increased risk of TMD in females younger than 30 years[11].

TMD is categorized as intra-articular (within the joint) or extra-articular (involving the surrounding musculature)[12]. Musculoskeletal conditions are the most common cause of TMD, accounting for at least 50% of cases[13,14].

Diagnosis of TMD:

The diagnosis of TMD is based largely on history and physical examination findings. The symptoms of TMD are often associated with jaw movement (e.g., opening and closing the mouth, chewing) and pain in the pre-auricular, masseter, or temple region. Another source of orofacial pain should be suspected if pain is not affected by jaw movement. Adventitious sounds of the jaw (e.g., clicking, popping, grating, crepitus) may occur with TMD, but also occur in up to 50% of asymptomatic patients.1 A large retrospective study (n = 4,528) conducted by a single examiner over 25 years noted that the most common presenting signs and symptoms were facial pain (96%), ear discomfort (82%), headache (79%), and jaw discomfort or dysfunction (75%)[15].

A variety of diseases affects the TMJ and includes the following:

1) Congenital and developmental malformations of mandible and cranial bones

2) Acquired disorders including neoplasia and fractures, dislocation, ankylosis and disc displacement

3) Inflammatory diseases that produce synovitis and capsulitis

4) A wide variety of arthritis

5) Various post treatment conditions

6) Habits related to stress such as clenching, bruxism.

According to some studies, the occlusal factors are of minor etiological importance for pain and functional disorders in the masticatory system, but the role of occlusion in the etiology of TMD is still controversial[16,17].

Malocclusion and TMJ disorders are 2 separate entities, but both are quite prevalent in different groups of population. As the function of TMJ is directly related to the mandibular movements as guided by occlusion, researchers from every part of the world have been trying to find the association between malocclusion and

TMJ disorders. Some investigators have stated that joint sounds are related to orthodontic malocclusions, but a final conclusion has not been reached[18,19].

The role of malocclusion as a potential risk factor for development TMDs has been progressively disproved in the past[20]. As a consequence, all treatment modalities and plans to correct malocclusions and/or to achieve ideal functional occlusion are not reliable treatment option for TMD management[21,22].

The currently available literature suggests that the orthodontic treatment does not provide any further advantages in management/prevention of TMD[23,24]. Hence, Orthodontic treatment cannot be considered to neither decrease nor increase the risk for TMD[24].

Several studies in spite of being longitudinal gave heterogeneous results, since they failed in defining TMD management as their primary treatment goal and include uninform sample with diverse forms of malocclusion and age groups including older individuals[25].

Even the studies using modern and sophisticated diagnostic tools such as magnetic resonance imaging(MRI) and long-term follow-up studies have failed to resolve the controversy concerning Orthodontic treatment-TMD correlation. The focus of etiological factors of temporomandibular disorders TMD has progressively shifted from physical to central factors[26].

Based on such an ongoing paradigm change, a much-diminished role is assigned to the features of natural dental occlusion as risk factors for TMD, in favor to central factors (ie, psychological and psychosocial factors, pain sensitivity, genetic determinants)[27].

Clinical Management:

An analysis of current non-invasive, minimally invasive, and fully invasive management options now follows. The ultimate goals of the presented modalities are to: 1) increase mandibular range of motion, 2) decrease joint and masticatory muscle pain and inflammation, and 3) prevent further degenerative change in articulating tissues, including direct or indirect joint damage.[28]

Non-Invasive:

The non-invasive modalities implemented most commonly include physical therapy, occlusal splints and/or adjustments, and pharmacologics. Beginning first with physical therapy, electrophysical modalities and manual/exercise techniques are used to relieve pain in the joint and masticatory muscles, and improve range of motion.[29] Electrophysical modalities include transcutaneous electric nerve stimulation (TENS), ultrasound, and laser.[30] Such modalities are implemented to reduce inflammation, increase local blood flow, and promote muscle relaxation.[28] Current research does not point to any significant decrease in pain in electrophysically treated patients. In fact, one study of 23 bruxists showed a significant increase in range of motion and a decrease in muscular activity with muscular awareness relaxation training over the TENS treatment group.[31] Furthermore, these techniques offer the potential to "re-teach" and rehabilitate the musculature. This observation is especially noted in patients exhibiting stress-related habits.

Also non-invasive, occlusal splints and occlusal adjustments work to establish balance in the occlusion and TMJs. The occlusion, or bite position, is a third and important element in the joint system and is the element often addressed by general dentists. The ultimate goal of splints and adjustments is to minimize pain in the joint and masticatory muscles by establishing stability. Furthermore, as reviewed by Ingawale and Goswami,[32] splints may be used to control bruxism, which has been associated with tooth attrition, malocclusion, myofacial pain, and masticatory muscle strain, fatigue, and fibrosis. Occlusal splints and adjustments may be suggested to reestablish balance in the joint system, but the long-term effectiveness of this therapy remains controversial.[32]

Regarding pharmacologic agents, commonly prescribed non-steroidal anti-inflammatory drugs (NSAIDs) offer advantages in reducing inflammation. Research, however, is needed to exploit long-term use and to identify whether the advantages in management

of pain and inflammation outweigh the negative side effects.[33] Muscle relaxants may also be prescribed for treatment of muscle pain and/or spasm.[34] However, studies have failed to demonstrate that muscle relaxants are any more effective in pain relief than NSAIDs. To improve their benefit, muscle relaxants are often used in combination with NSAIDs.

Minimally Invasive:

Minimally invasive modalities for management of TMD symptoms include sodium hyaluronate and corticosteroid injections, arthrocentesis, and arthroscopy. With research indicating both regenerative and degenerative responses to such injections, their use remains controversial.[34] The pathophysiology of the disease indicates there may be more significant potential for these injections in early stages of degeneration when inflammation first begins to exacerbate tissue catabolism.[35]

Similar to intra-articular injections, arthrocentesis and arthroscopic surgery are minimally invasive techniques requiring entrance into the joint capsule to lubricate articulating surfaces and reduce inflammation. During arthrocentesis, a sterile needle is used to drain fluid from the joint.[36] After draining, the joint is flushed of debris and inflammatory cytokines using a sterile solution.[36]

While arthroscopic surgery and arthrocentesis may be used to lubricate joint surfaces and reduce inflammation, further research is needed to identify long-term advantages especially in the absence of disc repositioning or replacement.[37, 38]

Invasive:

For the 5% of TMD patients whose nonsurgical methods fail, open joint surgery may be necessary to restore mandibular motion and mitigate orofacial pain.[39] Most commonly, open joint surgery may include discectomy, reshaping or reconstruction of the articulating surfaces, and implantation of autologous or alloplastic materials.[40] Total joint replacement, the most invasive option, may become necessary when joint degeneration and pain exceed the potentials of the less invasive surgical methods. Condylar replacements in clinical use include autologous costochondral grafts, but autologous full joint replacements are not currently available.

