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Isolation and Molecular Analysis of *Cladosporium* Species from Siddi Tribal Community Residing in North Karnataka Region, India

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Abstract

Dermatophytes are the common etiological agent to cause superficial mycosis, however non-dermatophytes like yeast and non dermatophyte mould (NDM) are emerging as potential agent to cause superficial mycosis. In this study, we evaluated epidemiological, clinical and mycological characters of non-dermatophytes causing superficial infection in the Siddi tribal community. A total of 1004 samples were collected from 937 Siddi community patients with superficial infection. In that 158 samples shown culture positive, *Candida species* (32, 20.25%) was the predominant agent to cause superficial infection other than dermatophytes followed by *Aspergillus species* (12, 7.59%), *Fusarium species* (10, 6.32%) and *cladosporium species* (2, 1.26%). Further, *Cladosporium species* isolated from tineacapitis infection was subjected to PCR, sequencing of ITS region and identified as *Cladosporium halotolerans*. Therefore, this study also revealed non dermatophytic fungi are emerging as important cause of superficial infection.

Key words: Dermatophytes, Mould, Yeast, Trichophyton, *Cladosporium*, Onychomycosis and Tinea, Polymerase chain Reaction (PCR)

Introduction

Superficial mycosis is the fungal infection of skin and its appendages like nail and hair, it is a public health problem and of worldwide importance in developing countries. Potential reason for proliferation of the infection may be low economic status, poor hygiene, inadequate health facility and exchanging of footwear and cloth⁽¹⁾. Even though it is not a life threatening infection but may affect the social life and day to day activities. Dermatophytes are common cause of superficial mycosis worldwide, there is an increase in the infection by non-dermatophyte mould (NDM) and

yeast has been observed^(1,2). Change the incidence of infection by pathogen may affect the clinician capability to diagnose and can change the approach to treat⁽³⁾.

Siddis are tribal community residing in India who brought from eastern African countries before many generations. They live in different parts of Indian states like Andhrapradesh Maharashtra Gujarat and Karnataka. In Karnataka they reside in North Karnataka region and adapted to local social and religious lifestyle. We undertook this study to see the common non dermatophytes causing the superficial fungal infection in Siddi tribal community^(4,5).

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Materials and Method

Study was conducted during 2015 to 2017 in north Karnataka region. A total of 1004 clinical samples like hair nail and skin scrapping were collected from 937 Siddi tribal patients with suspected superficial fungal infection. Clinical details were collected with patient consent. Samples were subjected to direct microscopy

by 10 % potassium Hydroxide (KOH) and inoculated in pairs in plain Sabourdose Dextrose Agar (SDA) and SDA with cycloheximide (0.5% 0.5 mg/ml), chlortetracycline (0.1% 0.1 mg/ml) and Gentamicine (0.1% 0.1 mg/ml) and incubated at room temperature. Cultures were noted for colony character, surface color and color on the reverse. Culture was identified by macroscopic and microscopic examination.

PCR and sequencing

Genomic DNA was extracted by phenol-chloroform isoamyl alcohol method and the extracted genomic material was eluted with 50 µl Tris-EDTA buffer. Polymerase chain reaction was carried out using internal transcribe spacer (ITS); ITS 1 and ITS 4 primer (ITS1, 5' TCCGTAGGTGAACCTTGCGG 3', and ITS 4, 5' TCCTCCGCTTATTGATATGC 3'), with final volume of 50 µl containing 0.5 µg of template DNA, 20 µl of Emerald Amp GT PCR Master Mix (2X premix composed of a DNA polymerase, optimized reaction buffer, dNTPs, and a density reagent) 15 pmol of each primer. PCR was performed in a thermo cycler (Eppendorf) with initial denaturation of 94°C for 6 minutes followed by 35 cycles of 94°C for 30 seconds, 58°C for 30 seconds and 72°C for 1 minute 30 second and final extension at 72°C for 10 minutes. PCR products were separated on 1.5% agarose gel stained with ethidium bromide and visualized in UV transilluminator and imaged. PCR sequencing was done from PCR product using ITS 1 and ITS 4 primer and BigDye Terminator Cycle sequencing kit version 3.1 (Applied Biosystems). ABI 3130 genetic analyzer (Applied Biosystems) was used for purification and analysis of all sequencing reaction. Sequences were compared with the GenBank DNA database using the NCBI BLAST tool (<https://blast.ncbi.nlm.nih.gov>), the ISHAM ITS database (<http://its.mycologylab.org/BioloMICSSequences.aspx>), and the CBS database (<http://www.westerdijknstitute.nl/Collections/BioloMICSSequences.aspx>).

Phylogenetic analysis

Phylogenetic analysis of study isolates and standard sequences retrieved from NCBI were done by aligning sequences using multiple sequence alignment mode in ClustalX2 software. The aligned sequences were exported to Molecular Evolutionary Genetics Analysis software version 7 (MEGA7)⁽⁶⁾ and neighbor joining

tree was constructed using Kimura 2 parameter model with 1000 bootstrapping replicates.

Results

A total of 1004 samples were collected from 937 patients with suspected superficial mycosis. Tineaunguim was the most commonly seen clinical condition followed by tinea corporis and tinea capitis. A total of 158 samples have shown the culture positive. Dermatophytes were the most common etiological agent isolated from 102 (64.55%) cases. Whereas non dermatophytes were isolated from 56 (35.44%) cases. Most of the patients were agriculturist (32, 57.14%) and field workers (9, 16.07%). Commonest clinical condition seen in superficial infection with nondermatophytes was tinea unguim (48, 85.71%) in which 52.08% cases were Proximal subungual onychomycosis (PSO), 22.91% of cases were white subungual onychomycosis, 16.66% of cases were Distal lateral subungual onychomycosis and 6.25% of cases were endonyxonychomycosis whereas, Tinea corporis (5, 8.92%) and Tinea capitis (3, 5.35%) was seen in 5 (8.92%) and 3 (5.35%) cases respectively.

In this study, *Candida* species (32, 20.25%) was the predominant agent to cause superficial infection other than dermatophytes followed by *Aspergillus species* (12, 7.59%), *Fusarium species* (10, 6.32%) and *Cladosporium species* (2, 1.26%). Further repeat sample was collect to confirm the infection with *Cladosporium species*.

Cladosporium species was isolated from twin's patients of age 7 years old with tinea capitis infection since from one year. Morphological feature included unbranched cylindrical conidiophores bearing ovoidal to ellipsoidal intercalary and terminal conidia.

Both *Cladosporium species* were used to sequence ITS region and were identified as *Cladosporium halotolerans* (accession number MT588811 and MT588810) Phylogenetic analysis of both strains were done with standard *Cladosporium species* stains retrieved from the NCBI database [*Cladosporium halotolerans* (LN834374, LN834375 and DQ780364), *Cladosporium angustisporum* (LN834356), *Cladosporium asperulatum* (LN834357), *Cladosporium allicinum* (LN834353), *Cladosporium cladosporioides* (LN834358), *Cladosporium flabelliforme* (LN834361), *Cladosporium funiculosum* (LN834364), *Cladosporium*

herbarum (LN834378), *Cladosporium subinflatum* (LN834391), *Cladosporium tenuissimum* (LN834398)]. Study isolates have clustered with *Cladosporium halotolerans*.

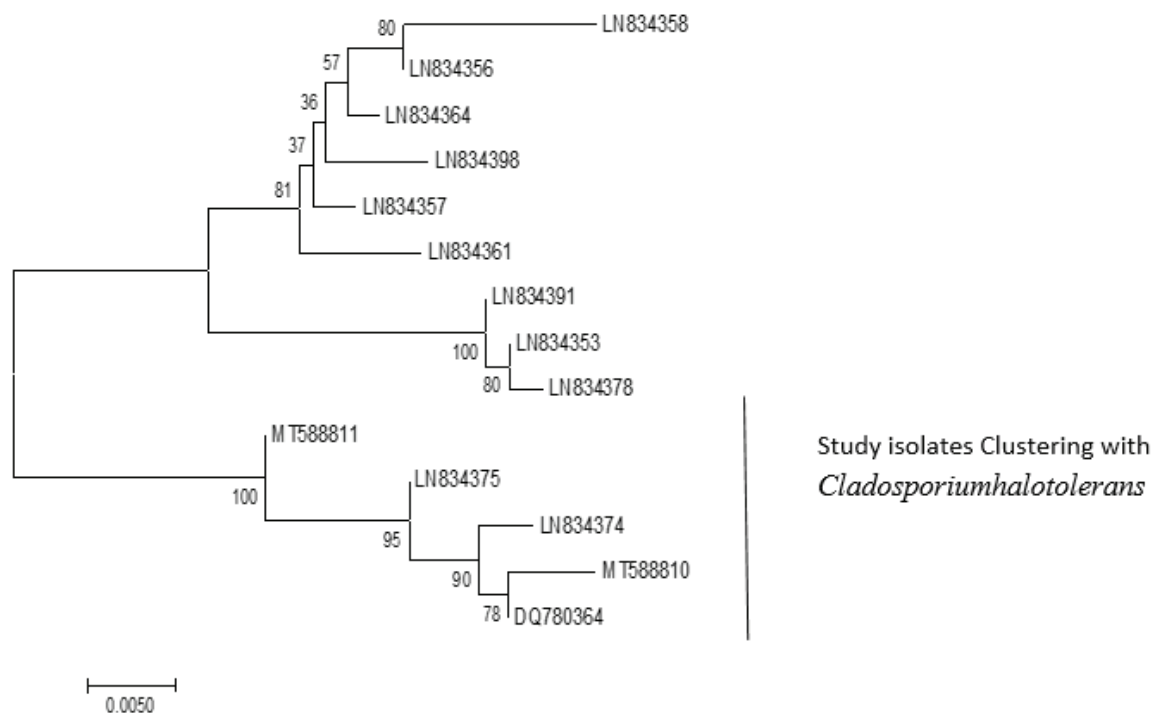


Figure.1 Neighbor-joining (NJ) derived dendrogram of internal transcribe spacer (ITS) gene based sequences. Phylogenetic analysis was done with the study isolates and standard CBS stains retrieved from the NCBI database [*Cladosporium halotolerans* (LN834374, LN834375 and DQ780364), *Cladosporium angustisporum* (LN834356), *Cladosporium asperulatum* (LN834357), *Cladosporium mallicinum* (LN834353), *Cladosporium cladosporioides* (LN834358), *Cladosporium flabelliforme* (LN834361), *Cladosporium funiculosum* (LN834364), *Cladosporium herbarum* (LN834378), *Cladosporium subinflatum* (LN834391), *Cladosporium tenuissimum* (LN834398)] study isolates (MT588811 and MT588810) have clustered with *Cladosporium halotolerans*.

Discussion

The present study showed 5.97% prevalence of superficial infection with non dermatophytes including yeast and moulds other than dermatophytes. It appears tineaunguim as the common clinical condition accounted for 85.71%, the risk factor for increase prevalence of tineaunguim in superficial mycosis by non dermatophytes might be due to frequent contact with soil during their day today life, Age, history of similar infection or frequent sharing of foot ware. Tinea corporis and tinea capitis was seen in 8.92% and 5.35% of the cases respectively. Similarly Kaur et.al. in 2015 found nail infection the most common site to cause superficial infection(7), whereas Lakshmanan et al. in 2015 have

found skin is the common site of superficial infection followed by nail and hair⁽⁸⁾. Infection rate was highest in the outdoor workers like farmers (57.14%) and daily wage workers (16.07%) which in accordance with studies done in other parts of India⁽⁹⁻¹¹⁾. *Candida* species (20.25%) was the predominant agent followed by *Aspergillus species* (12, 7.59%), *Fusarium species* (10, 6.32%) and *Cladosporium halotolerans* (2, 1.26%). Hazarika et.al in 2020 reported NDM were more prevalent than yeast to cause superficial infection⁽¹²⁾. Kaur et.al. in 2015 have found NDM was the most common agent to cause superficial mycosis followed by dermatophytes and yeasts⁽⁷⁾. *Cladosporium halotolerans* has been isolated from twin's patients with tinea capitis to confirm the infection with *Cladosporium halotolerans* repeat

samples were collected from both the patient shown the growth *Cladosporium halotolerans*. *Cladosporium* usually considered as indoor fungus being isolated in the environmental sources and geographic location, however many species of *Cladosporium species* are important pathogens to cause infection in plants animal and even in humans^(13,14). In most of the cases *Cladosporium species* isolated lack molecular confirmation, however in the present study *Cladosporium species* isolated were sequenced using ITS region and identified as *Cladosporium halotolerans*. Possible reason for the isolation of fungus like *Cladosporium halotolerans* in Siddi tribal community might be due to their low socioeconomic condition and poor hygiene, as majority of the Siddi tribal community live their life in poverty.

In conclusion, this study showed other than dermatophyte, non-dermatophytes like yeast and non dermatophytic moulds are also responsible for the superficial infection in the Siddi tribal community with prevalence rate of 5.97%. Tineaungum was the most commonly seen clinical condition to cause superficial infection by non dermatophytes in 85.71% of cases. *Cladosporium halotolerans* which is considered as the indoor fungus can also cause superficial infection like tinea capitis in the Siddi tribal community, a detailed study on Siddi tribal community and native Indians to find out such fungal superficial infection may reveal interesting findings, which may further help clinician diagnosis and may change the approach to treat.

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Ethical Clearance: Taken

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Covid-19 and Spanish Flu Pandemics: Insights into the Viral Vehicles of Life and the Concept of Dispersed Organisms

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Abstract

To understand diseases at a deeper level, we propose the concept of dispersed organisms as those having their constituent units spatially, and may be even temporally, separated in existence but still conforming to the definition of being an organic wholeness, having functionally dependent and non-spatio-temporally interconnected components. A living organism is characterized by elementary units (cells), each having the same DNA. This definition though specifically valid for multicellular complex organisms (eukaryotes), can very well be extended to include localized bacterial colonies as is evidenced by the phenomenon of quorum sensing, even though the DNA may only be partially identical. Starting with quorum sensing in bacteria as a preliminary indication, quantum entanglement among component units deriving from the same initial cause as a possible explanation, we draw upon a specific deeper vision of the causes of the Spanish flu pandemic of 1918-20 to establish the concept of dispersed organisms. We discuss the COVID-19 pandemic as a similar dispersed organism with its specific targets, severity, endemicity, span and consequences.

Keywords: COVID-19, Spanish flu, Pandemic, Quorum sensing, Multicellular organism

Introduction

An organism is a highly ordered, complex, self-organized structure of various kinds of components mutually related in an interdependent manner to ensure its survival, growth and reproduction. For a unicellular organism, the components are the organelles, while for multicellular organism they are cells. A bacterium lives and multiplies as a single individual but when there is a bacterial colony, they show a collective behavior called quorum sensing, which can be seen as a precursor to multi-cellularity^[1]. In this case cell-to-cell communication has been established to be happening via bio-molecular routes by release of autoinducers *such as* pheromones and other signaling molecules^[2-4]. It is as if the colony were a single organism in spite of the fact that it is a colony of separate individuals. Such behavioral traits must be present in the genetic material of each of the bacteria forming the colony for otherwise such

a collective behavior cannot come about. Identity of genetic material is the defining characteristic of the wholeness of the integral structure that is an organism. DNA level differences among individuals are more prominent in higher evolved eukaryotes. The unicellular organisms and the prokaryotes have their respective DNA almost the same for all members of each species due to extremely low mutation rates in ideal environments. On the basis of such near identity of DNA, we propose the concept of dispersed organism whose elementary units may have any spatial separation among themselves, but still they would all form one single organically connected wholeness, a dispersed individuality that has evolved to live in and for the many individuals forming the group. In case of RNA viruses such as the SARS COV-2, obviously RNA similarity will be the ground for understanding the COVID-19 as an organism^[5].

Thus commonality of DNA does point to some kind of interconnectedness among the organisms and as such, their collective behavior as a first approximation may be assumed to be proportional to such commonality. The molecular basis of such common behavior is the

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sameness of genomic arrangement. It is because of this arrangement that the communicating individuals are able to send and receive signals. Further all bacteria of a particular species have identical virulence factors and cause the same disease in the same kind of hosts. This is another aspect of their commonality which follows from their DNA. Similarly, no matter where on earth the HIV infects a human, it produces the same kind of symptoms and that is the commonality of all the AIDS viruses, encoded in their DNA. To explain organized and concerted behavior of such unicellular organisms, if we assume some kind of non-local correlation among them irrespective of their spatial separation *i.e.* whether they are in direct contact or not, then it becomes easier to visualize them all as forming but dispersed units of a single global organism which is the AIDS organism. Cancer as an organism has been discussed at length by us in our previous works^[6-10]. Similarly, all other virus and bacteria species can be visualized as forming globally dispersed single organisms with the corresponding individual viruses and bacteria as their basic cellular units. This is the new concept of dispersed organisms which we wish to establish in this article.

Dispersed Organisms

The cells in a multicellular organism are all manifestly interconnected and interdependent. The leap that we propose to take is that the physical components which may be individuals themselves, need not be spatially networked, but yet may be having a functional correlation to qualify to be called some sort of an organism, exactly like in the society of ants, bees or even humans. Strassmann and Queller analyzed such group-centric life and called them divided organisms^[11]. In our view, the society as a whole can be seen as an organism that has its existence dispersed among its individual members, which are now more akin to cells of a multicellular organism, but without all of them being necessarily in physical contact or communication and without having exactly the same DNA.

In case of a dispersed organism, the non-local correlations envisioned may be the effects of quantum coherence in biological systems^[12]. Quantum entangled bacteria have been experimentally demonstrated in their interaction with light^[13]. Even if the component systems are temporally separated, quantum entanglement may

still exist^[14]. It can be among fully or partially identical DNA leading to correlations among distinct component units (individuals) forming the dispersed organism.

Insight into diseases

The concept of dispersed organisms allows us to take a fresh look at the origin and evolution and also of treatment of diseases. There may be spatial separation of one bacterial colony from another in the same medium, but still all the elementary units being of the same kind having almost the same set of genes can be taken to form one organizational whole, like a multicellular organism. In this sense all bacteria of the same kind, no matter what their mutual separation is, form one organizational whole which is nothing but a kind of dispersed organism. The same can be extended to other elementary units such as viruses, in which case, all viruses of the same kind can be taken to form one dispersed viral organism. Hence, each disease can be said to result from the invasion of such dispersed organisms.

Spanish Flu pandemic in 1919-20

The spanish flu pandemic spread by the H1N1 virus that swept across the globe from 1918 to 1920 reached Japan in the late 1919 and created havoc till the end of January 1920^[15]. So far there is no established scientific reason as to why the pandemic subsided so fast after the second wave. Here are excerpts from an account given by the Mother of her own experience of getting infected by the virus and her fight for recovery^[16]:

“One day I was called to the other end of the town by a young woman whom I knew... I had to cross the whole city in a tramcar. And I was in the tram and saw all those people with masks on their noses, and there was in the atmosphere that of constant fear, and there came a suggestion to me – I began to ask myself – Actually what is this illness? ...I returned home with terrible fever. I had caught it... At the second day, as I was lying all alone, I saw clearly a being with a part of the head cut off, in a military uniform – or what remained of a military uniform – approaching me and suddenly flinging himself upon my chest, with that half head, to suck my force. I took a good look, then realized that I was about to die. He was drawing my life out... ..I was completely nailed to the bed, without any movement, in deep trance. I could not stir and he was pulling out my life. I thought,

“This is the end.” Then I called on my occult power, I gave a big fight and I succeeded in pushing him off so that he could not stay any longer. And I woke up...I had understood that the illness originated from the beings those who had been thrown violently out of their bodies. I had seen this during the First World War, towards the end, when people were staying in trenches and killed in bombardments. They were in perfect health, altogether healthy, and in the blink of an eye they were thrown out of their bodies, not conscious that they were dead. They didn’t know that they had no body any more and tried to find in others the life force they could not find in themselves... I know how much knowledge and force were necessary for me to resist. It was irresistible for ordinary persons.”

Then, as asked by the Mother, she was left alone for two days and concentrated on the evil that was sucking the life out of such a large number of humans. At the end of two or three days there was not a single case in Kyoto. And in a few days Spanish flu had disappeared from the world.

Illness, like every other object and subject, was a field of study for the Mother. All the ailments that occurred in her own body were studied thoroughly. She once said that, “there is nothing fundamentally incurable. It all depends... To be able to cure an illness you have to know its cause, not just its microbe.” and “What people assume to be microbe is quite simply the materialization of a vibration.”

The importance of reproducing the whole episode as recounted by The Mother herself can be gauged from the fact that our current scientific perspective on the origin of diseases is so different from it^[17].

We note that the particular discarnate being that produced Spanish flu in the Mother cannot be accepted scientifically as the cause as per our present understanding. We must say that she had those infectious viruses in her body which caused the flu. Thus the vision which she had can be matched with the scientific view only if we equate the discarnate being with the viruses, meaning thereby that it entered the body of the Mother in the form of those viruses. The Mother says that such beings are desperate to enter a living body to have their life from them. Does it not fit the definition of parasitic life? Don’t the viruses require the host’s life to get their

life functional?

This is positive proof of the fact of the existence of dispersed organisms. A desperate-for-life discarnate being infects as an organism dispersed among the viruses that cause the infectious diseases. The differences in symptoms and morbidity etc. in different individuals due to a single virus can then be explained as being due to differences in immunity as well as in the dispersed organisms (discarnate beings) that are infecting through those viruses.

How many such war casualties were on the rampage through the H1N1 viral vehicle and with what lethality each acted to kill humans till the Mother’s interference? These will surely remain unanswered. Further, can we associate the COVID-19 with world war-II casualties as dispersed organisms taking their toll through the viral vehicles such as MERS, SARS and SARS COV-2? What about the casualties of other wars and terrorist massacres?

Targeted victims of COVID-19

We have proposed earlier that the COVID-19 disease has behaved as a conscious organism having definite focus and intent^[5]. Many of the doctors, nurses, paramedical staff engaged in treatment of COVID-19 patients, researchers engaged in finding a cure or vaccine for it, police personnel, politicians and statesmen engaged in maintaining social distancing and enforcing lockdowns and shutdowns intended to curb the rapidity of the spread of the pandemic have been infected and many of them have succumbed to it too^[18-19]. Surprisingly, the lockdowns and shutdowns were utilized gainfully by the SARS COV-2 virus to continue its rampage because its only natural enemy seems to be UV radiation which depends on daylight duration^[20]. India imposed lockdowns and shutdowns as early as March 2020, when the total affected were less than 2000 and the rate of new cases was below 50 per day. But eventually the national financial threshold was reached and they had to relax it when the virus really had affected more than three lakhs and the rate of new infection reached more than 10000 per day in late June, when coincidentally humidity was also reaching its pre-monsoon peak! Humidity will certainly help microscopic droplet transmission by increasing the droplets’ life-in-transit. Now there is simply no stopping!

The strategy of countering it by development of herd immunity by exposure to and infection by the virus of large sections of the population failed miserably in UK and the prime minister himself was attacked by COVID-19 and had to be on ventilator in ICU for a week to recover.

Does a disease specifically target those who work against it by treating patients or trying to find a cure or a vaccine for it, though it may not be successful against all of them all the time in infecting or killing? It is not difficult to come across cases of cardiac surgeons succumbing to heart attack, TB specialists falling prey to TB, Cancer therapists dying of cancer and so on. Why has the USA suffered the worst in all pandemics after world war-II? Why NATO countries suffered the most in COVID-19? Why Russia? Why India? What will happen to China in the future pandemics?

Conclusion

Viruses are the ultimate frontier for biology to grapple with in future as they hold the key to understanding many fundamental aspects of life. They are the oldest known precursors of the living cell, though classified as nonliving. In fact the living cell can be seen as the habitat or niche constructed by the viruses for themselves for purposes of their reproduction. Viral eukaryogenesis must have been preceded by a viral prokaryogenesis. This means that the totality of viruses would exhaust all diversity of life as their reproduction niche. Indeed, all life on earth has been surmised to be an ontological individual. This ontological individual must then be the dispersed organism whose vehicles are the myriad viruses, the leaders among them being the oncoviruses, which have no competitors in the realm of survival and reproduction. The oncoviruses in their turn are agents of cosmic disorder that is pitted against cosmic order since the origin of the cosmos. Such is the origin of what we call "life" and we have so far grappled with to understand.

Ethical Clearance: Not required for this kind of work

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Sleep Patterns and its influence on Sleep Problems among Children in India: A Systematic Review & Meta-Analysis

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Abstract

Sleep is equally important to the food we eat, the liquids we drink, or the safety of the children. Each living being needs sleep. It is the essential activity of the mind during each stage of development. Whereas inadequate sleep can lead to the development of various health issues. Although a generous group of literature has explored the relationship between sleep patterns and problems, comprehensive reviews and far-reaching conclusions are lacking. This systematic review was conducted to describe the sleep pattern or habits present in Children and also to identify its influence on the onset of various sleep problems among 3 to 18 years. Electronic databases were searched for articles published up to August 2019 and no limits for study designs were kept. The articles for review were obtained from databases like MEDLINE, PubMed, Cochrane, and Google Scholar along with a handful of references of experts using Boolean operators' search criteria. The guidelines adopted were Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). The nighttime sleep duration was the most common sleep measure or variable in 73% of the articles. The average sleep duration (night time) is 9.811 hours (3 to 5 years), 9.082 hours (6 to 12 years) and 7.944 hours (12 to 18 years). The result from this review suggested that sleep patterns tend to delay as the age increases leading to insufficient sleep and irregular bedtime schedules leading to the onset of some of the sleep problems like snoring, nightmare, bedwetting, etc. A few reviews suggested that it was difficult to define the sleep problem effectively as families vary greatly in their tolerance of their children's sleeping habits.

Keywords: Sleep, Sleep Pattern, Sleep Problems, Children's Sleep

Introduction and Background of the Study

Each living being needs sleep. It is the essential activity of the mind during each stage of development. Sleep is equally important to the food we eat, the liquids we drink, or the safety of the children. Circadian rhythms or the sleep-wake cycle begin to develop at about six weeks, and by three to a half year, most infants have a regular sleep-wake cycle. By the age of two, most of the children have spent more energy and time in sleep than being alert. Hence, a child is spending 40% of his or her childhood asleep. There are two states of sleep in the sleep-wake cycle. They are: Non-Rapid Eye Movement (NREM) or "quiet" sleep and Rapid Eye Movement (REM) or "active" sleep.

Neonates spend 50 percent of their time in each of these states and the sleep cycle is about 50 minutes. But

when the child is at about six months of age, REM sleep comprises about 30 percent of sleep. At the preschool age, the duration of the sleep cycle increases and is about every 90 minutes. Children should get sound and enough sleep according to their age so that they can play, and develop cognitive skills during the day time.

The children of India suffer from various sleep disorders due to lack of adequate sleep. Many studies have proved that Asian countries are more sleepless as compared to Western countries. The most common sleep disorders seen in children are daytime sleepiness, restless sleep, difficulty falling asleep, and sleepwalking are a few. It is very much important to early detect sleep disorders and identifies sleep deprivation as it is associated with conditions like cardiovascular morbidities, ADHD, and obesity. As far as we are aware, no systematic review was conducted in the age group

3 – 18 years of age in India. Unlike adults, the children cannot complain about sleep problems or they could get the treatment for it. Hence it is necessary to identify the sleep pattern of Indian children and to identify the common sleep disorders they are affected with through an extensive systematic review. This systematic review was conducted to describe the sleep pattern or habits present in Children and also to identify its influence on the onset of various sleep problems among 3 to 18 years. The benefit of collating a systematic review is to measure abnormal sleep patterns which in turn can be helpful to frame policies and strategies for the resolution of the sleep problems.

Purpose

This systematic review aims to review the pattern of sleep among children age between 3 to 18 years and its influence on sleep problems.

Methods:

The designing of protocol and data extraction was conducted according to the 2009 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

Literature Review Strategy

A search strategy was developed to identify studies related to sleep patterns and sleep problems from 3 to 18 years of age. Electronic databases were searched for articles published from 2005 to August 2019 and no limits for study designs were kept. The articles for review were obtained from databases like MEDLINE, PubMed, Cochrane, and Google Scholar along with a handful of references of experts using Boolean operators' search criteria. The search was limited to the articles in the English language only. An extensive literature search was done whose title, abstract or keywords included references to sleep, sleep pattern, sleep problem, child (age between 3 to 18 years). The articles extracted from the database were examined to extract potentially relevant articles, which was examined later in more depth to meet the inclusion or exclusion criteria set by the authors. The guidelines adopted were Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).

Inclusion and exclusion criteria

The inclusion criteria used in the current systematic

review are given below:

- Original article
- Non-clinical studies
- The age group of the participants between 03 to 18 years
- Studies in which samples are well described as the number of subjects, gender, etc.
- Studies with one or more of the variables like sleep pattern or duration, various sleep problems or disorders mentioned like sleepwalking, daytime sleeps, etc.

- Data were presented numerically

The exclusion criteria followed in the study are:

- If the study was published at more than one place then only the first published study will be included.
- Clinical studies.
- Studies published before the year 2005

Scientific literature quality assessment

The quality of the studies selected and used in the systematic review was assessed and evaluated by the Quality Assessment Checklist for observational studies by Hoy et al. The checklist consists of 09 items. The highest possible score was 09 and the minimum score was 0. The two investigators scored the articles independently and discrepancies were resolved through discussions.

Data extraction

The mean and standard deviation (SD) data from variables like duration of nighttime sleep and day time nap was extracted from the articles regarding sleep pattern. Further, the variables selected for sleep problems were categorized into three headings namely, sleep latency, hypersomnia (irresistible urge to fall asleep during the day, narcolepsy) and parasomnias (sleep talking, teeth grinding, sleepwalking, night terrors, nightmares). When the studies included weekend and weekday data, the average was extracted to align the majority of studies to represent the routine sleep pattern. When data for gender was separately available, the data were combined.

Meta-analysis and reference values

Meta-analysis was conducted for sleep measures in three age-bands identified by the investigators such as Pre-schooler (3 to 5 Years), Schooler (6 to 12 Years) and Adolescents/Teenagers (12 to 18 Years) The analysis was performed with the Open-Meta (Analyst) statistical software using the mean and standard deviation (SD) for each study to produce the pooled estimate mean and the 95% confidence intervals (CIs) in sleep pattern (duration of nighttime sleep) of the children. Additionally, the variables selected for analysis of the sleep problems were analyzed using the prevalence rate (number of each event occurred) and the 95% confidence intervals (CIs) for the estimation of pooled prevalence rate according to the identified age-bands.

Results

Database searches

The search criteria from all databases (with

duplicates eliminated) rendered 44 articles. Of those, 31 found to be potentially relevant papers based on title and abstract and were used for the application of inclusion and exclusion criteria. 15 articles were excluded, leaving 16 articles for review. During data extraction, a further 05 were excluded because age ranges were too wide or articles contain limited data for meta-analysis. Data were captured from 11 cross-sectional designs (among these 02 studies were not included for quantitative analysis). The detailed search criterion is represented in Figure 1.

Articles Reviewed

Table 2 summarizes the important aspects of the 11 articles included in this review. All studies recruited both boys and girls; some did not supply a breakdown of gender. The review included studies from 09 different states in India. 02 articles were considered good quality based on the criteria, with 08 of moderate quality and 1 of poor quality. But no study was neglected for data accuracy.

Table 1: Articles included in this review with Quality Index Score

First Author	Year	Population/Region/ Area of study	Study numbers	M:F	Age	Instument/ Mcausurc	Design	Variables	Quality Index Score
C. Barathy	November, 2017	Pediatric Out Patient Department (OPD), Indira Gandhi Medical College and Research Institute, Puducherry	650		1-12 years	Semi-structured questionnaire (for pattern & Reporting by parents or self (for problems))	Cross-sectional observational study	Bedtime, wake-up time, night awakening, day nap, weekend sleep schedule and sleep problems	3
Ravi Gupta	April - June, 2017	Primary schools of the semi - urban areas of Dehradun, Uttarakhand	435	0.65	4 - 9 years	Pediatric Sleep questionnaire (Hindi translated)	Cross-sectional observational study	Various sleep problems like sleep latency, hypersomnia & parasomnia	5
J. C. Suri	January, 2008	School-going children residing in Delhi	2475		5 - 18 Years	Pediatric Sleep Questionnaire	Cross-sectional observational study	Various sleep problems like sleep related breathing disorders, snoring etc.	4
Munish Kumar Kakkar	May-August, 2016	School-going adolescents in urban and rural Rajasthan	565	1.03	10 - 18 years	Questionnaire-based study	Cross-sectional Study	Various sleep patterns	6
Modi Sarita	March, 2016	Under graduate students of Sri Aurobindo college of medical sciences and technology, Indore (M. P.)	1056	1.12	17 and 25 years	Questionnaire based study	Cross-sectional observational study	Sleep pattern and problems	6
Dr. Cyril Ignatius Rozario	May, 2017	Primary school going children visiting OPD of MCH Vandanam, Alappuzha, Kerala	400	1.44	6 - 12 years	Questionnaire based study	A preliminary questionnaire survey	Sleep pattern and problems	5
Dr. Bhavneet Bharti	January, 2006	School going children visiting Advanced Pediatric Center, PGI, Chandigarh	103	1.71	3-10 years	Questionnaire based study	Cross-sectional prospective study	Sleep pattern and problems	6
Apurva Mishra	October, 2017	Boys and girls attending regular government elementary schools in Lucknow, Uttar Pradesh	1050	1.73	4 -15 years	Self structured questionnaire	Cross sectional study	Pre sleep habits, duration and pattern of sleep	7
Ravi Gupta	July, 2016	School going children from four each schools from the rural and urban areas of Dehradun, Uttarakhand	831	1.04	9 - 14 years	Childhood-Sleep Habit- Questionnaire (CSHQ, Hindi version)	Cross-sectional observational study	Sleep schedule, pre-sleep behavior, co-sleeping and parent's perception of sleep	5
Gowtham Murugesan	2018	School-going adolescents from 8 schools in 3 districts of Thiruvallur, Thiruppur and Namakkal, Tamil Nadu	538	0.99	10 - 17 years	Modified questionnaire of Adolescent Sleep Hygiene Scale	Cross-sectional survey	Sleep patterns, hygiene and daytime sleepiness	3
Ravi Gupta	November, 2007	School-going adolescents from Grade 9th to 12th of 3 schools situated in Delhi	1920	1.56	12 - 18 years	Questionnaire-based study	Cross-sectional Stud,	Sleep pattern and sleep problems	5

Sleep duration:

The nighttime sleep duration was the most common sleep measure or variable in 73% of the articles. Meta-analyses were conducted within age-bands for 3 - 5 years (Pre-school), 6 – 12 years (School going), and 12 – 18 years (Adolescent). The results of which appeared are illustrated in Table 3. The meta-analysis to produce these values or pooled mean and ranges are given in Figure 2, Figure 3 and Figure 4 (sleep duration at 3-5, 6 – 12 and 12-18 years of age). The reference value (or pooled mean estimate) is 9.811, 9.082 and 7.944 hours respectively for the mentioned ages and pooled estimated lower and upper 95% CIs as mentioned in the forest plot.

Table 2: Summary data for nighttime sleep duration (hours) across the age category.

Age-band or category	Study Reference serial number	Mean	Lower limit	Upper limit	I ²
Pre – school 3 – 5 years	1, 8	9.811	9.046	10.575	98.26%
Schooler 6 – 12 years	1, 4, 6, 7, 8, 9	9.082	8.789	9.374	98.42%
Adolescents 12 – 18 years	4, 5, 8, 10, 11	7.944	6.844	9.044	99.82%

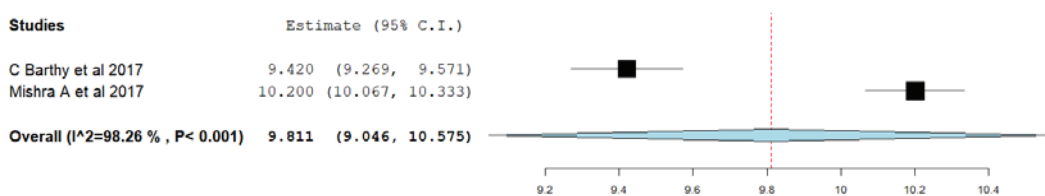


Figure 1: A forest plot example of the meta-analysis to calculate the pooled mean estimate for sleep duration at 03 – 05 years of age.

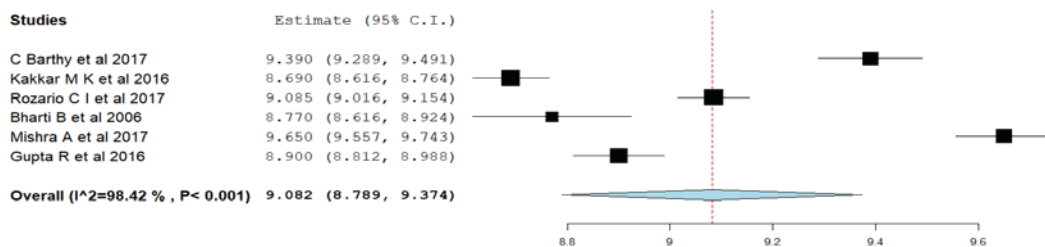


Figure 2: A forest plot example of the meta-analysis to calculate the pooled mean estimate for sleep duration at 6 – 12 years of age.

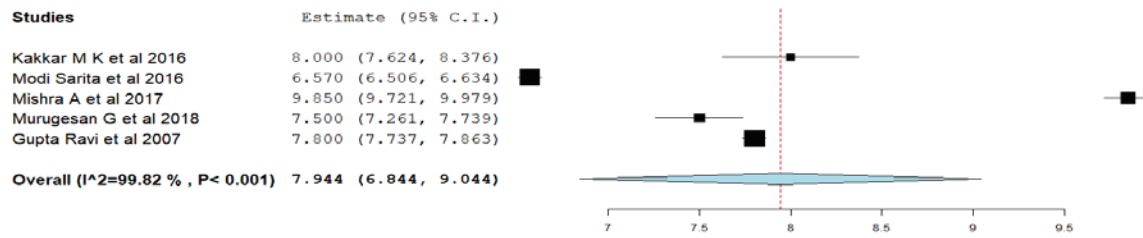


Figure 3: A forest plot example of the meta-analysis to calculate the pooled mean estimate for sleep duration at 12 – 18 years of age.

In India, the number of studies conducted is very few regarding the sleep pattern of children. Hence the paucity of data is evident in the results. The analysis also showed significant heterogeneity among the selected studies at $P < 0.001$. The above-mentioned table shows that the night time sleep duration is declining as the age advances.

Sleep latency:

In pre-school age band 12.3% (47/375) had pooled prevalence of sleep latency (CIs: 95%, 6% to 23.6% with $I^2 = 83.7%$, $P = 0.013$). The summarized prevalence rate for 6 – 12 years is 9.4% (CIs: 95%, 2% to 35.4% with $I^2 = 98.44%$, $P < 0.001$) and for 12 – 18 years is 43.3% (CIs: 95%, 36.5% to 50.3% with $I^2 = 89.85%$, $P < 0.001$).

Hypersomnia:

These data were confined to the School going (3 studies contributed) and adolescent (2 studies contributed) age group. A total of 1179 samples were analyzed out of 95 were identified with the hypersomnia with a pooled prevalence rate of 2.7%. In adolescents, 1436 out of 2458 subjects were detected with hypersomnia and the pooled prevalence rate was estimated at 60.7%.

Parasomnia:

No data was extracted from 3 – 5 years of age. At 6 – 12 years age 43.6% pooled prevalence was identified with CIs: 95% (Range: 32% to 55.8%). In the age band, 12 – 18 years 20.6% prevalence rate pointed out with a range of 7.4% to 45.8%.

Discussion

Since the meta-analysis combined data from different states of India and cultures (South India and North India), the reference values should be considered as norms for entire India, rather than based on cultural norms. But the paucity of data and the number of studies conducted in the country limit the generalization of the findings across the country. The results, we believe, will be useful to assess the normal range of sleep at various age groups.

In majority of the studies, sleep measures were assessed at a one-time point and the study variable used in most articles was on sleep duration. A very few studies have been found with other variables like duration of day time naps, lifestyle, bedtime routines, etc. Disappointingly, many research articles collected sleep duration data but were excluded because the values were not reported numerically. For example, sleep duration was often subdivided categorically and some articles were rejected because they reported data by education grade rather than age.

The importance of measuring sleep patterns and identifying sleep problems at the earliest is reflected in almost all literature. Many cross-sectional studies show that the lack of required amount of sleep can result in various negative impacts like difficulty in falling asleep, lip biting, etc, and also can lead to poor academic performances. The sleep duration in our selected studies shows that the children in India are not getting the recommended sleep duration of various age bands by the experts of the National Sleep Foundation. Further, it is also noticed that the night time sleep duration is

declining from pre-school to adolescents. This may be influenced by the school days and later bedtimes. The mean reference values for sleep duration we have analyzed are given in Table 02.

Carskadon, et al., and Yang, et al., mentioned in their studies that a decrease in sleep time happens with advancing school grades and it may be due to academic demands of higher grades. This agrees with the pooled mean findings from our study.

Many literatures did not define sleep problems properly. Few had administered same tool to different population but obtained different pattern of data. This is because the perception of sleep problems varies from one person to another. Further, it was also observed that the differences in the instrument and the geographical location/cultural differences might have influenced the result of the studies selected to identify the pooled prevalence of common sleep problems like sleep latency, hypersomnia, and parasomnia. The scarcity of Indian literature on the selected topic also is a major factor in the determination of the prevalence of various sleep problems among children.

Conclusion

In conclusion, standardizing information over the childhood lifestyle is essential to realize what is outside of normal; to evaluate sleep problems, to manage sleep issues, or to give preventive advice. The information from the present study can set a benchmark and we reiterate that the reference values should be considered in planning, policy-making, and implementing the sleep pattern norms in adherence to the guidelines of the National Sleep Foundation. However, a nationwide study with proper randomized coverage of the population is essential to ensure the ethnic and cultural variations in the sleep pattern of India.

Ethical Clearance: For this Systematic Review we have taken the consideration of ethical issues. No significant ethical concerns were raised during the study. Ethical Clearance was obtained from SMVDPEC (Shri Mata Vaishno Devi Project Evaluation Committee)

Conflict of Interest: There are no conflicts of interest in this study as per the knowledge of the investigators.

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Perception of Undergraduate Medical and Dental Students Towards Learning Anatomy in Google Classroom

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Abstract

Background: Google Classroom is one of the online learning system developed by Google which enables both the teachers and learners to engage in ‘beyond the classroom’ learning in an innovative way. The present study mainly focus to assess the perception of students towards learning Anatomy in Google Classroom **Methodology:** A study was conducted in undergraduate medical and dental students of ACS Medical College and Thai Moogambigai Dental College, Chennai who are residing in their homes due to Covid 19 lock down. Anatomy virtual class was created in Google classroom individually for medical and dental students and students were asked to join the class by means of class code. The materials were uploaded on a daily basis based on the syllabus. Assignment and assessment were also given and graded. After two months of learning experience in Google Classroom, perception of students and challenges faced by them towards this learning system was collected by structured questionnaire in Google form and it was statistically analysed **Results:** About 163 students responded to the questionnaire. 79 (48.2%) students were males and 85(51.8%) students were females. Overall the students gave positive response towards their learning experience in Google classroom and few problems also have been found out like issues regarding accessing course materials and navigating the system, difficulty in submission of assignments, poor internet connection and they also want to make the classes more interactive **Conclusion:** Sensitisation and proper training should be given to the students regarding the use of Google Classroom. Quizzes, mind mapping, clinical based questions can be given to make the participants more engaged and interactive. Hence Google classroom is definitely a student centered online learning platform with the teacher as facilitators which helps to make the students competent.

Keywords: online learning, medical and dental students, technology, Google classroom, perception

Introduction

Teaching and learning is no more confined within the chalk and talk method in today’s modern world. Nowadays teachers are expected to provide better learning environment to the students both inside and outside the classroom which can be termed as “beyond the classroom” learning^[1]. This type of learning ensures

personalized, competency based and student centred environment. The first and foremost challenge is the growing dependence on technology which has made wide impact toward education system. Hence learning is no longer bound by space, distance and time with technological advances. Both the lecturers and students have already got the advantage of technology to support their teaching learning activities^[2]. Many people believe that use of technology for learning can be able to replace the current learning situation”learning with effort” into ”learning with fun”^[3]. Online learning is one kind of learning which is done not only in the classroom but it can also be done through online or computer devices. Khan et al reported that “online instruction as an innovative approach to delivering an instruction and

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materials of learning to a remote audience using the web as the media” [4]. One such example for online learning is Google Classroom.

Google Classroom (GC) is a virtual class launched by Google Apps for Education (GAPE) in 2014. To use this application, the users need g-mail account and it is free of charge. This application can be used in smartphone and other computer devices. The facilitator need to create a class and share the class code to the students so that they can join with the class created. Google Classroom gives teachers opportunities to expand the techniques of classroom management and activities. This also facilitates the teachers to upload their classes, create and organize assignments quickly, provide feedback efficiently and communicate with their classes with ease [5]. In Google Classroom, both the lecturer and students have the assessment record and the lecturer cannot miss any students’ mark and works. They can be checked anytime. Google classroom integrates with other Google products like Google Docs, Google Drive, YouTube, Google Forms, Google Calendar in one place which allows class teacher and students to send and share office docs or multimedia files, to do collaborative project, to have an online discussion and assessment. Iftakhar [6] stated that “Google Classroom is meant to help teachers manage the creation and collection of student assignments in a paperless environment, basically leveraging the framework of Google Docs, Drive and other apps. Google classroom allows teachers to spend more time with their students and less time on the paperwork; which is now even better”

Online learning has many challenges like limited implementation of online learning since it is used only to deliver and submit the task, poor internet connection which can lower students motivation and miscommunication between the students and teacher can also happen if the instructions are unclear.

The teachers are basically regulating the activities in the Google classroom but it is the students can only tell the pros and cons of it since they are practically dealing with it for learning. Hence the aim of the present study is to investigate the perception of students towards learning Anatomy in Google Classroom.

Objectives

To assess the perception levels of undergraduate medical and dental students and to identify the challenges and barriers faced by the students towards learning Anatomy in Google Classroom

Methodology

The study was done in the undergraduate medical and dental students (2019-2020) of ACS Medical College and Hospital, Thai Moogambigai Dental College and Hospital, Dr.M.G.R Educational and Research Institute, Chennai who were residing in their homes due to Covid-19 lockdown. Hence the online classes were planned in Google classroom.

Anatomy virtual class was created in the google classroom individually . They were asked to join Anatomy class by typing a class code. The class was filled by teachers self made lesson materials like downloadable videos and voice over power point related to Anatomy and they were accessible by any student at any time .It was uploaded on a daily basis following the order of class discussions . Submission of assignments related to the topic were done and it was graded. Two Internal Assessment Examination were also conducted in Google classroom.

After 2 months, students were asked to fill pre formatted structured questionnaire in Google form to assess their perceptions and challenges faced towards learning Anatomy in Google Classroom. The questionnaire was prepared with reference to Shahanee et al [7] and Khaleel et al [8]. The questionnaire included questions on demographics, five predictor variables, student satisfaction and issues faced by the students. All the items excluding demographics were measured using a five-point nominal scale ranging from 1 (strongly disagree) to 5 (strongly agree). Pre-testing and pre validation were done in the questionnaire. Questionnaire was shared to the students through whats app. The Google form contained consent form in first section and questionnaire in second section. The link was made accessible to the students for one week (26th May 2020-30th May 2020). Then the data was statistically analysed.

Results and Discussion

About 163 students of I year undergraduate medical

and dental students responded to the questionnaire .Out of 207 students, 164 students participated in the study which shows a response rate of 79.22%. 79 (48.2%) students were males and 85(51.8%) students were females. The main access of application is through mobile phone(90.9%) rather than desktop, laptop and tablets and the internet data usage in google classroom per day is less than 1GB/day(44.5%) (Fig.1).

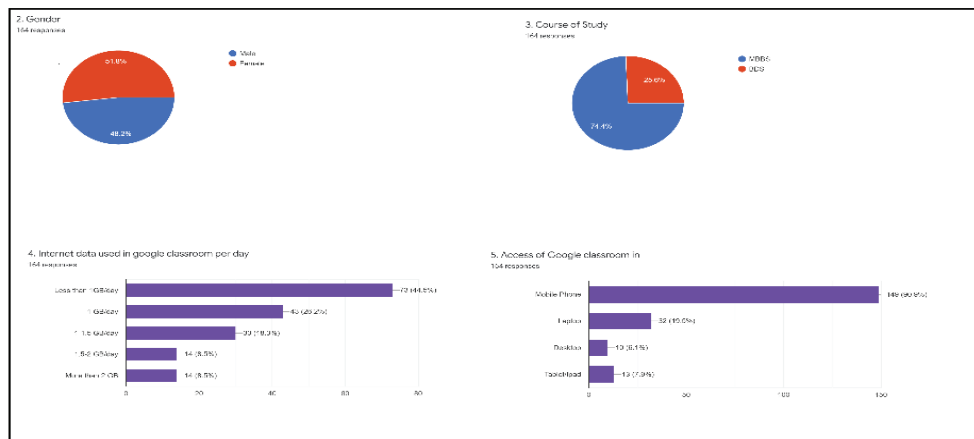


Fig.1: Gender distribution and Course of participants/

Mode of Access and internet data usage in Google classroom

Regarding ease of access in google classroom, students agreed that it was easy to sign into the google classroom and about understanding the system with mean of 4.04 ±0.93 and 4.01± 1.35 and is lower in the component of submitting and receiving assignments with 3.35. Hence the students should be sensitised regarding the submission of assignments in google classroom. But in the study done by Shaharane et al^[7], respondents strongly agreed that the introduction of Google Classroom in their class makes the process of submitting assignment easier with 4.52 and disagreed about accessing course materials and navigating the system with 3.05 and 3.44 Hence teacher should pay

more attention on helping the students with necessary materials to help them understand about navigating the system easily.

Students strongly agreed that the feedback provided by the lecturer is useful with highest mean of 4.32±0.92. The items of learning quality and the grading system in Google classroom have the mean value of 4.01 and 4.12 respectively.. Students disagreed that about learning activity in google classroom helping to evaluate new ideas and develop self learning and critical thinking skills with mean value of 3.54± 1.17 and 3.36 ± 1.15 and hence the teachers have to concentrate more on the platform that should improve the students critical thinking skills and idea generation [Tab.1].

Tab.1: Mean value and S.D of items of Perceived usefulness in google classroom(n=164)

S.No	Item	Sum	Mean	Standard Deviation
1.	The quality of learning activity was excellent	658	4.01	0.83
2.	An excellent medium for social interaction (lecturer vs students and students vs student)	675	4.11	1.16
3.	Help me to submit assignment on time	682	4.15	0.54
4.	Helped me to examine issues, to evaluate new ideas, and to apply what I have learned.	582	3.54	1.17
5.	The feedback provided by the lecturer is useful	710	4.32	0.98
6.	The grading system help in monitoring my performance and understanding the current topic discussed	677	4.12	0.74
7.	Help to develop self learning skills and critical thinking skills	552	3.36	1.15

The item with highest mean is instruction regarding feedback given by the lecturer that allowed the student to better understand the content of the course with mean value of 4.54±1.07. In the study done by Shaharane et al^[7] the lowest mean value goes to feedback that allowed to better understand the content of the course provided by lecturer with mean value of 4.33. The lowest mean value goes to lecture clearly communicated course topics and making the course participants on task with mean value of 3.77±1.01 and 3.79±0.98 respectively. Therefore, steps has to be taken to keep the course participants on task by including activities like quizzes,

picture based questions and clinical based questions as a part of learning activity[Tab.2].

The highest mean is the item regarding lecturers being friendly, approachable and could be easily contacted and also the enthusiasm of lecturers in teaching and explaining The lowest mean value goes to lecturer helping to keep course participants engaged and comfortability of interacting with other participants in learning activity with mean value of 3.46±1.13 and 3.25±1.20. Therefore, action should be taken on making interactive platform of online learning [Tab.2].

Tab.2: Mean and S.D of course Instruction Delivery/communication and Interaction in Google Classroom(n=164)

S.No	Item	Sum	Mean	Standard Deviation
Course instruction delivery				
1.	Lecturer provided clear instructions about course learning activities.	730	4.45	0.95
2.	Lecturer clearly communicated important due dates/time frames for learning activities.	732	4.46	0.99
3.	Lecturer clearly communicated important course topics.	619	3.77	1.01
4.	Lecturer helped keep the course participants	623	3.79	0.98
5.	Lecturer provides feedback that allowed me to better understand the content	745	4.54	1.07
Communication and Interaction				
1.	Feeling comfortable conversing through this medium for this activity	683	4.16	0.62
2.	Lecturer helped to keep course participants engaged and participating in productive discussion	569	3.46	1.13
3.	Felt comfortable interacting with other participants in this activity	534	3.25	1.20
4.	My point of view was acknowledged	679	4.14	0.71
5.	Lecturers are enthusiastic in teaching and explaining via the Google Classroom.	694	4.23	0.91
6.	Lecturers are friendly, approachable and could be easily contacted.	721	4.39	0.64

Regarding students satisfaction in Google classroom, the highest mean value pointed to the students would recommend this method of learning to be applied in the near future with mean value of 4.22 ± 0.56 . This reveals that students were satisfied with the introduction of Google classroom as an active tool of learning and would recommend

it in the near future too. The lowest mean value goes to Google classroom as first choice in active learning and liking towards Google classroom as a learning initiative and motivation booster with mean value of 4.10 ± 1.34 and 4.15 ± 1.28 . Hence the teachers should concentrate on the activities in Google classroom which enhance active learning and provide motivation to the students (Tab.3).

Tab.3: Mean and S.D of Students satisfaction in Google Classroom(n=164)

S.No	Item	Sum	Mean	Standard Deviation
1.	The subject met my personal goal through the medium introduced.	684	4.17	1.09
2.	I would recommend this method of learning to be applied in the near future	693	4.22	0.56
3.	Google classroom is my first choice in active learning compare to other method	673	4.10	1.34
4.	I like the Google Classroom as a learning initiative and motivation booster.	681	4.15	1.28

The higher mean score was for the items “I’m suffering from poor communication network” and “I think that Google classroom focus on the cognitive side more than technical skills and emotional aspects” with mean value of 3.30 ± 1.29 and 3.28 ± 1.07 . This reveals that few students had poor communication network in their mobile phones and activities in Google classroom mainly focus on cognitive domain than psychomotor. Students disagreed about being upset in doing assignment

and assessment in Google classroom with mean value of 2.89 ± 1.25 . All the items show the scores below 4 which reveals that students are satisfied with their learning activity in Google classroom in spite of the minor issues and challenges faced by them and it can be inferred that a common challenges and issues faced by the students in Google classroom belong to any type of online learning in general and they are not belong to Google classroom in specific since it was reported in earlier findings Perry (2003)^[9], Facer, et al, (2005)^[10] [Tab.4].

Tab.4: Mean and S.D of Issues/Challenges faced by the students in Google Classroom (n=164)

S.No	Item	Sum	Mean	Standard Deviation
1.	Feeling bored when read my course by google classroom	526	3.20	1.28
2.	Feeling upset when doing assignment and assessment by google classroom	474	2.89	1.25
3.	Application would negatively affect the acquisition of the skills of reading and writing to me.	508	3.09	1.22
4.	Difficult to store large files	510	3.10	1.27
5.	Application does not lead to social isolation for students.	501	3.05	1.13
6.	Focus on the cognitive side more than technical skills and emotional aspects	539	3.28	1.07
7.	Difficult to enter the information on the small screen size of mobile phone	522	3.18	1.27
8.	Poor communication network	542	3.30	1.29
9.	Problem of low mobile battery continuously.	479	2.92	1.31
10.	Cons of Google classroom more than the positives	511	3.11	1.16

Conclusion

This study showed that Google Classroom is an effective teaching and learning tool since students gave a positive response for most of the items in the questionnaire. The problems also have been found out like difficulty in submission of assignments which may be due to lack of proper technological knowledge. Hence proper training should be given on its use which will enhance the students performance and a successful learning . Interactive platform should be created to enhance the critical thinking of the learners. Every new learning environment has issues and challenges that can be overcome in the near future. Hence Google classroom can be used as an effective tool for teaching and learning activity in addition to traditional classes. Here the

teachers play the role as facilitators which enhances collaborative learning and making the students more competent in this era of competency based curriculum.

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Ethics Committee: Institution Ethics Committee

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A Study to Evaluate Subclinical Muscle Strength Decrease and Quality of Life among Diabetes Individuals

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Abstract

Background : Diabetes mellitus is a metabolic disorder of multiple aetiologies characterized by chronic hyperglycemia resulting from defects in insulin secretion or insulin action. Muscle strength is influenced by insulin resistance, through higher plasma levels, and lipid content in the muscle, therefore it could be a marker for impaired skeletal muscle. These structural and functional changes in the skeletal muscle caused by defective insulin action could be associated with muscle weakness and reduced endurance capacity. This study evaluates the subclinical changes in muscle strength in diabetes and its functional performance comparing with age-matched healthy subjects.

Methods: This observational study totally includes 80 male and female individuals, 40 of type 2 DM and another 40 of age matched healthy individuals without any difficulty in Activities of daily living were recruited above 60 years of age, and assessed with HHD and functional measure (FTSTS) and quality of life measure (SF 36) used.

Results: Independent sample T test and Pearson correlation coefficient was used to analyze the difference and correlate among lower extremity muscle strength, FTSTS, and SF 36 in diabetic and healthy individuals; the data obtained were statistically significant, except SF 36 emotional limitation and physical limitation factor were non-significant. Pearson's coefficient found to have weak negative correlation in SF 36 and muscle strength.

Conclusion: Type 2 diabetes mellitus has correlated with reduction in muscle strength particularly in lower limb which remains subtle and unidentified as the disease progresses the muscle weakness may become progressive and lead to immobility.

Key words: Type 2 diabetes mellitus, subclinical, lower extremity, muscle strength

Introduction

Diabetes mellitus (DM) is a chronic metabolic disease which is characterized by an increase in blood glucose level resulting from a relative insulin deficiency or insulin resistance¹. Numerous studies have highlighted various complications of DM, which includes vision loss, chronic kidney disease, reduced muscle strength

and other long term consequences that have a significant influence on the quality of life of an individual².

DM is often accompanied by loss of mobility which can have a major impact on the independence of an individual. Limited mobility leads to inactivity and henceforth leads to loss of muscle mass resulting in decreased muscle strength³. Even though musculoskeletal manifestations like muscle weakness significantly compromises the quality of life among the diabetes mellitus population during the later stages, muscle weakness is usually subclinical which means the symptoms are not severe enough to produce observable clinical manifestation, therefore it is less valued, and adequate importance was not given for evaluation of

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muscle strength in clinical practice.

Long lasting suboptimal glycemic control is associated with protein catabolism in skeletal muscle that may lead to sarcopenia, muscle fat infiltration leading to loss of muscle strength and reduced functional capacity⁴. There is a strong association of diabetes with lower extremity muscle strength reduction and quality of life. The mechanism for lower extremity weakness is due to the accumulation of Intramuscular Noncontractile Tissue (IMNCT) particularly in lower limb which may contribute to a reduction in muscle blood flow and in turn lead to insulin dysfunction capacity increasing the fatty acids and resulting in the insulin resistance of skeletal muscle⁵.

There is no evidence demonstrating the muscle strength evaluation as a subclinical factor, in well ambulatory and well-functioning older adults with diabetes and comparing with normal subjects of same age and Body Mass Index (BMI). Lower extremity muscle strength loss remains subtle and unidentified among the diabetic individual; hence do not exhibit major changes in their quality of life, later stages this may lead to severe muscle weakness and impaired mobility.

There are evidences showing muscle strength decrease has been related to functional limitation and quality of life which was evident in diabetic individual, so we decided to identify the impact of muscle strength with functional performance and quality of life, using Five Times Sit To Stand (FTSTS) and for quality of life (QOL) 36-Item Short Form Survey (SF-36) questionnaire will be evaluated for both diabetic and age-matched healthy individuals.

The main objective of this study is to determine whether a clinical scenario might exist where there will be a subclinical muscle power decrease without any reflections on functions performed and quality of life in diabetic individuals when compared with age-matched healthy individual and to identify the association between DM and muscle strength in the lower extremity and their influence on the quality of life.

Aim of the Study

The aim of the study is to identify the subclinical lower extremity muscle strength decrease among

type 2 diabetic individuals with age-matched healthy individuals.

Objectives

To correlate the lower extremity muscle strength with functional performance and quality of life in diabetic and healthy individuals.

Methodology

The study protocol was approved by the Institutional ethics committee for student proposal of Sri Ramachandra Institute of Higher Education and Research (SRIHER) and obtained REF: CSP/18/SEP/73/253. This study was registered in Clinical Trial Registry-India(CTRI) with registration number CTRI/2019/01/016824.

This observational study includes 80 male and female individuals, in which 40 are type 2 DM and another 40 are age-matched healthy individuals without any difficulty in Activities of daily living were recruited from SRIHER, Endocrinology and Diabetes department. Convenient sampling was used, and written informed consent was obtained from every individuals. Inclusion criteria includes: Male and female subjects with type 2 DM of known duration, HbA1c levels and aged above 60 years. He/she should be cooperative and able to understand instruction given by the therapist. The diabetic individuals are compared with healthy individuals without any known comorbidities. They should have good functional transitional movements like, sitting without support, sit to stand and able to walk independently, and excluding cardiac and renal insufficiencies, muscular disorders/rheumatoid arthritis foot ulcers/foot amputations, and complaints like difficulty to perform activities of daily living, usage of mobility aids to get around or any other neurological impairments.

Basic demographic data (age, gender, BMI) was obtained from both groups **Instrumentation:**

Maximal isometric strength was measured using Handheld Dynamometer (HHD) force gauge. The testing of muscle strength was performed in high sitting position for Knee Extensors, Ankle DF and supine lying for Ankle PF^{8,9}. The subject was shown a demonstration of the movement before being tested. All measurements were taken for bilateral lower extremities for both

diabetic and age matched healthy individuals.

Outcome Measure

FTSTS: The individuals will be asked to do sit to stand from 43 cm high armless chair, quick as possible, for 5 repetitions with instructions to cross their arms across the chest and perform sit to stand completely, making firm contact during sitting. Timing will begin with the command given by therapist and will end by the stopwatch when individuals sit after 5th stand up. Two trials were taken and the better one was considered for this analysis.

Rand SF-36 questionnaire: This questionnaire contains 36 items of health related measure based on

functional status, well-being and overall evaluation of health. The higher score at SF 36 questionnaire better functioning and positive outcome under health related QOL will be present; scoring will be done by SF36 online calculator.

Results

SPSS software version 17.0 used for Independent T- test and Pearson correlation coefficients. 40 Healthy individuals (male, female) and 40 type 2 diabetic individuals (male, female) were assessed. Age, BMI were matched with diabetic patients and healthy individuals.

Table 1: Comparison between Lower Extremity Muscle Strength, FTSTS and SF 36 in diabetic and healthy individuals

Variables	Type 2 Diabetic individuals	Healthy individuals	p value
	Mean (SD)	Mean(SD)	
R Knee Ext	9.452(2.59)	14.91(3.44)	.000
R Ankle DF	6.087(1.77)	10.73(2.52)	.000
R Ankle PF	9.07(1.40)	14.19(2.25)	.000
L Knee Ext	9.147(2.33)	14.71(3.2)	.000
L Ankle DF	6.194(1.79)	10.95(2.56)	.000
L Ankle PF	8.93(1.68)	13.95(2.58)	.000
FTSTS	15.52(3.02)	11.34(1.61)	.000
SF36- Physical Functioning	78.75(12.74)	90.37(9.76)	.000
SF 36 –limitation physical	100(0.00)	100(0.00)	NA
SF 36-limitation- emotional	99.15(5.37)	100(0.00)	.320
SF 36-energy fatigue	80.13(13.75)	86.08(10.14)	.031
SF 36-emotion-well being	79.10(17.80)	93(10.50)	.000
SF 36- social	84.80(18.25)	94.77(6.78)	.002
SF 36-pain	85.93(15.67)	91.93(10.53)	.048
SF 36-general health	58.25(10.65)	64.05(10.95)	.019
SF 36-heath change	65.62(20.94)	78.5(19.45)	.006

In Table 1, Independent sample T test was used to analyze the difference between lower extremity muscle strength, FTSTS, and SF 36 in diabetic and healthy individuals; the data obtained were statistically significant, except SF 36 emotional limitation and physical limitation factor were non-significant between these two groups.

Reduced muscle strength in lower extremities was found in diabetic individuals when compared with healthy individuals. The time taken to perform FTSTS was higher in diabetic individuals, when compared with healthy individuals indicating reduced functional strength.

Table 2: Correlation between muscle strength and SF-36 measure in diabetic individuals

SF 36	Knee extensor R	Knee extensor L	Ankle dorsiflexor R	Ankle plantarflexor L	Ankle dorsiflexor L	Ankle plantarflexor R
Physical function						
r value	-0.003	0.028	-0.067	0.084	-0.054	0.11
p value	0.987	0.862	0.683	0.257	0.74	0.499
Limitation –physical	Nil	Nil	Nil	Nil	Nil	Nil
Limitation- emotional	Nil	Nil	Nil	Nil	Nil	Nil
Energy fatigue						
r value	-0.001	-0.136	-0.325	-0.31	-0.309	-0.195
p value	0.996	0.404	0.04	0.052	0.052	0.227
Emotional wellbeing						
r value	-0.161	-0.066	0.032	0.01	0.01	-0.018
p value	0.322	0.685	0.845	0.953	0.949	0.911
General health						
r value	-0.051	-0.014	-0.101	0.274	0.005	0.218
p value	0.757	0.933	0.536	0.087	0.974	0.176
Health change						
r value	0.266	0.309	0.147	0.274	0.244	0.178
p value	0.097	0.052	0.364	0.087	0.128	0.272
Social						
r value	-0.027	-0.063	-0.058	-0.137	-0.087	-0.215
p value	0.868	0.699	0.723	0.398	0.593	0.182
Pain						
r value	0.027	-0.047	0.082	-0.038	0.085	-0.163
p value	0.614	0.772	0.614	0.814	0.602	0.315

In Table 2, Correlation among muscle strength in diabetic individuals with SF-36 Measure was done. The results shows Weak negative correlation and non-significance.

Discussion

The results in this study reveal that individuals with diabetes mellitus had a significant reduction in lower extremity muscle strength when compared with their normal counterparts which is supported in the studies earlier as adults with type 2 diabetes had a reduced muscle strength, than those without diabetes and muscle quality consistently reduced regardless of sex and muscle groups. This explains the risk of functional limitation and disability with type 2 diabetes¹⁰.

Even though lower extremity muscle strength reduction was obvious it proved to be subclinical, i.e. the diabetic individuals did not exhibit any changes in their daily activities and did not show an obvious decline in the scores of quality of Life. Evidence shows lower extremity muscle strength is reduced in type 2 diabetes people, with or without polyneuropathy and is associated with impaired mobility and reduced quality of life³. In contrast, our present study showed the diabetic individuals did not show ambulatory difficulties, reduction was shown in physical functioning, energy fatigue, emotional well-being, social, pain, general health, health change in QOL measure but no changes seen in physical and emotional limitation factor.

Functional lower extremity muscle strength was evaluated by FTSTS, it showed a similar decline in strength for diabetic. This measure showed increased time duration to perform sit to stand activity in diabetic individuals, which reveals an apparent decline in lower extremity functional strength even though they did not exhibit any variation in the activity of daily living. In the previous studies, a longer FTSTS time has found to predict falls and disability in older adults and the performance of FTSTS in our diabetic individuals was found to be poorer than age-matched non-diabetic individuals⁷. The diabetic individuals even though are able to ambulate and perform their daily activities these changes remain subtle and may lead to permanent disability in the future.

This study further found that the ankle dorsiflexors strength was reduced significantly among diabetic individuals. According to the earlier study, dorsiflexors is the only significant determinant for FTSTS. The ankle dorsiflexor torque not only can stabilize the contact between the feet and the ground but also rotate the lower

leg forward and help to add to the knee extension torque in bringing the body forward and upward⁷. The ability to generate ankle dorsiflexion torque (i.e. Ankle DF strength) could be particularly important for the diabetes group who had poorer knee extension strength. This could be the reason for the poor performance of FTSTS in the diabetes group.

The findings in our study shows the fact that longer duration and poor glycemic control, in diabetic was associated with marked reduction in lower extremity muscle strength which strongly suggests that the duration and severity of diabetes plays a very important role in muscle strength, and no association was found in age, BMI, newly diagnosed diabetes. The severity of diabetes had a negative correlation with FTSTS and lower extremity muscle strength. The HbA1c levels found to have a negative correlation with knee extensors in diabetic individuals, other values showed a positive correlation indicating that the HbA1c level does not influence distal muscle strength.

Earlier studies suggested that no single factor explained the association of diabetes and disability, several comorbidities and impairments could be the causes of disability among diabetes⁶. Factors like obesity, depression may be associated with disability. Even though the findings cannot be used to impute the association between diabetes and reduction in muscle strength in lower extremity, the results do suggest that reduction of muscle strength is related to diabetes, and in spite of it, increased duration in FTSTS participants in this study did not have any ambulatory impairments and remained unidentified which prove the hypothesis that it is subclinical and more obvious only in diabetic individuals than normal individuals.

Based on the above results we can conclude that individuals with type 2 diabetes mellitus had a reduction in muscle strength particularly in lower limb which remains subtle and unidentified and as the disease progresses the muscle weakness may become progressive and lead to immobility and various musculoskeletal complications.

Limitation

Reduced sample size in diabetic individuals

Future Studies

To include large number of DM population with varied duration

To develop an exercise protocol for lower limbs, to prevent any further decline in mobility.

Conclusion

Type 2 diabetes mellitus has a reduction in muscle strength particularly in lower limb which remains subtle and unidentified and as the disease progresses the muscle weakness may become progressive and lead to immobility and various musculoskeletal complications. The decline in lower extremity muscle strength resulted in longer duration with FTSTS in diabetic individuals but it did not show any changes in ambulation and quality of life, thus it becomes very mandatory to evaluate lower extremity muscle strength at early stage of diabetes to prevent musculoskeletal complications at the later stages.

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Conflict of Interest- Nil

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Role of Computed Tomography in the Evaluation of Intracranial Posterior Fossa Lesions

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Abstract

Background : The prime imaging modality available for imaging the posterior fossa are CT and MRI. CT is non-invasive, provides 3-D cross sectional anatomy of brain, which can be reformatted in multiple planes. CT provides more detail about the nature of calcification.

The posterior fossa lesions can be broadly classified into 1) **Mass lesions** 2) **Inflammatory lesions** 3) **Traumatic lesions** 4) **Vascular lesions** 5) **Congenital malformations**. Objective is to evaluate the computed tomography features of various types of lesions in the posterior fossa, their appearances and to determine the age and sex distribution.

Materials and Methods: This was a prospective study carried out on 60 patients, age range was 0-80 years, who were referred to the Department of Radio-Diagnosis for CT at Rohilkhand Medical College and Hospital for a period of one year from November 2018 to October 2019 using 16 slice GE Brightspeed Elite third generation CT machine.

Results & Conclusion: CT was highly accurate and efficient in diagnosing various posterior fossa lesions. It has an upper hand over MRI in characterization of bony changes and calcification.

Keywords: - *Cerebellum, Computed Tomography, Paraganglioma, Pilocytic astrocytoma, Pons, Posterior Fossa.*

Introduction

The posterior fossa lies below the tentorium cerebelli and contains the cerebellum, pons and medulla oblongata. It is bounded anteriorly by posterior surface of petrous part of temporal bone, posteriorly by occipital bone and laterally by squamous and mastoid parts of temporal bone, and inferiorly by the foramen magnum.

The prime imaging modality available for imaging the posterior fossa are computed tomography and magnetic resonance imaging. Computed tomography is non-invasive and provides three-dimensional cross

sectional anatomy of brain, which can be reformatted in multiple planes. Computed tomography provides more detail about the nature of calcification and can characterize soft tissue abnormalities with high contrast and good spatial resolution. Now-a-days, many modern CT scanners are equipped with artifact reduction algorithm. Magnetic resonance imaging is excellent in depiction of soft tissue anatomy of the brain in multiple planes.

The posterior fossa lesions (Table 1) can be broadly classified into 1) **Mass lesions** (benign or malignant), 2) **Inflammatory lesions** (Tuberculoma, Neurocysticercosis, abscess etc.), 3) **Traumatic lesions** (Hematoma, Cerebellar Hemorrhage, Contusion), 4) **Vascular lesions** (Arteriovenous malformation, aneurysm) 5) **Congenital malformations** (Dandy Walker malformation, Chiari malformation, arachnoid

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cyst, mega cisterna magna etc.).¹

Medulloblastoma, astrocytoma and brainstem gliomas are the most common pediatric posterior fossa neoplasms whereas in adults metastatic lesions are most commonly encountered. Other less common lesions include schwannomas, arachnoid cysts, meningiomas, etc. Pilocytic astrocytoma is the most common pediatric central nervous system glial neoplasm and the most common pediatric cerebellar tumor.^{2,3}

Aim and Objectives

To evaluate the computed tomography features of the various types of lesions in the posterior fossa region and their appearances.

To determine the age and sex distribution of various lesions in posterior fossa.

Materials and Methods

This was a prospective study, carried out on 60 patients (33 female and 27 male) who were referred to the Department of Radio-Diagnosis for CT at Rohilkhand Medical College and Hospital, Bareilly, Uttar Pradesh, India. This study was conducted for a period of one year from November 2018 to October 2019 using 16 slice GE Brightspeed Elite third generation CT machine.

Inclusion Criteria - Patients of both sexes of all age groups who were found to have posterior fossa lesions on computed tomography for relevant symptomatology. Only patients willing to participate and ready for follow up were included.

Risk of contrast reaction was explained to the patient and consent was taken. Contrast was not given to patients with history of hypersensitivity to i.v. contrast agent, eGFR <40ml/kg body weight.

Exclusion Criteria - Pregnant women and uncooperative patients.

CT scan of the head was done in supine position with axial sections of 3 mm thickness with pitch of 1, taken from the level of second cervical vertebra to vertex. Plain scan was followed by contrast scan when needed. Iohexol (350 mgI/ml) with dose of 1-2 ml/kg body weight was given as intravenously. Pre and post contrast attenuation values, size, location of masses, presence of

calcification, mass effect and other associated findings were studied.

Results

Patients included in our study ranged from 5-80 years of age with a mean age of 45 years. Out of the total 60 patients, 33 were females and 27 males. Male-female ratio was 9:11. Out of 60 patients, 12 were children (20%) and 48 were adults (80%). Most of the patients presented with non-specific symptoms of headache, vertigo and vomiting.

Topographically, most lesions were located in the cerebellum, consisting 60% of the total cases. 8.33% cases were found in the pons. Rest 31.66% cases were extra-axial. Cerebellum was involved in 9 cases out of 12 (75%) in pediatric age group and 24 cases out of 48 (50%) in adults.

Hypodense lesions were noted in 31 cases, hyperdense lesions in 17 cases, 4 lesions were isodense with mixed density lesions in only 8 cases, out of total 60 cases.

Hydrocephalus was noted in 23 cases out of 60, corresponding to 38.3% of total cases. Adults constituted most of the cases with hydrocephalus, being 65.2% and children formed the rest 34.8% cases. 65.2% of cases with hydrocephalus were females and 34.8% males.

Calcification was seen in 7 out of 60 cases, i.e. 11.6% of total cases. Male-female ratio was 6:1. 62% of cases with calcification were adults and 38% were pediatric patients.

Spectrum of posterior fossa lesions in pediatric age group was – cerebellar abscess – 1 (8.33%), pilocytic astrocytoma – 1 (8.33%), medulloblastoma – 1 (8.33%), tectal plate glioma – 1 (8.33%), NCC - 2 (16.66%), tuberculoma - 2 (15.38%), cavernoma - 1 (8.33%), infarct – 1 (8.33%), mega cisterna magna – 1 (8.33%), arachnoid cyst - 1 (8.33%).

Spectrum of posterior fossa lesions in adults was – pilocytic astrocytoma -1 (2.08%), brainstem glioma – 1 (2.08%), ependymoma – 1 (2.08%), schwannoma – 5 (10.41%), meningioma - 2 (4.16%), cerebellar metastasis – 2 (4.16%), glomus jugulare – 1 (2.08%), epidermoid cyst - 2 (4.16%), mega cisterna magna – 3

(6.25%), arachnoid cyst – 2 (4.16%), ADEM – 1 (2.08%), tuberculoma – 2 (4.16%), NCC – 3 (6.25%), infarct- 10 (20.83%), traumatic hemorrhage/contusion – 5 (10.41%), hypertensive bleed – 7 (14.58%).

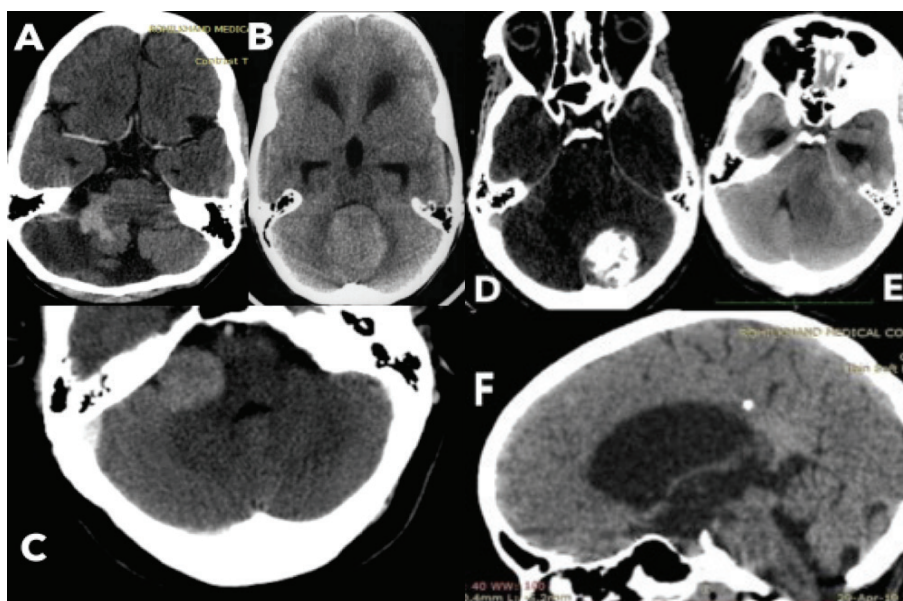


Fig.1. MASS LESIONS: A) PILOCYTIC ASTROCYTOMA - Large cystic lesion in the right cerebellar hemisphere having irregular peripheral enhancing solid component and causing obstructive hydrocephalus. B) MEDULLOBLASTOMA – Midline well defined hyperdense mass with effacement of 4th ventricle. C) SCHWANNOMA - Well-defined extra-axial mass lesion showing homogenous contrast enhancement in right cerebello-pontine angle. D) MENINGIOMA - Well defined extra-axial lobulated heterogeneously enhancing mass lesion along the left cerebellar convexity posteriorly with dense calcification and subtle hyperostosis of the overlying occipital bone. E) BRAINSTEM GLIOMA - Mass lesion having its epicenter in the left middle cerebellar peduncle causing obstructive supratentorial hydrocephalus. F) TECTAL PLATE GLIOMA - Non-visualization of aqueduct of sylvius with enlarged tectal plate.

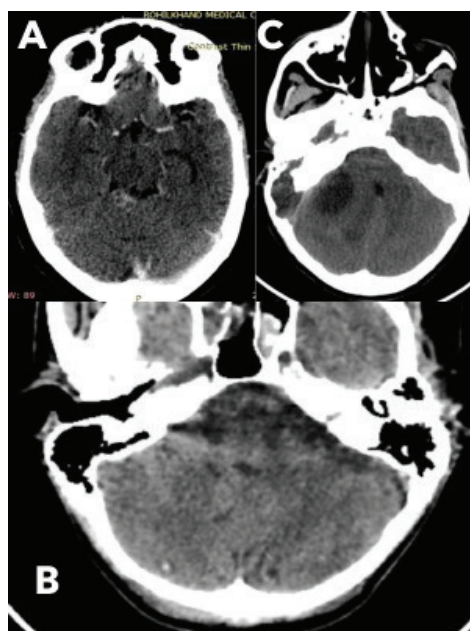
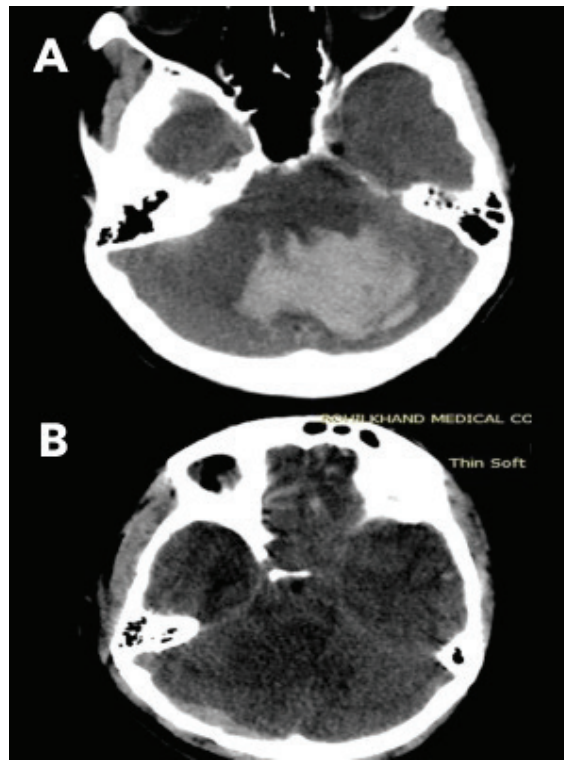


Fig.2. INFECTIVE LESIONS: A) TUBERCULOMA – Conglomerated ring enhancing lesions in vermis on right side. B) NCC - Small cystic lesions showing eccentric hyperdense nidus in bilateral cerebellar hemispheres. C) CERBELLAR ABSCESS - Cystic lesion in the right cerebellar hemisphere with destruction of sinus plate on the right side, right sigmoid sinus thrombosis and effacement of 4th ventricle.



3. TRAUMATIC LESIONS: A) CEREBELLAR HEMORRHAGE - Large hyperdense intraparenchymal bleed in the left cerebellar hemisphere with compression of brainstem and fourth ventricle. **B) EXTRADURAL HEMATOMA** – Lentiform shaped hyperdense collection along the right occipital convexity.