Conclusion

To address the mechanically demanding and biochemically active environment of the TMJ, tissue engineering is emerging as a suitable option for replacing diseased, displaced, or degenerated tissues. Characterizing the biochemical and biomechanical properties of the joint structures, including the condyle, TMJ disc, superior articulating surface, and disc attachments, in both healthy and diseased cases, continues to facilitate the development and validation of tissue engineering strategies. Simultaneously, characterization efforts are aiding researchers and clinicians in developing their understanding of TMD etiology and progression. Thus far, native tissue characterization studies have identified distinct differences between the biochemical and biomechanical properties of the TMJ disc and condyle, thus calling for concurrent, yet independent, tissue engineering strategies. With refined design objectives and validation metrics, and with a growing awareness of TMD as a pathology in need of clinical action, it can be expected that tissue engineering for both the mandibular condyle and TMJ disc will progress significantly over the next decade.

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Application of Video Analysis for Enhancing Kinematic Parameters and Techniques of Yoga Performers

M. Srinivasan

*Assistant Professor, Sri Ramakrishna Mission Vidyalaya Maruthi College of Physical Education,
SRKV Post, Periyanaickenpalayam post, Coimbatore, Tamil Nadu, India*

Abstract

Background: Yoga asanas help to increase the wholesome development of an individual. At the same time, the execution of the asanas gives complete benefits to the practitioners.

Aim: The purpose of the study was to find out the application of video analysis for enhancing kinematic parameters and techniques of yoga performers.

Methods and Material: For this study, three men yoga performers selected from SRMV Maruthi College of Physical Education, Coimbatore, Tamil Nadu, India. The age of the participants was 24 years. He had a good experience in performing yoga including difficult classical asanas. For this study angle of joints, movement of body parts and position of balance, holding time were selected as dependent variables. Sports Insight motion analysis cameras and software were used to find out the angle of joints, movement of body parts and body balance. The baseline kinematic variables were tested before intervention. At the time of intervention, the execution of the asana (virksasana) was recorded by the researcher through the sports motion analysis camera and software.

Statistical analysis used: Descriptive statistics were used to analyse the performance of the yoga performers.

Results: The captured video was showed to the participant to understand his execution of asana. The researcher gave the necessary guidance to correct the mistakes and provide opportunities for self-evaluation. After the 10 days of training, post-test was conducted and data were collected from the participant.

Conclusion: It is concluded that the application of video analysis produced a significant difference in angle of joints, movement of body parts among the yoga performers. It is concluded that the application of video analysis produced significant improvement in the position of balance, holding time among the yoga performers.

Keywords: *video analysis, kinematic parameters, techniques, asanas, virksasana. the angle of joints, movement of body parts and position of balance, holding time, sports motion analysis camera and software.*

Introduction

Motion analysis method has been used in the study of human movement. [1] Kinematic values are analysing with body-mounted sensors (Veltink et al. 1996:375-85; Bussmann et al. 1995:2-7; van den Bogert et al. 1996:949-54; Dai et al 1996:63-72; Luinge et al. 1999:455-9; Tong et al. 1999:87-94; Veltink et al. 1999:383-91). The yoga practitioner is performing and compares it with a video of the same `asana' performed by an expert. Thus, it helps to detect and eventually correct errors induced in practising the art using only a webcam and an expert video as aides for the user (Patil et al. 2011;43-46).

The yoga instructor gives feedback about performing various asanas (Fishman et al. 2009:47-53). (Video analysis increase performance among the badminton players (Srinivasan M. 2012:12-14). The

skill acquisition has been taken place by using video. [11] Feedback procedure is more important for yoga practice and improves performance. [12] The skill performance variables namely, bowling speed, bowling accuracy and bowling ability significantly improve due to the e-content assistive and imagery specific training with traditional training. [13]

The use of video analysis has been used in sports and play activities. [14] Video modelling and video feedback were used to increase the performance. [15], [16], [17 Boyer et al. (2009) examined the effectiveness of a video treatment and feedback for gymnastic skills. [15] Nielsen et al. (2009) evaluated the effectiveness of video modelling and feedback procedures for increasing safe and correct patient lifting transfers. [16],

For these reasons, the researcher was in exploring to overcome the mistakes committed by the yoga performers. The video analysis is the innovative approach to give proper feedback and motivate the yoga practitioners to perform at their highest potential. The video analysis help to understand the angle on the joints while perform the poses; aware about body movements; maintain the body balance; increase holding time.

Subjects and Methods

Materials and methods

Selection of participants: For this study, three men yoga performers selected from SRMVC Maruthi College of Physical Education, Coimbatore, Tamil Nadu, India. The age of the participants was 24 years. He had a good experience in performing yoga including difficult classical asanas.

Selection of variables: For this study angle of joints, movement of body parts and position of balance, holding time were selected as dependent variables.

Criterion measures: Sports Insight motion analysis cameras and software were used to find out the angle of joints, movement of body parts and body balance.

Procedure: The baseline kinematic variables were tested before intervention. At the time of intervention, the execution of the asana (virksasana) was recorded by the researcher through the sports motion analysis camera and software. The captured video was shown to the participant to understand his execution of asana. The researcher gave the necessary guidance to correct the mistakes and provide opportunities for self-evaluation. After the 10 days of training, a post-test was conducted and data were collected from the participant.

Video analysis training: The participants were asked to perform virkasasana for capturing the pose. The captured postures were analysed by the sports motion analysis package. The feedback and postural correction, body movement, body balance, angle of the position were discussed with the participants. Ten days of postural training were given to the participants and the feedback of the participants were also recorded for further application.
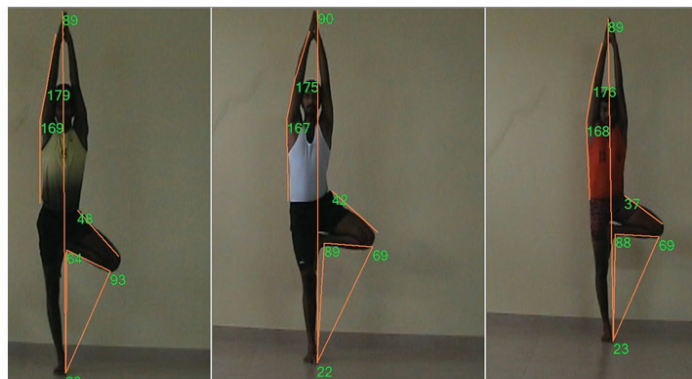
Analysis of Virksasana performance

Figure 1: Bar diagrams showing the means difference of pre-test and post-test scores on the angle of joints

Results

Table 1: Table showing the means difference of pre-test and post-test scores on the angle of joints

Joint	Average Angles	
	Baseline	Post-test
Standing leg and hands	82^0	89^0
Shoulder and hands	182^0	176^0
Standing leg, folding ankle joint and knee joint	$22^0, 70^0, 92^0$	$22^0, 80^0, 77^0$
Trunk joint of the folding leg and knee joint	46^0	42^0

The results of the study reveal that the movement of the body parts was well synchronized with less effort when compared with the baseline test. Further, the body balance of the poses was significantly improved when compared with the baseline test. And also, it shows that the holding time of the poses was significantly increased when compared with the baseline test.
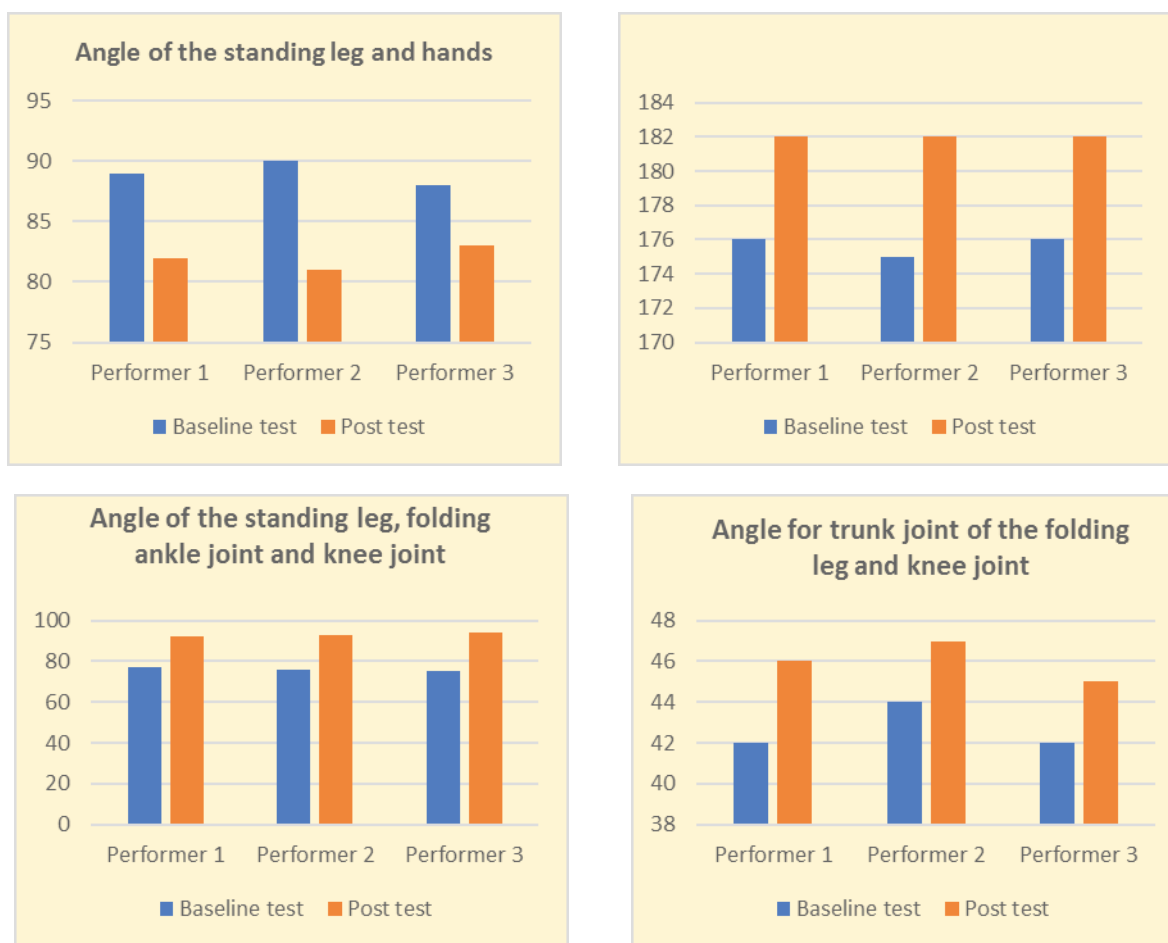
Figure 2: Bar diagrams showing the means difference of pre-test and post-test scores on the angle of joints

Discussion

The study analyzed the efficacy of video analysis for enhancing kinematic parameters and techniques of yoga performers. The application of video analysis increased the performance in virkasasana. It also reduced the errors unintentionally committed by yoga practitioners. The researcher could find out the difference in the angle of joints between the baseline test to post-test. The application video analysis increased the confidence among the yoga practitioners. Video analysis acted as a tool to prevent the injury because the practitioners could understand the possibilities of movement of the joints.

Furthermore, such an application provides more evidence that individuals can evaluate their performance through video to increase their performance. The video analysis software and cameras are very sophisticated to show the video in ultra-slow motion. It provides 64 slides in one second and can draw different angles and other measurements too. The finding of the study shows that the holding time of the poses significantly increased due to video analysis. The results of the study show that there is a significant difference between the execution of virkasasana. They have followed the techniques properly throughout the intervention.

The results of this study are comparable to those of studies evaluating similar procedures including self-monitoring and self-evaluation from video. [18] and video feedback with self-evaluation. [19]. Muhammad Usama Islam (2018) investigated that Yoga posture recognition by detecting human joint points in real-time using Microsoft Kinect. It analysed various joints of the human body to calculate the accuracy of the particular yoga pose. [20]

Furthermore, video feedback increases performance. [14] Schmid (2009) suggesting that yoga may be an exemplary intervention to manage Fear of Falling and improve balance, and reducing fall risk. [21] Teja Kiran Kumar Maddala (2019) studied that Yoga Net: 3-D Yoga Asana Recognition Using Joint Angular Displacement Maps with Conv Nets. It captures the lateral and rotational spatiotemporal variations. It accurately recognizes 3-D yoga actions. [22]

Conclusion

It is concluded that the application of video analysis produced a significant difference in angle of joints, movement of body parts among the yoga performers. Furthermore, it is concluded that the application of video analysis produced significant improvement in the position of balance, holding time among the yoga performers.

Ethical Clearance: Taken from Research Advisory Committee, SRKV MCPE.

Conflict of Interest: The researchers claim no conflicts of interest.