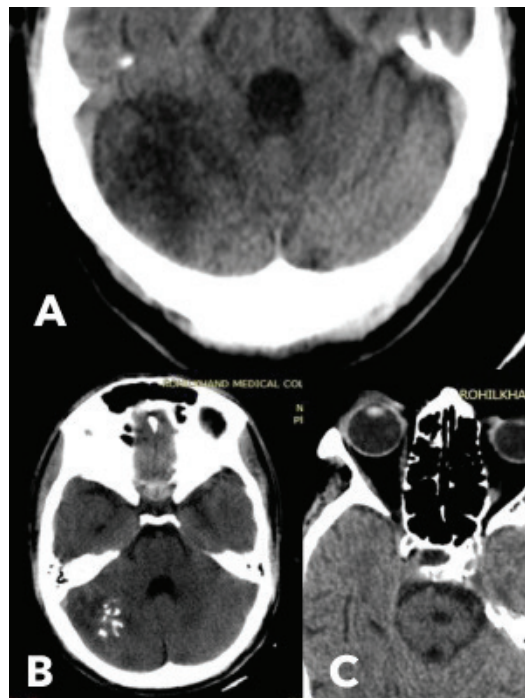
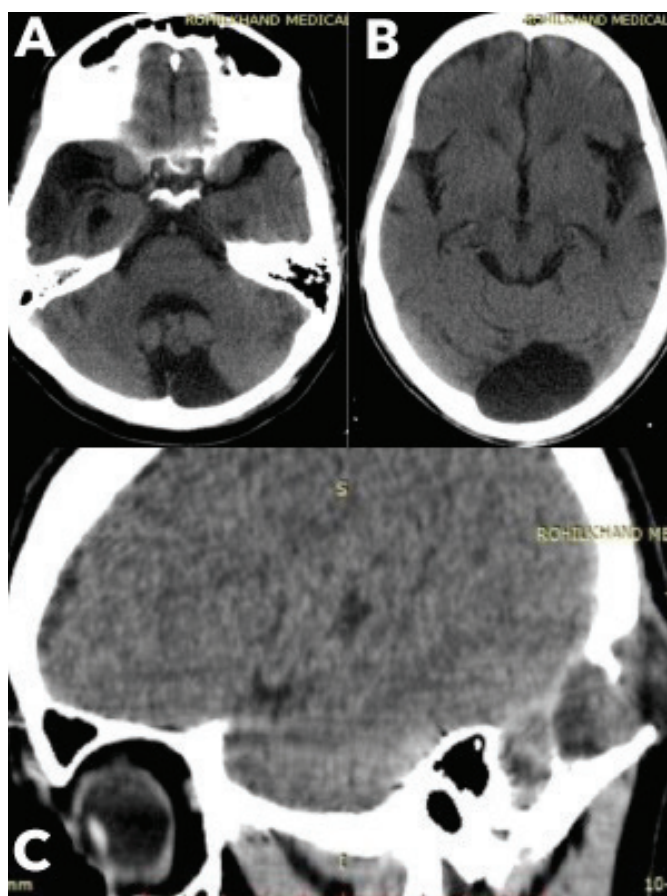


Fig.4. VASCULAR LESIONS: A) SUBACUTE CEREBELLAR INFARCT - Focal hypodense lesion in right cerebellar hemisphere. **B) CAVERNOMA** - Heterogeneous calcified non-enhancing lesion in the right cerebellar hemisphere. **C) PONTINE INFARCT** – Small hypodense lesion in left hemipons.



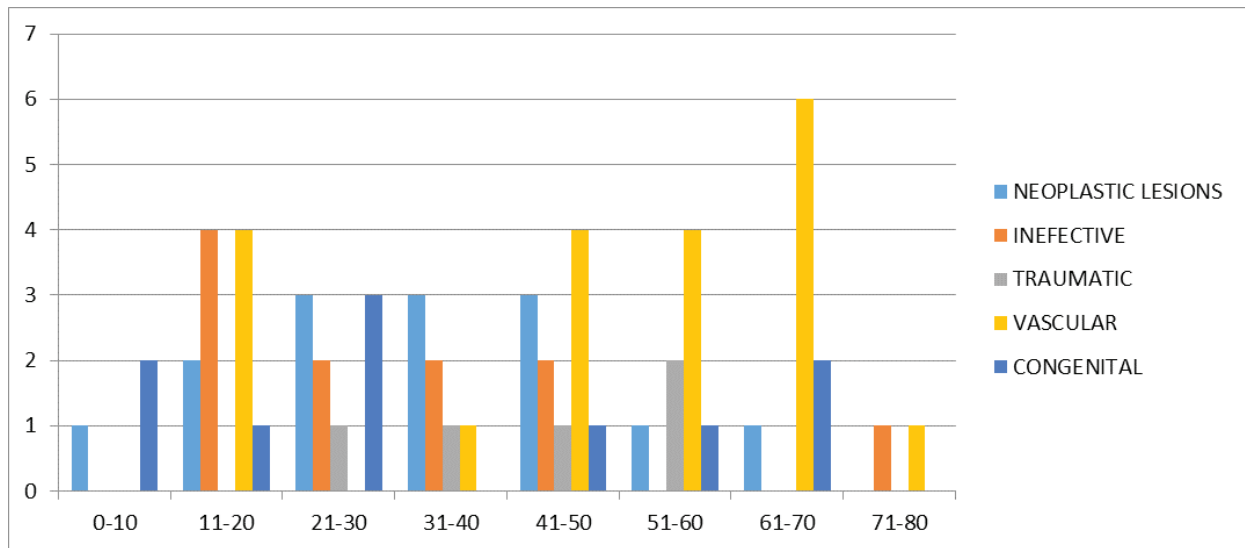
**Fig.5. CONGENITAL LESIONS: A) MEGA CISTERNA MAGNA - Large retro-cerebellar CSF space
 B) ARACHNOID CYST - Large thin-walled fluid-density lesion in the midline, extending towards the left causing mild scalloping of overlying occipital bone and underlying cerebellar parenchyma. C) EPIDERMOID CYST – Well-defined hypodense osteolytic lesion in the region of right occipito-parietal suture, abutting the right cerebellar hemisphere intracranially.**

TABLE 1 – CT DIAGNOSIS OF VARIOUS POSTERIOR FOSSA LESIONS

CT DIAGNOSIS	SUB-CATEGORY	NO. OF CASES	PERCENTAGE (%)
1) Neoplastic lesions (Benign & malignant)	Brainstem Glioma	2	3.33%
	Astrocytoma	2	3.33%
	Ependymoma	1	1.66%
	Metastasis	2	3.33%
	Meningioma	2	3.33%
	Schwannoma	5	8.33%
	Medulloblastoma	1	1.66%
	Paraganglioma	1	1.66%
2) Inflammatory/infective lesions	Tuberculoma	4	6.66%
	Neurocysticercosis	5	8.33%
	Abscess	1	1.66%
	ADEM	1	1.66%
3) Traumatic lesions	Hematoma/ Contusions	5	8.33%

Cont... TABLE 1 – CT DIAGNOSIS OF VARIOUS POSTERIOR FOSSA LESIONS

4) Vascular lesions	Arteriovenous Malformation	1	1.66%
	Infarcts	11	18.33%
	Intraparenchymal hemorrhage	7	11.66%
5) Congenital malformations	Arachnoid cyst	3	5%
	Mega cistern magna	4	6.66%
	Dermoid/Epidermoid cysts	2	3.33%



Bar chart 1 - showing age-wise distribution of posterior fossa lesions with predominance in 2nd and 5th decades.

Discussion

Before the advent of CT as an imaging modality, diagnosis of intracranial lesions was a tedious process. CT has been a prime imaging modality for diagnosing various posterior fossa lesions among other intracranial lesions. In this study the relative frequencies and gamut of CT features of various intracranial posterior fossa lesions are presented.

Groswasser RI *et al*⁴ in their study on CT findings of various posterior fossa lesions found a female prevalence with 57% of total cases and males forming 43% cases, very close to that found in the current study.

Most of the patients presented with non-specific symptoms of headache, vertigo and vomiting. In children, clinical manifestations of increased intracranial pressure

were seen. Most common presenting feature was headache. Other symptoms were projectile vomiting, seizures, blurring of vision, limb weakness etc. Clinical symptomatology found was similar to a study done by Haque *et al*.³ Otologic symptoms were associated with schwannoma and meningioma.

Groswasser RI *et al*⁴ found vascular and metastatic lesions to be more prevalent with increasing age. They also concluded that extra-axial lesions were commoner in adult population. This is in coherence with results obtained in our study.

Neoplastic Lesions

Brain tumours are the most common neoplasms in the pediatric population. Infratentorial tumours (Fig.1) comprise 45-60% of total brain tumors.⁴ Common

pediatric posterior fossa tumors are juvenile pilocytic astrocytoma, medulloblastoma, ependymoma and brainstem glioma.⁵

In current study, mass lesions formed 27% of the total cases of posterior fossa lesions. We found an equal prevalence of intra-axial and extra-axial mass lesions in-toto. Pilocytic astrocytoma was more common than Medulloblastoma, which is in coherence with various studies done by Haque *et al*³, Poretti *et al*⁶ and Aquillina *et al*.⁷ Two cases of PCA were found in our study group with children-adult ratio of 1:1.

Ependymomas show a bimodal peak with most of the cases seen in children <5 years of age and the second peak in the fourth decade.⁸ Brainstem gliomas comprise 10-20% of pediatric CNS tumours.^{7,8} Among brainstem gliomas, diffuse glioma is the most common type, accounting for 60-75%.⁶

In adults, schwannomas and meningiomas were found to be more prevalent, as was also found by Saleh EA *et al*.⁹ Wrensch M *et al*¹⁰ stated that meningiomas are 80% more common in females. We also found both the patients with meningioma being female.

Metastases were stated as the commonest intra-axial mass lesions in posterior fossa in adults, in a study done by Ghods AJ *et al*.¹¹ In our study, 50% of intra-axial masses in adults were metastases, making them the most common entity in adults. We found two cases of cerebellar metastases, in known cases of lung carcinoma.

Infective Lesions

Neurocysticercosis (Fig.2b) and tuberculoma (Fig.2a) were the most common infective lesions in our study, which is in coherence with a study done by Maheshwarappa RP *et al*¹² and Chander R *et al*¹. In adults, most cases of neurocysticercosis were of stage IV disease, as also found by Chander R *et al*.¹ Manjunath MN *et al*¹³ in their study on CNS tuberculosis found predilection for younger population in 60-70% of cases. Our results were similar with 66% cases appearing in the first two decades. Nathoo N *et al*¹⁴ in their study on 973 patients with brain abscess found otorhinogenic sepsis to be the commonest cause in the first two decades. Our findings also revealed otomastoiditis being the commonest cause of cerebellar abscess (Fig.2c).

Traumatic Lesions

Loli V *et al*¹⁵ stated that traumatic brain injuries (Fig.3) are a major health issue responsible for mortality and morbidity worldwide. They concluded that CT is the modality of choice for traumatic brain injury, allowing better detection of acute intra-axial and extra-axial hematomas. Traumatic lesions comprised 8.3% of total cases in the current series. Cerebellar hemorrhage/contusions formed 40% of traumatic lesions.

Loli V *et al*¹⁵ and Gentry LR¹⁶ found parenchymal hemorrhage/contusions to be the most common intracranial post-traumatic injuries. Sub-arachnoid hemorrhage, epidural hemorrhage and cerebellar contusion formed 20% each of total traumatic cases in our study. We found cerebellar hemorrhage to be more common than other traumatic lesions with 50% of cases associated with overlying bone fracture.

Vascular Lesions

Vascular lesions (Fig.4) formed the bulk of cases in our study, comprising 32% of total cases. Out of total 19 cases, 11 were infarcts, 7 were parenchymal hemorrhage/contusions and 1 case was of arteriovenous malformation. Infarcts constituted 57.89% of total vascular lesions, parenchymal hemorrhage/contusions formed 36.8% cases and arteriovenous malformation rest 5.2% of cases. Arora R¹⁷ in their study also found infarcts to be more common than hemorrhage, comprising ~1.5-2.3% of all strokes.

In a study done by Amarenco P¹⁸, cerebellar infarcts were commoner than cerebellar hemorrhage and had a male predominance. We found similar results in our study. Intraventricular extension of hemorrhage was found in 42% of parenchymal hemorrhage of posterior fossa region. Most patients with infarcts presented with sudden onset posterior headache with vertigo, ataxia and dysarthria, similar to the clinical presentation found in a study by Amarenco P¹⁸. Intraventricular extension of hemorrhage was found in 2 cases of cerebellar hemorrhage and one case of pontine hemorrhage, forming 66.6% and 33.3% of total such cases respectively.

Congenital Lesions

Mega cisterna magna formed 44.4% of total cases of congenital lesions, arachnoid cyst and epidermoid cysts

formed 33.3% and 22.2% cases respectively (Fig.5). Kollias *et al*¹⁹ had concluded that mega cisterna magna forms about 54% of total cyst-like posterior fossa lesions and are mostly detected incidentally. Incidence of mega cisterna magna was close to that found by Kollias *et al*¹⁹. Bosemani *et al*²⁰ have stated similar findings in their study. We found 33.3% cases of epidermoid cysts which is consistent with the study done by Chander R *et al*.¹

Conclusion

- The role of CT in the diagnosis of posterior fossa lesions is crucial regarding localization, characterization, extension pattern and typical features.

- CT has advantage over MRI when it comes to evaluation of bony changes and characterization of intralesional calcification.

- A reliable prediction of tumor histology or grade by neuroimaging is not yet possible for posterior fossa tumors.

- CT is widely available imaging modality when compared with MRI.

- CT still plays an indispensable role in neuroimaging in developing countries because of easy accessibility and cost effectiveness.

Conflict of Interest – None.

Source of Funding – Self

Ethical Clearance – was taken for the study.

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Is Palliative Care a Perceived Need of Medical Post Graduate Students of Mumbai, India?

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Abstract

Introduction : Present health care in India relies on secondary prevention with less attention on palliative care. Knowledge, attitude and practices among palliative care does not seem to be uniformly distributed in India, more so in the second most populous state Maharashtra. Hence, a study was conducted among post graduate students of a medical college, Mumbai to assess the same.

Material and Methods : A cross sectional study was conducted amongst conveniently selected 100 final year post graduate students of clinical departments in a randomly selected medical college in Maharashtra. The data was collected through pre tested questionnaire from May 2019 to July 2019. It was entered in Microsoft excel and analyzed in percentages. Necessary permissions and written consent were obtained from the participants.

Results : All the participants 100 (100%) knew about palliative care. Forty (40%) were aware about palliative care needs of the patients like pain relief, spiritual, psychosocial care but none of them (0%) were aware that it helps to reduce financial hardships. Only 19 (19%) of participants were aware that palliative care starts when the patient is diagnosed with chronic illness. Eighty (80%) participants said that they would advise palliative care to chronically ill patients but 70 (70%) did not know which hospitals provide palliative care. None of the participants received training in palliative care. Majority of participants 98 (98%) were interested in receiving training for palliative care.

Conclusions: Though post graduate students knew concept of palliative care, but did not have detailed knowledge including its practical application .

Keywords: Palliative Care, Knowledge, Attitude and Practices, Post Graduate Students Mumbai.

Introduction

Palliative care is an approach that improves the quality of life of patients and their families who are facing problems associated with life-threatening illnesses. It prevents and relieves suffering through the early identification, correct assessment and treatment of pain and other problems, whether physical, psychosocial or spiritual.¹ Palliative care is a one of the developing speciality for chronic medical and surgical illnesses

. Though it is perceived as care for the dying, it should begin when the patient is diagnosed with a chronic illness .

The majority of adults in need of palliative care have chronic diseases like cardiovascular diseases (38.5%), cancer (34%), chronic respiratory diseases (10.3%), AIDS (5.7%) and diabetes (4.6%) etc. Forty million people are in need of palliative care globally but 14% of them receive it at present.¹

Access to adequate pain relief among the patients suffering from cancer is less than 3% in our country.² In India 10 million patients require palliative care of which 1 million patients are from Maharashtra.³

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Growing demand for palliative care shows that health professionals are expected to provide palliative care as a part of their practice. Several initiatives are under way to promote palliative care principles and practice in healthcare training. The challenge is how to develop these skills in the face of increasing demand on our time. There should be capacity building in palliative care for the existing medical workforce of our country through continued medical education.

Worldwide there are studies about assessing palliative care awareness among health care providers including impact about its educational interventions, however there is limited published evidence about similar literature from India.^{4-12,13-18} There is a dearth of similar literature from Maharashtra, which is expected to bear higher burden of palliative care.¹⁹⁻²¹ Hence a study was conducted to assess the knowledge, attitude and practices about palliative care amongst the post graduate students of medical college in Mumbai.

Material and Methods

This was a cross sectional questionnaire based survey. Study area was a randomly selected medical college in Mumbai. Study participants included 100 final year post graduate students working in the clinical departments of the college who had been selected conveniently. Semi structured questionnaire consisting of a) Socio-demographic information b) Knowledge, Attitude and Practices was used. Questionnaire was pre-tested and validated by pilot study. Approval from institutions ethics committee and written valid informed consent from all participants was taken before enrolling them in study. The study included post graduate students who were willing to participate in the study and were available at the time of data collection period. Those who were not present at the time of data collection and were not willing to take part in the study were excluded. Data was collected from May 2019 to July 2019. It was entered Microsoft excel and results were calculated in terms of percentages. Strict confidentiality was maintained during process of data collection and analysis.

Results

All the study participants were in the age group of 25-30 years with 59 males (59%) and 41 females (41%).

Knowledge:

Amongst the 100 post graduate students interviewed, majority 44 (44%) thought that palliative care provides relief from pain, distressing symptoms, support to live actively till death, spiritual and psychosocial care. While in addition to this 14 (14%) thought that palliative care also provides spiritual care and psychosocial care. Role of palliative care was limited to provision of relief from care, distressing symptoms as per 24 (24%) of the post graduate students. None (0%) thought that palliative care provides reduction in financial hardship. Around 59 (59%) of post graduate students said that palliative care is an approach that improves quality of life, 14 (14%) said it improves quality of life and needed in life threatening illness and 25 (25%) said it is needed only in life threatening illnesses. Two percent of the post graduate students did not respond.

Sixty (60%) said that palliative care begins when patient is critically ill. Twenty (20%) said it begins when patient is diagnosed with illness and another 20 (20%) of the participants said palliative care was needed for both after the time of diagnosis as well as in the later stage of the diseases.

Hospice was perceived as end of life care by 59 (59%) of the respondents while 41 (41%) said that it is palliative care itself. Palliative care as fundamental right was echoed by most of the 98 (98%) of the respondents while 2 (2%) did not answer this question.

Though majority of the post graduate students 70 (70%) had correctly said that palliative care was needed for both cancerous and non cancerous conditions, it was needed for only cancerous conditions was thought by 60 (60%) of the respondents and 10 (10%) thought that it was needed only for non cancerous conditions

Most of the participants 80 (80%) were keen to advise palliative care to the chronically ill however (70%) of them did not know about hospitals that provide palliative care. Majority of the participants 85 (85%) were not aware about names of the hospices. Only 39 (39%) of post graduate students knew that palliative care has started under public health system in Maharashtra.

Most 90 (90%) of post graduate students said that training for breaking bad news to the patients and their

relatives is very important. Eighty (80%) of post graduate students agreed they were confident about breaking bad news. None of the participants (0%) in our study knew other avenues along with palliative care which can be added to a chronically ill patient's treatment plan.

Majority of the participants 70(70%) were of opinion that lack of knowledge of palliative care was major barrier and 11(11%) perceived unavailability of standard clinical guidelines and protocols. Rest 19(19%) did not give their opinion.

Though 62(62%) of post graduate students said that they follow guidelines for pain management, however 78(78%) of the post graduate students had no idea about the ladder for pain control developed by World Health Organization.

None of the post graduate students (0%) had experience in providing palliative care to the patients. However 60(60 %) of the participants said that they were satisfied with their performance while dealing with terminally ill patients. Maximum post graduate students (90%) agreed that palliative care should be incorporated in undergraduate medical curriculum. All the post graduate students (100%) were interested in getting trained for palliative care.

Discussion

In our study, 44% of the postgraduate students had good knowledge of palliative care. In a study conducted in Nigeria, among medical interns in a tertiary care hospital respondents have poor knowledge about palliative care.⁶ In another study, 28(60.9%) doctors working in a tertiary teaching hospital in Nigeria, said that palliative care is about pain management while majority 40 (85.1%) thought that it is about active care of dying and 35 (72.9%) doctors thought that palliative care is needed for all dying patients.⁴ In a study conducted among undergraduate students in Oman medical college, 60.3% of the students indicated that palliative care was active care of the dying.⁸ A study conducted among doctors working in medical colleges across India, 480 doctors (74.0%) mentioned about pain control as the primary aim for palliative care management.¹⁷ In a study conducted in Pakistani doctors aims of palliative care were mentioned as pain control (45.7%), rehabilitation (30%) and counselling (18.5%) respectively.⁹ A study

was conducted in a tertiary government hospital in Pune among III-year undergraduate, nursing and physiotherapy students. Overall knowledge about palliative care was poor among three groups, though third year nursing students had a greater knowledge about various domains of palliative care than other two groups.²¹ Majority of medical interns (87.6%) had correctly defined palliative care in a study conducted elsewhere in India.¹⁹

In our study, 60% post graduate students said that palliative care begins when patient is critically ill. Only 19% said it begins when patient is diagnosed with illness, 20% agreed for both. In a study conducted in Manipal university in India amongst the undergraduate medical students, around 67.5% felt that all dying patients needed palliative care.¹⁸

In our study, 70(70%) said that palliative care is needed for both cancerous and non cancerous conditions. In a study conducted among medical undergraduate students in India, 80% and 52% thought that it was needed for metastatic cancers and for noncancerous conditions as well.²⁰ Similarly more number of medical undergraduate students 78.1% thought that palliative care was needed for cancers with uncontrollable pain as compared to 55% for end stage heart failure, in a study conducted elsewhere in India among medical undergraduate students.¹⁸ Whereas in a study conducted among doctors working in medical colleges across India, majority thought that cancer (85.2%), followed by stroke, (7.4%) and neurodegenerative diseases (3.7%) were the main diseases to call for palliative care.¹⁷

Awareness about hospices providing palliative care was 85 % in our study. In a study conducted in India, 77% of doctors were aware about hospice while 57.1% of Pakistani doctors stated that they have heard about the same.^{9,17}

In our study, 90 (90%) of post graduate students said that training for breaking bad news is essential. In similar study conducted in eastern India, 77% doctors working in government medical colleges thought that it was crucial to break bad news to the patient.¹⁷ In a study conducted in neighbouring country of India, 60% of the doctors agreed that bad news should be conveyed appropriately.⁹

In our study, 78% did not have idea about pain control ladder developed by WHO while 22% of doctors working in medical colleges in Eastern India knew correctly sequence of analgesia defined by WHO ladder of pain control.¹⁷ Awareness regarding the same was similar (39.8%) in the studies conducted in medical undergraduate students in Pakistan and Malaysia.^{7,10} Higher level of awareness about the same was seen among 50% interns in a tertiary health institution in Nigeria.⁶ In the studies conducted in India awareness about the ladder of pain control was higher in medical undergraduate students (90.8%).^{22,23}

In our study, 80% of residents agreed they were confident about breaking bad news, however their competency was not assessed. In the study conducted in Turkey, the competency in giving bad news was assessed in physicians, and 32 of the participants (34%) stated their competence as very good, 51 (54%) stated as good, and 12 (13%) stated as moderate.¹¹ About 60% of Pakistani doctors thought that they broke bad news properly to the patients; 59% were satisfied with their own performance while dealing with an incurable patient.⁹

In our study 62% of post graduate students followed guidelines for pain management but 0% received any training in palliative care. In a study conducted amongst the emergency medicine physicians in Turkey, most respondents (77%) reported getting no training in palliative care.¹⁹ (20%) of the physicians stated their competence in pain management as very good, 60 (63%) of them stated as good, and 16 (17%) of them stated as moderate.¹¹

In this study 0% knew about other avenues along with palliative care which can be added to a chronically ill patients treatment plan. In a study conducted in Pakistani Doctors, majority (67.1%) were open to other forms of treatment apart from allopathy mainly in the form of spiritual (32.8%), herbal/hikmat (22.8%), homeopathy (20%), acupuncture (8.5%) while 15.7% did not mention other alternative treatment or left to the patients or family's discretion.⁹ In a study conducted in India, also similar number of doctors (62.9%) were open to other modalities of treatment mainly to the spiritual (25.9%), aroma therapy (5.55%), acupuncture (27.7%) etc.¹⁷

In our study, 98% of residents were interested in getting trained for palliative care. In a study conducted in Turkey, maximum participants (91%) agreed that special training is required to acquire palliative care skills, and 69% of emergency physicians wanted to get training on palliative care.¹¹

Conclusions

The findings of this study showed that though the post graduate medical students knew concept of palliative care, however there was a gap between awareness and practice about the same.

Recommendations

There is a need to emphasize on the provision of training on palliative care in the curriculum of post graduate students not only from clinical departments but also from non clinical departments. Also undergraduate medical students should be sensitized about need of palliative care through workshops. There should be continued medical education about recent advances in palliative care to the post graduate students after completion of studies.

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Declarations

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Conflict of interest: Nil

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Study of Cardiovascular Risk Assessment in Patients with Fatty Liver Disease

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Abstract

Background- The term ‘fatty liver disease’ (FLD) is used to describe a variety of liver diseases of different severity, from pure steatosis to steatohepatitis and cirrhosis and hepatocellular carcinoma. **Objective-** To Study Of Cardiovascular Risk Assessment In Patients With Fatty Liver Disease. **Methodology-** This prospective single center study was conducted from 1st March 2015 to 1st March 2016, in the Department of Gastroenterology in collaboration with Department of Community medicine at Global hospitals. All Adult (18 years to 70 years) patients, both sexes, reporting to Medical Gastroenterology with FLD were included in the study which were 32. **Result** - Maximum 28 subjects (87.5 %) were male while 4(12.5%) were female. Male to female ratio was 7:1. Maximum patients 20(62.5%) belonged to Grade II fatty liver followed by 09 (28.12%) Grade I and 03(9.3%) Grade III. 11(34.37%) were overweight, 17 (53.12%) were obese, only 4 patients had normal BMI. 27(96.42%) out of 28 male patients had abnormal waist while four (100%) out of 4 female patients had abnormal waist circumference. 12(37.50) Patients with FLD had significantly higher levels of total cholesterol. **Conclusion-** . FLD may serve as a trigger for assessment of cardiovascular risk factors, and such patients should undergo further cardiovascular assessment.

Keywords- Cardiovascular risk assessment; fatty liver disease.

Introduction

The importance of the liver in the regulation of metabolism has been recognized for over a century and a half. Several pathological conditions are associated with intra-hepatic triacylglycerol accumulation, but fatty liver has long been considered a trivial finding. The term ‘fatty liver disease’ (FLD) is used to describe a variety of liver diseases of different severity, from pure

steatosis to steatohepatitis (NASH) and cirrhosis and, rarely, hepatocellular carcinoma. The large majorities of patients with FLD are overweight or obese or have type 2 diabetes; another common associated clinical feature is atherogenic dyslipidemia i.e; high triacylglycerol, low HDL-cholesterol and increased small dense LDL-cholesterol levels. A large body of evidence suggests that FLD is the hepatic manifestation of the metabolic syndrome¹. Accordingly, the cardiovascular disease (CVD) risk dictates the outcome(s) of these patients more frequently and to a greater extent than does liver disease progression²

In the community, the prevalence of ultrasound-diagnosed FLD is ~30%, this figure being largely influenced by obesity and/or alcohol consumption³. Hence this study is carried out to highlight the cardiovascular risk factors among patients of FLD.

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Aim and Objective- To Study Of Cardiovascular Risk Assessment In Patients With Fatty Liver Disease.

details of the subject. Workup of these patients was done on standard lines [history, anthropometry, physical examination etc.]

Material & Methods-

This prospective single center study was conducted from 1st March 2015 to 1st March 2016, in the Department of Gastroenterology in collaboration with Department of Community medicine at Global hospitals, Hyderabad, Telangana State, India. All Adult (18 years to 70 years) patients, both sexes, reporting to Medical Gastroenterology and Hepatology outpatient department with FLD were included in the study. A total of 39 subjects were enrolled into the study over this period of time, but 7 subjects could not complete the protocol and hence were excluded. Therefore, data pertaining to a total of 32 subjects were analyzed. After explaining the purpose of study and obtaining verbal informed consent from the patients, all patients were interviewed with the help of preformed structured questionnaire comprising of questions related to epidemiological and clinical

Statistical Analysis

Data was entered in Microsoft excel sheet and it was analyzed with Epi info software. Statistical analysis was done by using simple proportions, percentages and mean±SD Throughout the study anonymity of all patients was maintained and privacy as well as confidentiality of the data was assured.

Results

This prospective study was conducted from 1st March 2015 to 1st March 2016 in the Department of Gastroenterology and Hepatology in collaboration with Department of Community medicine at Global hospitals, Hyderabad, Telangana State, India.

Table No. 1: Distribution of study subjects according to sex-

Sex	Number	Percentage (%)
Males	28	87.5
Females	04	12.5
Total	32	100

Table No. 1 shows Distribution of study subjects according to sex. Maximum 28 subjects (87.5 %) were male while 4(12.5%) were female. Male to female ratio was 7:1.

Table No. 2: Distribution of study subjects according to Grades of fatty liver-

Grades of fatty liver	Number of patients (n)	Percentage (%)
Grade I	9	28.12%
Grade II	20	62.5%
Grade III	3	9.37%
TOTAL	32	100%

Table No. 2 shows Distribution of study subjects according to Grades of fatty liver. Maximum patients 20(62.5%) belonged to Grade II fatty liver followed by 09 (28.12%) Grade I and 03(9.3%) Grade III.

Table No. 3: Distribution of study subjects according to clinico-social factors

Clinico-social factor	Number (n=450)	Percentage
B.M.I		
18.5-24.9	04	12.50
25-29.9	13	40.62
30-34.99	14	43.75
35-39.99	01	03.12
Waist Hip Ratio (Male)		
Normal	01	03.12
Abnormal	27	84.37
Waist Hip Ratio (Female)		
Normal	00	00
Abnormal	04	12.50
Total cholesterol		
<200	20	62.50
>200	12	37.50

Table No. 3 shows Distribution of study subjects according to clinico-social factors. Eleven patients (34.37%) were overweight while seventeen patients (53.12%) were obese. Thus only 4 patients had normal BMI. 27(96.42%) out of 28 male patients had abnormal waist while four (100%) out of 4 female patients had abnormal waist circumference. 12(37.50) Patients with FLD had significantly higher levels of total cholesterol.

Discussion

During this prospective single centre study, a total of 32 patients of fatty liver disease (FLD) were enrolled. The mean age of subjects in the study was 43.12 years (SD=10.53 years), while median age was 45.5 years (range from 20 to 61 years).

Our study had a male preponderance, 28 subjects (87.5%) were male while 4(12.5%) were female. Male to female ratio was 7:1. Studies by Guleria et al and Agarwal et al showed that similar finding comparable with our study^{5,6}

Table No. 2 shows Distribution of study subjects according to Grades of fatty liver. Maximum patients 20(62.5%) belonged to Grade II fatty liver followed by 09 (28.12%) Grade I and 03(9.3%) Grade III. The study findings are parallel to a study done by Greenland P et al⁴.

Table No. 3 shows Distribution of study subjects according to clinico-social factors. Eleven patients (34.37%) were overweight while seventeen patients (53.12%) were obese. Thus only 4 patients had normal BMI. No statistically significant association was found

between BMI of the subjects and grades of fatty liver ($F = 1.006$; $p=0.378$). 27(96.42%) out of 28 male patients had abnormal waist while four (100%) out of 4 female patients had abnormal waist circumference. Statistically highly significant association was found between WHR of the subjects and grades of fatty liver ($F = 3.419$; $p<0.05$).

Similar findings were reported by Guleria et al⁵ Thirteen (65%) patients were obese in the NAFLD group compared to 7 (35%) among controls. Five (25%) patients were overweight among the cases compared to 7 (35%) among controls ($p=0.127$). Thus, only 2 (10%) patients in the NAFLD group and 6 (30%) among controls had normal BMI. Eight (66.7%) out of 12 male patients in the NAFLD group had abnormal waist circumference in comparison to 3 (25%) male controls ($p=0.041$). 7(87.5%) out of 8 female patients in the NAFLD group had abnormal waist circumference in comparison to 6 (75%) female controls. However Mohammadi et al⁷ reported statistical significant association between BMI and NAFLD (BMI 29.88 (± 3.88) vs 25.29 (± 4.19) $p=0.001$).

12(37.50) Patients with FLD had significantly higher levels of total cholesterol. Similar observations were also reported by Mohammadi et al⁷

Limitations Of The Study-

Sample size was somewhat limited ($n=32$) and may have affected our ability to detect more subtle grades of fatty liver. The small number of patients also limits our study but the results suggest that patients with FLD have increased cardiovascular risk. Further studies with larger sample size are required to establish a link between increased cardiovascular risk in patients with FLD.

Conclusion-

In conclusion, FLD may be an independent risk factor for developing atherosclerosis. Therefore, FLD without other cardiovascular risk factors can be associated with increased risk of cardiovascular events in patients with FLD incidentally diagnosed on abdominal ultrasonography. FLD may serve as a trigger for assessment of cardiovascular risk factors, and such patients should undergo further cardiovascular assessment.

Ethical approval: The study was approved by the Institutional Ethics Committee.

Funding- There are no sources of funding for this study.

Conflict of interest - All authors declare that there are no conflicts of interest in this study.

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Reproductive Health Status of Rural Women in Coimbatore District, Tamil Nadu

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Abstract

Background: In India, the dietary patterns and lifestyle has considerably changed in the recent past. This has considerably altered the reproductive physiology of women, thereby making them susceptible for various problems. One of the most important factors influencing a woman's reproductive health is pelvic inflammatory disease. This study was carried out to evaluate the reproductive health status of rural women in South India.

Methods: This cross-sectional study was carried out among 1233 women of the reproductive age group residing in a rural area of Coimbatore district. A structured interview schedule was used to obtain information regarding sociodemographic, menstrual, lifestyle and reproductive health status of the study participants.

Results: It was observed that pelvic inflammatory disease was present in 5.1%, anemia in 5.3%, Type 2 Diabetes Mellitus in 2.1%, Thyroid disorders in 4.1%. Majority of the participants had BMI between 18.5- \leq 23 (47.7%). Primary infertility was present in 8.43% of the study participants.

Conclusion: This study has highlighted that although the actual prevalence of reproductive health problems is fairly low, the risk factors for reproductive health problems, namely overweight and obesity, anemia, lack of physical activity and irregular menstrual cycles were significantly higher.

Key words : *Infertility, pelvic inflammatory disease, obesity, reproductive health*

Introduction

The health and wellbeing of a woman is a mirror of the health status of the society. Women are the backbone of a family, and it is important to realize that woman's health is to be at optimum. Health hazards affecting women are predominantly related to the reproductive health, although the other problems like nutritional, psychological and general well-being are also involved to an extent. Therefore, there is a need to evaluate the reproductive health of the women in a community at

all times. The reproductive system of men and women are complex, yet sensitive to various extrinsic and intrinsic factors. A failure in the effective functioning of the reproductive system could be due to the extrinsic factors, which are, however, been influenced by religious, cultural, political and socioeconomic factors. [1]The effective functioning of the reproductive system is also influenced by intrinsic factors like body mass index, hormonal levels, metabolic disorders like diabetes mellitus.

An effective functioning of the reproductive system is witnessed by fertility. The higher fertility in India is attributable to universality of marriage, lower literacy rates, poor level of living, traditions and customs. [2] Though these factors are majorly social, there are several individual factors which promote fertility. These include lower age at marriage, absence of co morbid conditions,

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brisk and active lifestyle, etc.

In India, the dietary patterns and lifestyle has considerably changed in the recent past. This has considerably altered the reproductive physiology of women, thereby making them susceptible for various problems. One of the most important factors influencing a woman's reproductive health is pelvic inflammatory disease. It is roughly estimated to affect 24%-32% of the Indian women.^[3] The other diseases include hypothyroidism, anemia, type 2 diabetes mellitus, to name a few. Among the social factors, age at marriage, consanguinity, menstrual hygiene, etc. significantly influence a woman's reproductive health.

Although several studies have been done to evaluate individual problems of a woman's reproductive health, there is a need to evaluate the larger perspective of reproductive health, in terms of the intrinsic and extrinsic factors and in relation with the sociodemographic parameters. This will help in identifying the primary and secondary preventive strategies that will go a long way in restoring optimum health and well-being of women of the reproductive age group. It is indeed consequential that a community-based study is carried out, especially among the rural women, to obtain the actual picture of the problem. Moreover, this study will serve as a base to formulate the research question in terms of early detection and prevention of infertility and other reproductive health problems in the rural area of Tamil Nadu, and thereby for the entire country.

Objectives

This study was carried out to assess the reproductive health status of the rural women of Coimbatore district.

Methodology

Study setting and participants

This cross-sectional study was carried out among the women of reproductive age group residing in the rural field practice area of our tertiary care hospital in Coimbatore district. This study was carried out for a period of 18 months between November 2016 and April 2018.

Inclusion criteria

- a. Married couple where wife is in reproductive

age group between 15 and 49

- b. Couples living together
- c. Couple living in the field practice area for more than one year
- d. If more than one eligible couple got selected from the same household then the both will be included in the study.

Exclusion criteria

- a. Couples separated >6 months per year
- b. Underwent hysterectomy surgery.
- c. Those who were seriously ill, not cooperative and not willing to participate in the study

Sample size and sampling technique

Based on intensive literature review for various reproductive health problems, pelvic inflammatory diseases were found to be prevalent among 24% of the Indian women.^[3] At 95% level of significance and 10% relative precision, the sample size was calculated as 1216 and was rounded off to 1220. The total list of women in the reproductive age group was obtained from the field staff attached to the rural health and training center of our medical college. From this list, the required sample of 1220 participants were selected using simple random sampling, using table of random numbers.

Ethical approval and informed consent

Approval was obtained from the institutional ethics committee prior to the commencement of the study. Each participant was explained in detail about the study and informed consent was obtained prior to the data collection.

Data collection

A structured interview schedule was used to obtain information regarding the sociodemographic, menstrual and obstetric history and prevalence of various risk factors of reproductive health problems among the study participants. Socioeconomic status was classified based on Modified Prasad's classification based on per capita income computed in relation with the Consumer Price Index (CPI) for Coimbatore, determined by the Labor

Bureau of India for the year 2017.^[4] Clinical examination was carried out to look for pallor. Height and weight were measured using standard scales and body mass index (BMI) was calculated. The BMI was classified based on WHO classification of obesity for the Asian population.^[5]

Data Analysis

Data was entered and analyzed using SPSS software ver.21. The prevalence of reproductive health problems and their risk factors were expressed in percentages. Chi square test was used to compare the sociodemographic and other risk factors with the reproductive health problems. A p value <0.05 was considered statistically significant.

Results

This cross-sectional study was carried out among 1233 women of the reproductive age group residing in the rural field practice area of our medical college. A majority of the participants belonged to the age group of 21 to 30 years (50%). In the study, 43.4% of the participants were educated up to high school level and 98.3% belong to class I socio economic status. (Table 1)

Table 2 represents the reproductive characteristics of the study participants. In our study out of 1233 eligible couple mean age of wives was 31.40 ± 6.747 years while mean husbands' age was 36.87 ± 7.688 years. About 53.8% of the participants attained Menarche in ≤ 13 years and about 84.9% of the participants had regular menstrual cycles while 15.1% of the participants had irregular cycles. In this study, 31.7% had pain during menstrual cycles.

Table 3 shows the lifestyle factors among the study participants. It was observed that 83.5% of the women did not perform any regular physical exercise, none of the female participants were smokers, passive smoking was present in 27.1% of the participants and alcohol consumption was present in 39.25% of the spouses. Among the study participants, the women who consumed coffee was 49.6%.

Table 4 shows the possible morbid risk factors for reproductive health problems. It was observed that pelvic inflammatory disease was present in 5.1%, anemia in 5.3%, Type 2 Diabetes Mellitus in 2.1%, Thyroid disorders in 4.1%. Majority of the participants had BMI between $18.5 - \leq 23$ (47.7%). Primary infertility was present in 8.43% of the study participants.

Table-1: Background characteristics of the study participants

S. No	Characteristics		Frequency N=1233	Percentage (%)
1	Age (in Years)	<20	24	1.9
		21-30	616	50.0
		31 –40	441	35.8
		>40	152	12.3
2	Education	Illiterate	71	5.8
		Primary school	18	1.5
		Middle school	121	9.8
		High school	535	43.4
		Higher secondary	241	19.5
		Graduate	247	20.0

Cont... Table-1: Background characteristics of the study participants

3	Socio economic status	Class-I	1212	98.3
		Class-II	15	1.2
		Class-III	0	0
		Class-IV	1	0.1
		Class-V	5	0.4

Table-2: Risk factors of reproductive health problems among the study participants:

S. No	Factor	Categories	Frequency N=1233	Percentage (%)
1	Age at menarche in years	<13	663	53.8
		>13	570	46.2
2	Regularity of menstrual cycle	Regular	1046	84.9
		Irregular	187	15.1
3	Pain during cycle	Yes	391	31.7
		No	842	68.3
4	Age at marriage (in years)	≤30	1196	97
		>30	37	3
5	Consanguinity	Present	187	15.2
		Absent	1046	84.8

Table-3: Lifestyle factors:

S. No	Factors	Category	Frequency N=1233	Percentage %
1	Physical exercise	Yes	202	16.4
		No	1031	83.5
2	Smoking	Yes	0	0
		No	1233	100
3	Alcohol	Yes	0	0
		No	1233	100
4	Smokeless tobacco	Yes	84	6.8
		No	1149	93.1
5	Coffee	Yes	611	49.6
		No	622	50.4

Table-4: Reproductive health risks and problems:

S. No	Conditions	Frequency N=1233	Percentage (%)	
1	Pelvic inflammatory disease	64	5.1	
2	Anemia	66	5.3	
3	Type 2 Diabetes Mellitus	26	2.1	
4	Thyroid disorders	51	4.1	
5	Body Mass Index	<18.5	134	10.9
		18.5 - ≤ 23	588	47.7
		>23	511	41.4
6	Infertility	Primary	104	8.43
		Secondary	20	1.62

Discussion

A woman's health and wellbeing are of utmost importance in any society and adequate efforts must be taken to evaluate and address the issues associated with women's health. This cross-sectional study was carried out among 1233 eligible couples in the rural field practice area of our medical college to evaluate the reproductive health status of the women. A majority of the participants belong to the age group of 21 to 30 years (50%). In a study done by Adamson P.C, the mean age of the participants was 25.9 years, which is similar to our study in our study.^[6] In a study done by Moumita Pal the mean age of the participant was 29.7 years which is also similar to our study.^[7] The mean age at Menarche in our study was 13 years. Menarche and menstrual cycles are the foundations for a healthy menstrual and reproductive life of a woman. Age at Menarche is influenced by environmental, socio economic and nutritional factors. In India, Mital Prajapati of Ahmadabad showed that mean age of menarche was 13.2 years which is similar to our study.^[8] In Tamil Nadu the mean age at menarche in rural areas according to a study done by Tamilselvi K was 13.6 years, which is also comparable with our study.^[9]

About 84.9% of the participants had irregular menstrual cycles and 31.7% had dysmenorrhea. It is essential that a woman maintains the healthy menstrual cycle throughout her reproductive age in order to facilitate easy conceivability. In our study a number of participants who got married before 30 years of age were higher (97%). Moreover, consanguinity marriages were present in 15.2% of the participants. According to NFHS-3 and NFHS-4, age at marriage below 18 years significantly reduces the risk of infertility.^[10] India is religiously and culturally rich in heritage and tradition. Therefore, marriages have been the entry points to fertility for a long period of a time.

In our study, we elicited certain personal factors which were proposed to be risk factors for reproductive health problems. We observed that 94.1% of the women did not perform any regular physical exercises. An optimal physical activity is said to improve the blood circulation and improve the vitality.

In our study, the prevalence of infertility was 10.05%, of which primary infertility was prevalent in 8.4% of the study participants and secondary infertility was prevalent in 1.6% of the participants. As per NFHS data, there has been a steady decrease in the prevalence

rates of infertility. Moreover, the prevalence of primary infertility in Karnataka as per DLHS 2008 report was 7.7% in the rural areas, which is similar to our study. [11] Similarly, pelvic inflammatory disease was prevalent in 5.1% of the study participants. A higher prevalence was observed with respect to the body mass index, showing 47.7% prevalence of overweight. Studies have proven that increase in the body mass index predisposes the women to other syndromes like Polycystic Ovarian Syndromes and Metabolic syndrome, which in turn predisposes to infertility.^[12]

Conclusion

This study has highlighted the overall reproductive health status of the rural women in South India. We observe that although the actual prevalence of reproductive health problems is fairly low, the risk factors for reproductive health problems, namely overweight and obesity, anemia, lack of physical activity and irregular menstrual cycles were significantly higher. This warrants an urgent action towards screening women of the reproductive age group at the population level in order to identify the risks at an early stage and address effectively in the primary care set up. This study has also paved way for further research to explore individual reproductive problems at the community level by way of in-depth clinical examination and laboratory evaluation.

Declaration

Conflict of Interest – Nil

Funding – Self

Ethical approval – Obtained

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Correlational Study of Academic Stress and Suicidal Ideation among Students

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Abstract

The purpose of the study was to investigate the correlation between academic stress and suicidal ideation among students. The sample of this study included 200 students from Allen Institute of Kota(Rajasthan) . 100 were IIT aspirant students and 100 were NEET aspirant students. Academic stress measured using the academic stress scale developed by Rao, and suicidal ideation measured using the suicidal ideation scale was developed by Sisodia and Bhatnagar. The result of this study showed that no significant difference in academic stress among IIT and NEET aspirant students and significant difference was found in suicidal ideation among IITand NEET aspirant students. There are several factors that can affected academic stress and suicidal ideation like parental pressure, personal relationship issues, addiction issues, competitive atmosphere etc. The study revealed the significant relationship of academic stress and suicidal ideation among students.

Key words - academic stress, suicidal ideation, students of Allen Institute.

Introduction

Stress is a negative physiological, psychological and behavioural process that occurs as a person tries to deal with stressor (Bernstein et al., 2008)¹. Stress is constantly regarded as a mental process that involves an individual's personal interpretation and response to any threatening event. Psychologist assert that moderate stress motives individuals to achieve and feels creativity. Although stress may hinder individuals from performance on difficult task (Auerbach&Garmlig, 1998)². Stress is not necessarily something bad. It all depends on how you take it. The stress is beneficial for creative and successful in work ,While that of failure humiliation or infection is detrimental (Selye,1956)³. Stress is an unavoidable consequences of modern life

style with the pressure of education. In the present scenario what we see that throat cut competition , where every people is facing challenges in one way and each has high level of ambition but lack of time to achieve these goals . ultimately results in the occurrence of stress. Academic stress is refers to the force to perform well in examinations, horror from punishment and spirited examinations that is experienced by students. Academic stress has increased over the past few years. Teachers and parents also burden the students with a lot of pressure of getting good grades. The academic stress is one of the significant barrier to students academic performance. It may be adversely affect their emotional, physical, and psychological health. Kota is the centre of India's private coaching industry. The current expectations from the students of Kota is to be an IITian and doctor. Every year approximately 1.5 to 2 lack students come to Kota to realise their dream to getting into an engineering or medical college. Academic stress among students have long been researched on and researchers have identified there is no single factor that contributes to stress among students. Upbringing, family condition, friend circle, aspiration not in sync with individual capabilities. Overwhelming academic environment, pressure from

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coaching institutions, lack of regular positive interaction with parents and friends.

Suicide is the third leading cause of death among 15 to 24 year olds. And second leading cause of death among college students (Schwartz, 2006)⁴. Suicide is not a illness. It's a complex set of behaviour that exists on a continuum from ideas to actions. The word "suicide" is derived from two Latin words "sui" meaning of one self and "edium" meaning killing. It means the act of taking one's own life. Suicide is defined as death by injury, poisoning, or suffocation with the intent of the deceased. That the deceased intended to kill himself or herself (O'Carroll & Berman et al., 1996)⁵. The term suicide is often used which usually refers to the idea of suicide, including the planning conduct and consequences of suicidal behavior, particularly as a final revision of ideas about the reaction of others (Jose & Alexandra et al., 2005)⁶. In Kota the rise in the number of suicides equal with the growth of the coaching industry. National crime bureau reported, in 2014 there has been 61.3 percent increased in suicide cases in kota , mostly involving students.⁷ The data of 2013 shows that 62 suicide deaths were recorded .The number of suicide cases in Kotais higher than other cities of Rajasthan.

Review of Literature

Deb et al. (2014) studied the prevalence of academic stress and exam anxiety among private secondary school students in India. Sample were 400 students (52 percent male) from five private secondary school in Kolkata. Result revealed that 35 to 37 percent reported high level of academic stress and exam anxiety. But those who had lower grades reported higher levels of stress than with higher grades.⁸

Arun and Chavan (2014) examined the stress, psychological health, and presence of suicidal ideas in school students and to find out any correlation between these variables. The sample included 2402 students from Chandigarh city .The analysis of data revealed that there was significant correlation between student's perception of life as burden and class they were studying, students with academic problems and unsupportive environment at home perceived life as a burden and had higher rates of suicidal ideations.⁹

Prabu (2015) assessed the level of academic stress among higher secondary students. The sample included 250 students studying in higher secondary schools situated in Namakkal district of Tamilnadu (India). Result revealed that the higher secondary students are having moderate level of stress . The male students academic stress is higher than female students. The urban students academic stress is higher than rural students . The government school students academic stress is less than private school students .The science subject students academic stress is higher than arts students.¹⁰

Akhtar and Alam (2015) examined the stress and suicidal ideation among school students. The sample included 120 students of different boards of secondary examination. The age of the students ranged from 14 to 18 years. Study revealed that there is no significant difference in suicidal ideation as far as gender is concerned. The results also found that stress and suicidal ideation were significantly and positively related to each other.¹¹

Gill (2017) examined the level of academic stress among students of class 11 having different streams. The sample included 200 students from Ferozpur district of Panjab. The study reveal that the students of class 11 are having moderate level of academic stress and irrespective of sub samples of students are having moderate level of academic stress.¹²

Maria et al., (2018) examined the prevalence of suicidal ideation and associated factors in medical students. Seventeen studies including a total of 13,244 medical students from 13 western and non western countries were included. The diffusion of suicidal ideation ranged from 1.8% to 53.6%. The most frequent factors associated with suicidal ideation in medical students were depression, lower socio economic status, financial difficulties, having a history of drug use, feeling neglected by parents.¹³

Fayaz (2019) studied the correlation between irritability and suicidal ideation among the adolescents of Kashmir. Sample were 100 adolescents (50 boys adolescents and 50 girl adolescents) selected from different areas of Kashmir. The result revealed positive correlation between irritability and two dimensions of suicidal ideation. The results also found that there was no significant difference between adolescent boys and

girls on suicidal ideation and irritability.¹⁴

Objectives

- To determine the level of academic stress among IIT aspirant students of Allen Institute of Kota (Rajasthan).
- To determine the level of academic stress among NEET aspirant students of Allen Institute of Kota (Rajasthan).
- To determine the level of suicidal ideation among IIT aspirant students of Allen Institute of Kota (Rajasthan).
- To determine the level of suicidal ideation among NEET aspirant students of Allen Institute of Kota (Rajasthan).
- To find out the correlation between academic stress and suicidal ideation among students of Allen Institute of Kota (Rajasthan).

Hypotheses:-

1. There would be significant difference between

IIT aspirant students and NEET aspirant students on academic stress.

2. There would be significant difference between IIT aspirant students and NEET aspirant students on suicidal ideation

3. There would be significant correlation between academic stress and suicidal ideation among students of Allen Institute of Kota (Rajasthan).

Research Methodology

Sample:- (100 were IIT aspirant students and 100 were NEET aspirant students) from Sample was collected through purposive sampling techniques. Students who have been studying in Kota for at least 2 years. Those who do not belong to Kota and live in hostels were included.

Psychological Tools:-

- Academic stress scale (Rao, 2013)¹⁵
- Suicidal ideation scale (Sisodia and Bhatnagar, 2011)¹⁶

Results and Discussion

Table 1 : Mean, standard deviation and t-value of Academic stress of IIT aspirant students and NEET aspirant students.

Groups	N	Academic stress		t-value
		Mean	SD	
IIT aspirant students	100	48.64	26.64	1.79NS
NEET aspirant students	100	42.02	25.45	

NS-Not significant

Table 1 shows that mean and standard deviation of academic stress of IIT aspirant students is (48.64, 26.64) and NEET aspirant students is (42.02, 25.45) and t-value is 1.79. This shows no significant difference in the level of Academic stress of IIT aspirant students and NEET aspirant students. So hypothesis-1 is rejected

and shows that there is no significant difference in level of Academic stress of IIT aspirant students and NEET aspirant students. Stress is necessary to challenge students to learn. During their preparation both students face various academic problems including exam stress, disinterest in attending classes and the inability to

understand a subject. Academic stress includes mental distress about anticipated academic challenges or failure or even the fear of the possibility of academic failure. They are made to believe that after two years of hard work if they make it to the IIT and medical college. Which would be end of their struggle. The competition

to get into IIT results in a lot of pressure to perform and crack the entrance exams. One of the most prominent factor behind the stress is academic pressure because of the vastness and time constraints to complete the syllabus demand extraordinary efforts from the students.

Table 2: Mean, standard deviation and t-value of Suicidal ideation of IIT aspirant students and NEET aspirant students.

Groups	N	Suicidal ideation		t-value
		Mean	SD	
IIT aspirant students	100	54.84	14.52	3.02**
NEET aspirant students	100	48.33	15.90	

**significant at p 0.01 level

Table 2 :shows that mean and standard deviation of Suicidal ideation of IIT aspirant students is (54.84, 14.52) and NEET aspirant students is (48.33, 15.90) and t-value is 3.02. This shows significant difference in the level of Suicidal ideation of IIT aspirant students and NEET aspirant students. So hypothesis-2 is accepted and shows that there is significant difference in level of Suicidal ideation of IIT aspirant students and NEET aspirant students. IIT aspirant students has higher level of suicidal ideation as compare to NEET aspirant students.

This findings was consistent with the result of a previous study done by Kale (2018) Failure in examinations being the major cause of suicide.¹⁷Frustrated to fail in the desired outcome or competition. lead some students aiming for NEET and IIT commit suicide. Kota is a place with lots of distractions. The tataInstitute of social sciences report blamed,study stress, parental pressure, depression, homesickness, love affairs, drug abuse and emotional issues for the suicide. More than 55 students have committed suicide in Kota in 2019.

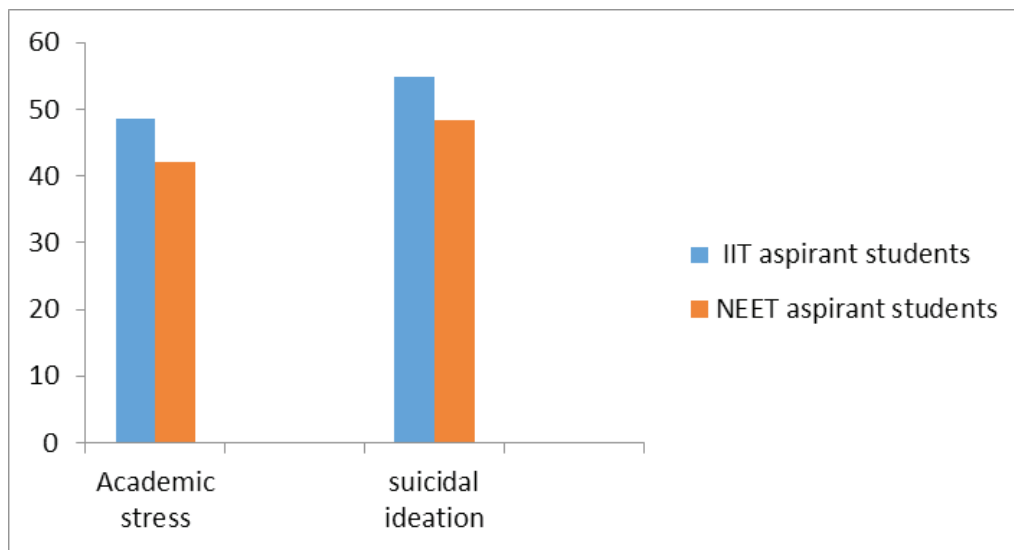


Fig. 1: Graphical representation of mean scores of academic stress and suicidal ideation between IIT aspirant students and NEET aspirant students.

Table 3 : Correlation between Academic stress and suicidal ideation

S.N.	Variables	N	df	r-value
1.	Academic stress	200	198	0.259**
2.	Suicidal ideation	200		

**significant at p 0.01level

Table 3: Shows that the obtained value of r (0.259) is significant at 0.01 level. Because the calculated value of r is higher than the tabulated value. Thus the hypothesis 3 is accepted. Therefore it is found that there is positive significant correlation between the academic stress and suicidal ideation of Allen students. Kota is famous for its result in the field of medical and engineering examinations. This city has more than 300 coaching Institutes that trains young aspirants for AIIMS/ NEET, JEE mains and JEE advanced examinations. Every year more than 2 lakh students come here in the hope of fulfilling their dream in Kota. But every student is not able to crack these exams. Students with academic stress and academic problems, unsupportive environment at home perceived life as a burden and had higher rates of suicidal ideation (Arun&Chavan, 2014).⁹

Conclusion

The present study revealed that there is no significant difference was found between IIT aspirant students and NEET aspirant students on academic stress. The IIT aspirant student's suicidal ideation is higher than NEET aspirant students. It is found positive significant correlation between academic stress and suicidal ideation. Experts say that most of the suicides are due to fear of failure and the burden of expectations from family, Sudden change in surrounding, test results, batch reshuffle issues. Apart from these career related issues. The parents should rather make their children psychologically stronger and keep telling their wards that whatever be the results of the exams (success or failure) they are always with them and will support them under any circumstances. Coaching Institutes should also come forward and keep counselling the weaker students. Especially those who suffering from academic stress, depression and suicidal ideation.

· Written informed consent was obtained from all the participants before commencement of the study .

· I am a research scholar . i am not taking any kind of scholarship. No funding from any source .

· Conflict of interest is nil.

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Psychological Perception Towards Novel Coronavirus (Covid-19) Among General Public In Tamilnadu State, India- An Exploratory Analysis

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Abstract

Background: Novel coronavirus (COVID-19) is an infectious respiratory disease and it begins to spread globally. In India, the first COVID-19 case was detected in Kerala and then it slowly starts spreading various parts of India. Due to the rapid spreading of coronavirus (COVID-19) the people become more panic and it affects the psychological health of the people.

Aim: The aim of this study is to assess the psychological perception of the people towards COVID-19 among general public in Tamilnadu, India.

Materials and Method: A cross sectional study was conducted among 170 subjects in Tamilnadu based on the simple random sampling method and their psychological perception towards COVID-19 were assessed by using a 15 item questionnaire. The data were analyzed and tabulated using descriptive statistics and chi square test. $P < 0.05$ were considered to be statistically significant.

Results: There was a statistically significant difference was found in sleep quality ($p=0.04$), scared of being treated indifferently ($p=0.01$) and financial loss ($p=0.002$) among males and females. No statistically significant difference was found in the overall psychological perception towards COVID-19 in relation to age and gender.

Conclusion: Majority of the people had a moderate level of stress towards the disease. This paper points out the importance to address psychosocial impact of COVID-19 to reduce the vulnerability of this condition by enhancing better coping and resilience of the public.

Keywords: COVID-19, Psychological, Perception, People, Impact.

Introduction

Novel corona virus (COVID-19) is an infectious respiratory disease begins to emerge throughout the world which is zoonotic in nature and can be transmitted from animals to humans. The current outbreak of Novel corona virus (COVID-19) was first emerged in Wuhan,

China on 31st December 2019 with a confirmation of 80,881 coronavirus affected cases and then it starts spreading to other countries globally [1].

World Health Organization had declared this outbreak as a public health emergency concern on 30th January 2020. The term COVID-19 for this virus was given by WHO on February 11th 2020 [1]. WHO announced coronavirus outbreak as pandemic on 11th March 2020. Previously two strains of corona virus such as Severe Acute Respiratory Syndrome Coronavirus (SARS- CoV) and Middle East Respiratory Syndrome (MERS- CoV) have infected human begins but the only strain Novel coronavirus (COVID- 19) is found to be

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pandemic [2].

World Health Organization (WHO) has updated a guideline to reduce the spread of corona virus infection which involves washing hands with soap and water. The preferred element is frequent washing of hands with soap and water and if soap and water is not available, use alcohol based hand rub, cover the nose while sneezing and coughing to avoid the spread of infection, avoid close contact with person having cold or flu like syndrome and avoid contact with wild or farm animals or visiting live or wet market. The incubation of corona virus is 5 days and approximately 2-14 days. Since corona virus starts with mild symptoms they are several cases reported among children in Shenzhen, china that they do not have symptoms but developed coronavirus [3].

The outbreak of novel corona virus (COVID-19) is increasing rapidly and affects people in worldwide distribution. The COVID-19 infected patients will be kept under quarantine which is the most unpleasant experience among the public this affects the psychological health of people which includes insomnia, fear of contact with others and travelling, tachycardia and diarrhoea. Due to the high negative impact of quarantine among the public causes more depression this may also makes them to commit suicide [4]. The panic due to COVID-19 may also causes and worsens other psychological problems such as Obsessive Compulsion Disorder (OCD). WHO reported that the COVID-19 crisis is generating more panic among the public and has advised the people to avoid hearing, listening or watching the news which creates anxiety and negative impact on them [5].

The outbreak of corona virus (COVID-19) begins to spread in India with the first case confirmed in Kerala on 30th January 2020, and then slowly it starts spreading to the other states. In India, the first death due to corona virus (COVID-19) was reported on 12th March in Karnataka [6,7]. Among the various states of India, Tamil Nadu ranks second place after Maharashtra with a highest of corona virus. In Tamilnadu the first COVID-19 case was reported on March 7th, 2020 and then the number of cases was found to be rapidly increasing with a confirmation of 19,372 cases by the Department of Health and Family Welfare as of 28 May 2020. This creates more panic and might affect the mental health of the public [8]. Hence, this present study aims to evaluate the psychological

perception towards COVID-19 among public in Tamil Nadu state, India.

Materials and Method

A descriptive, cross-sectional study was conducted among people in Tamilnadu to evaluate their psychological perception towards COVID-19. The ethical approval for this study was obtained from the Institutional review board AND Institutional Ethical Committee of SRM Dental College, Ramapuram and the IRB approval number was SRMU/M&HS/SRMDC/2020/PG/005. The sample size was estimated to be 170 by setting a confidence level 95% and margin of error as 5% based on the previous study [9].

A total of 170 subjects were recruited from the various public areas of Tamilnadu based on the multistage sampling method and the study was conducted for a period of two months (April 2020- May 2020). The inclusion criteria are only people of aged 18 years and above were recruited and the subjects who were willing to participate in the study are included whereas those subjects who didn't fulfill the questionnaire and consent form were excluded from the study.

The questionnaire consists of 20 items was validated by conducting a pilot study among 30 subjects based on convenience simple random sampling method and it was pretested and validated to check the internal consistency using Cronbach's alpha (0.83) which was found to be good. The questions which outfits and ambiguous to the study were excluded and the final perform of the questionnaire were prepared to minimize bias. The subjects who participated in the pilot study were excluded from the main study.

The finally prepared 15 item questionnaire was distributed among 170 subjects after obtaining the consent form. The questionnaire consists of demographic data and their psychological perception towards the disease. The subjects were asked to fulfill the questionnaire using yes or no format. For each response, the scores were calculated by considering the score to be 0 for No response whereas the score one was given to the response yes. The total number of scores was found to be 15. The score ranges from 1-5 was to be no stress related to COVID-19, the scores between the ranges 6-10 were considered to be moderately stressful whereas the

scores 11-15 were considered to be most stressful due to coronavirus. The data were entered and interpreted using the IBM Statistical Package for the Social Sciences 23.0 (IBM Corp., Armonk, New York). The data was then analyzed and tabulated using chi square test. $P < 0.05$ was considered to be statistically significant.

Results

The descriptive statistics frequency analysis, percentage analysis were used for categorical variables and the mean and S.D were used for categorical variables. The pearson's correlation was used to assess the relationship between the variables whereas the chi-square test was used to find the significance in categorical data. In both the above statistical tools the probability value < 0.05 was considered as significant level

TABLE 1: DESCRIPTIVE STATISTICS

S.NO.	VARIABLES	FREQUENCY	PERCENTAGE
1.	MALE	86	50.6%
2.	FEMALE	84	49.4%
3.	NO STRESS	15	8.8%
4.	MODERATE STRESS	90	52.9%
5.	SEVERE STRSS	65	38.2%

Table 1 shows about the frequency and distribution of the stress levels due to COVID-19

TABLE 2: ASSOCIATION OF GENDER AND PSYCHOLOGICAL IMPACT ON COVID-19

S.NO	QUESTIONNAIRE REGARDING PSYCHOLOGICAL IMPACT OF COVID-19	RESPONSES	GENDER		P VALUE
			FEMALE	MALE	
1.	Do you feel anxious about the pandemic of COVID-19	NO	32.1%(27)	30.2%(26)	0.78
		YES	67.9%(57)	69.8%(60)	
2.	Have you been scared of being infected with COVID-19?	NO	36.9%(31)	46.5%(40)	0.20
		YES	63.1%(53)	53.5%(46)	
3.	Do you worried about the risk of being infected with COVID-19?	NO	22.6%(19)	29.1%(25)	0.33
		YES	77.4%(65)	70.9%(61)	
4.	Do you feel tense when you think about the threat of COVID-19?	NO	42.9%(36)	33.7%(29)	0.22
		YES	57.1%(48)	66.3%(57)	
5.	Are you scared about the death due to COVID-19?	NO	28.6%(24)	38.4%(33)	0.17
		YES	71.4%(60)	61.6%(53)	
6.	Have you been being quarantine from your family?	NO	51.2%(43)	55.8%(48)	0.54
		YES	48.8%(41)	44.2%(38)	

Cont... TABLE 2: ASSOCIATION OF GENDER AND PSYCHOLOGICAL IMPACT ON COVID-19

7.	Do you think that being quarantine will affect your social status?	NO	50%(42)	52.3%(45)	0.76
		YES	50%(42)	47.7%(41)	
8.	Does COVID-19 outbreak affect your sleep?	NO	36.9%(31)	52.3%(45)	0.04
		YES	63.1%(53)	47.7%(41)	
9.	Are you scared of being treated differently if you have been infected with COVID-19?	NO	31%(26)	48.8%(42)	0.01
		YES	69%(58)	51.2%(44)	
10.	Are you afraid of going to public/crowd places?	NO	17.9%(15)	30.2%(26)	0.059
		YES	82.15%(69)	69.8%(60)	
11.	Do you have any trouble/difficulty in concentrating your work due to this disease?	NO	34.5%(29)	37.2%(32)	0.71
		YES	65.5%(55)	62.8%(54)	
12.	Are you scared of eating outside foods due to this disease?	NO	20.2%(17)	23.3%(20)	0.63
		YES	79.8%(67)	76.7%(66)	
13.	Have you been worried about the financial loss if you get exposed to this disease?	NO	48.8%(41)	25.6%(22)	0.002
		YES	51.2%(43)	74.4%(64)	
14.	Do your regular activities gets affected due to this disease?	NO	23.8%(20)	33.7%(29)	0.15
		YES	76.2%(64)	66.3%(57)	
15.	Thinking about the disease makes you feel anxious?	NO	21.4%(18)	31.4%(27)	0.14
		YES	78.6%(66)	68.6%(59)	

Table 2 shows that there was a statistically significant difference was in psychological problems such as sleep quality (p=0.04), being treated indifferently in the society (P=0.01) and financial problems (p=0.002).

TABLE 3: OVER ALL PYSCHOLOGICAL IMPACT ON COVID- 19 IN RELATION TO GENDER

SCORE LEVEL	GENDER		P VALUE
	FEMALE	MALE	
NO STRESS	7.1%(6)	10.5%(9)	0.28
MODERATE STRESS	48.8%(41)	57.0%(49)	
SEVERE STRESS	44.0%(37)	32.6%(28)	

Table 3 shows that there was no statistically significant difference was found in gender and psychological perception towards COVID-19(p=0.28).

TABLE 4: OVERALL PSYCHOLOGICAL IMPACT ON COVID-19 IN RELATION TO AGE

AGE	P VALUE
N- 170 MEAN- 33 MEDIAN- 32 S.D. 32	0.53

Table 3 shows that there was no statistically significant difference was found in age and psychological perception towards COVID-19($p=0.53$)

Discussion

In this study the psychological impact of the people related to the COVID- 19 has been evaluated. The corona virus drastically affects many people globally especially in India and the cases were increasing day by day this might make the people more panic about the disease and cause many psychological problems. Hence this study has been conducted to evaluate the psychological impact of the people in Tamilnadu related to this disease.

Table 1 shows about the percentage and frequency of the participants and their stress levels related to the COVID-19. The study has been conducted among 86 number of males (50.6%) and the 84 number of females (49.4%) of that fifteen number of people (8.8%) had no stress whereas 90 number of people (52.9%) had moderate level of stress and 65 number of people (38.2%) had severe stress. Table 2 shows about the association of the gender and questionnaire regarding psychological impact on COVID-19. There was a statistically significant difference was in psychological problems such as sleep quality ($p=0.04$), being treated indifferently in the society ($P=0.01$) and financial problems ($p=0.002$). The outbreak of COVID-19 affects the sleep quality of fifty three (63.1%) number of females and forty one (47.7%) number of males whereas the fifty eight (69%) number of females and forty four (51.2%) number of males have been scared of being treated indifferently due to the COVID-19, the forty three (51.2%) number of females and sixty four (74.4%) number of males have been scared due to the financial loss of this disease.

The table 3 shows about the overall psychological impact towards COVID-19 in respect to gender. Most of the people had moderate level of stress due to the outbreak of COVID-19. The forty one (48.8%) of females and forty nine (57.0%) of males had moderate levels of stress. There was no statistically significant difference was found gender and psychological impact on COVID-19 ($P=0.28$). The table 4 shows about the overall psychological impact towards COVID-19 in respect to age. The mean age of the participants involved in this study was thirty three. There was no statistically significant difference was found in the psychological impact on COVID-19 and age ($p= 0.53$).

The outbreak of coronavirus (COVID-19) starts spreading rapidly to various countries especially in India. The infected persons were kept in quarantine for at least 14 days. Quarantine is the best and the effective approach to prevent the transmission of this disease but unfortunately it affects the psychological health of patients. This causes the high potential threat to the mental health of the people.

The coronavirus (COVID-19) affects the people in many ways such as physical, psychological, social and economical impact. Social media plays a pivotal role in creating more panic among the public by telecasting and updating the information about the COVID-19 in order to create awareness. This not only creates awareness but also causes many psychological problems among the public. So the people must avoid constant hearing or listening to the negative impact of news related to the disease [10].

Limitations:

Further longitudinal studies should be conducted among large number of population to get more appropriate results. There might be a chance social acceptability bias due to over exaggerated response which might affects the outcome of the study.

Conclusion

The health of the people prioritized more than anything in the world by taking proper preventive measures, and prompt action of the government helps to control the COVID-19 outbreak. The government should take proper action in spreading awareness among the

public and should enlighten the positive attitude towards people which helps them to overcome the problem. This study will be more helpful and paves a pathway for the researchers to conduct further studies.

Ethical Clearance: The ethical approval for this study was obtained from the Institutional review board AND Institutional Ethical Committee of SRM Dental College, Ramapuram and the IRB approval number was SRMU/M&HS/SRMDC/2020/PG/005.

Source of Funding: Self

Conflict of Interest: Nil

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A Detailed Essay on the Pandemic COVID-19

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Abstract

The name “coronavirus” comes from the crown-like projections on their surfaces. “Corona” in Latin means “halo” or “crown”. Coronavirus is causing an outbreak that was first identified in Wuhan City, Hubei Province, China. Since then, the virus has spread to nearly every country, leading the World Health Organization (WHO) to declare this as a pandemic. According to WHO, common signs include fever, cough, and respiratory difficulties. Serious cases can lead to pneumonia, kidney failure, and even death. Researchers believe that the viruses transmit via fluids in the respiratory system. Centre for Disease control and Prevention (CDC) recommends that all people wear masks in public places where it is difficult to maintain a 6-foot (2-meter) distance from others. Social distancing is advised as currently there are no drugs or other therapeutics approved by the US Food and Drug Administration (FDA) to prevent or treat COVID-19. Current clinical management includes infection prevention, control measures, and supportive care, including supplemental oxygen and mechanical ventilator support when indicated. However, hydroxychloroquine and chloroquine are under investigation in clinical trials for pre-exposure or post-exposure prophylaxis infection, and treatment of patients with COVID-19. Also, FDA has issued guidance for administering and studying the use of convalescent plasma therapy which aims at using antibodies from the blood of a recovered COVID-19 patient to treat those critically affected by the virus. People can take steps to prevent the spread of coronavirus and help protect themselves and others.

Key Words: Coronavirus, COVID-19, SARS-CoV 2, Viral Infection, Pandemic.

Introduction

At the beginning of December 2019, a novel coronavirus has caused an international outbreak of respiratory illness termed as COVID-19.⁽¹⁾ The pathogen has been identified as a peculiarly enveloped RNA β -coronavirus that has presently been named as Severe acute respiratory syndrome coronavirus 2 (SARS-CoV

2).⁽²⁾ Phylogenetic data implies a zoonotic origin and the rapid widespread suggests an ongoing person to person transmission.⁽³⁾ It emerged from Wuhan, China, and spread to other countries both in and outside china leading WHO to declared coronavirus disease 2019 (COVID-19) a public health emergency of international concern.⁽²⁾

Coronaviruses (CoVs) are the largest group of viruses affiliated to the *Nidovirales* order, which incorporates *Coronaviridae*, *Arteriviridae*, *Mesoniviridae*, and *Roniviridae* families. The *Coronavirinae* consists of one of two subfamilies in the *Coronaviridae* family, with the other being the *Torovirinae*. In *Nidovirales* order the viruses are enveloped by non-segmented positive-sense RNA viruses.⁽⁴⁾

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The *Coronavirinae* are further separated into four genera, the alpha, beta, gamma, and delta coronaviruses. The viruses were initially categorized into these genera based on serology and later separated by phylogenetic clustering.⁽⁴⁾

Seven types of coronavirus that can infect humans are identified by the doctors. Common types include⁽⁵⁾ :

- 229E (alpha coronavirus)
- NL63 (alpha coronavirus)
- OC43 (beta coronavirus)
- HKU1 (beta coronavirus)

Since the beginning of the 21st century two β -coronaviruses have induced the plague of deadly pneumonia in humans. In humans the severe acute respiratory syndrome coronavirus (SARS CoV) arise and was liable for an epidemic that circulated to five continents with a fatality rate of 10% before being contained in 2003. In the Arabian Peninsula in 2012, the Middle East respiratory syndrome coronavirus (MERS-CoV) emerged and induced recurrent outbreaks in humans with a fatality rate of 35%. SARS-CoV and MERS-CoV are zoonotic viruses that navigated across the species barrier using bats/palm civets and dromedary camels' respectively.⁽⁶⁾

Structure

The virions are spherical with a diameter of roughly 125nm. The most distinguishable feature of coronaviruses is the club-shaped spike projections emanating from the surface of the virion. These spikes are defining features and give the appearance of a solar corona, suggesting the name, coronaviruses. Coronavirus particles contain four main structural proteins. These are the spike (S), membrane (M), envelope (E), and nucleocapsid (N) proteins, all of these are encoded within the 3' end of the viral genome. The S protein utilizes an N-terminal signal sequence to gain access to the endoplasmic reticulum and is heavily N-linked glycosylated. Homotrimers of the virus-encoded S protein make up the distinctive spike structure on the surface. The M protein is the most abundant structural protein and is thought to give the virion its shape. The nucleocapsid constitutes of N protein and is helically symmetrical composed of two separate domains, an N-terminal domain, and a C-terminal domain, both capable of binding RNA in vitro. A fifth structural protein, the hemagglutinin-esterase (HE), acts as a hemagglutinin, binds sialic acids on surface glycoproteins, and contains acetyl-esterase activity.⁽⁴⁾

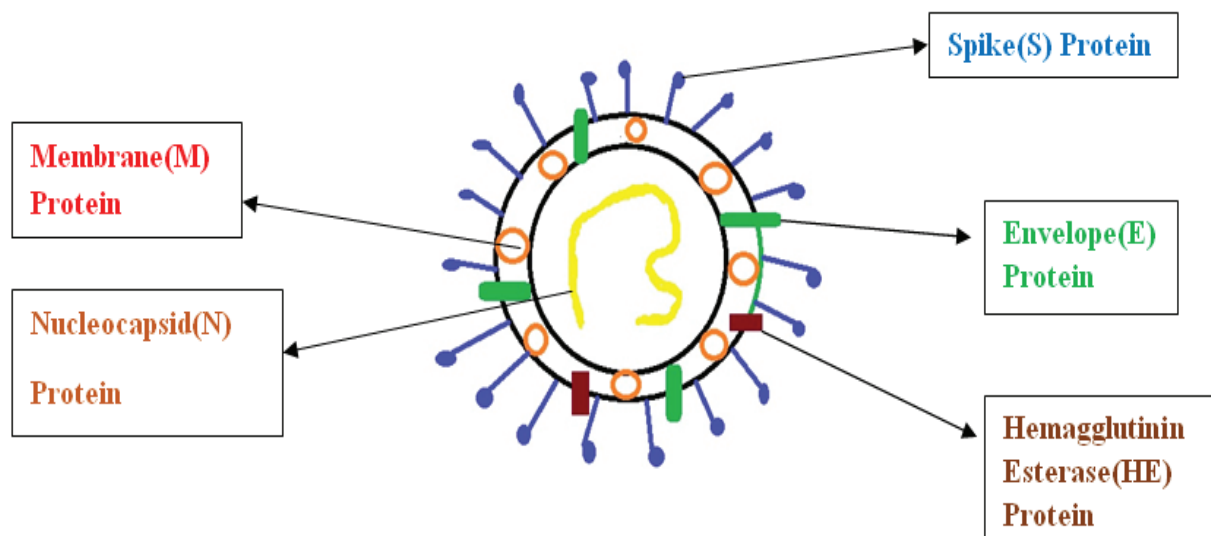


Figure 1: Structure

**This Image is just for better understanding and may differ from original viral structure.*

Life Cycle

Attachment and Entry

The initial attachment to the host cell by the virion is initiated by interactions between S protein and its receptor. Virus acquires entry into host cell cytosol which is attained by acid-dependent proteolytic cleavage of S protein. This is accompanied by the fusion of virus and cellular membrane.

Replicase Protein Expression

Further there is a transfer of the replicate gene from virion genomic RNA. This is accompanied by the replicated gene that encodes two large open reading frames (ORFs), repla, and replb, which express two co-terminal polyprotein pp1a and pp 1b. This causes ribosomal frameshifting from the repla reading frame into replb ORF. The pseudoknot is unwound by the

ribosome and this continues till it reaches stop codon.

Replication and Transcription

After the translation is done the viral RNA synthesis occurs which produces both RNA and subgenomic RNA which are further formed by negative intermediates. After viral RNA synthesis, viral replicase complexes are formed.

Assembly and release

Viral structural proteins S, E, and M are translated and inserted into the Endoplasmic Reticulum. These proteins move along the secretory pathway into ERGIC (Endoplasmic Reticulum-Golgi Intermediate Compartment). Viral genomes encapsulated by N-protein bud into membranes of ERGIC which contains viral structural proteins. And form mature virion.⁽⁴⁾

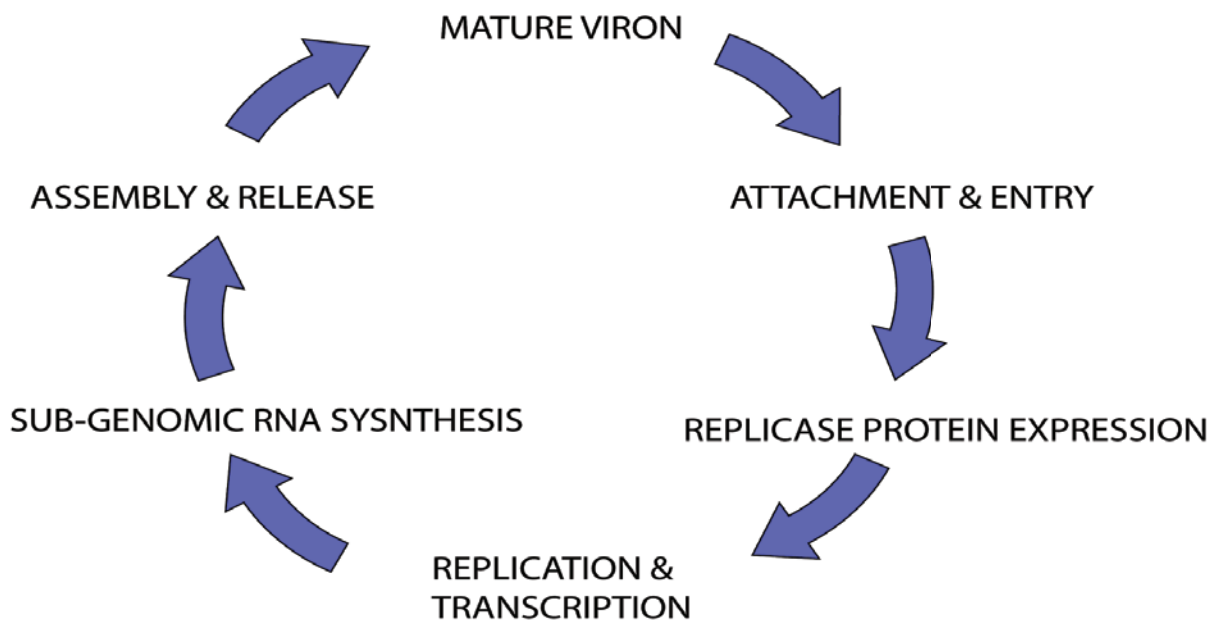


Figure 2: Life Cycle

Epidemiology

According to WHO dashboard, the worldwide reports are as follows⁽⁷⁾ :

Weeks	Date	No. of infected patients worldwide	No. of Deaths
1st	26/1/2020	2014	56
2nd	2/2/2020	14557	305
3rd	9/2/2020	37558	813
4th	16/2/2020	51857	1669
5th	23/2/2020	78811	2461
6th	1/3/2020	87137	2977
7th	8/3/2020	105836	3584
8th	15/3/2020	153517	5735
9th	29/3/2020	634813	29891
10th	5/4/2020	1133758	62784
11th	12/4/2020	1696588	105952
12th	19/4/2020	2241778	152551

Transmission

The first cases of the COVID-19 disease were linked to direct exposure to the Huanan Seafood Wholesale Market of Wuhan, the animal-to-human transmission was presumed as the main mechanism. However, subsequent cases were not associated with this exposure mechanism. Hence, it was concluded that the virus could also be transmitted from human-to-human.⁽⁸⁾

Due to the limited research it is not clear as to how the human coronavirus spreads and further studies are needed to understand the mechanisms of transmission, incubation times and clinical course, and the duration of infectivity. However, researchers believe that the viruses transmit via fluids in the respiratory system, such as mucus.⁽⁹⁾ Coronaviruses can spread in the following ways⁽⁹⁾ :

While coughing and sneezing, not covering mouth by tissues or masks can scatter droplets.

Touching or shaking hands with the patient who has the virus can infect other individuals.

Making contact with a surface or object with the virus and later touching the nose, eyes, or mouth.

Some animal coronaviruses, such as feline coronavirus, may spread through contact with feces. However, it is unclear whether this also applies to human coronaviruses.

Symptoms

It may take 2–14 days for a person to notice symptoms after infection.

According to the CDC, children are not at higher risk of COVID-19. Although there are currently no published scientific reports about the susceptibility of pregnant women, the CDC notes that: "Pregnant [women] have had a higher risk of severe illness when infected with viruses." The CDC also recommends that infants born to mothers with suspected or confirmed COVID-19 go into isolation. Also people aged 65 years or older, living in nursing home or care facilities and people of any age who have serious underlying medical conditions, including chronic lung disease, serious heart conditions, severe obesity, a compromised immune system, or diabetes are at higher risk.