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Therapeutic Effect of Luteolin Natural Extract Versus its Nanoparticles on Oral Squamous Cell Carcinoma Cell Line: in Vitro Study

Safaa Baz[1], Heba Farag[2], Safa Fathy[2]

[1]Ph.D. Candidate, [2]Professor, Department of Oral and Maxillofacial Pathology, Faculty of Dentistry, Cairo University

Abstract

Oral squamous cell carcinoma still has no satisfactory treatment. Luteolin is a natural flavonoid, exhibiting anti-cancer activity. Nanomedicine has been implemented in cancer therapy, utilizing the benefits of nanoparticles. In this context, this study was conducted to examine whether luteolin and nano-luteolin exert an inhibitory effect on oral squamous cell carcinoma cell line; SCC-25 by inducing apoptosis, and to assess whether nano-luteolin is more efficient compared to luteolin and the gold-standard; 5-fluorouracil. nano-luteolin was prepared and has fulfilled the criteria of nanoparticles. The cytotoxicity of luteolin, nano-luteolin, and 5-fluorouracil were assessed at three-time intervals using the MTT assay. IC50 doses of each intervention were applied to SCC-25, then caspase-3 levels were assessed at three-time intervals, using Real-Time polymerase chain reaction. Our results demonstrated dose- and time-dependent reduction in the % viabilities and IC50 values when SCC-25 treated with luteolin, nano-luteolin, and 5-fluorouracil. Among all the groups, nano-luteolin expressed the highest levels of caspase-3 (nano-luteolin > 5-fluorouracil > luteolin) and its highest value was at 48 h. In conclusion, both luteolin and nano-luteolin exerted cytotoxic effect and have succeeded to induce apoptosis against SCC-25 cells, with superior effect offered by nano-luteolin compared to luteolin and even 5-fluorouracil.

Keywords: *Luteolin, Nano-luteolin, Nanoparticles, Oral squamous cell carcinoma, SCC-25, Caspase-3, Apoptosis, Cytotoxicity*

Introduction

According to the International Agency for Research on Cancer (IARC) in 2018, the annual incidence of oral cancer (ICD C00-06 code: Lip, oral cavity) is about 354,000 cases, worldwide [1]. The primary modalities for oral squamous cell carcinoma (OSCC) are surgical intervention, radio- and chemotherapy. Unfortunately, the estimated 5-year survival rate remains 50% [2]. This unsatisfactory prognosis might be due to the ability of conventional therapies to work well for some time and eventually develop serious complications, primarily cancer resistance and non-selective toxicity [3, 4]. Hence, the scientists face a challenge to identify innovative therapeutic approaches destroying cancerous cells

professionally and avoiding such major problems for cancer patients.

The naturally-occurring flavonoids have been reported to offer a good safety profile; damaging cancerous cells selectively [5]. Luteolin (Lut), a 3',4',5,7-tetrahydroxyflavone, is isolated from a wide range of fruits, vegetables, and medicinal herbs [6-9]. Lut has exhibited a wide range of activities, including anti-cancerous effects [9, 10]. However, poor solubility and fairly low bioavailability might hinder the pharmacological potential of Lut [11]. Nanotechnology has been reported to improve drug delivery, pharmacokinetics, and pharmacodynamic profiles, besides their ability to enhance the bioavailability of

poorly water-soluble drugs [12].

To the best of our knowledge, few studies were conducted to examine the effect of Lut in OSCC in the available English literature, although it was adequately examined in other cancers. Even more, the current study was the "pioneer" to investigate the effect of nano-luteolin (NLut) toward OSCC cells. The present work was designed to assess the inhibitory effect of Lut and NLut, compared to the gold standard 5-fluorouracil (5-FU), on OSCC cell line by inducing apoptosis, using microculture tetrazolium (MTT) assay and real-time quantitative polymerase chain reaction (RT-qPCR). By engaging the superlative properties of nanotechnology to the natural extract Lut, it seems very interesting to determine whether its nanoparticles' (NPs) has advantages superior to Lut in inducing apoptosis on OSCC.

Materials and Methods

Materials

The OSCC cell line (SCC-25) was purchased from the ATCC (# CRL-1628) (Manassas, VA, USA). 1:1 RPMI 1640 and 10% FBS were purchased from Gibco™; Thermo Fisher Scientific, Inc. (Waltham, MA, USA). L-glutamine dissolved in DMSO (Product # C6164), Lut (Product # L9283), 5-FU (Product # F6627–1G), PLA-PEG polymer (Product # 659657), 1% PVA solution (Product # P1763), 5 mg/ml MTT reagent (Product # M-5655) and MTT Solubilization Solution (Product # M-8910) were purchased from Sigma-Aldrich (Louis, MO, USA). RNeasy Protect Mini Kit (Product # 74126) was purchased from Qiagen (Venlo, Netherlands), iScript™ One-Step RT-PCR Kit with SYBR® Green (Product # 170-8892) was purchased from the Bio-Rad Laboratories (Hercules, CA, USA). Primers: CASP3 (NM_004346.4) and beta-actin (ACTB) (NM_001101.3).

Methods

The entire procedure was carried out in the National Research Centre and the Confirmatory Diagnostic Unit of the Research and Development sector, VACSERA, Cairo, Egypt.

Preparation of NLut

NLut in the current study was formulated according to *Majumdar and colleagues*, using the emulsion solvent evaporation technique [13]. A diblock copolymer polylactic acid (PLA), polyethylene glycol ether (PEG), was utilized for encapsulation of Lut (100 mg in 60 mL MeOH and 1 gm in 10 mL MeOH, respectively). The mixture of Lut-PLA-PEG-OMe solution was added carefully to polyvinyl alcohol (PVA) emulsifier (200 ml of 1% w/v). The mixture was continuously stirred for one day, and centrifuged (6000 rpm). Then, at the bottom, the unencapsulated Lut precipitate was accumulated, and the supernatant was filtered (Millex® Syringe Filter: cut-off 0.20 μm) and purified (Amicon® Ultra -15 Centrifugal Filter: cut-off 30,000), to remove unencapsulated Lut. The mixture was sonicated for 30 minutes. Ultimately, pure and homogenous NLut was obtained.

MTT Cytotoxicity Assay and IC50 Value Determination

The effect of Lut, NLut, and 5-FU on cell viability of SCC-25 cells was assessed using the MTT assay after 24 h, 48 h, and 72 h of treatment to assess the cell viability. The half-maximal inhibitory concentration (IC50) value was calculated and used for the following investigation [14].