Cold or flu-like symptoms usually set in from 2–4 days after a coronavirus infection and are typically mild. However, symptoms vary from person-to-person, and some forms of the virus can be fatal.⁽⁹⁾

Symptoms may include⁽¹⁰⁾ :

Sneezing

Runny nose

Fatigue

Cough

Breathlessness

Fever

Sore throat

The potential loss of taste or smell

Exacerbated asthma

Diagnosis can be done by suggested procedures: performing real-time fluorescence reverse transcriptase-polymerase chain reaction (RT-PCR) to detect the positive nucleic acid of SARS-CoV-2 in sputum, throat swabs and secretions of lower respiratory tract samples and also by taking a sample of respiratory fluids, such as mucus from the nose, or blood.⁽⁹⁾

Concerning laboratory examinations, in the early stage of the disease, a normal or decreased total white blood cell count and a decreased lymphocyte count can be demonstrated. Increased values of liver enzymes, lactate dehydrogenase, muscle enzymes, and C-reactive

protein can be found. In critical patients, D-dimer value is increased, blood lymphocytes decreased persistently, and laboratory alterations of multiorgan imbalance (high amylase, coagulation disorders, etc.) are found.⁽⁵⁾

Treatment

There is no cure for coronaviruses that cause symptoms resembling the common cold. Treatments include self-care and over-the-counter medication.⁽⁹⁾ Currently there are no drugs or other therapeutics approved by the US FDA to prevent or treat COVID-19. Current clinical management includes infection prevention and control measures and supportive care, including supplemental oxygen and mechanical ventilatory support when indicated. Interim guidelines for the medical management of COVID-19 will be provided soon by the Department of Health and Human Services COVID-19 Treatment Guidelines Panel.

Remdesivir:

Remdesivir is an investigational intravenous drug with the broad antiviral activity that inhibits viral replication through premature termination of RNA transcription and has in-vitro activity against SARS-CoV-2 and in-vitro and in-vivo activity against related β -coronaviruses.

Hydroxychloroquine and Chloroquine:

Hydroxychloroquine and chloroquine are oral prescription drugs that have been used for the treatment of malaria and certain inflammatory conditions. Hydroxychloroquine and chloroquine are under investigation in clinical trials for pre-exposure or post-exposure prophylaxis of SARS-CoV-2 infection, and treatment of patients with mild, moderate, and severe COVID-19. FDA issued an Emergency Use Authorization (EUA) to authorize the use of chloroquine and hydroxychloroquine external icon from the Strategic National Stockpile for treatment of hospitalized adults and adolescents (weight ≥ 50 kg) with COVID-19 for whom a clinical trial is not available or participation is not feasible.

Other Drugs:

Several other drugs (e.g., investigational antivirals, immunotherapeutic, host-directed therapies) are under

investigation in clinical trials or are being considered for clinical trials of pre-exposure prophylaxis, post-exposure prophylaxis, or treatment of COVID-19 in the United States and worldwide. FDA has issued guidance for administering or studying the use of convalescent plasma therapy.⁽¹¹⁾

Plasma Therapy:

Amongst the myriad clinical trials for vaccines to prevent COVID-19 and drugs to treat infections, doctors are looking to survivors' plasma for a possible therapy. The US FDA released a statement stating that investigators can request to use plasma from COVID-19 survivors to deliver antibodies to seriously ill patients, under an emergency investigational new drug (IND) protocol. It is based on the premise that because antibodies were developed in the survivor were throughout the course of their infection, donating blood to those who became recently ill would give the recipients' immune systems a leg up. To bring the treatment up to modern standards, plasma donations would be processed and purified, creating a serum to transfuse into critically ill patients. While an eventual vaccine would ideally provide long-lasting immunity by spurring the recipient to create their own antibodies, receiving antibodies via the convalescent treatment would only form a temporary immunity, so multiple treatments would be required over the course of illness.

There are still certain details that needs to be figured out in using convalescent plasma for COVID-19 treatment, which also includes determining an effective dosing size. In its statement announcing the emergency IND access protocols, the FDA outlined standards for donor and recipient eligibility.

Plasma transfusions are commonplace nowadays, but are not without risks. Severe lung injury or allergic reactions can occur after receiving donor plasma which is contradicted in COVID-19.⁽¹²⁾

Ineffective Therapies:

Many patients were administered with lopinavir and ritonavir. It wasn't much effective because even highly active antibacterial agents have limited efficacy in advanced bacterial pneumonia. Secondly, lopinavir isn't particularly potent against SARS-CoV-2. The

concentration necessary to inhibit viral replication is relatively high as compared with the serum levels found in patients treated with lopinavir-ritonavir. We currently know little about drug concentrations in the tissues.⁽³⁾

Preventive Measures:

COVID-19, a contact-transmissible infectious disease, is thought to spread through a population via direct contact between individuals. Outbreak control measures aimed at reducing the amount of mixing in the population have the potential to delay the peak and reduce the final size of the epidemic. To evaluate the effect of location-specific physical distancing measures such as extended school closures and interventions in workplaces are advised.⁽¹³⁾

The virus is contagious because of its ability to mutate effectively. To prevent transmission, people should maintain social distancing, stay at safe place and isolate themselves if symptoms are active. Covering the mouth and nose at public places with a mask can also help prevent transmission. Also, washing hands regularly and the use of sanitizers and disinfectants are vital. It is important to dispose of any tissues after use and maintain hygiene.⁽¹⁴⁾

The CDC recommends that everyone wear cloth face masks in public places where it is difficult to maintain a 6-foot (2-meter) distance from others. This will help slow the spread of the virus from asymptomatic people. People should wear cloth face masks while continuing to practice physical distancing. **Note:** Surgical masks and N95 respirators must be reserved for healthcare workers.⁽⁹⁾

The disadvantaged socio-economic positioned individuals are more likely to be affected by the virus because of occupation, income, and education. We rely on quarantine, isolation, and infection-control measures to prevent disease spread and on supportive care for those who become ill.⁽¹⁵⁾ The proposal should converge on four fundamental values: maximizing the benefits produced by scarce resources, treating people equally, promoting and rewarding instrumental value, and giving priority to the worst off. These procedures must be transparent to ensure public trust in their fairness.⁽¹⁴⁾

Conclusion

Non-pharmaceutical interventions based on sustained physical distancing have a strong potential to reduce the magnitude of the epidemic peak of COVID-19 and lead to a lesser number of overall cases. Lowering and flattening of the epidemic peak is particularly important, as this reduces the acute pressure on the health-care system. The premature and sudden lifting of interventions could lead to an earlier secondary peak, which could be flattened by relaxing the interventions gradually. Governments and policymakers must do all they can to prevent the scarcity of medical resources. Maximization of benefits can be understood as saving the most individual lives or as saving the most life-years by giving priority to patients likely to survive the longest after the treatment.

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Factors Related to the Event of Dengue Hemorrhagic Fever (DHF) in Toddlers in Sumbawa Regency

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Abstract

Background : Dengue Hemorrhagic Fever is an endemic disease in most parts of Indonesia, including in other tropical regions. Not all infected with dengue virus will show severe DHF manifestations. There are several risk factors that are suspected of causing DHF patients to experience shock. In a study conducted showed that children aged 5 years are more susceptible to DHF because of the immune response. The purpose of this study was to determine the factors associated with the incidence of DHF in toddlers in Sumbawa Regency.

Method : The study design that will be used in this study is an analytic study with a case control design. The number of cases 97 (total cases) of families who have toddlers with DHF diagnoses from 2018 to March 2020 (from 5 working areas of community health centers with the highest number of DHFs in toddlers) while control of 194 families who have toddlers who are neighbors of the cases.

Result: From this study it can be concluded that the variables which have relationship with the incidence of DHF in toddlers in Sumbawa Regency are age and nutritional status. While the variables of napping habits, income, mother's education and mother's occupation are controlling variables (confounder). The most influential variable on the incidence of DHF in toddlers in Sumbawa Regency is nutritional status. This can be seen from the OR value of nutritional status = 3.19 (95% CI 1,616-6,298).

Conclusion: The most influential variable on the incidence of DHF in toddlers in Sumbawa Regency is nutritional status. This can be seen from the OR value of nutritional status = 3.19 (95% CI 1,616-6,298).

Keywords: *Dengue Hemorrhagic Fever; Toddler, Sumbawa Regency*

Introduction

Dengue Hemorrhagic Fever (DHF) is an acute viral infection caused by dengue virus characterized by fever 2 - 7 days accompanied by manifestations of bleeding, decreased platelets (thrombocytopenia), the presence of hemoconcentration marked by plasma leakage (increased hematocrit, ascites, pleural effusion, hypoalbuminemia). There may be non-typical symptoms such as headache,

muscle & bone pain, skin rash or back pain in the eyeball¹.

Before 1970, only 9 countries had experienced DHF plague, but now DHF has become an endemic disease in more than 100 countries, including Africa, America, Eastern Mediterranean, Southeast Asia and the Western Pacific, America, Southeast Asia and the Western Pacific have the highest rates DHF case. In 2013 there were reported as many as 2.35 million cases in the United States, of which 37,687 cases were severe DHF².

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Dengue Hemorrhagic Fever is an endemic disease in most parts of Indonesia, including in other tropical

regions. Dengue hemorrhagic fever was discovered in 1954 and entered Indonesia in 1968. In 2003, this disease had spread to most regencies / cities in Indonesia and often became a disease outbreak with a still high risk of death³.

Based on data from the Sumbawa Regency Health Office report the Prevention of Disease Eradication, from 2013 to 2016, the number of DHF cases continued to decline. In 2017 the number of cases more than doubled from the previous year in 2016. In 2018 the number of cases dropped dramatically, then jumped back in 2019, higher than the number of cases two years before, in 2017. The number the case in the last year of 2019 resulted in IR = 74.5 per 100,000 population. This number is still higher than the national IR target of 49 per 100,000 population.

Not all infected with dengue virus will show severe DHF manifestations. There are only mild fever manifests that will heal by itself or even some with no symptoms of pain (asymptomatic). Some will suffer from dengue fever which does not cause plasma leakage and result in death¹.

Dengue Shock Syndrome (DSS) is a medical emergency situation with a high mortality rate, DSS started from Dengue Hemorrhagic Fever (DHF) which then experienced shock. WHO estimates that 2.5 billion people globally are at risk of suffering from this disease. There are several risk factors that are suspected of causing DHF patients to experience shock, namely age, nutritional status, gender, platelet levels and hematocrit levels. This is associated with the theory that in children, younger age affects the incidence of DSS, in a study conducted showing that children aged 5 years are more susceptible to DHF because the immune response with specificity and immunological memory stored in dendritic cells and lymph nodes is not perfect. Other studies have shown that younger children have higher mortality due to capillary endothelial blood vessels being more prone to cytokine release resulting in increased permeability⁴.

Related to the problem that has been explained above, that DHF is still a problem in Sumbawa Regency and children aged 5 years are more susceptible to DHF, researchers are interested in researching about the factors associated with the incidence of DHF in toddlers

in Sumbawa Regency.

Methods

The study design that will be used in this study is an analytic study with a case control design. Case control studies are also known as case referrals, case histories, or retrospective studies involving backward or nondirectional designs that compare groups of cases with respect to the current or previous level of study factors⁵.

The study was conducted in Sumbawa Regency in April 2020 with samples from the working area of 5 community health centers with the highest incidence of DHF in toddlers in Sumbawa Regency. The population in this study were all families who have toddlers in Sumbawa Regency. The sample in this study was a portion of families who are residents of Sumbawa Regency, who have toddlers, who come from 5 working area health centers with the highest case of DHF in toddlers in Sumbawa Regency. The research sample consisted of case and control samples.

Cases are families who have toddlers in Sumbawa Regency who have been diagnosed with DHF by the authorized health workers in the period 2018 to March 2020. Control is a family who has toddlers in Sumbawa Regency who have never suffered from DHF at the same time and are neighbors of the cases. The ratio of the number of cases and controls used in this study is 1: 2. Case samples will be taken from all cases, and for control samples will be taken using a technique of *Simple Random Sampling*. So it can be concluded the number of cases 97 (total cases) of families who have toddlers with DHF diagnoses from 2018 to March 2020 (from 5 working areas of community health centers with the highest number of DHFs in toddlers) while control of 194 families who have toddlers who are neighbors of the cases. Data collection was carried out by recruiting enumerators from local university students who had been briefed and trained in advance.

Analysis of data through 3 stages, namely univariate, bivariate and multivariate. Univariate analysis is carried out with the aim of explaining / describing the characteristics of each variable studied, presented in the form of a frequency distribution table and the proportions of each variable. The bivariate analysis used

in this study is chi-square. Multivariate analysis in this study uses multivariable logistic regression ⁶.

Results

Of the 291 samples planned at the start of the study, 242 samples took part until the end of the study. The rest did not go along with reasons of moving house and refused to become respondents. In the case group, the proportion of toddlers aged <3 years was 34.7% and in the control group was 55.7%. The proportion of male toddlers in the case group was 41.3% lower than the control group that was 53.3%. The proportion of toddlers whose mother's last education in elementary school level in the case group is 9.3% higher than the control group as much as 4.2%. The proportion of toddlers with mothers who do not work in the case group is 61.3% lower than the control group that is 89.2%. The proportion of the income level of toddlers' families is smaller than the regional minimum wage of 49.3%, lower than the control group of 73.7%. The proportion of toddlers with normal nutritional status in the case group was 61.3% lower than the control group as much as 83.2%. The proportion of toddlers with insufficient mother's knowledge in the case group was 57.3% lower than the control group as much as 58.7%. The proportion of toddlers with mothers who used to take naps in the case group was 64% lower than the control group as much as 78.4%. The proportion of toddlers with mothers used to use mosquito coils in

the case group was 72% higher than the control group as much as 64.1%. The proportion of hanging clothes in a toddler's home in the case group was 56% lower than the control group as much as 62.3%. The proportion of the use of mosquito netting in the case group was 17.3%. The proportion of the presence of mosquito wiggler in the case group was 18.7%, lower than the control group of 21%. The proportion of health promotion in the case group was 44% higher than the control group as much as 41.9%. The proportion of fogging focus in the case group was 41.3% lower than the control group by 43.7%.

From the bivariate analysis in table 1, it can be seen that factors that are statistically proven to be related to the incidence of DHF in toddlers are age, mother's education, mother's occupation, income level, nutritional status and napping habits. From the table above also can be known factors that are not statistically related to the incidence of DHF in toddlers are gender, mother's knowledge, the use of mosquito coils, hanging clothes, the use of mosquito netting, the existence of mosquito wiggler, health promotion and fogging focus.

From the final multivariate model in table 2 it is known that the variables associated with the incidence of DHF in toddlers in Sumbawa Regency are age and nutritional status. While the variable napping habits, income, mother's education and mother's occupation as a controlling variable.

Table 1. Bivariate Analysis of Factors Related to the Event of DHF in Toddlers

Variable	OR	95% CI	P Value	Information
Age	0.422	0.24-0.743	0.004	Candidate
< 3				
>= 3				
Gender	1.62	0.933-2.81	0.114	Candidate
Female				
Male				
Mother's Education	0.228	0.119-0.438	0.0001	Candidate
Elementary, Junior High, Senior High				
University				

Cont... Table 1. Bivariate Analysis of Factors Related to the Event of DHF in Toddlers

Mother's Occupation				
Working	5.219	2.658-10.246	0.0001	Candidate
Not Working				
Income Level				
< Regional Minimum Wage	0.348	0.197-0.615	0.0001	Candidate
>= Regional Minimum Wage				
Nutritional Status				
Very Low/ Low	3.269	1.757-6.083	0.0001	Candidate
High/ Normal				
Mother's Knowledge				
Low (< 4.40)	0.946	0.545-1.642	0.844	Not Candidate
Good (>= 4.40)				
Napping Habit				
Yes	0.489	0.268-0.889	0.018	Candidate
No				
The Use of Mosquito Netting				
No	0.694	0.383-1.257	0.289	Not Candidate
Yes				
Hanging Clothes				
Yes	0.771	0.443-1.340	0.435	Not Candidate
No				
The Use of Mosquito Netting				
No	0.686	0.323-1.456	0.432	Not Candidate
Yes				
The Existence of Mosquito Wiggler				
Yes	0.866	0.434-1.726	0.812	Not Candidate
No				
Health promotion				
No	0.918	0.530-1.592	0.871	Not Candidate
Yes				
Fogging Focus				
No	1.102	0.635-1.914	0.837	Not Candidate
Yes				

Note : OR = Odds Ratio; *significant statistic $p < 0.05$

Table 2. Multivariate Final Model

Variable	P value	OR	95 % CI
Age	0.006	0.415	0.222-0.774
Nutritional Status	0.001	3.19	1.616-6.298
Napping Habit	0.289	0.688	0.345-1.373
Income Level	0.191	0.62	0.303-1.270
Mother's Education	0.11	0.483	0.198-1.18
Mother's Occupation	0.075	2.275	0.92-5.621

Note: OR = Odds Ratio; *significant statistic $p < 0.05$

Note : OR = Odds Ratio; *significant statistic $p < 0.05$

Discussion

From this study it can be concluded that the variables that have relation with the incidence of DHF in toddlers in Sumbawa Regency are age and nutritional status. While the variables of napping habits, income level, mother's education and mother's occupation are controlling variables (confounder). The most influential variable on the incidence of DHF in toddlers in Sumbawa Regency is nutritional status. This can be seen from the OR value of nutritional status = 3.19 (95% CI 1,616-6,298).

Several previous studies examined the relationship of nutritional status with the incidence of DHF. One study showed 2 OR values. The OR 1 value indicates a large risk of wasting nutritional status on the incidence of DHF, which is 0.371. While the OR 2 value indicates a large risk in the fat nutritional status against DHF events that is equal to 0.297. At $p \text{ value} > 0.05$, it can be interpreted statistically that there is no relationship between nutritional status and the incidence of DHF. While judging by the OR value in the wasting and fat nutritional status, it can be said that the skinnier a person is, the more susceptible to DHF ⁷. Other studies have shown a significant relationship between nutritional status ($p = 0.013$) and the degree of dengue infection. In multivariate analysis, it was obtained OR = 9,474 (95% CI: 1,177-76,227) which showed that respondents with low / less nutritional status had a 9.474 times greater chance of suffering from DHF ⁸.

Nutrition is one of the determining factors for achieving prime and optimal health. Nutritional conditions can be either malnutrition, good, or normal or

over nutrition. Lack of one nutrient can cause a disease in the form of a deficiency disease (Bestari et al, 2014). Until now, the countermeasures that are taken to prevent DHF are still limited to eradicating the infectious mosquitoes. The cure for DHF is only symptomatic and supportive (Ministry of Health, 2011) and vaccination for this disease is in the process of clinical trials ⁹.

Nutrition is an important determinant of the body's immune response and malnutrition is the cause of lack of immunity (immunodeficiency). Evidence shows when micronutrient deficiencies: Zn, Se, Fe, Cu, Vitamins A, C, E and Vitamin B6 and folic acid, have an important influence on the immune response. For example, vitamin A deficiency can cause "impaired defense" on the epithelial surface caused by damage to the epithelial structure, but also changes mucous and decreased secretory IgA and decreases the function of neutrophils, macrophages and natural killers. Vitamin A deficiency conditions will change B cells and T cell proliferation ¹⁰.

In this study there are 4 controlling variables, namely napping habits, income, mother's education and mother's occupation. Certain behaviors can increase or decrease a person's risk of contracting a disease. Sleeping habits in the morning and / or evening ($p = 0.001$) ¹¹ have relation with the incidence of DHF. Other studies have shown a relationship between income levels ($p = 0.01$, 95% CI, OR = 4.04) and occupation ($p = 0.03$, 95% CI, OR = 1.8) and the incidence of DHF ¹². One of the goals of education is to increase knowledge. Increased knowledge can certainly affect someone or even the community will care about something and change behavior. In the research it was proven that there

was a relationship between knowledge ($p = 0.030$) and the incidence of DHF¹³. A significant relationship was also shown between the education level variable and the DHF prevention behavior ($p = 0.008$)¹⁴.

Conclusions

In this study, it was proven that age and nutritional status had something to do with the incidence of DHF in toddlers in Sumbawa Regency. While the variables of napping habits, income, mother's education and mother's occupation are controlling variables (confounder). The most influential variable on the incidence of DHF in toddlers in Sumbawa Regency is nutritional status. This can be seen from the OR value of nutritional status = 3.19 (95% CI 1,616-6,298).

Ethical Considerations: Not required

Competing Interests: None declared

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The Psychological Impact of the Covid-19 Lockdown on Medical Students of a College in North India

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Abstract

In response to COVID 19 spread Government of India imposed lockdown across the country to prevent the spread of virus and thus protecting the health of the community. This happened with restrictions to be at home and between the media hype of pandemic which may lead to a rise in the stress, anxiety, and depression among the community. Universities started online classes in between lockdown. Online classes would not solve the purpose of the students are not in a status to absorb the learnings and concepts. So before starting the online classes an online survey was done among the medical students to observe any distress and help them to come out of it to make online classes successful.

An online questionnaire was made using the Impact of event scale- revised (IES-R) to assess the stress among medical students. The questionnaire was posted on the batch WhatsApp group of students across all semesters with a message showing the purpose of the study and how to approach the form. The decision of filling the form was kept completely on a volunteer basis.

The response was received from a total of 331 medical students among them 130(39.3%) and 201(60.7%) were males and females respectively. The mean score was 21.60 still 38.95 students were prone to be victims of Post-traumatic stress disorder (PTSD) and there was no significant difference between males and females. Involvement with family was found to be inversely associated with stress, possible financial instability in the future, and uncertainty about the duration of MBBS and exams were positively associated with stress.

Key Words- COVID-19, Lockdown, Medical Students, Stress

Introduction

WHO's announced Covid-19 as pandemic on March 11,2020¹.A decision to announce a disease as deadly and pandemic in nature has a consequence beyond

the physical health domain. Every nation affected by the spread of pandemic not only faces economic and political challenges but also witnesses a severe impact on the mental health component on the general public². By April 7, 2020, more than one million (1,383,436) persons have been globally infected due to the convergence of this uncontrollable infectious disease. Most of the global population has been depressed and threatened due to the exponential growth of infection and the increasing number of fatalities³To avoid the mass spreading of this pandemic virus, the decision regarding nationwide lockdown has been taken. No doubt, this

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will save the masses of life. However, this lockdown is also creating chaos and huge difficulties for the people⁴. This pandemic has also significantly affected the mental state of the students. They are also in the dilemma of being infected with this unfortunate pandemic virus. The massive transmission of the fake news over social sites (Whatsapp, Twitter, Facebook) and media has created chaos and stressful atmosphere for the students. The scary atmosphere is affecting the concentration level and the learning ability of the students. Furthermore, examinations have been postponed due to this zoonotic virus and there is complete uncertainty about the examination policies i.e. how and when it will be conducted. The postponement of the examinations is also causing frustration and stress among the students. These different kinds of tensions disrupt the sleep time of the students which eventually decreases the body's immunity and hence makes them more susceptible to infection⁵. Furthermore, due to the dilemma of lockdown and to maintain the social distancing, the authorities have instructed the teaching fraternity to take their classes online⁶. The thought behind this study was the current psychological stress students may face in the situation of Pandemic. Online classes would not solve the purpose of the students are not in a status to absorb the learnings and concepts provided to them by the teachers. So before starting the online classes an online survey was done among the medical students to observe any distress and help them to come out of it to make online classes successful.

Methodology

The study was done in a Medical College of North India between 10th Apr 2020 to 16 Apr 2020. As all the classes were suspended and the lockdown was imposed an online questionnaire was made using Google forms. The form was designed in a way that maintains confidentiality yet takes general information. Impact of event scale- revised (IES-R)⁷ was used in Google form to assess the stress among students. This 22-item questionnaire is composed of three subscales and aims to measure the mean avoidance, intrusion, and hyperarousal. The total IES-R score was divided into 0–23 (normal), 24–32 (mild psychological impact), 33–36 (moderate psychological impact), and >37 (severe

psychological impact). The questionnaire was posted on the batch WhatsApp group of students with a message showing the purpose of the study and how to approach the form. The decision of filling the form was kept completely on a volunteer basis. A total of 450 students got the questionnaire 331 responded. Due permission was taken from the institutional ethical committee The questionnaire was sent to all students from the first year to the final year. The analysis was done using SPSS 21.

Results

The response was received from a total of 331 medical students among them 130(39.3%) and 201(60.7%) were males and females respectively. Table-1 shows the scoring of participants according to the gender on the IES-R scale.

TABLE 1- : DISTRIBUTION AND MEAN, SD & RANGE OF IES-R SCORE OF PARTICIPANTS

IES-R SCORE	GENDER		Total
	Male	Female	
<24	86(66.1%)	116(57.7%)	202(61.0%)
24 to 32	22(16.9%)	32(15.9%)	54(16.3%)
33 to 36	8(6.2%)	12(6.0%)	20(6.1%)
>37	14(10.8%)	41(20.4%)	55(16.6%)
TOTAL	130(100%)	201(100%)	331(100%)
MEAN	21.26	21.95	21.60
SD	13.27	12.74	12.84
RANGE	1 TO 54	1 TO 63	1 TO 63

There was no significant difference between the average scores of males and females. Table 2 shows the association of various factors with stress according to IES-R scoring.

Table -2 . ASSOCIATION OF VARIOUS FACTORS WITH STRESS.

FACTORS		SCORES				Total		p-VALUE
		<24(Normal)		>24(Stress)				
		FREQ	%	FREQ	%	FREQ	%	
WHERE DID YOU SPEND LOCKDOWN PERIOD	AT HOME	191	94.6%	120	93%	311	94%	0.630
	NOT AT HOME	11	5.4	9	7%	20	6%	
LOCKDOWN IS A NECESSARY MEASURE TO PREVENT CORONA VIRUS SPREAD	YES	200	99%	126	97.7%	326	98.5%	0.380
	NO	2	1%	3	2.3%	05	1.5%	
YOU CAME TO KNOW YOUR FAMILY BETTER THAN EARLIER DURING LOCKDOWN	YES	170	84.2%	93	72.1%	263	79.5%	0.008
	NO	32	5.8%	36	27.9%	68	20.5%	
HOW WILL YOU RATE YOUR FAMILY LIFE DURING LOCKDOWN	HAPPY	52	25.7%	21	16.3%	73	22.1%	0.130
	MIXED	118	58.4%	85	65.9%	203	61.3%	
	NOT HAPPY	32	15.9%	23	17.8%	55	16.6%	
HAVE YOU FIND YOUR PARENTS WORRIED ABOUT THEIR EARNINGS DURING OR AFTER LOCKDOWN	YES	152	75.2%	113	87.6%	265	80.0%	0.006
	NO	50	24.8%	16	12.4%	66	20.0%	

Cont... Table -2 . ASSOCIATION OF VARIOUS FACTORS WITH STRESS.

DID YOU EVER FEEL STRESSED DURING LOCK DOWN	YES	68	33.7%	72	55.8%	140	42.3%	<0.001
	NO	134	66.3%	57	44.2%	191	57.7%	
LOCKDOWN WILL DELAY COMPLETION OF MBBS	YES	91	45%	87	67.4%	178	53.8%	<0.001
	NO	111	55%	42	32.6%	153	46.2%	
TOTAL		202	100%	129	100%	331	100%	

Figure 1 shows what students did most of the time during the lockdown period.

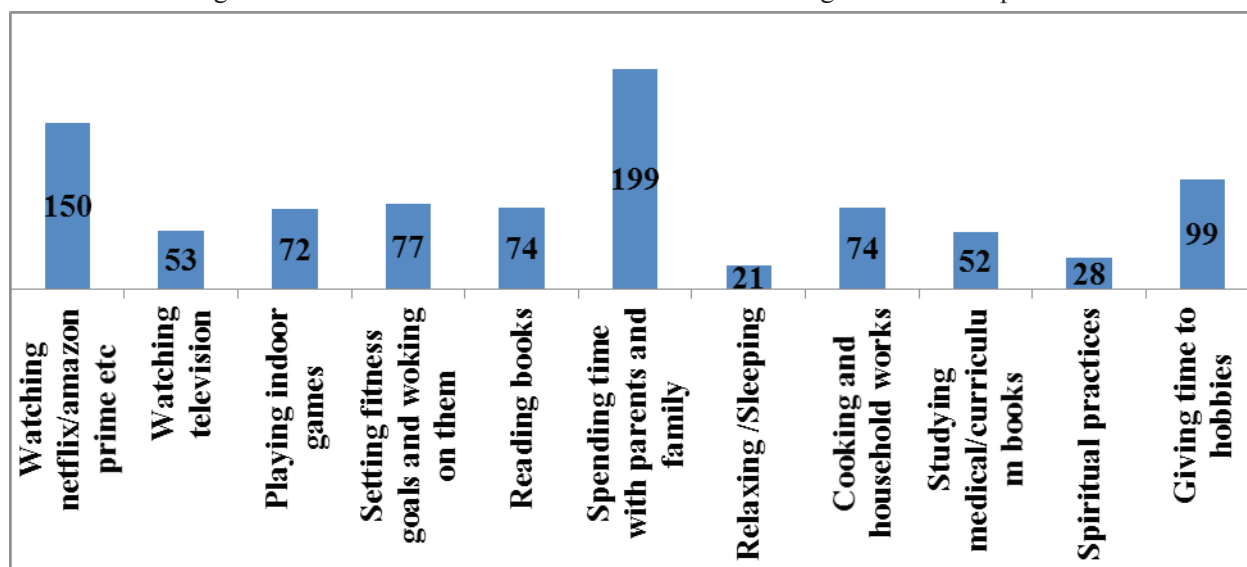


FIGURE 1- STUDENTS DID IN MOST OF THE TIME THEY SPEND THEIR LOCKDOWN PERIOD.

Discussion

In the study conducted female participants were more than the male that is because the same is the ratio of male to female among medical college students of the college. In table 1 Mean IES-R score of students was normal for both the genders and the difference was not statistically significant although from table 1 it appears that females have a higher prevalence of severe stress(score>37) but it was also not statistically significant, this finding is

consistent with a study⁸.

Where they found no significant difference between the groups of undergraduates in terms of post-traumatic stress symptoms or general mental health problems after quarantine during the 2009 H1N1 epidemic. It was predicted that the entire study population was undergraduate students who are generally young, and perhaps have fewer responsibilities than adults who are employed full-time so may not feel that much stress.

Table 1 also shows overall 129(38.9%) students have scores greater than 24 which is of concern, this percentage is higher when compared to a study done among medical students in China during COVID 19 epidemic⁹.

Where they found 24.9% of students suffering from stress although they used a different scale

for measurement of stress i.e 7-item Generalized Anxiety Disorder Scale (GAD7).

When the factors which may affect the stress in the students were analyzed it was found that gender and location of spending lockdown did not have any statistical association. Whether stressed or not was not associated with awareness of the fact that lockdown is necessary for the prevention of COVID 19 the finding is not consistent with many studies¹⁰⁻¹².

A possible reason for the discrepancy is in our study 98.5% of students were aware of the necessity of lockdown and the comparison is left only with 1.5% of students.

Those who spend their time with family and came to know the family better than earlier were lesser stressed in our study. This finding is in coherence with a study¹³.

Where their social support and staying with parents were negatively correlated with stress among students.

In a few studies, the economic loss as a result of quarantine manifested as serious socioeconomic distress¹⁴ and was proved to be a risk factor for psychological disorders¹⁵ and both anger and anxiety even several months after quarantine¹⁶

In our study also the same thing was seen as the students who have seen or listened to their parents being worried about their earnings in the lockdown period were having significantly higher stress.

The apprehension that lockdown may delay the MBBS by few months and thus students may not be able to appear in a few competitive exams converted into stress as seen in table2. Uncertainties about the career brought stressful feelings among students.

Further, although there was no significant difference in stress felt by male and female students as per scores

of IES-R scale still when asked as a subjective feeling of stress females felt significantly more stress than males.

Activities done during the lockdown to spend the time inside the house were considered important to understand the interest of students and thus getting an idea on feasible interventions to reduce stress which students also love to involve in. Students were asked to mention various activities they did most of the time. Maximum students spend time with parents and family which involves random talking, watching television together, assisting in the kitchen and household work, and playing indoor games with family. Many students gave time to their hobbies also. Watching Netflix, amazon prime, and Zee5, etc were also preferred by many students, students preferred mostly web series to watch in these channels. So interventions to make students in positive spirits should involve their family members too ie family-based intervention not only student-based. Hobbies of the students can be used as a tool to deviate the from negativity in atmosphere. Various online stations(NetFlix, Amazon, etc) can be used by suggesting students watch inspiring stuff from there and this can be given as a task to them.

Conclusion

After going through the analysis it was found that almost 40% of students were prone to Post-traumatic Stress Disorder(PTSD) ranging from mild to severe symptoms. Starting the online studies straightway to students would not solve the purpose of providing the knowledge as stressed students may not accept the new method of learning. Involvement with family was found to be inversely associated with stress, possible financial instability in the future, and uncertainty about the duration of MBBS and exams were positively associated with stress.

Online videos addressing the issue were made by senior faculty in Hindi and send to students and they were advised to watch the videos with parents so that a family gets benefitted. Parents were also requested to write feedback. Students were encouraged to take their hobbies to the next level and the achievements could be shared with teachers and student groups. Few very inspiring autobiographies and documentaries were selected from web channels and students were given a task to watch and review them according to their area

of interest.

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COVID-19 as a Dispersed Organism: Host Manipulation and Psychosocial Impacts

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Abstract

We have proposed the concept of dispersed organisms as a way forward to have a deeper understanding of diseases and their eradication and also of evolution of life and of species. Taking COVID-19 as a dispersed organism we investigate its impact in the sociological and psychological realms as a conscious force on humanity to set it on the right track, both individually and collectively. The aftermath of COVID-19 is not going to be a repetition of that of Spanish flu a hundred years back. The implications for mankind are going to be profound. We discuss the well accepted notion of evolution of multicellulars from unicellulars and propose that the case may not be of evolution from pathogens as such, but of building progressively better quality nests by them, which we call the hosts for the pathogens. Infection of host is in reality only nesting for the pathogen. This turns evolutionary hierarchy upside down.

Keywords: COVID-19, Dispersed Organism, Multicellularism, Malaria, Niche

Introduction

The concept of dispersed organism has been proposed by us to have a new way of understanding and treating diseases¹⁻². Loosely bound bacterial colonies exhibit almost multicellular properties just as eusocial species behave as superorganisms³⁻⁵. Unicellular organisms, by reproducing through budding, fission or conjugation, lead to competition for the available resources. However, when resources deplete, they either go for competitive elimination or for cooperative organization. Competitive multicellulars and cannibals resort to the first option but a cooperative social organization has the distinct advantage of guaranteed survival for the species. In a society of unicellulars *e.g.* a bacterial colony, division of functions is natural since the peripheral ones are in direct contact with environment and have to facilitate the inward and outward transport of materials⁶. This is the origin of quorum sensing⁷. Germ-soma differentiation in the green alga *volvox corteri* has been established by whole RNA transcriptome analysis⁸⁻⁹.

In studying eusocialism, the concept of superorganism has been proposed to explain altruistic social behavior^{4,5,10}. Genetic relatedness was proposed as a determinant in evolution of eusocialism which was a long-standing problem with Darwinism¹¹. In metaevolution the collective psyche connects all the individuals¹². Such connectedness may be achieved through quantum entanglement of the individual psyches with their shared DNAs forming the substrates for such space-time transcending quantum-entangled communication networks². Quantum entanglement of systems due to shared origins has been discussed earlier¹³. All biomolecules having the common shared tendency for self-proliferation via identical ligand-receptor relations can be similarly entangled from the very beginning with self-proliferation as their common shared characteristic. We have proposed that life as an agent of the principle of disorder (POD) has been there since the big bang ever trying to mold matter in the direction of unrestrained self-proliferation (cancer) through the entire history of the cosmos¹⁴⁻¹⁶.

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COVID -19 as dispersed organism

As far as virulence is concerned, the oncovirus

supersedes all other viruses due to its mutational pluripotency and other functional mechanisms inherent in the core of the corresponding globally dispersed organism that is cancer¹⁷⁻¹⁹. Treating each such disease-causing individual pathogen as one elementary unit of the corresponding globally dispersed organism can help us identify the core and thus tackle the disease at a deeper level^{1,2}. A pathogen is an unalienable link in the evolutionary chain of the cosmic process of evolution of life. Its origin lies in an imbalance or disturbance in the realm of the psyche as part of the principle of cosmic disorder as opposed to the principle of cosmic order which stands for the condition of vitality and good health of an organism¹⁴. The core characters like virulence and pathogenicity are consequences of the psychic make-up of the dispersed organism and the eradication of the disease is to be achieved by successfully employing such psychic implements as would nullify the action of the former². The original virulent core as a destructive principle in the psyche ramifies into myriad traits and each trait becomes a core for specialized organisms with their respective specific roles in the appearance and spread of diseases. This is the reason why we find that for a particular disease, there is often an interlinked chain of organisms which are mutually obligatory, as in case of malaria parasite and their mosquito vectors²⁰.

Malaria as a dispersed organism

Surprising insights come up when we analyze the life cycle of the malaria parasite¹. It develops to sporozoites in the mosquito and waits for it take a blood meal from a vertebrate such as a human. It can reproduce in the human if not killed by the host's immune response within the first 30 min of its entry. Within this time it has to make it to the human liver which stores specific food for its growth and subsequent maturity for reproduction²¹⁻²³. Its reproductive process is thus of an extremely specialized kind and is fraught with every possibility of total failure, but nevertheless it has continued to survive and reproduce to successfully spread malaria. The mosquito does not take the blood meal for quenching its hunger nor does it purposively transmit the parasite. Rather, it is manipulated by the parasite to do that for providing the suitable environment for growth of sporozoites. The host, on its part, wants to avoid or kill the mosquito and has appropriate mechanisms in place within its immune system to kill the parasite but still the parasite propagates

and its purpose of reproduction is assuredly fulfilled!

Are hosts mere nests?

The Darwinian idea that evolution starts with unicellular parasites and that they evolved into more complex multicellular organisms can be reassessed given the pathogenicity, virulence and lethality of the parasites and the susceptibility of the multicellulars²⁴. Did they evolve into their so-called higher evolved hosts by gradual natural selection or they just made their nests more and more complex, durable, dynamic and specific in the process of efficient niche construction?

All organisms do niche construction for ensuring their own survival and perpetuation²⁵⁻²⁷. Each unicellular species including viruses is a parasite or pathogen for some species or the other which is not below their evolutionary status. The pathogens seek nothing but their niche in the host to survive and to reproduce. It is most often not the host as such, but the specialized organ/tissue/cells of the host that they recognize as their niche and accordingly try to reach there. The coronaviruses for example need to reach the human respiratory apparatus, the malaria parasites the human liver, the *E. coli* the intestines and so on, because those are their nests for living and reproducing, irrespective of what we think of them and of ourselves. The vector and the host merely serve as parts of the composite biotic niche for the parasite. It is reasonable therefore to propose that the parasite, in the process of its niche construction, leads to the evolution of such traits in the vector and in the host as would guarantee its survival and reproduction^{1,20}. This is further supported by the fact that the vector and the host are later evolutes while the parasite is the oldest of the three and hence must have been the fittest, even from purely Darwinian considerations!

Psychosocial Impacts of COVID-19

COVID-19 has forced most of the countries of the world to impose severe restrictions on all human activities leading to reversal of the trends of economic growth and environmental degradation since the industrial revolution. The growth of pollutants in the biosphere has drastically come down as the pandemic continues to graze over all continents. By the end of its current phase of activity, the virus itself will no doubt accumulate too many mutations which will presumably

make it ineffective soon, but will nevertheless enhance its virulence factors in the long run, may be after another hundred years when it makes the next appearance with all necessary preparations. The question is whether the human host will remain unaffected psychologically, sociologically, epigenetically and genetically by passing through this two years' intense all round stress of the pandemic²⁸⁻³¹.

The very first behavioral change demanded by COVID-19 is social distancing - a continuous awareness of maintenance of a distance of 2-8 meters from other individuals. The long practiced greeting behaviors like hugging, hand-shaking, high fives etc are now dangerous. Even normal exhalations of a COVID positive individual are sufficient to infect another through microscopic droplet transmission.³² Suppression of normal emotions and feelings will have psycho-biological repercussions. The psyche is closely related to the endocrine system. Imbalances in the secretion of oxytocin, serotonin, glucocorticoids, catecholamines and other hormones will start modulating human behavior possibly leading to over-expression and immune suppression, both of which endanger human life.³³⁻³⁴

Fear of contagion will gradually take the form of a psychological complex leading in extreme cases to touch phobia and anthro-phobia. Obsessive compulsive disorders (OCD) such as germaphobia, mysophobia, haphophobia and hypochondria may develop. Being confined in lockdowns and shutdowns for prolonged periods in the era of nuclear and single families, may also lead finally to such mental disorders like agarophobia. Failure of the allopathic medical system to come up with effective treatment or dependable vaccine so far has only increased the stress burden on the people. Anxiety, desperation, exasperation, reactivity and irritability characterizing GADs (Generalized Anxiety Disorders) are already visible in the common man's psyche following the helpless situation in which he is placed³⁵⁻³⁷. Peculiar vectorial behaviors among the infected patients such as human vector mentality (HVM) for intentional spreading of COVID are on the rise.

In the larger social sphere, railway stations, airports, parks, festival sites, religious places, theaters, restaurants, supermarkets, political gatherings where large and happy crowds were the norm can no longer be the same. Now,

there has to be order and organization in gatherings and movements at all places without exception.

The most important events of life which invariably and unavoidably warranted large gatherings of kith and kin such as birth, marriage and death etc. now have to be done with social distancing norms. Celebrations and mournings have changed forever. One can weep and wail over the dead only from a distance, lest one suffers the same fate. Self-imposed and governmental restrictions on movements further add to these unpalatable changes through serial lockdowns, shutdowns, quarantines and containments. Emotions and passions have to become truly private and the so called freedom of expression, its own restrictions.

Conclusion

The pathogens (viruses and the bacteria) being the oldest and most experienced obviously call the shots in evolution which is the result of niche construction by them. Humans being the latest lack any such expertise and finesse like pathogens in shaping up evolution. But having an identity and selfhood as an individual human being one can strive for one's own evolution by conscious aspiration²⁸⁻²⁹. It seems that morphological evolution having reached its completeness in the *homo sapiens* they have to mold themselves in dimensions that are beyond the physical^{12,30-31}.

AIDS made humans learn the value of having more a rational and restrained approach to physical intimacy, while COVID is forcing us to have restraints over emotional expressions in addition¹. Is there not a teleological reason of gradual movement from passion to emotion and then on to reason lurking behind these epidemics to lead the human beings to higher levels of realization through the dimension of rational restraint of instincts and conscious effort to go beyond them²⁸⁻³¹? It is difficult to comprehend and predict the genetic mutations through stress-induced epigenetic modifications that COVID-19 would bring in us if it remains in force for around two years as did Spanish flu. We can only hope that it does not coevolve to become resistant to vaccination and does not come back again with higher virulence factors in, say, another hundred years or so which seems to be the period of such pandemics²⁹⁻³¹.

The other aspect that comes up by a straightforward conceptual extension of the concept of entangled individual life-forms of dispersed organisms is that all life on earth can be considered to be organically connected as an evolving living wholeness. In the same way, life in the whole cosmos in all its variegatedness can be seen as one cosmic life in essence. The blueprint for such a cosmic life as encoded in the cosmic mind has continuously directed the course of all physical evolution of the cosmos and biological evolution on earth, and possibly elsewhere as well, for its own purposes. It gives us the route to future human evolution beyond the physical.

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Conflict of Interest: Nil

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Echocardiographic Changes in Patients with Chronic Obstructive Pulmonary Disease in a Study of Indian Population

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Abstract

Background: Chronic obstructive pulmonary disease (COPD) is a significant risk factor of cardiovascular morbidity and mortality including tricuspid regurgitation (TR), right ventricular hypertrophy (RVH), left ventricular dysfunction (LVD) and right atrial enlargement (RAE) among others. Echocardiography is a rapid, non-invasive, and accurate method to evaluate cardiac functions and used to diagnose cardiac changes in COPD patients. This study aimed to assess the prevalence of echocardiographic changes in COPD patients and its association with disease severity, duration of disease and smoking.

Methods: Two hundred thirty four patients of COPD fulfilling the inclusion criteria coming to Respiratory Clinic and Medicine OPD of Assam Medical College and Hospital were recruited. They were evaluated by echocardiography. Adjusted odd ratios (ORs) (adjusted to age, gender and BMI) with 95% CIs of echocardiographic changes were computed for different stages of GOLD standard using multiple logistic regression with GOLD stage I as reference. Test for trend was done using chi-square test and statistical significance was taken p-value<0.01.

Results: Most common echocardiographic finding was TR, which was present in 63.25% of cases, followed by RVH (56.84%), LVD (33.33%) and RAE (30.33%). Echocardiographic findings of TR, RVH and RAE increase with GOLD stage progression of COPD (p-value<0.01). Disease duration was correlated with echocardiographic findings of TR, RVH and RAE. A significant trend of change in LVDD was seen for smoking status with severity of GOLD. The similar echocardiographic findings were RAE, RVH and LVD.

Conclusions: Our study finds that echocardiographic examinations of TR, RVH, LVD and RAE are essential for early diagnosis of cardiac screening for COPD patients. The incidence of TR is more common as severity of COPD increases followed by RVH. There is a significant correlation between severity of COPD with echocardiographic findings of TR, RVH and RAE.

Keywords: COPD, echocardiography, echoabnormalities, odd ratios

Background

Cardiovascular disease is most frequent co-

morbidity and a cause of death among patients with chronic obstructive pulmonary disease (COPD). One of the most important risk factor for the development of COPD is smoking although it alone does not fully explain the frequency. COPD is projected to be the third leading cause of death by 2020 by World Health Organization (WHO).^[1,2] In India, a crude estimate of about 30 million people suffering from COPD, and the

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death rate is among the highest in the world.^[3,4] COPD causes considerable effect on the cardiac function, including those of the right ventricles, left ventricles as well as the pulmonary blood vessels.^[5] These lead to the development of cardiovascular disease like right ventricular (RV) dysfunction, pulmonary hypertension (PH), coronary artery disease (CAD), and arrhythmias.^[6] Arrhythmia, myocardial infarction, or congestive heart failure are significantly higher in occurrence and cause of morbidity among patients with COPD.^[7]

Echocardiography is a rapid, non-invasive portable method to detect the arrhythmia, pulmonary hypertension, the right ventricular and left ventricular dysfunction. The detection can serve as a guide to initiation of early treatment and to prolong the survival and improvement of the quality of life of the COPD patients. The present study was addressed to investigate various echocardiographic changes among the COPD patients in the north-eastern part of India and its association with the severity of the disease.

Materials & Methods

The present study was conducted among COPD patients attending Respiratory Clinic and Medicine OPD of Assam Medical College and Hospital who were available during data collection period. Two hundred thirty four adult patients who fulfilled the inclusion criteria were taken for the study. The patients were recruited randomly whenever they obeyed the inclusion and exclusion criteria. The Ethics Committee of the Assam Medical College and Hospital, Assam, approved the study. A written well-informed consent was obtained from all participants and the study was performed according to the Declaration of Helsinki, 1975.

All patients above 40 years of age with or without smoking history, with or without chronic cough and/ or sputum production with $FEV_1/FVC < 0.7$ and post bronchodilator $FEV_1 < 80\%$ predicted are included in this study.

The patients who were not made as a part of the study were the one with known diagnosis of tuberculosis, bronchial asthma, interstitial lung disease, previous lung surgery, coronary artery disease, diabetic cardiomyopathy, chronic alcoholism, uremia.

After obtaining a detailed clinical history of each case, all patients were subjected to thorough clinical examination and necessary investigations including spirometry. Then fulfilling the inclusion and exclusion criteria for the study all the recruited patients were undergone echocardiography. The presenting symptoms and signs, spirometric value and echocardiographic data were recorded for each patient.

Spirometry was carried out on Transfer Test Model 'C', P K Morgan, Chatham, Kent, UK. All patients withheld the inhaled short acting bronchodilators 6 hours before test, long acting β_2 agonists 12 hours before test, and sustained release the ophyline 24 hours before test. The calibration of the spirometer was done before the beginning of each day's test according to the standard age and sex matched data of the population. The patients were counseled and demonstrated about the procedure of the test. Then the patient was asked to do the procedure repeatedly till the procedure was correct. Spirometric indices were calculated using best out of 3 technically satisfactory performances as per recommendations of American Thoracic Society.^[8] The diagnosis of COPD was based on the criteria defined by 'Global Initiative for Chronic Obstructive Lung Disease (GOLD 2008) update'.

Echocardiography was carried out by Aloka SSD- 4000, MNI-1175 model, Tokyo, Japan. The basic procedure was as follows: An echocardiographic examination begins with real-time 2D echocardiography, which produces high-resolution images of cardiac structures and their movements. These images are usually obtained from four standard transducer locations—parasternal, apical, subcostal, and suprasternal—by manually rotating and angulating the transducer. Qualitative and quantitative measurements of cardiac dimensions, area, and volume are derived from 2D images or 2D-derived M-mode recordings. Also, 2D echocardiography provides the framework for doppler examination and color flow imaging. An M-mode recording is derived from 2D tomographic images and graphically represents the motion of cardiac structures. It is used primarily to measure cardiac chamber size and timing of cardiac events and to display subtle abnormalities of cardiac motion. The following parameters in echocardiography were observed: i) Right ventricular hypertrophy/enlargement

(M-Mode), ii) Right atrial enlargement (M-Mode), iii) Tricuspid regurgitation (continuous-wave Doppler echocardiography for an estimate of systolic pulmonary artery pressure), iv) Left ventricular ejection fraction (M-Mode/2D-Mode), v) Left ventricular systolic or diastolic dysfunction [M-mode, 2D, and Doppler (blood flow, tissue, and color)].

Statistical Analysis

Categorical variables were expressed as numbers and percentages and continuous variables were presented with means and standard deviations of the variables. Differences in baseline characteristics were examined with one way ANOVA or chi-square test, when appropriate. Odd ratios (OR) were computed analyzing multivariate logistic regression. Unadjusted and adjusted odd ratios (OR) with 95% confidence interval were calculated for each diagnostic of echocardiogram to evaluate the risk developed in each GOLD stage. Adjusted ORs were calculated with adjusted to age, gender and BMI. ORs with 95% confidence interval were also used to find the association of duration of COPD and smoking status with the different echocardiogram abnormalities. Association between different measures of echocardiogram abnormalities were assessed by chi-square test for trend. A cluster analysis was performed to combine cardiac abnormalities with similar appearance. P-value <0.01 was considered to be statistically significant. All the statistical analysis were performed in R 3.4 statistical software.

Results

Two hundred thirty four patients were screened during the course of the study, out of which two hundred thirty four spirometrically confirmed COPD patients were included for the study. The echocardiography of all the patients was done following the method described in the method sub-section and the results were recorded.

The participants were divided into four GOLD stages based on FEV1% predicted and most of the participants belonged to the GOLD Stage III (40%) and least were in the GOLD Stage I (5%). The characteristics of the participants under different categories of GOLD are presented in Table 1. No significant difference in average age of participants under GOLD categories. Among the participants, 63% were male. The average BMI and duration of illness of the participants for different categories of GOLD were not significant. Moreover, gender and biomass exposure were not significantly related to GOLD. Table 2 presents the occurrence of all possible echocardiography changes in the selected GOLD population. Table 2 revealed that the TR was the most common findings in echocardiography (63.25%) followed by RVH (56.84%) and LVD (33.33%). RAE (30.33%) was present in 29.91% of patients. Table 3 revealed the adjusted and unadjusted OR of TR, RAE, RVH Echo and LVD under different stages of GOLD.

The studied parameters of echocardiographic changes are now correlated with GOLD stages to establish the relationship between disease severity and echocardiographic changes. Table 3 of adjusted ORs showed that the percentage of patients with TR, RVH and RAE increases with GOLD stage progression of COPD i.e. the increased severity of COPD is positively associated with echocardiographic changes.

In the present study the average duration of the disease was 8.06 years with the longest disease duration of 28 years. Disease duration was correlated with the different echocardiographic abnormalities. The results are shown in the following tables. Table 4 demonstrated that with the increase in disease duration the echocardiographic abnormalities like TR, RVH and RAE also increased. Table 5 showed a significant trend of abnormality in LVD for smoking status with severity of GOLD.

Table 1: Baseline characteristics of the study population stratified by severity of COPD according to the GOLD stage

Characteristics	GOLD Stage				p-value
	I	II	III	IV	
Age (years, SD)	66.33 (5.13)	63.72 (11.64)	64.67 (11.66)	61.33 (10.98)	0.803

Cont... Table 1: Baseline characteristics of the study population stratified by severity of COPD according to the GOLD stage

Gender	Male	12	51	54	27	0.144
	Female	4	16	39	31	
Smoking (pack/years)		27.67 (5.86)	25.72 (17.54)	22.88 (23.17)	15.47 (19.63)	0.492
FEV1 (%pred, SD)		84.67 (6.43)	58.89 (8.55)	43.25 (6.05)	24.07 (3.73)	0.000
Duration of Illness (Years)		7.00 (2.65)	7.28 (3.36)	10.21 (12.68)	7.87 (3.58)	0.684
BMI		21.97 (1.83)	19.72 (4.03)	19.38 (3.43)	19.60 (3.99)	0.729
Biomass Exposure	No	12	51	54	27	0.144
	Yes	4	16	39	31	

Table 2: Echocardiogram changes in COPD patients:

Echocardiogram changes	No. of patients	% of patients
TR	148	63.25
RAE	70	29.91
RVH	133	56.84
LVD	78	33.33

Table 3: Relationship between GOLD Stage and Echocardiographic Changes

Echocardiographic changes		GOLD Stage				Test for trend
		I	II	III	IV	
TR (%)	Unadjusted OR	1	1.15 (0.32,5.28)	1.94 (0.54,6.99)	2.20 (0.50,9.61)	<0.01
	Adjusted OR	1	2.83 (0.62,8.62)	3.38 (0.91,12.55)	4.11 (0.86,19.57)	<0.01
RVH (%)	Unadjusted OR	1	2.13 (0.64,8.39)	4.0 (1.09,14.42)	8.0 (1.61,39.64)	<0.01
	Adjusted OR	1	4.74 (1.33,25.45)	8.13 (1.90,34.88)	20.86 (3.17,137.2)	<0.01
RAE (%)	Unadjusted OR	1	1.11 (0.14,2.23)	1.07 (0.27,4.15)	1.73 (0.40,7.46)	>0.01
	Adjusted OR	1	1.21 (0.15,3.25)	1.45 (0.36,5.86)	2.35 (0.51,10.89)	<0.01
LVD	Unadjusted OR	1	0.83 (0.14,2.33)	1.07 (0.27,4.15)	2.97 (0.69,12.62)	>0.01
	Adjusted OR	1	1.19 (0.21,3.87)	1.44 (0.37,5.68)	4.25 (0.94,19.27)	<0.01

Table 4: Relationship of duration of the COPD with Echocardiographic changes

Echocardiographic changes		Duration (Years)				P-value
		0-5	06-10	11-15	>15	
TR (%)	Unadjusted OR	1	0.58 (0.17,1.95)	3.38 (0.57,19.17)	4.54 (1.46,24.69)	<0.01
	Adjusted OR	1	0.51 (0.15,1.80)	4.46 (0.65,44.29)	6.32 (1.63,58.69)	<0.01
RVH (%)	Unadjusted OR	1	3.95 (1.14,13.71)	4.95 (0.98,24.87)	6.62 (1.45,30.12)	<0.01
	Adjusted OR	1	4.06 (1.14,13.71)	5.43 (1.00,29.45)	6.44 (1.82,41.12)	<0.01
RAE (%)	Unadjusted OR	1	1.69 (0.46,6.19)	1.92 (0.86,15.97)	3.00 (1.23,27.23)	<0.01
	Adjusted OR	1	1.28 (0.46,6.19)	1.37 (0.23,8.12)	2.17 (0.14,32.49)	<0.01
LVD	Unadjusted OR	1	0.47 (0.13,1.71)	1.25 9 (0.28,5.52)	0.5 (0.04,5.70)	>0.01
	Adjusted OR	1	0.42 (0.11,1.58)	1.31 (0.28,6.19)	0.75 (0.06,10.25)	>0.01

Table 5: Relationship of smoking status with Echocardiographic changes

Echocardiographic changes	Smoking status				P-value
	No	1-25	26-50	51-100	
TR	1	1.17 (0.28,4.83)	1.75 (0.44,6.93)	0.19 (0.02,2.24)	>0.01
RAE	1	0.29 (0.07,1.21)	0.17 (0.04,0.67)	0.19 (0.02,2.24)	>0.01
RVH	1	1.03 (0.26,3.99)	1.57 (0.45,5.50)	0.9 (0.10,7.78)	>0.01
LVD	1	1.08 (0.26,4.59)	1.23 (0.28,6.13)	6.5 (0.55,76.18)	<0.01

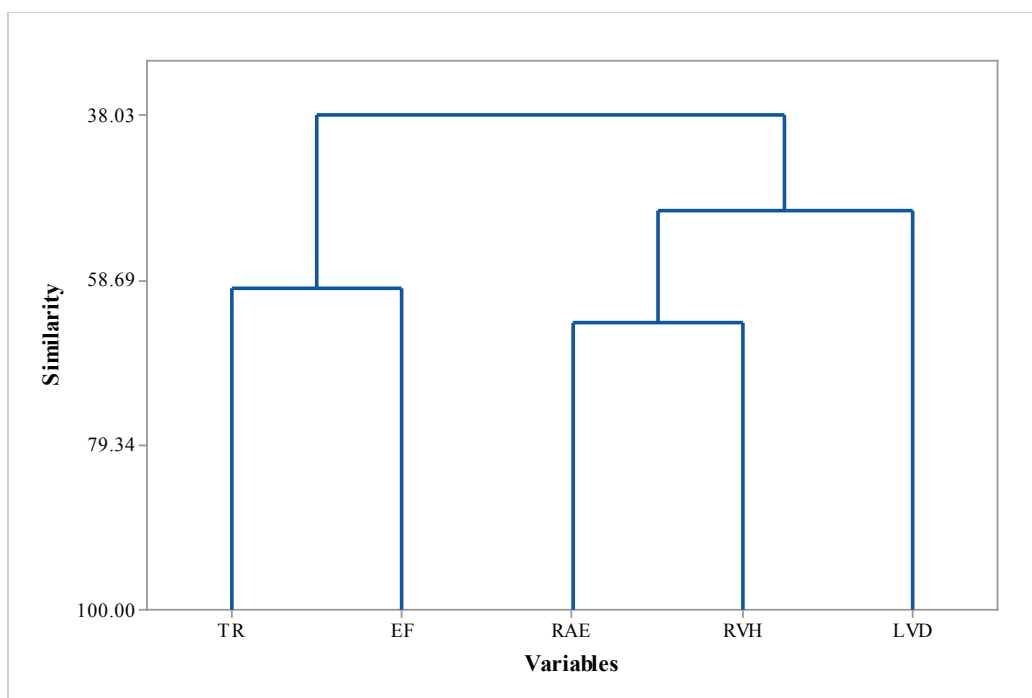


Fig 1: Dendrogram showing similarity among different echocardiographic changes

The dendrogram showed the abnormalities which might be combined, by totaling. We have found that a group of patients had common abnormalities in RAE, RVH and LVD whereas TR and EF were common to other group of patients.

Discussion

Typical signs of cor pulmonale in 2D echocardiography are right ventricular and atrial enlargement with a normal or reduced left-ventricular cavity and eventually reversal of the normal septal curvature. In the presence of tricuspid regurgitation, continuous-wave Doppler echocardiography may provide an estimate of systolic pulmonary artery pressure (PPA). However, tricuspid regurgitation (TR) is not always present in COPD, the incidence ranges between 24–66% of patients [5,6,7], therefore limiting the possibility to estimate PPA in a number of patients. In our study the TR was present in 63.33% of patients. Higham et al.^[9] found measurable TR was observed in 56/73 patients (77%) in their study. The incidence of TR ranges between 24-66% of patients in different studies. [5,6,7]

The current study showed that the percentage of patients with TR increases with the GOLD stages i.e.

the decrease in FEV1 or increase in the severity of the COPD. The other studies [9,10] also confirmed that there is an inverse relationship between FEV1 expressed as % predicted.

In the present study LVD was present in 33.33% of patients. The present study also demonstrates the direct relationship between the LVD and the GOLD stages (i.e. inverse relationship with FEV1 expressed as percentage predicted). In a study by Rander et al.^[11] of patients with moderate to severe COPD, 32% who presented with clinical deterioration had LVD contributing to their poor exercise tolerance.

Funk et al.^[12] showed a good relationship between the LVD and decrease in FEV1 expressed in percentage predicted. Suchoń et al.^[13] found that LVD is significantly impaired and its magnitude is related with increase in pulmonary artery pressure in COPD patients. In another study diastolic dysfunction appeared in about 70% of advanced COPD patients independent of the presence of ischemia or hypertension. Low FEV1 (less than 35% predicted) was one of the risk factors for developing diastolic dysfunction.^[14]

In the present study 41.66% of COPD patients were having RVH and there is direct relationship between

RVH and GOLD stages (i.e. inverse relationship with FEV1 expressed as percentage). The study by Suchoń et al.^[12] found RV end-diastolic diameter and RV wall thickness was significantly larger in COPD patients. One study by Vonk-Noordegraaf et al.^[15] found that concentric RV hypertrophy is the earliest sign of RV pressure overload in patients with COPD. This structural adaptation of the heart does not alter RV and LV systolic function.

Disease duration at any stage of GOLD in almost all cases determines the severity of echocardiographic change which increases more rapidly with duration when adjusted to age, gender and BMI. Again LVD in echocardiography had an increasing trend with the severity of smoking status.

In our study, OR of TR, RVH and RAE showed a uniformly increasing trend with the severity of GOLD stages i.e. the chances of developing TR, RVH and RAE increases with severity of GOLD stages. Gunen et al.^[16] in their study showed that the longer duration of COPD is related to significant morbidity and mortality because of pulmonary hypertension. Similarly study by Vij et al.^[17] revealed that incidence of right ventricular hypertrophy, right atrial enlargement and left ventricular diastolic dysfunction all increases with the longer duration of the disease.

Conclusion

In this study most of the echocardiography parameters showed a strictly increasing trend of cardiac disorders with the severity of COPD i.e. the severity of complication increases with severity of COPD. Therefore, echocardiographic evaluation in timely basis has pivotal role in early detection of the hemodynamic and mechanical alterations like LVDD, TR, RAE, RVH etc. The severity of the echocardiographic changes increases with the duration of the disease except LVDD, which is a non-specific finding. A prospective longitudinal study with more number of patients will be more informative in this respect.

Conflict of Interest: There is no conflict of interest and financial disclosure of authors with this study.

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Assessment of Prevalence of Anaemia in Pregnant Women Attending Kims, Hubballi

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Abstract

Background: Anaemia in pregnancy is one of the major causes of maternal morbidity and mortality in India as well as in the world. It continues to be a problem in spite of national programs for its prevention and control. It accounts for 1/5th of maternal deaths worldwide and 16% in India and is the major factor responsible for low birth weight, abortions, premature birth, and Post-partum haemorrhage. Hence determining the status and factors influencing anaemia among pregnant women is essential to treat and prevent the same.

Objectives : To study the prevalence and risk factors associated with anaemia among pregnant women.

Methods: A cross sectional study was conducted among 100 pregnant women attending at KIMS OPD from May to June 2012. A pretested, semi-structured questionnaire was used to collect data.

Results: Prevalence of anaemia among pregnant women was found to be 92%; majority were mildly anaemic 75 %. Majority of the study participants were in the age group of 20-30 years and 55% belonging to lower socioeconomic status and 79 % residing in rural areas. Factors influencing anaemia were multi-parity, short inter-pregnancy interval and poor socio-economic status.

Conclusion: In the present study, the prevalence of anaemia among pregnant women was found to be very high i.e. 92% especially in low income groups, multiparous women, short inter-pregnancy interval despite of high ANC check up and Iron and folic acid supplementations.

Key Words: Anaemia, pregnant women, risk factors

Introduction

Anaemia is the most common nutritional deficiency disorder in the world. WHO has estimated that prevalence of anaemia in developed and developing countries in pregnant women is 14% in developed and 51 per cent in developing countries and 65-75% in India⁽¹⁾. It continues to be a major health problem in many

developing countries and is associated with increased rates of maternal and perinatal mortality, premature delivery, low birth weight, and other adverse outcomes^(2,3).

The most common cause of anaemia in pregnancy worldwide is iron deficiency⁽³⁾. Iron deficiency in late pregnancy results in poor foetal iron stores^(4,5). Latent iron deficiency is known to alter brain iron content and neurotransmitters irreversibly in foetal life and postnatal babies⁽⁶⁾.

The predisposing factors include grandmultiparity, low socioeconomic status, malaria infestation, late booking, HIV infection, and inadequate child spacing – among others⁽⁷⁻¹⁰⁾. The World Health Organization (WHO) defined anaemia as haemoglobin concentration

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below 11g/dl in pregnancy. Anaemia in pregnancy is classified as: Mild (9-10 g %), Moderate (7-8.9 g %), Severe (4-6.9g %) and Very severe (<4g %) ⁽¹¹⁾.

In view of the low dietary intake of iron and folate, high prevalence of anaemia and its adverse health consequences, India became the first developing country to take up a National Nutritional Anaemia Prophylaxis Program (NNAP) to prevent anaemia among pregnant women. NNAPP was initiated in 1970 during the fourth 5-year health plan with the aim of reducing the prevalence of anaemia to 25%. The Government of India recommends a minimum dose of total 100 iron and folic acid tablets to be prescribed during pregnancy. However, high prevalence of anaemia among pregnant women persists despite the availability of this effective, low-cost intervention for prevention and treatment ⁽¹²⁾. Therefore, the present study was conducted to investigate the prevalence and risk factors of anaemia in pregnant women of KIMS, Hubballi.

Methods

This was a cross sectional study conducted in the month of May and June 2012 in KIMS OPD, Hubballi, to assess the prevalence and risk factors for anaemia among pregnant women.

Permission was obtained from Head of the Department, OBG, KIMS and verbal informed consent

was taken from the pregnant woman.

Convenient sampling method was used with a sample size of 100.

A pre tested, semi structured questionnaire was prepared which consisted of socio demographic data and specific history such as menstrual history, Obstetric history and physical examination. Gestational age of present pregnancy, iron folic acid supplementation and nutritional supplements were included. Risk factors includes age of 1stconception, multiple pregnancies, inter pregnancy interval, rectal bleeding, and regular ANC check-ups. Physical examination was done to measure height, weight, BMI and pallor.

Statistical Analysis

Data was entered in MS-Excel and analysed using SPSS-21 software and Chi-Square test was applied as test of significance and p-value of <0.05 was considered statistically significant

Results

Majority of the study participants were in the age group of 20-30 years (71%), Hindu (88%), literate (69%), from rural area (79%), belonging to class-V socio-economic status (55%) according to modified B G Prasad classification.

Table 1: Socio-demographic profile of the study participants

Variables		Percentage
Age in years	<20	25
	20- 30	71
	>30	4
Religion	Hindu	88
	Muslim	12
Husband's occupation	Professional	9
	Skilled	25
	Unskilled labourer	66
Residence	Rural	79
	Urban	21

Cont... Table 1: Socio-demographic profile of the study participants

Education	Illiterate	31
	Literate	69
Socio-Economic status	Class IV	45
	Class V	55
Type of Family	Nuclear	40
	Joint	58
	Three Generation	2
Type of diet	Vegetarian	40
	Mixed	60

Table 2: Risk factors of anaemia

Risk factors	Percentage
Regular ANC Check-up	96
IFA Supplementation	96
H/O helminthic infestation	3
H/O recent infections	9
Abnormal menstrual bleeding	3
Birth interval >3	6

Majority of the study participants visit Regular ANC check-up (96%), took iron and folic acid supplementations (96%) (Table 2).

Table 3: Signs and symptoms of Anaemia among the study participants

Signs and Symptoms	Percentage
Pallor	76
Palpitations	6
Breathlessness	4
Chest pain	4
Swelling of feet	4

Majority of the study participants presented with pallor (76%) and few of them with complains of palpitation, breathlessness, chest pain and swelling of feet (Table 3).

Table 4: Grading of Anaemia among the study participants

Grade of Anaemia	Number (percentage)
Mild Anaemia	75
Moderate Anaemia	12
Severe Anaemia	5
No Anaemia	8

Only 8% of the participants were not anaemic. Among those anaemic, 75% were having mild anaemia followed by moderate (12%) and severe anaemia (5%) (Table 4).

The types of Anaemia mentioned in the above table was according to WHO guidelines

In this study, majority of the participants with anaemia were in the age group of 20-30 years. 73% with anaemia were residents of rural areas and surprisingly majority of the participants were literate but the prevalence of anaemia was even higher among them (64%). All the study participants belonged to lower middle and lower socio-economic class according to modified BG Prasad classifications and the prevalence of anaemia was found to be very high in both the groups. Majority of the participants did not give any history of helminthic infestation. Multigravida mothers were at more risk of anaemia when compared to primigravida mothers.

The overall prevalence of Anaemia in this study was found to be 92% (Table 5).

Table 5: Risk factors and their relation to anaemia

Variables		Anaemia	No Anaemia	p value
Age	< 20	23	2	0.97
	20-30	63	6	
	>30	4	0	
Residents	Rural	73	4	0.97
	Urban	19	1	
Education	illiterate	28	3	0.7
	literate	64	5	
Socio-economic status	Lower Middle	40	5	0.46
	Lower	52	3	
Type of Family	Nuclear	38	2	0.47
	Joint/ three generations	54	6	
Helminthic infestation	Yes	2	1	0.1
	No	90	7	
Type of Diet	Mixed	55	5	0.88
	Vegetarian	37	3	
Gravida	Primi	43	6	0.12
	Multigravida	49	2	

Discussions

This study demonstrated that the prevalence of anaemia is 92%. In our study, total 100 pregnant women participated, out of which 71% of the study participants were in the age group of 20-29 years, 88% were Hindu by religion, 58% resided in joint family, 55% belonged to low socio-economic class and 69% were literate. In a similar study conducted by Mirzaie F et al., 62.75 were in the age group of 20-29 years, 61% were literates⁽¹³⁾.

In our study 51% were multiparity, 96% had taken iron and folic acid supplementation. Similar findings were found in the study conducted by Mirzaie F et al. where 55.2% of the participants were multiparity and 91% had used iron supplements during pregnancy⁽¹³⁾.

It was found that 66 % husband's of the study participants were unskilled workers by occupation and 25% were skilled workers. 75% of pregnant women attained menarche in 14-16 years age group and 34 % between the ages of 12-14 years. 73% of pregnant women were pregnant for first time in 20-25 age group and 23% between 15-20 years age group. 61 % of pregnant women were in third trimester of present pregnancy and 39% in second trimester.

49% were primipara and 27% had a birth interval of 2 years. 97% did not have any history of abnormal menstrual bleeding, 91% had no history of recent infection and 97% had no history of helminth infestations. 96% had regular ANC Check-ups as well taking regular IFA supplements.

In our study, 75 % were mildly anaemic and 12% were moderately anaemic. Similarly, in the study conducted by Dim CC et.al, 90.7% were mildly anaemic and 9.3% were moderately anaemic⁽¹⁴⁾.

54.66% with mild anaemia were between the age group of 20-25 years and 60% with severe anaemia were in same age group. 82.66 % with mild anaemia and 80% with severe anaemia were residents of rural areas. 29.33 % of and 40% with severe anaemia were illiterate. 53.33 % with mild anaemia and 60% with severe anaemia belong to poor socio-economic 57.33 with mild anaemia were from joint family and 60% with severe anaemia from nuclear family. 65.33% with mild anaemia were in third trimester of

pregnancy and 60% with severe anaemia were in second trimester. 48% with mild anaemia and 60% with severe anaemia were multipara.

Conclusions

Pregnant women were particularly vulnerable to anaemia with a high prevalence of 92%. Majority of the anaemic women had mild anaemia (75%). Social factors like socioeconomic status, type of residents, type of family and maternal factors like gestational age, parity, inter-pregnancy interval were contributing to the higher prevalence of anaemia. Even though majority of the study participants were literate, anaemia among them was still found to be high.

Limitations

The study has some limitations. Firstly, since it was a hospital based study the results might not be generalizable. Secondly, despite the study participants responded on being regular ANC check-up, regular intake of iron and folic acid supplementations and high level of literacy, the prevalence of anaemia was still found to be very high. Since no intervention was planned due to limited study period, further assessment could not be carried out.

Recommendations

Efforts should be made to focus not only to improve the health status of antenatal, intra-natal and post-natal stage but also on the adolescent health. All pregnant women should be educated to utilise the available ANC services.

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A Study to Assess the Various Risk Factors Associated with Breast Cancer Among Patients Attending KIMS and Cancer Hospital in Hubli

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Abstract

Background: Breast cancer is the most common cancer in females worldwide, and the second leading cause of cancer deaths in women. The incidence is on the rise in India, and is the second most common malignancy among the Indian women.

Objective : To assess the risk factors of breast cancer among the patients attending cancer OPD in KIMS and cancer Hospital, Navanagar in Hubli.

Materials and Methods: A cross sectional study was conducted to assess the various risk factors associated with breast cancer among patients attending KIMS and Cancer hospital in Navanagar, Hubli from May to June of 2014. A pre-designed, pre-tested and semi structure questionnaire was used to collect the data.

Results: Breast cancer was common in the age group of 50-70yrs, 36% of patients attained menarche <12, 62% had 1-3 children, 20% had oral contraceptive usage, 10% had family history of breast cancer, 88% had breast fed for >12 months, 98% of patients were unaware of breast self examination.

Conclusions: Awareness about symptoms of breast cancer and self examination of the breast were lacking in the study population. Health care personnel should be trained to spread the awareness of breast cancer in the community and to identify the vulnerable groups at the primary care settings itself. As majority of the risk factors for breast cancer are modifiable, prevention and early detection of these risk factors along with increase awareness amongs the population will have significant impact on the occurrence of the breast cancer.

Keywords: Breast cancer, risk factor, breast self examination.

Introduction

According to global cancer statistics for the year 2008, breast cancer was the most frequently diagnosed malignancy among women worldwide (incidence, approximately 1.38 million per year) and resulted in

46 million deaths. [1] Global burden rises to 1.4 million new cases and 8.2 million cancer deaths in 2012. One of the most commonly diagnosed cancers worldwide was Breast cancer (1.7 million, 11.9%). Breast cancer is also the most common cause of cancer death among women (522,000 deaths in 2002) and most frequently diagnosed cancer among women in 140 of 184 countries worldwide. It now represents one in four of all cancers in women. [2] In India, it is the most commonly diagnosed malignancy in women, ranks next to cervical cancer. [3] About 1.3 lakh fresh cases of breast cancer are reported in India every year; a decade ago the number stood at 54,000. [4] An increasing trend in incidence is reported from

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various registries of National cancer registry project and now India is a country with largest estimated number of breast cancer deaths worldwide. [3] The burden of breast cancer is increasing in both developed and developing countries. India is facing a cancer epidemic and by 2020, the breast cancer is set to overtake cervical cancer as most common type of cancer among all women in India. [5]

Older age increases risk of breast cancer and most women are over the age of 60 years when they are diagnosed although there is evidence that Indian women are more likely to develop breast cancer at earlier ages than their Western counterparts and that breast cancer peaks from ages 45-50 years in India. [6] Women who have an early age at menarche (<12 years) have a 30% increased risk of breast cancer while those who have a late age of menopause (>65 years) will have a 20-50% increased risk of disease. [6] A family history of breast cancer in mother, father, sister or daughter increases the risk of breast cancer and the risk is even stronger if the family member was diagnosed before age of 50 years and or with pre-menopausal breast cancer. Specifically, if a woman has a first degree relative >50 years diagnosed with post-menopausal breast cancer, her risk increases by 80% where as a first degree relative with pre-menopausal breast cancer increases a woman's risk by 30%. [6] Personal history of benign breast or other breast disease i.e. a history of atypical hyperplasia, lobular carcinoma insitu or ductal carcinoma insitu (as determined by a breast biopsy) increases the risk of developing invasive breast cancer. [6] History of breast cancer was found to be a risk factor for breast cancer.

Women who never had children or those who are more than 30 years at the time of their first childbirth are twice as likely as to develop breast cancer than women who had their first child before age of 20 years. Moreover women who have 5 or more children have half the risk of breast cancer as women have never had a child. [6] Women who have taken menopausal hormone replacement therapy have a 20% greater risk of breast cancer. [6] Also exogenous hormone like oral contraceptive pills shows high risk of breast cancer. [7] Women who do not breast feed or breast fed for short duration are at higher risk of developing breast cancer. Thus breast feeding was a protective factor. [6] The risk level for non-vegetarian diet is higher than vegetarian

diet because non-vegetarians consume more fat than vegetarians and a diet with high animal fat intake has been shown to increase the risk of breast cancer. [3] Exposure to ionizing radiation also increases risk later in life, particularly when exposure is during rapid breast formation i.e. teen age. [8] The present study was conducted to assess the various risk factors of breast cancer among patients attending KIMS and Cancer hospital, Navanagar in Hubli.

Objectives

1. To assess the socio-demographic profile of patients with breast cancer.
2. To determine the various risk factors associated with breast cancer.

Methodology

This was a cross sectional study conducted among the patients attending Karnataka Institute of Medical Sciences, Hubli and Cancer hospital in Navanagar, Hubli to assess the various risk factors associated with breast cancer in the month of May and June 2014. Convenient samplings of 50 diagnosed breast cancer patients were taken up for study.

Inclusion criteria: Female patients diagnosed with breast cancer attending KIMS and Cancer hospital Navanagar, Hubli who had given consent to participate.

Method of data collection:

A pre-designed, pre-tested and the semi structure questionnaire was used for data collection after obtaining oral consent. The questionnaire consisted of various socio-demographic parameters like name, age, address, occupation, literacy, marital status, socio-economic status and questions regarding non-modifiable risk factors such as age, age of menarche, age of menopause, family history of breast cancer, personal history of benign breast or other breast diseases and history of abortion; and modifiable risk factors such as age at first childbirth, age at last childbirth, hormone replacement therapy, breast feeding, use of oral contraceptive pills, diet and exposure to radiation.

Statistical analysis: The data collected was entered in Microsoft Excel and analyzed using SPSS version 20. Appropriate descriptive statistics and inferential

statistics were used for analysis.

Results

Table 1: Socio-demographic details of the participants

Variables		Number	Percent
Age (years)	30-40	13	26
	40-50	18	36
	50-70	30	60
Address	Rural	34	68
	Urban	16	32
Occupation	Homemaker	27	54
	Laborers	19	38
	Service	4	8
Education	Literate	23	46
	Illiterate	27	54
Marital status	Married	40	80
	Widow	9	18
	Unmarried	1	2
Socioeconomic Status	class I	4	8
	class II	8	16
	class III	19	38
	class IV	16	32
	Class V	3	6

Majority of the participants were in the age group of 50-70 years. Majority were from rural area (68%), majority were married (80%).

Table 2: Non- modifiable risk factors

Non- modifiable risk factors		Number	Percent
Age of menarche	<12	18	36
	>15	1	2
	13-15	31	62
Menstrual cycles	Regular	49	98
	Irregular	1	2
History of abortion	Yes	10	20
	No	40	80
Age of menopause (years)	<40	4	8
	40-50	22	44
	>50	1	2
	No menopause	23	46
Family History of breast cancer	Yes	5	10
	No	45	90
Cancer in other breast	Yes	4	8
	No	46	92
Previous history of benign breast tumors	Yes	8	16
	No	42	84

Majority of the participants attained menarche before the age of 15 years and menopause before 50 years of age. 10% had family history of breast cancer, 8% had cancer in the other breast and 16% had previous history of benign breast cancer (Table 2.).

Table 3: Modifiable risk factors

Variables	Number	Percent	
Age of marriage (years)	<18	26	52
	≥18	23	46
	Unmarried	1	2
Age at last child birth	< 25	23	46
	≥25	24	48
	No children	3	6
History of OCP intake	Yes	10	20
	No	40	80

Cont... Table 3: Modifiable risk factors

Diabetic	Yes	5	10
	No	45	90
Hypertension	Yes	3	6
	No	47	94
History of tobacco chewing/smoking	Yes	9	18
	No	41	82
Type of diet	Mixed	26	52
	Vegetarian	24	48
BMI	< 25	36	72
	≥25	14	28
Awareness of breast self examination	Yes	1	2
	No	49	98

52% were married before 18 years, 46% had the last child birth after 25 years and 6% did not have any children. 20% had history of OCP intake and 98% were not aware of the breast self examination (Table 3).

OCP usage is more in literate people as compare to illiterate but it is not statistically significant ($P > 0.05$).

46% were among the literate, out of which only 2% were aware of breast self examination, none of the illiterate were aware of breast self examination but it is not statistically significant ($P > 0.05$).

Even though 10% had family history of breast cancer, none of them aware of breast self examination and it is not statistically significant ($P > 0.05$).

Discussion

In the present study majority of the breast cancer patients were in the age group of 50 to 70 years which is consistent with other studies. In Bhadoria AS et al. study, 62.5% were in the age group of 30 to 50 years^[8] and according to breast cancer fact sheet by Gupta A et al, breast cancers is common in western countries above the age group of 60 yrs and in India it is found to be 45 to 50yrs. The reason for the above difference could be due to the various ethnic, socio-demographic, geographical

and life style factors.^[5] Overall, the risk of breast cancer increases as the age progresses.

In our study, 68% of the breast cancer patients were from rural areas and 32% from urban. Whereas, in the similar study conducted by Das S et al. among women in eastern India, 65.7% cases were from rural areas and 34.3% from urban areas.^[9]

In our study, 54% of breast cancers were illiterate which was consistent with the study conducted by Das S et al. where 86.7% were illiterate.⁹

In our study, 98% of the cases were married and 2% were unmarried. Similarly, 96% were married in Bhadoria AS et al. study in North India^[8] and 96.3% were married in Lodha S R et al. study conducted among women in Urban Bhopal.^[10]

Women in higher socio-economic status have an increased risk of breast cancer compared to those belonging to the low socioeconomic status. Socio-economic status per se does not increase the risk but other factors like delayed age at marriage and first child birth after 30 years may play a significant role [24, 27]. In our study majority of the cases belong to lower socio-economic status (38% were from class III and 32% were from class IV according to modified B G Prasad

socioeconomic status classification) and this could also be due to the various socio-demographic, geographical and life style factors and needs further studies. Similarly, in Parameshwari P et al. study, 50% from class IV and in Das S et al., 64.8% from low socioeconomic status as well. [9]

In our study, 62% attained menarche at 13-15 years of age and 36% below the age of 12yrs. In Parameshwari P et.al study, 55% attained menarche below 13 years. Bhadoria AS et al. study, [8] majority of the cases attained menarche between the age group of 12-13 years. In Das S et al study, 69% of the cases attained menarche below 12yrs and 47% of cases between 13-15yrs of age. Many studies have shown that breast cancer risk is more for women whose menarche occur at an early age, in India and other countries. [11, 12] Early age at menarche is associated with increased risk of breast cancer and there appears to be a 20% decrease in breast cancer risk for each year if menarche is delayed [13, 14]. Studies reported that women who began menstruating at an early age (before age 12) and those who reach menopause after age 55 years had an increased risk of breast cancer. [15, 16]

In our study, 46% married after the age of 18 years and 52% below 18 years. 62% had 1-3 children and only 6% were nulliparous. In most studies single and nulliparous married women were found to have a similar increased risk for cancer of the breast as compared with parous women of the same age. [17]

In our study, 20% of the cases had history of abortion. Whereas in the similar study conducted by Lodha S R et al. [10] and Kamath R et al, [3] 14% and 25% had history of abortion respectively. [3]

In our study 88% of the patients had breast fed for more than 12 months and 8% had never breastfed. Similar findings were seen in the study conducted by Parameshwari P et al. in which 70% had breastfed for more than 2 years. [6]

According to our study, 40% gave birth to last child between 20-25yrs of age and 42% between 25-30yrs of age. In Bhadoria AS et al. study, 66.9% of the patients gave birth to their last child below the age of 28 years and 33.1% above the age of 28 years. [8]

In our study, 20% of the patients had history of Oral contraceptive usage. Whereas in the similar study

conducted by Das S et al., 37% had history of Oral contraceptive intake [9] and in Lodha S R et al., 10% had history of Oral contraceptive intake. [10]

In our study, 81% of the patients attained menopause between 40-50yrs of age. In Das S et al. study, 91.7% attained menopause below the age of 40 years, 43.4% between age group of 42 to 49 and 63.6% above 50. [9] In Lodha S R et al., 36% of the patients attained menopause below the age of 45yrs, 24% between 45-50 years and 40% above 50 years. [10]

In our study, 10% of patients had family history of breast cancer. In Kamath R et al. study, 5% had family history of breast cancer [5] and in Lodha S R et al. study, 6.5% cases had family history of breast cancer. [10]

In our study, 16% of patients had history of previous benign disease of breast, 92% of patients had unilateral breast cancer. Only 2% of patients had done breast self examination and 98% of cases were unaware of it. In Parameshwari P et al. study, 25% were aware of breast self examination. [6]

In our study, 72% had body mass index (BMI) <25 and 28% had BMI more than or equal to 25. Whereas, in Parameshwari P et al. study, 35% had BMI <25 AND 65% had BMI \geq 25. [6]

Conclusion

Breast cancer was more common in the age group of 50 to 70yrs. Illiterate, poor socio-economic rural female with early menarche, early marriage, having mixed-diet are at greater risk for breast cancer in our study. Only 2% of breast cancer patients were aware of breast self examination (BSE). 10% of patients even though having family history of breast cancer were unaware of BSE. As majority of the risk factors for breast cancer are modifiable, prevention and early detection of these risk factors along with increase awareness among the population is the key for prevention and will have significant impact on the occurrence of the breast cancer.

Limitations

The study had several limitations. Firstly the sample size was small and since, it was hospital-based rather than community-based the cases may not be entirely representative to the general population. Secondly, a

comparative study between case and control could be way better and we could not assess that. Thirdly, genetic mutations, nutritional factors, obesity, radiation exposure and environmental exposure could not be ascertained.

Recommendations

Active steps should be taken to train and sensitize the medical and paramedical personnel about identifying symptoms of breast cancer in the primary care settings itself and periodical follow up should be given. Women with family history of breast cancer and other vulnerable groups must be identified and appropriate preventive measures like awareness creation with regard to breast self examination, symptoms of breast cancer and mammography. Suitable Information, Education and Communication activities must be formulated to sensitize the vulnerable population for seeking immediate health care as and when the symptoms arise. Policy makers can consider encouraging community participation by involving the Non-Governmental Organizations, Women Self Help Groups and Public Private Partnerships with the support of the grass root level health workers in spreading the awareness of breast cancer. A larger studies considering the immunomarker status and genetic studies is recommended in further research

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Right to Health & Medical Care in the Time of Covid-19 Pandemic

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Abstract

Health is not merely the absence of disease but a state of complete physical, mental and social wellbeing. The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being globally. The World Health Organisation (WHO) as the global leader in public health is responsible to ensure public health globally. Every member states of the United Nation (UN) have developed own healthcare infrastructure and medical services to ensure citizen's health. The unprecedented health crisis aroused due to the Covid-19 pandemic has proved the healthcare infrastructure and medical services exist in India and abroad insufficient. The Pandemic has affected the socio-economic fabric of the world and forced the people to face new challenges. The study investigates the constitutional and legal position of right to health and medical care in India and the impacts of Covid-19 thereupon. The study critically examines the working of the WHO in the time of Covid-19 pandemic. Doctrinal method of research is applied in this study.

Keywords: Health Rights, Medical Care, WHO, Covid-19, Pandemic, Law, Judiciary

Introduction

Right to health and Medical care is the most fundamental rights of citizens. The Supreme Court of India has observed in *Vincent Panikurlangara vs. Union of India*⁽¹⁾ maintenance and improvement of public health have to rank high as these are indispensable to the very physical existence of the community and on the betterment of these depends on the building of the society of which the constitution-makers envisaged. Attending to public health, in the opinion of the court, therefore, is of high priority- perhaps the one at the top⁽²⁾. Under the flagship of the UN, all member states have made efforts to ensure public health. The countries have developed their healthcare infrastructure to meet the health needs of citizens. The unprecedented Public

health emergency of International concern declared by the WHO has put several question marks on the existing healthcare infrastructure and medical services throughout the world. Since December 2019 when China reported the first case of Covid-19 to the WHO, about 15 million cases of Corona positive and a death toll of 615,000 people have been reported worldwide⁽³⁾. Every day this number is spiking very fast. After the USA and Brazil, India is the third most affected country in the world. According to the Ministry of Health and Family welfare, more than 11.5 Million Covid-19 cases have been recorded till 20 July 2020. The spread of Coronavirus is on a spike in India, within 24 hours of July 20, 2020, 37,148 cases was reported. Till July 20, 2020 about 28 thousand people have been died due to Covid-19 disease⁽⁴⁾.

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Half of the world population were confined into their homes due to Covid-19 pandemic. The Government of India also imposed national lockdown to control and prevent the spread of Coronavirus and confined citizens inside their homes. During the national lockdown in India, several socio-economic challenges were faced

by the people. The basic rights like the right to learn, earn, freely movement etc. which are essential to the right to life remain seized during the lockdown. Several medical professionals, who were the frontline warriors in the fight against Coronavirus were infected and lost their life. This study was undertaken to demonstrate the impacts of Covid-19 pandemic over the Right to Health and Medical care in India.

Material and Methods

The study is based on analytical method of legal research by surveying national, comparative and international law relating to health and medical care. The case decided by various judicial and quasi-judicial forums has to be analysed for internal and external consistencies. Internal consistencies here mean consistencies *vis-a-vis* that particular issue amongst various case situations; external consistencies mean consistency *vis-a-vis* statutes, guidelines, rules etc. The primary sources like statutes, regulations, conventions and treaties are interpreted following the established canons of statutory interpretation in public law discourse. The secondary sources consisting of treatises, commentaries and glossaries are contextually analysed to reach the objective of the study.

Findings

The Covid-19 pandemic has affected the entire world directly or indirectly. The pandemic has affected the socio-economic life of the people as well as health rights globally. The readiness of the WHO as well as state governments around the world towards the fight against Covid-19 pandemic has proved insufficient. People's right to health, medical care as well as other basic human rights are at risk everywhere. The WHO as the world leader in public health has proved no more effective body to meet the present time health needs of the world.

Discussion

International Laws on Right to Health and Medical Care

The International Bill of Rights has strongly advocated healthcare rights and adequate system for their protection in favour of the people worldwide. Consequently, all the signatories of the international

conventions are conscious of healthcare and adequate medical services for their citizens. The modern International laws have a sufficient number of legal provisions to deal with human health, medicine and healthcare system throughout the world. In this regard, the UN and its subordinate agencies have made several legal efforts to regulate the medical and health sector.

Universal Declaration on Human Rights (UDHR), 1948

Article 25 (1) of the UDHR provides that, everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, cloth, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.

International Covenant on Civil and Political Rights (ICCPR), 1966

ICCPR is dedicated to people's health worldwide. Article 6 (1) of the Covenant states that everyone has an inherent right to life which cannot be deprived arbitrarily. Therefore, the state is under an obligation to give primacy to public health and access to medical services. This provision relating to medical services and health rights is impliedly recognising legal protection against medical malpractices and negligence.

International Covenant on Economic, Social and Cultural Rights (ICESCR), 1966

Article 12 of the ICESCR recognizes the right of everyone to the highest attainable standard of physical and mental health. This covenant urges the member states to take the right steps to ensure that everyone has access to medical services. These medical services must be proper and safe. In case of health damage due to improper and deficient health services state will be held liable to compensate victims.

The World Health Organisation

The Constitution of the WHO adopted by the International Health Conference held on 19 June to 22 July 1946 in New York and enforced from 7 April 1948 recognises the health rights of the people worldwide.

The Preamble of the WHO states that health is not merely the absence of disease or infirmity but a state of complete physical, mental and social wellbeing. The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being. The WHO provides global leadership in public health. The organisation works worldwide to promote public health, keep the world safe, and serve the vulnerable.

Role of World Health Organisation in Combating Covid-19 Pandemic

The WHO as the global leader in public health coverage has been at the heart of the battle against the Coronavirus since the first reported outbreak in Wuhan, China. The Organisation is trying to bring the world's scientists and health professionals together to accelerate the research, develop new norms and standards to contain the spread of the coronavirus pandemic and help those who are affected. During the Covid-19 pandemic, the Organisation played an important role in the fight against the unprecedented world health crisis. When the China on the last day of December 2019 reported to the WHO about a cluster of pneumonia cases of unknown cause in Wuhan, the WHO activated a crisis group, putting the body on an emergency footing for dealing with the outbreak. A day later, it published its first Disease Outbreak News destined for scientists and public health specialists on the Novel Coronavirus. The WHO Chief Tedros Adhanom Ghebreyesus convened an emergency committee to assess whether the outbreak constituted a public health emergency of international concern. A delegation travelled to Beijing, led by Tedros, who agreed with the Chinese government that an international team of scientists would visit China. On January 30, 2020 the WHO declared Covid-19 pandemic to be a public health emergency of international concern. The organisation alarmed the world to face a new health crisis and urged member states to speed up the development, production, distribution of treatments and vaccines and ensure universal access to therapeutics. Recently the WHO has remarked, the virus may never go away and could become a disease that the world has to learn to live with⁽⁵⁾.

The Research and Development (R&D) Blueprint which is a global strategy and preparedness plan that allows the rapid activation of research and development

activities during epidemics. It has a broad global coalition of experts come from medical, scientific and regulatory backgrounds have contributed to the Blueprint. It aims to fast-track the availability of effective tests, vaccines and medicines that can be used to save lives and avoid large scale crisis. The R&D Blueprint is working to accelerate diagnostics, vaccines and therapeutics for the epidemic⁽⁶⁾.

Criticism over the Working of the WHO during the Covid-19 Outbreak

The working of the WHO in the time of the Covid-19 pandemic has disappointed the people. Critics say the WHO ignored its early warning about the Coronavirus because of Chinese influence. When Coronavirus spread forced China to impose lockdown in parts of Hubei province in late January 2020, the WHO was reluctant to declare pandemic as global health emergency. The Organization officially called the spread of Coronavirus a global pandemic on March 11, 2020, it was too late. The delay in making such a declaration deprived countries to prepare hospitals for handling the rush of Covid-19 patients. In Japan, the Deputy Prime Minister Taro Aso noted that some people have started referring to the World Health Organization as the Chinese Health Organization because of what he described as its close ties to China. The US President Donald Trump has announced to halt payments to the WHO pending a review of its role in allegedly severely mismanaging and covering up the spread of the coronavirus, and accused it of being biased towards China.

The pandemic has affected international relations and caused diplomatic tensions between countries. International trade and transport of medicines, diagnostic tests and medical equipment used to cure Covid-19 disease have affected due to the tension. There will be time later to assess the success and failure of the WHO in dealing with public health in the time of Covid-19 outbreak.

Recently, the WHO has remarked as the virus may never go away and could become a disease that the world has to learn to live with. Only to warn the world about the severity of the Covid-19 disease is not enough to fight against deadly Coronavirus. The overall efforts made by the WHO in the way of control and prevention of the spread of Coronavirus are not sufficient. Drugmakers

across the world have been rushing to develop a vaccine for the Covid-19. Leading pharma companies have reached to human trial of their anti Corona vaccines. Glenmark Pharmaceutical Ltd. had received approval from India's drugs regulator to make and sell oral antiviral drug Favipiravir for treating mild to moderate Covid-19 patients in India. The world is awaiting still for an effective anti Covid vaccine from the WHO.

The Constitution of India and Right to Health & Medical Care

The right to health is recognised in India as a fundamental right. The right to health as fundamental right grew as an offshoot of environmental litigations in India. In *M.C. Mehta vs. Union of India*⁽⁷⁾ the right to healthy environment was recognised as a fundamental right in the first instance and the right to health and healthcare are derived from that. The right to health is inseparable from the right to life. Right to health and medical facilities are collateral of the right to health as part of the right to life under Article 21. It does not provide any special rights to the patient but the patient's rights are arising from the relevant provisions of the Constitution. Right to health and medical treatment of patients are the fundamental rights as well as human rights of citizens. The Supreme Court of India has observed in case of *Balram Prasad vs. Kunal Saha*⁽⁸⁾ hospitals, nursing homes, clinics are liable to provide treatment to best of their capacities to all patients. Erring or negligent doctors, hospitals are to be dealt with strictly.

Article 32 provides constitutional remedies on the violation of fundamental rights. It enables the victim to move the Supreme Court through an appropriate proceeding for the enforcement of his fundamental rights conferred by the Constitution. The right to constitutional remedies, therefore, allows citizens to stand up for their rights against anybody even the Government.

In the landmark judgment in *Parmanand Katara vs. Union of India*⁽⁹⁾ the Supreme Court has emphasised that the right to life covered within its scope the right to emergency healthcare also. In this case, a scooter rider injured severely in a road accident, when taken to the nearest hospital he was refused to admission with an excuse that the hospital was not competent to handle the medico-legal case. The Supreme Court held that the medical professionals are bound to provide treatment in

cases of emergency and they cannot refuse to treat the patient. The Supreme Court stated that Article 21 of the Constitution casts an obligation on the state to preserve people's life, not only government hospitals but also every doctor whether at government service or otherwise has the professional obligation to extend his services for protecting people's life.

In *Paschim Bangla Khet Majdoor Samiti vs. State of West Bengal*⁽¹⁰⁾ the Supreme Court further emphasised on the right to emergency healthcare and treatment. The court stated that the failure on the part of the government hospital to provide timely treatment to a person in need results in a violation of his right to life guaranteed under Article 21 of the Constitution. In this case a person suffering from head injuries occurred in a train accident was refused from giving treatment by various hospitals on the excuse of lack of adequate facilities and infrastructure required to provide treatment.

Further the Judiciary demonstrated its activism in the time of Covid-10 pandemic when the basic rights including right to health and medical care of the public were at high risk. The situation attracted the judiciary for taking necessary action in the public interest. The Supreme Court has emphasised that the Covid-19 lockdown does not eclipse personal liberty and the fundamental right to life. Right to health is imbibed in the right to life guaranteed under Article 21 of the Constitution⁽¹¹⁾.

Taking the notice on the gravity of the Covid-19 situation, Delhi High Court has directed the Centre and Delhi government to increase the number of the beds for Covid-19 patients and also try to increase the number of ventilators so that all Covid-19 patients in need can avail their right to healthcare⁽¹²⁾.

Recently, the Supreme Court on the petition of Advocate Shashank Deo Sudhi passed an interim order and asked the government to arrange for carrying out Covid-19 testing by private laboratories certified by the National Accreditation Board for Testing and Calibration Laboratories (NABL) free of charge⁽¹³⁾. And a bench of the Supreme Court has asked the Centre to identify private hospitals that can treat Covid-19 patients for free or at a very low price. The Apex Court had also taken sue moto cognizance on media reports of improper handling of Covid-19 patients and undignified disposal

of the victims' dead bodies in the country⁽¹⁴⁾.

Conclusion

The unprecedented Covid-19 pandemic has impacted the entire world directly or indirectly. Basic rights like right to life, health, liberty and livelihood etc. are at risk throughout the world. About one half population of the world is facing several health issues emerged due to the pandemic. The growing number of Corona positive cases throughout the world has proved the existing healthcare infrastructure and medical facilities exist in the world insufficient. The WHO as the global leader in public healthcare is no more effective body to meet the global public health needs. The organisation must be reorganised, financed and powered to fight against diseases like Covid-19 and future epidemics. During the pandemic heavy puucity of healthcare professionals, hospitals and infrastructure is recorded in India. The healthcare sector demands more investment and adequate policies to meet the needs of public health.

6. Ethical Clearance- No

7. Source of Funding- No

8. Conflict of Interest- No

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Protocols and ‘Nine Parameter Model’ in the Prevention of COVID 19 A Single Centre Experience

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Abstract

Background: Coronavirus disease 2019 (COVID-19) is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and is global pandemic. MUMBAI HEART CLINIC is a tertiary care centre in the heart of chembur with more than 60 health care workers and catering more than 500 patients per month for OPD services and almost 100 in door patients with more than 50 Cath lab procedures and almost equal number of surgical cases in a month. **Objective:** protocols and ‘nine parameter model’ in the prevention of COVID 19, single centre experience.

Methods: Core team was established. Internal check points were identified and policies were framed to minimise contact and prevent spread of infection. We followed ‘Nine parameter model’ of hand washing, physical distancing, temperature measurement, saturation measurement, face mask, hand sanitization, prophylaxis of HCQS, symptoms of SARS-CoV-2 and wearing Personal protective equipment’s. **Results:** It was found that nine parameter model was practically feasible and highly effective in avoiding spread of SARS-CoV-2. **Conclusion:** The ‘Nine parameter model’ adopted by our hospital is a simple and effective method not only to prevent but also to early detect the presence of SARS-CoV-2 infection. These simple measures along with identifying internal check points were instrumental in preventing spread of SARS-COV-2 infection and at the same time allowing for smooth working of hospital.

Key works: covid-19, hospital policy, hand washing, face mask, personal protective equipment, sanitizations, SARS-CoV-2, nine parameter model

Introduction

The COVID-19 pandemic, also known as the coronavirus pandemic, is an ongoing global pandemic of coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).^[1] The outbreak was first identified in Wuhan, China, in December 2019.^{[2][3]} The World Health Organization declared the outbreak a Public Health Emergency of International Concern on 30 January 2020 and a pandemic on 11 March.^{[4][5]} As of 23 July

2020, more than 15.2 million cases of COVID-19 have been reported in more than 188 countries and territories, resulting in more than 623,000 deaths; more than 8.66 million people have recovered.^[6]

Methods and Materials

MUMBAI HEART CLINIC is a tertiary care centre in the heart of Mumbai with more than 60 health care workers and catering more than 500 patients per month for OPD treatment and almost 100 indoor patients with more than 50 Catheter laboratory procedures and almost equal number of surgical cases in a month. To ensure safety of HCW on forefront of fighting SARS-CoV-2 the following key changes were undertaken.

Core Team: A core team for the management of the event was established; it included a member of the hospital management, the hospital infection control team,

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an infectious disease expert, and experts representing the intensive care unit (ICU) and emergency room (ER). All the team members were informed of, and trained in, their roles and responsibilities; contact list and documentations were centrally accessible. Core team met once fortnightly via video conference.

Key Internal Check Points:

Reception:

Made sure workplaces were clean and hygienic. Surfaces (e.g. desks and tables) and objects (e.g. telephones, keyboards) were wiped with disinfectant regularly. Good respiratory hygiene was promoted. It was pillar to implement and supervise the nine parameter model in work place.

Pharmacy:

Only authorized persons had access to the Store department. All materials received at the store house and person / department concerned notified promptly on receipt. Hazardous materials were to be stored separately.

EMERGENCY, ISOLATION AND IPD POLICY:

For pre-planned procedures patient and relative should have a SARS-CoV-2 nasopharyngeal swab report which was negative. All suspected and confirmed cases of Covid -19 to be shifted in tertiary care hospital. Screening of the patient to be done in the hospital entrance in casualty department on separate beds only. The EMT will wear the full body PPE like disposable mask, full hand gown, face shield, shoe cover, gloves. Patient was kept in isolation room if he was suspected as SARS-CoV-2 case. N95 masks was used for suspected or confirmed positive patient. Mask was changed every 6 hours or earlier if it becomes soiled. Hand hygiene was followed before and after contact with the patient and patient surrounding. Terminal cleaning was done after the patient had vacated the room, it was thoroughly cleaned before next admission. Proper biomedical waste segregation was done as per the guidelines.

VISITOR'S POLICY:

Only one relative was allowed from the time of admission till discharge in designated visitor area.

Food and place to stay was provided to the relative till discharge. No visitors were allowed in the ICU. Relatives were allowed to have video confrontation with patients during specific time of day.

OPD :

OPD patients entered and exited only through separate entry doors and exit doors. On OPD days only 5-6 chairs were kept at distance in waiting room and patient's area accordingly. No crowding at any cost was allowed.

2D ECHOCARDIOGRAPHY, TREADMILL TESTING AND REHABILITATION DEPARTMENT:

Transthoracic echocardiography (TTE), stress echocardiography, and transesophageal echocardiography (TEE) were performed only if they were expected to provide clinical benefit. TEE was postponed or cancelled if an alternative imaging modality provided the necessary information. Treadmill stress testing in patients lead to exposure because of deep breathing and/or coughing during exercise. These tests were generally deferred or converted to pharmacologic stress echocardiography. Meticulous and frequent hand washing was crucial. Rehabilitation of patients was carried out with physical distancing and following the 'nine parameter model.'

CATH LABORATORY & OPERATION THEATRE COMPLEX:

Early intubation, sedation and possible paralysis was considered for patients who were thought to require high flow oxygen supplementation approaching intubation or those who had difficulty lying still. Transfer protocols (especially between Cardiology ward/ICU-Emergency department-ICU and the catheter lab) were strictly followed so that risk was mitigated and patient flow was improved. Staff ensured that complete set of PPE were available for primary operator, scrub nurse. Hand sanitisers were made ready just outside the procedure room for PPE removal. Operator and scrub nurse to scrub and gown. Everyone is to be ready and waiting in room prior to transfer of patient. Ready access to equipment (catheters, guides, wires, balloons etc) should be made simple and means of conveyance to

in-lab operators planned to minimise risk of infection. Anaesthetic/ICU and support staff who are needed in the catheter lab during the procedure should don lead gowns prior to donning PPE before initiating transfer of the patient. All scrubbed staff stayed in room until patient transferred out of room directly to destination. HCW to then remove PPE as per protocol. Procedure area and lab used to undergo terminal clean and the time for lab re-use. Procedure area of lab was sealed until after terminal clean. If equipment was needed urgently from the room, PPE was donned to enter.

BIOMEDICAL WASTE MANAGEMENT:

The facemasks, hand gloves and other protective equipment used by the patients, health workers, laboratory personnel were collected separately in yellow plastic bags with biohazard symbol and marked as "SARS-COV-2 Waste". The 'Yellow' bags were handed over to the Biomedical Waste Common Treatment Facility (CTF) after spraying disinfectant at the point of generation. The 'Yellow' bag waste were collected and transported by the CTF operator through dedicated vehicle for treatment at CTF.

CLEANING:

All areas where BMW was generated and disposed, from hospital (was cleaned with sodium hypochloride 1%) and were cleaned thoroughly with disinfectants.

KEY EXTERNAL CONTACT POINTS:

Key external contact points and their backups including necessary local/regional/national contacts (e.g. for case notification, management of cases, suppliers, other hospitals, local authorities, etc.) were identified and gathered in an easily accessible contact list, and staff involved has been made aware of it.

TRAINING: HCW was trained in 'nine parameter model'. Also latest, updated information and relevant information pertaining to SARS-COV-2 were passed onto healthcare workers and were discussed with pros and cons.

The NINE PARAMETER MODEL:

1. FACE MASK:

Masks can be made of different materials and

designs which influence their filtering capability. [7] Of the mask to protect the wearer from infectious particles N95 (the American standard) respirators are recommended for health workers conducting aerosol-generating procedures during clinical care of SARS-COV-2 patients. One approach that has been studied for handling N95 respirator shortages is sterilization and re-use, which can be effective. [8] It was emphasised on source control, because if everyone is wearing masks to decrease the chance that they themselves are unknowingly infecting someone, everyone ends up being more protected. Another important benefit of recommending universal mask wearing would be to serve as a visible signal and reminder of the pandemic, and given the importance of ritual and solidarity in human societies, [9] it is plausible that visible, public signalling via mask wearing can potentially increase compliance with other health measures as well, such as keeping distance and hand-washing.

2. PHYSICAL DISTANCING:

Physical distancing is a method to minimize crowd interactions and prevent the spread of disease within groups of people. This is a common practice which has been carried out over generations. Physical distancing of at least 1 meter was always maintained between two HCWs. Norms of physical distancing were abided during working hours especially during interaction with relatives of patient, having lunch, meetings, and reception. Floors were marked at distance of 1 metre so as to maintain physical distancing. Any two persons always ensured it their responsibility to maintain a physical distancing of 1 meter and to ensure that the third person will follow the same.

3. HAND SANITIZATION:

Alcohol based hand sanitizers were used for hand sanitization. Solutions containing at least 70 % ethyl alcohol, 0.725% glycerol, and 0.125% hydrogen peroxide; or chlorhexidine gluconate 0.5 % were used. Contact period of at least 1 minute was ensured for proper effectiveness of hand sanitization.

4. HAND WASHING:

All 7 steps of hand washing were thought to HCWs and were followed religiously. Hand washing was done

after every contact with patient or object. Wash basin were equipped with soap based hand wash solutions. Adequate and uninterrupted water supply was also in place.

5. PERSONAL PROTECTIVE EQUIPMENTS:

Healthcare workers (HCWs) are at an elevated risk of contracting SARS-CoV-2. Proper donning and doffing rooms were made available in every internal check points. All HCWs were trained in donning and doffing technique.

6. SYMPTOMS SCREENING:

It was mandatory to report any symptoms of fever, cough, sore throat, breathlessness, malaise or body ache. Each hospital healthcare worker was made aware of early detection of any symptoms of COVID 19 disease. Every hourly announcement was done via speakers emphasising the importance of 'nine parameter model'.

7. HYDROXYCHLOROQUINE:

Currently, there are no approved vaccines against SARS-CoV-2, which makes the alternative of using chemotherapeutic agents an attractive proposition. Hydroxychloroquine (HCQ), a repurposed antimalarial drug, was empirically recommended as prophylaxis by the National Covid-19 Task Force in India for health care worker.^[10] Every Healthcare worker had his/her electro cardiogram and fundus examination done. They received hydroxychloroquine tablets if reports were normal. Standard dose of 400 mg BD was given on first day and then 400 mg was given once weekly for 4 weeks. All healthcare workers were observed for any adverse effects of hydroxychloroquine. Detailed medical record of every healthcare worker was obtained.

8. THERMAL SCREENING:

Every hospital healthcare worker entering the hospital premises was subjected to mandatory thermal

screening. Temperature was screened twice daily and those who were found to have abnormal values were screened for symptoms of COVID 19. Abnormal temperature was recorded and the healthcare worker was quarantined and closely monitored for symptoms associated with fever. If necessary, nasopharyngeal swab was sent for qRT PCR SARS-CoV-2. Close contact of suspected candidate was also closely monitored and relevant investigations were also done.

9. SATURATION MONITORING:

All HCWs were subjected to mandatory saturation monitoring at various check points. Any abnormal valve was recorded and necessary measures were taken for safety of HCW by core team.

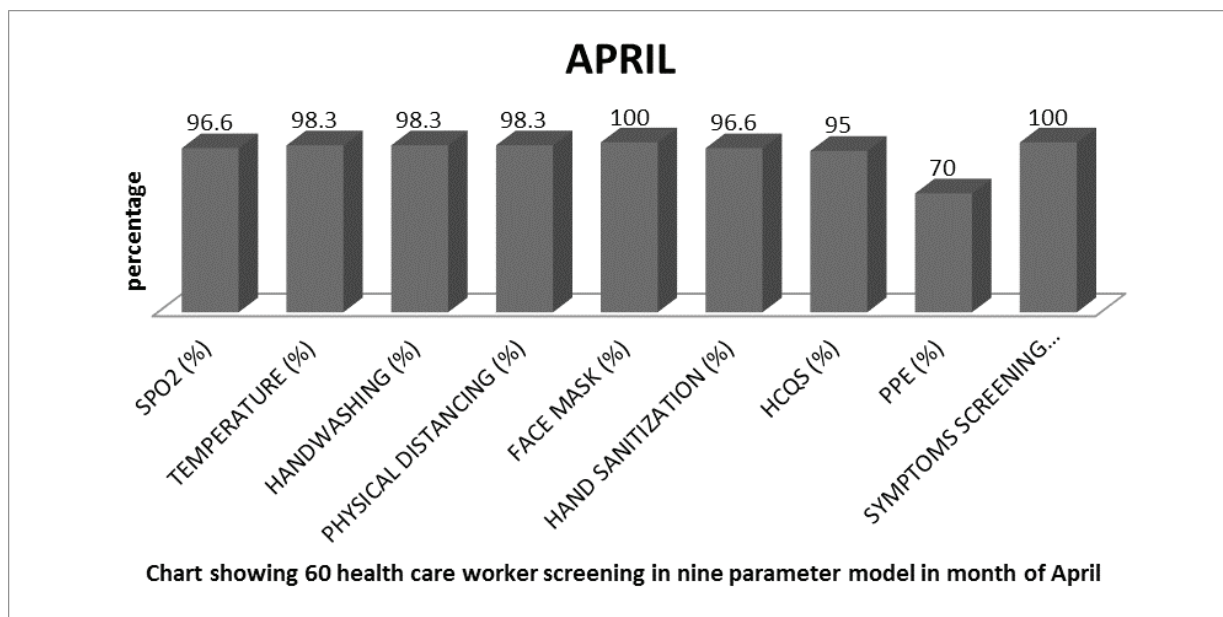
Results

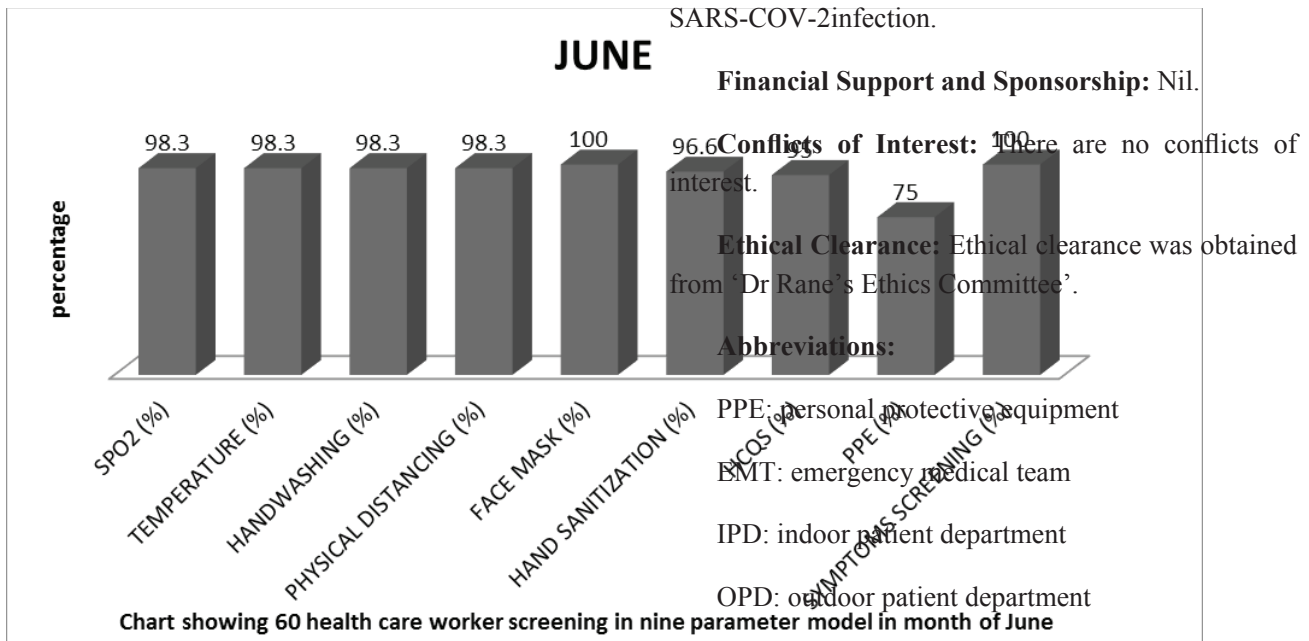
58, 59, 59 HCWs had saturation within normal range in April, May and June respectively. 59, 59, 59 HCWs had body temperature within normal range in April, May and June respectively. 59, 59, 59 HCWs followed the hand washing protocols in April, May and June respectively. 59, 59, 59 HCWs followed social distancing norms in April, May and June respectively. All 60 HCWs always wore masks during working hours in hospital from April to June. 58, 59, 58 HCWs followed hospital policy of hand sanitization in April, May and June respectively. 57 HCWs received HCQS prophylaxis. 42, 41 and 45 HCWs required PPE kits during working hours in hospital. Team leaders observed that all the internal check points had their all protocols ready and ensured that there was no breach of protocol or any shortcomings in the process. Any shortcoming was informed to the core team member on priority basis. The importance of preventing spread of SARS-CoV-2 lies in avoiding being 'source' and it was ensured at every step to break chain of transmission. Table 1 shows that Nine parameter model is a simple and effective method not only to prevent but also to early detect the presence of

SARS-CoV-2infection.

Table 1 showing 60 HCW screening for ‘nine parameter model’ from April to June 2020.

MONTH	HCW SCREENED	SPO2 (%)	TEMPERATURE (%)	HANDWASHING (%)	PHYSICAL DISTANCING (%)	FACE MASK (%)	HAND SANITIZATION (%)	HCQS (%)	PPE (%)	SYMPTOMS SCREENING (%)
APRIL	60	96.6	98.3	98.3	98.3	100	96.6	95	70	100
MAY	60	98.3	98.3	98.3	98.3	100	98.3	95	68.3	100
JUNE	60	98.3	98.3	98.3	98.3	100	96.6	95	75	100





Conclusion

SARS-COV-2 is a highly contagious virus. Given the rapid rate of spread as seen in current outbreaks in Europe and USA, we need to be aware of the difficulty of controlling SARSCoV-2 once it establishes sustained human-to-human transmission in a new population. Hence all efforts should be directed to prevent spread of SARS-CoV-2 transmission. The importance of preventing spread of SARS-CoV-2 lies in avoiding being ‘source’ and it can be effectively implemented at every step to break chain of transmission. Screening of symptoms and also ‘Nine parameter model’ is a highly effective method to prevent spread to disease. Core team should be formed and team leaders should ensure that protocols of every department is followed which can lead to highly safe and ambient environment for health care workers, patient and relatives. It can be further inferred that symptoms screening for lung infection, saturation monitoring, thermal screening, hand washing, physical distancing, face mask, hand sanitization, HCQS prophylaxis, personal protective equipment’s were all equally important and none of the method can be deemed inferior to other. It can be concluded that every step of contact point, likewise, reception, pharmacy, emergency, isolation, IPD, OPD, 2D echocardiography department, rehabilitation department, catheter laboratory, operation theatre complex, biomedical waste management can have set protocols so as to prevent spread of SARS-COV-2 infection and such measures are highly effective and can be followed to break chain of transmission of

SARS-COV-2infection.
Financial Support and Sponsorship: Nil.
Conflicts of Interest: There are no conflicts of interest.
Ethical Clearance: Ethical clearance was obtained from ‘Dr Rane’s Ethics Committee’.
Abbreviations:
 PPE: personal protective equipment
 EMT: emergency medical team
 IPD: indoor patient department
 OPD: outdoor patient department
 TEE: trans oesophageal echocardiography
 TTE: trans thoracic echocardiography
 HCW: health care worker
 ICU: intensive care unit
 ER: emergency room
 Covid 19: corona virus disease 2019
 CTF : Common Treatment Facility
 BMW: bio medical waste
 SARS-CoV-2: severe acute respiratory syndrome coronavirus 2

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Breakup among Medical Students: Aftermath and Resumption

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Abstract

Breakup is a metaphor for intense emotional and most distressing events in which one feels at experiencing great & deep longing. The person is broken into pieces, reaches rock bottom & may go in the very depressed state of life. To overcome this feeling, one may indulge in positive or negative activities. A person may have the extreme emotional energy, be it jealousy, depression, insecurity, stress, or anxiety, which needs to come out. This study was done with objectives of assessing the frequency and pattern of a breakup, change in Physical, Mental, Social & Spiritual Health concerning breakup and compare the change in productivity immediately after a breakup and 8 weeks (2months) after breakup.

Materials and Methods: This was a cross-sectional study done among 378 MBBS students in a medical college of North India. A pre structured, pretested, pre-validated, and close-ended questionnaire was used in the study

Results: In our study, 104(27.5%) of medical students experienced a breakup in their life. Among 104(27.5%) who experienced a breakup, 52(50%) were males and 52(50%) were females. Various emotional experiences of students during the breakup were being depressed, stressed, sense of relief, and neutral. Spiritual practice was found to be effective in overcoming the emotional stress of breakup and increased post-breakup productivity. Indulgence in hobbies and health care activities were commonest activities done just after a breakup to overcome it.

Conclusion: Breakups are common among medical students, spiritual orientation and involvement in hobbies help students to overcome breakup stress and increase their productivity hence in medical education there should be a special place for spiritual orientation.

Keywords: Relationship breakup, Medical students, stress

Introduction

A relationship breakup often referred to simply as a breakup, is the termination of an intimate relationship by any means other than death^[1]. The term Breakup is less

likely to be applied to a married couple, where a breakup is typically called a separation or divorce. John H. Harvey, Perspectives on Loss (1998) has argued that the dissolution of dating and cohabiting relationships can be as painful as or more painful than divorce because these non-marital relationships are less socially recognized.^[2]

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Several psychological models have been proposed according to which 'relationship dissolution occurs in stages'. Lee L. (1984) reported that there are five stages ultimately leading up to a breakup^[3]. Dissatisfaction, one or both partners grow dissatisfied with the relationship. Exposure, both partners mutually become aware of problems in the relationship. Negotiation, both partners

attempt to negotiate solutions to problems. Resolution and transformation, both partners apply the outcome of their negotiation. Termination, proposed resolution fails to rectify issues and no further solutions are accepted or applied. According to Steve Duck (2011), there is a six-stage cycle of a breakup [4]. Dissatisfaction, Social withdrawal, Discussion of reasons for discontentment, Going public, Tidying up of memories, Recreating, Sense of social value.

A Sociologist Diane Vaughan proposed that there exists a “turning point” in the dynamics of a breakup – ‘a precise moment when they “knew the relationship was over”, “everything went dead inside” – followed by a transition period where one partner holds onto the relationship despite knowing that the relationship’s end is near.’ [5]

Evidence shows that even in the direst of situations, there is scope for growth and positive emotions. Breakups are no different, giving individuals opportunities for stress-related growth, improving their future relationships, and providing feelings of relief and freedom. [6]

Research demonstrates breakups are highly representative of a stressful situation, many individuals experience them several times throughout their lives and have been known to self-report instances of growth because of the experience. [7]

Research has also shown that there have been cases where individuals that have been victims of a breakup recognize that their past relationship was sub-optimal, which allows them to display the same emotions of relief, freedom, and happiness. [8]

Individuals post-breakup are likely to experience several different positive and negative effects, this can manifest in varying degrees in different individuals. Several mitigating factors minimize or amplify the extent to which one feels the consequences of a breakup. [9]

Chung, M.C. et al. (2002) explained that while negative symptoms observed may not necessarily fit the definitions of post-traumatic stress as described by the DSM-IV from the American Psychiatric Association, certain symptoms mirror those from disasters and

traumatic events in a person’s life. However, not all individuals experience the same impact post-breakup because of variable mitigating factors based on the quality of the relationship before the dissolution takes place.

Individuals who had just recently experienced the dissolution of a romantic relationship reported symptoms of acute psychological distress like a flashback and intrusive memories associated with their partner, avoidance behavior, emotional distress, an attempt at denying or ignoring the circumstances of the current situation, or those that led to the dissolution of the relationship. Overall, these psychological distress symptoms resulted in a lower level of self-esteem among individuals. [10]

Additionally, individuals undergo a significant redefinition of their self-concept with attempts to understand themselves without their ex-partner. This compounds upon the psychological distress symptoms that they feel from the loss of the relationship and is the most significant negative effect that people undergoing a breakup experience. [11]

Individuals undergoing a breakup display grief reactions that include symptoms like sleeplessness, depression, and suicidal thoughts. The tendency to express grief and depression is highly prevalent such that researchers believe it to be a significant contributor to the first onset of major depressive disorder in young adults. Individuals suffering through a breakup also report a general decline in their psychological well-being. This negative emotion triggers their behavior and habits that are either detrimental to their mental health or signify poor mental health conditions. These include increased alcohol use, weight loss, worsening physical health, psychiatric help, increased criminal behavior, increased risk of suicide, and negative emotions.

Maintaining unwanted contact from another is stalking. This behavior stems from unhappiness with circumstances following the dissolution of the relationship, as well as a misguided belief that the stalking behavior may result in the reforming of the relationship. [12]

The Present study was done among medical students to assess the prevalence of breakup and its determinants

and to develop a supporting mechanism for any student undergoing breakup trauma.

Committee. Microsoft Excel was used for analysis.

Materials and Methods

This was a cross-sectional study done on 378 MBBS students in a college in North India. A pre-structured, pretested, pre-validated, and close-ended questionnaire was used. Inclusion criteria were students who were available on the day of study and were willing to participate in the study. Exclusion criteria were students who were not willing to participate in the study. Due consent was taken before participation in the study. The study was approved by the Institutional Ethical

Results

This study was done among 378 medical students in North India. Out of them, 202 (53.4%) were males and 176(46.65%) were females. 104 (27.5%) experienced a breakup in their life, 112 (29.6%) were never in a relationship and 162 (42.9%) were in a relationship and never experienced a breakup.

Among 104 who experienced a breakup, 52(50%) were males and 52(50%) were females. Table 1 tabulates experiences of student’s post-breakup period

Table.1- Various experiences during breakup.

Sr no	Parameter	Males(n=52)	Females(n=52)
1	It was my decision to do breakup	33(63.5%)	40(76.9%)
2	First shared breakup with friends	28(53.8%)	21(40.3%)
3	First shared breakup with family	13(25%)	08(15.3%)
4	Didn’t share news of breakup with anyone	11(21.1%)	23(44.2%)
5	Friends helped to overcome breakup stress	46(88.4%)	37(71.1%)
6	Relation with friends became closer after breakup	41(78.8%)	44(84.6%)
7	Efforts to reconnect with old friends/colleague	23(44.2%)	21(40.3%)
8	family helped to overcome breakup stress	43(82.6%)	39(75%)
9	Relation with family became closer after breakup	47(90.3%)	38(73%)
10	Realize that There is a Significant role of relationships in life	49(94.2%)	47(90.3%)
11	Increased amount of time given to hobbies	43(82.6%)	49(94.2%)
12	Inclination towards healthy eating and/or exercise	30(57.6%)	24(46.1%)
13	Increase in determination towards your work and career	38(73%)	44(84.6%)
14	Increased productivity post breakup	32(61.5%)	39(75%)
15	Desire to look more attractive after breakup	38(73%)	29(55.7%)
16	Still followed by the thoughts of ex-partner	47(90.3%)	26(50%)
17	Thinking about a new relationship	42(80.7%)	32(61.5%)

Table 2- Effect of Spiritual practice on overcoming breakup stress.

	Males(n=52)			Females(n=52)		
Believed and practice spirituality in life (Before breakup)	(26)50%			(26)50%		
Spiritual belief was intact during breakup stress	Yes 13 (50%)	No 8 (30.7%)	On and off 5 (19.2%)	Yes 18(69.2%)	No 1(33.8%)	On and off 7(26.9%)
Spiritual practice helped to overcome stress	Yes 17(65.3)	No 9(34.6%)		Yes 24(92.3%)	No 2(7.7%)	

Table 3 shows the impact of spirituality on post-breakup productivity and it was found that those who practiced spirituality during the period of the breakup had higher post-breakup productivity which was statistically significant too.

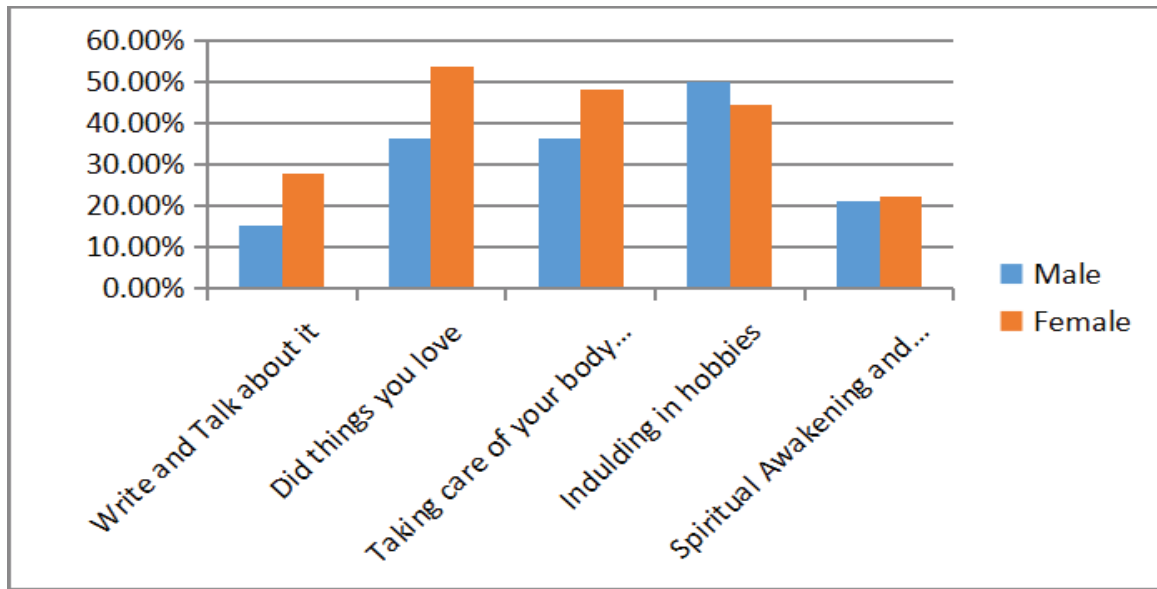
Table 3- Effect of spiritual orientation on productivity post breakup.

		Productivity post breakup		Total
		good	bad	
Spiritually orientation	yes	41	11	52
	no	30	22	52
Total		71	33	104
*P value=0.03,Chi square value=5.37				

Table 4 highlights a statistically significant improvement or inclination towards positive feelings in individuals 8 weeks after the breakup.

Table 4- Feelings after the breakup (multiple options selected)

Emotion experienced	males		females	
	Just after breakup	8 weeks after breakup	Just after breakup	8 weeks after breakup
depressed	18	7	26	12
stressed	20	4	18	8
Sense of relief	14	21	19	28
suicidal	3	1	5	0
Neutral	12	24	5	17
Other	2	3	0	3
Chi square-21.6, p=0.0001			Chi square-24.3, p=0.0001	



Graph 1 shows the activities performed to cope up with post-breakup stress.

Discussion

Human relations cannot be compartmentalized so naturally, a romantic relationship enmeshes various aspects in one’s life. Thus, its dissolution has a diverse impact. One of the objectives of this study was to identify the impact of a breakup on Physical, Mental, Social & Spiritual Health

We observed a higher inclination towards distress symptoms like depression, accompanied by a feeling of betrayal and rejection, anxiety, intrusive thoughts about the ex-partner, and sleep disturbances findings were in coherence with a study conducted by Anne M. Verhallen [13]

Field T, Diego M, et al in 2011 also observed similar results explaining how depression, feeling of betrayal, and time is important contributors to distress and can result in an increased risk of development of depressive episode. [14]

Najib A, et al. 2004 also observed that brain activity changes during acute grief. [15] Signifying that breakup is an emotionally upsetting event.

Kendler et al found that both heredity and occurrence of stressful events contributed to the onset of depressive episodes independently. Their epidemiological data indicated an association between the occurrence of a breakup and the first onset of major depression in a young

population [16] Hence, research focusing on stressful and upsetting events provides insights into stress-related coping and the link between stress and depression. Our study demonstrates the effect of spiritual practice in overcoming breakup stress. Amongst the various coping mechanisms studied, spirituality also had some impact on overcoming stress and improving productivity, which is also statistically significant. Similar results were seen in the study The Roles of Spirituality and Sexuality in Response to Romantic Breakup, conducted by Hawley, Anna R. [17]

Also, in the paper Spirituality and Humility, written by Barnaby Lin, it is suggested that spirituality positively impacts well-being and can be helpful in situations of stress, or in this case, romantic breakup. [18]

In our study, we also tried finding differences in depression symptoms between the genders. Data from a United States survey revealed a 1.7 times higher lifetime prevalence of depressive episodes among women. [19] Our study reflects a difference in stress sensitivity between the genders. Similarly, Lin Y elucidates different stress responses between males and females rodents. [20]

Nolen-Hoeksema also explores an association between gender differences and rumination. It is known that women tend to ruminate more during periods of stress. [21]

To compare the change in productivity immediately and 8 weeks after the breakup we found that after 8 weeks students recovered significantly from breakup stress. This finding suggests that students were able to recover from breakup blues after some time but immediately after the breakup they need support to pass through it.

Conclusion: Breakups are common among medical students, spiritual orientation and involvement in hobbies help students to overcome breakup stress and increase their productivity hence in medical education there should be a special place for spiritual orientation.

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Ethical approval- Taken from institutional ethical committee.

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Prevalance of Overweight and Obesity among School Going Children in India - A Narrative Review of Literature

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Abstract

Back ground: Childhood obesity is a common concern to all developed and developing countries. Most of the children who are obese continue to be obese in adulthood. With the increasing rates of non communicable disease striking the general population one of the most common culprits who out stand as a contributing factor is obesity.

Methods: A review of literature on prevalence of childhood obesity in India from 2015 January to 2019 December was done using different database strategies such as Google scholar and Pub med.

Results: The study findings show in summary the prevalence of obesity in different parts of country. However studies are heterogeneous and hence pooled data was not obtained. Further almost all studies identified were school based and age group kept varying in between 5-19 years.

Conclusions: The prevalence of overweight and obesity showed an increasing trend in India in comparison to data collected before 2010 and after 2010.

Key words: *Overweight, Obesity , Child hood Obesity ,Prevalence , BMI Standards.*

Introduction

Obesity is a public health problem and is a growing epidemic concern. The increased prevalence of obesity has a direct effect on health care expenditure. Despite increasing attention to the health and economic effects of obesity the prevalence continues. Further the prevalence of obesity & overweight varies in different states of India. Hence it is difficult to generalize the national scenario .Obesity as such if grows significantly in Indian population it would drain our health care resources.

Aim of the Review: This review identifies the published prevalence studies done in different parts of India from 2015 to 2019 .Literature search was done using Google Scholar & Pub Med using the search terms

childhood obesity, overweight, prevalence BMI and school children.

Objectives of the Review: To examine and review related published studies and other articles regarding prevalence of overweight and obesity among school children in 5-19 years age group done in different states of India.

Methods and Materials

Search Process: Here both descriptive and quantitative approach were used .Potentially relevant review of studies published from 2015 to 2019 which reported on prevalence of childhood over weight and obesity in the age group of 5 to 19 years in different parts of India using a systematic approach were selected by screening the titles and screening the abstracts . Initially the search revealed related titles or abstracts after which full texts were retrieved for papers in which abstracts mentioned the search terms. Literature search was done using different strategies such as Google scholar and Pub

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med using following search term for childhood obesity, school children, overweight, prevalence. There was no attempt made to locate unpublished studies. Data related to age group or class of students, place of study done, period of data collection done, setting, design, sample and sampling method, and important significant findings were extracted.

Eligibility criteria:

The studies were critically reviewed based on the eligibility criteria. All reported findings were directly taken from the primary reported studies.

Inclusion criteria:

Cross sectional studies that were conducted in last five years January 2015 till December 2019. Results that reported with both overweight and Obesity findings were included. Studies related to prevalence of overweight and obesity among 5-19 years old school children. Studies that mentioned standard definitions of overweight and obesity. Literature published in English language were only included. Studies which mentioned the period of data collection and all data that were collected in the period January 2015 to December 2019 were only included.

Data abstraction:

Based on eligibility criteria the studies were evaluated. Out of the search results only specific and relevant studies were included. Out of total 26 studies only 18 were included. Few studies published after 2015 but data collection were done before 2010 were not considered.

Data Analysis

A preliminary analysis were done by tabulating the data as Author, Year of study, Region and setting Age group/ class of study, standards defining overweight & obesity, setting and design, prevalence of overweight, prevalence of obesity.

The findings are summarized as follows:

A cross sectional study was done in Telangana, Hyderabad among students of Class 4-10, were screened on the day of data collection in January 2018. The BMI was estimated using IAP & CDC standards. Out

of 544 students 15.4% were obese while 26.1% were overweight. Girls were more obese than boys while obesity was found to be highest in 8-10 year age group¹.

A school based cross sectional study was done in Ludhiana, Punjab among 1959 students by using simple random sampling strategy for schools while stratified sampling study was done for students in the age group of 11-17 year old. Data collection was done in March 2016-July 2017. Using IAP classification, 2.7% were found to be obese in rural area while 11% were obese in urban area. Boys were more overweight & obese than girls².

In a school based cross sectional study done among 5-16 years old children in rural Bangalore present on the day of survey during August –December 2017 among 1127 students the overall prevalence of overweight and obesity were 7.09% and 4.08%. Girls were more obese and overweight than boys and in 11-16 years age group 6.8% & 10% children were found to be obese & overweight³.

In a cross sectional study done in Udipi, Karnataka, using stratified cluster random sampling among 1185 students from 9 schools studying in Class 8-10 students during March –Aug 2012, it was found that 11.0% of males were overweight & 7.1% were obese while 10.6% were overweight & 5.4% were obese⁴.

A cross sectional, observational study was conducted in both rural & urban private schools among 188 subjects in 10-18 Years age group in Vadodara, Gujarat. The data collection was done from September to November 2016. The study findings showed 17.6% were obese while 20.2% were overweight. Similarly 65.22% urban boys & 62.26% girls were obese or overweight compared to 15.78% of rural boys & 3.92% were girls⁵.

A cross-sectional study was done among both government & private schools in Udaipur, Rajasthan among 12-15 yrs children studying in class 8th to 10th during July 2014 to January 2015. Simple random sampling was done among 1000 study subjects. Using BMI standard methods over weight was found to be 8.20% and obesity was found to be 2.40%. High prevalence (14%) was seen in private schools while 7.20% prevalence was seen in Government schools. Prevalence of overweight & obesity was reported higher

among girls (12.60) % than boys (8.60%)⁶.

In a comparative cross-sectional school study done among 2 govt & 2 private schools from Class VI to X, in Sambalapur ,Odisha during December 2016 to April 2017 using systematic sampling method among 600 school children was found with overweight 8.9% & obesity was found to be 3.4% with an overall prevalence of 12.3%. Further obesity was found more in private schools and the study used WHO Child Growth reference was used.⁷

A descriptive cross sectional study done among 600 high school students in 13-16 years at Urban Shimoga, Karnataka during July 2015-September 2015 using WHO Child Growth reference. Overweight was found to be 7.67% and Obesity was found to be 5.83%⁸.

A school based study using stratified multistage random sampling method among 300 school going children in 10-12 year old during 2012-13, in Sambalpur ,Odisha. The study used IOTF Standards where overweight was found to be 6.3% & obesity to be 3.3%. Boys were 5.6% overweight & 3.4% obese while 7.4% girls were overweight while 3.3% were obese⁹.

A cross sectional school based study was done in 3 private English medium schools using simple random sampling among 150 students in 12-17 year age group studying in class 8th, 9th & 10th in Nagpur, Maharashtra during May 16-December 2016. Using WHO BMI classification for children 2007, 12% of students were overweight and 2% were obese¹⁰.

In a cross sectional school based study done in Pondicherry ,South India among 2465 students from 5 schools in 10-18 yrs age group during June 2014 to December 2014 using IAP age and gender specific body mass index. The prevalence of overweight & obesity were high among students who belonged to private schools of urban region (14.8%) There was no significant difference among both boys & girls. Overall overweight was found to be 9.7% while obesity was found to be 4.3%. Overall prevalence of overweight & obesity among early adolescents (10-15 yrs) was 12.3%¹¹.

In a cross sectional school based study done in

December 2014-January 2015 in private & government schools of students studying in Class 5th to 10th, 1828 students were screened from 4 schools in South Mumbai and it was found that overweight was 17.5% and obesity to be 7.8%. There was significant difference seen among boys & girls .Khadilkar criteria & Cole et al was used to describe the BMI¹².

In a school based cross sectional study among 2465 students from 5 schools in Pondicherry ,South India conducted in June 2014 to December 2014, it was found that the prevalence of overweight & obesity were high among students who belonged to private schools of urban region (14.8%) There was no significant difference among both boys & girls. Overweight was found to be 9.7% while obesity was found to be 4.3%. Overall prevalence of overweight & Obesity among early adolescents (10-15 yrs) was 12.3%. IAP age and gender specific body mass index was used to describe the BMI¹³.

In a school based cross-sectional study using multistage simple random sampling done among 4560 students of 12-19 years studying in class 9-12. The data collection was done in July 2012-June 2014 of both govt and pvt schools. Overall prevalence of overweight was found to be 5.6% & obesity was found to be 1.0%. In private schools it was found to be 63.3% & 58.7% while in government schools it was found to be 36.7% & 41.3%¹⁴.

In an observational cross-sectional school based study done among 6-17 year old children in Dehradun, Uttarakhand, among 1266 students from 13 government and private schools The data collection was done during June 2013 –May 2014 . The BMI for age z-score cutoffs WHO Anthro plus was used. Overall prevalence of overweight was found to be 15.6% and obesity was found to be 5.4%. Overweight in urban private school was found to be 32.7% and in rural private school was found to be 22.4%¹⁵.

In a cross sectional school based study using random selection of schools, 60 students from 2 schools of 10-19 years were selected for data collection during Jan-March 2015 in Guwahati. Using WHO criteria, the prevalence of overweight & obesity was found as 13.3% & 1.7% while using Agarwal BMI standards it was 6.7% & 10%. Obesity was higher among students from private school,

boys & nuclear families¹⁶.

In Kanpur, a school based cross sectional ,multistage random sampling was done among 806 subjects in 12-15year age group. Data collection was done in September 2013-August 2014 Using CDC-BMI Cut off point the prevalence of obesity & overweight was found to be 3.97% & 9.70%¹⁷.

An observational cross sectional study was conducted among 10-18 year old children studying in Class VI-XII in Delhi . The data collection was done in July 2013 –June 2014 using BMI Standard methods . Prevalence of overweight was found to be 11.8% & Obesity was 7.5%. Overweight was maximum seen in 11 yr old with 20.1% & minimum in 17 yr old as 5.3%. Similiarly obesity was maximum in 18yr old with 15% & minimum in 15 yr old with 3.2%.Moreover males were both overweight & obese than female¹⁸.

Strength and limitation on review.

The study is limited only to articles reported in the published search data bases The review collects details from various states of India to present the overall scenario. Unpublished studies were not included and there are chances that the results may be affected by publication bias. In addition to that the author may have missed studies that are not listed in the databases or referenced in any other published studies or reviews.

The strength of the systematic review is that it has covered findings from most of the states from India and are recent data to correlate the present existing figures. Further the author has made an attempt only to include those published studies that mention data collection done after 2010 .

Conclusion

Overweight and Obesity among school children is in increasing trend. The study concludes that awareness among parents have to be created and they have to be encouraged to educate and adapt healthy life practices in children The school authorities also have to establish practices to support healthy behavior among children. Further physical activity classes can be included in syllabus making it mandatory for all schools to follow.

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Primary Prevention of Type 2 Diabetes Mellitus: Multiple Health Care Strategies

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Abstract

Kerala being the diabetic capital of India, need to evolve a less expensive method to reduce the tangible and intangible cost of type 2 diabetes mellitus (T2DM). Hospital based single blinded randomised controlled trial was undertaken at Indian Institute of diabetes, Kerala, India with an aim to assess the effect of multilateral health care strategies on metabolic profile. Pre-diabetic individuals were screened using American Diabetic Association criteria and randomly allocated to experimental and control group. Experimental group received 3 weeks training in yoga, exercise and healthy diet preparation. Control group received only health counselling alone on diabetes prevention. Subjects were followed up for one year. The multiple health strategies were planned based on evidences and successfully implemented to curtail the menace of DM in India. The present paper details the multiple health care strategies and methodology addressing the primary prevention of primary prevention of T2DM.

Key words: pre-diabetes, metabolic profile, life style modification, yoga

Introduction

Diabetes is a metabolic disease demonstrated by hyper glycaemia resulting from defective insulin secretion, insulin action, or both. This hyper glycaemia is often associated with long-term complications of vital organs like eyes, kidneys, nerves, heart, and blood vessels.¹ The World Health Organization and International Diabetes Federation estimated that 246 million people in 2007 had diabetes, with numbers increasing to 380 million by 2025. ^(2, 3) 79% of adults with diabetes are living in low- and middle-income countries. ⁽⁴⁾

India has 69.1 million people with DM and is estimated to have the second highest number of cases of DM in the world.⁽⁵⁾ The diabetic capital of India is

Kerala. Overall prevalence of type 2 diabetes in an urban district of Kerala was 16.3%. In the 30-64 age group, age standardised prevalence was 13.7%. ^(6, 7) Delaying the onset of the disease in high-risk individuals is urgently needed. ⁽⁸⁾ Large randomised controlled trials (RCTs) from the USA, ⁽⁹⁾ China, ⁽¹⁰⁾ Finland, ⁽¹¹⁾, India ⁽¹²⁾ and Japan ⁽¹³⁾ have now demonstrated that lifestyle interventions can prevent T2DM by up to 60% among individuals with pre-diabetes. The present study utilised multiple health care strategies to combat this disease which has multiple aetiologies.

The present paper mainly illustrates the multiple health care strategies and methodology used in the study which aimed to assess the effect of these strategies to prevent the incidence of type 2 diabetes mellitus.

Methodology

Study Setting

The setting was, Indian Institute of diabetes (IID), Pulayanarkotta, Thiruvananthapuram, Kerala.

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Study design

A hospital based cross sectional survey was conducted for detecting pre diabetics in phase 1. Phase 2 of the study was single blinded randomised controlled clinical trial (RCT) among in subjects who were diagnosed as pre-diabetes according to the American Diabetes Association (ADA) criteria i.e. Fasting blood glucose (FBS) 100 mg/dl to 125 mg/dl and or Oral glucose tolerance test (OGTT) 140 mg/dl to 199 mg/dl.: Group 1(control group) subjects were given standard health care counselling on diabetes prevention, Group 2 (experimental group) subjects followed multilateral health care strategies which included yoga, exercises and dietary modifications based on 3 weeks training given from the Institute. The sample size was 130 in each group after accounting for a type 1 error of 5%, 80% power, and allowing a dropout rate of 10%. Using block randomisation, a total of 65 blocks were created using a 1:1 allocation ratio.

Data collection

Following human ethical clearance, the subjects were invited for the screening for pre diabetes. The subjects were informed about the study and base line information was collected from those who consented for the study subjects were randomised into the experimental group and control group randomly using block randomisation.. Subjects in experimental group received the group-based training for 3 weeks on multilateral health care strategies for the prevention of diabetes mellitus and the control group received only the routine counselling . Both groups were followed up for one year. Every 6 months, subjects in both groups were called for (metabolic profile, anthropometric, knowledge, psychological stress and quality of life assessment. The internal safety committee monitored the quality of the study monthly.

Result

8610 subjects attended the screening. Pre-diabetes was detected among 677 subjects (7.86 %). The socio demographic characteristics of pre diabetics are outlined in Table 1. 32.3% and 35.4% of pre-diabetics belonged to the age group of 45 -49 years in the experimental and the control group respectively, 66.2% of the experimental and 69.2% of the control group were females (Table 1).

Prevalence of diabetes and pre-diabetes

Pre-diabetes was detected among 677 subjects (7.86 %). There were 1740 (20.20 %) old diabetic patients and 185(2.14%) were newly detected diabetics.

1. Multilateral health care strategies

Refers to the training on yoga, exercises, and healthy dietary preparation given to the pre diabetic individuals

Yoga training

They were taught a sequence of asanas and pranayamas for stress reduction which is selected from Patanjali Yoga sutras for 5 days. The asanas and pranayamas taught were depicted in Table 2

Exercise training

Training based on WHO recommendation which was 150 minutes of moderate-intensity aerobic physical activity throughout the week or 75 minutes of vigorous-intensity aerobic physical activity throughout the week or an equivalent combination of moderate - and vigorous-intensity activity. All subjects underwent a 12 lead ECG and blood pressure was recorded to exclude any cardiac abnormalities prior to the training.

Menu preparation

Menu preparation based on recommended daily allowances for Indians (National Institute of Nutrition, India). Table 3 describes the daily caloric requirement of Indian adults .

2. Effect

Refers to the outcome of multilateral health care strategies on metabolic profile among pre diabetics

3. Pre diabetics

Refers to subjects with fasting blood sugar level 100 – 125 mg/ dl (5.6 to 7.0 mmol/L) or 2 hour OGTT value of 140- 199 mg/ dl (7.8 to 11.1mmol / L)

4. Metabolic profile

Refers to the biochemical parameters like fasting blood sugar, oral glucose tolerance, Hb A1C, serum total cholesterol, high density lipoprotein, low density lipoprotein and very low density lipoprotein .

Fasting capillary blood glucose (CBG) was determined using a One Touch Ultra glucose meter (Johnson & Johnson, Milpitas, CA, USA). Oral glucose test was done after the administration of 75 g of anhydrous glucose and a 2 h post load blood glucose assessment. The centre had fully equipped ISO and NABH certified laboratory where the equipment's are calibrated on a regular basis.

5. Anthropometric measurements

Measurement included in the study were body mass index (BMI) and waist hip ratio (WHR)

Body mass index (BMI).

By following WHO standard protocol,⁽¹⁴⁾ height was measured in meter (using SECA 213 standalone stadiometer), weight in kilogram (using SECA 813 Electronic flat weighing scale).

Waist-to-Hip Ratio (WHR)

Waist circumference was measured using a SECA constant tension tape to the nearest 0.1 cm. Anthropometric measures were defined as per Asian Indian cut offs ⁽¹⁵⁾

Data collection instrument

Tool I: Interview schedule

The interview schedule consist of 2 sections

Section 1 – Socio demographic data

Section 2 – Clinical data

Tool II : Questionnaire to assess the knowledge in relation to the prevention of type 2 DM

Tool III : General physical activity questionnaire

(WHO)

Tool IV : General stress index scale

Tool V : Quality of life scale (WHO QOL BREF-26)

Tool VI : Glucometer, auto analyser for biochemical assay, weighing machine, inch tape

for anthropometric assessment

Description of adapted tools

1. Translated version of General physical activity questionnaire (WHO)

GPAQ which comprised 19 questions about physical activity performed in a typical or usual week. ⁽¹⁶⁾The GPAQ measure asked about the frequency (days) and time (minutes/hours) spent doing moderate- and vigorous-intensity physical activity in three domains: (i) work related physical activity (paid and unpaid including household chores), (ii) active commuting (walking and cycling), and (iii) discretionary leisure-time (recreation) physical activity.

2. General stress index scale

General Stress Index (GSI) was designed to measure the general stress of the patients as well as normal. ⁽¹⁷⁾ The test consists of 10 items aimed to measure the general stress.

3. Translated version of WHOQOL-BREF- 26

WHOQOL-BREF - 26 was translated to the local language, Malayalam in a cross sectional study in Kerala. ⁽¹⁸⁾

Table 1: Socio demographic characteristics of pre diabetics

Socio personal data	Experimental Group (N=130)		Control Group (N =130)		p-value
	N	%	N.	%	
Age					
35 - 39	26	20	21	16.2	
40 - 44	27	20.8	22	16.9	0.637
45 -49	42	32.3	46	35.4	
50 - 55	35	26.9	41	31.5	
Gender					
Male	44	33.8	40	30.8	0.596
Female	86	66.2	90	69.2	
Religion					
Hindu	82	63.1	87	66.9	0.542
Christian	20	15.4	14	10.8	
Muslim	28	21.5	29	22.3	

2 Details of yoga training

Pranayamas		Duration
1.	Anulom vilom	5 min
2.	Bhramari pranayama	5 min
3.	Pranav Pranayama	5 min
Asanas		
1.	Kaya Kriya	6- 10 min
2.	Uttana Shishosana	5 min
3.	Shavasana	10 min

Table 3: Details of the daily caloric requirement of Indian adults

Man		Energy requirement (k cal/ day)
1.	Sedentary work	2320
2.	Moderate work	2730
3.	Heavy work	3490
Woman		
1.	Sedentary work	1900
2.	Moderate work	2230
3.	Heavy work	2850

Discussion

Prediabetes is not only a clinical entity but also increases the risk for diabetes and cardiovascular disease (CVD).⁽¹⁹⁾

The primary outcome in this study was to assess the development of diabetes, diagnosed using ADA criteria.⁽²⁰⁾

Numerous clinical studies has provided evidence that a substantial number of individuals with prediabetes will develop into diabetes later accounting to an average annual risk approximating, 5–10% compare to below 1 % in normo glycaemic subjects.⁽²¹⁻²³⁾

This was a hospital-based cross sectional study done as phase 1 of an RCT (phase 2) which could provide a reasonably precise and reliable estimate of the prevalence of pre diabetes and newly diagnosed diabetes among persons who reported for screening in the centre.

Ours was the ever first study in Kerala that estimated the prevalence of pre-diabetes and newly detected diabetes in a hospital setting.

In the present study, we evolved, a methodology that curtail the multiple modifiable aetiologies to prevent the conversion of pre-diabetes to diabetes. Many prospective randomised controlled studies such as the Diabetes Prevention Program (DPP) in the USA (10), the Finnish Diabetes Prevention Study⁽¹²⁾ (DPS),

the Da Qing IGT and Diabetes Study in China.⁽¹¹⁾ have shown that lifestyle modification involving diet and enhanced physical activity helps to delay or prevent the progression of prediabetes to diabetes. Primary prevention is desirable in India which is facing an enormous burden from a high diabetic prevalence.⁽²³⁾

The Indian Diabetes Prevention (IDPP) study was an RCT over 3 years with 4 groups mainly control with standard advice, life style modification (LSM), metformin and with LSM and metformin. It was shown that the relative risk was 29 % with LSM, 20 % with metformin and 20 % with LSM and metformin.⁽¹²⁾

Chennai Urban Population Study used individual and population based intervention for increasing physical activity and the result revealed that proportion exercise in the residents increased from 14% to 59 %.⁽²³⁾

We used yoga as an intervention to reduce the psychological stress. Psychological stress mobilizes biological responses implicated in type 2 diabetes mellitus (T2DM), including the release of glucose and lipids into the circulation, inflammatory cytokine expression and increased blood pressure⁽²⁴⁾. Yoga mediate parasympathetic system to reduce the stress response thereby brings glycaemic control.^(25,26).Yoga decreases the need for oral hypo glycaemia medications, decreasing low density lipoproteins (LDL) and increasing HDL⁽²⁶⁾

Regular practice of yoga has been shown to be beneficial in reducing depression and anxiety and therefore may affect diabetes control. (27)

This was an ever first RCT in Kerala state incorporating multiple strategies to prevent type 2 diabetes mellitus. We sort a low-cost strategies after identifying at-risk individuals, followed by the implementation of group-based, inexpensive lifestyle interventions along with yoga.

The strength of our study was we could identify at risk population of diabetes that is pre-diabetes. Its inferred that, diabetes prevention programme should target and counsel those at high risk of diabetes development regarding reduction of stress, health diet and exercise.

Conclusion

The methodology adopted in the study was designed based on scientific evidences from previous epidemiological and clinical trials. The present study successfully combined modern medicine with yogic science for better prevention of type 2 DM.

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Awards

- Selected and nominated for the best paper award in 30 th Kerala Science Congress

- Got best paper award at the 15th International conference on publishing with impact at Sree Ramachandra Medical University, Chennai, India.

Conflict of Interest: None

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Ethical Clearance: Human Ethics Committee, Govt. Nursing College, Medical College Thiruvananthapuram, Kerala.

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Assessment of Urinary Complications and Drug Induced Effects in the Department of Urology in Tertiary Care Teaching Hospital

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Abstract

Urology: The branch of medicine and physiology concerned with the function and disorders of the urinary system. It deals with disease of the male and female urinary tract i.e., kidneys, ureters, bladder and urethra. It also deals with male organs such as penis; testes; scrotum; prostate. The Urinary system consists of two kidneys, two Ureters and one Urethra. **Urology Department:** A urologist is a physician who specializes in diseases of the urinary tract and the reproductive system. It has seven sub specialist areas: 1. Pediatric Urology 2. Urological Oncology 3. Renal Transplantations 4. Male infertility 5. Calculi 6. Female Urology 7. Neuro Urology.

Materials and Methods : Place of Study: The study “Assessment of Urinary Complications and Drug Induced Effects in Department of Urology in a Tertiary Care Teaching Hospital” which was carried in patient wards of “Urology Department” IP at Narayana Hospitals, Nellore, in collaboration with a 1440 bedded multidisciplinary teaching hospital.

Discussion: In our study, out of 510 patients 450 are willing to provide the information in which maximum are females 275(61.1%) and minimum were males 175(38.8%) **Conclusion:** Our study concluded that most of the people (or) patients in the urology department due to urinary complications were arised by using urology questionnaire and drug induced complaints are also estimated. Out of this the mainly some of the drugs are inducing urology problems in the patients. Some methods and surgical procedures are performed. It is cluster for the health care professionals and clinical pharmacist to reduce the patient in view of health condition in which, it is beneficial for the health outcome. Mostly, Clinical pharmacist should educate the patients regarding conditions and treatment to be effective.

Key words: Urinary Complications, hyperplasia, renal calculi, renal transplantation.

Introduction

Urology: The branch of medicine and physiology concerned with the function and disorders of the urinary system. It deals with disease of the male and female

urinary tract i.e., kidneys, ureters, bladder and urethra. [1,2] It also deals with male organs such as penis; testes; scrotum; prostate. The Urinary system consists of two kidneys, two Urethras and one Urethra [1]

Urology Department: A urologist is a physician who specializes in diseases of the urinary tract and the reproductive system. [3,4]

Assessment: It is the evaluation of the health status by performing a physical exam after taking a health

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history.

Complications: A secondary disease or a condition that develops in course of a primary disease or condition and arises either as a result of it or from independent causes.

Drug Induced Effect: The unintended effect of a drug that results in mortality or morbidity with symptoms sufficient to prompt a patient seek medical attention and to require hospitalization and may persist even after the offending drug has been withdrawn.^[4,5]

Tertiary care Hospital: It is a hospital that provides tertiary care from specialists in a large hospital after referral from primary care and secondary care.

Materials and methods

Place of Study: The study “Assessment of Urinary Complications and Drug Induced Effects in Department of Urology in a Tertiary Care Teaching Hospital” which was carried in patient wards of “Urology Department” IP at Narayana Hospitals, Nellore, in collaboration with a 1440 bedded multidisciplinary teaching hospital,

Study Design: The study was prospective observational study conducted in the inpatients ward of Urology Department of tertiary care teaching hospitals.

Study Population: This study was conducted in 450 patients who are suffering with Urological Complications and Drug Induced Effects in Department of Urology.

Study Duration: This study was conducted for a period of 6 months.

Study Criteria: Patients are considered for the study based on inclusion and exclusion criteria.

Inclusion Criteria:

1. All the patients suffering with different types of

Urological Complications and Drug Induced Effects in Department of Urology.

2. Patient age group in between 20 to above 60yrs.
3. Patients with co-morbid conditions.
4. Who are willing to provide the information?
5. Past history of renal problems.
6. Patient dependent upon medication.

Exclusion Criteria:

- Pregnancy women.
- Lactating women
- Lack of interest to provide information.
- Pediatrics.
- Whose verbal communication was poor.
- Unconscious patients.
- Mentally retarded patients.

Study Material:

- Patient informed consent form.
- A specially designed Urology questionnaire

STUDY METHOD: The study was conducted after obtaining the permission from Head of the institution and Head of Department of Urology.

The data for the study will be collected by “Patient Chart Review Method”, which is well suited to identify all the necessary and relevant baseline information, which will be collected on a specially designed patient data questionnaire on respiratory tract infections.

Results

Table-1 Shows Reasons for admission in the Department of Urology for their condition

Reasons for admission	No of Patients	Frequency
1. Blood in urine:		
a) Bladder infection	20	4.4%
b) Kidney infection	20	4.4%
c) kidney stones	140	31.1%
d) Bladder cancer	10	2.2%
e) kidney cancer	5	1.1%
g) prostate cancer	5	1.1%
2. poor bladder control	10	2.2%
3. Painful Urination:		
* Bladder stones	40	8.8%
* Chlamydia	5	1.1%
* Cystitis	5	1.1%
* STDS	5	1.1%
* Prostate Inflammation	5	1.1%
* Vaginal infection	15	3.3%
* Yeast Infection	5	1.1%
4. Pain in Lower stomach, side of back or groin region		
♦ Severe pain;	40	8.8%
♦ Moderate & mild	20	4.4%
♦ Nausea, Vomiting	15	3.3%
Fever		
5. Fallen Bladder Protrusion:		
1) Age:	5	1.1%
2) Obesity:	5	1.1%
3) Vaginal child birth	5	1.1%
4) Weakened muscles	0	0%
6. Hernia	0	0%
7. Male sexual problems	10	2.2%
8. Over active bladder	0	0%
	15	3.3%
9. HTN, DM	35	7.7%
10. other disease condition	5	1.1

Table-2 Shows Drug Induced Urinary complications in the patients of Urology department

Drug induced Urinary Complications	No of Patients	Frequency
1. Phenothiazine		
a.Perphenazine (Irifafon)	25	5.5%
b.Mesoridazine (Serentil)	20	4.4%
c.Promazine (Robinnl)	5	1.1%
2. Cyclophosphamide (Cytosan)	70	15.5%
3. Ifosfamide	10	2.2%
4. Cocaine	15	3.3%
5. Papaverine induced priapism	10	2.2%
1. Risperidone (Risperidol)	25	5.5%
2. Clozapine (Clozaril)	30	6.6%
3. Disopyramide (Norpace)	35	7.7%
4. Flecainide (Tambocor)	10	2.2%
5. Hyoscine Butyl Bromide (Buscopan)	15	3.3%
6. Amantidine (Symmentrel)	20	4.4%
Astemizole (Hismanal)	15	3.3%
7. Ipratropium (Atrovent)	15	3.3%
8. Fluoxetine (Prozac)	10	2.2%
9. Atropine (Atropen)	20	4.4%
10. Benztropine Mesylate (Cogentin)	15	3.3%
11. Fesoterodine (Toviaz)	10	2.2%
12. Clonazepam (Klonopin)	25	5.5%
13. Diazepam (Valium)	10	2.2%
14. Methylenedioxymetamphetamine (Ecstasy)	15	3.3%
15. Pramipexole (Mirapex ER)	10	2.2%
16. Morphine (Avinza)	15	3.3%

Table 3: Shows urinary complications in the patients of Urology department

Urinary Complications	No of Patients	Frequency
1.Acute kidney disease	20	4.4%
2.Chronic kidney disease	30	6.6%
3.Urinary incontinence	10	2.2%
4.Urolithiasis	40	8.8%
5.Kidney stones	140	31.1%
6.Urinary tract infections		
a. Cystitis	20	4.4%
b. Urethritis	10	2.2%
c. Pyelonephritis	5	1.1%
7. Prostatitis	10	2.2%
8. Vaginal Candidiasis	20	4.4%
9.Fallen bladder protrusion	5	1.1%
10.Over active bladder	10	2.2%
11.Fascia (Hernia)	10	2.2%
12.HTN, DM	35	7.7%
13.CKD with Palmar Psoriasis	5	1.1%
14.Atrophic Rt kidney with Endometrial polyp	5	1.1%
15.PUJ Obstruction With Congenital Hydronephrosis	10	2.2%
16.CKD -v stage with chronic alcoholism	5	1.1%
17.Distal Penile hypospadias	5	1.1%
Renal cell carcinoma/ Kidney cancer	5	1.1%
Obstructive Uropathy with Grade-II prostomegaly	5	1.1%
20.Bladder cancer	25	5.5%
21. Prostate cancer	5	1.1%
22. Congenital Urological Anomalies	10	2.2%
23.Bladder stones		

Table 4 Shows Drug used in Department of Urology for Better outcomes

Drugs for urinary complications	No of patients	Frequency
1.Tab.staphenex (Flucloxacillin)	100	22.2%
2.Tab.Rantac(Ranitidine)	250	55.5%
3.Tab. Calpol(Paracetamol)	375	83.3%
4.Tab.Chymorol forte(Multi vitamins)	275	61.1%
5.Tab.Cifran-TZ(Ciprofloxacin)	50	11.1%
6.Tab.Mucomix-ET(Acetyl cysteine)	75	16.6%
7.Tab.Rabium-DSR(Rabiprazole)	300	68.8%
8.Tab.Clopidab(Clopidogrel)	250	55.5%
9.Tab.Sevelamer(Sevelamer)	100	22.2%
10.Tab.Febugut(Febuxostat)	175	38.8%
11.Tab.Fexofenadine(Allegra)	100	22.2%
12.Tab.Reclide(Gliclazide)	200	44.4%
13.Inj.cefglobe(Cefoperazone &Sulbactam)	350	77.7%
14.Tab.Cilacar(Cilnidipine)	250	55.5%
15.Tab.Shelcal(Calcium carbonate and vitamin D2)	200	44.4%
16.Tab.Metrogyl(Metronidazole)		
17.Syrup.Cremafine(Magnesium hydroxide+Paraffin)	350	77.7%
18.Syrup.Reswal(chlorpheniramine malate)	125	27.7%
19.Tab.Amlong(Amlodipine)	50	11.1%
20.Tab.Sobosis(sodium bicarbonate)	250	55.5%
21.Tab.Veltam(Tamsulosin hydrochloride)	325	72.2%
22.Tab.Telma kind (Telmisartan)	60	13.3%
23.Inj.Tramadol(Ultram)	210	46.6%
24.Inj.Emeset(Ondansetron)	260	57.7%
25.Inj.Amikacin(Amikin)	275	61.1%
26.Syrup.Taxim(Cefotaxime)	310	68.8%
27.Syp.P125(Paracetamol)	220	48.85%
28.Syrup.Ibugeric plus (Ibuprofen)	75	16.6%
29.Tab.Faronem(Fraenum)	50	11.1%
30.Tab.Nicardia-R(Nicardipine)	65	14.4%
31.Tab.Voglistar(Voglibose)	175	38.8%
32.Tab.Supradyn(Multi vitamin)	200	44.4%
	175	38.8%

Table: 5 Shows Class of Drugs used in Department of Urology

Classes of drugs for urinary complications	No of patients	Frequency
1.Drugs with anti - cholinergic properties	20	4.4%
2.Alpha-adrenergic Blockers	5	1.1%
3.Calcium channel blockers	100	22.2%
4. Anti-neoplastic	50	11.1%
5. Anti-depressants	10	2.2%
6. Diuretics	0	0%
7. Antibiotics	75	16.6%
8. Anti-viral drugs	10	2.2%
9.Anti hypertensives	75	16.6%
10. (NSAIDS) Non-steroidal anti-inflammatory drugs	10	2.2%
11. Fluoroquinolone's	5	1.1%
12. Anti-epileptics	0	0%
13. Calcium supplements	10	2.2%
14. Proton pump inhibitors	25	5.5%
15. Statins	0	0%
16. Anti-anginal drugs	0	0%
17.Anti-coagulants	0	0%
18. Anti-platelets	0	0%
19. Anti-psychotics	5	1.1%
20. Anti-diabetics	50	11.1%
21. Anti- histamines	0	0%

Table: 6 Shows Surgical procedures performed in Urology Department to Overcome the Urinary Complications

Surgical procedure	No of patients	Frequency
1.Urethral Catherization	75	16.6%
2.Endoscopic Procedures		
a. Bladder	25	5.5%
b. Prostate	30	6.6%
c. Urethra	25	5.5%
d. Ureter	25	5.5%
3.Open procedures on the Foreskin		
a. Vas	15	3.3%
b. Bladder instillation	15	3.3%
c. Prostatic biopsy	20	4.4%
4. Laser therapy		
a. BPH cancer	10	2.2%
b. Kidney Stones	25	5.5%
5. Laparoscopy	20	4.4%
6. Urodynamic Evaluation	25	5.5%
7. TRUS/BX of Prostate Endoscopy	35	7.7%
8.SWL and other Lithotripsy Techniques	25	5.5%
9.Cystectomy	10	2.2%
10.Anti-Incontinence Procedures	25	5.5%
11. Urinary Diversion	10	2.2%
12.Prosthetics	25	5.5%
13.Micro Surgical technique	10	2.2%

Discussion

In our study, out of 510 patients 450 are willing to provide the information in which maximum are females and minimum were males and with different age groups are considered for the study out of which more than year old are suffered with Urinary tract problems, 51-60yrs suffered equal to that of older and rest was found to be 1-30 yrs. Environmental factors of the patient was and least was found to be Better and Nutritional status of the patient was found to be and minimum was Better and also Hygienic conditions also analysed by using Questionnaire which shows maximum were Poor and minimum were better and all the people belongs to Indian , Employment rate was found to be maximum was Employed and Un employed with marital status of Married were and last was unmarried. Reasons for admission in the hospital is mainly due to different types of problems like Kidney stones, Burning michuration, Prostate inflammation, Pain in lower stomach, side of back or groin region.