RNA Extraction and Real Time-Quantitative Polymerase Chain Reaction (RT-qPCR) Analysis

In this work, performed to determine the mRNA levels of caspase-3 (CASP3) expression in the SCC-25 treated cells was detected using the RT-qPCR assay. The mRNA level of the housekeeping gene; beta-actin (ACTB) was used as a reference to normalize the values [15]. The treated SCC-25 cells in the presence or absence of interventions were harvested. Total RNA was extracted using RNeasy Protect Mini Kit. Then, the reverse transcription was generated using iScript™ One-Step RT-PCR Kit with SYBR® Green. The results were analyzed using Corbett Rotor-Gene rotary analyzer PCR 5-PLEX with Q-6000 Series (Software 1.7, Build

87). The used primer sequences: CASP3, forward 5'-TTCATTATTCAGGCCTGCCGAGG-3' and reverse 5'-TTCTGACAGGCCATGTCATCCTCA-3'; and ACTB, an endogenous control, forward 5'-GTGACATCCACACCCAGAGG-3' and reverse 5'-ACAGGATGTCAAAACTGCCC-3'. The relative expression levels of CASP3 were calculated and normalized to ACTB in each sample using a double delta crossing threshold ($\Delta\Delta$CT) method [16].

Statistical Analysis

Statistical analysis was then performed using a commercially available software program (SPSS 18; SPSS, Chicago, IL, USA). Values were presented as mean ± standard deviation (SD) of ≥ 3 independent experiments for each group. Data were explored for normality using the Kolmogorov-Smirnov test. Since data were parametric, a one-way analysis of variance (ANOVA) test was used to compare all groups and to compare different observation times within the same group. This was followed by Tukey's post hoc test when ANOVA revealed a significant difference. The level of statistical significance was set at $P < 0.05$.

Results and Discussion

Characterization of NLut

To ensure that the prepared NLut has fulfilled the criteria of NPs, it was characterized to identify their size and shape using Visible Near Infra-Red (Vis-NIR) spectroscopy (Ocean Optics; Model LS-1). It consists of a Tungsten halogen light source; a versatile white-light source optimized for Vis-NIR (360 nm - 2000 nm) range and a sensor connected to the computer that detects the change in the amount of emitted light passed through NLut solution. The light source and the sensor were connected through two optical fibers and the cuvette containing NLut solution was placed in-between these fibers (Figure 1a). Data were recorded using special computer software (Ocean Optics Software) and the absorption rate curve was drawn (Figure 1b). The optical absorption spectrum of the NLut solution represents the surface characteristic of NLut, which shift to longer wavelengths with increasing particle size. The absorption rate of the NLut was with a maximum peak of 405 nm, indicating spherical NPs.

Interestingly, a diblock copolymer; PLA-PEG is already approved by the FDA, because it is biocompatible, biodegradable, and safe. Besides, this polymer can increase drug loading and encapsulation efficiency and reduce drug resistance [17, 18]. Moreover, PLA-PEG has a core-shell structure with amphiphilic molecular properties. This allows the hydrophilic PEG to diffuse into a shell of spherical particles, and the hydrophobic PLA to cohere and enwrap the same hydrophobic target drug to form the inner core "nucleus" of the spherical particles [13, 19].
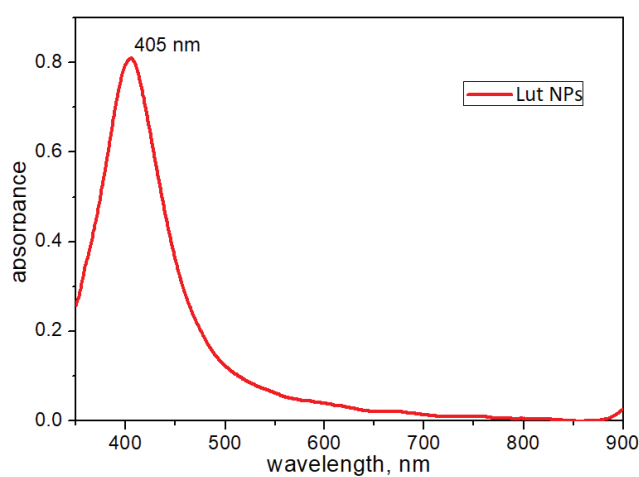
(a)   **(b)**

Figure 1. Vis-NIR Spectroscopy: (a) Tungsten Halogen Light Source, Sensor and Cuvette containing NLut solution placed in-between two optical fibers; (b) Absorption rate curve of NLut.

Cell Viability and Cytotoxicity Determination

The summary of % viability results in different experimental groups was demonstrated (Figure 2). Among all groups, the group treated with 100 µg/ml of NLut at 72 h recorded the lowest % viability (12.7302 %), however, the group treated with 0.01 µg/ml of Lut at 24 h recorded the highest % viability (86.1195 %). In the present study, % viability and the IC50 values revealed an overall time-dependent decline in SCC-25 treated with the different interventions. Besides, the results showed a considerable dose-dependent reduction in the % viability in the different experimental groups.

The IC50 doses for the different study groups were estimated. Statistical results of IC50 values in different experimental groups are summarized and represented graphically (Table 1,2, Figure 3). Interestingly, our results pointed out that NLut has provided the greatest cytotoxicity against OSCC cells, which even exceeded that of 5-FU when compared with Lut. Such results suggested that the increased duration as well as the higher doses of both Lut and NLut could promote the desired cytotoxicity against OSCC cells.
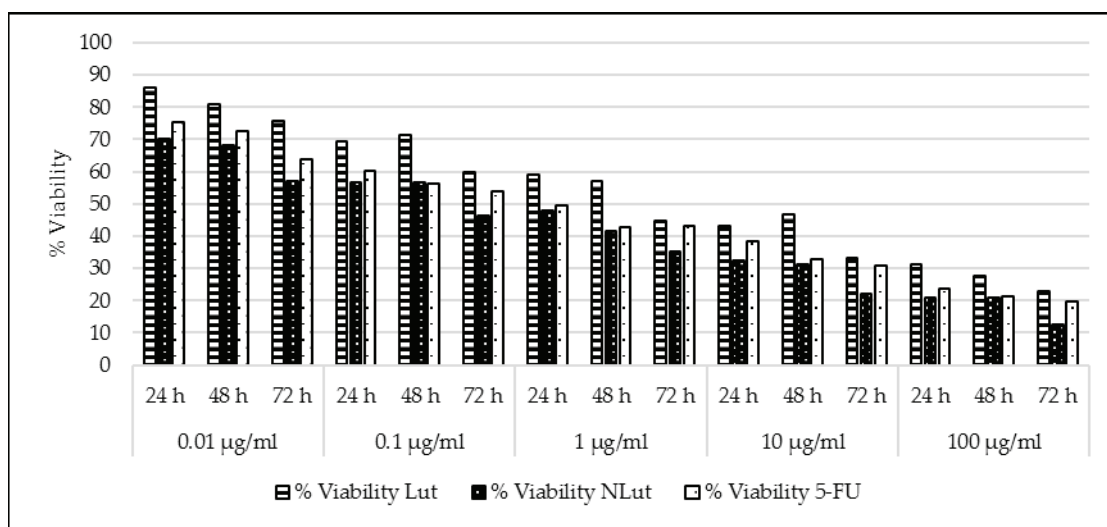
Figure 2. A clustered column chart comparing the % viability across the different groups.