Different types of drugs induced urinary complications in the patients are many due to cyclophosphamide, Disopyrimide, Clozapine, perphenazine, Clonazepam, Mesoridazine, Amantadine, Atropine, Cocaine, Hyoscine, Astemizole, Ipratopium, Bzotropine, Amphetamine, Morphine, and the least

were found to be Ifosfamide, Papaverine, Flecanide, Fluoxetine, Fesoterodine, Diazepam, Pramipexole.

Complaints observed in the department of Urology with different diseases were identified in which maximum were kidney stones Urolithiasis HTN, DM, Chronic kidney disease, Prostate cancer, Acute kidney disease, Cystitis, Vaginal candidacies, Urinary incontinence, Urethritis, Prostatitis, Overactive bladder, Fascial PUG obstruction with congenital hydronephrosis, Bladder stones , and the least were Pyelonephritis, Fallen bladder protusion, CKD with palmar psoriasis, Atrophic right kidney with endometrial polyp, CKD carcinoma or kidney cancer, Obstructive uropathy with grade2-prostomegaly, Bladder cancer, Congenital urological anomalies and different drugs used in the department of urology and different drugs used in the department of urology for better outcomes were maximum Tab. Paracetamol, Tab. Cefoperazone, sulbactam, Tab.Metronidazole, Tab.Sodiumbicarbonate, Inj.Amikacin, Tab.Rabeorazole, Inj.Ondansetron, Tab.Chymoral, Inj.Tramadol, Tab.Ranitidine, Tab. Clopidogrel, Tab.Cilnidipine, Tab.Amlodipine, Syp. Cefotaxime, Tab.Telmisartan, Tab.Voglibose, Tab. Glicazide, Tab.Calciumcarbonate&vitaminD2, Tab. Febuxostat, Tab.Nicardipine, Tab.Multivitamin, Syp. Magnesiumhydroxide¶ffin, Tab.Flucloxacillin,

Tab. Sevelamer, Tab. Acetylcysteine, Syp. Paracetamol, Tab. Fraenum, Tab. Tamsulosin hydrochloride and the least were found to be Tab. Ciprofloxacin, Tab. Chlorpheniramine maleate, Syp. Ibuprofene.

Different types of surgical procedures performed in the department for Urinary complications are Urethral Catheterization, TRUS/BX endoscopy, prostate endoscopy, Bladder endoscopy, Urethra endoscopy, Ureter endoscopy, Kidney stones, Urodynamic evaluation, SWL and other lithotripsy, Anti incontinence procedure, Prosthetics, Laproscopy, Prostatic biopsy, vas, Bladder instillation and the least were found to be BPH cancer laser therapy, Cystectomy, Urinary diversion, Micro surgical technique.

Conclusion

Our study concluded that most of the people (or) patients in the urology department due to urinary complications was arise by using urology questionnaire and drug induced complaints are also estimated. Out of this the mainly some of the drugs are inducing urology problems in the patients. Some methods and surgical procedures are performed. It is cluster for the health care professionals and clinical pharmacist to reduce the patient in view of health condition in which, it is beneficial for the health outcome. Mostly, Clinical pharmacist should educate the patients regarding conditions and treatment to be effective.

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Conflict of Interest: Yes

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Ethical Committee Approval: We have Memorandum of Understanding with Narayana Medical College and Hospitals to conduct the Study.

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To Determine the Safety and Efficacy of Transdermal Nitroglycerine Patch as Shortterm Tocolytic in Preterm Labor

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Abstract

Background and Objectives: Preterm labour complicates 5-10% of pregnancies and is a leading cause of neonatal morbidity and mortality worldwide. It is a major public health problem in terms of loss of life, long-term disability (cerebral palsy, blindness, deafness, chronic lung disease) and health care costs both in the developing and the developed world.

There is need for tocolytic therapy to reduce perinatal mortality and morbidity by delaying delivery at least for 48 hours to allow time for therapeutic effects of corticosteroids

Methodology : This study was undertaken at Sri Siddhartha medical college and hospital research centre tumakuru between October 2017 to October 2019.

76 Antenatal cases with gestational age 28weeks-37weeks as per the inclusion and exclusion criteria's who were admitted and clinically diagnosed as preterm labour were selected . The selected patients were treated with Nitro-glycerine patch

Results : Success rate for acute tocolysis was 88.2%.Mean prolongation of pregnancy was 14.46 days and mean birth weight of babies was 2.19 kilograms. Most common side effect with Nitroglycerine patch was headache (5.3%).

Conclusion: Nitroglycerine patch is effective in suppression of preterm labor as short term tocolytic in prolongation of pregnancy. Nitroglycerine is well tolerated and safe for the mother and fetus with minor side effects

Keywords: Preterm labor; nitroglycerine patch, prolongation of pregnancy, side effects.

Introduction

Preterm birth, the leading cause of neonatal morbidity and mortality worldwide, is a major public health problem in terms of loss of life, long term

disability and health-care costs. The magnitude of the problem is evident from the fact that after exclusion of genetic and anatomic defects, it accounts for 75-80% of perinatal mortality and morbidity.¹

The outcome of preterm infants is directly related to the gestational age at delivery .With the advent of new born special care units ,there have been dramatic improvement in neonatal survival rates of preterm infants but neonatal intensive care is very expensive .so preterm labour is not only a medical and social problem ,but also an economic one.

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Each day that delivery is delayed between 28 and 34 weeks of gestation survival increases by 3%. There is ample evidence that tocolysis delays delivery for long enough to permit administration of a complete course of antepartum glucocorticoids and to facilitate in utero transfer to a tertiary care unit where neonatal care will be optimal.²

In many instances preterm labour represents the desperate needs of the growing foetus to escape from the unfavourable intrauterine environment. Many modalities of treatment are presently being recommended to halt preterm labour. Although many drugs are now routinely available, and no single drug has clear therapeutic advantage.¹

Nitro-glycerine, a nitric oxide donor is a recently used drug as a transdermal patch, a direct smooth muscle relaxant without any reported cardiovascular side effects. It is a vasodilator that is essential for maintenance of normal smooth muscle tone of uterus.³

Pregnancy is prolonged by its direct effect on uterine blood flow. This drug was studied in U.K during December 1994 –august 1996 and proved to be a safer alternative compared to other tocolytics with fewer maternal side effect profile and treatment discontinuation rates.

Methodology

This study was undertaken at Sri Siddhartha medical college and hospital research centre tumakuru between October 2017 to October 2019.

76 Antenatal cases with gestational age 28weeks-37weeks as per the inclusion and exclusion criteria's who were admitted and clinically diagnosed as preterm labour were selected. The selected patients were treated with Nitro-glycerine patch.

Inclusion Criteria:

- Gestational age between 28-37weeks.
- Painful uterine contractions of 4 in 20 minutes or 8 in 60 minutes each contraction lasting for 30 seconds.
- Intact membranes.
- Cervical effacement of >80%.
- Cervical dilatation >1cm and <3cms.

Exclusion Criteria:

- Antepartum haemorrhage.
- Eclampsia and severe preeclampsia.
- Heart disease causing moderate to severe functional impairment.
- Severe anaemia.
- Foetal demise.
- Foetal congenital malformations.
- Documented ruptured membranes.
- Cervical dilatation >3cms.
- Chorioamnionitis
- Sensitivity or contraindication to Nitro-glycerine.
- Hypotension (systolic bp<90mm of hg).

When a case of preterm labour meeting the inclusion, criteria was admitted detailed history was taken regarding age, occupation, socioeconomic status and any history of infections, obstetric history and history of previous preterm deliveries, abortions, history of diabetes mellitus, heart disease, chronic renal failure, hypertension and asthma.

Patient's general physical examination should be done. Vitals should be recorded Cardiovascular system and respiratory system to be examined.

Period of gestation to be calculated from naegles rule in patients with known last menstrual period, otherwise assessed by clinical examination and ultrasound.

Abdominal examination –uterine heights, presentation, position, lie of the foetus, liquor volume, foetal heart rate to be recorded. Uterine contractions to be evaluated with respect to frequency and duration.

Per speculum examination-speculum to be introduced into the vagina and high vaginal swab to be taken for culture and sensitivity. Any discharge /leak / bleed to be noted. presence or absence of herniation of membranes noted.

Per vaginal examination to be done-consistency, position, effacement, dilatation of cervix, status of membranes, and station of presenting part to be noted.

Routine investigations like Hb%, total count, differential count, ESR, Urine for albumin, sugar and microscopy, blood grouping and Rh typing, HIV, HBsAg, Ultrasound examination, non-stress test, cervical swab or high vaginal swab for culture and sensitivity, urine for culture and sensitivity. Must be sent.

After informed consent Transdermal nitro-glycerine patch releasing 10mg/24 hours in a drug release area of 20cm² to be applied to a clean, dry area of intact skin on the fundus of uterus. Uterine contractions should be reassessed after 2 hours of application of the patch, and if relaxation of uterus occurred the patch should be continued for 24 hours or till the full dose of steroid administration .In instances where Uterine contractions did not subside after 2hours of application of the patch ,a second patch should be applied. With the application of second patch, if uterine contractions subsided it was continued for 24hours.on the second day another patch should be applied for completion of steroid course. In spite of second patch on the first day, if the uterine contractions did not subside then patch should be discarded and another rescue tocolytic should be used.

Monietring:

1.Half an hourly abdominal palpation to note frequency and strength of contractions for 2 hours and then 6th hourly.

2.Pulse, BP, foetal heart rate monitoring every ½ hourly for 2 hours and then 6th hourly.

3.Close monitoring for any side effects.

Treatment should be discontinued, if there will be any maternal tachycardia greater than 120 beats/min, drop of blood pressure 15mm of Hg or more from baseline diastolic pressure, fever more than 100degree F or premature rupture of membranes. If the contractions subside, patients will be discharged and assessed antenatally every week until delivery.

Treatment will be considered successful if uterine contractions subsides and tocolysis to be achieved for more than 48 hours.

All patients received injection Betamethasone 12mg 1M 24 hours apart 2doses.

Patients received antibiotics if indicated.

Gestational age at delivery, mode of delivery, birth

weight, APGAR at 1

minute and 5 minutes were recorded in followed up cases.

The Following data was collected from each case:

- 1) Gestational age at tocolysis
- 2) Gestational age at delivery
- 3) Prolongation of pregnancy
- 4) Maternal side effects
- 5) Birth weight of the baby
- 6) APGAR Score at 1 and 5 minutes.
- 7) NICU admissions.

Results

During the study period of 24 months, Total numbers of threatened and established preterm labour cases were 93, out of which 85 patients needed tocolysis. Of the 85, 09 patients were lost to follow up and were excluded from further analysis.

Total cases in the study- 76.

Majority of cases were between 18 and 24 years of age. Mean age of mothers was 22.7 years. Out of 76 subject’s majority were Unbooked cases. Primigravidas are of 37 subjects and multigravidas were 39 in number.

Gestational age at tocolysis are more in between 33-36 weeks and mean gestational age was 32.73 at presentation.

Majority of patients delivered between 33-36 weeks and mean gestational age was 34.9 weeks

Prolongation of pregnancy in maximum cases is between 3-7 days, mean prolongation of pregnancy was 14.46 days.

Table 1: Baseline characteristics of subjects

Parameter	value
Age	mean age-22.7 years
Distribution	Booked 26
	Unbooked 50
Parity	Primi 37
	Multi 39
Gestational age Tocolysis (weeks±SD)	32.73 weeks

The outcome is assessed by gestational age at delivery and prolongation of pregnancy and is shown in table 2.

Table 2. outcome assessment

Parameter	value
Gestational age at delivery (weeks±SD)	34.9 weeks
Prolongation Of pregnancy (mean)	14.46 days
Mode of delivery	Lscs 26
	Vaginal delivery 50

This shows majority of subjects delivered at mean age of 34.9 weeks and mean prolongation was 14.46 days and majority of the subjects delivered by vaginal delivery.

Table 3. Maternal side effects

None	69(90.8%)
Yes	7(9.2%)
• Headache	4(5.3%)
• Hypotension	1(1.3%)
• Tachycardia	2(2.6%)
• Skin rash	0

The various side effects noted were headache, hypotension, tachycardia among the subjects is shown in table 3.

Table 4: Neonatal outcomes

Birth weight in kgs (mean)	2.19 kg
APGAR (Majority)	1min- score 4-6(56.6%)
	5min- score 7-10(92.1%)
NICU admission	12(15.8%)
RDS	10(13.2%)

Majority of Apgar is in range of 5min 7-10 score which shows a good prognosis of 92.1%.

Discussion

Preterm labour remains one of the unconquered frontiers in the present era Obstetrics. Throughout the years a variety of drugs with different pharmacologic principles are used to suppress preterm labour. The choice is limited by their efficacy, safety and side effects.

Despite the availability of tocolytic agents the rate of prematurity has not declined over the past few years for several reasons.

Firstly, the aetiology is usually not known. So, it is difficult to devise a method that will predict which group of patients go into labour and delivery.

Second, the signs and symptoms of threatened preterm labour are frequently subtle. Thus, very often patients present themselves for care too late to the obstetricians to attempt to inhibit preterm labour and prevent a premature delivery.

Third, although most cases fall into the category of idiopathic preterm labour certain clinical entities like PIH, APH etc, may require immediate termination regardless of maturity of foetus.⁴

Recently used drug is Nitro-glycerine, a transdermal patch, a nitric oxide donor, a direct smooth muscle relaxant without any reported cardiovascular side effects.⁵

The incidence of preterm labour in Sri Siddhartha Medical College, Hospital and Research centre between October 2017 to September 2019 is 5.84%. Present study incidence is comparable to chythra R rao study 5.8%

In the present study Majority of cases were between 18 and 24 years of age. Mean age was 22.7 years. Thus its comparable with Peter wagura et.al, chythra R rao et.al, Mohammed Zolad et.al

In the present study distribution according to parity it is seen more in multigravidas comparable to Goffinet F study.

Mean gestationl age at tocolysis is 32.73 weeks comparable with kumar aruna, smith GN⁶ studies.

Success rate with present study is 88.2% comparable with Rowland study⁷

Most common side effect in the present study was headache which is compared with the study conducted by Kumar Aruna et al.

In another study conducted by Smith GN⁶ et al, side effects were seen in 69.7% and in this also commonest side effect was headache.

In the present study mean birth weight after tocolysis was 2.19 kilograms. Comparable with Krishna et.al.

Conclusion

Nitroglycerine patch is effective in suppression of preterm labor as short term tocolytic in prolongation of pregnancy. Nitroglycerine is well tolerated and safe for the mother and fetus with minor side effects hence improves perinatal outcome.

Ethical Approval: Taken from institutional ethical committee

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Study of Bacterial Contamination of Mobile Phones of Anaesthetists and other Doctors in Surgical Departments During Theatre Sessions

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Abstract

Background: Personal items such as mobile phones are commonly used by doctors working in the operation theatre. The hands and personal use items of anaesthetic doctors working in the operation theatre may serve as vectors for transmission of nosocomial pathogens among surgical patients. Our aim was to determine the mobile phones contamination among anaesthetists working in the operation theatres of anaesthetic doctors.

Method : Forty anaesthetic doctors and other surgical department doctors working in the operation theatres at Sri Lakshmi Narayana Institute of Medical sciences, puducherry and Bharath Medical college and Hospital, Chennai were enrolled in the study. Swabs from fingertips and keypads of mobile phones were taken using moist sterile swabs and plated on Mac Conkey and Blood agar plates. The bacteria isolated were identified by biochemical tests.

Results: Hand washing was performed by 50% (n=20/40) doctors entering the theatre. 95% (n=38/40) brought their mobile phone to the theatre and 80% used it at least once during the theatre session. Bacterial growth was detected from mobile phone swabs. Staphylococci were predominantly cultured from all the specimens tested. Staphylococci 15%, Methicillin- resistant *Staphylococcus aureus* (MRSA) 10%, pseudomonas 5%, coagulase negative staphylococci 15%,pseudomonas 5% and total 50% anaesthetist and other doctors mobile phones growth were detected.

Conclusion: Personal use items of doctors such as mobile phones show a high percentage of bacterial contamination. Hand washing compliance was moderate among the study population. Thus personal use items and hands may act as an important source of nosocomial pathogens in the operation theatre settings. Therefore it is important to encourage higher compliance to hand washing practices and routine surface disinfection of personal use items brought to the operation theatre. Mobile phone disinfection should be part of infection prevention protocols in Operation Theatre.

Key Words: Mobile Phones, Bacterial Contamination, Nosocomial Infections, Contamination, HealthCare Workers.

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Introduction

Mobile phones (MPs) are becoming commonplace in both community and hospital settings. More than 50% of healthcare workers (HCWs) admit using MPs (either personal or professional devices) in their clinical environment and practice,including during physical

contact with patients [1-4]. The use of MPs can improve the quality, rapidity and efficiency of communication in healthcare settings [1]. Approximately 2 million nosocomial infections occur in the USA [1]. Bacterial contamination on these devices has been described [1], with up to 25% of MPs being found to be contaminated [5]. Nosocomial bacteria such as methicillin-resistant *Staphylococcus aureus*, *Acinetobacter* species, vancomycin resistant enterococci, *Pseudomonas* species and coli forms have been retrieved from MPs [2,5-7]. These devices may thus serve as a reservoir of bacteria known to cause nosocomial infections [4-5] and may play a role in their transmission to patients through the hands of HCWs [8]. Extensively, the mobile phones are being used in hospital halls, laboratories, outpatient department, operation theatres, and various areas in the hospital. Hospital acquired infections are increasing as these may be spread through the hands of health-care personnel, use of stethoscope, and other daily instruments used by health-care personnel. Source of infection may be exogenous such as from the air, medical equipment, hands of surgeons and other staff or endogenous such as the skin flora in the operative site, or rarely from blood used in the surgery [2].

These mobile phones harbor a wide array of microorganisms which includes Coagulase negative Staphylococci (CONS) *Staphylococcus aureus*, *Escherichia coli*, *Klebsiella pneumoniae*, *Acinetobacter* species, *Enterococcus faecalis*, and *Pseudomonas aeruginosa*. [9-10] Multidrug resistant strains like Methicillin resistant *Staphylococcus aureus* (MRSA) and Extended spectrum beta lactamases producing organisms (ESBL), high-level aminoglycoside-resistant *Enterococcus*, and carbapenem-resistant *Acinetobacter baumannii* [11-12] have also been isolated from mobile phones. Majority of the staff neither clean their mobile phones regularly nor wash hands after using these mobile phones [13]. There are no restrictions on the use of mobile phones in the hospital setting and no guidelines have been formulated on cleanliness of mobile phones in the healthcare settings. Further sharing of mobile phones between the hospital staff may distinctly facilitate the spread of potentially pathogenic bacteria to the community [10].

Centers for Disease Control and Prevention (CDC) guidelines recommend several preoperative preparation

practices important in preventing nosocomial infections in surgical patients which include hand scrubbing procedures of the surgical team [3]. The use of mobile phones should be weighed against the risk of contamination and transmission of infections in hospitals and other health associated units. It is of utmost importance that the role of electronic gadgets like mobile phones in spreading infections are identified at an earlier stage so that preventive measures can be taken [5]. Mobile phones are used at every possible place, home, kitchen, washroom, market place exposing them to different types of microorganisms. They are rarely cleaned being electronic gadgets. There are reports of colonization of bacteria on cell phones exposing our patients to nosocomial infections through contact [5]. Operation Theatre (OT) of any hospital offers cleanest and sterile environment for patients undergoing surgeries. The cell phones are possessed by all HCWs working in OT. Before entering the operating theatres anaesthetists change into sterilised theatre suits but do not perform routine hand washing or decontamination. However the practice of hand washing and decontamination is strictly followed when performing invasive procedures. Therefore it is possible that the use of personal items in the theatre will contribute to contamination of anaesthetists hands and be a source of transmission of pathogenic organisms from the hospital wards and the community in to the operation theatres.

Most of the Doctors and Health Care Workers of Surgical department are not aware that their mobile phones. As such mobile phones can act as a potential source of hospital acquired infections and increase the spread of multidrug resistant organisms among the patients. Back ground of this information our study was conducted with the aim to screen the mobile phones of health-care personnel for various bacteria and fungi with special reference to methicillin-resistant *Staphylococcus aureus* (MRSA), Staphylococci, pseudomonas, coagulase negative staphylococci and pseudomonas and to evaluate the amount of contamination of the hand and mobile phones in anaesthetists working in the operation theatre and formulate suitable guidelines for their decontamination to screen the mobile phones of healthcare workers so as to elucidate all possible contaminants which can act as a source of infection, with their antibiotic resistance pattern.

Materials and Methods

Forty anaesthetic doctors and other surgical department doctors working in the operation theatres at Sri Lakshmi Narayana Institute of Medical sciences, puducherry and Bharath Medical college and Hospital, Chennai were enrolled in the study. Study includes Doctors surgical operation theatre. Consent was obtained from the Doctors before inclusion in the study. Samples from mobile phones and fingertips were taken by sterile wet (sterile distilled water) swab stick. Microbiological cultures of all the samples were done and culture growths were subjected to antibiotic sensitivity. The procedure of specimen collection was explained to the volunteers and a questionnaire was filled after obtaining informed consent. Institute Ethical clearance for the study was obtained from the Ethical review committees of Sri Lakshmi Narayana Institute of Medical sciences, puducherry and Bharath Medical college and Hospital,

Chennai

The swabs were in the laboratory to inoculate on Blood Agar and Mac.Conkey Agar plates. The plates were incubated at 37°C for upto 48 hours. Colonies were counted and the organisms were identified up to species level by using Gram’s staining, colony morphology and appropriate bio chemical tests. For identification of Gram positive cocci (GPC); *Staphylococcus aureus* was identified by the catalase and coagulase tests. They were further checked for sensitivity to methicillin to differentiate between Methicillin Resistant *Staphylococcus aureus* (MRSA). Nonhaemolytic, catalase-positive, coagulase negative GPC were identified as *Micrococcus* species while the other catalase-positive, coagulase-negative Gram positive cocci were grouped as coagulase-negative *Staphylococci* (CNS). The Oxidase and catalase test was carried out for the Gram negative bacilli.

Results

Table.1: Shown Microorganism isolated from mobile phones.

Microorganism isolated from mobile phones	Doctors (n=40)
Staphylococcus aureus	6 (15%)
Methicillin-resistant Staphylococcus aureus(MRSA)	4 (10%)
Pseudomonas	2 (5%)
Candida	0
Coagulase negative staphylococci	6 (15%)
Bacillus subtilis	2 (5%)
Total	20 (50%)

Discussion

The mobile phone use is highly prevalent among medical staff playing a significant role in day-today life and contributes positively to their ability to

communicate concerning hospital affairs [14] However; this referred only to technical aspects and gives no consideration of their possible role in transmission of infections [15] Jeske *et al.* found that the rate of bacterial contamination of HCWs’ hands was 95% while that of

mobile phone was 90% [15] Tambekar *et al.* [16] stated that 95% of mobile phone showed bacterial contamination and among *S. aureus* isolates 83% were methicillin resistant. Snigh *et al.* [17] reported that out of 50 mobile phones that were cultured, 98% were positive. On the same context, Goldblatt found that, one fifth of the cellular phones used by HCWs harboured pathogenic microorganisms and may serve as vectors for health care transmission of microorganisms [18]. Fukada [19] reported that anaesthetists should perform hand hygiene before and after anaesthesia and remove gloves after each procedure and before using any equipment. Lower rates were observed by Ramesh *et al.* who stated that 45% of mobile phones which were swabbed grew microorganisms [14]. Similarly, Ali *et al.* [20] found that 43.6% of HCWs carried infective microorganisms on their cell phones and they recommended that cell phones should be cleaned regularly.

In present study, microorganism contamination rate of mobile phones were 50%. The predominant pathogenic microorganisms isolated from the mobile phones of Doctors of Surgery department were *Staphylococcus aureus*, followed by Methicillin-resistant *Staphylococcus aureus* and *Pseudomonas*. In present study, Methicillin-resistant *Staphylococcus aureus* and *Pseudomonas* both were important nosocomial microorganisms isolated from mobile phones of Doctors in our surgical department. Doctors are carrying their mobile phones with pathogenic microorganisms to their surgical outpatient department, surgical wards, surgical intensive care unit, surgical operation theatre, surgical post operative ward and also to their homes. Further study may be required to find out whether Mobile phones of Doctors are involved in transmitting nosocomial infection. Other studies had also shown contamination of White coats of Doctors, Security Swipe Cards and Scanners of Hospital, Stethoscope of Doctors by pathogenic microorganism [21-24].

The present study reports were obtained Hand washing was performed by 50% (n=20/40) doctors entering the theatre. 95% (n=38/40) brought their mobile phone to the theatre and 80% used it at least once during the theatre session. Bacterial growth was detected from mobile phone swabs. *Staphylococci* were predominantly cultured from all the specimens tested. *Staphylococci* 15%, Methicillin-resistant *Staphylococcus aureus*

(MRSA) 10%, *Pseudomonas* 5%, coagulase negative *Staphylococci* 15%, *Pseudomonas* 5% and total 50% anaesthetist and other doctors mobile phones growth were detected. Doctors should be aware that their personal objects used in the hospital environment may be contaminated by pathogenic microorganism. Few studies were done in Nurses but we didn't concentrate in this study on Nurses.

Conclusion

Doctors and Health Care Workers both should be aware that they may carry pathogenic microorganism on their mobile phones. Cleaning of mobile phones with antiseptic solution along with emphasis on correct hand-washing technique should be given. Use of hands free kit for mobile phones may be useful in preventing direct contact of hands with mobile phones in hospital. Bacterial contamination on mobile phones may be reduced by making them with special material which prevents growth of microorganism which required further research.

Restriction of mobile phone use in clinically sensitive areas, such as operating environment and

ICU as a start point, is recommended. Moreover, screening of Health Care Workers mobile phones inside the hospital should be done while doing environmental screening. The use of mobile phones in clinically sensitive areas should be weighed against the risk for contamination and transmission of infections.

Adoption of new communication technologies will always be a part of clinical medicine and healthcare facilities, and there will always be cross-contamination risks of mobile communication devices. Finally, new designs and technologies, especially new materials to reduce handling, contamination, and to ease cleaning, are welcome.

A significant number of mobile phones in the Operation Theatre were found to be contaminated with bacteria. Most of these bacteria though are nonpathogenic in normal circumstances but may become significant among the patient population. Daily disinfection practice of mobile phones of all Health Care Workers should be part of Operation Theatre safety protocols for prevention of infection.

Developing active preventive strategies like routine decontamination of mobile phones with alcohol containing disinfectant materials might reduce cross-infection. Another way of reducing bacterial contaminations on mobile phones might be the use of antimicrobial additive materials. We could easily avoid spreading bacterial infections just by using regular cleansing agents and rearranging our environment. Further studies are required in the Large number of doctors and other Health Care Workers and they are more contaminated by their mobile and other objects.

Conflict of Interest: Nil

Source of Funding: None

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Assess Health-seeking Behavior on Cancer among Women Residing at Rahata Taluka

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Abstract

Introduction: The cancer is a major problem in developing countries. Cancer is most advancing health problem faced by overall world including India.

Aims: The aim of the study was to assess the health-seeking behavior and identify the hindrance factors on health-seeking behavior on cancer among women.

Methods: Using a descriptive, cross-sectional study design with stratified random sampling 400 women residing in Rahata taluka were interviewed using a questionnaire. Descriptive statistics was calculated with the mean for variables that were normally distributed. Statistical Analysis was performed with SPSS software.

Results: Demographic data show that 41.75% of women were from the age group of below 35 years, 29.75% had a higher secondary education, 81.75% of women are Hindu, 47.75% of women live in nuclear family, 80.75% of women are married, 38.25% of mothers were house maker, and 48.5% of women have monthly family income of 1866–5546 Rs. The proportion of health-seeking behavior for cervical cancer among the study participants shows that majority of women's believed that cancer treatment can be done properly if economic condition is well enough, better health facilities available, cancer awareness educational program through the health workers. The hindrance factor contributes the health-seeking behavior among the women. Majority of women that have lack of knowledge about disease, social stigma, fear of relationship after exposure of disease, socioeconomic condition, inadequate knowledge related to treatment, delay health-care system, delay diagnosis. Providing some education program, educational booklet, strait play, and handouts medical camp, and short films are helpful for cancer prevention.

Conclusion: The awareness of cancer among women residing at Rahata Taluka was low. The result of the study concludes that certain factor contributes the health seeking behavior among the women. Hence, it is necessary to give them the right information on cancer and its prevention to women.

Keywords: *Assess, behavior, cancer, health, study, women*

Introduction

In day-to-day life, a non-communicable disease is challenges for health sciences among them the cancer is most advancing health problem faced by overall world including India. ^[1]

The term cancer is used for malignant uncontrolled growth of cells and tissues. Cancer is a disease of the cell, in which the normal mechanism for control of growth and proliferation has been altered.

Prevalence estimates for 2012 shows that there were 32.6 million people (over the age of 15 years) alive who had had a cancer diagnosed in the previous 5 years.

In urban areas, cancer of the cervix accounts for over 40% of cancers while in rural areas, it accounts for 65% of cancers as per the information from the cancer registry in Barshi. ²

Need of the study

Cancer is progressively becoming prominent health threat in high- and low-income nations among the chronic health problems. It is a worldwide problem affecting people in both wealthy and poor countries. [3]

A study conducted by Mounita Dason, the gendered experience with respect to health-seeking behavior in an urban slum of Kolkata, India. The result shows that both men and women utilize formal and informal care, but with different motives and expectations, leading to contrasting health-seeking outcomes. The role of women in following and maintaining sociocultural norms leads them to focus on care that involves long discussions mixed with sociocultural traits that help avoid economic and social sanctions. [4]

Statement of Problem

“Health-seeking behavior on cancer among women residing at Rahata Taluka.”

Objectives

The objectives of the study were as follows:

1. To assess the health-seeking behavior on cancer among women.
2. To identify the hindrance factors on health-seeking behavior on cancer among women.

Materials and Method

Study Setting and design: This descriptive cross-sectional study was done in the women who are residing at Rahata taluka, Ahmednagar District, Maharashtra, India.

Sample size, Sampling Technique, Study duration and study population: The study sample size was 400 women. Study Participants were selected by stratified random sampling. During the study period 400 women who consented for the study were enrolled and were interviewed as per schedule, demographic data were asked first, followed by the question related to hindrance factor which affects the health-seeking behavior of women. An average 15 women were interviewed per day, and the duration for the interview was being approximately 20 min. Ethical approval from the institutional ethics committee of Pravara Institute

of Medical Sciences –Deemed to be University, Loni (Bk) was obtained. **(Registration No: PIMS/IEC/Dr/2018/69 dated on 11.12.2018)**

Data Collection

The data was collected by face- to -face interview held in a home at selected village of Rahata Taluka. The interview lasted for 20 minutes. Data Collection was guided by a pretested, Semi-Structured questionnaire consisting of both open as well as closed questions. The questionnaire had two Parts. They were, Socio-demographic characteristics of the study population and contributing and hindrance factors of cancer

Data Analysis

The collected data were organized, tabulated, and analyzed using descriptive and inferential statistics methods wherever required. The descriptive statistics such as percentage, mean, SD, and inferential statistics such as correlation and coefficient will be used. Further, the analyzed data will be presented in the form of tables, figures, and diagrams.

Results

Section 1: Demographic distribution

Demographic data show that 41.75% of women were from the age group of below 35 years, 29.75% had a higher secondary education, 81.75% of women are Hindu, 47.75% of women live in nuclear family, 80.75% of women are married, 38.25% of mothers were housemaker, and 48.5% of women have monthly family income of 1866–5546 Rs.

Interpretation

The proportion of health-seeking behavior for cancer among the study participants was only 77% of women sought medical help. About 83.5% of women took help from Pravara Rural Hospital. In the contributing factor, only 76% of women know about reproductive system and 29.5% of women are aware of the breast cancer. About 83% believe that support from family is required for cancer screening and treatment. About 55% believe that psychological support is necessary. About 66% affirm that the adequate economical support is required for cancer screening/treatment. About 100% of women say that test is costly. About 75% feel that

the relationship of partner plays an important role in effective cancer treatment. About 58.5% believe that face the difficult situations. About 74.5% believe that the live example of cancer person in the family and relatives makes you attempt for a cancer treatment. About 57.2% prepare mentally. About 46.5% feel that the decision-making in the family helps in seeking medical help. About 62.5% believe that on time and prompt decision to take treatment helps to prevent Cancer. About 51.5% acknowledge that the availability of health facility made you to seek medical help. About 71.65% says because of facility is available in private hospital like PRH. About 53.75% believe that the availability of treatment facility/hospital is not far away; is the factor for seeking medical help. About 31.63% prefer Pravara Rural Hospital. About 57.2% believe that the severity of cancer will make an individual to seek medical help. About 75.65% are get motivation to fight against cancer. About 67.5% are the advice and guidance from friends and relatives made you to seek medical help for cancer. About 78.5% are got correct and adequate information about cancer. About 75% believe that the low/free of cost treatment for cancer in Pravara Rural Hospital made to seek medical help for cancer. About 47.5% believe that available facilities. About 70.5% feel comfortable to interact with health-care professional and social workers. About 100% are known/understand the information about illness and available facilities in it. About 77% believe that role of health-care provider and social workers made you to seek medical help. About 100% believe that the way. It helps to get appropriate direction and prevent the delay in care. About 68.25% believe that the conduction of screening camp for cancer helps you to seek medical help. About 100% are known the available facility for cancer screening. About 85.5% feel any other factor make you to seek medical help. About 57.5% are want to prevent cancer disease, is must get information about healthy life style, diet, etc.

Conclusion

The proportion of health-seeking behavior for cancer among the study participants shows that majority of women's believed that cancer treatment can be done properly if economic condition is well enough, better health facilities available such as hospital infrastructure, cancer awareness campaigning program, educational program through the health workers, and social work

with the help of social workers helpful for the health-seeking behavior's on cancer.

Interpretation

the findings regarding hindrance factors on health-seeking behavior on cancer among women are showed that 76% of women are says no hesitate to contact health facility for their reproductive organ disease. About 52% are says fear of relationships with family and husband. About 83% of women say no they believe that the poor economic status is the reason for not seeking medical help. About 58.46% believe that cost of treatment was high. About 66.6% says no that the lack of awareness on cancer is chief the reason for not seeking medical help. However, 64.93% are unaware about screening test. About 75.25% of women say no they feel that the hospital facility is far away from the native place, which hindrance the seeking of medical help. However, 67.68% believe that not getting time to attend hospital. About 74.5% say no they feel that the fear of diagnosis as a cancer disease is the hindrance factor for seeking medical help but 100% have lack of knowledge and misunderstanding about disease. About 53.5% are believe that the fear related to treatment's/side effects make you not to seek medical help. About 100% have seen patient with cancer and side effects of treatment therapy. About 51.5% accept that the workload/family commitment make you not to seek medical help. About 65.5% are not getting time to attend the hospital. About 53.75% says no they feel that the lack of time from household work make you not to seek medical help. About 52.96% said that they have too much household work. About 57.5% says no they believe that the financial dependency is one of the hindrance factors for seeking medical help. About 46.47% of women's does not have earning member. About 67.5% are not feel that the fear, trust on god/spiritual belief, and practice made not to seek medical help. About 53.85% are fear of family support. About 70.75% says no the violation of privacy and confidentiality at health center is the factor for not seeking medical help. About 52.6% are believes that somebody may discuss about others health. About 70.25% not feel that the relationship with partner may be disturbed due to cancer diagnosis and its treatment, so you are not seeking medical help. About 76.47% are fear of breaking of relationship. About 77% are not believe that the inappropriate judgment/lack of decision-making

make you not to seek medical help and 56.52% social stigma. About 68.25% not affirm that the inadequate information, unavailability of specialty doctors is the reason for not seeking medical help. About 84.25% believe that specialty doctors are available only in big cities. About 85.5% not feel that any other factor which makes you not to seek medical help. About 100% are Lack of family support.

Analysis shows the hindrance factor that contributes the health-seeking behavior among the women. Majority of women that have lack of knowledge and misunderstanding about disease, fear of people knowing, cultural practice like social stigma, fear of relationship after exposure of disease, socio economic condition since cost of treatment if high, inadequate knowledge related to treatment, health care system delay related factor since specialty doctors are available only in big cities which cause delay diagnosis.

Discussion

Results of the study conclude that the proportion of health-seeking behavior for cervical cancer among the study participants shows that majority of women's believed that cancer treatment can be done properly if economic condition is well enough, better health facilities available such as hospital infrastructure, cancer awareness campaigning program, educational program through the health workers, and social work with the help of social workers helpful for the health-seeking behavior's on cancer.

The hindrance factor contributes the health-seeking behavior among the women. Majority of women that have lack of knowledge and misunderstanding about disease, fear of people knowing, cultural practice like social stigma, fear of relationship after exposure of disease, socio economic condition since cost of treatment if high, inadequate knowledge related to treatment, health care system delay related factor since specialty doctors are available only in big cities which cause delay diagnosis.

A study on survival of patients with cervical cancer in rural India.. The effect of socioeconomic factors was assessed using Cox proportional hazards regression analysis. The 5-year observed survival was 32.5%, ranging from 9% for Stage IV to 78% for Stage I cancers. Women with poor socioeconomic status (SES) had up to

70% higher risk of death. Higher household income was significantly associated with poorer survival. However, most women in the higher income group were married women and housewives, hence with no personal income, cervical cancer survival was disappointingly low in these rural populations of India and stage of disease at diagnosis was the strongest determinant. A higher household income is not always associated with women being empowered in terms of seeking healthcare. [6]

A study on perceived factors for delayed consultation of cervical cancer among women at a selected hospital in Rwanda: An exploratory qualitative study. Result revealed patient, health-care providers, and health-care system factors emerged from the participants' narratives as factors that contributed to the delay in seeking early diagnosis and treatment. The perceived patient-related factors were a lack of knowledge, cultural practices, age-related factors, fear of people knowing, and socioeconomic factors. Furthermore, the health-care provider delay-related factors were inadequate knowledge, unnecessary treatment, poor communication, and minimizing patients' symptoms, false diagnosis; health-care system delay-related factors included an ineffective transfer system and delayed diagnosis. [7]

A study on barriers for early detection of cancer amongst Indian rural women, among 35 years and above. Result revealed that awareness about symptoms, possibility of early detection, available tests, and possibility of cure of disease were low. Main barrier for screening was cognitive, that is, "don't know" answer by 83.99% of women for cancer cervix, 84.93% for cancer breast, and 67.26% for oral cancer. Awareness score was significantly associated with age ($\chi^2 = 17.77, P = 0.001$), education ($\chi^2 = 34.62, P = 0.000$), and income ($\chi^2 = 16.72, P = 0.002$) while attitude score with age ($\chi^2 = 16.27, P = 0.012$) and education ($\chi^2 = 25.16, P = 0.003$). Practice score was significantly associated with age ($\chi^2 = 11.28, P = 0.023$), education ($\chi^2 = 32.27, P = 0.003$), and occupation ($\chi^2 = 10.69, P = 0.03$). Awareness, attitude, and practice score of women having history of cancer in family or relative was significantly high than women without history. [8]

A study on beliefs, perceptions, and health-seeking behaviors in relation to cervical cancer: Among 36

women, aged 25–49 years, with no previous history of cervical cancer symptoms or diagnosis. Result revealed that three themes emerged: Feeling unprotected and unsafe, disbelief and wondering about cervical cancer, and fear of the testing procedure. Participating women had heard of cervical cancer but preferred to wait to access cervical cancer screening until symptom debut. It was evident that there are still barriers to cervical cancer screening among women in Uganda, where there is a need for culture-specific, sensitive information and interventions to address the issues of improving the cervical cancer screening uptake among these women.^[9]

A study on factors affecting uptake of cervical cancer screening among African women in Klang Valley, Malaysia, among ages 18–69 was conducted in three different churches with high numbers of African participants. Result revealed that the response rate was 98.2%, the majority (68.1%) of the respondents being aged 31–50 years and married. The prevalence of screening among the respondents over the past 3 years was 27.2%. Using $P = 0.05$ as the significance level, the final model showed that marital status ($P = 0.004$), knowledge ($P = 0.035$), perceived barriers ($P = 0.003$), and having a regular health-care provider ($P < 0.001$) were the only significant predicting factors of uptake of cervical screening among African immigrant women in Klang Valley, Malaysia.^[10]

Conclusion

Cancer is a major life-threatening disease and the most important obstacle to the increase in life. The result of study concludes that the hindrance factor contributes the health-seeking behavior among the women. Hence, it is necessary to give them the right information on cancer and its prevention.

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Coping Mechanisms Used by Women with Major Depression

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Abstract

The purpose of this study is to compare women with major depression against their matched healthy controls about their coping mechanisms and the severity of their symptom condition.

Method: This cross-sectional hospital-based survey recruited 37 women with major depression and 40 non-depressed women as healthy controls. Simple random sampling was used to select the participants. Data was collected by using self-reported tools. Descriptive statistics and interpretative analysis of data was performed by using independent-samples *t*-test, ANOVA, and post hoc Tukey HSD multiple comparison tests to find out the accurate differences between levels of depression.

The **results** show that women who used more self-blame, rumination bordering on to brooding, and less positive reframing had higher levels of depressive symptoms. Among the positive coping mechanisms, it was noted that in the clinical sample used instrumental and emotional supports. With regard to negative strategies for coping depression, self-blame, self-distraction, denial and venting were common. The use or non-use of a given coping mechanisms varied with the severity of depression.

Conclusion: The study concludes that women with major depression use qualitatively different coping mechanisms for coping depression than healthy controls. This has implications for planning psychotherapeutic programs for the affected women.

Keywords: Coping, major depression, venting, self-blame, denial.

Introduction

Adequate coping mechanisms are a prima necessity for successful adaptation for depression. Women cope with stress in social contexts differently¹. They use emotion-oriented behaviors and seek social supports. They tend to be less instrumental or direct in their approach to social stress problem-solving. They engage in a discussion of their problems and emotionally vent². The extent to which women with major depression use adaptive or maladaptive coping mechanisms has not been fully evaluated.

Depression being the second cause of disease burden for the year of 2020, affects around 57 million people in India³. The prevalence of depression is 9%, for the major depressive episode is 36%, and the average age of onset of depression is 31.9 years in India. Studies suggest higher disease burden in females than males^{4,5}.

The status-role of women is fast changing in India. From a homemaker, modern Indian women are doing several occupations that were earlier exclusive for men. They are gaining economic and personal independence. Along with it, adjustment challenges, interpersonal interactions, and heterosexual relationships are changing at home and in their workplace. Their stress coping mechanisms are in flux^{6,7}. Therefore, identifying the most effective adaptive coping mechanisms is associated with better quality of life and the maladaptive coping mechanisms happen to negatively affect individuals the most.

Review of Literature

Available literature shows that women are more likely to use maladaptive coping mechanisms^{8,9,10,11}.

When emotion-focused coping mechanisms are used in response to stress women experience more depressive

and anxiety-related symptoms^{12,13}. In terms of gender variable, significant differences are found men coped by increasing their sports activity and consumption of alcohol and women through emotional release and religion. Women felt the effects of depression in their quality of sleep and general health, whereas men felt it more in their ability to work¹⁴. Going by all this, there is no complete picture about women, depression and its coping. There is need for more work on this theme. Therefore, it was the generic aim of this inquiry to investigate the coping mechanisms used by women with MDD. More specifically, the objectives were:

- (i) To study whether women with MDD differ from healthy controls in their coping mechanisms.
- (ii) To examine whether women with MDD differ in the use of their coping mechanisms about the severity of their symptoms.
- (iii) To determine whether women with MDD use more maladaptive or adaptive coping mechanisms.

Method

It is a cross-sectional hospital-based study. Data collected from outpatient psychiatric department at IMS & SUM Hospital, Bhubaneswar, Odisha from Nov 2019 and Jan 2020. The clinical sample included were women with the diagnosis of MDD currently in acute phase as well as those already diagnosed but currently under remission as confirmed by screening by psychiatrists based on criteria prescribed by the Diagnostic and Statistical Manual of Mental Disorder-IV-TR. The written consent was taken from the patients and confidentiality was assured. The ethical clearance was taken from IMS and SUM hospital, Siksha O Anusandhan (Deemed to be University) Ethical committee.

Sample:

A total 37 women with major depression and 40 healthy controls were taken for the study using simple random sampling. The age range of participants was 20 to 65 years. Out of 37 most of depressed women were educated up to graduation (49%), homemaker (67%), married (78%), hailing from joint family (62%), middle socioeconomic status (57%), rural with a family history of depression (54%) and more than three years duration of illness (43%).

Tools:

The HAM-D¹⁵ with a score of at least seven or more was used to support diagnostic procedures. This scale has 17 items, rated from 0 to 3 or 0 to 5 Likert-type in terms of intensity. The study recruited 37 women participants with clinical diagnosis of major depression ranging from ages 20 to 65. For the normal healthy controls, participants who scored at least five or more on GHQ¹⁶ were used. The Brief COPE¹⁷ was used to capture the frequency of coping strategies of respondents. This tool has 28 statements across two scales. The focus is on understanding the frequency with which people use different coping strategies in response to various stressors. Respondents score from 1-4 from least to most. Internal reliabilities for the subscales range from $\alpha = 0.57-0.90$. The study included 40 age-matched healthy controls. An investigator developed Socio-Demographic Personal Data Sheet was used to elicit background details of participants.

Data Analysis

SPSS 20th version was used to analyze the data. Descriptive methods were used to study the demographical variables and frequency of other variables. Inferential statistics were used to compute the statistical differences between the two groups by using independent sample t-tests.

Results

The findings of this study are presented under the following sub-headings:

- (i) Women with major depression and healthy controls;
- (ii) Coping mechanisms with the severity of their symptoms; and,
- (iii) Maladaptive and adaptive coping mechanisms.
- (iv) **Women with major depression and healthy controls:**

On the whole, it is seen that women with MDD show an overall greater score for depression on HAM-D (N: 37; Mean: 25.20; SD: 3.42) than their matched HC (N: 40; Mean: 2.11; SD: 0.74). The difference between the two groups is statistically significant (t: 41.6792; df: 75; p: 0.0001).

Various adaptive coping mechanisms reportedly by the clinical sample (Table 1) are use of religion, emotional social support and instrumental social supports are high, attempts at active coping and acceptance of the condition are medium, while positive reframing, humor, and planning is least used. Among the negative or maladaptive coping mechanisms used by them, venting, self-blame, self-distraction, behavioral disengagement

and denial are foremost, as compared to substance use which is the least. Contrasting this, the HC reportedly use wider variety of adaptive coping mechanisms including planning and positive reframing that are used less by the clinical group of women. The use of humor as means of positive coping and substance use as negative coping is minimal in both groups (p: <0.01).

Table 1: Distribution of scores measuring different coping strategies for MDD and HC

Coping Strategies	MDD (N: 37) Mean ± SD	HC (N: 40) Mean ± SD	T value	P
Active coping (+)	4.38± 0.80	5.70±1.20	5.43	.000
Planning (+)	2.27±0.65	4.80±1.04	12.4	.000
Use of instrumental social support (+)	5.11± 0.88	5.65±0.98	2.55	.013
Use of emotional social support (+)	6.54±0.87	5.70±1.34	3.17	.002
Acceptance (+)	4.38±1.94	5.70±1.27	5.39	.000
Positive reframing (+)	3.24± 0.64	3.95±0.75	4.42	.000
Religion (+)	6.70±0.97	5.65±0.98	4.75	.000
Humor (+)	2.27±0.45	2.53±0.64	2.00	.049
Self blame (-)	5.86±1.45	3.15±0.86	10.03	.000
Self distraction (-)	5.43±0.96	3.48±0.99	8.86	.000
Behavioral disengagement (-)	5.22±1.31	2.90±0.84	9.28	.000
Denial (-)	4.49±1.77	2.50±0.60	6.69	.000
Venting (-)	6.57±0.90	5.35±1.21	4.98	.000
Substance use (-)	-	-	-	-

[Key: MDD: Major Depression Disorder; HC: Healthy Controls;

(+): indicate positive, adaptive or healthy coping mechanisms;

(-): indicate negative, mal-adaptive or unhealthy coping mechanisms]

(i) Coping mechanisms with the severity of their symptoms:

The analysis of the type of coping mechanisms used by women with MDD based on severity of their symptoms was attempted across three groups (Table 2). One-way ANOVA comparison between the three

groups, assuming that the samples are independent, the variable is normally distributed, and the variances of populations are equal, shows there is no significant difference (p: >0.05) only for the domain of using humor as coping mechanism by this sample of women. It is an effective coping mechanism when things are not going well even for healthy people. In this study, no humor appears to have been invoked by women respondents to combat their depression or supplement their even healthy lifestyle.

A significant result on ANOVA indicates that at least three groups differ from each other. It does not identify which of the groups differ. Therefore Tukey test was attempted to determine where the differences lie

exactly among three groups in coping mechanisms. Such a test will keep the level of Type I error (i.e., finding a difference when none exists) equal to the chosen alpha level (e.g., $\alpha=0.05$ or $\alpha=0.01$).

Table 2: Coping mechanisms with the severity of symptoms

Coping Mechanisms	Mean ± SD			F	p value
	HC (n=40)	Moderate(n=19)	Severe(n=18)		
Active coping (+)	5.70 ^{bc} ±1.20	4.63 ^b ±0.90	4.11 ^a ±0.58	16.2	.000
Planning (+)	4.80±1.04	5.21±0.85	5.00 ^a ±0.91	38.72	.000
Use of instrumental social support (+)	5.65±0.98	6.63±0.96	6.44±0.78	3.49	.036
Use of emotional social support (+)	5.70 ^b ±1.34	3.89 ^a ±1.29	4.22 ^{ab} ±1.22	5.08	.009
Acceptance (+)	5.70±1.27	3.11±0.66	3.39±0.01	14.89	.000
Positive reframing (+)	3.95±0.75	6.74±0.99	6.63±0.97	10.64	.000
Religion (+)	5.65±0.98	2.37±0.50	2.17±0.38	11.16	.000
Humor (+)	2.53±0.64	5.79±1.62	5.94±1.30	2.62	.079
Self blame (-)	3.15±0.86	5.53±0.96	5.33±0.97	49.90	.000
Self distraction (-)	3.48±0.99	5.26±1.45	5.17±1.20	38.72	.000
Behavioral disengagement (-)	2.90±0.84	4.48±1.80	4.11±1.71	42.53	.000
Denial (-)	2.50±0.60	6.63±0.96	6.50±0.86	24.44	.000
Venting (-)	5.35±1.21	2.00±0.00	2.00±0.00	12.33	.000
Substance use (-)	-	-	-		

Note: mean values with different superscripts are significantly different from each other as indicated by Tukey’s HSD ($\alpha=.05$)

Post hoc measures indicate that “active coping” strategy (F: 16.2; p: 0.001) and “use of emotional social support” (F: 5.08; p: 0.009) are the only two coping mechanisms that distinguish the three groups. There is a linear decrease in the mean scores with increase in the severity of depression. The sample of women respondents with severe symptoms show the least “active coping” strategies (Mean: 4.11; SD: 0.58) compared to

those with moderate depression (Mean: 4.63; SD: 0.90) and HC (Mean: 5.70; SD: 1.20).

(ii) Maladaptive and adaptive coping strategies:

In this study, it is noted that almost five out of eight positive domains, viz., active coping, planning, use of instrumental social support, use of emotional, social

support, and positive reframing are used as coping mechanisms as compared to the less use of humor, and religion by the women with MDD. Among the negative coping mechanisms, denial, self-blame, and self-distraction are used more by them. There appears to be a generic disinclination by all women to use emotional humor as coping mechanism. The women with moderate-severe depression are prone to use social-behavior than cognitive based strategies to cope with depression. Unlike in the reports from the West, the use of substance is not at all found in this clinical sample of women with MDD¹⁸.

Discussion

The study sought to see if there are any differences in coping mechanisms used by women with MDD and HC. The results match many previous studies that women with MDD have fewer or poor coping mechanisms than matched HC. It is found that they are more likely to cope using emotion-based mechanisms like denial, behavioral disengagement, self-blame and by seeking social supports¹⁰. By contrast, the healthy non-clinical sample of women use additional cognitive based strategies like planning, positive reframing, and religion rather than negative strategies like self-blame, rumination, catastrophizing, and other-blame. There exists positive correlation between depression symptoms and use of maladaptive coping mechanisms¹⁹. Negative thoughts and wrong beliefs about events and use of dysfunctional coping methods are the result of inability to take control of negative emotions which can lead to depression. Individuals with improper use of coping mechanisms have lower mental health and life satisfaction^{20,21}.

Complex relationship between gender, coping, and psychopathology targeting at-risk populations can be validated by further research. The relationship between the coping mechanisms and depressive symptoms

Such as self-blame, positive reframing is the cause or consequence of depression is not still very clear.

Finally, the other aspects of etiological factors of the disease may tend to perpetuate or maintain the negative affectivity in women i.e., stressful life events, genetic predispositions, or social learning contingencies. In sum, this study attempts to establish a relationship between adaptive-maladaptive coping mechanisms and depression.

The present study has few limitations. Some responses were retrospective due to the use of self-reported measures. There is likelihood of response bias, influence of social desirability and retrospective falsification in reporting. Finally, the design of the study is cross-sectional and does not allow for the evaluation of causal relationships. Generalization of the findings is limited because of the relatively small size of the non-depressed adult sample.

Conclusion

Despite these limitations, this study suggests that women experience major depression. Their coping mechanisms are more emotion-focused and less problem-centered. Helping women to achieve a greater sense of control over their circumstances and to engage in problem-solving rather than emotionality when dealing with stressors, as well as changing the social circumstances that cause these reactions, would be useful. Coping mechanisms are also associated with the patient's understanding of their symptoms and how one manages the illness.

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Pattern of Ocular Disorders in Adolescent population : Data From Tertiary Care Centre

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Abstract

Aims: This study was carried out to determine ocular disorders and visual impairment among adolescents attending Out Patient Department of Ophthalmology in a tertiary care center

Methodology: A retrospective study was carried out among adolescents attending out patient department of Ophthalmology in VMMC and Safdarjung Hospital New Delhi. Data of 191 patients between 10-19 years with ocular disorders were analyzed.

Findings: 191 adolescent cases and 382 eyes were evaluated for various ocular disorders and visual impairment. The mean age of the cohort was 14.7 years.

Uncorrected refractive error and difficulty in seeing objects at distance (far vision) is the commonest among the adolescent group. Blindness was observed in 2.8% with a slight female preponderance.

Severe visual impairment is caused by corneal opacity, central nervous system abnormality and phthisis was observed in 13%. Refractive error, corneal opacity, posterior segment diseases and cataract cause moderate impairment in 39.2%. Mild impairment is caused mostly by refractive error.

Conclusion: The frequency was higher in females than males across all categories of visual impairment. Uncorrected refractive error is common in adolescent age group and often detected late in the absence of regular screening among adolescent.

Keywords: Ocular disorders, Adolescent, Refractive error

Introduction

Ocular disorders among adolescents is a common cause of poor vision. Blindness and visual impairment are major public health concerns globally and more importantly in developing world. Global initiative has been set up to achieve goal of eliminating avoidable blindness by 2020. It aims to reduce prevalence of avoidable visual impairment by 25% by 2019 compared

to 2010 data. Majority of the disorders resulting in poor vision are preventable and correctable if detected early. There is often a delay in diagnosis and correction of common ocular disorders. The major causes of blindness differ, depending upon geographical areas.

According to WHO the prevalence of blindness in lower socio economic strata is 1.5/1000 children. (1) Worldwide about 19 million children are visually impaired of which 12 million are due to uncorrected refractive error. Out of 1.4 million cases of blindness, two-thirds are from Asia⁽²⁾

In India prevalence of childhood blindness or low vision is 0.8/1000. Many of these ocular problems such as refractive error, cataract, glaucoma, amblyopia are amenable to interventional measures, are detected

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through vision screening of selected population. (3-5)

These figures and also the fact that timely intervention of visual impairment could not only correct the correctable but also improve the quality of life, academic performance and overall development in the vulnerable age group, encouraged us to analyze our data of ocular disorders in adolescent age group attending Out Patient Department of Ophthalmology at Vardhman Mahavir Medical College and Safdarjung Hospital.

Materials and Methods

Medical records of all patients between 11-19 attending Out Patient Department of Ophthalmology at VMMC and Safdarjung Hospital between Jan 2016-Dec 2017 were reviewed.

191 patients and 382 eyes were evaluable during the study period. All patients underwent routine vision check up irrespective of their complaints.

Ophthalmic examination procedure included

(i) Vision Assessment: Visual acuity was determined separately for each eye at 6 meters using the Snellen’s chart. Where the visual acuity was 6/9 or less, a pinhole was presented for that eye and the test repeated.

(ii) Binocular Motor function by Hirschberg test. Nystagmus assessed by cover test and prism cover test.

(iii) Cycloplegic dilatation and Refraction

(iv) External and Anterior segment : Eyelids, conjunctiva, cornea, iris and pupil were examined.

(v) Best Corrected Visual Acuity

(vi) Fundus examination: Detailed evaluation with direct ophthalmoscopy was performed for all patients to ascertain the diagnosis

Blindness defined as presenting visual acuity in better eye <3/60.

Severe visual impairment is presenting visual acuity in better eye <6/60-3/60.

Moderate impairment is when presenting visual acuity in better eye<6/18-6/60,caused by refractive error, corneal opacity, posterior segment diseases and cataract.

Mild impairment is when visual acuity in better eye is <6/12-6/18, caused mostly by refractive error.

Data including demographic characteristics, clinical symptoms, clinical symptoms and associated ocular disorder were analyzed

Findings

191 adolescent cases and 382 eyes were evaluated for various ocular disorders and visual impairment. The mean age of the cohort was 14.7 years.

The demographic and clinical presentation are summarised in Table 1.

Table 1:Ocular Symptoms n=191.

Symptoms	Frequency	Percentage
Difficulty in vision	123	64.3
Itching	29	15.1
Eye pain	73	38.2
Watering	56	29.3

The distribution of various categories of visual impairment observed in the cohort is depicted in Table 2.

Table 2: Categories of Visual impairment Total number of eyes 382

Age group 11-19 years	Blind <3/60	Severe impairment <6/60-3/60	Moderate impairment <6/18-6/60	Mild impairment 6/12-6/18
Male	3	21	64	74
Female	8	29	85	98
Percentage %	2.8	13	39.2	45

Uncorrected refractive error and difficulty in seeing objects at distance (far vision) is the commonest among the adolescent group. Distribution of various ocular disorders is depicted in Table 3.

Table 3: Distribution of Ocular disorders n=382 eyes

Disorder	Frequency(%)
Refractive error	297(77%)
Corneal opacity	16(4.1)
Posterior segment disorder	11(2.9)
Cataract	22(5.7)
Others	36(9.4)
Glaucoma	2
Trauma	2
CNS*	2
Strabismus	28(14 eyes)

*CNS Central Nervous System

Blindness was observed in 2.8% with a slight female preponderance. Of the 11 eyes 3 had leucomatous corneal opacity, 2 had glaucoma, 2 had CNS abnormalities and remaining 4 had traumatic optic atrophy

Severe visual impairment is caused by corneal opacity, central nervous system abnormality and phthisis was observed in 13%. Refractive error, corneal opacity, posterior segment diseases and cataract cause moderate

impairment in 39.2%. Of 149 eyes refractive error was seen in 115, corneal opacity was observed in 13 eyes and 11 had macular degeneration. Glaucomatous and traumatic optic atrophy was observed in the remaining 6 eyes. Mild impairment is caused mostly by refractive error, intermittent exotropia observed in 28 eyes. The frequency was higher in females than males across all categories of visual impairment.

Discussion

The present study was intended to determine ocular disorders and visual impairment among adolescents attending a tertiary care center. Our study observed refractive error(77%) as the most common cause of visual impairment. Similar observation was made by Sarkar et al and Kumar et al⁽⁶⁻⁷⁾ though the figures are higher in our study which could be attributed to ethnic variations and life style. Several other studies have also reported similar finding⁽⁸⁻¹⁰⁾ However the present study showed a higher proportion of children with refractive error compared to existing literature possibly due to difference in sample size, and all cases were already symptomatic while seeking ophthalmic services in contrast to cases picked up at screening. The current study also reported that the frequency was higher in females than males across all categories of visual impairment. This was in line with observation by Sarkar et al⁽⁶⁾ .However this was in contrast to other studies reported from Maharashtra and Puducherry where higher prevalence was reported in males⁽¹⁰⁻¹¹⁾

The common barriers for accessing eye care could possibly be include need not felt which is commoner in females, cost of treatment, poor access to health care. This highlights younger children should be regularly and thoroughly examined for detection and reducing long term visual impairment.

Health education campaign to improve awareness among parents and adolescent children will be helpful in resource constraint setting for ophthalmic services.

Conclusion:

From the findings of the above study the leading causes of preventable blindness and visual impairment in adolescent population remains to be uncorrected refractive error, corneal opacities. Detection is often late

in the absence of regular screening among adolescent. However our results may be interpreted with caution due to retrospective nature of the study. A larger sample size and a prospective study in future would be helpful .

Conflict of Interest Nil

Source of Funding : Nil.

Ethical Clearance: Taken from Institute ethics committee of VMMC & Safdarjung Hospital, New Delhi

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Association of Personal Protective Equipments with Respiratory Morbidity among Puffed Rice Workers of Davanagere City

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Abstract

Introduction : Personal Protective Equipments (PPE) are designed to protect employees from various workplace injuries or illnesses which resulting from contact with chemical, radiological, physical, electrical, mechanical or other workplace hazards. The protection of workers from workplace hazards is crucial to reduce mortality and morbidity. These morbidities and mortalities will occur long after the workman has left the work.

Methods: A Cross sectional study was conducted among puffed rice workers in Bashanagar, urban field practice area of SSIMS & RC, Davanagere from January to December 2017. The study population included 550 puffed rice unit workers. Data was entered in the Microsoft excel and analysed using SPSS v20.

Results: In this study majority of the workers (93.4%) were non users of any personal protective equipments. In this study Respiratory morbidity was higher among non-users of personal protective equipment but no statistical significant association was found between personal protective equipment and respiratory morbidity.

Conclusions: In present study no significant association was found between respiratory morbidity and personal protective equipments.

Keywords: Personal protective equipments, Respiratory morbidity, Davanagere

Introduction

Personal Protective Equipment (PPE) are designed to protect employees from various workplace injuries or illnesses which resulting from contact with chemical,

radiological, physical, electrical, mechanical or other workplace hazards, The equipments are face shields, safety glasses/goggles, hats/safety helmets, safety shoes, coveralls, gloves, ear protection (ear plugs and muffs), vests, respirators, etc.¹ Sir Thomas Morrison Legge was identified the roles of the employer and those of the employee in reducing workplace hazards and consequently achieving a healthy workplace environment. The protection of workers from workplace hazards is crucial to reduce mortality and morbidity. These morbidities and mortalities will occur long after the workman has left the work.² Puffed rice is

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a popular food item, Karnataka has some of the largest number of clusters of Puffed Rice units. Davangere is the largest supplier of puffed rice not only to other districts of Karnataka but also to other states. The fuels used in ovens are mainly rice husk, wood shavings, groundnut shell and automobile tires as they generate high heat and are of low cost. Subjects with workplace exposure to organic dust have high risk of prevalence of respiratory diseases.³ This study was taken up in order to assess the compliance of personal protective equipments and to determine its association with respiratory morbidity among the puffed rice units workers of Davanagere city.

Materials and Methods

A cross sectional study was conducted during January to December 2017 among the workers of puffed rice units situated at Bashanagar, Urban field practice area of SSIMS&RC, Davanagere. Ethical clearance was obtained from the Institutional Ethical Review Board. The workers working in these units aged above 14 years, Workers working for greater than 1 year and Workers willing to participate were included in the study. Pregnant women, those who have undergone cardiothoracic surgery and recent history of Myocardial infarction were excluded from the study. A study by Energy Research Institute among the puffed rice production workers in Davanagere showed that the respiratory morbidity was 15.6%.

Where $p =$ prevalence of respiratory morbidity 15.6,
 $q = 100 - p = 84.4$, $d = 20\%$ of $p = 3.12$

Hence $n = 4 \times 15.6 \times 84.4 = 541$

3.12×3.12

$N = 541$, rounded for 550.

In order to collect data from 550 workers, out of 1200 puffed rice production units situated in Bashanagar, 550 production units were selected by using simple random sampling method using random number table. From each unit only one worker was taken randomly by lottery method. A pretested semi structured and validated questionnaire were used to collect information from each worker after taking informed consent. Respiratory morbidity assessment, occupational and exposure history were taken from American Thoracic society (ATS)⁴. The questions related to Occupational

Safety and Personal Protective Equipment were taken from National Institute for Occupational Safety and Health (NIOSH) questionnaire⁵. Spirometry was carried out by the instrument RMS (Helios's) Spirometer. The following parameters were used in the spirometry

1. Forced Expiratory Volume in the 1st Second (FEV1): It is the volume of air in liters that can be forcefully and maximally exhaled in the 1st second after a maximal inspiration.

2. Forced Vital Capacity (FVC): It is the volume of air in liters that can be forcefully and maximally exhaled after a maximal inspiration. **3. FEV1/FVC Ratio.** It is the amount of air exhaled in the first second divided by all of the air exhaled during a maximal exhalation. Any person with spirometer reading showing FEV1 <80% of the predicted normal for age and sex, FVC usually reduced but to a lesser extent than FEV1 and FEV1/FVC ratio reduced to <0.7 were considered to have Obstructive pulmonary disease and spirometer showing FEV1 <80% of the predicted normal, FVC <80% of the predicted normal and FEV1/FVC ratio being normal (i.e. >0.7) were diagnosed to have Restrictive pulmonary disease. The results of spirometry were assessed according to the criteria followed by American Thoracic Society⁵.

Data was entered in MS EXCEL and statistical analysis was done using SPSS version 20 and results were expressed in terms of percentages and proportions. Analysis was carried out by chi square test to find out the association between respiratory morbidity compliance of personal protective equipments.

Results

The prevalence of respiratory morbidity among the puffed rice workers in the present study was found to be 41.0%. Among them 51(9.2%) puffed rice workers reported Obstructive lung diseases and majority of the workers 175(31.8%) reported Restrictive pattern of lung diseases. The patterns of the respiratory morbidity are explained in the Table 1.

In this study, duration of the work of the majority of the workers was 11-20 years i.e. (39.5%), majority of them were involved in salt mixing process (25.3%) and majority of the workers work less than 9 hours per day (81.9%). The distribution of study participants based

on occupational and exposure history are explained in the table 2.

In this study majority of the workers (93.4%) were non users of any personal protective equipment. Among the users majority of them were using Goggles (3.7%). The compliance of personal protective equipments among study participants are explained in Table 3.

In this study Respiratory morbidity was higher among non-users of personal protective equipment but no statistical significant association was found between personal protective equipment and respiratory morbidity.

The association between respiratory morbidity with personal protective equipments are explained in the table 4.

In this study the study participants reported various reasons for non compliance of personal protective equipments. Majority of the participants (60.6%) were reported that they were uncomfortable to personal protective equipments. Other reasons includes it's unnecessary (33.2%) and non availability of personal protective equipments (6.2%) . The reasons are explained in the table 5.

Table 1: Distribution of study participants based on pattern of respiratory morbidity.

Variables	Frequency	Percentages
Normal lung function	324	59.0
Obstructive	51	9.2
Restrictive	175	31.8
Total	550	100
Grading of obstruction based on FEV1 ratio		
Mild obstruction (FEV 1 > 70 % pred.)	8	16.0
Moderate(60–69%)	19	38.0
Moderately severe(50–59%)	13	26.0
Severe(35–49%)	11	22.0
Grading of restrictive disease based on FVC ratio		
Mild restriction (FVC>70% pred.)	26	15.0
Moderate restriction (60-69%)	77	44.0
Moderately severe (50-59%)	45	26.0
Severe (30-49%)	23	13.0
Very severe (<35%)	4	2.0

Table 2. Distribution of study participants based on Occupational and exposure history.

Variables	Frequency(n)	Percentage (%)
Duration of work in years		
1-5 years	77	14.0
6-10 years	107	19.5
11-20 years	217	39.5
> 20years	149	27.0
Type of work		
Puffing	88	16.0
Salt mixing	139	25.3
Water filling	66	12.0
Soaking	48	8.7
Paddy boiling	57	10.3
Rice drying	100	18.2
Rice carry for dehusking	52	9.5
Duration of hours/day		
Less than 9 hours per day	450	81.9
More than 9 hours per day	100	18.1
Total	550	100

Table 3. Distribution of study participants based on compliance of Personal protective equipment.

Variables	Frequency(n)	Percentage(%)
Non users	514	93.4
Users		
Mask	13	2.4
Goggles	20	3.7
Gloves	3	0.5
Total	550	100

Table 4. Association of respiratory morbidity with personal protective equipment

Variables	Spirometry pattern			Total	X2 Value	Df	P value
	Normal	Obstructive	Restrictive				
Personal protective equipments							
Users	18(50.0%)	3(8.3%)	15(42.0%)	36(100.0%)	1.73	2	0.421
Non users	306(60.0%)	48(9.3%)	160(31.1%)	514(100.0%)			
Total	324(59.0%)	51(9.2%)	175(31.8%)	550(100.0%)			

Table 3: Reasons for non compliance for personal protective equipments

Reasons		
	Frequency	Percentage (%)
1. Non availability	34	6.2
2. Uncomfortable	334	60.6
3. Unnecessary	182	33.2

Discussion

This study was conducted among workers employed in puffed rice units which are located in Bashanagar, urban field practice area of SSIMS &RC, Davanagere. In this study duration of work of the majority of workers was 11-20 years (39.5%). Similar result was found by study conducted by Uma R et al⁸. In this study majority of the workers work less than 9 hours . In contrast to this a study done by Rana MC et al.⁹ showed the workers works more than 9 hours/day. In this study majority of the workers involved in salt mixing process .In this study Majority of the workers did not use any form of personal protective equipment and respiratory morbidity was higher among non-users of personally protective equipment but no statistical significant association was found. Similar results were found from study done by

Ratnaprabha GK et al.⁷ In contrast to this a study done by Rana MC et al.⁹ showed that significant association was found between personal protective equipment and respiratory morbidity. In this study the reasons cited for non compliance of personal protective equipments were felt Uncomfortable(60.3%), unnecessary(33.2%) and Non availability (6.2%). In present study prevalence of respiratory morbidity among puffed rice workers was 41.0%.Among them 51(9.2%) puffed rice workers reported obstructive lung diseases and majority of the workers 175(31.8%) reported restrictive pattern of lung diseases. Similar results were found by A case study done by the Energy Research Institute, Bangalore at Davanagere city³ which Showed that majority of the workers were reported restrictive pattern of lung diseases and Tawade PM et al.¹¹ In contrast to this study a study done by Rana MC et al.⁹, Ghosh T et al.¹⁰ showed that

majority of the workers in their study were reported obstructive pattern of respiratory diseases.

Conclusion

In this study majority of the workers did not use any form of personal protective equipment and respiratory morbidity was higher among non-users of personally protective equipment but no statistical significant association was found.

Recommendations

1. To initiate provision and promotion of personal protective equipment (such as respiratory mask) to all who were involved in puffed rice units.

2. Pre-placement examination of workers be carried out before they join the puffed rice units.

3. Regular periodic medical examination is required.

4. Health education must be done about the dangers of rice dust exposure, occupational lung diseases and other occupational hazards and use of personal protective equipment for protection from hazards.

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Declarations

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Ethical approval: The study was approved by the Institutional Ethics Committee

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Efficacy of Intravitreal Dexamethasone implants in Diabetic Macular Edema Unresponsive to Anti-VEGF Therapy

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Abstract

Background: Diabetic retinopathy is a common microvascular complication of diabetes leading to Diabetic Macular Edema (DME) and visual impairment in the working age population¹. About one third of diabetic individuals had some degree of Diabetic retinopathy and less than 10% develop DME.

Intravitreal dexamethasone implant in cases unresponsive to anti VEGF therapy has a beneficial role in improving visual acuity and macular morphology. The possible mechanism of action could be resolution of edema that was resistant to anti VEGF agents

Aims and Objectives: To determine the efficacy of intravitreal dexamethasone implant for DME unresponsive to anti Vascular Endothelial Growth factor (VEGF) treatment

Methodology: A retrospective analysis of refractory 21 cases, 30 eyes of DME to primary anti VEGF treatment was performed to analyze the profile of presentation and treatment outcome to Intravitreal dexamethasone implants. Ranibizumab (0.5 mg) administered monthly and if, were unresponsive after 5-6 injections were switched to Intravitreal Dexamethasone implants (0.7 mg).

Failure to therapeutic response was characterized by increase in central macular thickness from baseline finding or no response to treatment. Intravitreal dexamethasone implant was administered every two months

Best corrected visual acuity, Intraocular pressure and central macular thickness was evaluated at baseline and following intravitreal dexamethasone implant.

Result: The mean age was 56.3± 5.9 years. The mean Intra ocular pressure was 17.3±2.7 mmHg.

The mean anti VEGF treatment sessions was 5.8±1.2. The mean BCVA improved significantly from LogMar 0.76 ±0.16 to 0.67 ±0.19 (p value=0.029) and CMT improved significantly from 431.6 ±100.9µm to 379.1 ±80.72µm (p value =0.0005).

Conclusion: Intravitreal dexamethasone is effective in refractory cases of DME unresponsive to anti VEGF therapy. Optimal evaluation and tailoring therapy with the therapeutic response will be beneficial.

Key Words: Diabetic Macular edema, DME, Intravitreal Dexamethasone, Diabetic retinopathy

Introduction

Diabetic retinopathy (DR) is the leading cause of visual impairment in the working age population

worldwide.¹ Diabetic macular edema (DME) is macular thickening secondary to diabetic retinopathy. The global prevalence of DME is 6.8% and observed to be related to the duration of diabetes.²⁻⁴

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Treatment of DME remains controversial among various centers and treating specialists. Focal and grid photocoagulation had been treatment of choice in the past but had the limitation of little role in improving

vision.⁵ Improved understanding of the pathogenesis of DME has facilitated treatment be directed to the cause.

The pathogenesis of DME is complex with a possible role of hyperglycemia initiating capillary endothelial damage in the retina leading to angiogenesis and inflammation. Vascular endothelial growth factor (VEGF) also plays a key role in the pathogenesis.

Corticosteroids have been used to treat DME due to their anti inflammatory and anti angiogenic effect with the added risk of cataract and raised intra ocular pressure.

Currently anti-VEGF agents are the most effective agents for improvement of visual acuity and macular morphology. Despite significant improvement in visual and anatomic outcome large numbers of patients remain unresponsive to anti VEGF treatment and fail to resolve macular edema. It may impose a burden for patient by frequent administration⁶⁻⁸.

The Diabetic Retinopathy Clinical Research Network (DRCR Net) observed that about 40% of eyes treated with anti VEGF have central subfield thickness of 250 μ m at 2 years post treatment⁹. The role of inflammation in progression of DR is well documented and therefore the hypothesis of sustained release steroid implant is justified for anatomical improvement with the added advantage of reduced number of intravitreal injections compared to anti VEGF.

Several studies have observed beneficial role of intravitreal dexamethasone implant in cases unresponsive to anti VEGF therapy. The possible mechanism of action could be resolution of edema that was resistant to anti-VEGF agents¹⁰⁻¹¹

Lack of large prospective Indian data evaluating the effectiveness of intravitreal dexamethasone and the strong need to address the clinical situation encouraged us to analyze our data and determine the efficacy of intravitreal dexamethasone implant for DME, unresponsive to anti VEGF treatment in patients attending Retina clinic and outpatients department in the Department of Ophthalmology at Vardhman Mahavir Medical College and Safdarjang Hospital.

Methodology

Medical records of patients of diagnosed Diabetic Macular Edema {DME} attending Retina clinic and Out Patient Department of Ophthalmology at VMMC and Safdarjung Hospital between January 2018 and December 2018 were reviewed. 21 patients and 30 eyes were evaluable during the study period.

Inclusion criteria were the age \geq 18 years, diagnosed as DME, with prior anti-VEGF treatment, unresponsive or refractory to treatment after 5-6 injections administered monthly and thereafter switched to Dexamethasone implant at the discretion of treating physician were included in the study. Intra-vitreous Inj. Ranibizumab (0.5 mg) injections was administered monthly for six months duration. Unresponsive cases were switched to Intravitreal Dexamethasone implants (0.7 mg) which was administered every two months.

Demographic and treatment details of the patients were recorded including Visual Acuity (Snellen), Intraocular pressure [IOP] and Central Macular Thickness (CMT). The Best Corrected Visual Acuity (BCVA) was converted from Snellen VA to logarithm of minimum angle resolution (LogMAR) VA using standard conversion chart. OCT was performed using Heidelberg Spectralis spectral domain OCT [Heidelberg Engineering, Heidelberg, Germany]. Failure to therapeutic response was characterized by increase in CMT baseline finding or non responsive to treatment or (CMT) \geq 350m(SD-OCT). The changes in the BCVA, IOP and CMT values were recorded at baseline, 3 months and 6 months after Intravitreal Dexamethasone Implantation.

Patients treated within 6 months prior with intravitreal or sub-Tenon's injections of steroids, focal/grid macular laser photocoagulation, panretinal photocoagulation, cataract surgery, or pars plana vitrectomy, or in whom the macular edema was secondary to a cause other than diabetes were excluded from the study.

Statistical tests were 2 tailed, paired tests (using SPSS 24.0) were used for parametric paired variables.

Results

Thirty eyes of 21 patients were considered as per inclusion criteria. Demographic details have been

tabulated in Table1. The mean age of the group was 56.3± 5.9 years with a slight male preponderance. The mean number of anti VEGF injections and Intravitreal dexamethasone were 5.8±1.2 and 2.8±0.9 respectively.

The mean LogMAR VA was 0.67±0.19 and mean CMT was 431.6±100.9µm at baseline prior Intravitreal Dexamethasone implant.

At 3months of implantation, the mean BCVA improved significantly from LogMar 0.76±0.16 to 0.75 ±0.17 (p value = 0.05) and CMT improved from 431.6 ±100.9 µm to 409.6 ±77.6µm (p value =0.08). [Table-2]

At 6 months of implantation, the mean BCVA improved significantly from LogMar 0.76 ±0.16 to 0.67 ±0.19 (p value=0.029) and CMT improved significantly from 431.6 ±100.9µm to 379.1 ±80.72µm (p value =0.0005). [Table-2]

There was mean reduction of CMT (52.5 µm) from baseline values . IOP values did not change significantly from baseline 17.3 ±2.7 to end of 6months 18.6±2.9 (p value =0.44) [Table 2]. Four patients required topical anti Glaucoma medications during the course of the study.

Table1: Demographic Details

	Mean +SD(Standard Deviation)	Unit
Age	56.3+ 5.9	Years
Visual Acuity	0.67+ 0.19	LogMAR
IOP	17.3+ 2.7	mmHg
Anti VEGF (Ranibizumab)	5.8+ 1.2	Number of injections
Intravitreal Dexamethasone Implant	2.8+ 0.9	Number of injections
Gender	Male -12	57.14%
	Female-9	42.86%
Eye	Right 18	60%
	Left-12	40%

Table 2: Effects of Intra-Vitreous Dexamethasone Implant in Anti VEGF unresponsive Eyes

	Best Corrected Visual Acuity(BCVA)		Central Macular Thickness(CMT)		IOP		Eyes
	Mean+ SD	P value	Mean+ SD (µm)	P value	Mean+ SD	P	n
Baseline	0.76+0.16		431.6+100.9		17.3+2.7		30
3 months	0.75+0.17	0.05	409.6+77.6	0.08	19.3+2.1	0.31	30
6 months	0.67+0.19	0.029	379.1+80.72	0.0005	18.6+2.9	0.44	30

Discussion

The present study was intended to evaluate effectiveness of Intravitreal Dexamethasone implants in DME unresponsive to anti VEGF treatment. Vascular endothelial growth factor(VEGF) is an important mediator in the pathogenesis of DME. It has been established that Intravitreal anti-VEGF injections are the mainstay of treatment for DME.

The Diabetic Retinopathy Clinical Research Network (DRCRnet) Protocol I showed that 52% of patients treated with Anti VEGF (ranibizumab) failed to achieve more than 2 line improvement in BCVA and 40% of eyes treated with anti VEGF have central subfield thickness of 250µm at 2 years post treatment.⁹ Several studies have observed that patients treated with previous Ranibizumab injections may demonstrate tachyphylaxis or diminished therapeutic response^{12,13}

Hence it is logical to switch from anti VEGF agents. Intravitreal Dexamethasone has the advantage of reducing inflammation and also decreases frequency of intravitreal administration.

Lim et al. reported visual and anatomical improvements after switching to aflibercept who had refractory DME to bevacizumab and ranibizumab injections¹⁴. Bahrami et al showed a improved response with aflibercept injections in patients refractory to previous Bevacizumab injections.¹⁵ Wood et al demonstrated only anatomical improvements in a prospective study with aflibercept injections in poor response patients with ranibizumab injections.¹⁶ Though it seemed that there was greater visual improvement after switching to aflibercept injections it was proven to be not statistically significant. Switching to intravitreal steroids like Dexamethasone implants is a logical option in case of failure to treatment of DME with other anti-VEGF injections.¹⁷

Both anti VEGF and steroid injections have different pharmacological properties and side effects. Steroids have anti-inflammatory, anti-permeability, and angiostatic effects in DME.¹⁸

In our study , there was significant improvement in BCVA and central macular thickness at the end of three and six months post intra-vitreous implantation with Dexamethasone. This finding is in line with the similar

study.¹⁹

A transient initial rise in IOP though not statistically significant was observed as a side effect to dexamethasone implantation. This observation concurred with other studies reported earlier.²¹

The morphological improvement was more significant than BCVA, and this incongruity between morphological and functional improvements can be explained on the basis of irreversible damage of photoreceptors due to prolonged edema in the retinal layers, whereas the CMT is reduced due to clearing of edema from the retinal layers.²²

Given the limitation of small sample size and retrospective design of the current study, the findings emphasize the beneficial role of Intravitreal Dexamethasone in refractory DME.

Conclusion

Intra-vitreous Dexamethasone implants showed significant morphological improvements in CMT in comparison to BVCA and functional achievements . In addition to the advantage of fewer injections, Intravitreal Dexamethasone implant has a definite beneficial effect in switching from regular anti-VEGF in refractory DME.

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Conflict of Interest: None

Ethical Clearance: Taken from the Institute ethics committee of VMMC & Safdarjung Hospital.

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Living in Urban Areas, Low Education, Cognitive Function, and Medication Adherence Are Factors Related to Major Depression among Epilepsy Patients in Manado, Indonesia

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Abstract

Purpose: The aim of this study was to identify factors related to major depression among epilepsy patients in city of Manado.

Methods: This was a cross-sectional study conducted in Neurology Clinic and appropriate bivariate analysis was used to test the relationship between sociodemographic and clinical variables with major depression.

Findings: Living in urban areas, low education, low cognitive function, and low medication adherence are factors related to major depression. The relationship between medication adherence and depression is found in previous studies but the other significant factors in this study are not.

Conclusion: Our region has some particular factors related to major depression among epilepsy patients. These findings considered in designing local treatment strategy and health policy.

Keyword: Epilepsy, major depression, Manado-Indonesia, related factors.

Introduction

Depression is one of the comorbid symptoms that often occur in patients with epilepsy. Depression is a neuropsychiatric complication that often occurs in patients with chronic epilepsy. The prevalence rates reported more than 30% in the population with epilepsy, and between 20% - 55% in epilepsy centers.¹ However, until now there are no available data regarding these cases in Manado the capital city of North Sulawesi.

Depression problems in epilepsy can be influenced by sociodemographic factors and clinical factors. This prompted the writer to conduct a study on the role of sociodemographic and clinical factors in epilepsy

patients with depression in the neurology outpatient clinic from general hospital of Prof. Dr. R. D. Kandou Manado.

Purpose

The purpose of this research is to know and analyze depressive disorders in epilepsy, the prevalence of depressive disorders in people with epilepsy, the differences in sociodemographic and clinical characteristics between epilepsy patients who suffer from depression and those who do not experience them, and to know the association between both sociodemographic and clinical factors and epilepsy with depression

Method

This was a cross-sectional study. The sample population were the epilepsy patient at general hospital of Prof. Dr. R. D. Kandou Manado period December 2018 to February 2019. The research data collection in this study used a cross-sectional method. Recruitment of 107 research subjects, who met the inclusion criteria

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took part in the study, who can speak Indonesian, aged 18-65 years, get antiepileptic drug therapy, willingness to participate.

Examination of epilepsy patients, who are outpatient at the neurology clinic is carried out with anamnesis, physical examination, neurological examination, investigation, and MMSE. If it meets the inclusion criteria, a depressive disorder (NDDI-E) will be examined. Data on sociodemographic factors and data on clinical factors were also recorded on the research form.

The distribution of sociodemographic factors and clinical variables is presented in the tabulation form according to the type of variable. Numerical scale variables are presented as the median and interquartile range (IQR) because the “Shapiro Wilk” test shows that all distribution is abnormal. Categorical scale variables are shown in total N and proportions. Differences in sociodemographic and clinical characteristics according to depression status (major vs no depression) were tested with the “Mann-Whitney U” test for numerically classified variables, and chi-square test for categorical variables. Logistic regression models for binary outcomes were used to quantify the relationship of depression status and independent variables both at the bivariate level (univariable regression) and multivariate. All variables released from the univariate regression results were included in the variable selection for multivariate modeling. The regression modeling results were reported as Odds Ratios (OR), lower and upper limits of the 95% confidence interval, CI, and p values. The research data management was mostly taking place in R 3.5.2 statistical software application, which was also the main tool of statistical analysis.

Result

There were 107 subjects recruited in this study with half of the subject is female patients and the mean of age 29,42 years. More than half of the subjects live in a rural area. Senior high school graduates found in 77% subject. Unmarried subjects found in 63%. Most of the subject (74%) is Minahasa ethnic. Epilepsy onset during childhood are 37%, adolescents are 37%, and the rest is adult. Subjects with monotherapy found in 72%, mainly with phenytoin (52%), carbamazepine (11%), and valproate (7%). Median duration of taking antiepileptic

medication is 2.0 (1.0-9.5) years. Median of MMSE is 28.0 (27.0-29.0). Highly medication compliance found in 73% subjects. Sociodemographic factor that influences major depression is subjects living in urban ($p=0,039$) and who are not reached senior high school ($p=0.002$). The clinical factor is MMSE ($p=0,001$) and low medication compliance ($p=0,026$).

The selection of the final model for multivariate analysis was assisted by the “*forward selection*” facility in application R. Overall residence, education, AED therapy, administration of folic acid, MMSE value, type of epilepsy, and MMAS-8 categories were selected as independent variables of multivariable regression. However, the results are quite consistent with the findings of the univariable level. The magnitude of the relationship between major depression and place of residence, the level of education (especially elementary-junior high school vs. high school) in this multivariable regression appeared smaller than the univariable results.

Discussion

The prevalence of depressive disorders in patients with epilepsy in the neurology department at 69% for a period of 3 months of data collection using NDDI-E. This study included 10 subjects (9.35%) who had the desire to suicide.

The total sample of this study was also the majority unmarried because it belongs to the age group of 18-25 years. Comparison of the percentage between the number of men and women married to major depression (16% vs. 22%), while the percentage between the number of unmarried men and women with major depression was equally large with both of them in 31%. During this study, it has been found that the increase of mayor depression by unmarried patients are mostly because of the condition of the patients, that they cannot share their depression to someone.

The research in 74 subjects who experienced major depressive disorders were 39 people women and 35 people men ($p=0.846$). But from the results of statistical calculations, there was no significant difference between sex differences towards major depression ($p=0.846$). It was suspected that there were hormonal differences, the effects of childbirth, differences in psychosocial stressors between men and women.²

Many of the subjects with focal epilepsy experienced major depression and most of all with temporal lobe epilepsy (65%). This is consistent with Sheline's literature study report that depression in patients with temporal and frontal lobe epilepsy has a higher likelihood of depression. Hippocampal atrophy is a characteristic of mesial temporal lobe epilepsy, which is commonly found in people with depression with epilepsy.³

The variables that are most associated with the occurrence of major depression, were places of living between city or village, and education as the sociodemographic factors and MMSE values and medication compliance as the clinical factors. People with epilepsy, who live in urban/urban areas, have more major depression, possibly because medication adherence was low⁴ due to more daily activities, stress levels was also higher when living in cities than in villages. Subjects in this study who experienced major depression were found at the level of education who graduated from elementary school to junior high school. The patient will cause frequent feelings of unconfident and have limited knowledge, because of the low level of education. This limited knowledge will be impacting that they do not know the importance of compliance with taking medication.

Focal epilepsy mostly uses AED treatment with carbamazepine and phenytoin, but carbamazepine is an AED often causes Steven Johnson syndrome and HLA-B*1502 examination, which as a genetic marker in Steven Johnson syndrome due to carbamazepine is not yet known by the general public in Indonesia. While phenytoin is more often used because of its smaller incidence, it causes Steven Johnson syndrome smaller than carbamazepine, and phenytoin is included in drugs that are included in the Indonesia government insurance. The most widely used AED of polytherapy is a combination of phenytoin and clobazam because the AED is included in the government insurance, all subjects in this study were the government insurance participants. It's just that the use of AED levetiracetam in the subjects of this study has little effect on major depression because the samples are very limited or few so that they cannot provide a statistically significant correlation. Harsono's study found depression was one of the side effects of using AED phenytoin⁵ pregabalin, levetiracetam. Felbamate is also a depressogenic drug.

The drug lamotrigine also has an effect on mood.⁶ Phenobarbital and Phenytoin reduce free tryptophan plasma levels, while carbamazepine increases free tryptophan plasma levels, free tryptophan plasma influences serotonin replacement.⁷ From an analysis of the relationship between AED therapy and the risk of major depression, the use of polytherapy or combination AED is statistically significantly associated with the occurrence of major depression.

The subjects who received low dose of folic acid were found to have major depression. Alpert and Froscher's study showed a resemble result that epilepsy patients who were given very low concentrations of folic acid generally showed higher depression than those who were given normal levels of folic acid concentration. Low levels of folic acid 5-methyltetrahydrofolate derivatives are associated with depression severity.^{8,9} According to Setiawan, the need for folic acid needed is 0.5-1 mg daily orally.¹⁰

MMSE has a role to determine the decline in cognitive function that is often found in epilepsy, which depends on several factors including etiology, seizure type, certain epilepsy syndrome, location of the lesion or seizure focus, frequency and duration of seizures, age at onset, other psychiatric disorders such as anxiety and depression, and anti-epileptic drugs taken by them.¹¹ Higher depression scores are associated with lower cognitive function. Every decrease in 1 score point from the MMSE value will have a higher risk of causing depression.

The subjects who had low medication adherence were found to experience major depression, and according to multivariate analysis of low compliance to drink the medication (MMAS-8: 0-5) with a value of $p = 0.026$, which lead to a significant relationship with the occurrence of depression on the patient. This is in accordance with "Gidal and Garrett's" research regarding medication adherence is one of the factors that can still be improved, found that low drug compliance will cause uncontrolled epilepsy seizures. This continuous uncontrolled seizure will cause major depression.^{6,12}

The subjects of this study were obtained during uncontrolled seizure frequency with major depression as much as 53%. Based on the Indonesia government insurance rules, epilepsy patients with controlled

seizures will be treated more in hospital type B or C, whereas the referral system is the patient epilepsy that was found to have major depression with uncontrolled seizures became more prevalent in this study sample.

The weakness of this study is that folic acid levels were not examined because epilepsy patients who were given very low concentrations of folic acid generally showed high depression, and limited use of AED types. Clobazam given can be a confounder between Clobazam which causes depression or indeed there have been symptoms of depression before then given Clobazam. The study also did not have data on the history of status epilepticus that might have been experienced by the study subjects.

The weaknesses of this study are that the low concentrations of folic acid, clobazam masked the research result, and no status of epilepticus history on the patients. The folic acid levels were not examined because epilepsy patients who were given very low concentrations of folic acid generally showed high depression and limited usage of AED types, because AED. Clobazam that given to the patients can be the trigger to causes depression or the depression already happened before the given Clobazam. The research also did not have the historical data of status epilepticus, which has been through by the study subjects.

Conclusion

Epilepsy patients with major depression have different sociodemographic and clinical characteristics compared with epilepsy patients who do not experience depression. The sociodemographic factors associated with epilepsy sufferers with depression are epilepsy onset and education, while the clinical factors are AED, MMSE and medication adherence.

Conflict of Interest : There is no any conflict of interest within this study and publication

Ethical Clearance : This study has obtained the ethical approval of the research from the Health Research Ethics Committee of general hospital Prof. Dr. R.D. Kandou, Manado, with the registration number of 172 / EC-KEPK / IX / 2018.

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Relationship of Blood Vitamin-D Levels on Neoadjuvant Chemotherapy Response of Caf (Tumor Size Based on Ultrasonographic Examination) in Post Menopause Women With *Locally Advance Breast Cancer* in Dr. Soetomo General Hospital Surabaya

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Abstract

Background : Breast cancer is one of the most prevalent cancer in Indonesia and the most prevalent cancer in women. Patients in Dr. Soetomo Hospital Surabaya generally comes in an advanced stage condition (*locally advanced breast cancer*). 52% of the patients with breast cancer in Dr. Soetomo hospital did not respond well to chemotherapy treatment. This is related to low levels of vitamin D in the blood, which decreases the therapeutic response of breast cancer.

Method: The design of this research is a prospective cohort of patients with locally advanced breast cancer. Patients were examined for vitamin D levels and tumor mass size 1 day before the chemotherapy regiment was carried out and after 3 of CAF chemotherapy regimens were administered, an evaluation of the therapeutic response in patients was done by comparing tumor mass size before and after chemotherapy with ultrasound.

Results: There were 30 patients evaluated. 17 people (56.7%) with low level of vitamin D and 13 (43.3%) with normal level of vitamin D. The therapeutic response was obtained as follow, 13 people (43.3%) with partial response, 16 people (53.3%) with stable disease, and 1 person (3.3%) with progressive disease. Statistical tests proved a significant relationship between levels of vitamin D with chemotherapy response in patients with locally advanced breast cancer ($p = 0.026$).

Conclusion: There is a relationship between levels of vitamin D in blood with the size of the tumor, based on ultrasound examination, as a response to neoadjuvant chemotherapy of CAF in postmenopausal women with locally advanced breast cancer in Dr. Soetomo General Hospital Surabaya

Keywords: *locally advanced breast cancer, vitamin D, chemotherapy response, breast cancer*

Background

Breast cancer is one of the most prevalent cancer in Indonesia and the most prevalent cancer in women.

According to research done in Indonesia by Riskesdas in 2018, breast cancer is amounted to 42.1 per 100,000 population, with an average mortality of 17 per 100,000 population in Indonesia.

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At Dr. Soetomo Hospital Surabaya in 2009, it was obtained 207 patients were diagnosed with breast cancer in 1 year. Patients with breast cancer, especially in

developing countries often came too late to the hospital, they tend to come at an advanced stage.

Locally advanced breast cancer (LABC) is a stage III breast cancer which fulfilled the criteria: tumor with the size of more than 5 cm with regional lymphadenopathy or tumor with any size with extension directly into the chest wall without any distant metastases. LABC is related to the risk of treatment failure, locoregional, and systemic recurrence¹.

Neoadjuvant chemotherapy has developed into an important part of therapy for LABC. Neoadjuvant chemotherapy can play a role in shrinking tumors, reducing tumor staging, assessing response to a cytostatic before adjuvant chemotherapy, and improving prognosis by overcoming micro-metastases that have occurred¹.

Patients with LABC require first-line neoadjuvant chemotherapy such as cyclophosphamide, Adriamycin (doxorubicin hydrochloride), fluorouracil (CAF), or cyclophosphamide, epirubicin, fluorouracil (CEF) to reduce tumor size. Issues that need to be concerned is the radiological response of this first-line neoadjuvant chemotherapy².

Data in Dr. Soetomo Hospital showed that 52% of patients with neoadjuvant chemotherapy have a stable disease response. These data implicated in many studies that discuss the factors that influence successful chemotherapy. Antioxidants are one of the agents that give potentiation effects on chemotherapy agents which concurrently reducing the side effects of chemotherapy agents. Vitamin D is one of the antioxidants in the form of a steroidal hormone. Vitamin D functioned by regulating the homeostasis of calcium and phosphorus, vitamin D has an effect on the activity of the drug and reduce the toxicity of chemotherapy agents. In vivo and in vitro studies mention that calcitriol gives potentiation effect and synergism of the chemotherapy³.

Tumor responses for each individual to neoadjuvant chemotherapy are varied. Previous research demonstrated that patients who were given neoadjuvant chemotherapy can provide better clinical responses (70-98%) and better pathological response (3-34%). But there is still a 2-30% chance of the patient showed a negative response. Detection non-responder patients are important to do so that the more effective treatment can be given to these

patients. The response of neoadjuvant chemotherapy determines the further management of the patient and also can be used as an indicator of prognosis.²

The deficiency of vitamin D is associated with the possibility of not achieving pathologic complete response (pCR). The inability to achieve pCR is independently associated with a deficiency of vitamin D, the level of response of patients with LABC with a deficiency of vitamin D to chemotherapy neoadjuvant CAF can be detected by using breast ultrasound. Imaging evaluation to assess response to neoadjuvant therapy can be considered, not only by the measurement of the size and number of lesions, but also the functional analysis (absorption medium contrast, neo-vascularization), or on detection of pathological activity of the tumor⁵.

Based on that findings, this research was done to find the relationship between the level of vitamin D in blood with the neoadjuvant chemotherapy of CAF response (based on the size of the tumor on ultrasound) in postmenopausal women with locally advanced breast cancer in Dr. Soetomo General Hospital Surabaya.

Method

This study was an observational analytic study with a prospective cohort design. Patients women with LABC who meet the criteria for inclusion and exclusion of studies. Inclusion criteria were women with LABC stage IIIA who are getting 3 cycles of CAF neoadjuvant chemotherapy, postmenopausal women, breast cancer with ≤ 10 cm in diameter and there is no ulcer, and consented to be research subject by signing *the informed consent*. Exclusion criteria were patients with kidney diseases, liver diseases, recurrence breast cancer, patients with the weak general condition; described with Karnofsky score $\leq 70\%$, and patients never get chemotherapy/radiotherapy before.

The research subjects have then explained the purpose and benefits of the examination and were asked for approval to participate in the study by signing *informed consent* and *informed consent*. The research subjects then underwent examination of vitamin D levels in the blood and tumor size by ultrasound examination 1 day before undergoing neoadjuvant chemotherapy. Subjects will undergo chemotherapy according to the CAF regimen administration procedure. The CAF

administration cycle is repeated every 3 weeks until reaching the third cycle. Determination of the dose of CAF based index of the mass of the body, with a dose of cyclophosphamide 500 mg / m² iv, doxorubicin 50 mg / m² iv, 5FU 500 mg / m². The next will be done measuring the size of the tumor is based on inspection of ultrasound in patients after undergoing chemotherapy third, 2 weeks after chemotherapy the patient was evaluated again. Evaluation of response to chemotherapy was divided into four categories, namely: *progressive disease, stable disease, partial response, and complete response*. Ultrasound breast is done by using a machine ultrasound GE Logiq E9 with probe Linear 7.5 to 10 MHz. The number, size, and morphology of ipsilateral axillary lymphadenopathy were also assessed.

Data analysis was performed using SPSS 23.0. Data is presented in the form of frequency distribution

tables and cross-tabulations. Data from independent and dependent variables in the form of nominal data will be tested using the chi-square test, contingency test.

Results

The research subjects consisted of 30 women (100%), the research subjects were homogeneous data of women (100%) with menopausal status (100%). The youngest is 35 years old and the oldest is 69 years old. The average age of the sample is 51.1 years. At the study 's patients with *locally advanced breast cancer* is found most in Stage III B that is as many as 23 patients (76.7%) with the results of pathological anatomy most is *Invasive carcinoma of no special type* (infiltrating ductal carcinoma) Grade III that as many as 11 patients (36.7 %) and the most subtype is Luminal A, which is 10 patients (33.3%). Patient characteristics can be seen in Table 1

Table 1: Characteristics of Research Subjects

		Positive response	Negative Response	p
Age	<50 years old	5	9	0.431
	> 50 years old	8	8	
Profession	Indoor occupation	7	6	0.310
	Outdoor occupation	6	11	
PA	Ductal Ca	13	15	.201
	Non-Ductal Ca	0	2	
Subtype	Basal likes	1	2	.982
	Erb-B2 overexpression	2	3	
	Luminal A	4	6	
	Luminal B-like (negative HER-2)	3	3	
	Luminal B-like (positive HER-2)	3	3	

In the study, it found that patients with *locally advanced breast cancer* who underwent chemotherapy of CAF most great experience deficiency of vitamin D that 17 patients (56.7%), and only 13 patients (43.3%) who had levels of vitamin D were normal, namely 20 mg/dl. Vitamin D levels in patients with *locally advanced breast cancer* who underwent chemotherapy of CAF is presented in Table 2

Table 2 Levels of Vitamin D in patients with *locally advanced breast cancer* who underwent chemotherapy of CAF

Vitamin D	Frequency	Percentage (%)	Average
Vitamin D deficiency	17	56.7	17.5 ± 0.86
Vitamin D insufficiency	13	43.3	
Total	30	100.0	

In the study it found that the size of the tumor prechemotherapy was measured with ultrasound, the average size of the tumor before chemotherapy was 10.4 ± 3.9 and the mean size of the tumor after chemotherapy is 8.08 ± 4.10. The average table of tumor size is shown in Table 3

Table 3 Size of Tumors for Pre- and Post- Chemotherapy

	N	Range	Minimum	Maximum	The mean		Std. Deviation
	Statistics	Statistics	Statistics	Statistics	Statistics	Std. Error	Statistics
Pre- Chemo Tumor Size	30	9 .80	2.50	10 .30	10.4733	.72703	3,98211
Tumor size post Chemo	30	10 .30	2.00	10 .30	8,067	.74908	4,10288

From the data it appears to decrease the size of tumors were seen on average before chemotherapy and after chemotherapy, which after chemotherapy CAF size of the tumor is getting smaller. The response then grouped. Most of it was a stable disease, seen on 16 patients (53%). It was described in Table 4

Table 4 Response chemotherapy of patients with *locally advanced breast cancer* who underwent chemotherapy CAF

Chemotherapy Response	Frequency	Percentage (%)
Partial Response	13	43.3
Stable Disease	16	53.3
Progressive disease	1	3.3
Total	30	100.0

In the study, it found that patients who do not respond to drug chemotherapy are 17 patients and most large suffers a deficiency of Vitamin D (<20 ng/dl) which amounted to 14 patients and only 3 patients who had levels of vitamin D were normal, whereas patients who experienced response (+) consisted of 13 patients and most large possessed levels of Vitamin D were normal (> 20 ng / dL) that as many as 10 patients. Vitamin D levels and chemotherapy responses can be seen in Table 5

Table 5 Vitamin D Levels and Chemotherapy Response

		Chemotherapy Response		Total
		Response (+)	Response (-)	
Vitamin D Category	Vitamin D deficiency	3	14	17
	Vitamin D insufficiency	10	3	13
Total		13	17	30

From the results, it then does test the relationship between levels of vitamin D in the blood with the response of chemotherapy, of testing the correlation with the use of test lambda then obtained indigo $p\text{-value} = 0.026$ ($P < 0.05$) that of the value that can be concluded that there is a relationship which is significant in statistics between levels of vitamin D blood to the response of chemotherapy neoadjuvant CAF (the size of the tumor based on ultrasound examination) in women after menopause with locally advanced breast cancer. The test for the relationship between blood vitamin D levels and tumor size based on ultrasound examination in response to CAF neoadjuvant chemotherapy was shown in Table 6

Table 6 Test lambda levels of vitamin D blood with the size of the tumor is based on inspection of ultrasound as a response to chemotherapy neoadjuvant CAF

			Value	Asymptotic Standard Error a	Approximate T b	Approximate Significance
Nominal by Nominal	Lambda	Symmetric	.538	.183	2,229	.026
		Vitamin_D Dependent Categories	.538	.188	2,076	.038
		RESPON_KEMO Dependent	.538	.188	2,076	.038
	Goodman and Kruskal know	Vitamin_D Dependent Categories	.351	.176		.001 c
		RESPON_KEMO Dependent	.351	.176		.001 c

Discussion

Vitamin D levels are related to various factors, menopause is a unique factor where vitamin D deficiency occurs in many postmenopausal women. Several observational studies have linked low vitamin D levels with a greater risk of cancer and a poor prognosis. This is related to the effect of calcitriol on the microenvironment of tumor cells which is anti-proliferative and pro-apoptotic.

Tumor responses for each individual to neoadjuvant chemotherapy was varied. Previous studies have shown that patients given neoadjuvant chemotherapy can provide high clinical response rates (70-98%) and pathologically (3-34%). But there is still a 2-30% chance of the patient not showing a response. Detection of patients who are included in the non-response group is important to be done so that more effective management can be given to these patients. Tumor response to neoadjuvant chemotherapy determines the patient's subsequent management and can also be used as an indicator of prognosis, so an appropriate examination modality is needed to assess it²

In the study of Keune et al, found that a greater proportion of tumors could be measured using ultrasound rather than using mammography and that, overall, breast ultrasound was more accurate than mammography in predicting tumor size residues after neoadjuvant chemotherapy⁴. In the research of Thomas et al., Ultrasonography was the best predictor of tumor size in breast cancer, compared to physical examination, mammography, and resonance. With this result helping the decision-making processes such as the type of surgery, the possible need for oncology surgery, or the decision to start neoadjuvant therapy, in patients with unifocal tumors.

Vitamin D deficiency is associated with the possibility of not achieving a pathologic complete response (pCR). Inability to achieve pCR independently related to vitamin D deficiency, the response rate of LABC patients with vitamin D deficiency to neoadjuvant CAF chemotherapy can be detected using breast ultrasound. Imaging evaluations to assess therapeutic neoadjuvant responses can be considered, not only based on measurements of size and number of lesions, but on a functional analysis (absorption of contrast media, neo-

vascularity), or the detection of a physiopathological tumor activity⁵. Several confounding variables need to be tested before looking for an association between vitamin D levels and the clinical response of chemotherapy.

These chemotherapy responses are then further categorized as negative responses (progressive disease and stable disease) and positive responses (partial response and complete response). From these results, the chemotherapy response of patients with locally advanced breast cancer classified as CAF chemotherapy was classified. From the results it appears that the majority are in stable disease, amounting to 16 patients (53%). These results are consistent with the study of Audrina et al in which 52% of patients undergoing neoadjuvant chemotherapy experienced a stable disease response.

In this study, it was found that patients who did not respond to chemotherapy drugs were 17 patients and most suffered from Vitamin D deficiency (<20 ng/dl) in the amount of 14 patients and only 3 patients who had normal Vitamin D levels, while patients who experienced a response (+) consisted of 13 patients and most of them had normal Vitamin D levels (> 20 ng/dl) in 10 patients. In the test using the Lambda chi-square test showed that there is a relationship between the levels of vitamin D pre-chemotherapy with the response of chemotherapy after neoadjuvant chemotherapy (p-value = 0.026). This is following other studies and indirectly becomes evidence that calcitriol that binds to VDRE causes inhibition of breast cancer cell proliferation. Another study by Clark et al. showed that there was a significant weak relationship. Research by Clark also has samples with low levels of vitamin D samples in large quantities so that the limitations are comparable with this study.

The relationship between pre-chemotherapy vitamin D levels and post-neoadjuvant chemotherapy responses also showed differences in the chemotherapy response in the study sample based on vitamin D levels in the blood. The chi-square test to look for OR subsequently showed that there was a risk of female patients who had advanced breast cancer with low vitamin D levels getting a poor chemotherapy response as much as 10.5 times (OR 10.5).

Conclusion

There is a relationship between levels of vitamin D

blood with the size of the tumor is based on inspection of ultrasound as a response to chemotherapy neoadjuvant CAF in women after menopause with locally advanced breast cancer in hospitals Dr. Soetomo Surabaya.

Ethical Clearance: Taken from Dr. Soetomo General Hospital Ethical, Research, and Development Committee.

Source of Funding: Self

Conflict of Interest : Nil

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Relationship between Vitamin D Receptor Expression with VEGF-A in Women with Metastatic Breast Cancer in Dr. Soetomo General Hospital Surabaya

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Abstractg

Background: Breast cancer is a malignancy in breast tissue. Breast cancer is the second highest cause of death from cancer in Indonesia. One of the main causes of death in breast cancer is metastatic breast cancer which the 5-year survival rate is only 23.3%. Vitamin D levels and expression of Vitamin D receptors are very important in the process of angiogenesis, especially in endothelial cells of tumor's blood vessels. Activation of vitamin D receptors and vitamin D will inhibit the process of neo-angiogenesis thereby reducing the risk of metastasis. Decreased angiogenesis activity can be seen from VEGF-A expression.

Method: The research's design is cross-sectional research. The study was done by immunohistochemical staining of breast cancer tissue of patients with metastatic breast cancer for the expression of vitamin D receptors and VEGF-A.

Results: Total patients of this study are 24 patients. It was obtained 19 people (79,2%) aged <50 years and 5 people (20,8%) aged > 50 years. It was also obtained 4 people (16,6%) with liver metastases, 6 people (25%) with contralateral breast metastases, 4 people (16,6%) with pulmonary metastases, and 10 people (41,8%) with bone metastases. The mean expression of vitamin D receptors was 67,1%±14,1% and the mean VEGF-A was 67,5%±6,7%. It was found that there was a significant relationship between the expression of vitamin D receptors and VEGF-A (p = 0.007). The cut-off point of VDR is 74,38% and VEGF-A is 69,1%.

Conclusion: There is a positive correlation between VDR expression and VEGF-A expression in patients with metastatic breast cancer

Keywords: metastatic breast cancer, vitamin D receptors, VEGF-A, breast cancer.

Background

Breast cancer is a malignancy in breast tissue. Breast cancer is the second most common cause of death in all cancers in Indonesia. Breast cancer is also cancer with a large global population of 1 million new cases per year.

Breast cancer is 30% of all cancer cases experienced by women. Most breast cancer events occur in women aged over 55 years.¹

In America, the incidence of breast cancer reaches 2,000,000 in 2018, or 11.6% of all cancer occurrences. Breast Cancer was ranked first inpatients in Indonesia where out of 100,000 women 26 women were treated for breast cancer. In Indonesia, 70% of patients with breast cancer come to the hospital for treatment when they have distant or advanced stage metastases, where

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patients need more therapeutic modalities. The mortality rate of breast cancer patients in Indonesia is quite high where it reaches 17 deaths in 100,000 population.²

One of the main causes of death in breast cancer is distant metastasis. According to research data from the American Cancer Society (ACS), the average overall survival rate in breast cancer patients with metastasis since the discovery of distant metastases is only 3 years, it is also mentioned that the 5-year survival rate in breast cancer that has metastasized is 23.3%.³

Vitamin D has been known to play an important role in calcium homeostasis, bone metabolism, and the functioning of the immune, cardiovascular, and reproductive systems. In some studies, it was found that there is an inverse relationship between Vitamin D and the prevalence of breast cancer. The prevalence of vitamin D deficiency in the world is still quite high reaching 1 billion population.⁴

Several laboratory and epidemiological studies have shown that vitamin D levels and vitamin D receptor expression are associated with an increased risk of breast cancer. (Goodwin, 2009). Research conducted by Hamonangan at Dr. Soetomo District Hospital also shows that there are significant differences in blood levels of vitamin D in postmenopausal women with locally advanced breast cancer (LABC) with Metastasis Breast Cancer (MBC), wherein the group of locally advanced breast cancer (LABC) showed higher mean expression of vitamin D compared to the Metastasis Breast Cancer (MBC) group.⁵

Vitamin D receptors are found in nearly 80% of breast tumor specimens in humans. (WHO, 2016). Research conducted by Chung shows that to inhibit the process of calcitriol angiogenesis requires/depends on vitamin D receptors so that calcitriol cannot work actively without vitamin D receptors.⁶

Angiogenesis is a very important factor for tumor growth and tumor cell metastasis. Angiogenesis is a multilevel process that depends on several pro-angiogenic factors including vascular endothelial growth factor (VEGF) and several other growth factors. Calcitriol (1,25 (OH) 2D) can directly inhibit the proliferation of aortic endothelial cells and tumors to stop cell growth and elongation of endothelial cells caused by VEGF.

This mechanism is mediated by vitamin D receptors which are found in many cells, one of which is in blood vessel endothelial cells.^{6,7}

Among the VEGF subtypes, VEGF-A is a subtype that has the most uses both quantitatively and qualitatively. In one study it was found that VEGF-A plays a very important and angiogenesis role.⁸

Vitamin D levels and expression of Vitamin D receptors are very important in the process of angiogenesis, especially in endothelial cells of tumor blood vessels. In the 2009 Chung study, it was found that vitamin D can suppress the proliferation of angiogenesis that appears from VEGF expression. This ability depends on the presence of vitamin D receptors in tumor blood vessels. With the presence of these two components, it is hoped that there will be an emphasis on tumor neo-angiogenesis to reduce the incidence of metastases in breast cancer.⁶

Based on the above thought, this study will analyze whether there is a relationship between the expression of Vitamin D receptors and VEGF-A expression in female patients with metastatic breast cancer (MBC) in Dr. Soetomo

Research Methods

Research in the form of observational analytic research with *cross-sectional* design. Medical record data from breast cancer patients with metastatic breast cancer who met the study inclusion and exclusion criteria. Furthermore, general subject data such as name, age, gender, address, and telephone number are recorded. Other data is recorded according to the data collection form. The results of anatomic pathology in the form of paraffin blocks from breast cancer patients with metastatic breast cancer then underwent an examination of Vitamin D and VEGF-A receptor expression at the anatomical pathology laboratory Dr. Soetomo. To then see whether there is a relationship between Vitamin D Receptor Expression and VEGF-A.

Peng processed the data was performed using SPSS 22.0. Data is presented in the form of frequency distribution tables and cross-tabulations. Data from independent and dependent variables in the form of numerical data will be tested using the Pearson

correlation test.

Results

The study subjects consisted of 24 women, with the most age having metastatic breast cancer (MBC) were under 50 years of age namely 19 patients (79.2%) with an average of 46.2 ± 9.9 years. In this study, it was found that the most types of anatomical pathology of metastatic breast cancer (MBC) patients were ductal carcinoma was found in 16 patients (66.7%). The characteristics of the subjects in this study can be seen in Table 1

Table 1 Research Subjects Characteristics

Subject Characteristics		Frequency	Percentage (%)
Gender	Female	24	100
Age	<50 years	19	79.2
	> 50 years	5	20,8
Anatomical Pathology	Ductal Carcinoma	16	66.7
	Non-Ductal Carcinoma	8	33.3

In this study, the most metastasis site is on bone was seen in 10 patients (41.8%). Characteristics of metastasis metastatic breast cancer are shown in Table 2

Table 2 Characteristics of metastasis in metastatic breast cancer

Characteristics of Metastases		Frequency	Percentage (%)
Metastases Location	Liver	4	16.6
	Contralateral Breast	6	25.0
	Lungs	4	16.6
	Bone	10	41.8

In this study, the VDR mean value was 67.1% with a standard deviation of 14.1%. After doing the normality test using Shapiro Wilk, the P value was 0.006, this value indicates that the VDR data was not normally distributed. In this study, the VEGF-A mean value was 67.5% with a standard deviation of 6.7%. After doing the normality test using Shapiro Wilk, the P value was 0.869, this value indicates that the VEGF A data is normally distributed.

From these results, it was obtained that the VDR mean was 67.1% and the VEGF mean was 67.5%, then from these results in this study the maximum VEGF value was 81.7% with the minimum value was 51.4% so that the cut was obtained. the off point is 69.1%. While the maximum value of VDR is 82.83% with the minimum value is 37.36% so that the cut-off point is 74.38%.

Table 3 - Average VDR Expressions in Metastatic Breast Cancer

Category	Average	Minimum	Maximum	Cutoff Point
VEGF-A	67.5%	51.44%	81.77%	69,1%
VDR	67.1%	37.36%	82.83%	74,38%

The Spearman correlation test between VDR expression and VEGF expression found that the correlation was statistically significant with a P value of 0.007 and the value of the Correlation Coefficient was positive, so these results indicate that there is a positive correlation between VDR expression and VEGF-A expression in patients with metastases. Breast Cancer which was statistically significant.

Table 4 - Pearson Correlation Test between VDR and VEGF expressions

		VDR
VEGF-A	Correlation coefficient	0.535
	P value	0.007
	Number of subjects	24

Discussion

Decreased expression of VDR and increased VEGF is associated with high rates of distant metastases in breast cancer. In this study, it was found that there is a relationship between VDR and VEGF-A expression with the incidence of breast cancer metastases. This is consistent with a study conducted by Santos in 2017 which stated that the bond between vitamin D and its receptors (VDR) has been shown to reduce the process of carcinogenesis and metastasis in various pathways. It has been found that the binding of vitamin D with VDR decreases the survival of cancer cells and reduces depression of transporters (GLUT-1) and glycolytic enzymes: GLUT-1, hexokinase II (HKII), and lactate dehydrogenase A (LDHA)⁹. Previous research has shown that increased glycolysis is essential for cancerous growth and metastasis. Thus, inhibition of this important pathway can prevent the development of cancer. This inhibition of glycolytic enzymes has been shown to reduce cell proliferation and replace apoptosis in cancer cells⁹. Also, vitamin-D / VDR binding also has anti-proliferation effects and vitamin D has also

been shown to have anti-oxidative anti-invasion, and anti-angiogenesis activity, and most recently also anti-metastasis by targeting inhibition of tumor development differentiation 1 gene (ID1). The lack of expression of Vitamin D receptors in cells affects TDEC in regulating the growth and formation of new blood vessels or angiogenesis in tumors. Also, the production of COX-2 and HIF-1 which is a factor of proangiogenesis is not well inhibited, causing the process of angiogenesis to continue to occur. This effect will lead to tumor progression, especially in metastasis.⁶

In this study, it was also found that there was a correlation between VDR expression and an increase in VEGF-A with the incidence of breast cancer metastases, where the lower VDR expression and increased VEGF-A expression were associated with an increase in the statistically significant increase in breast cancer metastasis. According to the results of research by Chung in 2009, VDR played a major role in mediating the antiproliferative effects of calcitriol on TDEC and the development of tumor angiogenesis in vivo. TDEC which was isolated from the tumor and implanted in

VDR showed very high VDR expression and its growth was inhibited by calcitriol. Calcitriol via VDR induces the termination of the G0 / G1 cell cycle in TDEC⁶. The absence of VDR in TDEC in tumor blood vessels causes aberrant blood vessel growth and tends to be higher in blood vessel growth. This is associated with fewer pericytes and the tumor will contain more angiogenic factors such as VEGF 4,6 So with an increase in VEGF, the angiogenesis of the tumor tissue will increase and this will support the process of metastasis.

Angiogenesis is very important for the expansion of tumor growth and tumor cell metastases. This is a multicellular, multicellular process that relies on a variety of pro-angiogenic factors including vascular endothelial growth factor (VEGF), basic fibroblast growth factor (bFGF), and the growth factor of BB homodimer derivatives (BB PDGF). Calcitriol (1,25 (OH) 2D) can inhibit the development of tumor blood vessels necessary for the development of solid tumors and this can occur due to effects on endothelial or epithelial cells. Calcitriol (1,25 (OH) 2D) can directly inhibit the proliferation of aortic endothelial cells and tumors and can stop cell growth and elongation of endothelial cells caused by VEGF.

Stimulation of angiogenesis in response to hypoxia is mediated by hypoxia-inducible 1 factor (HIF-1), which directly increases the expression of several proangiogenic factors including VEGF. Early studies indicate that calcitriol is a potent inhibitor of tumor cells induced by angiogenesis in experimental models. Calcitriol inhibits the formation of induced endothelial cell tubes. Calcitriol and its analogs also directly inhibit endothelial cell proliferation leading to inhibition of angiogenesis. VDR suppresses the expression of IL-8 proangiogenic factors in a way that is dependent on NFκB. The proangiogenic effect of PGE2 produced by COX-2 may be a result of its action to increase the synthesis of HIF-1α protein in cancer cells. Therefore suppression of COX-2 expression by calcitriol provides an important indirect mechanism where calcitriol inhibits angiogenesis, in addition to the direct suppressing effect on proangiogenic factors such as HIF-1 and VEGF.¹¹

Conclusion

There is a significant relationship between VDR expression and VEGF-A expression in patients with

metastatic breast cancer.

Ethical Clearance: Taken from Dr. Soetomo General Hospital Ethical, Research, and Development Committee.

Source of Funding: Self

Conflict of Interest : Nil

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Relationship of Obesity Recurrence Events in Triple Negative Breast Cancer Patients in Dr. Soetomo General Hospital Surabaya

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Abstract

Background : Breast cancer is one of most major cause of death in women. One of the forms of breast cancer that has poor prognosis is triple negative breast cancer (TNBC). TNBC occurs in 10-20% of breast cancer, with high number of relapse/recurrence and metastasis. In some earlier research, it was found that the number of TNBC was higher in patients with obesity. Therefore, obesity is associated with poor prognosis in patients with breast cancer. This research wants to study the relationship of obesity with recurrence in TNBC patients .

Method: This research is a prospective cohort research in patients with triple negative breast cancer. Research was carried out by recording patients with TNBC and measurement of the degree of obesity by calculating the body mass index (BMI). Patients was followed-up for 6 months after surgery to monitor if there is any recurrence.

Results: In this research, it was obtained a total of patients of 58, 33 people (56.9%) with normal BMI and 25 people (43.1%) with obesity. From the terms of recurrence, it was obtained 30 people (51.7%) did not experience recurrence and 28 people (48.3%) experienced a recurrence. Statistical tests proved that there is significant relationship between obesity with the incidence of recurrence ($p = 0.002$) with an odds ratio (OR) of 6.29.

Conclusion: Increased BMI increase the incidence of recurrence cases in patients with Triple Negative Breast Cancer

Keywords: *triple negative breast cancer, recurrence, obesity, cancer breast.*

Background

In the past 25 years, the prevalence of obesity increased by two times as much in 70 countries, including the United States, and nearly a third of the adults in the entire world are now excess weight or obese¹. Obesity is concerned because obesity is a risk factor in a variety of chronic diseases, diseases that weaken the immune

system, as well as diseases that threaten life, for example, in diseases like rheumatoid arthritis, diabetes mellitus type 2, cardiovascular disease, and cancer².

Cancer Breast is a case of cancer causes of death most in women. The incidence of breast cancer in developing countries in Asia is increasing. Studies in the year 1970 show a woman obese has a risk of cancer of the breast is high³.

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In the treatment of breast cancer, there are currently developments in the form of estrogen receptor blockers, progesterone receptors, and human epidermal growth

factor receptor 2 (HER2 / neu). Therapy that is a component of therapeutic cancer is breast when this in patients with the receptor of estrogen and progesterone, and HER2- positive⁴.

Triple-Negative Breast Cancer (TNBC) is a subtype of cancer breast that is based on immunohistochemistry (IHC) with receptors estrogen (ER) negative, receptor progesterone (PR) negative and human epidermal growth factor receptor 2 (HER2) negative. TNBC is associated with special characteristics, including aggressiveness, poor prognosis, and poor response to treatment⁴.

TNBC occurs in 10-20% of the entire cancerous breast, which has several recurrences, and metastasis is high. The relationship between obesity and TNBC is still not fully explained. The theory of insulin resistance, an increase in hormones such as leptin and adiponectin, is a suspected cause of the increased incidence of TNBC and other malignancies in obese patients⁵.

Patients obesity with a receptor of estrogen-positive has the result that bad if it had a high BMI. This has been seen from several studies, especially in postmenopausal patients. The relationship between obesity and poor prognosis in breast cancer is caused due to an increase in the production of estrogen from tissue adipose, thus increasing the stimulation of cells cancerous breast with a receptor of estrogen positive. But the case is not to be applied to the cancerous breast with receptors estrogen negative⁵.

Figures incidence of patients TNBC with obesity is high in comparison with patients with non- obese. In patients with TNBC, several recurrence events tend to occur early, and survival after diagnosis of disease metastasis is only about one year although it was managed early, 19% of patients reported with TNBC who had a recurrence, the reported mortality risk occurred within 2 years of the first after the diagnosis⁶.

Also, according to the results of basic health research or Riskesdas, the level of obesity in adults in Indonesia increased to 21.8 percent. This prevalence increased from the results of Riskesdas 2013 which states that the obesity rate in Indonesia only reached 14.8 percent. Obesity itself refers to the condition in which the index of the mass of the body above 27. The prevalence of obesity with BMI between 25 to 27 also increased

from 11.5 percent in 2013 to 13.6 percent in 2018. In the position of the highest that is North Sulawesi, then located in DKI Jakarta, East Kalimantan, and West Papua.

Method

This study was an observational analytic study with a prospective cohort design. Patients women with cancer breast stage III which meet the criteria for inclusion and exclusion of studies that the criteria of inclusion in the form of breast cancer patients which examined the results in the pathology department of Dr. Soetomo Hospital, the examination result of immunohistochemistry staining are TNBC, aged 18-65 years, the patient was first diagnosed with breast cancer between December 2017 - December 2019, agreed to be followed up in oncology outpatient clinic of Dr. Soetomo hospital and agreed to be research subject by signing informed consent. Criteria for exclusion in the form of breast cancer patients with liver disease, kidney failure, histopathology examination is Luminal A, B, and HER (+), incomplete medical records, patients cannot be contacted, and patients can not control regularly at the RSUD Dr. Soetomo.

The research subjects have then explained the aims and benefits of the study and were asked to participate in the study by signing informed consent. Furthermore, the data common subjects such as name, age, type of sex, address, and a number of the phone are recorded. Other data is recorded according to the data collection form. The study subjects then underwent a BMI examination.

Data verification is done by recording data from the medical record to the research sheet that has been made. Furthermore, the research subjects were examined for the completeness and suitability of the data with the operational limitations set.

After all, data has been collected, data entry is made to the SPSS 23.0 for Windows program. Data are grouped according to type, between nominal, scale, or ordinal.

Results

The subjects of the study consisted of 58 women (100%), with the age of majority is the age > 50 years ie 30 patients (51.7%). In research it got kind of pathological anatomy most is infiltrating ductal carcinoma as many as

46 patients (79.3%). The characteristics of research subjects can be seen in Table 1.

Table 1: Characteristics of Research Subjects

Subject Characteristics		Frequency	Percentage (%)
Sex	Female	58	100
Age	Premenopause	28	48.3
	Postmenopause	30	51.7
Anatomical Pathology	Infiltrating Ductal Carcinoma	46	79.3
	Mixed Carcinoma	7	12.1
	Infiltrating Lobular Carcinoma	1	1.7
	Mucinous Carcinoma	2	3.4
	Phyllodes Tumor	2	3.4

From the study, it in terms of age and rate of recurrence found that in the group aged > 50 years obtained the recurrence of the number is high compared with the group of age <50 years of which as many as 16 patients. From these results, a regression test was performed to determine the relationship of age with the recurrence rate of TNBC patients, and the *p*-value = 0.389 was obtained, meaning that age was not statistically related to the level of recurrence, but old age increased the risk of recurrence by 1.68 x than younger age (OR = 1.68). The description of the age group with the recurrence of TNBC patients is seen in Table 2.

Table 2 Overview of the age group with the recurrence of TNBC patients

		Recurrence		Total	P-value	OR
		No Recurrence	Recurrence			
Age group	Premenopause	16	12	28	0.389	1.68
	Postmenopause	14	16	30		
Total		30	30	28		

From the research, it reviewed the results of pathological anatomy found that *I infiltrate ng ductal carcinoma* have a level recurrence much higher compared with the type of pathological anatomy else that is as much as 24 patients. From the results of these then do the test regression to determine the relationship pathological anatomy at the level of recurrence of

patients with TNBC, and obtained the value *p*-value = 0.736, which means that the pathological anatomy is statistically not associated with the level of recurrence but increases the risk of recurrence by 0.9 x (OR = 0.09). An overview of anatomic pathology with the recurrence of TNBC patients is seen in Table 3.

Table 3: An overview of anatomic pathology with recurrence of TNBC patients

		Recurrence		Total	P-value	OR
		No Recurrence	Recurrence			
Anatomical Pathology	Infiltrating Ductal Carcinoma	22	24	46	0.736	0.90
	Mixed Carcinoma	6	1	7		
	Infiltrating Lobular Carcinoma	1	0	1		
	Mucinous Carcinoma	1	1	2		
	Phyllodes Tumor	0	2	2		
Total		30	28	58		

In this study, there were 58 subjects. Characteristics anthropometric from the subject of the study are as follows: high body obtained value of the minimum of 147cm, the value of a maximum of 165cm, and a mean of 156.88 5.03 cm. The minimum weight value is 45kg, the maximum value is 83kg, and the average 60 is 9.74kg. The BMI obtained the results of a minimum value of 18, a maximum value of 31, and a mean of 24.3 3.31 (Table 5.1). From the category of BMI obtained patients with normal BMI as many as 33 people (56.9%) and 25 (43.1%) with BMI *Obesity*. At recurrence obtained in 30 (51.7%) and 28 (48.3%) without recurrence.

Table 4 - Anthropometric Characteristics of Research Subjects

Characteristics	Minimum Value	Maximum Value	Average	Standard Deviation
Height	147	165	156.88	5.03
Body weight	45	83	60	9.74
BMI	18	31	24.3	3.31

Table 5 - Characteristics of BMI and Recurrence

		Amount (n)	Percentage
BMI group	Normal	33	56.9%
	Obesity	25	43.1%
Recurrence Group	No Recurrence	30	51.7%
	Recurrence	28	48.3

From the data then performed a statistical test with the *chi-square* test. The results of the *chi-square test* found

that there is a difference in meaning between the two groups ($p = 0.002$, $p < 0.05$). It is demonstrated that with an increase in BMI is obtained an increase in the incidence of recurrence in cases of Triple-Negative Breast Cancer with an increase in the recurrence of 6:29 times in the group obese compared to a group of nonobese (OR = 6.29)

Table 6 - Relationship between BMI and TNBC Recurrence

		Recurrence		P-value	OR
		No Recurrence	Recurrence		
BMI category	Normal	22 (37.9%)	11 (18.9%)	0.002	6.29
	Obesity	8 (13.7%)	17 (29.3%)		

Discussion

Triple-Negative Breast Cancer (TNBC) is a breast cancer subtype based on immunohistochemistry (IHC) with estrogen receptor (ER) negative, progesterone receptor (PR) negative and human epidermal growth factor receptor 2 (HER2) negative. TNBC is associated with special characteristics, including aggressiveness, poor prognosis, and poor response to treatment⁴

In this study, it was found that patients suffering from Triple Negative Breast Cancer (TNBC) 43.1% were obese. This is in line with the clinicopathological study obtained from 112 TNBC patients at Ege University Medical Oncology Clinic over 5 years reporting that 82 patients (73.2%) were overweight/obese and 30 patients (26.8%) had normal weight and underweight at diagnosis.

Similarly, researchers from Louisiana reviewed a database of a total of 183 TNBC patients, including 24 patients (13.1%) having normal weight (BMI <25 kg / m²), 42 (23.1%), overweight (BMI = 25- 30 kg / m²), and 117 (63.7%) are obese (BMI> 30 kg / m²). Ademuyiwa et al reported patient data classified by BMI in a retrospective study and reported that out of a total of 418 patients, 124 patients (29.7%) had normal or underweight, 130 (31.1%) overweight and 164 (39, 2%) are obese³.

In this study, patients who were obese experienced more recurrence, as many as 17 patients (29.3%) than those who were not obese and from the results of the chi-square test found that there were significant differences between the two groups ($p = 0.009$, $p < 0, 05$). This shows that with an increase in BMI, there is an increase

in the incidence of recurrence in Triple-Negative Breast Cancer cases. The results of this study are in line with research from Berclaz et al. reported that in their study of 6,792 women who participated in the International Breast Cancer Study Group Therapeutic Trials, patients who were overweight (BMI: 25.0 -29.9) or obese had significantly shorter survival and more recurrence rates high compared with patients with a BMI of 24.9 or less ($p < 0.01$)

Obesity is an independent prognostic factor for the development of metastases away from breast cancer. The risk of developing breast cancer to distant metastasis after 10 years increased significantly by 46% in obese patients. In the long run, adjuvant therapy appears to be less effective in obese breast cancer patients. A retrospective study conducted by Osman et al. in 118 patients with metastatic breast cancer found a significant relationship between chemotherapy response and first-line metastatic chemotherapy in non-obese patients compared with obese patients. Likewise, survival rates and recurrence in non-obese patients are much better than non-obese ones⁹

Recent studies have identified several potential mechanical relationships between obesity and TNBC initiation, TNBC development, and recurrence in TNBC. The mechanism is there are several namely

1. Insulin in Akt / mammalian rapamycin (mTOR) and glycolysis signals;
2. Obesity-mediated inflammatory cytokine, such as leptin, and the activation of signaling pathways that encourage invasion and metastasis;
3. Microenvironment breast cancer tissue in an

obese patient

Usually, when eating, insulin is released in response to an increase in blood glucose. Increased insulin levels stimulate the synthesis and secretion of leptin. The circulating leptin then sends a full signal through the hypothalamus and acts on the pancreas to inhibit insulin release.

In obesity, circulating levels of both insulin and leptin increase. Leptin levels increase even in the absence of hyperinsulinemia in obesity. A feedback loop that limits food consumption and reduces insulin circulation does not work. High-level leptin acts to directly stimulate mitogenesis and reduce apoptosis in breast cancer cells. Furthermore, insulin stimulates the excess of leptin and its receptors in breast cancer cells, which form an autocrine loop that stimulates the growth of breast cancer cells. Leptin also stimulates proinflammatory cytokine secretion from macrophages IL-6 and tumor necrosis factor (TNF)- α , as well as T cells and mononuclear cells (IL-2 and interferon- γ). Obesity increases the inflammatory state which is characterized by an increase in serum and tissue inflammatory cytokines. Inflammatory cytokines are increased in obese individuals including IL-6, IL-8, TNF- α , and leptin. Together these inflammatory cytokines increase tissue inflammation and activate signaling pathways that promote aggressive TNBC biology. IL-6, IL-8, and leptin are increased in obese individuals and activate STAT3, NF- κ B, and Wnt / EZH2 signaling. Activation of STAT3, NF- κ B, and Wnt / EZH2 increases invasion and metastasis and predicts a poor prognosis in women with TNBC⁹.

Conclusion

In the study, it was found that patients who suffer from Triple Negative Breast Cancer (TNBC) 43.1% experiencing obesity. At the study 's patients who undergo obesity is much to experience recurrences that as many as 17 patients (29.3%) than that is not experiencing obesity and of the results of chi-square test found that there is a difference in meaning between the two groups ($p = 0.009$, $p < 0, 05$). It is demonstrated that an increase in BMI is obtained an increase in the incidence of recurrence in cases of Triple-Negative Breast Cancer.

Ethical Clearance: Taken from Dr. Soetomo General Hospital Ethical, Research, and Development Committee.

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Effectiveness of Oral Care Using Normal Saline and Baking Soda Towards Pain and Comfort in Mucositis Patients Undergoing Chemotherapy

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Abstract

Objects: to identify the effectiveness of oral care using normal saline and baking soda towards pain and comfort in mucositis patients undergoing chemotherapy.

Methods: this is a quasi-experiment pre-posttest with a control group design. The sampling technique was used for consecutive sampling. The sample was 40 divided into two groups.

Results: the results of this study used the Paired t-test in the intervention group before and after treatment showed a significant difference in pain intensity ($t=14,257$, $p=0,000$) and comfort ($t=-11,103$, $p=0,000$). In the control group there were also significant differences in pain intensity ($t = 10,341$, $p=0,000$) and comfort ($t=-6,842$, $p=0,000$). Based on the Independent t-test, there was a significant difference in pain ($t=-3.287$, $p=0.002$) and comfort ($t=4.001$, $p=0.000$) after gargling using normal saline and baking soda.

Conclusion: the results of this study indicate that gargling using a solution of normal saline and baking soda sodium bicarbonate is effective in reducing mucositis pain and improving the comfort of patients undergoing chemotherapy.

Keywords: Mucositis; Normal saline; Baking soda; Pain; Comfort

Introduction

The Ministry of Health of the Republic of Indonesia said that cancer as the cause of death ranks seventh (5.7% of all causes of death) after death from stroke, tuberculosis, hypertension, injury, perinatal, and diabetes mellitus. Based on the prevalence of cancer in the population category of all ages in Indonesia in 2013 was 1.4 ‰ population or around 347,792 patients with Yogyakarta Province which ranks highest for cancer in the amount of 4.1 ‰ or around 68,638 patients⁽¹⁾.

Chemotherapy is a cancer therapy that involves the use of chemicals or drugs whose purpose is to kill cancer cells. Chemotherapy treatment can reach cancer cells that have spread to parts of the patient's body. The side effects of chemotherapy vary depending on the modification of the chemotherapy drug given⁽²⁾. Based on the National Cancer Institute that side effects that can occur due to chemotherapy are nausea, vomiting, diarrhea, stomatitis/mucositis, alopecia, susceptible to infection, thrombocytopenia, neuropathy, and neuropathy, and that is nausea, vomiting, diarrhea, stomatitis/mucositis, alopecia, susceptible to infection, thrombocytopenia, neuropathy, and neuropathy myalgia⁽³⁾.

In the condition of pain and discomfort experienced by mucositis patients, the action taken is to perform oral care. Oral care is an action taken to clean the mouth, brush teeth and gargle to prevent odors and caries, maintain the integrity and hydration of the oral mucosa

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and lips, maintaining oral mucosa, increasing self-esteem and comfort⁽⁴⁾. One of the treatments for oral care uses normal saline and baking soda. Salazar et al. said that Normal saline is the recommended way to take oral care. Gargling with the frequency that often can moisturize the mouth and prevent crusting and soothing gums and mouth mucosa⁽⁵⁾. Whereas Ignatavicius and Workman said that cancer patients who had mucositis received oral treatment with warm water, normal saline, and baking soda given in 4 times a day and performed according to the condition of the oral cavity⁽⁶⁾.

Methods

The study was used a quasi-experimental design with a pretest-posttest with a control group. This study was conducted at two public hospitals in Medan. The respondents were 40 using consecutive sampling, divided 2 groups with inclusion criteria: 1) respondents with medical diagnoses of cancer with mucositis as a result of chemotherapy in the inpatient hospital in Medan, 2) experiencing pain in the mouth, 3) aged over 17-65 years, 4) willing to follow the treatment until the

end of the study. Exclusion criteria: 1) respondents with unilateral reasons to stop participating in the study and 2) not continuing chemotherapy.

The procedure was carried out following the SOPs that the researchers attached such as the oral care SOP in the hospital, only the researchers added the materials according to the researcher's intervention. Oral care was done 4 sessions in 1 day at 07.00a.m, 13.00p.m, 19.00p.m, and 10.00p.m. Respondents will rinse their mouth for 30 seconds. After the researchers gave the mouth rinse treatment using normal saline and baking soda to respondents for 5 days then the researcher reassessed (post-intervention) pain and comfort level. Pain measurement was performed using the Numeric Rating Scale (NRS) with the category of no pain (0), mild pain (1-3), moderate pain (4-6), controlled severe pain (7-9), severe pain uncontrolled (10) while the measurement of comfort was done using the Daily Comfort Scale (DCS) with very bad categories (score

1), slightly bad (score 2), slightly good (score 3), very good (score 4). Data were analyzed through paired t-test and independent t-test because of the data normally distributed.

Results

Table1. Frequency distribution of characteristics of cancer patients suffering from mucositis undergoing chemotherapy

Variable	Intervention group		Control group	
	N	%	n	%
Ages				
17-25 years	1	5	1	5
26-35 years	7	35	4	20
36-45 years	4	20	6	30
46-55 years	8	40	8	40
56-65 years	8	40	1	5
Total	20	100	20	100
Mean±SD	51,45±8,918		42,55±9,822	
Min–Max	34-65		17-60	
Gender				
Male	11	55	12	60
Female	9	45	8	40
Cancer type				
NPC			10	50
Breast	9	45	2	10
Larynx	5	25	2	10
Tongue	1	5	1	5
Tonsils	4	20	1	5
Ovary	1	5	3	15
NHL			1	5
Rhubdo Neo Carcinoma				
Long suffered from the disease				
Acute (<6 months)	7	35	8	40
Chronic (>6 months)	13	65	12	60
Length chemotherapy				
<6 months	14	70	14	70
6 months-1 year	4	20	4	25
>1 years	2	10	2	12,5
Mucositis degree				
Degree 1	3	15	6	30
Degree 2	3	15	6	30
Degree 3	6	30	5	25
Degree 4	8	40	3	15

Table 1. shows that characteristics of cancer respondents undergoing chemotherapy based on age in the intervention group majority were late elderly respondents (56-65 years), while for the control group majority were initial elderly respondents (46-55 years). Based on the gender intervention and group the majority was male. Based on the type of cancer in the intervention and control group majority was NPC. Based on the

length of time suffering from cancer showed that in the intervention and control group majority were more 6 months (chronic). Based on the length of chemotherapy intervention and control group majority had less than 6 months. Based on the degree of mucositis due to the effects of chemotherapy showed that in the intervention group was degree 4 mucositis (40%), whereas the control group was 1 and 2 degree (30%).

Table 2. frequency distribution of pain with mucositis patients

Mucositis pain	Intervention group				Control group			
	Before		After		Before		After	
	n	%	n	%	n	%	n	%
Scale 1-3			12	60			3	15
Scale 4-6	8	40	8	40	9	45	17	85
Scale 7-9	12	60	20	100	11	55	20	100
Total	20	100			20	100		
Mean ± SD	6,60±1,09		3,45±0,99		6,60±0,75		4,40±0,82	
Min – Max	4-8		2-5		5-8		3-6	

Table 2. shows that the distribution of pain intensity of respondents who experienced mucositis before being given mouthwash treatment of normal saline and baking soda in the intervention group was severe pain (60%), after being given treatment for 5 days was mild pain (60%). Whereas the control group obtained who experienced mucositis before was severe pain scale (55%), after 5 days was moderate pain (85%).

Table 3. frequency distribution of comfort of patients with mucositis

Mucositis comfort	Intervention group				Control group			
	Before		After		Before		After	
	n	%	n	%	n	%	n	%
Score 1	7	35	1	5	5	25	5	25
Score 2	11	55	6	30	14	70	13	65
Score 3	2	10	13	65	1	5	2	10
Score 4	20	100	20	100	20	100	20	100
Total								
Mean ± SD	1,75±0,63		3,60±0,59		1,80±0,52		2,85±0,58	
Min – Max	1-3		2-4		1-3		2-4	

Table 3. shows that the distribution of comfort of respondents who experienced mucositis before being given mouthwash treatment of normal saline and baking soda in the intervention group was a little bad comfort

(score 2) (55%), after being given treatment for 5 days was very good comfort (score 4) (65%). Whereas the control group obtained who experienced mucositis before was a little bad comfort (score 2) (70%), after 5 days was slightly good comfort (score 3) (65%).

Table 4. comparison of pain and comfort before and after oral care

Variable	Intervention group			Control group		
	Mean Differences	t	Sig	Mean Differences	t	Sig
Pain	3,150	14,257	0,000	2,200	10,341	0,000
Comport	-1,850	-11,103	0,000	-1,050	-6,842	0,000

Table 4. shows that there was a significant comparison between pain (t=14,257, p=0,000) and comfort (t=-11,103, p=0,000) in the intervention group before and after oral treatment using normal saline and baking soda. Whereas in the control group there was a significant difference between pain (t=10,341, p=0,000) and comfort (t=-6,842, p=0,000).

Table 5. the difference in pain and comfort of patients with mucositis after oral care

Variable	Mean Differences	t	Sig
Pain	-0,950	-3,287	0,002
Comport	0,750	4,001	0,000

Table 5. shows that there was a significant difference in pain (t=-3.287, p=0.002) and comfort (t=4.001, p=0.000) after the mouth rinse was performed using normal saline and baking soda.

Discussions

This study indicated that the average age in the intervention group due to mucositis was 51.45 years where less than half were late elderly aged 56-65 years. While the average age in the control group was 42.55 years where less than half the number of respondents were early elderly with ages 46-55 years. In line with the study Panghal et al. that cancer cases experienced mucositis in group one 60 years, group two 45 years, and group three 50 years⁽⁷⁾.

The results obtained in the intervention group who experienced mucositis more than half of the number of respondents male sex (55%) and the control group of male sex more than half of the number of respondents (60%). Accordance with Adha that pain responses

based on sex differ between women and men, it occurs because men are more resistant to receiving the effects of pain while women often complain of pain and crying. Based on the type of cancer experienced by respondents, researchers found the results in the intervention group 31.30% had NPC cancer types and in the control group 45% had NPC cancer types and in the control group also found 50% had NPC cancer⁽⁸⁾.

Panghal et al. said that the types of cancer that have mucositis are categorized as cancer of the tongue, oral, and oropharyngeal⁽⁷⁾. Meanwhile, according to Saldanha and Almeida that clinical consequences occur mucositis in head and neck carcinoma (HNC) patients that show the location of primary tumors including the oropharynx, larynx, oral cavity including the lips, hypopharynx, and

nasopharynx⁹⁾.

Based on the duration of undergoing chemotherapy in patients with mucositis, the study found that in the intervention group more than half of the respondents underwent chemotherapy for less than six months (70%), six months to one year (20%) and above one year as much (10%). In line with Meirovitz et al. that of the 15 respondents, 30% had mucositis up to grade fourth occurred in the fourth week after the patient took chemotherapy treatment⁽¹⁰⁾.

Based on the results of research conducted by researchers on cancer patients who experienced mucositis due to side effects of chemotherapy that in intervention patients experiencing mucositis painless than half of the number of respondents (40%) experienced moderate pain (4-6 scale) and more than half of the number of respondents (60%) experienced severe controlled pain (7-9 scale) before being given treatment. Whereas in the control group the results were less than half of the number of respondents (45%) had moderate pain (4-6 scale) and more than half of the number of respondents (55%) had controlled severe pain (7-9 scale). Supported by Cakmak & Nesrin said that patients who experience mucositis experience pain (4.8%), difficulty speaking (4.8%), erythema (4.8%), burning sensation (4.1%), bleeding (1.4%), dry and chapped lips (41.5%), difficulty swallowing (11.6%)⁽¹¹⁾.

The results of researchers to respondents who experienced mucositis that in the intervention group more than a quarter of the total respondents experienced very bad comfort (score 1) (35%), more than half of the number of respondents (55%) experienced slightly poor comfort (score 2) and comfort is a slightly good (score 3) (10%). Whereas in the control group it was found that respondents felt comfortable that a quarter of the respondents (25%) felt very bad comfort (score 1), more than half of the number of respondents (70%) felt the comfort was a little bad (score 2) and the rest as many as (5%) felt slightly good comfort (score 3). According to Hack that ignoring comfort problems can affect a patient's psychological condition, even causing prolonged depression. Depression was found to be a significant factor that can cause despair in patients, apart from pain and lack of family support⁽¹²⁾. Supported by Nuraini et al. that patients feel discomfort because they

feel pain, pain that is felt due to illness, the presence of lumps or painful swelling, a dosage of medication, and types of drugs given⁽¹³⁾.

The results showed that there were significant differences in the intervention group namely pain ($t=14,257$, $p=0,000$) and comfort ($t=-11, 103$, $p=0,000$). While in the control group there were also significant differences between pain ($t=10,341$, $p=0,000$), comfort ($t=-6,842$, $p=0,000$). In line with the results of a study conducted by Sutomo in saltwater rinses on pain reduction in dental sufferers, it was found that respondents after saltwater rinse had decreased pain levels on an average scale of 2 (slight pain)⁽¹⁴⁾. According to Saldanha and Almeida explained that normal saline (0.9%) is not irritant and is believed to help the formation of granulation tissue and increase the healing of mucositis. Mouthwash that is safe, economical, and available. Saltwater mouthwash is considered an excellent treatment when we have mouth sores. The reason is that saltwater is not only a natural disinfectant but also removes swelling from the tissues. Giving mouthwash to patients with normal saline can prove to be very economical and beneficial for patients in terms of healing and alleviating symptoms and also in their future use and preventing complications⁽⁹⁾.

The results showed that there was a significant difference between ($t=-3.287$, $p=0.002$) and comfort ($t=4.001$, $p = 0.000$) after oral treatment using normal saline and baking soda. According to Gandhi et al. that the main treatment for mucositis is palliative therapy, which includes oral hygiene at home, pain control through the use of topical analgesics or anesthetics, oral rinse without drugs, ie mouth rinses of 0.9% saline or sodium bicarbonate 4-6 times/day⁽¹⁵⁾. Furthermore according to McGuire et al. that normal saline is a harmless rinse that can help maintain oral hygiene and patient comfort and sodium bicarbonate is a harmless rinse that can help maintain oral hygiene and patient comfort. However, sodium bicarbonate may not be useful in children, who might find it unpleasant⁽¹⁶⁾.

Conclusions and Recommendation

This study indicates that gargling using normal saline and baking soda is effective in reducing mucositis pain and improving the comfort of patients undergoing chemotherapy, in providing oral care. This study is expected to be a reference for future researchers

and it is advisable to look at the degree of mucositis, controlling it strictly as long as the intervention is given to respondents.

Conflict of Interest: Nil

Source of Funding: No funding this is a study

Ethical Consideration: This research has passed the test of ethics from the health research ethics committee of the Nursing Faculty of Universitas Sumatera Utara, with registration number 1704/III/SP/2019.

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Awareness About Non-Communicable Diseases among Rural Population in Remote Villages of Nepal

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Abstract

Non-communicable diseases constitute a significant part of the overall morbidity and mortality in Nepal. Prevention of non-communicable diseases involves lifestyle modification which is directly dependent on the awareness of the population of the risk factors for diseases and methods of prevention. The aim of this study was to estimate the levels of awareness about three common non-communicable diseases among the residents of remote villages in Nepal. The study was conducted in villages in 5 districts of Nepal using a direct interview method after obtaining verbal consent of the participants. The study included 218 participants, of whom 127 were female and 91 were male. The participants ranged in age from 18-93 years. Levels of awareness about causative factors of hypertension, asthma and diabetes among the respondents were 62.2%, 22.5% and 50.9% respectively. Levels of awareness of preventive methods among the participants were 52.8%, 38.9% and 55.3% for hypertension, asthma and diabetes respectively. The difference in levels of awareness among both genders, different age groups and differing educational status was also studied.

Key words: awareness; hypertension, asthma, diabetes, non-communicable diseases, rural Nepal

Introduction

Nepal has a population of 28.61 million and is the 49th populated country in the world. ⁽¹⁾ Non-communicable diseases remain a public health issue in the country. ⁽²⁾ The health of a nation depends significantly on the literacy rates and awareness about health issues in the general population. The aim of this study is to record the levels of awareness about three common non-communicable diseases in various parts of rural Nepal. The research was done in remote villages in Eastern, Mid-Western and Western Nepal. The villagers belonged to one of the ethnic groups, tribal groups or Brahmin- Chettri castes, and were mostly poor. The research was conducted in remote areas isolated from the mainstream population due to lack of education, poor economic status and socio-cultural differences. Because of the geographical structure of the locations, the people have to walk hours to get medical facilities. The study was done to assess the level of awareness about 3 non-communicable diseases, viz., hypertension, asthma and diabetes in remote rural Nepal.

According to this study conducted in Nepal about the hypertensive population in suburban areas, the overall

prevalence of hypertension was 28.9% of which male 28.8% and female 29%. According to the latest WHO data published in 2017, asthma deaths in Nepal reached 2.03% of total deaths and the WHO profile shows that 9.1% of the Nepali population are living with diabetes according to the 2016 record which includes 10.5 % men and 7.9 % women.

Material and Methods

The study was conducted in the remote villages of 5 districts: Palpa, Nuwakot, Jhapa, Morang and Surkhet, from July 2019 to November 2019. A total of 218 attendees at the mobile health outpatients clinics in remote villages were interviewed in local dialects after obtaining their verbal consent. The questions were prepared and each participant was interviewed personally. The researcher collected the demographic details, level of education and basic sociocultural background of the participants in addition to their knowledge about three non-communicable diseases: hypertension, asthma and diabetes. Questions concerning their knowledge of causative factors and methods of prevention of the three diseases were asked. The participants were given choices and could mark more than one choice for each

question. The responses to the questions on the causes and the methods of prevention of the three diseases were categorized as a) correct (choose one or more right answer without any wrong answers), b) not correct (choose more wrong answers than right answer), c) did not know and d) did not respond. Data was collected and levels of awareness were correlated with the age, gender and level of education of the respondents. The findings are compared with published literature from Nepal and from rural areas in other developing countries.

Results

A total number of 218 participants took part in the study. 127 were female and 91 were male. The youngest participant was 18 years old and the oldest was 93. There were 43 respondents in the 18-34 age group, 83 in the 35-54 age group and 92 in the 60 - and - above age group. 84 were uneducated and 93 had some education. The rest of the participants did not volunteer information on their educational status.

Levels of awareness about causative factors of hypertension, asthma and diabetes among all the respondents were 62.2%, 22.5% and 50.9% respectively. Levels of awareness of the preventive methods among the participants were 52.8%, 38.9% and 55.3% for hypertension, asthma and diabetes respectively. (Table 1)

Age group and awareness:

The distribution of responses according to age group and the percentage of responses in each age group is given in Tables 2 and 3 respectively. Awareness about the causative factors of hypertension was highest in the 35-59 age group. Awareness about preventive methods of hypertension was slightly higher in the 60 and above age group. Awareness about causes of asthma was highest in the 18-34 age group but knowledge about preventive methods of asthma was slightly higher in the 35-59 age group. Knowledge about both causes and prevention of diabetes was highest in the 35-59 age group. When comparing the awareness among different age groups, the only statistically significant difference was observed in those below 34 and those above 34 about prevention of asthma (p value= 0.05). Those below 34 years of age seem to be significantly less aware of how to prevent asthma.

Awareness and educational status:

The distribution of responses in the educated and uneducated groups is given in Table 4. 76.3% of educated respondents knew about the causes for hypertension when compared to 52.4% of those who did not have formal education. 59.1% of the educated group was aware of the preventive methods of hypertension when compared to 55.9% of those who did not have formal education. 27.9% and 39.8% of the educated group answered correctly about causes and prevention of asthma respectively when compared to 13.1% and 43.9% of those who did not have formal education. 61.3% and 62.4% of the educated group had awareness about causes and prevention of diabetes respectively when compared to 46.4% and 52.4% of those who did not have formal education.

There was a significant increase in the percentage of people with awareness of causes of hypertension (p value=0.009) causes of asthma (p value= 0.01) and causes of diabetes (0.04) among those who had formal education and those who did not. The educated group seemed to know more about the preventive methods of hypertension and diabetes and the uneducated group showed more awareness about the preventive methods of asthma. However there was no statistically significant difference in awareness of preventive methods between the educated and uneducated groups.

Awareness and gender

The distribution of responses across both genders is given in Table 5. 65.93% and 58.2% of male respondents had awareness about causes and prevention of hypertension respectively when compared to 59.1% and 54.3% of female participants. 15.4% and 46.2% of men had awareness regarding causes and prevention of asthma respectively when compared to 27.6% and 33.9% of women. 54.9% and 59.3% of men had awareness about causes and prevention of diabetes respectively when compared to 47.2% and 51.9% of women participants.

In comparing the genders, females seem to be significantly more aware of the causes (p value 0.03) and males seem to be more aware of the prevention methods for asthma (p value 0.06). There were no significant differences in the awareness about the other diseases in the two groups.

Discussion

Non-communicable diseases tend to be ignored in developing countries where infectious diseases still cause a major proportion of mortality and morbidity. Non-communicable diseases (NCDs) refer to diseases or conditions that occur over an extensive period of time and for which there are no known transmissible aetiologic agents. ⁽³⁾

According to WHO Global Status Report 2014, in Nepal, NCD was the cause for premature mortality (death between 30-70 years) in 22.3% of cases in 2010 and 21.6% in 2012. ⁽²⁾ A population-based survey of non-communicable diseases in Nepal in 2019 shows a prevalence of 8.5% for diabetes mellitus and about 37% for hypertension and 11.7% for chronic obstructive lung diseases in individuals more than 20 years of age. ⁽⁴⁾ A population based survey in Surkhet in 2001 revealed a 9.9% prevalence of hypertension. ⁽⁵⁾ Out of the total non-communicable diseases, 38% were having heart disease followed by chronic obstructive pulmonary disease (33%), whereas diabetes and cancer accounted for 19% and 10% cases respectively. Out of the total heart diseases, nearly half of the patients suffered from hypertension. ⁽⁶⁾ The prevalence of type 2 diabetes was 11.7%. ⁽⁷⁾

Despite this burden, there is very little published literature on the level of awareness about these diseases in rural Nepal. A total of 62.2% had awareness about the risk factors for hypertension and 52.8% had correct knowledge about preventive measures. Only 22.5% of respondents had correct knowledge about asthma and 36.4% gave correct answers about its prevention. 50.9% knew the risk factors for diabetes and 55.3% had knowledge about the methods of prevention. The results are being compared with similar studies published from other countries.

In a study of 1200 respondents from urban and rural areas in Kosovo, awareness about aetiological factors and preventive methods of diabetes was 15% and 22% respectively. ⁽⁸⁾ In a study from Mysur, Karnataka, the awareness of risk factors for hypertension was highest in urban patients with one or more NCD and least with rural people without hypertension. A statistically significant difference ($p < 0.001$) in awareness was also seen among the urban and rural population. The mean

knowledge scores for diabetes mellitus were also highest in the urban patients with at least one NCD and was least in the rural patients without NCD. 60-70% of the urban populations were aware of the risk factors contributing to NCD when compared to the rural population (40-50%). The overall difference in risk factor awareness among urban and rural population with or without NCDs varies from 1-4% and 10-15% respectively. Least awareness of risk factors for NCDs studied was observed among rural people without any NCDs. This difference in awareness between urban and rural population was almost the same, irrespective of the type of NCD. ⁽⁹⁾

Gupta R. found that awareness, treatment and control of various risk factors for hypertension in India range from 20 to 60 per cent. The awareness was lowest in rural women and highest in urban men. ⁽¹⁰⁾ P. Devi et al. recorded that the awareness of hypertension in the Indian population ranged from 20 to 54%. ⁽¹¹⁾ Mohan D et al., in CURES-9 study conducted at Chennai among the general population emphasized that more than 25% of the 26,000 subjects screened by standard questionnaires were unaware of the term diabetes. ⁽¹²⁾ Gupta R. pointed out that the status of diabetes awareness, treatment and control has been reported to be greater in urban women than men and remains to be studied in a rural area. ⁽¹⁰⁾ In a study by Wolde et al. from suburban regions of Ethiopia, family members of diabetic patients had better knowledge than others. Those with higher education were more likely to have a good level of knowledge, as compared to those who were illiterate. ⁽¹³⁾

Conclusion

In the current study, those who had formal education had significantly better awareness of the causes of the different NCDs. Awareness of methods of prevention, although higher in the educated group, was not statistically significant. Female participants showed significantly higher awareness of the cause of asthma, whereas men seemed to know more about its preventive methods. There was no difference in awareness about other NCDs in the 2 genders. There was no significant difference in the awareness among different age groups studied except for awareness about the causative factors of asthma, the knowledge of which was significantly lower in participants younger than 35 years.

Table 1: The number of participants categorized according to appropriateness of response to questions

Questions	Correct response	Wrong response	Do not know	Not given
Causative factors of hypertension	135 (62.2%)	20	43	20
Methods of prevention	123(52.8%)	26	42	27
Causative factors of asthma	49 (22.5%)	100	38	31
Methods of prevention	85 (38.9%)	99	4	30
Causative factors of diabetes	109 (50.9%)	62	9	38
Methods of prevention	119 (55.3%)	3	67	29

Table 2: The distribution of responses to the questions among different age groups is given in table .

Age group/questions		18-34	35-59	60 and above
Causes hypertension	Y	27	54	54
	N	2	10	8
	DNK	6	11	26
	NG	8	8	4
Prevention hypertension	Y	22	47	54
	N	5	16	5
	DNK	5	12	25
	NG	11	8	8
Causes asthma	Y	12	16	21
	N	10	44	45
	DNK	8	14	16
	NG	13	9	10
Prevention asthma	Y	11	36	38
	N	21	38	40
	DNK	0	0	4
	NG	11	9	10
Causes diabetes	Y	20	47	42
	N	12	19	31
	DNK	0	4	5
	NG	11	13	14
Prevention diabetes	Y	24	48	47
	N	1	1	1
	DNK	10	22	35
	NG	8	12	9

(Y = correct answer, N =wrong answer, DNK= do not know, NG= not given)

Table 3 : Percentage of participants who answered correctly in each age group

Age	18-34	35- 59	60 and above
Hypertension causes	62.8	65.1	58.7
Hypertension prevention	51.1	56.6	58.7
Asthma causes	27.9	19.3	22.8
Asthma prevention	25.6	43.4	41.3
Diabetes causes	46.5	56.6	45.7
Diabetes prevention	55.8	57.8	51.1

Table 4. Distribution of responses among those who had formal education and those who did not

Education level /questions		Educated	Uneducated
Causes hypertension	Y	71	44
	N	4	6
	DNK	9	25
	NG	9	9
Prevention Hypertension	Y	55	47
	N	14	8
	DNK	10	19
	NG	14	10
Causes asthma	Y	26	11
	N	41	44
	DNK	14	14
	NG	12	15
Prevention asthma	Y	37	37
	N	43	32
	DNK	1	1
	NG	12	14
Causes diabetes	Y	57	39
	N	17	26
	DNK	3	4
	NG	16	15
Prevention diabetes	Y	58	44
	N	3	0
	DNK	18	28
	NG	14	12

(Y = correct answer, N =wrong answer, DNK= do not know, NG= not given)

Table 5. Distribution of responses between male and female respondents

Gender /questions		Male	Female
Causes Hypertension	Y	60	75
	N	7	13
	DNK	18	25
	NG	6	14
Prevention Hypertension	Y	53	69
	N	14	12
	DNK	16	26
	NG	8	20
Causes Asthma	Y	14	35
	N	51	48
	DNK	16	22
	NG	10	22
Prevention asthma	Y	42	43
	N	40	59
	DNK	2	2
	NG	7	23
Causes diabetes	Y	50	60
	N	28	35
	DNK	2	7
	NG	11	25
Prevention diabetes	Y	54	66
	N	0	3
	DNK	29	38
	NG	8	20

(Y = correct answer, N =wrong answer, DNK= do not know, NG= not given)

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was conducted according to the Helsinki principles, after obtaining verbal consent of all participants. As of now, there is no official organization in Nepal for ethical clearance of an independent research in social sciences and hence clearance cannot be submitted.

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The Cross Cultural Adaptation and Psychometric Evaluation of the Bully Survey Swearer - Student Version (BYS-S) Indonesian version

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Abstract

Background. A valid instrument to measure the bullying in primary schools is needed to determine the actual conditions.

Aim. This study aimed to adapt the BYSS questionnaire and psychometric evaluation with a cultural approach.

Method. This psychometric testing applies the cross cultural adaptation method which consists of five translation stages. Item validity was analyzed by Rank-Spearman (r) and Cronbach's alpha (α) correlation test and followed by tests to obtain discriminatory power and difficulty level for each item.

Result. The results showed that the items had a high level of validity and reliability with some discriminatory items and the difficulty level of each item was very good. Discriminated and difficulty items in the form and impact on bullying victims were higher than the bullies and bystanders.

Conclusion. BYSS questionnaire Bahasa Indonesia's version can be considered valid and reliable and has excellent discriminatory and difficulty power.

Keyword: *bullying questionnaire, primary school students, cross cultural adaptation, psychometric*

Introduction

Bullying in primary schools has been reported to have a tendency to increase throughout the year and cause mental health problems¹, while the prevalence occupies the highest cases in the school age group. The highest is in Europe where 70.4% of bullying occurred, in the United States there was 11.1% and the remaining 18.5% happened in other countries, particularly Australia and Canada.² In Indonesia, the prevalence of bullying is 40%³, which is considered the highest within ASEAN countries⁴. One study in West Java show that 48% of bullying cases occurred in the classroom during school hours.⁵

Students who experience bullying are difficult to detect because victims generally do not report the incident to parents or teachers⁶. The reluctance of students to report for fear of revenge, shame⁷, always supervised⁸, inaccurate teacher responses and privacy disturbances⁹. Therefore, reliable questionnaires are needed to overcome the difficulties of students to state the current conditions associated with bullying.

Meanwhile, the existing questionnaire was not able to assess the status of students in the bullying incident. This situation makes the results of any study about incident of bullying in Indonesia not accurate in providing information related to the incidence of bullying in Indonesia. Accordingly, we developed a valid and reliable instrument that is adapted to the local culture to assess the incidence of bullying. In Indonesia, Swearer Bully Survey-Student Version (BYS-S) has

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not been used as a tool for screening of bullying among primary school students. Currently, there is no official BYSS translation into Bahasa Indonesia yet.

Materials and Methods

Original BYSS instrument

The use of the BYSS instrument for the psychometric test was approved by the original author, Susan Swearer. These include the following aspects: students as victims, as bullies, as bystanders and students' attitudes about bullying.