Table 1. Summary of IC50 values ± SD in different experimental groups with their *P*-values and pairwise comparisons at different durations.

Intervention	IC50 results (µg/ml)			P-value
	24 h	**48 h**	**72 h**	
Lut	3.71a ± 0.6	3.32a ± 0.51	0.62 b ± 0.15	0.00 *
NLut	0.44 a ± 0.12	0.28 b ± 0.07	0.04 c ± 0.01	0.00 *
5-FU	0.89 a ± 0.25	0.41 b ± 0.11	0.2 b ± 0.04	0.0001 *

Significance level *P* < 0.05, * Significant. In Tukey's post hoc test: means sharing the same superscript letter are not significantly different.

Table 2. Summary of IC50 values ± SD in different experimental groups with their *P*-values and pairwise comparisons of different interventions.

Duration	IC50 results (µg/ml)			P-value
	Lut	NLut	5-FU	
24 h	3.71 a ± 0.6	0.44 b ± 0.12	0.89 b ± 0.25	0.00 *
48 h	3.32 a ± 0.51	0.28 b ± 0.07	0.41 b ± 0.11	0.00 *
72 h	0.62 a ± 0.15	0.04 c ± 0.01	0.2 b ± 0.04	0.00 *

Significance level *P* < 0.05, * Significant. In Tukey's post hoc test: means sharing the same superscript letter are not significantly different.
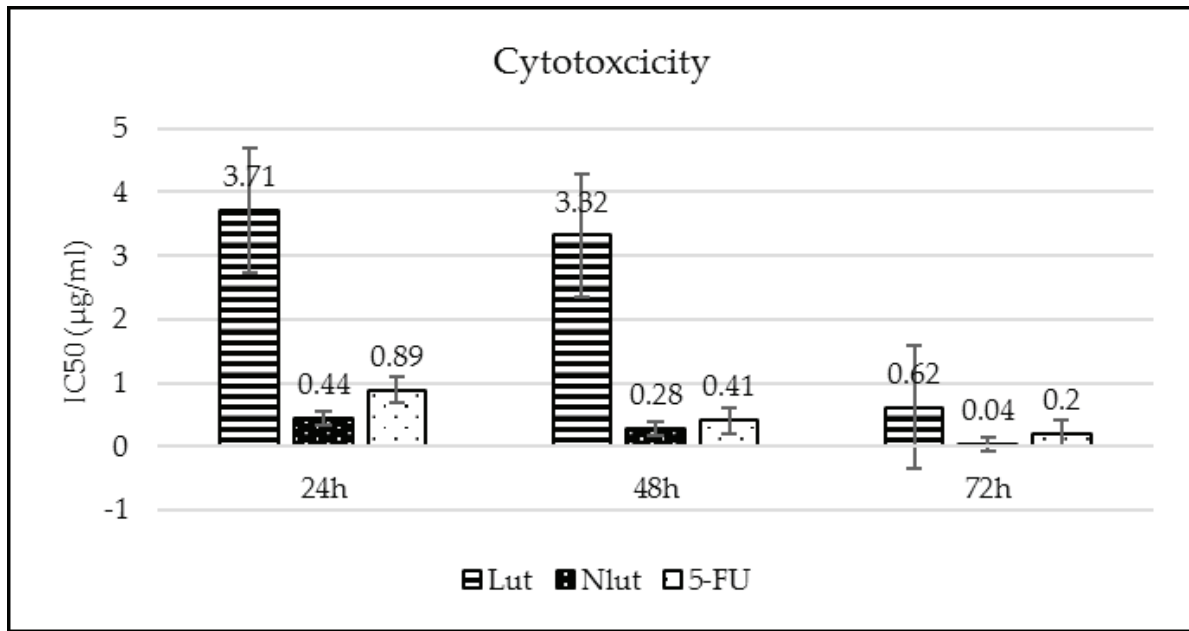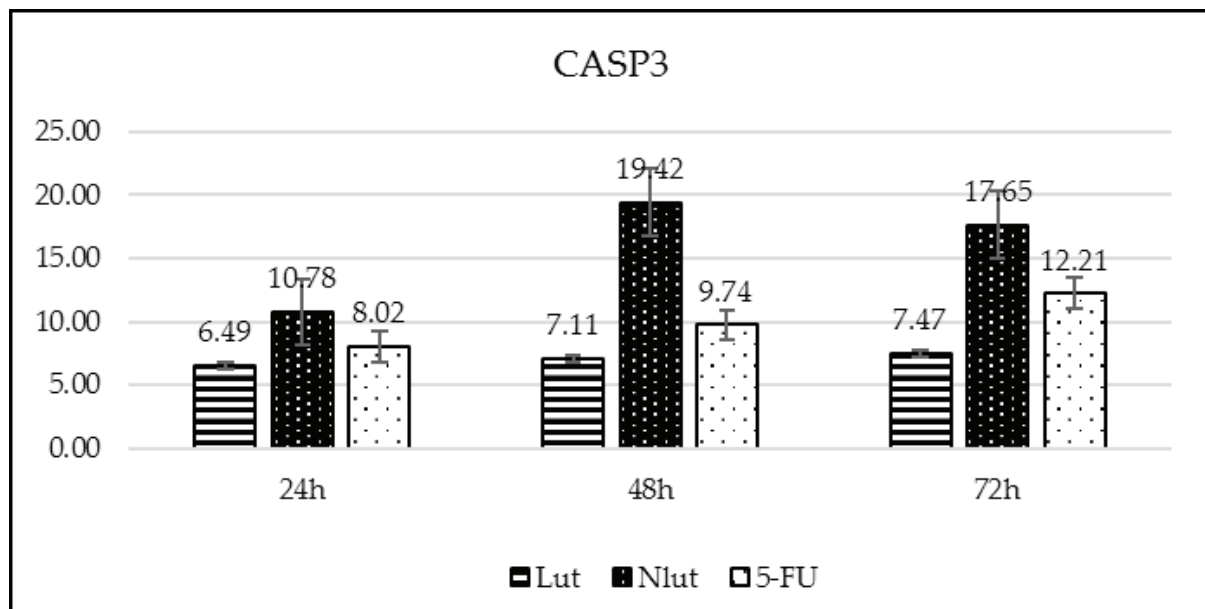

Figure 3. Column chart illustrating the different IC50 values of each group.