Cross-cultural adaptation process

Cross-cultural adaptation of this questionnaire applied guidelines by Beaton.¹⁰ In this study, we only measured questionnaires on a Likert scale, while our essays and multiple-choice questions were not measured.

Participants

Respondents in this study were primary school students totaling 30 respondents, aged 10 to 12 years, from both public and private schools in Yogyakarta, both rural and urban areas. Data was collected after participant willing to participate in the study and sign the informed consent.

Procedure

First, the English version questionnaire was translated into an Indonesian version by two sworn translators. After that, the translation results were compared and discussed to reach a consensus within the Indonesian context, then it became a synthesis translation for back translation. The next step was back translation by two independent native translators who have no medical or psychological background and have never known about the BYSS instrument. The results of the back translation were then compared and synthesized again to obtain the complete back translation. In the next stage (the fourth stage) an expert review by practitioners (primary school teachers), linguists, methodologists and professionals was done. The review's results were used to make a consensus about any discrepancies. The final results of this meeting produced an outcome of a pre-final version. The last stage was the pre-testing stage, where the questionnaire was completely tested for every question item. The questionnaire was given

to students after an explanation on how to complete it. The researcher gave 15 minutes for each student to complete the questionnaire. After collecting the data, the researcher interviewed the students to find out the level of understanding of the question items. The results from the students and teachers were then reviewed and adjusted based on the expert input to become a standardized research instrument.

Outcome measures

The expected outcome of this study was to obtain a reliable and valid instrument that is adaptable to the local culture in primary school students. This questionnaire describes the status of students as bullies, victims and bystanders as well as students' attitudes about bullying incidents in schools.

Statistical Analysis

Respondent data obtained to get the mean and standard deviation ($\mu \pm SD$) and percentage (%). The results of the correlation analysis are then carried out an index discrimination analysis to get an equation of the level of correlation and representation of each item.¹⁰ The validity of the questionnaire was measured using *pearson correlation* ($r > 0.3$). Internal consistency value uses Cronbach alpha with a value higher than 0.60.

SPSS software version 22 was utilized for the statistical analysis to develop a validity index and reliability index. The outcomes were then further analyzed using Item Response Theory (IRT) in STATA 14 with Grade Response Model (GRM) and Generalized Partial Credit Models (GPCM) approach. IRT was assigned to generate the validity (discriminated and difficulty) of each item parameter.¹¹ GRM is a test to determine the level of difficulty of an item.¹² GPCM measures how each item cannot be generalized because each item has its own discriminatory power.¹³

Results

The resulting translation was closely reported by the author for disagreement. Next, there was detailed discussion about words or sentences that fit the culture and characteristics of primary school students until reaching agreement. Some agreements that were made for example are the following: the word "bullying" is more familiar among students compared to the word

“perundungan”, so the word “bullying” was selected and used.

The word “gym” was changed to “ruang olah raga”; “kemayu (male)” or “tomboy” (female) replaced “Gay/lesbian”; “girlfriend/ boyfriend” agreed to change to “pacar”; “Face looks funny” was modified into “wajah jelek”; “Rumors” became “gosip”; and “Gang up on” was interpreted as “secara bersama-sama”. Some interfacing of instructions occurred for face validity: i.e., writings and commands layout were adjusted to the level of student understanding for instance “check all

that apply” modified into “pilihan boleh lebih dari satu”.

Table 1 illustrates the validity level for victims, bystanders and bullies items by measuring item discrimination and validity index to obtain validity and reliability of each item. Discrimination test results showed that the highest level of discrimination for victim was item g, while item d was the highest for bystanders and item c was the highest for bullies. There were two invalid items on the validity index: item l for bystanders and item f for bullies.

Table 1: Discriminated test, validity and reliability for items of bullying action

Item	Statement	Victim			Bystanders			Bullies		
		D	IV	Alpha	D	IV	Alpha	D	IV	Alpha
g	Attacked him/her (me)	6.19	0.89	0.87	0.87	0.70	0.87	1.24	0.57	0.88
b	Made fun of him/her (me)	1.35	0.75	0.88	1.41	0.71	0.86	0.98	0.74	0.87
k	Got pushed or shoved	1.07	0.69	0.88	0.56	0.46	0.88	0.99	0.65	0.87
a	Called him/her (me) names	1.18	0.69	0.88	0.68	0.42	0.88	0.89	0.67	0.87
e	Wouldn't let (me) him/her be a part (a part of their) of my group	0.86	0.64	0.88	0.60	0.59	0.87	1.07	0.59	0.88
f	Broke his/her (my) things	0.94	0.57	0.89	2.01	0.75	0.86	0.75	0.33*	0.89
j	Said mean things behind his/her back	0.62	0.61	0.89	0.72	0.59	0.87	1.05	.063	0.87
c	Said I will do bad things to him/her (me)	0.62	0.59	0.89	0.44	0.49	0.88	1.53	0.69	0.87
h	Wouldn't talk to him/her (Nobody would talk to him/her)	0.45	0.45	0.89	0.46	0.55	0.87	0.98	0.57	0.88
d	Played jokes on him/her (me)	0.49	0.49	0.89	2.08	0.75	0.86	0.73	0.53	0.88
i	Wrote bad things about him/her	0.42	0.48	0.89	0.85	0.64	0.87	1.05	0.62	0.87
l	Wrote mean things or made things up online about me (i.e., Facebook, Instagram, Twitter, etc.)	0.36	0.51	0.89	0.18	0.29*	0,88	0.71	0.49	0.89

Note: †

D = Coefficient discriminated *) not valid

IV = Index Validity **) not reliable

Reliability = Cronbach's Alpha

Modelling is important to obtain the optimal value of item discrimination. The results from the modelling identified that item e1 and f1 did not meet the requirements in the IRT criteria. Table 2 shows the complete result. For the impact of bullying, one item (a1) was not valid and one item (b1) was not reliable from bystanders item while from bullies, one item was not reliable.

Table 2: Discriminated test, validity and reliability for impact of bullying on victims, bystanders and bullies

Item	Statement	Victim			Bystanders			Bullies		
		D	IV	Alpha	D	IV	Alpha	D	IV	Alpha
d1	Made it difficult for to learn at school	2.93	0.53	0.74	1.85	0.57	0.55	2.43	0.77	0.48**
b1	I couldn't make friends	1.22	0.51	0.74	3.48	0.64	0.53**	0.94	0.26*	0.68
c1	Made me feel bad or sad	0.99	0.64	0.69	2.27	0.54	0.56	1.32	0.49	0.61
a1	Made me feel sick	0.65	0.44	0.75	0.12	0.05*	0.75	0.88	0.31	0.67

Note: † Item e¹ and f¹ does not meet the requirements for being a model

Table 3: The validity and reliability of students' attitudes towards bullying incidents

Item	Statement	Attitude		
		D	IV	Alpha
c	I don't like bullies.	4.37	.603	.880
m	I feel sorry for kids who are bullied.	3.35	.575	.882
l	Bullies make kids feel bad.	2.64	.580	.881
i	I can understand why someone would bully other kids.	2.34	.770	.872
g	It's okay to be friends with a bully.	2.32	.801	.870
j	I think bullies should be punished.	1.97	.390	.888
d	Bullies scare people.	1.88	.629	.880
f	Bullies hurt kids.	1.77	.411	.888
h	It's okay to bully others online.	1.63	.786	.873
k	Bullies don't mean to hurt anybody.	1.57	.685	.876
a	Most people who get bullied ask for it.	1.31	.558	.882
b	Bullying is a problem for kids.	1.01	.295*)	.893
e	Bullying toughens wimpy kids.	.95	.607	.880
n	Being bullied is no big deal.	.43	.345	.891
o	It's okay to bully others if I don't get caught.	-.23	.307*)	.891

Note: †

Most items under students' attitudes towards bullying were valid and reliable, however items b and o were not valid (table 3). The highest score on discrimination was item c that indicates if all student do not like bullying. The lowest score on discrimination was item o.

The researcher then continued the analysis process to find out whether students face any challenges in answering the questionnaire. This analysis used STATA 14 with the Grade Response Model (GRM) approach. Figure 1 shows the level of difficulty in the questionnaire item under type of bullying group, while Figure 2 illustrates the level of difficulty on the impact of bullying. Figure 1 indicates the level of difficulty, the likelihood of students maximum score, within 95% confidence interval (z values: -1.96 to 1.96). The highest difficulty level for victims (equal to 39.2) and lowest for bullies (equal to 30). The higher the score, the more difficult the statement item.

Table 4 illustrates that the higher score came from the victims of bullying. The bullies had the lowest score,

while bystanders' score was in the middle of victims and bullies.

The items of bullying impact the highest level of difficulty on the victim (equal to 12.6) and the lowest on the bullies (equal to 0.668). These data explain that it is highly likely that the victims felt it was easier to describe their experiences than the bullies and bystanders. On the contrary, the bullies did not realize that his/her behavior is an act of bullying.

Bullying perception that the difficulty level of student perception was the highest (equal to 67.5) compared to the other groups of items. The value within 95% confidence interval shows that the items about students' attitudes of bullying in primary school was the highest level of difficulty compared to victims, bullies and bystanders.

Table 4: Item of BYS-S bullying survey questionnaire difficulty in elementary school

No	Item's difficulty level on variables	Expected score /Theta	
		-1.96	1.96
1	Bullying incident		
	a. Victim	3.19	39.2
	b. Bystanders	3.74	36.7
	c. Bullies	1.85	30.0
2	The impact of bullying		
	a. Victim	.972	12.6
	b. Bystanders	1.69	11.2
	c. Bullies	.668	9.5
3	Bullying perception	22.8	67.5

Discussion

In general, there was no significant problem in the translation process because the team worked well together finding the most appropriate words to replace the English terms based on the level of student understanding and the local culture. The final results became the standard

version for the validity and reliability tests. At the end, the final BYS-S Indonesian version was confirmed to be equivalent to the English version.

Some translated terms were adjusted based on current language among primary school age children, for instance, term “tomboy” used for girls acting like boys,

and “kemayu” used for feminine boys. These changes were agreed on by the translator, primary education practitioners, and the methodology expert. Most terms were not translated directly for the literal meaning but based more on contextual meaning.

The BYS-S questionnaire English version assesses the students’ experiences of being a victim, a bully and a bystander as well as their attitudes about bullying in primary school setting. The reliability of this questionnaire had been tested with Cronbach’s Alpha values of 0.91 (physical victimization) and 0.76 (verbal victimization). Furthermore, the latest version of the questionnaire was developed to get a fuller picture of bullying by looking at victims, bystanders, bullies and to explore student attitudes about bullying at the school.

The discrimination power showed the reliability of questionnaire items¹⁴. Therefore, the BYS-S item has the discrimination power to distinguish the bullying type and the bullying impact for bullies, victims and bystanders. Item discrimination compared the options made by one student to the other students to determine the items’ strengths. Additionally, the level of difficulty was assigned to examine the tendency of students’ selection.

The results of item discrimination and difficulty indicate that a victim would experience a deeper feeling than those who witness or even do the bullying. The victims tend to remember the event in very detailed recall.¹¹

This BYS-Y questionnaire has the disadvantage of being a long questionnaire with many questions and in the Indonesian version, we have not yet assessed the test-retest reliability and validity aspects (construction validity and validity related to the criteria) with other versions.

Conclusion

In general, the BYS-S questionnaire had an excellent level of validity and reliability in distinguishing the forms of bullying and the impact of bullying on bullies, victims and bystanders in primary school students. There were three items that have low validity and one effect of bullying by the bullies was considered unreliable. The levels of discrimination and difficulty are important measurements to be applied to the primary school

students. For future applications, it is better to do a test and retest to get a more valid and reliable instrument.

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Is Low Birth Weight a Risk Factor for Early Childhood Caries? : A Nationwide Retrospective Cohort

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Abstract

Objectives: We investigated the impact of birth weight on early childhood caries (ECC) to identify the association between birth-related factors and oral health using Korea's national health screening database.

Methods: Children born between 2008 and 2012 who had undergone the first and second health screening at least once and had been confirmed ECC through ECC examination in the first to third oral health screening were included. They were classified according to the presence of dental caries (ECC or non-ECC group) and their birth weight (low [LBW; <2,500 g] or normal birth weight [NBW; 2,500–4,000 g]). We analyzed the association of multiple variables with ECC and examined the impact of birth weight on ECC by logistic regression and log binomial modeling to determine the odds ratio (OR) and relative risk (RR).

Findings: ECC prevalence among the 47,633 included infants and children was approximately 29%. Logistic regression and log binomial modeling showed that the OR and RR for ECC were 0.82 (95% CI, 0.73-0.91) and 0.86 (95% CI, 0.79-0.94), respectively, for children with LBW against those with NBW.

Conclusions: Our results indicated that LBW is not a risk factor for ECC. ECC is a preventable disease for which early detection is crucial. Therefore, oral health screening programs for infants and children should be further promoted to prevent oral diseases and improve oral health.

Keywords: Early childhood caries, Low birth weight, Oral health

Introduction

Birth weight is a vital indicator of children's health. Low birth weight (LBW) of less than 2,500 g and preterm birth are associated with increased morbidity and mortality.¹ In addition, LBW also impacts the oral structures, leading to enamel defects, crown dilacerations, palatal distortion, and delayed eruption.² As infants are valuable human resources for the future society, their health is a critical issue; thus, countries worldwide are paying attention to birth weight in order to optimize infants' health.³

Another indicator of children's health is the prevalence of dental caries.⁴ The World Health Organization (WHO) reported that primary teeth caries is the twelfth most prevalent disease and that early childhood caries (ECC) poses a global burden,

medically, socially, and economically.⁵ ECC refers to severe carious lesions or one or more teeth with filled tooth surfaces due to a white spot or caries in the anterior and posterior primary teeth in children under the age of six.⁵ After a tooth is erupted, ECC occurs through various pathways, such as bacteria, diet, oral hygiene management, host factors, and maternal bacterial transmission.⁶ ECC has an array of negative effects, including pain, discomfort, abscess formation, caries lesions in primary and permanent dentition, risk of delayed physical growth and development, limitation of activity, and deterioration of oral health-related quality of life.⁵ Untreated caries in primary dentition is the tenth most prevalent condition affecting 621 million children worldwide.⁷ The 2018 Korean Oral Health Survey in Children reported that the prevalence of caries in primary teeth among Korean 5-year-olds increased from 62.2%

in 2012 to 68.5% in 2018. Moreover, the prevalence of caries in primary teeth was 33.9% in 2018, showing that an approximately 34 out of 100 children have untreated caries.⁸ With this background, Korea is not an exception to the global trend of endeavors to prevent and manage ECC as a predictor of poor oral health into adulthood and older adulthood.^{6,9}

While ECC is multifactorial, there are contradictory results on the association between birth weight and oral health. One study found that LBW is associated with a lower risk of ECC compared to normal birth weight (NBW),¹⁰ while other studies demonstrated that LBW is associated with a higher risk of ECC.^{11,12} Systematic reviews pertinent to LBW and ECC¹³ reported that the association between LBW and ECC is yet unclear and emphasized the need for further studies. Most of these studies were cross-sectional studies or utilized self-reported questionnaires and had varying participant inclusion criteria and study periods, which limits the examination of the causal relationship between the two variables. Therefore, a large-scale cohort study is needed to present empirical evidence for the association between LBW and ECC.

In this study, we utilized data from Korea's Oral Health Screening Program for Infants and Children to examine the association between birth-related factors and oral health, aiming to investigate the impact of birth weight on ECC in order to present evidence that would contribute to improvement of the measures for prevention and management of ECC and consequently, lower the social burden.

Materials and Methods

Ethical considerations: In accordance with the Declaration of Helsinki, the Institutional Review Board of Korea University reviewed and approved the study protocol (KU-IRB16-EX-249-A-1).

Study design and participants: Korea launched the National Health Screening Program for Infants and Children, led by the Ministry of Health and Welfare, in 2007, as an effort to provide age-appropriate health management. The Oral Health Screening Program for Infants and Children is conducted in three rounds, with the oral examinations performed at 18–24, 42–48, and 54–60 months of age. Each examination consists of a

questionnaire pertaining to the current oral state, oral health behaviors, and diet, and an oral examination. The examinations are performed at a dental clinic, and all 20 primary teeth are examined. Dentists examine the teeth for eruption, non-eruption, demineralization, caries, treated teeth, and sealants, evaluate the overall oral state, and provide examination results.¹⁴

For the present study, we used data from the NHIS-established database for the National Health Screening Program for Infants and Children, which is integrated with the health insurance claims database. The database was developed by sampling 5% of children born between 2008 and 2012 by year. The study population comprised children who had undergone the first and second screening examinations of the National Health Screening Program for Infants and Children at least once and who had been confirmed ECC through ECC examination in the first to third oral screening examinations for infants and children.

Variables: The dependent variable was ECC. We reviewed the results of the three oral screening examinations for all participants. The state of all 20 primary teeth was classified as follows: erupted, non-erupted, erupting, demineralized, caries, treated, or sealant. Therefore, we used the following operational definitions. Children were classified in the ECC group if there was at least one primary tooth with caries in the first oral examination or in the non-ECC group if there were no teeth with caries. For the latter group, the presence of caries in primary teeth was examined in the second and third oral examination.

The independent variable was birth weight. This was the weight reported in the "birth weight" item in the first health screening examination. Birth weight ranged from 500–5000 g. Children were classified into those with a LBW (< 2,500 g) and those with a NBW (2,500–4,000 g). Children with missing values and extreme values were excluded.

Statistical Analysis

The participants' demographic characteristics and variables were analyzed using frequency and chi-square analyses. The impact of birth weight on ECC was analyzed by logistic regression and log binomial modeling to determine the odds ratio (OR), relative risk

(RR), and 95% confidence intervals (95% CI).

Although the RR/prevalence ratio and OR are widely used in medical research or epidemiological studies, the OR through logistic regression is actually excessively used due to direct relations; thus, the interpretation of the OR in terms of RR may lead to an incorrect inference on the prevalence of a particular event.¹⁵ Therefore, in this study, we used log binomial models to reconfirm the impact of birth weight on ECC from the perspective of RR. Statistical significance was set to 0.05. All statistical analyses were performed using SAS Enterprise Guide version 7.13 (SAS Institute, Cary, NC, USA)

in children with LBW against those with NBW was 0.81 (95% CI, 0.73-0.91) and remained significant even after adjusting for the confounders (OR=0.82; 95% CI, 0.73-0.91). In other words, the odds for ECC was approximately 1.22 times higher in children with NBW than in those with LBW (Table 1).

In the log binomial model (Table 2), the RR for ECC in children with LBW against those with NBW was 0.86 in the univariate analysis and after adjusting for confounders. In other words, children with NBW had a significantly greater RR (1.16 times) for ECC than those with LBW.

REsults

Impact of birth weight on ECC: The OR for ECC

Table 1. The impact of birth weight on ECC – univariate and multivariate logistic regression models.

Variable	Category	OR	95% CI	Adjusted OR	95% CI
Gender	Male			1.09***	1.04-1.14
	Female			1	
Income	Low level			1.17***	1.09-1.25
	Middle-low level			1.07	1.00-1.14
	Middle level			1.02	0.95-1.10
	Middle-high level			1.07	0.99-1.15
Medical insurance	High level			1	
	Community-based			1.10	0.94-1.28
	Employment-based			1.02	0.88-1.19
Residence area	Medical aid			1	
	Metropolitan			0.94**	0.90-1.00
	Small city			1.0	0.95-1.07
Birth weight	Rural county			1	
	LBW	0.81***	0.73-0.91	0.82***	0.73-0.91
	NBW	1		1	

Dependent variable: ECC (ref. no). ECC, early childhood caries; LBW, low birth weight; NBW, normal birth weight, OR, odds ratio; CI, confidence interval.

** $p < 0.01$, *** $p < 0.001$

Table 2. The impact of birth weight on ECC – log binomial model.

Variable	Category	RR	95% CI	Adjusted RR	95% CI
Birth weight	LBW	0.86***	0.79-0.93	0.86***	0.79-0.940
	NBW	1		1	

Dependent variable: ECC (ref. no). ECC, early childhood caries; LBW, low birth weight; NBW, normal birth weight, OR, odds ratio; CI, confidence interval.

*** $p < 0.001$

Discussion

According to the life course approach, LBW, an early life event, is associated with diseases later in life.¹⁶ From this perspective, the impact of birth weight on oral health is an important issue to be considered in order to develop public health strategies and promote efficiency of social cost.

In our study, the prevalence of ECC was approximately 29%. ECC prevalence among infants and children has been reported to range from 25–95%, with great disparities between developed and developing countries. While the prevalence is high at about 85% in the Philippines, Laos, and Cambodia,¹⁷ it is only about 23% in the US¹⁸ and 27.9% in the UK.¹⁹ The prevalence of ECC among infants and children in our study was similar to that in developed countries, indicating that the National Oral Examination Program for Infants and Children has practical benefits.

In this study, we confirmed that LBW does not increase the risk for ECC. In Korea, children under the age of six are provided care in care facilities for young children upon need. As LBW infants show different growth patterns, care may be focused on these children, which may result in a different rate of exposure to institutional care. That is, children with NBW are likely to be exposed to institutional care earlier, thereby being placed in an educational environment that lacks meticulous nutritional intake and oral hygiene. Hence, this may have had an impact on our findings.²⁰ A US longitudinal study reported that at 8 months of age, streptococcus mutans was more prevalent among

children born with NBW than among those born with LBW (28.2% vs. 16.8%; $p = 0.007$).¹⁰ The authors of the said study attributed the result to the fact that medically compromised infants are routinely given antibiotics or are medically well-monitored during their hospital stay. A Brazilian cross-sectional study that investigated the association between LBW and delayed deciduous teething found that these two variables were positively associated in children under the age of 24 months (PR=2.27; 95% CI, 1.02-5.07). The authors presumed that LBW may contribute to delayed teething because nutritional factors influence odontogenesis and teeth eruption.²¹ Our results that infants with NBW were at a greater risk for ECC than those with LBW may be attributable to the delayed teething caused by LBW and the consequent delay in intraoral exposure. Moreover, a systematic review of studies on the relation of ECC and body mass index as an indicator of the body weight status reported that overweight children were at a higher risk for ECC than normal weight/underweight children, which supports our results that ECC is less likely to occur among LBW infants than among NBW infants.²² These findings suggest that increased body weight, and not LBW, is a risk factor for ECC. Moreover, personal factors, such as diet and oral hygiene, seem to have a greater impact on ECC.

ECC is a preventable disease for which early detection is crucial. Its outcome may be altered with interventions following tooth eruption. The WHO declared that countries need to develop strategies and interventions aiming to prevent and control ECC and that group-oriented oral health education for families

and community involvement for fluoride management are essential for such purpose.^{5,9} It also underlined the need to perform cost-effectiveness evaluation of ECC prevention interventions in addition to relevant research so as to adequately consider both cost problems and social impact. Moreover, as effective preventive measures to lower the prevalence of ECC, the FDI World Dental Federation also recommends dental care education for pregnant women, education pertaining to preventive dental care for healthcare and dental providers, easily accessible oral services for pregnant women, infants and children, interprofessional education and collaboration to enhance the quality of and access to dental care in developing countries, and government surveillance systems focused on the prevention of dental caries in infants and preschoolers (0-5 years).²³ Therefore, promotion of early oral health examination programs for infants and children as a national policy may reduce the adverse impacts of oral diseases such as ECC, including pain and discomfort, risk of delayed physical growth and development, deterioration of oral health-related quality of life, and burden of cost of care. Measures such as professional management of dental plaques, oral health education, primary care dentist system for children, and expansion of insurance coverage of preventive care may be some specific options for this purpose.

The limitations of this study pertain to the limitation of the NHIS cohort data. First, infants and children who did not undergo the first or second National Health Screening for Infants and Children were not included in the sample, and of the initially screened children, those who completed an oral examination were specifically screened. Thus, the sample is not representative of Korea's entire infant and children population and the results must be interpreted with caution. Second, we could not consider socioeconomic variables that may affect ECC, such as parents' characteristics, or the biological pathway of biological factors, such as mutans streptococci, in our study model. Nevertheless, this study is significant in that it conducted a retrospective follow-up using NHIS cohort data, which is large enough to be nationally representative, to provide evidence for the association between birth weight and ECC and highlighted the importance of birth group as an early intervention strategy to promote oral health of infants and children.

Conclusion

We examined the association between birth weight and ECC using Korea's national database for oral examinations for infants and children and found that LBW is not a risk factor for ECC. Further large-scale cohort studies on the association between these two factors conducted worldwide would be conducive to gaining more robust evidence on the risk factors of ECC. As ECC is a preventable disease for which early detection is crucial, oral health screening programs for infants and children should be further promoted to prevent oral diseases and improve oral health.

Ethical Clearance: Not required

Source of Funding: Self

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The Correlation between Meat Consumption with the Risk of Contracting *Toxoplasma Gondii* with the Occurrence of Patients with Toxoplasmosis in Bogor Aquatreat Clinic, Indonesia

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Abstract

Background : Toxoplasmosis is a zoonotic disease originated from parasite of *Toxoplasma gondii*. The purpose of this research is to analyze The Correlation between Meat Consumption with the risk of contracting *Toxoplasma gondii* with the occurrence of Patients with Toxoplasmosis in Bogor Aquatreat Clinic, Indonesia.

Method : In this research, case control research design is used with a quantitative approach. This research is an observational research using data of medical record in Bogor Aquatreat clinic Indonesia by selecting the positive serological test results of Toxoplasmosis (IgG) for the case group and selecting the negative serological test results of Toxoplasmosis (IgG) for the control group. Afterwards, interviews of the case and the control groups were done by filling out the questionnaire (GForm). The taken data is the data of patients who visited in 2019 with a total of 286 patients. The data that are willing to be used as a sample are the data of 108 patients. The data analysis techniques which used in this research were phased, those are: univariate, bivariate and multivariate analyzes which computerized by using a statistical program (SPSS Statistics 25).

Result: The results of this research showed that the proportion of the respondents who consumed meat are risked in the toxoplasmosis case group was 28 (51.9%) higher than the respondents who were not accustomed to consume meat are risked in the case of toxoplasmosis was 26 (48.1%). Logistic regression analysis of the final model showed a significant correlation between meat consumption at risk with the incidence of toxoplasmosis with OR 4.66 (95% CI: 1.87-11.59; p-value: 0.001), thus in the case group who consumed meat are at risk of contracting *Toxoplasma gondii* was 4.66 higher than the control group after being controlled by sex variables.

Conclusion: The correlation between meat consumption at risk with the incidence of toxoplasmosis in the case group who consumed meat are at risk of contracting *Toxoplasma gondii* was 4.66 higher than the control group after being controlled by sex variable.

Keywords: *Toxoplasma gondii*, Toxoplasmosis, zoonosis, meat, case control

Introduction

Toxoplasmosis is a zoonotic disease originated from parasite *Toxoplasma gondii*. Toxoplasmosis is also one of the five neglected parasitic infections, whereas the disease has significant economic and health impact as it reduces reproductive capacity, impaired growth, and fertility, including pregnant women who experience spontaneous abortion and fetal abnormalities

(hydrocephalus, chorioretinitis, intracranial calcification, mental retardation), brain and eyes neurological disorders.¹⁻⁴ Toxoplasmosis can cause Alzheimer's disease as its long-term effect.⁵

Based on the Public Health Agency of Canada in 2011, *Toxoplasma gondii* infection is estimated 15-18% in adults worldwide.⁶ The prevalence of Toxoplasmosis in China is 8.2%, France 61.0%, Brazil

84.5%, United States 38.0%, and India 24.0%.⁷ In Indonesia, the prevalence of Toxoplasmosis infection based on serological test reaches 2-51%.⁸ In 2015, ISIKHNAS stated the prevalence of Toxoplasma infection in Indonesia is about 43-88%.⁹ The prevalence of toxoplasmosis in Indonesia increased due to poor environmental sanitation and many sources of transmission.^{10 11}

WHO states that toxoplasmosis is a food-borne disease caused by parasitic infection of *Toxoplasma gondii* which contaminates food through animals and plants.¹² The factors of *Toxoplasma* infection to human occur through meat or vegetable at-risk consumption, cat fecal contamination in water and soil, blood transfusion, organ transplantation, and transmission during pregnancy.¹ Meat at-risk is the meat consumed in a half-cooked or raw that increase the risk of being contaminated by *Toxoplasma gondii* due to not cooked properly. A study in Bali shows that the risk factors that have a significant relationship in seroprevalence of toxoplasmosis in female consumed undercooked pork meat is 29.07 times higher compared to cooked pork (OR= 29.07), and undercooked chicken meat consumption has higher risk 8.23 times than cooked meat (OR=8.231). A study in Central Java mentioned that half-cooked meat consumption has a higher risk of 0.85 times compared to those who have never eaten undercooked meat (OR=0.85).¹³

Methods

In this research, case control research design is conducted with a quantitative approach. This research is an observational research using data of medical record in Bogor Aquatreat clinic by selecting the positive serological test results of Toxoplasmosis (IgG) for the case group and selecting the negative serological test results of Toxoplasmosis (IgG) for the control group. Toxoplasmosis diagnosis enforcement is confirmed through serum (IgG) laboratory tests data using Enzyme-Linked Immunosorbent Assay (ELISA) method. Data on age and sex were obtained from patient data. Other data for variables were obtained from interviews using questionnaires (GForm).

Data were collected and processed from March to June 2020. The patients visiting during 2019 are 286 in total with 108 patients were willing to be interviewed

using questionnaires (Gform) and met with the inclusion criteria.

Inclusion criteria: have complete data according to variables to be studied. Exclusion criteria: patients who are not willing to be interviewed/fill in the questionnaire and do not complete the answers in accordance with the variables studied. collected data were cleared and checked to ensure the correct data were received.

The dependent variable in this study is Toxoplasmosis and the independent variable is at-risk meat consumption behavior. The covariate variables of this study are age, gender, pet ownership, environmental hygiene, history of blood transfusion and history of flooding.

The data were analyzed gradually in univariate, bivariate, stratification, and multivariate analysis using statistical program (SPSS Statistics 25).

Results

There are 108 respondents from data Bogor Aquatreat Clinic patients being analyzed in this study. Table 1. shows the respondent proportion of at-risk meat consumption behavior in the toxoplasmosis case is 28 respondents (51,8%), higher than those who never consume at-risk meat that is 26 respondents (48,1%). Table 2. is the proportion of the respondent age shows most of the respondents' age is 20-40 (81,5%) and respondents who raising pet is 29 (53,7%). Table 3. Bivariate analysis result shows the behavior of at-risk meat consumption in case group is 28 (51,9%) higher than control group which is 12 (22,2%). While in the respondent in case group that doesn't use to consume at-risk meat is 26 (48,1%) compared to control group 42 (77,8%). Table 4. indicates the relation between pet ownership as covariate variables and Toxoplasmosis cases is statistically significant with OR=2,76 (95% CI:1,25-6,08) p-value 0,019. Table 5 shows the at-risk meat consumption behavior as the main independent variable and 2 covariate variables are gender and pet ownership that analyzed in multivariate method. Based on the confounding analysis in table 6, the behavior of at-risk meat consumption in toxoplasmosis case shows OR=4,66, and the difference between crude and adjusted OR is 8,12% or <10%. Pet ownership is not confounding variable. Gender variable is taken out in the model and the result of at-risk meat consumption behavior and

toxoplasmosis analysis shows OR=3,77 and the difference between crude and adjusted OR is 19,09% or >10%. Gender as a confounding variable has to be included in the model. Table 7. The logistic regression test as final model shows the significant relation between at-risk meat consumption and Toxoplasmosis case with OR=4,66 (95% CI:1,87-11,59; p-value: 0,001).

Table 1. Frequency Distribution of Variables with Toxoplasmosis

Variables	Toxoplasmosis		Total
	Case	Control	n (%)
	54 (100)	54 (100)	108 (100)
At-risk Meat Consumption			
Yes	28 (51,9)	12 (22,2)	40 (37,0)
No	26 (48,1)	42 (77,8)	68 (63,0)
Gender			
Male	18 (33,3)	34 (63,0)	52 (48,2)
Female	36 (66,7)	20 (37,0)	56 (51,8)
Age			
25-40	44 (81,5)	47 (87,0)	91 (84,26)
< 25 and >40	10 (18,5)	7 (13,0)	17(15,74)
Education			
Low (\leq Highschool)	6 (11,1)	7 (13,0)	13 (12,03)
High (> Highschool)	48 (88,9)	47 (87,0)	95 (87,97)
Job			
At risk	2 (3,7)	2 (3,7)	4 (3,71)
No risk	52 (96,3)	52 (96,3)	104 (96,29)
Pet ownership			
Yes	29 (53,7)	16 (29,6)	45 (41,67)
No	25 (46,3)	38 (70,4)	63 (58,33)
House hygiene			
Not clean	6 (11,1)	4 (7,4)	10 (9,26)
Clean	48 (88,9)	50 (92,6)	98 (90,74)
Flood History			
Yes	11 (20,4)	10 (18,5)	21 (19,44)
No	43 (79,6)	44 (81,5)	87 (80,56)
Blood transfusion history			
Yes	2 (3,7)	3 (5,6)	5 (4,63)
No	52 (96,3)	51 (94,4)	103 (95,37)

Table 2. Bivariate Analysis of Variables with Toxoplasmosis

Variable	Toxoplasmosis				Total	OR	95% CI	p-value
	Case		Control					
	n	%	n	%				
At-Risk Meat Consumption								
Yes	28	51,9	12	22,2	40 (37,0)	3,77	1,64-8,68	0,003
No	26	48,1	42	77,8	68 (63,0)			
Gender								
Male	18	33,3	34	63,0	52 (48,1)	0,29	0,13-0,65	0,004*
Female	36	66,7	20	37,0	56 (51,9)			
Age								
25-40	44	81,5	47	87,0	91 (84,3)	0,66	0,23-1,87	0,597
< 25 and >40	10	18,5	7	13,0	17 (15,7)			
Education								
Low (≤ Highschool)	6	11,1	7	13,0	13 (12,0)	0,84	0,26-2,68	1,000
High (> Highschool)	48	88,9	47	87,0	95 (88,0)			
Job								
At risk	2	3,7	2	3,7	4 (3,7)	1,00	0,14-7,37	1,000
No risk	52	96,3	52	96,3	104 (96,3)			
Pet ownership								
Yes	29	53,7	16	29,6	45 (41,7)	2,76	1,25-6,08	0,019*
No	25	46,3	38	70,4	63 (58,3)			
House hygiene								
Not clean	6	11,1	4	7,4	10 (9,3)	1,56	0,42-5,88	0,742
Clean	48	88,9	50	92,6	98 (90,7)			
Flood history								
Yes	11	20,4	10	18,5	21 (19,4)	1,13	0,43-2,92	1,000
No	43	79,6	44	81,5	87 (80,6)			

Cont... Table 2. Bivariate Analysis of Variables with Toxoplasmosis

Blood transfusion history								
Yes	2	3,7	3	5,6	5 (4,6)	0,65	0,11-4,08	1,000
No	51	96,3	51	94,4	103 (95,4)			

* = multivariate candidate

Table 3. Full Model Multivariate Analysis of The Correlation between At-risk Meat Consumption with Toxoplasmosis

Variable	OR	95%CI		p-value
		Lower	Upper	
At-risk meat consumption	4,31	1,71	10,88	0,002
Gender	0,22	0,09	0,54	0,001
Pet ownership	2,86	1,19	6,93	0,020

Table 4. Confounding Analysis Result of The Correlation between At-risk Meat Consumption with Toxoplasmosis

Model	OR	95%CI		ΔOR (%)	Adj.
		Lower	Upper		
Model 1 Full Model*	4,31	1,71	10,88	-	-
Model 2 Without pet ownership	4,66	1,87	11,59	8,12	Not Confounding
Model 3 Gender	3,77	1,64	8,68	19,09	Confounding

* at risk meat consumption behavior+pet ownership+gender

Table 5. Final Result Multivariate Analysis Model

Variable	B	SE	OR	95% CI	p-value
At-risk meat consumption	1,539	0,465	4,66	1,87-11,59	0,001
Gender	-1,434	0,443	0,23	0,10-0,57	0,001

B=Coefficients Beta, SE= Standard Error, OR=Odds Ratio, CI=Confidence Interval

Discussion

Based on the case-control study on Aquatreat Bogor Clinic, we evaluated the relation between undercook meat consumption behavior and Toxoplasmosis case has resulted OR 3,77 (95% CI: 1,64-8,68; p-value 0,003) in bivariate analysis. It shows statistically significant relation between at-risk meat consumption behavior with Toxoplasmosis in case group has risk 3,77 times higher to have Toxoplasmosis compared to control group. The final result in multivariate analysis that analyzed the relation between undercook meat consumption behavior and Toxoplasmosis case controlled by gender has OR=4,66 (95% CI: 1,87-11,59; p-value: 0,001) which means the behavior of at-risk meat consumption in case group has risk 4,66 times higher to have Toxoplasmosis compared to control group. This corresponds with the study from Jimma University, Ethiopia, which stated the meat consumption behavior has OR = 5,57 (95% CI: 2.82–11.68; p-value; 0,000) and the adjusted AOR 5.1 (95% CI:2.82–11.68; p-value;0,001).¹⁴ In Semarang, Indonesia, the proportion of at-risk meat consumption behavior (raw or undercook) in the case group is 60,7% and 21,4% in the control group. The proportion of respondents who do not use to eat undercook or raw meat is 39,3% in the case group and 78,6% in the control group with OR= 5,667% (95% CI = 1,743-18,423: p=0,003).¹¹ In Bali, the risk factor that has significant relation between seroprevalence Toxoplasmosis in female and the consumption of undercooked pork has risk 29,07 times higher compared to well-cooked pork (OR=29,07), the consumption of undercooked chicken has risk 8,23 times compared to well-cooked chicken (OR=8,231).¹⁵ It indicates the low hygiene of the meat and consumption of half-cooked meat has risk to lead *Toxoplasma gondii* through oocyst which pollute the meat. In this study, gender included as variable that affect the correlation between at-risk meat consumption behavior with the Toxoplasmosis occurrence. The biological difference affects the body response. Research states that female have risk 0,9 times to have Toxoplasmosis than male. The prevalence among female is 66,85% and 63,97% are male.¹⁶ Study in Minahasa shows number of seropositive Toxoplasma occurred in female 59,1%.¹¹ Other research in Sharjah, UAE purposed to find the correlation between the toxoplasmosis prevalence with hormone levels related to gender (progesterone, estradiol, and testosterone).

Serologist test shows toxoplasmosis infection in human by hormone that inducted the anti-parasite function as immunity. The study has stated that gender-related hormones affect directly the immunologist functions.¹⁷ Therefore, this study shows the correlation between meat consumption with the risk of contracting *Toxoplasma gondii* with the toxoplasmosis affected by gender in the case group compared to the control group.

Conclusions

The logistic regression test as final model shows the significant relation between at-risk meat consumption and Toxoplasmosis case with OR=4,66 (95% CI:1,87-11,59; p-value: 0,001) which means the behavior of undercooked meat consumption in case group has risk 4,66 times higher to have Toxoplasmosis compared to control group. Based on the study result, Toxoplasmosis can be prevented through hygiene improvement and promote to consume well-cooked meat. We also recommend researching about the other food variables that have risk to be polluted by *Toxoplasma gondii* oocysts such as vegetable and milk. We also recommend expanding the population of the study.

Ethical Considerations: This study was approved by The Research and Community Engagement Ethical Committee Faculty of Public Health Universitas Indonesia (Ket-380/UN2.F10.D11/PPM.00.02/2020).

Competing Interests: None declared

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The Effects of Cognitive Therapy on Changes in Symptoms of Hallucinations in Schizophrenic Patients

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Abstract

Schizophrenia is a disease that affects various areas of individual function, including thinking, communicating, accepting, interpreting reality, feeling, and showing emotions. Non-pharmacological therapy given to overcome hallucinations of schizophrenic patients is cognitive therapy. The purpose of this study was to determine the effect of cognitive therapy on changes in hallucinatory symptoms in schizophrenic patients at Prof. Dr. M. Ildrem Mental Hospital in Medan. The design of this study is Quasi-Experimental One Group Pre and Post-test design, The study population was all hallucinatory patients with a total of 286 and a sample of 19 respondents. The sampling technique uses purposive sampling. Data collection tools using a questionnaire that has been tested for validity. The statistical test used is the paired t test. The results of this study obtained the value of $p = 0,000$ ($p < 0.05$). In conclusion, there is a significant effect on changes in hallucinatory symptoms in schizophrenic patients before and after cognitive therapy.

Keywords: *hallucinations, schizophrenia, cognitive therapy, mental disorder*

Introduction

Schizophrenia is a chronic, severe, and disabling disease, a brain disorder characterized by chaotic thoughts, delusions, hallucinations, and strange behavior^{1,2}. Schizophrenia is a severe and chronic mental disorder that attacks 20 million people worldwide³. The highest number of schizophrenics is in the Western Pacific with a prevalence of 3 per 1,000 population, in developed European countries the prevalence of schizophrenia is 0.3 per 1000 population. More than 50% of schizophrenics get no attention, and 90% of them are in developing countries. Schizophrenia usually occurs in adulthood (productive age) between the ages of 18-35 years. In Indonesia, based on the results of⁴, it was estimated that the prevalence of people who had suffered schizophrenia in Indonesia was 1.8 per 1000 population.

That 20% of schizophrenic patients experience visual and auditory hallucinations simultaneously, another 70% experience auditory hallucinations,

and 10% experience other hallucinations⁵. Like hallucinations smell, touch and taste. To overcome the problem of hallucinations not only use pharmacological therapy but also use psychopharmaceutical therapy such as cognitive therapy.

Cognitive therapy is part of psychotherapy that can be given to several types of mental disorders. Cognitive therapy is a type of regular short-term therapy that provides a basis for thinking of patients to understand the problem, have words to express themselves and techniques to overcome difficult feelings, and problem-solving techniques⁶. Survey Results obtained by researchers from the medical record at Prof. Dr. Muhammad Ildrem Provsu Mental Hospital in Medan City was 4,341 people who had schizophrenia and those who had hallucinations, 3,435 people.

Methods

The design of this study is Quasi-Experimental One Group Pre and Post-test design. The population in this study were all hallucinatory patients. Based on medical record data at Prof. Mental Hospital Dr. M. Ildrem Provsu Medan in 2018. Samples in this study were 21

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people taken using a purposive sampling technique. Before conducting cognitive therapy interventions, researchers first measure the risk symptoms of violent behavior using a questionnaire that has been tested for validity and reliability with Cronbach's Alfa 0.765. The questionnaire contained 12 statements consisting of cognitive, affective, behavioral, and social responses. Statistical tests were used with paired t-test. with a p-value <0.05 with a significant level of 95%.

Results and Discussion

Table 1 can be seen that the majority of respondents were male as many as 11 people (57.9%), aged <40 years as many as 11 people (57.9%), elementary education background of 8 respondents (42.1%), the majority of jobs are not working as many as 12 respondents (63.2%), and most respondents are not married as many as 9 respondents (47.4%).

Table 1.: Characteristics of Respondents

Karakteristik	n	%
Gender		
Male	11	57,9
Female	8	42,1
Age		
30-40 years old	11	57,9
41-50 years old	7	36,8
51-60 years old	1	5,3
Education		
No school	2	10,5
Elementary school	8	42,1
Middle school	7	36,8
High school	2	10,5
Profession		
Student	3	15,8
Entrepreneur	4	21,1
Unemployment	12	63,2
Marital Status		
Married	7	36,8
Divorce	3	15,8
Not married	9	47,4

Table 2.: Hallucinations Symptoms of Schizophrenia Patients Before Cognitive Therapy is Given

Symptoms of Hallucinations	Mean	n	SD	SE
Cognitive	10,47	19	,841	,193
Affective	10,58	19	1.121	,257
Behavior	10,42	19	,692	,159
Social	10,58	19	,838	,192
Composit	42,05	19	3,492	,801

Table 3.: Hallucinations Symptoms of Schizophrenic Patients After Cognitive Therapy is Given

Symptoms of Hallucinations	Mean	n	SD	SE
Cognitive	4,63	19	,761	,175
Affective	4,53	19	1,124	,258
Behavior	4,53	19	,964	,221
Social	4,68	19	1,057	,242
Composit	18,37	19	2,9547	,896

Table 4.: Changes in Symptoms of Hallucinations in Schizophrenia Patients Before and After Cognitive Therapy is Given

Symptoms of Hallucinations	Mean Before	Mean After	Mean Difference	SD	SE	Df	p
Cognitive	10,47	4,63	5,842	1,068	,245	18	0,000
Affective	10,58	4,53	6,053	1,779	,408	18	0,000
Behavior	10,58	4,53	6,053	970	,223	18	0,000
Social	10,42	4,68	5,737	1,368	,314	18	0,000
Composit	42,05	18,37	23,685	5,185	1,19		0,000

Table 2 can be seen the average hallucinatory symptoms in schizophrenic patients before Cognitive therapy include cognitive responses of 10.47, affective responses of 10.58, social responses of 10.58, behavioral responses of 10.42 and composite values of 42.05 .

Table 3 can be seen the average hallucinatory symptoms in schizophrenic patients after Cognitive therapy include cognitive response of 4.63, affective response of 4.53, behavioral response of 4.53, social response of 4.68, and composite value of 18, 37.

Table 4 can be seen significant changes between hallucinatory symptoms in schizophrenia patients before and after cognitive therapy. This is reinforced by the average value of hallucinatory symptoms in patients before and after getting cognitive therapy.

Hallucinations Symptoms Before Cognitive Therapy Is Given

The results obtained based on the characteristics of respondents showed that 57.9% were male. Male respondents have higher cognitive abilities compared to women. This is in accordance with the statement of⁷. that a person's cognitive, especially men, is higher than women, because men in using relationships between individuals and their environment can understand how if an event occurs that causes problems that burden the individual which is used even though the response shown is emotion so that aggressive behavior appears. The average age of respondents with hallucinations is 30-40 years, which means the respondent is in the late adult stage. Research conducted by⁸. on schizophrenic clients who experience hallucinations in India shows that most clients are aged between 21-40 years.

Most respondent's work status is not working. Research conducted by⁹. also shows that schizophrenic clients who commit suicide generally commit suicide due to hallucinations and most clients do not work. The explanation above shows that hallucinations clients generally do not work or have quit their jobs. Most marital status is not married. Research conducted by¹⁰. results showed that marital status is closely related to the prevalence of schizophrenia, most are not married and do not have a life partner is one of the characteristics of clients with schizophrenia.

Based on the results of research conducted by researchers, it was found that the symptom value of each response varied, from the cognitive response value obtained a value of 10, 47 which means the value of hallucinogenic symptoms before therapy in the high category. In this case, the majority of respondents experienced auditory hallucinations and these symptoms are symptoms that are often experienced by patients with hallucinations.

Feelings experienced by patients with hallucinations often feel the stimulus that is not there, so that changes in mindset. Changes in thought processes will result in patients experiencing hallucinations, changes experienced like feeling that the sounds heard are really real. One characteristic of clients with hallucinations is impaired cognitive function. Disruption of cognitive function affects changes in memory, has damage in assessing and using memory and impaired long/short term memory. With this condition, the client becomes forgetful and not interested.

In the affective response, the value obtained before therapy is given at 10.58 is categorized high. In this case hallucinations experienced by patients there are two, namely hallucinations that are liked and hallucinations that are hated, but equally the patient's feelings lead to maladaptive responses. In the social response also obtained value in the high category with a value of 10.42. This is influenced by the patient's bad experiences in the past which made him always remember the events he experienced. Sociocultural factors are very triggering the occurrence of schizophrenia, this is because that individuals with lower socioeconomic classes experience greater symptoms of schizophrenia compared to those from higher social groups¹¹.

In the behavioral response, the value of 10.58 was obtained, which is the value of symptoms that appear in schizophrenic patients is still in the high category. From the results of the questionnaire that was filled out by respondents, most respondents said "I do not like to be disturbed by anyone when the sound of a whisper that appears, I will expel people who bother me when I hear the voice of the whisper and some respondents said aware that the sound of the whisper can interfere with their relationship other people.

Based on the results of the study, it was found that the average hallucinatory symptoms before cognitive therapy were performed in a high category with a value of 42.05. This means that the value of these symptoms is of great concern. Hallucinations are disturbances of sensory perception without any external stimulation that can cover all sensing systems which occur when the individual's consciousness is full or good⁵.

This research is assisted by the results of research conducted by¹². with the title controlling negative thoughts of schizophrenic clients with cognitive therapy in the working area of the Mangasa health center in Makassar. The results obtained before therapy from 13 respondents (92.9%) included in the bad category in controlling negative thoughts. This happens when they have a problem that is a burden on the mind, they tend to want to tell their problems to family members but on the other hand, they are afraid to tell family members because they feel that when telling about their problems family members are burdened with these problems so clients with schizophrenia prefer to bury their own problems and sometimes the problem, in the end, they can not overcome themselves.

Hallucinations Symptoms After Cognitive Therapy Was Given

The results showed that the average hallucinatory symptoms after cognitive therapy included cognitive responses of 4.63, affective responses of 4.53, social responses of 4.68, behavioral responses of 4.53, and composite values of 18.37. The results of this study indicate that the ability to control hallucinations in schizophrenic patients has increased.

Based on research results obtained indicate that there are changes in hallucinatory symptoms after cognitive therapy can be seen from each response value of the respondent. This was obtained from the results of a questionnaire that researchers distributed to respondents after cognitive therapy. Most respondents said they were no longer afraid of the whisper that was always heard, able to concentrate when the whisper came, and said that they were not sure of the whisper voices they always heard. From these statements, it can be concluded that the respondent is able to control its hallucinations independently after cognitive therapy.

Cognitive therapy provides a basis for patients to understand the problem, have words to express themselves, and be able to overcome difficult circumstances. Cognitive therapy is also a form of psychotherapy based on the pathology of the soul which focuses on its actions based on the modification of cognitive distortion and maladaptive behavior⁶. In the process of implementing cognitive therapy involves the attention and sincerity of patients in following this therapy.

Effects of Cognitive Therapy on Changes in Symptoms of Hallucinations in Schizophrenic Patients

The results of the study conducted obtained $p\text{-value} = 0,000$ ($p < 0.05$). Thus it can be interpreted that cognitive therapy has an influence on changes in hallucinatory symptoms in schizophrenic patients. The value of symptoms before treatment was 42.05, the value of symptoms after treatment was 18.37, and the value of the difference before and after was 23.668. Can be interpreted that there are significant changes in symptoms between before and after cognitive therapy.

One of the mental nursing actions with hallucinatory patients is cognitive therapy, which is where cognitive therapy is one of psychotherapy that provides a basis for the patient to be able to understand the problem, techniques to overcome difficult circumstances, and problem-solving techniques⁶. The success in conducting cognitive therapy refers to the patient following the therapeutic process. The benefit of cognitive therapy is to practice changing rational thoughts and the patient is able to realize that negative unpleasant events can disturb feelings.

The same research has not been found by researchers, but other research conducted by¹³. also supports this research. In his research, it was found that there were differences in depressive conditions after the implementation of cognitive therapy which showed that a decrease in depressive conditions in the elderly group who received cognitive therapy ($p\text{-value} = 0.001 < 0.05$). In this study, researchers conducted 9 sessions of therapy. It can be interpreted that the longer cognitive therapy is given, the possibility to eliminate negative thoughts that interfere is also a big influence. Related research is also¹⁴. which states that cognitive therapy

has an influence on a person's level of depression, where depression conditions before and after giving cognitive therapy (p -value = <0.05).

All humans have certainly, often experienced problems that can make humans more mature, mature, and intelligent when faced with positive thinking. But if negative thinking is used, problems can bring disaster. This is where the importance of positive thinking in dealing with every problem. For people who think positively, every problem is always a solution. There is a way out of every problem.

In this study, it is hoped that after being given Cognitive Therapy Schizophrenia clients can have the ability to control good negative thoughts. Any negative thoughts that are felt to interfere or make clients worry can be reduced or even no longer appear and can be replaced with positive thoughts and make the schizophrenic client have a good spirit/optimism in living his life. This is in line with research conducted by¹⁵. stating that cognitive therapy can increase optimism.

Conclusion

Results showed that there was a significant influence on changes in hallucinatory symptoms in schizophrenic patients before and after cognitive therapy with $p = 0,000$ ($p < 0.05$).

Ethical Clearance: Taken from Faculty of Medicine, Muhammadiyah of Sumatera Utara University. Certificate number 224/KEPK/FKUMSU/2018

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Conflict of Interest: Nil

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Relationship of Albumin-CRP Ratio on Neoadjuvan Clinical Response of Caf Regimen Chemotherapy in Women with *Locally Advance Breast Cancer* in Rsud Dr. Soetomo

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Abstract

Background : Breast cancer is the most common cancer in women and is the highest cause of death. As many as 2.1 million women in the world suffer from breast cancer each year. Data in Dr. Soetomo Hospital show patient cancer breast came with a case of locally advanced breast cancer as much as 47% and 52% of the cases do not respond well to neoadjuvant chemotherapy. The inflammatory state and nutritional status of the patient play a role in the therapeutic success of the patient. The presence of inflammation and the status of the nutrients are poorly related to the response of clinically against chemotherapy are low. The state of inflammation and status of nutrition it can be seen from the ratio between CRP with albumin.

Method: The research was a prospective cohort design, on patients with locally advanced breast cancer. Patients performed the examination levels of albumin and CRP before the chemotherapy is given and carried out the measurement of the mass of the tumor with a physical examination. Then the patient underwent neoadjuvant chemotherapy with the CAF regimen for 3 cycles and was examined for CRP, albumin, and tumor size again. Then evaluated for response to therapy.

Results: In this study, a total of 35 patients were obtained with 12 people (34.3%) with a low CRP / Albumin ratio and 23 people (65.7%) with a high CRP / Albumin ratio. From the clinical response found 0 people (0%) with progressive disease, 7 people (20%) with stable disease, 23 people (65.7%) with partial response and 5 people (14.3%) with complete response. Statistical test results showed that there was a significant relationship between CRP / Albumin ratio with chemotherapy response ($p = 0.004$).

Conclusion: It was obtained a significant relationship between the increased ratio of CRP / Albumin with a decrease in response to neoadjuvant chemotherapy of CAF in patients with Locally Advanced Breast Cancer.

Keywords: *locally advanced breast cancer, CRP, albumin, CRP/Albumin ratio, response to chemotherapy, breast cancer*

Background

Breast cancer is the most common cancer in women and is the highest cause of death. As many as 2.1 million women in the world suffer from breast cancer each year.

In the year 2018, estimated around 627,000 women die the world for cancer of the breast , namely 15% of entire cancer as a cause of death in women¹. The incidence and number of mortality breast cancer are also increased.²

Patients with locally advanced breast cancer (LABC) in particular, require neoadjuvant chemotherapy to reduce tumor size. In the research that is carried out by Oyan et al, on factors prognostic of patients who undergo chemotherapy CAF concluded that age, status

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gland lymph nodes, the number of focal tumors, and the status of the receptor and multicentric tumor affecting disease-free survival (DFS) either local or remote.

Data at Dr. Soetomo Regional Hospital shows that breast cancer sufferers come in with stage III proportions of 47%. A descriptive-analytic study by Audrina et al in 2011-2013 showed 52% of patients with neoadjuvant chemotherapy experienced a stable disease response. Basic at the top implicated in many studies that discuss the factor- factors that influence the success of chemotherapy

Inflammation regulates tumor behavior at each stage including initiation, promotion, conversion to malignancy, invasion, and metastasis³. Increased levels of C-reactive protein (CRP) inflammatory markers are found in various conditions, including malignancy⁴. Increased CRP is a result of their cancer was alone and the inflammatory chronicle that high into the cause of the main occurrence of carcinogenesis. Inflammation causes oxidative stress so it initiates carcinogenesis by activating tumor suppressor gene or modification of DNA-repair protein⁵.

Serum albumin is one of the markers most often used to assess a patient's nutritional status. Albumin is produced by the liver and is the main protein in the blood, acting as a key antioxidant, detoxifying, and transporting important nutrients. In patients with locally advanced breast cancer (LABC), the levels of serum albumin often experience a decline, due to malnutrition and response to inflammatory systematically against tumors both suppress the synthesis of albumin.⁶

C-reactive protein and albumin ratio (CAR) was initially used as prognostic value in predicting outcomes in sepsis patients. End- the end of this, the ratio of CRP to albumin promising as a factor prognostic in patients with cancer. Glasgow prognostic score is an indicator of the prognosis of patients with cancer by inflammation which consists of an increase in CRP and a decrease in the concentration of albumin. This marker reflects the systemic inflammatory response in cancer patients and has been reported as a significant prognosis indicator in cancer patients³. The CRP to albumin ratio has been used in several types of cancer, one of which is in breast cancer⁷.

By due reason in top researchers are very interested to investigate the value of the ratio of CRP compared to albumin in patients with locally advanced breast cancer (LABC) who underwent chemotherapy neoadjuvant based anthracyclines. Some considerations are cases of breast cancer in Surabaya quite a lot and most are found at a locally advanced stage, CAR examination can be done at Dr. Soetomo Regional Hospital and this research has never been done at Dr. Soetomo Regional Hospital before.

Research Method

This study was an observational analytic study with a prospective cohort design. Patients women with LABC who meet the criteria for inclusion and exclusion of studies that the criteria for inclusions are women with LABC which getting chemotherapy neoadjuvant line first CAF / CEF, and agreed to follow research by signing *informed consent*. Criteria for exclusion are patients with recurrent breast cancer, weak general condition; described with Karnofsky score <70%, and patient with a history of Chemotherapy/radiotherapy before.

The study subjects were explained the purpose and benefits of the examination and asked for approval to participate in the study by signing informed consent. Furthermore, the data common subjects such as name, age, type of sex, address, and a number of the phone are recorded. Other data recorded in accordance form and collection of data, includes the calculation of BMI and function physiology of the liver. Do measurements of tumor three days before chemotherapy. The subjects of the study then undergo the examination value of CRP compared to albumin in the blood shortly before chemotherapy neoadjuvant cycle Mining, a, to avoid the effects side of chemotherapy. Subjects will undergo chemotherapy according to the CAF regimen administration procedure. The CAF administration cycle is repeated every 3 weeks until reaching the third cycle. Determination of the dose of CAF based index of the mass of the body (IMT), with a dose of cyclophosphamide 500 mg / m² iv, doxorubicin 50 mg / m² iv, 5FU 500 mg / m². The next will be done measuring the response of clinical and levels of CRP / Albumin patients on a day to 12-14 after undergoing chemotherapy third.

Peng though the data is done using the program SPSS 23.0. Data from variable independent and dependent

form of ordinal data will be tested by using the *chi-square test*, test regression logistic, and *McNemar Test*.

Results

The subjects of the study consisted of 35 women (100%), with the age of majority is the age > 50 years ie 18 patients (51.4%). In the study, it found that the subtype of cancer of breast most are luminal A total 11

patients (31.4%) followed by Luminal B-like (HER-2 positive) as much as 8 patients (22.9 %) with a kind of pathological anatomy most is Invasive carcinoma of no special type (infiltrating ductal carcinoma) Grade III, 16 patients (45.7%). Characteristics of research subjects can be seen in Table 1

Table 1 Characteristics of Research Subjects

Subject Characteristics		Response (+)	Response (+)	Total	Average
Age	<50 years	14	3	17	50.31 ± 9.5
	> 50 years	14	4	18	
Mammae Ca subtype	Basal likes	5	1	6	
	Erb-B2 overexpression	5	0	5	
	Luminal A	5	6	11	
	Luminal B-like (negative HER-2)	6	0	6	

In the study it found that 35 patients had values mean albumin is was 3.4 ± 0.5 g / dl, with the value of the maximum was 4.0 g / dl and a minimum of 1.9 g / dl. On the results of CRP obtained results mean is 0.26 ± 0.2 mg / l with the value of the maximum CRP is 1.20 g / dl and a minimum of 0.10 g / dl. From the results of the research have obtained ratio CRP / Albumin average is 0.07 ± 0.06 uL with a value of at least 0.03 uL and a maximum of 0.36 uL. CRP / Albumin Ratios of study subjects are seen in Table 2.

Table 2 CRP / Albumin Ratios in study subjects

	N	Minimum	Maximum	The mean	Std. Deviation
	Statistics	Statistics	Statistics	Statistics	Statistics
Albumin	35	1.90	4.00	3.4	.50
CRP	35	0.10	1.20	0.26	.20
Ratio	35	0.03	0.36	0.07	.06

CRP ratio value compared to albumin: CRP ratio value compared to albumin is to calculate CRP type divided by albumin type calculation. The results of the examination of CRP and albumin in the blood with the unit uL value will be divided into two categories, namely low with values <0.03 uL and height with a value > 0.03 uL.

Response clinical chemotherapy response to clinical chemotherapy is an evaluation of changes in the size of the tumors were measured by an objectively thorough examination of the physical, divided into four categories, namely: progressive disease, stable disease, partial response, and complete response. In the study, it found that most large patients experienced a partial

response which is as many as 22 patients (64.7%).

In research, it then does test the relationship of variables independent and dependent form of the data ordinal and nominal. From the research data, it was found that the majority were responses (+) having a low CRP / Albumin ratio.

Table 3 Cross Tabulation of CRP / Albumin Ratios with Chemotherapy Response

		Chemo Response		Total
		Response (+)	Response (-)	
CRP / ALB category	Low	27	5	32
	High	1	2	3
Total		28	7	35

The relationship between the ratio of CRP / Albumin in response to clinical patient cancer breast up locally tested by using the *chi-square test* and coefficient contingency then obtained the result that there is a relationship that significant between the ratio CRP / Albumin in response to clinical patient cancer breast up locally with the value $p\text{-value} = 0.004 (p < 0.05)$ which means that there is a significant relationship as shown in Table 6 and Table 7

Table 4 Chi-Square Test CRP / Albumin ratio with clinical response of locally advanced breast cancer patients

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	11,292 a	2	.004
Likelihood Ratio	12,543	2	.002
Linear-by-Linear Association	4,928	1	.026
N of Valid Cases	35		

Table 5 Test Contingency Coefficient ratio CRP / Albumin in response to clinical patients of cancer of breast more local

		Value	Asymptotic Standard Error a	Approximate T b	Approximate Significance
Nominal by Nominal	Contingency Coefficient	.494			.004
Ordinal by Ordinal	Gamma	-.591	.267	1,950	.051
	Spearman Correlation	-.369	.178	-2,280	.029 c
Interval by Interval	Pearson's R.	-.381	.165	-2,365	.024 c
N of Valid Cases		35			

Discussion

In this study, it was found that an increase in CRP, a decrease in albumin (high CAR) decreased the response of neoadjuvant therapy from breast cancer. In studies, an increase in CRP correlates significantly with an increase in the stage, size, and extent of the tumor, and metastasis⁸.

Chronic inflammation is known to play a role in increasing carcinogenesis, which is associated with processes that contribute to the onset or development of cancer. Rapid tumor growth can cause an immune response, and many inflammatory factors are released. Inflammation can contribute to tumorigenesis by supplying bioactive molecules to the tumor microenvironment, including growth factors that cause proliferation; survival factors that reduce cell death; proangiogenic factors and extracellular matrix modifying enzymes that stimulate angiogenesis, invasion, and metastasis; and inductive signals that facilitate the epithelial to mesenchymal transition and other effects. Specifically, chronic inflammation can increase the risk of BC through activating redox transcription factors, increasing local estrogen production, and inducing angiogenesis. This in addition to increasing the stage of the disease also decreases the effectiveness of the chemotherapy given.⁹ Chronic inflammation not only changes the tumor microenvironment by dissolved mediators but also through the recruitment of differentiated cells into tumors and their microenvironment. Recent studies have shown that tumor carcinogenesis is characterized by important differences in the genetic and epigenetic transformation of the epithelium, stroma, structure of blood vessels, and immune cells. Thus, inflammation may not only be important in the initiation of DNA damage but through increased release of cytokines, reactive oxygen species, and relative hypoxia, it can also cause an increased cycle of epigenetic changes.¹⁰

Serum albumin has been used to assess disease severity, disease progression, and prognosis. Albumin is the main protective element that can stabilize DNA replication and cell growth, which can fight carcinogenesis by aflatoxin and nitrosamines. Also, several studies recommend that high concentrations of albumin can inhibit the growth of various tumor cells. Albumin formation can be suppressed by inflammation

and malnutrition, which are pathological factors of many cancers. Cytokines, such as TNF and IL-6, are produced by the inflammatory response, which can reduce albumin synthesis by smaller cells. Previous studies confirm that low levels are associated with poor prognosis in some malignancies¹¹.

The relationship between low albumin and decreased neoadjuvant chemotherapy response is not much related to the role of albumin as a vehicle for chemotherapy drugs. The albumin binding with cyclophosphamide and 5-fluorouracil is very low, so albumin has no role in bringing chemotherapy drugs to the cancerous area. This shows that the role of albumin, in this case, is more general.^{12, 13}

Several other studies have also evaluated the relationship between serum albumin levels and CRP ratio with the survival of locally advanced breast cancer patients with anthracycline-based neoadjuvant chemotherapy, as a result, that a higher CRP-albumin serum ratio is an indicator for worse survival and more therapeutic response. bad. Elevated serum CRP levels detected before treatment can indicate tumor aggressiveness and may be related to treatment resistance and adverse outcomes in patients with breast cancer¹⁴.

Six studies consisting of 2904 patients also reported results to see an association with disease-free survivability (DFS), and the results collected showed that increased CAR was associated with poor DFS¹⁴. Thus, CAR can be used as a parameter to see neoadjuvant chemotherapy responses in breast cancer patients.

Conclusion

There is a significant relationship between the increase in the ratio of CRP / Albumin with a decrease in response to chemotherapy neoadjuvant CAF in patients with *Locally Advanced Breast Cancer*.

Ethical Clearance: Taken from Dr. Soetomo General Hospital Ethical, Research, and Development Committee.

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Quality of live of HIV / AIDS Patients for Loss to Follow Up Antiretroviral Therapy in Semarang, Indonesia

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Abstract

Introduction: Loss to Follow up (LTFU) Antiretroviral (ARV) therapy of HIV and AIDS will have an impact on their quality of life indicated by a decrease in CD4 cell counts.

Objective: The purpose of the study was to explore the quality of HIV and AIDS patients who were Loss to Follow up ARV therapy.

Methods: A retrospective cohort study design on 140 HIV/AIDS patients receiving ARV regimen therapy was recorded in the PDP service in Semarang City in the period of January 2015 – Oktober 2019, aged 18-65 years old, the sample consisted of two groups of Loss to Follow Up and retention group. Statistical analysis using survival analysis with cox regression 95% confidence interval.

Result: The result showed that the Loss to Follow Up patient with ARV therapy showed a risk to the quality of life (HR, 1.85; 95% CI, 1.110-3.098), a decrease in the quality of life of patient group Loss to Follow Up occurred at 48th months.

Conclusion: Loss to Follow Up ARV therapy will decrease the quality of patients with HIV/AIDS (ODHA), therefore it is necessary to improve counseling to commit the consistency in therapy.

Keywords: Loss to Follow up, ARV Therapy, Quality of Life, CD4

Introduction

Epidemiological studies show that the prevalence of diseases by the Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS) of the world is increasing, until the end of 2017, around 36.9 million people and 35.1 million people of them were adults and 940,000 people died. From these data,

21.7 million people received antiretroviral treatment and 59% of people living with HIV received antiretroviral treatment.^(1,2) Reports of HIV / AIDS cases in Indonesia, there were 291,129 cases, with the percentage of deaths 0.28%. Based on cumulative numbers up to January 2019, the highest number was in Papua (22,538), East Java (19,829), DKI Jakarta (9,932) Central Java (10,111) and West Java (6,749).⁽³⁾

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Efforts to improve the survival of people living with HIV / AIDS (PLWHA), one of which is through special treatment and therapy, namely the use of a combination of antiretroviral drugs (ARV).^(1,4,5) Although it has not been able to cure HIV completely and add challenges in terms of side effect and chronic drug resistance, ARV therapy has dramatically reduced mortality and

morbidity, improved the quality of life of PLWHA and raised community expectations, so that HIV and AIDS have been accepted as a disease that can be controlled and is no longer considered as a frightening disease.⁽⁶⁾ Benchmark of quality life or health status of PLWHA are the numbers of Clusters of differentiation 4 (CD4), besides that CD4 is also used as a monitor for ARV therapy response ARV.^(3,6-8)

Antiretroviral treatment (ARV) requires HIV/AIDS patients to be more consistent in taking medication for a lifetime, so it takes a high commitment from PLWHA to survive longer.⁽⁹⁻¹¹⁾ This has led to an increase in the discovery of cases of Loss to follow-up (LTFU), based on the HIV and AIDS Information System of the Indonesian Ministry of Health until September 2017 it was found data of LTFU 43,707 (22%), for Central Java from 2005 to August 2018 data Loss to Follow up: 3.227 people (23%).⁽³⁾

Research in Zambia and Switzerland on observations of three and a half years of therapy showed an LTFU percentage of 29.3% in patients starting ART with a CD4 count <100 cells/ml and 15.4% for patients starting with ≥ 350 cells/ mL.⁽¹²⁾ Several studies have shown a low CD4 cell count (<100-200 cell/ml) increases the risk of LTFU.^(10,13,14) It is different from a study in Ethiopia stating the use of AZT increases the risk of LTFU by three times compared to d4T regimen.⁽¹⁵⁾ PLWHA who received substitution of ARV regimen during the treatment period were at greater risk of LTFU (HR 5,2; 95% CI 3,6-7,3) similar to studies in India which reported that substitution could be a risk factor for failure of ART.⁽¹⁶⁾ The majority of cases of substitution regimens are caused by drug reactions, patients may become concerned about side effects and the effectiveness of new drugs given so they choose to look for other treatment options. The fear of side effect is the main cause of failure of LTFU.^(17,18)

The prevalence of LTFU in Indonesia is according to reports from the Ministry of Health of September

2017 which was 22,89% (43.707 people out of 190.980 people received ART. Whereas the prevalence of LTFU in Central Java up to 23% (3.227 people out of 5.926 people who were actively consuming ART drugs and in the city of Semarang, the prevalence of LTFU was 31%, almost 50% of LTFU patients were identified died.^(3,19) The study of LTFU assessment and survival in Indonesia is still limited, thus it need further research related the quality of life of PLWHA with Loss to Follow up using survival analysis method to see when a low quality of life (event) with CD4 parameters stated in the Hazard Ratio (HR).

Method

This research was conducted with a retrospective cohort design approach and survival analysis for events. Cohort studies are non-experimental analytic epidemiologic studies that examine the relationship between risk factors and effects or disease. In this research, the risk factors/causes were HIV / AIDS (PLWHA) patients who were LTFU on ARV treatment, while the effect/event was the low quality of life indicated by CD4 count <350 cells/m³. The population of the research was patients of HIV/AIDS who received ARV regimen therapy in PDP services in the city of Semarang in the period of January 2015 – Oktober 2019 and aged 18-65, the total size of the study sample was 140 patients. Statistical analysis used survival analysis with cox regression (Cox Proportional Hazard Model) 95% confidence interval.

Results

The total number of HIV/AIDS patients (PLWHA) receiving regimen therapy of ARV was recorded in the Care, Service, and Treatment (CST) Service in Semarang City of 216 people. Based on the retrospective cohort study period of January 2015 – October 2019, From 216 patients, 140 patients meet the criteria for a sample consisting, shown in table 1.

Table 1. The Baseline of Sociodemographic Characteristics Loss to Follow Up (LTFU) and Retention Patient of HIV / AIDS with ARV Therapy in Semarang

Variable	Loss to Follow Up				Event		Log Rank
	Yes		No		(CD4 < 350)		(p-value)
	n	(%)	n	(%)	N	(%)	
Gender							
Male	33	47	45	64	42	67	0,28
Female	37	53	25	36	21	33	
Age							
15 – 25	9	13	13	19	7	11	0,716
26 – 35	25	36	30	43	26	41	
36 – 45	21	30	20	29	20	32	
> 45	15	21	7	10	10	16	
Education							
Primary School	10	14	14	20	7	11	0,423
Junior High School	12	17	11	16	11	17	
Senior/vocational High School	35	50	34	49	34	54	
Tertiary School	13	19	11	16	11	17	
Job							
Unemployment	18	26	23	33	15	24	0,499
Employed	52	74	47	67	48	76	
Marital Status							
Not Married	33	47	38	54	35	56	0,641
Married	37	53	32	46	28	44	
Supervisory Drink Drug (SDG)							
Yes	13	19	26	37	18	29	0,644
No	57	81	44	63	45	71	
Comorbid							
No	35	50	32	46	23	37	0,222
Yes	35	50	38	54	40	63	
Quality of Life							
Retention					37	59	0,025
LTFU					26	41	

* The Log-rank test (Mantel Cox) was used for all other characteristics

LTFU, Loss to Follow Up;

Male gender tends to experience a low quality of life (67%), this can be caused by Loss to Follow Up in committing ARV therapy (64%). Many of them are 26 – 35 years old experience Loss to Follow Up (43%) in antiretroviral therapy and they have CD4 <350 cells / m³ (41%). Patients with working status (67%) which ultimately tend to have a low quality of life (76%). Patients with married status are retention, meanwhile not married patients are LTFU (54%) therefore many

of them have low quality of life (56%). Supervisory Drink Drug (SDG) have an important role for patients' compliance to do therapy, the result of the research showed that patients with no SDG experience LTFU (63%) and have a low quality of life or CD4 count <350 cell/m³ (71%).

The final model of the analysis results with *cox regression (Cox Proportional Hazard Model)* can be seen in table 2.

Table 2. Results of the Cox Regression Analysis for overall survival

No	Variable	Cox Regression		
		HR	p-value*	95% CI
1	LTFU	1,854	0,018	1,110 - 3,098

LTFU, Loss to Follow Up; HR, hazard ratio; CI, confidence interval

* The cox regression (Cox Proportional Hazard Model)

Pasien Loss to Follow Up with ARV therapy showed a risk to the quality of life (HR, 1.85; 95% CI, 1.110-3.098). Each patient has a different distribution of life length or different quality of life. Out of 140 patients observed, it showed that patients who had a low quality of life were marked as having CD4 <350 cell/m³ (*event*) of 45%, while those who had a good quality life (*sensor*) of 55%. Median survival or time of decreasing quality of life at month 45.

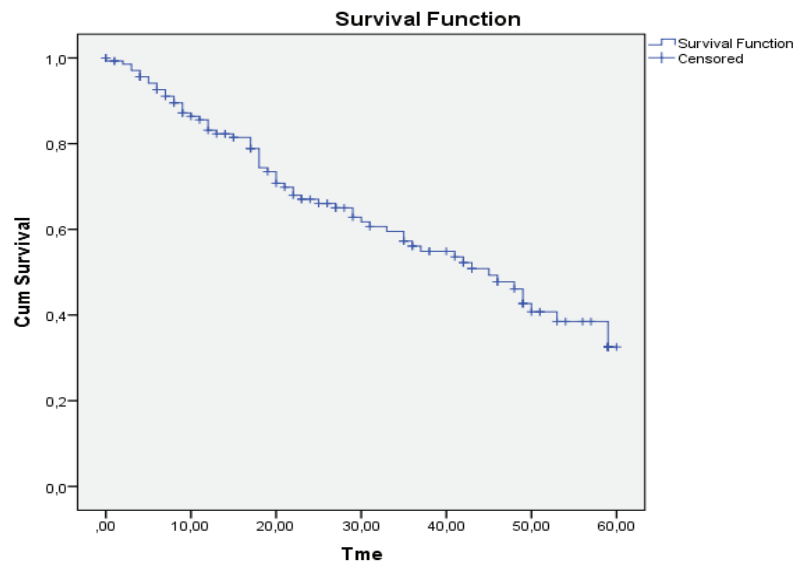


Figure 1. Probability Curve of Quality of Life for PLWHA

Median survival during the study period for the retention group experienced a decrease in quality of life at 39th months while the group Loss to Follow Up occurred at 48th months.

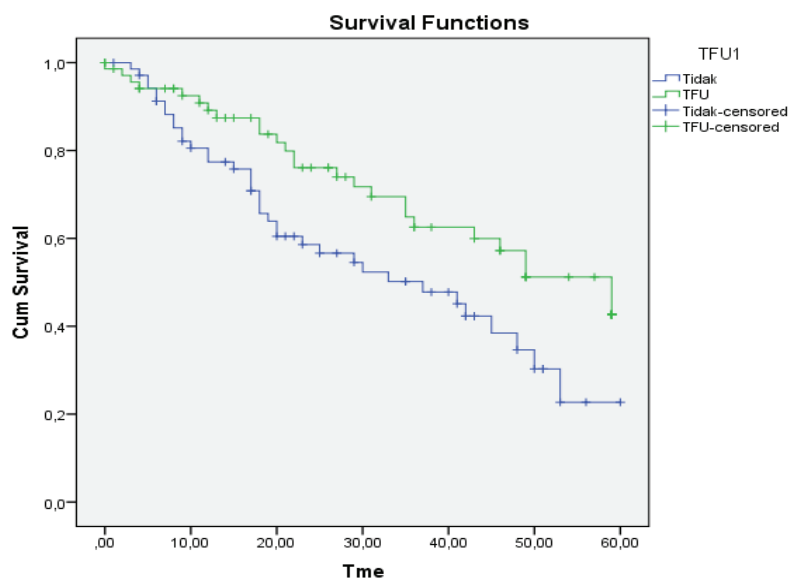


Figure 2. Probability Curve of Quality of Life for PLWHA Retention and Loss to Follow Up Group

Discussion

This research proves that Loss to Follow Up ARV therapy is at risk to CD4 (HR, 1.85; 95% CI, 1.110-3.098, $p=0,018$), and time off and time of decreasing quality of life is at 45th months. This research is in line with several studies in Zambia and Switzerland on observation of three and a half years of therapy showed an LTFU percentage of 29,3% in patients starting ART with a count of CD4 < 100 cell/ml and 15,4% for patients who starts with ≥ 350 cell/mL.⁽¹²⁾ Several studies have shown a low CD4 (<100-200 cell/ml) increases the risk of LTFU.^(13,20) CD4 gain at six months of treatment were both associated with retention.⁽²¹⁾

The Standard of antiretroviral therapy (ART) consists of a combination of the antiretroviral drug (ARV) to suppress HIV and stop the progression of HIV disease. Antiretroviral Therapy (ARV) require HIV/AIDS sufferers to be more consistent in taking medication for life, so it takes a high commitment from PLWHA to survive longer.^(7-11,22)

The results of this study indicate the reasons for LTFU patients related antiretroviral therapy are influenced by multy factors, this is also supported by their predisposing factors.⁽²³⁾ This was shown by patients whose LTFU turned out to have a CD4 cell count > 350 cells / mm³ more than retention patients, so they felt healthy and finally did not want any more ARV

therapy. However, in the 48 month, the study showed that LTFU patients experienced a decrease in quality of life indicated by a decrease in CD4 count <350 cells / mm³.

This research showed that loss to follow-up in the long term will give a negative impact on patients, namely a decrease in quality of life. That is because patients who are lost to follow-up do not get appropriate treatment for HIV and AIDS cases, the provision of ARV drugs and their clinical status, cannot be monitored. Estimates of the mortality rate are higher in patients with a follow-up of reaching 47.1% per year.⁽²⁴⁾ A Loss to Follow Up also resulted in serious consequences, such as treatment interruption, drug toxicity, treatment failure due to non-compliance, and drug resistance.⁷ Detectable p24 antigen concentration unlike viral load, no correlation found between p24 antigen concentration with ART status and length of therapy.⁽²⁵⁾

Conclusion

Loss to Follow Up ARV therapy will decrease the quality of patients with HIV/AIDS (PLWHA), therefore it is necessary to improve counseling to commit the consistency in therapy.

Conflict of Interest : NIL

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Ethical Clearance:The research ethics was obtained from Ethics Committee Faculty of Public Health Diponegoro University Semarang, Indonesia (No.497/EA/KEPK-FKM/2019).

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Relationship between Mother Care Behavior and Quality of Life Stunting children in Kota Masohi District, Central Maluku Regency

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Background: Stunting is a health problem in children that can cause obstruction of various functional aspects of the child such as physical, motor and emotional social of children, this will have an impact on the quality of life children in the future. **Objective:** This study aimed to determine the relationship between maternal care behavior and the quality of life of stunting children aged 12-59 months in the Kota Masohi District, Central Maluku Regency. **Method:** The research design used was cross-sectional, with a total sample of 98 people carried out in the District of Masohi City, Central Maluku Regency, sampling using consecutive sampling techniques. Data on maternal care behavior and quality of life in children were obtained through questionnaires. The results of the study were analyzed using the chi square test and multivariate analysis with multiple logistic regression, with a significant level of $p < 0.05$. **Results:** More than half of maternal care behaviors and stunting under five are poor. Chi square test values indicate that there is a relationship between maternal care behavior with stunting toddler quality of life. The results also obtained that children aged 12-24 months are more at risk of experiencing poor quality of life compared to children aged 49-59 months. **Conclusion:** There is a positive relationship between maternal care behavior with stunting toddlers' quality of life in the Masohi District District of Central Maluku Regency, where children aged 12-24 months are most at risk of experiencing poor quality of life.

Keywords: Maternal care behavior, Quality of life, Stunting

Introduction

Quality life is a goal to be achieved at all age levels including children¹. Quality of life of children related to health is a subjective perception of the mother in assessing the functional status of children including seven domains of functions including physical (body), motor, autonomous, cognitive, social, positive mood and negative mood^{2,3}. Assessment of quality of life is very important to evaluate changes in children's health and determine care in children stunting¹.

Stunting is a condition of failure to thrive in children under five due to chronic malnutrition so that the child's

body is too short for his age which affects the child's survival⁴.

Parents tend to assume that stunting is a natural thing so care is only given when the child is sick. This can affect the health conditions of children. Quality of life of stunting children depends on maternal care behaviors⁵ such as feeding, caring for children when sick, stimulating child development and interacting more often with children^{6,7,8}.

Stunting is a problem in Indonesia and is spread throughout Indonesia, including Central Maluku Regency, where in the last three years the prevalence of stunting under five has increased⁹. The purpose of this study was to determine the relationship between maternal care behaviors and quality of life of stunting children in the District of Masohi City, Central Maluku Regency.

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Material and Methods

This research was conducted in April to May 2019. The research design used was cross-sectional. The sample selection is done by consecutive sampling technique, with inclusion criteria; mothers and children stunted (12-59 months), residing in the District of Masohi City, Central Maluku Regency and willing to sign informed consent by mothers, be able to read and write. Exclusion criteria in this study are mothers and children who have disabilities and suffer from chronic diseases. During data collection mothers and children do not experience illness. To ensure that mothers and children do not experience pain (figure 1). Respondents approval was requested by signing an informed consent.

Figure 1. How to take samples

Instrument (1) Maternal care behavior questionnaire, was adopted from the Ulfi (2018)¹⁰. The value of validity obtained is 0.413-0.800 and cronbach's alpha 0.932. The questionnaire consists of 37 questions using a Likert scale; often (score 5), always (score 4), sometimes (score 3), rarely (score 2), and never (score 1).

(2) Questionnaire quality of life, was adopted from the Manongga (2011)², with a validity value of 0.413-0.839 and its reliability, the cronbach's alpha value is 0.844. Child's quality of life related to health is obtained from the mother's report through filling in the quality of life questionnaire, by looking at the functional status of the child in the last month which consists of various aspects; physical, motor, autonomic, social, cognitive, and emotional both negative and positive³. Each aspect consists of 8 questions using a Likert scale that is often (score 0), always (score 1), sometimes (score 2), rarely (score 3), and never (score 4)³.