Detection of CASP3 Gene Expression

CASP3 is a critical effector enzyme in the caspase cascade, that acts as a junction between the intrinsic and extrinsic apoptotic pathways. Ultimately, the activated CASP3 can lead to the same execution pathway [20]. The CASP3 results for the different study groups were estimated (Table 3,4, Figure 4). All the treated groups showed upregulation of CASP3 gene expression relative to control. The fold-changes in both Lut and 5-FU treated groups were presented in a time-dependent manner, with the highest values appeared at 72 h, except in NLut groups at which the highest value was presented at 48 h. Among all groups, the highest values were offered by NLut, followed by 5-FU, then Lut.

Table 3. Summary of CASP3 levels ± SD in different experimental groups with their *P*-values and pairwise comparisons at different durations.

Intervention	CASP3 results (fold-changes)			P-value
	24 h	**48 h**	**72 h**	
Lut	6.49 ± 1.18	7.11 ± 1.43	7.47 ± 1.56	0.55 NS
NLut	10.78 b ± 2.51	19.42 a ± 4.61	17.65 a ± 4.17	0.0099 *
5-FU	8.02 b ± 1.67	9.74 a,b ± 2.08	12.21 a ± 3.13	0.046 *

Significance level *P* < 0.05, * Significant, [NS] Non-significant. In Tukey's post hoc test: means sharing the same superscript letter are not significantly different.

Table 4. Summary of CASP3 levels ± SD in different experimental groups with their *P*-values and pairwise comparisons of different interventions.

Duration	CASP3 results (fold-changes)			P-value
	Lut	**NLut**	**5-FU**	
24 h	6.49 b ± 1.18	10.78 a ± 2.51	8.02 a,b ± 1.67	0.0176 *
48 h	7.11 b ± 1.43	19.42 a ± 4.61	9.74 b ± 2.08	0.0001 *
72 h	7.47 b± 1.56	17.65 a ± 4.17	12.21 b ± 3.13	0.0009 *

Significance level *P* < 0.05, * Significant. In Tukey's post hoc test: means sharing the same superscript letter are not significantly different.

Figure 4. Column chart illustrating a summary of CASP3 results.

The success of Lut to upregulate CASP3 levels in all treated SCC-25 groups support its use as a potential chemotherapeutic candidate. Meanwhile, in this work comparing between levels of CASP3 of the different interventions at the same duration, Lut revealed the lowest values. This might be linked to the structural features of Lut, including hydroxyl groups moieties and 2−3 carbon double bond, which affect its biochemical and biological features [21]. Also, the chemical structure offers Lut with differential binding abilities which could be one of the possible reasons behind its anti-cancer activity.

5-FU has higher cytotoxic activity against OSCC cells than that of Lut, though having several adverse effects; mainly toxicity to normal cells and resistance which limit its use. On the other hand, although Lut showed lowered cytotoxicity compared to 5-FU, it has a safe nature and fewer adverse effects. In this light, to circumvent the drawbacks of 5-FU alongside the limited cytotoxic effect of Lut, NLut was prepared and used in this study. Thereby, NLut combines the advantages of Lut natural extract with the advantages of nanotechnology.

Superiorly, in this work NLut offered the highest levels of CASP3 expression (NLut > 5-FU > Lut), supporting its use as a novel chemotherapeutic agent against SCC-25 cells. Among NLut-treated groups, the highest level of CASP3 expression was found at 48 h (19.42-fold). Noteworthy, this result advocates NLut to be the drug of choice to treat OSCC cells with a recommended IC50 dose at 48 h (NLut: 0.28 µg/ml), to get the maximal apoptotic rate in the lowest possible time.

The supreme results of NLut in this work might be referred to: *first*; the characteristics of NPs which offer optimal size, shape, and efficient surface-to-volume ratio, with unique physicochemical and even biological features than that of the raw Lut. Besides, the global reduction of the amount of drug. *Second*; encapsulation properties of hydrophobic Lut into amphiphilic PLA-PEG nanocarrier as an attempt to make the drug hydrophilic. These NPs, which comprise a hydrophobic core and a hydrophilic shell, are excellent candidates for carrying highly hydrophobic chemotherapeutic agents [22]. *Third*: the ultrasonication can de-agglomerate and disperse NPs in aqueous-based media, improving the homogeneity and stability of the suspension, hence provides an open way for synthesizing such nano-sized core/shell structures [23]. *Fourth*: nanoencapsulation offers packaging to enhance cellular uptake, which mainly contributed to NLut's higher cytotoxicity [19, 24]. Consequently, NLut with several promising qualities could provide an alternative therapy to overcome the drawbacks of the naturally-occurring drug; Lut, as well as the undesired effects of the conventional chemotherapeutic drug; 5-FU.

Conclusion

Our result offers Lut and NLut as potential chemotherapeutics for OSCC treatment. NLut revealed the upper hand over Lut and even exceeding 5-FU, in inducing apoptosis of neoplastic cells. These data highlight NLut to be a drug of choice to treat OSCC, using the recommended dose and duration (NLut: 0.28 µg/ml for 48 h). Although of its drawbacks, the potent cytotoxic effect of 5-FU against cancer cells cannot be ignored. In this light, the combination between 5-FU and the "supreme" NLut could provide a compound utilizing their benefits, alongside avoiding the side effects of 5-FU, via reducing its dose. Such an adjuvant compound could fight the cancerous cells more efficiently. Furthermore, utilizing the ability of Lut to enhance the sensitivity of tumor cells toward other anti-cancer drugs could be beneficial to combine Lut with 5-FU, offering another alternative therapy with a lower dose and associated toxicity.

Conflicts of Interest: The authors declare no conflict of interest.

Ethical Clearance: Taken from Research Ethics Committee, Faculty of Dentistry, Cairo University.

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Joints Problems among Patients with Diabetes Mellitus Attending to Al-Hilla Teaching Hospital in Hilla City

Jameel Tanseen Mehsen[1], Alaa A. Hussein al_algawy, Mohannand Ali Hasan[3]

[1]Lcturer FICMS Orthopedic, Hammurabi Medical College, [2]Lecturer/ FICMS Orthopedic, College of Medicine, [3]Lecturer/ College of Medicine; University of Babylon, Iraq

Abstract

Introduction: The prevalence of diabetes for all age groups worldwide was estimated to be increasing . This will inevitably result in an increasing prevalence of the diabetes and associated conditions including rheumatic manifestations ,especially Osteoarthritis (OA) , and the high rate of disability related to disease make it a leading cause of disability in the elderly **Method:** the cross - sectional survey was conducted in Al-Hilla teaching hospital department of orthopedic surgery in Hilla city during the period March 2015 to 31 December 2017. 300 patients with type 2 diabetes mellitus was selected non randomly 150 males and 150 females between ages 39 – 77years to show the prevalence of osteoarthrosis among type 2 D.M patients in relation to sex, duration of D.M and body mass index. **Results:** the occurrence of osteoarthrosis among D.M patients was 30%. Osteoarthrosis was statistically significant (P=0.0003). In D.M patients with BMI more than 25 (48%). Osteoarthrosis was found more in patients with long duration of D.M which was statistically significant (P=0.001) since more than 15 years duration was 52% of D.M patients while duration of less than 5 years was 8%. **Conclusion**: OA in diabetic patients is common and it's more prevalent in obese and in female DM with long duration of disease.

Keys word: *joint problems, diabetes mellitus, Al-Hilla teaching hospital, Babil province.*

Introduction

Diabetes mellitus is a metabolic illnesses in which an individual has elevated blood glucose level either because of the pancreas doesn't generate adequate insulin or for the reason that cells don't reply to the insulin that's formed[1]. elevated blood sugar creates the traditional problems of recurrent urination, raised thirst and increased hunger. We enclose three kinds of diabetes mellitus: I. Kind 1: derive from metabolism failure to generate insulin. II. Kind2: that produce from insulin resistance, where cells can't apply insulin correctly. III. Gestational diabetes happen particularly ladies who are pregnant without previous diabetes[2].

The occurrence of diabetes for almost every ages internationally was calculated 2.8% in 2000[3]. This rising occurrence will finally cause a rising occurrence for your chosen severe diabetes in addition to related disorders such as rheumatic symptoms [4]. The rheumatologically symptoms of diabetes mellitus are the next syndromes of limited joint ability to move, diabetic hand syndrome, frozen shoulder, flexion tenosynovitis, osteoporosis, neuropathies: Charcot joints, diabetic osteoarthropathy, carpal tunnel syndrome and so on[5].

Osteoarthritis (OA) will be the most common kind of arthritis. Its top occurrence, commonly in the older people, along with the elevated level of impairment dependent on illness make it a major reason for disability in the older people. As a result of the aging of Western world people as well as obesity, a significant factor rising in occurrence, the existence of osteoarthritis is present increasing. In the United States, osteoarthritis occurrence will

raise by 66-100% by 2020[6,7]. Osteoarthritis is the top reason for musculoskeletal handicap on this planet[5]. Hyperglycemia decreases dehydroascorbate transport into chondrocytes, which may compromise the synthesis of type II collagen, and hyperglycemia increases reactive oxygen species (ROS) well known major deleterious mediators for cartilage destruction[8,9].

Patients and Methods

Three hundred patients with type 2 diabetes mellitus attended the orthopedic unit at AL- Hilla teaching hospital in Babil province during the period March 2015 to 31 December 2017 were enrolled, 150 of them were males and 150 were females their ages ranged from (39 —77) years and the duration of disease ranged from (1 — > 15) years.

Detailed history was taken including the age, sex, duration of disease, duration of treatment, past medical, drugs history, and BMI. BMI was calculated for all the patients using the following equation: BMI=Weight (Kg)/ (height (M)^2.

All patients performed X- Ray (standing anteroposterior and lateral view) to the knee joint by using (Fixed X-ray Shimazu 2008). The following changes were taken into consideration for the proposal of analysis: (narrowing of joint space, osteophytes formation, subchondral calcinosis and subchondral cysts). In this study, other secondary causes of osteoarthritis, history of trauma and pregnancy were excluded. This study design was prevalence descriptive a cross sectional survey; statistics was performed using SPSS 16, p value of lower than 0.05 was reflected statistically significant

Results

Three hundred diabetic patients, 150 (50%) were females and 150 (50%) were males. The mean age of the patients was 50.78 ± 7.35 years ranging from 39 to 77 years. Out of 300, 90 patients (30%) had OA, 60 (of them are females (40%) and 30 are males (20%); the remaining (210) patients 70% without OA, (90) were females (42.8%), (120) were males (57.2%) with p value =0.029 which is statically significant as in table no.1.

Table 1.Relationship between gender and OA in DM2 patients.

Gender	No OA	%	OA	%	Total	%
female	90	60	60	40	150	100
male	120	80	30	20	150	100
total	210		90		300	

Out of 300 patients 129 patients had BMI >25 kg/m2, 171 patients had BM1 <25 kg/m2. From 90 patients with OA. 63 patients had BMI ≥25 kg/m2, 27 patients had BM1 <25 kg/m2. The relationship between obesity and OA was statistically significant (p =0.0003), as in table (2):

Table 2. Relationship between BMI and OA in DM2

BMI	No OA	%	OA	%	Total	%
<25	144	85	27	15	171	100
≥25	66	52	63	48	129	100
total	210		90		300	

OA was found more in patients with longer duration of DM which was statistically significant (p=0.0015) as shown in table (3)

Table 3: The relationship between period of DM and OA in diabetic patients.

Duration of DM (years)	No OA	%	OA	%	Total	%
1-5	69	92	6	8	75	100
6-10	60	84	12	16	72	100
11-15	48	58	36	42	84	100
>15	33	48	36	52	69	100
total	210		90		300	

Discussion

Diabetes mellitus (DM) can attack the bone and joint structure in a number of steps, the metabolic perturbations in diabetes : glycosylation of proteins; microvascular problems injure to blood vessels plus nerves; and collagen deposits in skin and periarticular structures lead in modifications in the connective tissue[10].

In this study, the prevalence of osteoarthritis (OA) in diabetic patients was 30%, OA was more common among females (40%), than in males (20%) and these result was similar to meta-analysis study done by Velandai K.[11], the same results obtained in study done in USA showed 43% of Osteoarthritis occur in male and 57% in female[12] with significant association between gender and osteoarthritis.

In this study there is a significant association between high BMI (≥25) and osteoarthritis in diabetic patients <25 (15%) and ≥25 (48%) similar to study done in Netherlands showed body mass index (BMI) >27.4 kg/m^2 had a significant association with osteoarthritis[13]. Also study done in Germany showed the same association between high BMI (≥25) and osteoarthritis in diabetic patients and say: "Obesity seems to be a mechanical rather than a systemic risk factor for OA with the knee joint being especially

susceptible."[14] also our study similar to study done by Büchele G showed significant between high BMI (≥25) and osteoarthritis in diabetic patients[15], this results also similar to results in study done in USA reported that BMI more than or equal to 25 kg/m2 was most powerfully connected with OA[12].

In our study a significant relationship between duration of DM in years and OA in diabetic patients more occur in patients with duration of DM 11-15 years and >15 years

statistically significant and these matching with study done in morocco reported that Most rheumatic problems appear to be related with the duration of DM and appear in[16] and also our study similar to done in Egypt state than the duration of DM in years associated with OA development[17].

Conclusion

OA in diabetic patients is common and it's more prevalent in obese and in female DM with long duration of disease. Overall, an association between DM and OA seems to exist and additional studies to alarm and explore the pathophysiology of the connection of the two disorders, including a large number of patients.

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