The total values obtained for both maternal care behaviors and the quality of life of children are divided by median values into two categories; "good and not good"

(3) Tools for measuring the growth status of children using height measuring instruments namely microtoice and infantometer. Z-score values for calculating height or body length by age were calculated using WHO Anthro Software, and adapted to TB or PB standards based on the decision of the Minister of Health of the Republic of Indonesia number 1995/Menkes/SK/XII/2010 regarding

anthropometric standards with indicators of children were severely stunted (SD score <-3) and stunted (SD score -3 to <-2).

*Statistics:*The statistical test used is the chi-square test with the confidence level used is 95%. Next, the researcher conducted a multivariate multiple logistic regression test with a stepwise backward method to look at the variables that affect the quality of life of the child. The variables included in this test are those that have a significant value ($p < 0.25$) where the analysis is seen in the value of p and the strength of the relationship. The variable is said to affect the dependent variable if the value of $p < 0.05$ and see the Odds Ratio (OR) value¹¹.

FINDINGS

A total of 98 couples of mothers and stunting children were respondents in this study. In table 1, the data shows that most mothers of children under five are stunting in the age range of early adulthood (52%), most of the mothers work as housewives (85.7%), with the most education at secondary education level (46.9%), and 53.1% of family income above. Based on the characteristics of children, the highest age is 12-24 months (37.8%), where between men and women have comparable numbers (50%) and on the nutritional status of children (TB or PB/Age), most were in the short category (81.4%).

Table 2 shows that more than half of maternal care behaviors (55.1%) and the quality of life of stunted children (52%) are in a poor category. The results also showed that maternal care behavior was significantly influenced by mother's education and family income, while the quality of life of children was affected by the age of the child ($p < 0.05$).

In table 3, data are obtained that children aged 12-24 months compared with children aged 49-59 months and maternal care behavior are less good compared to good maternal care behavior, significantly both groups have an influence on the quality of life of children who are not good ($p < 0,05$). The OR value between children aged 12-24 months is greater than maternal care behavior which is equal to 6.031, meaning that stunting children with an age range of 12-24 months are more at risk 6.031 times having a poor quality of life compared to stunting children with an age range of 49-59 months after being

controlled by the mother's bad behavior.

Table 1. Characteristic of mothers and children

Characteristics	Frequency (f)	Persentasi (%)	Mean ± SD
Mother Age (year) Late youth (17-25) Early adult (26-35) Late adult (36-45)	21 51 26	21,4 52 26,5	31,45 ± 6,17
Occupation Housewife Civil servants Farmer	84 4 10	85,7 4,1 10,2	
Educational level Lower secondary Upper secondary Unirvesity	30 46 22	30 46,9 22,4	
Parental income Low Hight	52 46	53,1 46,9	
Child Age (months) 12-24 25-36 37-48 49-59	37 30 16 15	37,8 30,6 16,3 15,3	31,57 ± 12,37
Sex Man Women	49 49	50 50	
Nutritional status Stunted Severely Stunted	80 18	81,6 18,4	

Table 2. Maternal care behaviors and quality of life children

Characteristics	Maternal care behavior				P	Quality of life child				P
	Good		Not good			Good		Not good		
	n	%	n	%		n	%	n	%	
Maternal care behavior	44	44,9	54	55,1						
Quality of life child						47	48	51	52	
Age child (months)										
12-24	13	35,1	24	64,9	0,331	12	32,4	25	67,6	0,032*
25-36	17	56,7	13	43,3		14	46,7	16	53,3	
37-48	8	50	8	50		10	62,5	6	37,5	
49-59	6	40	9	60		11	73,3	4	26,7	
Educational level mother's										
Lower secondary	8	26,7	22	73,3	0,043*	12	40	18	60	0,396
Upper secondary	23	50	23	50		22	47,8	24	52,2	
Unirvesity	13	59,1	9	40,9		13	59,1	9	40,9	
Occupation										
Housewife	42	50	42	50	0,013*	43	51,2	41	48,8	0,177
Civil servants & farmer	2	14,3	12	85,7		4	28,6	10	71,4	
Parental income										
Low	25	48,1	27	51,9	0,501	27	51,9	25	48,1	0,404
Hight	19	41,3	27	58,7		20	43,5	26	56,5	

*chi-square test; $p < 0,05$ **Table 3. The results of logistic regression test**

Variabel	P value	OR	CI (95%)
Maternal care behavior			
Good (reference)		1,00	
Not good	0,02*	2,837	1,179 - 6,824
Age child (months)			
12-24	0,01*	6,031	1,527 - 23,817
25-36	0,053	4,029	0,982 - 16,531
37-48	0,431	1,883	0,390 - 9,084
49-59 (reference)		1,00	

Cont ... Table 3. The results of logistic regression test

Variabel	P value	OR	CI (95%)
Occupation			
Housewife	0,107	0,230	0,038 – 1,375
Civil servants	0,192	0,163	0,011 – 2,483
Farmer (reference)	1,00	1,00	

* $p < 0,05$

Discussion

Maternal care behavior is part of parenting that is very necessary in stunting toddlers, especially in meeting the needs of children to prevent adverse effects that will occur and as a determinant of the quality of life of children in the future.

Needs that can be given to stunting children such as adequate and age-appropriate feeding of children, monitoring children’s growth and development, providing psychosocial stimulation, seeking treatment, and access to health services as well as providing a safe and hygienic environment⁷.

In this study, maternal care for stunting infants was mostly obtained in the less category. Mother’s care has a positive impact on children’s quality of life¹². Maternal care behavior is part of parenting that is useful for improving the quality of life of children which can be seen through the development and growth of children.

The results of this study indicate that maternal care behavior is influenced by mother’s education and work. Education is closely related to knowledge about how to care for children¹³. Lack of maternal care behavior associated with maternal education is due to lack of knowledge of mothers in child care such as nutrition, stimulation and utilization of health services¹⁴.

This condition is at risk for low motor, cognitive and socio-emotional development barriers in stunting children¹⁵.

Maternal care behavior is also influenced by the mother’s occupation, where most mothers who behaved poorly were found in mothers who worked as civil

servants and farmers. This is because the intensity and time of the mother are less shared with the child than the housewife. One of the care strategies in parenting recommended by WHO is to build interactions between mothers and children who are pleasant and provide stimulation and provide early learning that can be done through storytelling or playing with children. This interaction is more obtained if the mother has a longer time with the child and affects the relationship and closeness between mother and child¹⁶.

In this study, it was also found that the quality of life of children was not good, but the difference between the quality of life of good and poor children was not much different. Quality of life of children is influenced by maternal parenting⁵. Lack of maternal care for stunting children will have an impact on children’s survival. Some evidence has shown that stunting can result in children being susceptible to diseases¹⁷, changes in structure and brain development is slow so that it can affect; cognitive, emotional¹⁸, fine motor skills, and language³.

The functional barriers that occur in stunting children can be prevented through increasing maternal knowledge about care in stunting children by the way parents must increase nutrient intake, perform stimulation¹⁹, seek information, check and monitor child development by visiting health facilities, health workers and through social media. In addition, parents need to be made aware of the effects of stunting on children’s development which can affect the quality of life for children²⁰.

The results also found that children aged 12-24 months were more at risk of experiencing poor quality of life of children. Salonga (2007) states that stunting children experience stunted structural growth and brain function. At this age the child is in very rapid

brain growth²¹, especially the process of nerve cell myelination and synapse formation which increases gradually starting from the newborn and the fastest in the first 2 years. Both of these processes are useful for cognitive, language, motor, behavior and intelligence of children²². Walker et al. (2015) state that the impact of stunting that occurs at an early age is at risk for the next age²³. Therefore children with an age range of 12-24 months really need adequate care both nutrition and stimulation for functional functional maturity.

Conclusions: There is a relationship between maternal care behavior and the quality of life of stunting children in the area of Kota Masohi District, Central Maluku Regency.

Limitations of the study: In this study perceptual equations for measurement of TB or PB but not interrater reliability tests were carried out.

Conflict of Interest: None

Funding: The cost of this research is all borne by the researcher.

Ethical Clearence: Obtained from the ethics committee of the Faculty of Medicine, Public Health, and Nursing Gadjah Mada University with the number KE/FK/0421/EC/2019.

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Both ADC and rADC Average Rates in Hyperacute are Lower than those in Acute Stroke

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Abstract

Background: Radiology holds an important role in evaluating patients with suspected stroke. It is therefore important to distinguish hyperacute or acute. DWI-ADC is an important modality. For ADC value measurement, it is more accurate to use multiple b value. There is a significant variability of ADC values in MRI depending on the coil system, imager, vendor, magnetic field strength and multicentre. The purpose of the study is to find out the difference of ADC value in hyperacute and acute stroke. Analytical observational study with cross sectional study approach to determine ADC values differences in Saiful Anwar Hospital Malang. Head MRI of 3T with 3 b values (0, 500, 1000) was performed on every subject. The data were analysed using descriptive statistic.

Results: There were 12 subjects observed, 6 in the hyperacute group (onset <24 hours) and acute (onset 24 hours - 1 week). There was a significant difference with $p < 0.05$ on average ADC ($10^{-3} \text{ mm}^2/\text{s}$) and rADC (%) values between the hyperacute and acute groups. The ADC average mean \pm SD of hyperacute (0.23 ± 0.05) was lower than acute (0.37 ± 0.04), and so as the \pm SD rADC mean value of hyperacute (32 ± 8.1) was less than acute (52 ± 4.3).

Conclusion: The ADC and rADC average values in the hyperacute were lower than that in the acute group.

Keywords: DWI, ADC average value, rADC, hyperacute stroke, acute stroke

Background

Stroke is a non-traumatic focal vascular abnormality causing injury and permanent damage to the CNS which can be in the form of infarction, ICH, SAH, and is the cause of disability and death worldwide^{1,2}. The choice of therapy for stroke depends greatly on the time after the infarct to determine the degree of brain damage².

The AAN stated that MRI is better than CT Scan in diagnosing stroke. In the hyperacute phase of CT, a normal picture is often found; whereas DWI MRI can show ischemic lesions³.

The diffusion coefficient cannot be calculated with DWI, but it can be measured in ADC. The diffusion coefficient can be measured by examining the ADC values reflecting the diffusion speed of water molecules⁴. The cause of ADC current degradation is the theory of cytotoxic oedema⁵. If oedema occurs in cells with a

relative change of extracellular volume, it can cause ADC decrease⁶.

In a hyperacute, blood flow disruption occurs within minutes, which disturbs metabolism and ion pumps. This results in water movement from the extracellular to the intracellular oedema of the brain; and the diffusion restriction occurs, which results in DWI showing a hypertensive signal along with hypointense in ADC⁷. After ADC decreases, gradual increase occurs due to cell lysis and increased vasogenic oedema in the acute phase⁸.

Sasaki *et. al* stated that there is a significant variability of ADC values in MRI depending on the coil system, imager, vendor and magnetic field strength. There is a difference in ADC value of grey and white matter which is about 9% high among vendors, and 4-9% between 1.5T and 3T⁹. There is a difference in ADC values from multicentre and some vendors. To date, there has been

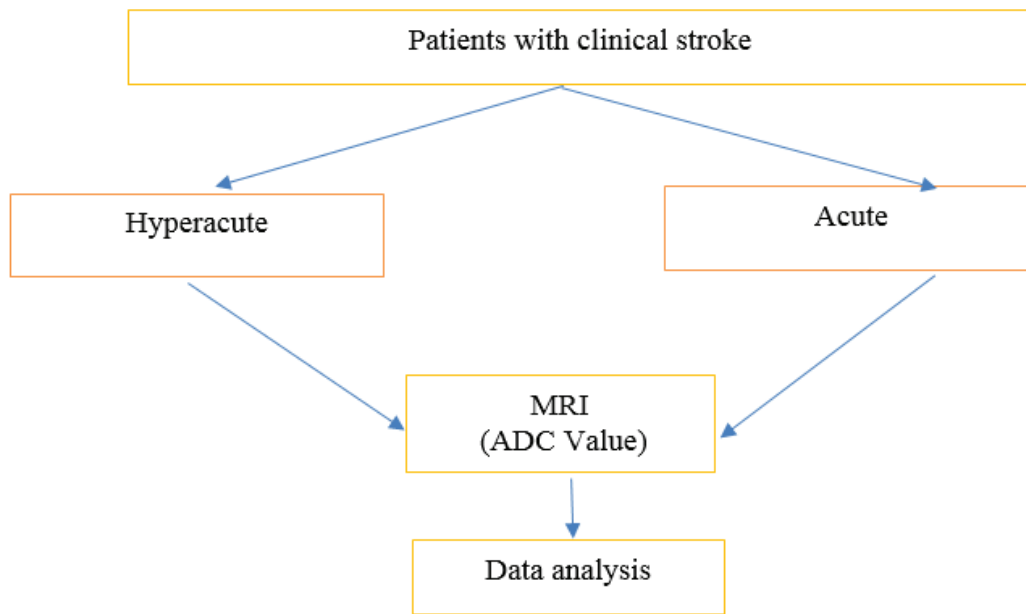
no clinically applicable standard among radiologists¹⁰.

The goal of stroke therapy is to save the penumbra and improve brain function as early as possible¹¹. Penumbra is a tissue at risk of infarction, in which perfusion is inadequate for neuronal function but is still sufficient for cell life¹². Ischemic therapy goes according to ischemic pathogenesis. Therefore, an initial intervention is required to restore blood flow and to protect neurons from ischemic damage. The treatment of ischemic stroke is divided into acute interventions, including endovascular therapy, intravenous rt-PA, and long-term prevention such as risk factor modification, and antithrombotic¹³. There have been no researches on ADC values differences between hyperacute and acute using multiple b values in Indonesian population.

Methods

This is an analytic observational with cross sectional approach using independent t-test to find out the average value difference of ADC and rADC between hyperacute and acute. The research was conducted in Saiful Anwar Hospital Malang. The inclusion criteria were patients with stroke with acute and hyperacute onset, whose MRI images showing areas corresponding to the focal neurological deficit. The exclusion criteria were patients with an unclear onset, and with MRI showing a possible picture of multiple sclerosis, tumor or abscess.

This research was conducted with consecutive non-random sampling. Head MRI examination was performed with the following procedures:



The MRI protocol used was as follows: examined by using head coils and sequences including axial SWIp (repetition time [TR] / echo time [TE] 31 ms/ 7.2 ms; field of view (FOV) 23 cm; thickness 2.4 mm; and matrix size 384x255), axial T2 FLAIR (TR / TE 4800/300; FOV 22 cm; thickness 4 mm; and matrix size 278x274), DWI (TR / TE 9449/80; FOV 23 cm; thickness 3 mm; and matrix size 116x114), with b value 0, 500 and 1000 s/mm², ADC map was processed with automation based on DWI signal by using formula $ADC = \ln(S0/S1)/(b1 - b0)$ on 2 DWI with $b0 = 500$ and $b1 = 1000$.

In the MRI, there was a description of diffusion restriction; were there a T2 shine through picture, the sample was excluded. The ADC values were obtained automatically from DWI using b value $b = 0$, $b = 500$, and $b = 1000$. The ADC value was obtained by placing 4 ROIs in central, pericentral, peri-edge and edge on infarct lesions, with an area of 5 mm² ROI, outside of the sulcus and ventricle, mm²/s units with an infarct at least 20 mm² and then, the ADC average value was calculated. Relative ADC (rADC) was calculated by the

ADC average value on the infarct side / ADC average value on the healthy side x 100%.

The independent sample t-test would be used to analyse the difference of ADC and rADC average values based on infarct age with 95% confidence degree $\alpha = 0.05$, if $p < 0.05$.

Results

Table 1. Characteristics

General	Hyperacute		Acute	
	Number	%	Number	%
Sex				
Male	5	83.3	2	33.3
Female	1	16.7	4	66.7
Age				
≤ 50 years	0	0	1	16.7
51-60 years	4	66.7	2	33.3
61-70 years	2	33.3	1	16.7
> 70 years	0	0	2	33.3
Clinical	Number	%	Number	%
Diabetes				
Yes	3	50	1	16.7
No	3	50	5	83.3
Hypertension				
Yes	6	100	3	50
No	0	0	3	50
Stroke Circulation				
Anterior	5	83.3	4	66.7
Posterior	1	16.7	2	33.3

In this research, ROI of ADC values was taken in 4 areas within the lesion, which were in central (ROI1), pericentral (ROI2), peri-edge (ROI3), and edge (ROI4). The measurement results were read by 2 reviewers. The ADC value obtained from each reader was calculated

(ROI1 + ROI2 + ROI3 + ROI4 / 4), so that the ADC average value was obtained. After obtaining the ADC average value, rADC was calculated; in which the formula used was the ADC average / ADC normal value x 100%.

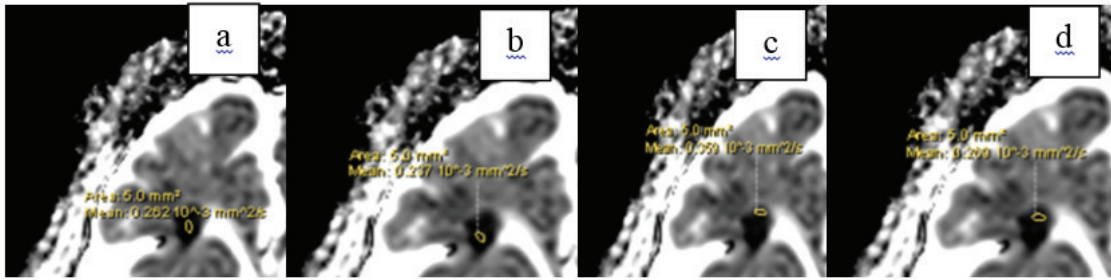


Figure 1. ROI placement in the infarct areas (a) central, (b) pericentral, (c) edge, (d) peri-edge
The results show that ADC and rADC average values are lower in the hyperacute group:

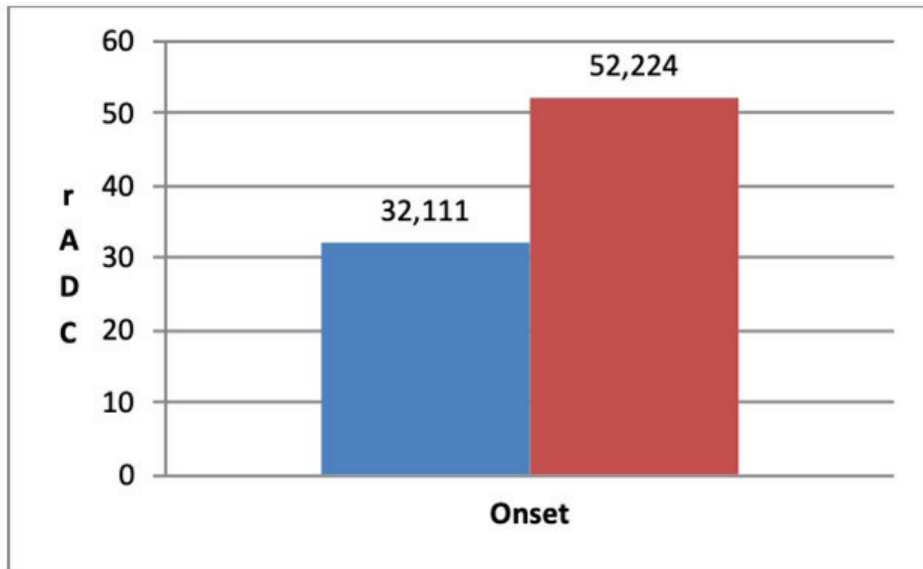


Figure 2. Chart of ADC average values

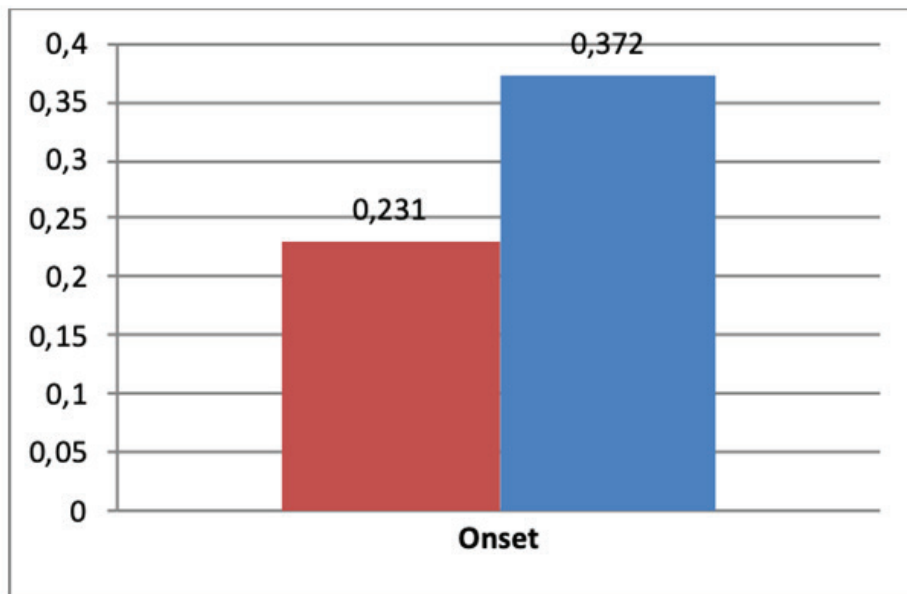


Figure 3. Chart of rADC average values

In this research, a significant difference between hyperacute and acute group was found with significance value of $p < 0.05$, in which the hyperacute had lower ADC and rADC average value than the acute group.

Table 2. T-test results of average ADC and RADC value

		Hyperacute	Acute	t-test Result p value
ADC (10-3 mm ² /s)	Mean ± SD	0.23±0.05	0.37±0.04	<0.05
	Median	0.24	0.35	
	Minimum	0.15	0.33	
	Maximum	0.27	0.45	
rADC (%)	Mean ± SD	32±8.1	52±4.3	<0.05
	Median	34.5	50.9	
	Minimum	19.0	48.1	
	Maximum	42.1	58.6	

Discussion

DWI is an important modality in a stroke case. The ADC can be calculated to quantify the water diffusion on the tissue. ADC is calculated in the intensity of MRI signal that is calculated based on some degree of diffusion using nonlinear regression¹⁶. This research used 3 b values (0, 500 and 1000) to obtain more accurate ADC value. This is based on a research by Graessner *et.al* that it is minimal to use 3 b values, because it will give more accurate calculation on ADC value. In large b value, for example at b = 1000, Signal Noise Ratio (SNR) is lower so that the standard deviation is higher, but it can be compensated with the median value of b = 500¹⁷.

ADC value is a measurement of fluid molecule diffuses in tissues. The ADC value is influenced by extracellular and cell volume ratio, extracellular composition and temperature¹⁸. ATP depletion occurs in ischemic tissue, resulting in Na-K ATPase pump trouble and the loss of ionic inter cell membrane gradient. When there is trouble in Na-K ATPase pump, there is water movement from extracellular to intracellular called

cytotoxic edema¹¹. Cytotoxic oedema causes a decrease in ADC values⁸. This is because at the occurrence of cytotoxic oedema, there is an increase in extracellular volume ratio with cells, so that extracellular diffusion will decrease¹⁸. In this research, ADC values in each ROI decreased both in hyperacute and acute groups, as compared in the normal parenchyma.

As time goes on, there are changes in DWI and ADC, while it seems that there is no change in conventional MRI and CT. In the acute phase, there is damage to the permeability of blood brain barrier, causing the movement of fluid molecules to move to extracellular; or because of cell membrane damage, intracellular fluid flows out to extracellular¹⁹. This causes the ADC value to start increasing. This is in accordance with the results of this research. There was a difference in the ADC average value of hyperacute and acute group with $p < 0.001$. The research obtained that the ADC average value of hyperacute group was lower with mean value in the hyperacute group (0.231 ± 0.05) and acute group (0.372 ± 0.04), with a median value of 0.248 in hyperacute and 0.357 in the acute group, minimum 0.15 and maximum 0.27 in the hyperacute group and 0.33,

0.27 in the acute group.

The main purpose of this research was to look at the comparison of ADC values in hyperacute and acute groups. If measurements were made on only one ROI, it would not represent a value yet. In this research, the measurement was done by using 4 ROI areas, namely central, pericentral, edge and peri-edge, assuming the perception among radiologists is the same. Shen *et.al* stated that the increase of ADC values in stroke from central to peripheral might be due to degrees of damage¹⁹. In this situation, there will be differences in ADC values in the central and peripheral areas. Therefore, the researchers used the ADC average value in the four areas mentioned earlier.

One of the factors influencing ADC value is the width of the ROI. A research conducted by Bilgili *et.al* stated that there is a significant variation of ADC values in the brain between the two observers, with different ROI areas²¹. To reduce this variation, this research used the area of 5 mm² to make it standardized.

The normal value of ADC does not change significantly with age. There is no significant difference between men and women, or between hemispheres²². In order to obtain normalized ADC values and to reduce differences among individuals, this research used a normal ADC value in the contralateral parenchyma that is the same lesion anatomic point with the infarct area to measure the relative ADC, which is comparing the ADC average value with a normal ADC value multiplied by 100%. rADC is better and may reduce the bias compared to ADC values for evaluation of diffusion abnormalities⁹.

In this research, there were different rADC values in the hyperacute and acute groups by using independent t-test. The significance value was $p < 0.05$. The data showed a higher rADC value in the acute group, with mean 52 ± 4.3 and lower in the hyperacute group of 32 ± 8.1 , with median of 50.9 in the acute group, and 34.5 in the hyperacute group.

The main therapy of ischemic stroke is to improve blood flow so as to reduce brain tissue damage by saving the penumbra area¹³. Until recently, the one approved by the FDA is thrombolytics using rtPA which is only for the limited patient¹¹. If reperfusion is performed over

a window period, the risks of bleeding will increase²³. The mechanism of cerebral hemorrhage as an ischemic complication is a phenomenon known as reperfusion injury. Reperfusion injury causes several inflammatory responses resulting in endothelial cell damage causing blood brain barrier damage, oedema and haemorrhagic transformation²⁴. In this research, the ADC and rADC average value were higher in the hyperacute group, this indicates that there is already blood brain barrier damage so that it causes vasogenic oedema leading to the change of ADC value.

This is a preliminary research. Although there is a statistically significant difference in ADC and rADC average values, in which ADC values are lower in the hyperacute phase, it cannot represent the cut off value of ADC yet. Therefore, further research by using a larger population is required. MRI examination, particularly DWI-ADC on hyperacute and acute strokes, can assist in the diagnosis of stroke and provide additional information as a consideration for therapy.

Conclusion

There is a significant difference in ADC and rADC average value in hyperacute and acute stroke, in which the average value of hyperacute is lower than that of acute.

It is necessary to conduct a further study by using larger population so that the cut off value difference of ADC and rADC can be determined.

The authors declare that they have no competing of interests.

Ethical Clearance taken from Health Research Ethics Committee of Saiful Anwar Hospital Malang Indonesia No. 400/106/K.3/302/2017.

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Identify Prediabetes Risk Factors, Awareness and Dietary Pattern among People in Dijil Discrete- Iraq-2019

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Abstract

Background: Diabetes is the major chronic metabolic disorder that affects 25 of the population in the world. uncontrolled diabetes leads to damage many systems of the body, especially the blood vessels and nerves. (1) Weight loss, Physical activity, healthy diet can reduce the progression from prediabetes to diabetes. (2)

Objectives

1. Identify prediabetes risk factors, awareness and dietary Pattern among people over 25 years.

Method: A Cross sectional descriptive-analytical study with convenience non probability sampling had been carried out during the period from February-April, 2019 that (200) persons over 25 years who attended the clinic in AL-Dijil Discrete were interviewed.

Results: The study revealed that 40% of the attendance who were over 45 had risk factors as family history, uncontrolled hypertension ($\geq 140/90$ mmHg), hyperlipidemia ((LDLP >140 mg/dl), (triglycerides >200 mg/dl)), FBS (100-125mg/dl), HBA1c (5.7-6.5%) that mostly were females from urban areas with low education. More than half the of attendance were obese (BMI >30 kg/m²), with physical inactivity. About awareness of the disease, less than half of the attendance said that the disease presented as frequent thirst and hunger, less said that the disease presented as frequent urination or blurred of vision and occurred due to have family history, obesity and diet, there was statically significance between awareness & education. Regarding to dietary pattern, more than half of attendance had poor intake of white meet, fruits and vegetables, 60% had good intake of full cream milk product, too much intake of carbohydrate as white bread & rice with oil/daily. Most of them had tea with sugar/daily and less than half had sweets/daily for both sexes.

Conclusion: Less than half of the attendance who were over 45 years had prediabetes risk factors, poor life style and dietary habits that mostly were females from urban areas with low education.

Key Word: *age over 25 years, prediabetes risk factors, awareness, Dietary Pattern.*

Introduction

Diabetes mellitus is a chronic metabolic disorder characterized by hyperglycemia with disturbances of carbohydrate, protein and fat metabolism that results from defects in insulin action, secretion or both with reducing of life expectancy and quality of life. (3) Prediabetes is a condition in which the blood glucose levels are higher than normal but not high enough to be classified as diabetes and without symptoms, 37% of the individuals with prediabetes may have diabetes in 4 years. Overweight and physical inactivity are considered as prediabetes factors. (4) Diabetes mellitus

is considered one of the main threats to human health in this century. The Epidemic of people with diabetes is due to urbanization, aging, population growth, and physical inactivity, and obesity. Worldwide, people with diabetes was expected to increase from 171 million to 366 million in 2030. (5) In 2012, the estimation of diabetes death was 1.5 million which mostly occurred in middle-and low-income countries. (6) The prevalence of diabetes in 2014 was 9% among over 18 years aged people and mortalities was 4.6 million for age 20–79 years with one death every 7 seconds. (7) In Iraq the prevalence is 10.2%, in Turkey is 14.9%, while in Saudi

Arabia the prevalence is (23.9%).⁽⁸⁻⁹⁾ In 2030 diabetes will be the 7th leading cause of death.⁽¹⁰⁾ Healthy diet, maintaining of normal body weight, regular physical activity and avoiding tobacco can prevent or delay the onset of the disease, while uncontrolled risk factors as high blood sugar, dyslipidemia and high blood pressure is increasing the risk of stroke 150%.⁽¹¹⁾ By WHO using of glycated hemoglobin (HbA1c) for diagnosis of diabetes with levels ranging between 5.7–6.4% are considered to be pre-diabetic, for level $\geq 6.5\%$ is considered diabetic.⁽¹²⁾ Poor control of blood glucose levels lead to high glycated hemoglobin, are associated with nephropathy, neuropathy, retinopathy and cardiovascular disease.⁽¹³⁾

Methodology

Study design: A Cross sectional descriptive-analytical study with convenience non probability sampling had been carried out during the period between February- April, 2019 that (200) available attendance over 25 years in the clinic in AL-Dijil Discrete were interviewed

Population: An interview questionnaire had been used among (200) available attendance in the clinic in AL-Dijil Discrete.

The questionnaire form had been designed by researcher that bases on:

Demographic characteristics & risk factors that include age, gender, education, marital and job status, family history of diabetes mellitus, hypertension, other diseases smoking status, exercise.

2. Awareness about Diabetes Mellitus:
- Has any knowledge about symptoms, risk factors of diabetes mellitus

3. Dietary pattern & Habits of drinking Tea with

sugar will be rated by frequency distribution table as; Dividing the food parts according to their groups as meat group, milk group, starch, vegetable group, fruits, tea with sugar, sweets that consider a good dietary pattern when there is daily intake or more than 4 times/ week, average dietary pattern when there is 2-3 times/week intake of food group while consider poor dietary pattern when intake of food group less than 2 time / week.⁽¹⁴⁾

Inclusion Criteria: - over 25 years, gender

Exclusion Criteria: alcohol intake, pregnancy, below 25 years, diabetic patient .

Measurements: -

Body Mass Index (BMI): For calculating Body Mass Index, body height and weight will be measured for attendance by using the equation = weight(kg)/height (m²), that regarded BMI above 30 obese.⁽¹⁵⁾

- **Blood sugar:** The AFIAS-6- Machine was used to measure blood sugar, the patient was considered prediabetes when fasting blood sugar FBS (100-125mg/dl), Hemoglobin Hb A_{1c} (5.7–6.4).⁽¹⁶⁾

- **Lipid profile:** The akary-Machine was used to measure lipid profile, the patient was considered prediabetes when LDLP >140mg/dl, triglycerides >200mg/dl.⁽¹⁶⁾

Analyses: Data was analyzed by using Statistical tests as Proportions, Measurement of variability, X².

ResultsTable1: Distribution of socio- demographic characteristics showed that 20% of attendance were between age 25-35 years and between 36-45 years, 40% was between 46-55 years, 20% was above 56 years. Females formed 60% of the study. 50% of attendance were working, 50% was without work. 30% was illiterate and same completed primary school, 20% completed secondary school and the same were graduated.

Table (1) Distribution of persons according to socio demographic characteristics

1. Age	Number of patient	%
25-35 years	40	20%
36-45 years	40	20%
46-55 years	80	40%
>56	40	20%
Total	200	100%
2. Sex	Number of patient	%
Males	80	40%
Females	120	60%
Total	200	100%
3. Education	Number of patient	%
Illiterate	60	30%
1st school	60	30%
2nd school	40	20%
Gradated	40	20%
Total	200	100%
4. Occupation	Number of patient	%
Working	100	50%
Without working	100	50%
Total	200	100%

Table 2: Distribution of risk factors showed that 40% of attendance had family history of diabetes mellitus, hypertension, ((LDLP >200mg g/dl), triglycerides >240mg/dl, FBS (100-125 mg/dl) and HB A_{1c} between (5.7-6.5 %) for both sexes. 80% with physical inactivity. 60% had BMI >30. 40% of males were smokers and 10% of females had previous history of gestational pregnancy.

Table (2) Distribution of risk factors

Risk factors	Number				Total	
	Yes		No			
1. Family history	80	40%	120	60%	200	100%
2. Hypertension	80	40%	120	60%	200	100%
4. Gestational diabetes	40	10%	160	90%	200	100%
5. Smoking cigarette	80	40%	120	60%	200	100%
6. Physical inactivity	160	80%	40	20%	200	100%
7. Lipid profile						
Triglyceride	>200mg/dl	<200mg/dl				
	80	40%	120	60%	200	100%

Cont... Table (2) Distribution of risk factors

LDLP	>140mg/dl		<140mg/dl					
	80	40%	120	60%			200	100%
8. Blood Sugar								
FBS	100-125		<100					
	80	40%	120	60%			200	100%
HB A1c	5.7-6.5%		<5.7%					
	80	40%	120	60%			200	100%
7. BMI	>30 kg/m ²		<30 kg/m ²					
	120	60%	80	40%			200	100%

Table 3: Distribution of attendance according to knowledge and awareness of diabetes showed that 40% of patients said that the disease presented as frequent thirst and hunger. 30% presented as frequent urination, 30% presented as blurred of vision. 30% said that the disease occurred due to have family history, obesity and 40% said that occurred due to the diet.

Table (3) Distribution of attendance according to knowledge and awareness of diabetes

1. knowing of symptoms	Number of patients	%
a. frequent thirst & hunger	80	40%
b. excessive urination	60	30%
c. blurred of vision	60	30%
Total	200	100%
2. knowledge about risk factors		
a. family history	60	30%
b. obesity	60	30%
c. diet	80	40%
Total	200	100%

Table 4: Association between awareness & education with statically significance

Education	Awareness	No awareness	Total
Illiterate	15	30	45
Primary	15	30	45
Secondary	30	20	50
Gradated	40	20	60
Total	100	100	200

$X^2 = 21.3$, $df = 3$, P value = 0.05, statistically significant

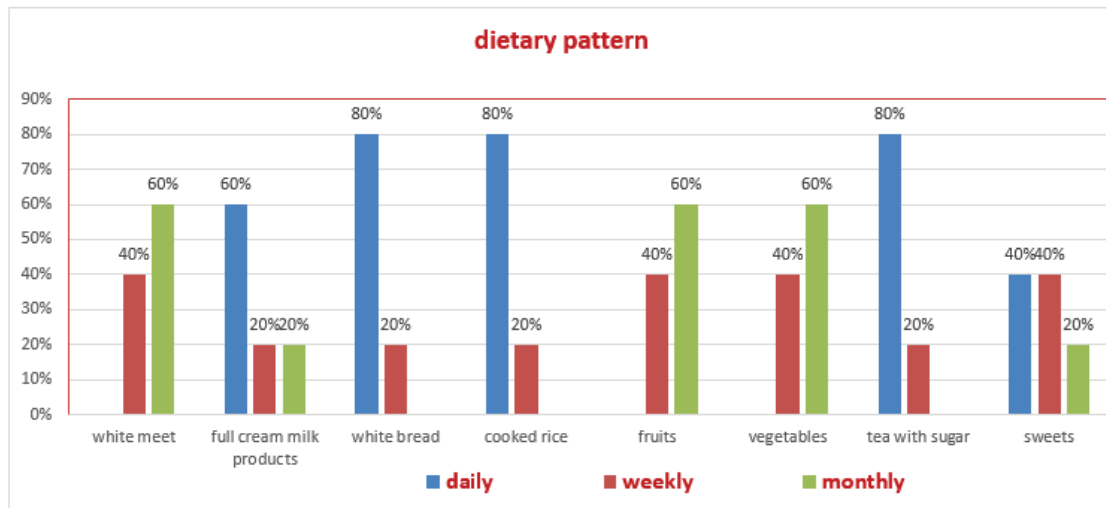


Figure1: distribution of dietary pattern showed that 40% had white meet weekly, 60% monthly. 60% had full cream milk product daily, 20% weekly and monthly. 80% had white bread & rice with oil daily, 20% weekly. 40% had fruits and vegetables weekly. 80% had tea with sugar daily, 20% weekly. 40% had sweets daily, 40% weekly,20% monthly.

Discussion

40% of the attendance who were over 45 years had pre-diabetic risk factors as family history, uncontrolled hypertension ($\geq 140/90$ mm Hg), hyperlipidemia ((LDLP >140 mg/dl), (triglycerides >200 mg/dl)) that mostly were females from urban area with low education. Same finding was found in Egypt that 13.5% of type II diabetes occurs among low education status in urban areas, in contrasts, in Lebanon 20% has type II diabetes with a higher population in urban areas. (17) Diabetes and cerebro-cardiovascular complications increase with high risk factors as high blood pressure ($\geq 140/90$ mm Hg), LDLP >140 mg/dl, triglycerides >250 mg/dl, BMI >30 kg/ kg/m² with physical inactivity, age older than 45 years with family history of the disease. (18) 40% of those (over 45 years) attendance had FBS between 100-125mg/dl, HB A_{1c} between 5.7-6.5%. People are considered pre-diabetic when have impaired fasting glucose (100–125 mg/dl and HB A_{1c} levels (5.7–6.4%).

More than half of the attendance were obese with physical inactivity. Obesity and sedentary lifestyle increases the risk of developing diabetes (20) while healthy diet and exercise are reducing 42% risk for developing diabetes. There was poor awareness about the symptoms, risk factors of the disease which was highly associated with education that the level of education allows

increased awareness about type II diabetes. (21) A study in Kuwait reported that 27.5% of diabetic patients were illiterate and 15.5% were educated. (22) Similar findings were reported in Jordan and Qatar that the prevalence of diabetes was 34% among the illiterate population and 23.5% respectively, while the prevalence was 7.7% and 11.3% among the educated people, respectively. (23) (24)

More than half of the attendance had poor intake of white meet, fruits and vegetables, good intake of full cream milk product with too much intake of carbohydrate as white bread & rice with oil. Most of them had good intake of tea with sugar for both sexes while the kind of food for pre-diabetic patients suggests reducing carbohydrate & fat with good intake of fruits and vegetables. (25) These dietary habits are associated with rising in the prevalence of chronic diseases and obesity in the region. (26) In a study from Saudi Arabia, the odds ratio for eating Kabsa was 5.5, while for eating vegetables was 0.4. (27)

Conclusion

Less than half of the attendance who were over 45 years had prediabetes risk factors, poor life style and dietary habits that mostly were females from urban areas with low education.

Ethical Clearance: The Research Ethical Committee at scientific research by ethical approval of both MOH and MOHSER in Iraq

Conflict of Interest: Non

Funding: Self-funding

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Effect of Laparoscopic Sleeve Gastrectomy (LSG) Surgery on Weight Reduction and Serum Visfatin, Ghrelin and Leptin Levels in Morbidly Obese Subjects

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Abstract

Aim: this study aimed to investigate how Laparoscopic sleeve gastrectomy (LSG) Surgery affect the weight reduction and level of serum adipokines (Visfatin , Ghrelin and Leptin) in Morbidly Obese Subjects because of the Conflicting results that obtained from previous studies regarding the changes of adipokines following sleeve operation and weight reduction. **Method:** 20 Iraqi severely obese patients (12 females and 8 males), Mean \pm SD of aged are 34.45 ± 9.47 , and 40 healthy lean controls (24 females and 16 males) Mean \pm SD of aged are 33.90 ± 9.31 were studied. Anthropometric parameters and biochemical parameters (insulin resistant IR) as well as visfatin, ghrelin and leptin were analyzed before and 6 weeks after the operation. **Results:** after surgery Anthropometric indices (BMI) decreased significantly. The reduction of visfatin and the elevation of ghrelin were statistically not significant, whereas leptin level decrease significantly and insulin resistant (IR) decrease not significantly. moreover, there is a significant positive correlation between the change of serum leptin and (BMI) and visfatin correlated positively with insulin resistant (HOMA-IR).

Conclusions: sleeve Gastrectomy resulted in significant decrease in the (BMI), decreased serum visfatin, insulin resistant and increased ghrelin levels statistically not significant, while significant decrease in leptin level. Further studies with different design are suggested to clarify these changes.

Keywords: Visfatin. Ghrelin. Leptin. obesity. Morbidly Obese. sleeve gastrectomy (LSG). Weight Reduction. insulin resistant.

Introduction

Obesity was considered as a chronic, relapsing, progressive, disease process that require intervention [1] Excess body weight, a burgeoning problem worldwide, which is a major risk factor for cardiovascular disease, Diabetes mellitus affects more than .180 million people around the world, .and the number of patients is.anticipate to increase to 300 million by 2025 [2].

Bariatric surgery is the most effective treatment for morbidly obese patients [3]. It is associated with significant

and sustained weight loss and is more effective than lifestyle or medical management in achieving glycemic control and reductions in morbidity and mortality from cardiovascular disease and even cancer [4].

Laparoscopic sleeve gastrectomy (LSG) is a restrictive procedure, although irreversible [5,6]. The SG has many advantages over other current operations. The SG is less technically demanding than other operations with minimal morbidity [7].

Adipose tissue acts as an endocrine organ and produces numerous bioactive factors such as adipokines that communicate with other organs and modulate a range of metabolic pathways, the dysfunction of adipose tissue as a causal factor is linked to obesity and its related disorders [8].

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Visfatin (known as pre-B-cell colony-enhancing factor - PBEF or nicotinamide phosphoribosyl transferase - NAMPT) which is insulin-mimicking adipocytokine constitutively secreted from visceral (VAT) and probably subcutaneous adipose tissue, as well as hepatocytes and it is thought to play a pivotal role in the pathogenesis of obesity and metabolic syndrome [9]. visfatin actions can be endocrine, paracrine, and autocrine as well. These autocrine effects of visfatin may play an important role in regulating insulin sensitivity in the liver [10]. concentrations of visfatin are increased by hyperglycaemia and lowered HDL-cholesterol level [11]. also visfatin plays a pivotal role as regulator of cell energy balance [12].

Ghrelin discovered in 1999 as a 28-amino acid acylated peptide first identified as an endogenous ligand for the growth hormone secretagogue receptor (GHSR) [13]. It is present along the whole gastrointestinal tract with decreasing concentrations from stomach to colon [14]. In addition to stimulating growth hormone (GH) release, ghrelin has been further implicated in the regulation of appetite, secretion of gastric acid, gut motility, and insulin secretion [15]. From a functional point of view, the ghrelin system has been found to be involved in the modulation of a multiplicity of pathophysiological functions such as hormonal secretions, memory and learning processes, food intake, body weight gain, insulin release, B-cell survival, adiposity, energy homeostasis as well as inflammatory processes and it is considered as a hunger hormone [16].

Leptin is an adipose-derived hormone secreted by white adipose tissue, Given its role in the maintenance of energy homeostasis and body weight [17]. Leptin expression and circulating levels show circadian fluctuations, and also change with nutritional state [18]. leptin controls feeding by regulating multiple orexigenic neuropeptides and it is considered as a satiety hormone [19].

The aim of this study was to evaluate the role of sleeve gastrectomy in weight reduction and changes in circulating visfatin, ghrelin and leptin levels in morbidly obese subjects.

Material and Methods

The study was performed in 20 Iraqi morbidly obese subjects (12 females and 8 males) aged range

(20-51 years), blood sample were collected before and 6 weeks after bariatric surgery. and in 40 healthy, non-obese subjects (24 females and 16 males) aged range (21-53 years). These patients received bariatric surgery after failure of other weight loss strategies. Subjects with the following conditions were excluded from the study: Patients who had an acute illness, acute or chronic inflammatory or infective diseases, end-stage malignant disease, menopausal women, women receiving contraceptive treatment, any prostatic diseases (male). All participants gave their informed consent, and the study was reviewed and approved by the Ethics and Research Committee. The type of this study is intervention (prospective) study.

Laboratory measurements

Blood samples were collected after a 12-h fast. The serum was separated and frozen at -20°C until analysis. Fasting plasma glucose was measured using Abbott ARCHITECT plus c4000 device. The serum insulin level was assayed using an immune radiometric method (Demeditec /Germany). The insulin sensitivity was determined using the Homeostasis Model Assessment Index of insulin resistance (HOMA-IR) according to the following formula: $\text{HOMA-IR} = \text{fasting insulin } (\mu\text{U/ml}) \times \text{fasting glucose concentration (mmol/l)} / 22.5$ [20]. The serum concentrations of visfatin, ghrelin and leptin were determined by commercially available ELISA kits (Shanghai Biological/China, Demeditec /Germany).

Statistical Analysis

The statistical analysis was done with SPSS (Statistical Packages for Social Sciences- version 25). Differences between morbidly obese (MO) and controls were calculated using Student's t-test for independent samples. Differences between preoperative and postoperative data were tested by paired t-test (Student's t-test). Statistical significance was considered whenever the P value was equal or less than 0.05.

Results

Twenty Iraqi morbidly obese patients, 12 women and 8 men, participated in the study. Their mean age was 34.45 ± 9.47 years and their mean BMI at baseline $43.04 \pm 5.2\text{kg/m}^2$, and 40 Iraqi healthy non-obese subjects 24 women and 16 male their mean age 33.90 ± 9.31 years and their mean BMI at baseline $22.29 \pm 2.01\text{kg/m}^2$, after

six weeks of surgery a significant reduction in the BMI was observed 37.34 ± 4.61 (P -value =0.0001). Concerning the circulating levels of the adipo/cytokines in the morbidly obese compared with controls this study shows that in MO visfatin and leptin were significantly higher, whereas ghrelin tended to be lower in MO compared with controls as shown in Figure 1,2,3. After six weeks of the (LSG) this study shows a reduction that statistically not significant in serum level of visfatin and in insulin resistant (HOMA-IR), elevation was statistically not significant in serum ghrelin level and a significant reduction was in serum level of leptin. Baseline levels of visfatin correlated positively with insulin resistant (HOMA-IR) ($r=0.496$, $P=0.026$) as shown in Figure 4, also the study shows a strong positive significant correlation between (BMI) and serum Leptin post operatively ($r=0.712$, $P=0.0001$) as shown in Figure 5. The clinical and biochemical variables of the controls, patients before and after bariatric surgery are summarized in table 1.

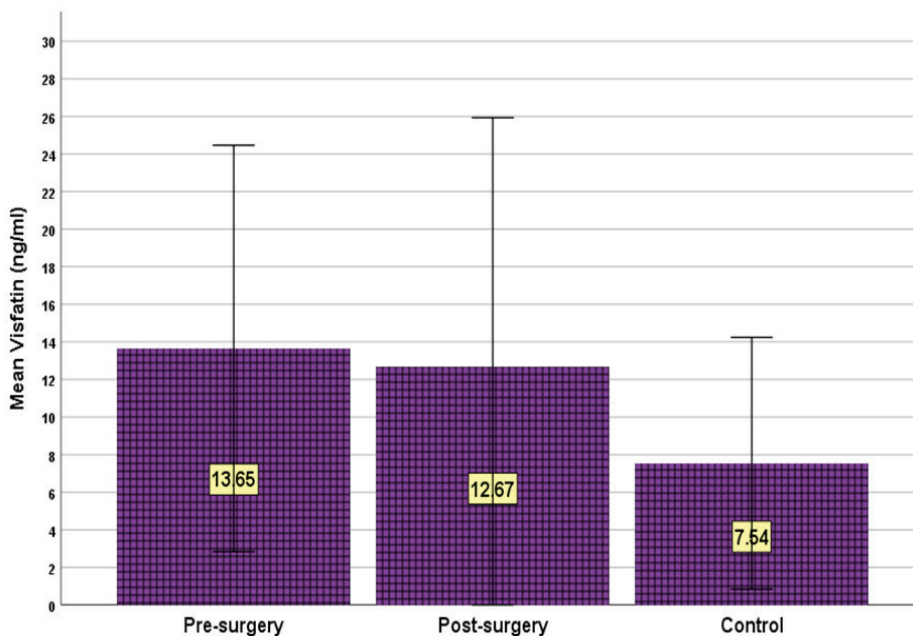


Figure 1. the Mean \pm SD of serum visfatin for patients (pre, post-surgery) and controls

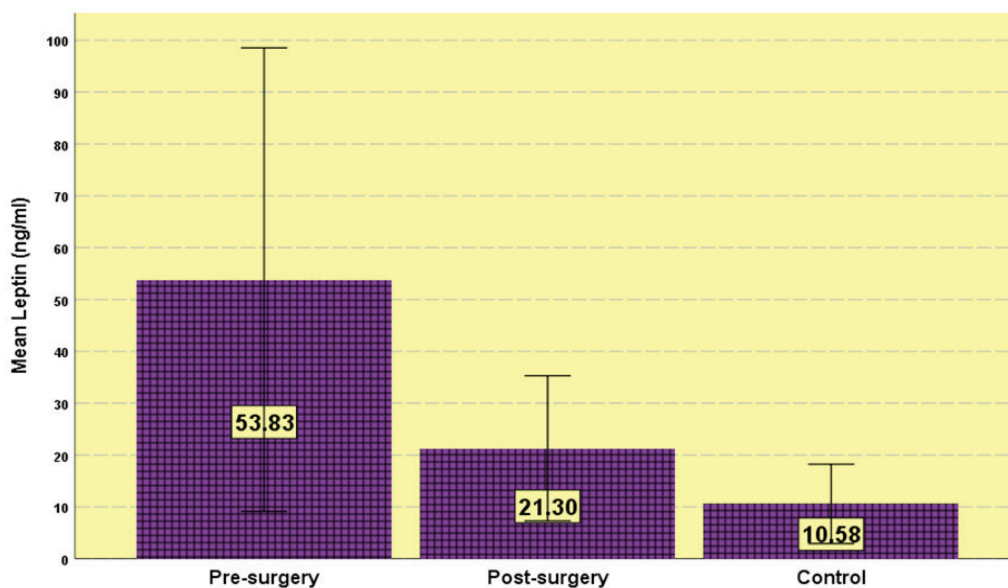


Figure 2. the Mean \pm SD of serum leptin for patients (pre, post-surgery) and controls

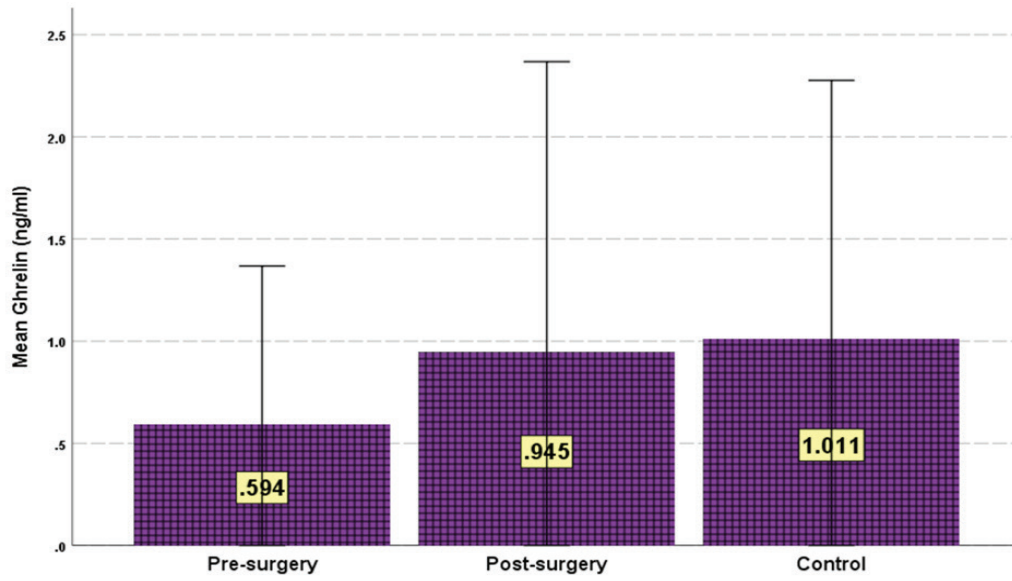


Figure 3. the Mean \pm SD of serum ghrelin for patients (pre, post-surgery) and controls

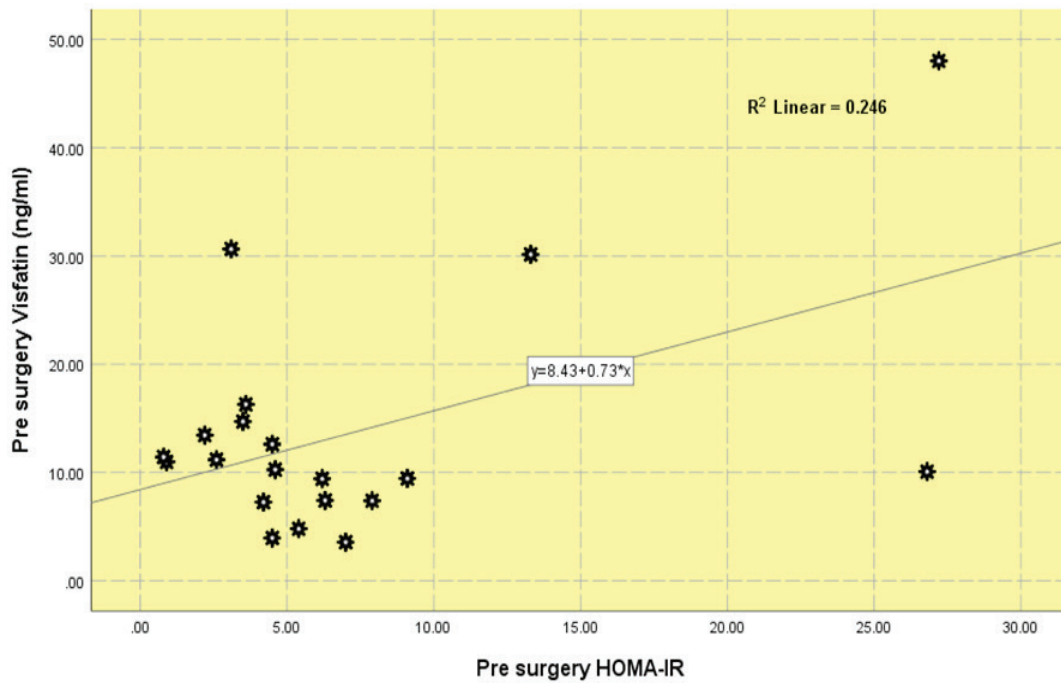


Figure 4. the linear correlation between pre-HOMA-IR and serum visfatin (ng/ml) among Pre-surgery morbid obese patients

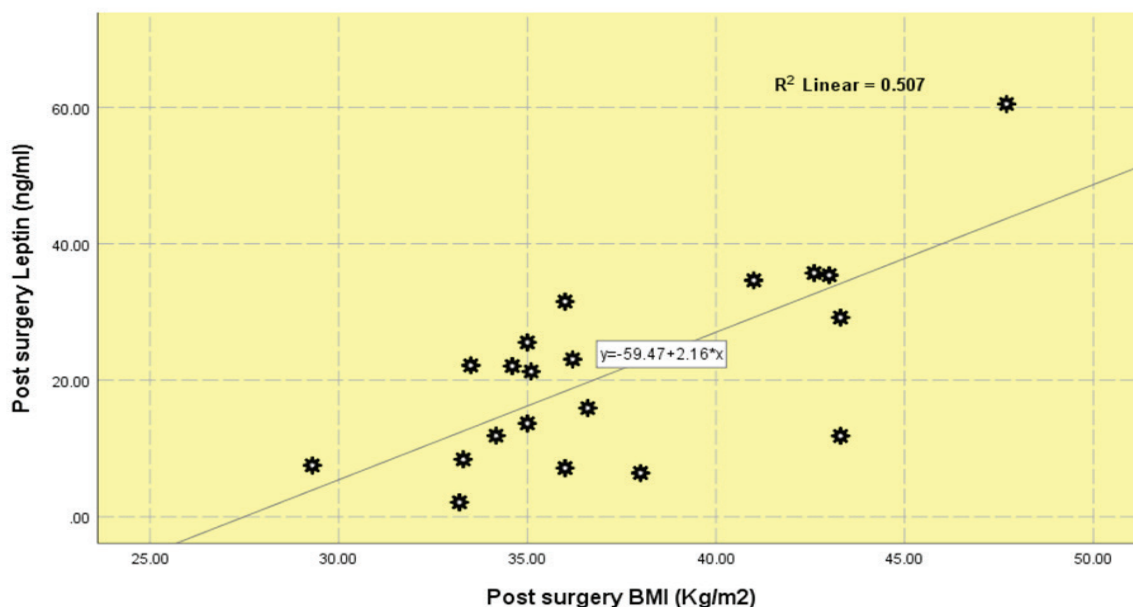


Figure 5. the linear correlation between post-BMI and serum leptin (ng/ml) among Post-surgery for morbid obese patients.

Table 1. the clinical and biochemical variables in healthy controls and morbidly obese subjects before and 6 weeks after Laparoscopic sleeve gastrectomy .

Variable	Pre-surgery No=20	Post-surgery No=20	Control N0=40	p-value (pre x C)	p-value (pre x post)
BMI	43.04±5.2	37.34±4.61	22.29±2.01	0.0001*	0.0001*
HOMA-IR	7.19±7.37	4.70±5.95	1.51±0.59	0.0001*	0.083
Visfatin	13.65±10.81	12.67±13.26	7.54±6.70	0.009*	0.778
Ghrelin	0.594±0.774	0.945±1.422	1.011±1.265	0.182	0.082
Leptin	53.83±44.70	21.30±14.00	10.58±7.66	0.0001*	0.002#

*Significant difference between two independent means using Student-t-test at 0.05

#Significant difference between two dependent means using Paired-t-test at 0.05

Discussion

The present study shows a significant reduction in the weight of patients after six weeks of surgery (P=0.0001), this result agrees with previous findings reported by (Hosseinzadeh-Attar, M. J. et al 2013) who find a significant decrease in the BMI of patients before and after six weeks of surgery [21]. In addition to the

weight loss (Auguet, T. et al., 2013) showed that visfatin level is higher significantly in morbid obese patients when make comparison to lean control (p < 0.001) [22]. data of the present study confirm these findings. visfatin level decreases after surgery but statistically not significant, which agrees with a previous study done by (El Makromy, G. M. 2017) that showed Weight reduction

after (LSG) is associated with a significant decrease in circulating level of visfatin in MO patients. It is worth to mention that, the difference in the follow up duration (three months) is the reason for their decreasing appear significantly [23]. Obesity is considered as a low-grade inflammation, which is improved following weight loss, therefore, it is expected that weight reduction modulates secretion of adipokines from adipose tissue. Visfatin has been considered as a new pro-inflammatory adipokine [24]. Since the main site of visfatin secretion is VAT, it was suggested that its plasma concentration is correlated with visceral obesity. A decreased amount of VAT following weight loss would suggest a reduction in visfatin concentrations after bariatric surgery [25]. This study present a reduction in the level of serum ghrelin in morbid obese patients when compared to control, this results is in agreement with previous study done by (Lin, E. et al. 2004) who have revealed that lean controls had significantly higher plasma ghrelin levels when compared with morbidly obese humans [26]. Regarding the level of ghrelin after surgery, this study shows elevation but statistically not significant in the level of Ghrelin for patients after six weeks of surgery, this finding is agreed with previous study reported by (Terra, X et al. 2013) who demonstrated an increase in ghrelin levels, after bariatric surgery-induced weight loss (SLG)[27]. A possible explanation could be that in restrictive bariatric surgery, passage of food through the stomach, although to a lesser extent, is still taking place. Gr cells are not exhausted and react with an increased production of ghrelin, which could result in increased appetite in patients after gastric restriction [27]. A confounding issue in comparing studies is the patients' actual state of energy homeostasis, whether patients are in phases of weight loss or in phases of a steady state. In operated patients still experiencing an active weight loss, increased ghrelin concentrations were found [28]. The present result also agrees with (Purnell, J. Q. 2003) who concluded that, as body mass index (BMI) decrease the ghrelin level increase because they are correlated negatively [29]. Concerning leptin (Wroblewski, E. et al. 2016) who find that obese patients had higher leptin level than non-obese controls [30]. this finding agrees with the result of this study that shows a significant elevation in the level of serum Leptin for the morbid obese patients in compare to controls. Also This study demonstrated that there is a significant reduction in the level of serum

leptin of patients after surgery from their base line. This result is consistent with previous findings which reported by (Varlık E. et al, 2019) concluded that, leptin level decrease significantly from its base line value after (SLG) [31]. About the correlation this study shows positive significant correlation between pre-HOMA-IR and serum Visfatin), that explained by the following, hyperinsulinemia (IR), is the most common biochemical abnormality seen in obesity [32]. Obesity induces the release of visfatin from adipocytes, in order to overcome the (IR) the body increase the production of visfatin [33].

In conclusion Laparoscopic sleeve gastrectomy has successful weight reduction associated with decrease in circulating visfatin, increase ghrelin level, decrease in leptin level and get improvement in insulin resistant.

Ethical Clearance: The Research Ethical Committee at scientific research by ethical approval of both MOH and MOHSER in Iraq

Conflict of Interest: Non

Funding: Self-funding

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Evaluation of Serum Oxytocin Hormone Level in Children with Autism

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Abstract

Background: Autism spectrum disorder (ASD) is a gathering of complex neuro-improvement issue portrayed by repetitive and characteristic patterns of behavior and difficulties with social correspondence and cooperation.

Aim: to study oxytocin levels in the serum of children with autism and its relation with disorder..

Patients and Methods: Across-section study was carried out at Pediatric Hospital- Kirkuk-Iraq in a period between the 10th of Jan 2019 30th July 2019. 55 children with autism and 25 healthy children, with the same age group, were subjected to this study. Biochemical tests were done for estimation of serum Oxytocin hormone levels in children with autism and comparing them with serum OT hormone levels in control group.

Results: The results showed that there was a significant ($P < 0.05$) decrease in the levels of serum Oxytocin hormone in children with autism which declined to 69.67 ± 10.122 Pg/ml as mean values among children with autism when compared with same parameters in control children which was 108.44 ± 4.33 Pg/ml.

Conclusion: It was concluded that children with autism disorder have lower serum level of oxytocin hormone than normal healthy children.

Keywords: Autism, Oxytocin Hormone, Children.

Introduction

The term autism is derived from the Greek word (autos) which means (self). It was introduced in 1910 by the Swiss psychiatrist Eugen Bleuler with schizophrenia to describe the withdrawal of schizophrenic patients into their fantasies¹. Autism spectrum disorder (ASD) refers to a group of complex neuron development disorders. The term "spectrum" refers to the wide scope of signs portrayed by difficulties with social skills, repetitive behaviors, speech and nonverbal communication difficulty building friendships appropriate to their age,

changes in their environment. "...Because autism is a spectrum disorder, every individual with this disorder has a particular arrangement of qualities and difficulties. Some individual with ASD may require noteworthy help in their every day lives, while others may require less help. Signs no ASD are typically recognized at age range between 2 and 3 years of age and affect daily functioning^{2,3}.

In 2018, Centers for disease control and prevention (CDC) increases estimate of autism's prevalence by 15 percent, to 1 in 59 children^{4,5}.

The new estimate represents a 15 percent increase in prevalence nationally: to 1 in 59 children, from 1 in 68 two years, previous ASD prevalence in Qatar is consistent with recent international studies.

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The incidence of ASD in many undeveloped countries families with low or-middle income is so far unknown. Based on epidemiological studies conducted over the past 50years, the prevalence of ASD appears to be increasing globally. There are many possible elucidations for this obvious rise, including improved alertness, development of diagnostic criteria, better analytic instruments, improved reporting and increasing the number of population ⁶. And it is known no racial, ethnic or social boundaries. autism’s occurrence does not affected by income of the family, lifestyle and knowledge ⁷.

There are no settled pharmaceutical methodologies that adequately treat social shortages in mental imbalance range issue (ASD).Autism spectrum disorder (ASD) has emerged as one of the most prevalent and poorly unexplained disorders of our time. Now, the etiology of autism stays poorly illuminated. This is because there are no recognized medical policies that successfully treat social debits in ASD ⁸.

Oxytocin, a neurohormone that assumes a role in various sorts of social practices, has been proposed as a potential helpful against social debilitation and different indications in ASD ⁹. Oxytocin (OT) has been Oxytocin (OT) has been involved to play a significant role in causes of autism due to its effects on emotional and social behavior¹⁰⁻¹². The present study aimed to find out the serum oxytocin hormone level in children with Autism and to Clarify relationship of serum levels of oxytocin hormone in children.

Material and Methods

Study Population:

Table (4.1) Distribution of autistic group and control group according to their age

Groups	Age	Age	Total
	(3-6 Y)	(7-13 Y)	
Autistic Group	35	20	55
Control Group	17	8	25
Total	52	28	80

Across-section study was carried out in Kirkuk City between 10th of January 2019 to 30th July 2019. 55 children (from both sex) admitted to Pediatric Hospital-Kirkuk-Iraq with autism were subjected to this study. Their ages ranged between 3 and13years . 25 healthy children with same age group were also subjected to the study as a control.

Sampling:

Three ml of venous blood was collected from each patient by vein puncture . The Blood sample was placed into the gel tube and left for 30 minutes at 37°C for clotting then were centrifuged at 3000 rpm for 10 minutes to separate serum from clot. The sera were obtained and transferred into a clean test tube and stored in a deep freeze at -20°C for later biochemical testing .

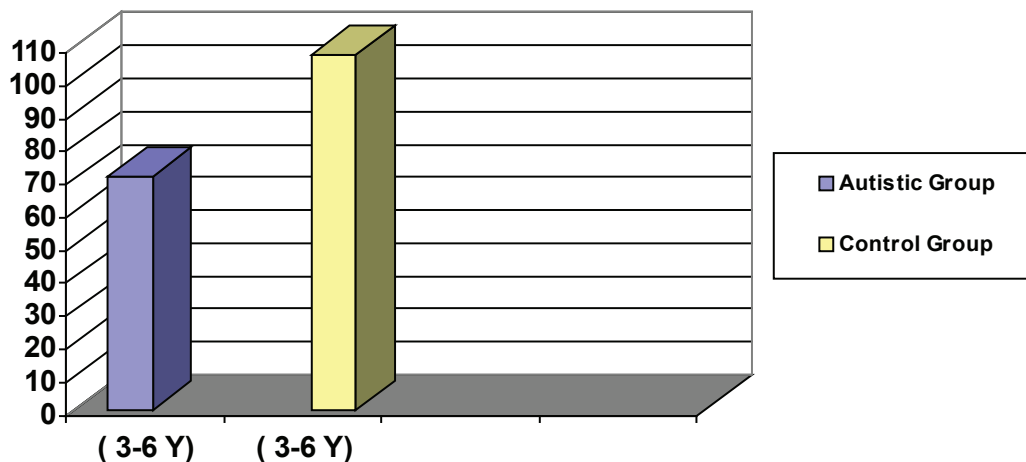
Oxytocin hormone level in serum of the patient estimated by using the Enzyme - linked Immune assay technique (ELISA- Biotech - U.S.A.). using kit biorbyt-U.S.A.

Results

Both the autistic group and control group were categorized into two

Subgroups according to their age, as shown in the table -1. Results of our study showed that there were differences between the levels of OT hormone in autistic children group (69.67 ± 10.12pg/mL) and the control group (108.44 ± 4.33 pg/mL) .

Mean values of serum Oxytocin hormone were different in autistic children group compared to the control group. There was a significant difference ($P < 0.05$) in the level of OT hormone in the autistic group at age (3-6 years) (70.97 ± 8.56 pg/mL) and control group at age(3 – 6 years) (107.64 ± 4.65 pg/mL) as shown in the figure1.



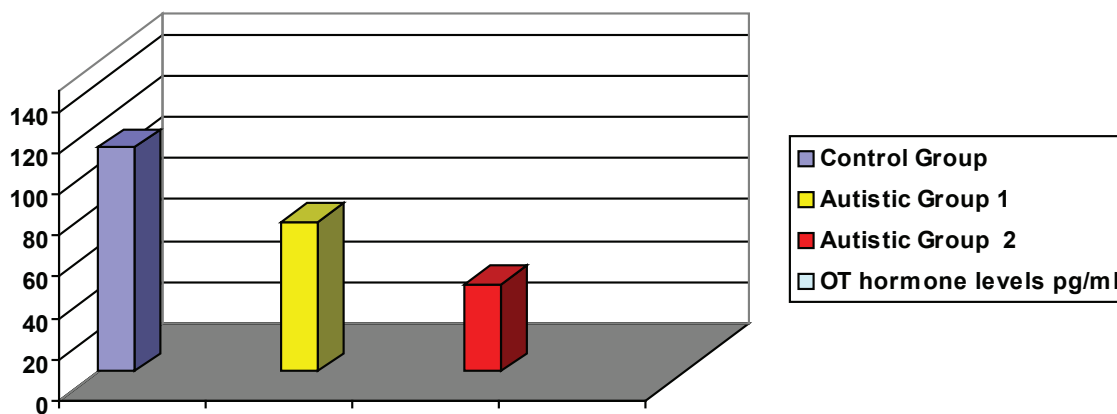
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Figure (1) Difference in mean values of OT hormone levels(pg/mL) in the autistic group and control group at age (3 – 6 years).

The significant ($P < 0.05$) difference of results of OT hormone levels in the autistic group at age (7-13 y) (68.14 ± 11.71 pg/mL) and control group at same age group (7 – 13 y) (109.91 ± 2.35 pg/mL).

In this study we recorded that the serum OT hormone level in autistic children are divided in to two groups according to their means, and compared with control group. OT hormone level in Group 1 (autistic

group) is significantly ($P < 0.05$) lower (72.39 ± 5.64 pg/mL) than in control group (108.44 ± 4.33 pg/mL) . This difference in the level of OT level between group 2 and control showed more decline in OT hormone level in autistic group than that in control group which was statistically significant ($P < 0.05$) and recorded (42.43 ± 2.31 pg/mL) and (108.44 ± 4.33 pg/mL) , respectively in both groups , as shown in figure 2.



\s

Figure (2):Difference in mean values of OT hormone levels (pg/mL) between autistic groups according to their autistic mean and compared with control group.

Discussion

ASDs are roughly one out of 68 youngsters are related to ASD as indicated by gauges from the Centers for Disease Control and Prevention (CDC)'s, evaluated worldwide ASD commonness of 20 for each 10,000 with high level of heterogeneity among inquiries. Determination has for some time been depended on clinical investigations¹³. Our study is to evaluation oxytocin hormone level in the autistic children and compared with normal children Control. Oxytocin hormone (OT) are mostly known for their role in labor lactation and maternal behavior ¹⁴ Released from the posterior pituitary gland but created in the hypothalamus ¹⁵. We participated in 80 children as a total of two groups, the first group includes 55 children in the case of autism and confirmed their condition through medical reports and did not receive any treatment to get the results more correct and close to the situation. And the second group includes 25 healthy children as control free of any organic or psychological diseases and both gender boy and girl, to measure the proportion of OT hormone in their serum. All children enrolled were between 3 to 13 years old. Children with autism were selected from the local Autism Centre for children in Kirkuk and Erbil. We measured the levels of OT hormone in the serum of both autistic children group and control group. In this study high significant difference between the serum OT hormone level in the autistic children groups and the serum OT hormone level in control children's group, this was in agreement with the same result high significant difference between the serum OT hormone level in the autistic children group, and the Serum OT hormone level in control children's group was reported by Amanda P., et al. done before ¹⁵

Acknowledgments :Authors offer their sincere thanks to all parents and their children for participation in the study. The study was supported by the Pediatric Hospital and private autism centers in Kirkuk and Erbil

Ethical Clearance: The Research Ethical Committee at scientific research by ethical approval of both environmental and health and higher education and scientific research ministries in Iraq

Conflict of Interest: The authors declare that they have no conflict of interest.

Funding: Self-funding

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Design An Electrical System for Adjustable Hearing Aid Based on Smartphone

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Abstract

In this project we have designed an adjustable hearing aid by using android smartphone application via Bluetooth connection for controlling the amplification process. Arduino Nano is used to execute all commands and HC-06 Bluetooth module is used in this system. The Bluetooth connection transmit the data to Arduino to provide digital outputs to the programmable gain amplifiers (PGA) and outputs the tone during the tuning state. The final constructed hearing aid's device was experimented on different set of people with different hearing loss degree. The final test showed that the device could improve the hearing for people with partial hearing problems.

Keywords: Smartphone application, PGA (Programmable Gain Amplifier), adjustable hearing aid, Bluetooth module, Arduino Nano.

Introduction

Hearing is one among the five sense of human being. A number of studies in the recent years has shown that the hearing aid benefits increases over the time after the initial fitting^[1-3]. About 10% of the world's population suffers from hearing loss. For these individuals, the most common amplification choice is hearing and are potential users of hearing aids. While some people are born with hearing problem some others develop it as they grow. This problem can occur as a result of disease, aging, injury from noise or intake of certain medicines(N.I.D.C.D, 2010). Digital hearing instruments ^{[4], [5]} uses advanced digital signal processing like multichannel compression, multiple memories and intelligent signal processing, which improves the performances of the hearing instruments and the satisfaction of the user. With the development of VLSI microelectronics technology, it is now possible to incorporate greater function modules of electronic circuits in a very small area, and hearing instruments now can be positioned completely inside the

ear canal^[6]. Over the years, improvements in hearing aids and hearing aid features have centered on the same goal: improving user satisfaction with hearing aids by improving comfort and speech recognition in noise. So that the introduction of digital wireless technology such as Bluetooth and newer methods of digital magnetic transmission is expanding hearing aid fitting possibilities and the way patients can connect to external devices. Wireless technology is becoming integrated into hearing aids and other instrumentation used in the profession of audiology in many more shapes and forms ^[7].

Existing System

Hearing aids are exactly same except the fact that the microphone, amplifier and loudspeaker are placed in a small plastic package which are usually worn inside the ear canal or behind the ear. The hearing-aids are of two types, Analog hearing-aids picks up the sound converts them and amplifies the current and converts it back to louder sound. The other type is much more sophisticated digital hearing-aid. The sound which is picked up is converted into a numerically coded signal and then it refines and processes the signal before converting it back to sound. This type of hearing-aids are mostly tuned so that they point up the sounds of a particular frequency and to block the unwanted noises

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with more efficiency, whilst the analog hearing-aids usually amplifies everything where the background noises will also be amplified. The digital hearing aid works by the combination of different techniques very broadly referred to as DSP (digital signal processing), including: Mic, Pre-amplifier, Anti-aliasing filter, Microprocessor, A/D converter, Digital filters, D/A converter and output.

Proposed System

The aim of the system is to build a low power, cost-effective hearing aid that has tuning functionality that allows the wearer to tune the amplification to his or her needs which adjusted wirelessly by using an application based on android smartphone via Bluetooth technology and keeping loud sounds within the range of comfort. This system's device is a very easy user interface to keep operation quick and simple and saves all data to memory so that the device can be quickly powered up and ready to use. The working of hearing aid's device is as follow: Firstly, the tuning state; patient with a specific hearing loss pattern can adjust the amplification function of the specific frequency by the hearing aid application in the android smartphone and programmable gain amplifier (PGA) that are programmed with Arduino. The tuning state is done very easy on a smart phone's application with Bluetooth technology. After the patient's satisfaction, all the tuning data will be saved to memory so that the device can be powered and ready to use. Secondly, after the tuning state, a signal picked up by the microphone first goes through a pre-amp stage. The signal then progresses to the filter stage where it goes through four parallel filters that divide the signal into four frequency ranges. The filtered signal is also passed to the gain-controlled stage where the signals are amplified based on tuning settings provided by the Arduino. The signal finally enters the output stage where it passes through a summer and the modified signal can be heard with a pair of ear phones.

Performance analysis of the proposed system

The Arduino Nano serves as the control center for

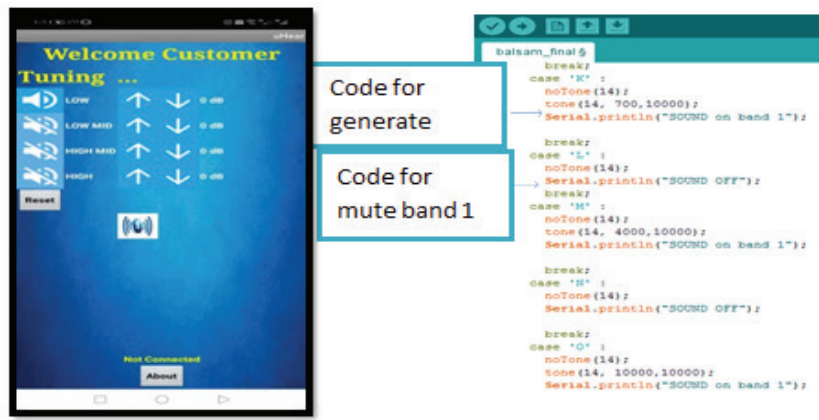
this proposed project. HC-06 Bluetooth module works on serial communication. The Android app is designed to send serial data to the Arduino via Bluetooth module when a button is pressed on the app. The Arduino at the other end (HA device) receives information's data from the android application via Bluetooth (TX and RX). The Arduino provides digital outputs to the programmable gain amplifiers (PGA) and outputs the tone during the tuning state. The function of the Arduino is to provide the tuning. Once the user connects the android application to hearing aid device via Bluetooth, the application will run and the user will select the frequency that he needs to be amplified according to the audiogram hearing loss profile and the related filter's band will pass only the frequency of the specific band and attenuates the other band according to the user needs. The user will select the gain that he needs from the application, the arduino will receive the gain's information selection via Bluetooth and outs it as a three-bit signal (G0-G1-G3) to controlled gain op-amp (PGA) to be amplified. During tuning, the digital op-amps (PGA) that are not being tuned have their gains set at zero so only the specific bandpasses. After the user tuning is complete, the gains are recorded to EEPROM and the HA device is ready to use.

Android Application

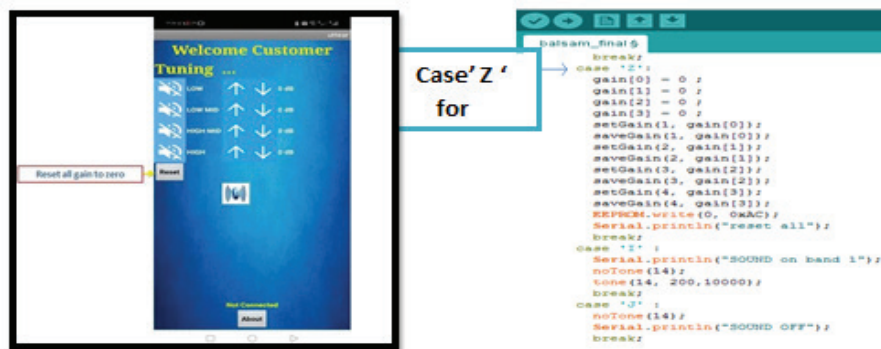
uHear is an android app that has been developed using MIT App Inventor for pairing the smartphone with the developed system. MIT App inventor is an open source web-based application used for Android Application development^[8].

Arduino IDE for uploading application sketches to the Arduino is as follow:

The Arduino IDE for generate tone and no tone (mute) for the specific frequency band using **tone** function (int pin number , Freq Hz, delay) as in figure (1(a)) and for resetting all setting gains to zero as in figure (1(b))



(a)



(b)

Figure (1). (a) Arduino IDE for Generate Tone and No Tone, (b) Arduino IDE for All- Reset Function

Arduino IDE for increasing–Decreasing gain according to patient’s need as in figure (2). Where a two conditions (if-break) is made, one for increasing gain and the other for decreasing gain then save gain function is used to save setting to EEPROM.

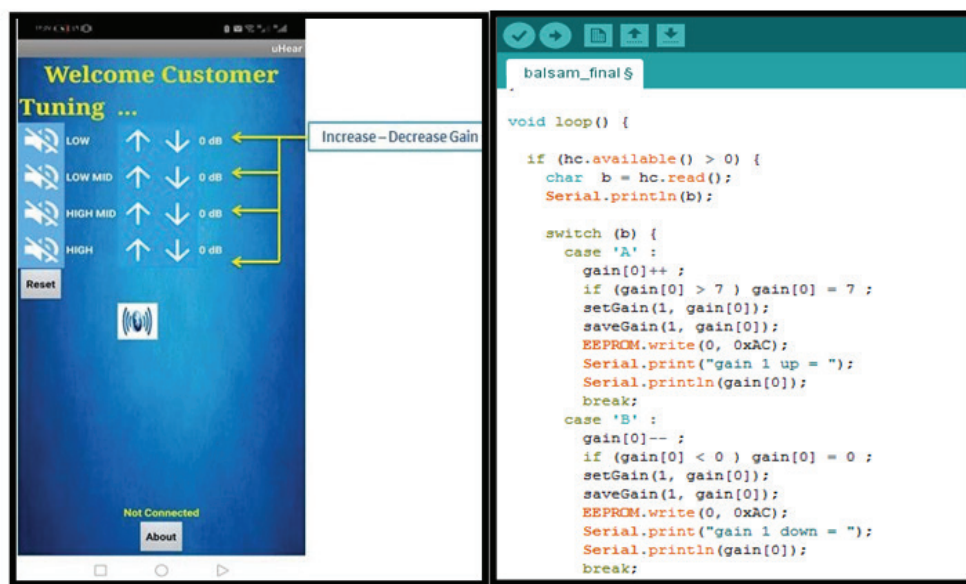


Figure (2). Arduino IDE for gain setting

Programmable Gain Amplifier (PGA)

For programming the PGA with arduino, firstly these three-bit digital outputs(G0-G1-G2) must be defined with Arduino IDE using for loop. On startup after Bluetooth connection, the EEPROM will be checked if there were a previous setting, outputs it and if not or want to start a new tune set all gain to zero and set gains from application as explained previously in 3.2 android application as in figure (3 (a,b))

```

for (int i = 2; i < 15; i++)
  pinMode(i, OUTPUT);

int check = EEPROM.read(0);
if (check == 0xAC)
{
  for (int i = 0; i < 4; i++)
  {
    setGain(i + 1, EEPROM.read(i + 1));
    gain[i] = EEPROM.read(i + 1);
  }
  setGain(1, gain[0]);
  setGain(2, gain[1]);
  setGain(3, gain[2]);
  setGain(4, gain[3]);
}
else
{
  setGain(1, 0);
  setGain(2, 0);
  setGain(3, 0);
  setGain(4, 0);
}
}

void saveGain (int loc, int gain) {
  EEPROM.write(loc, gain);
}

void setGain (int start, int gain) {
  switch (start) {
    case 1:
      digitalWrite(5, (gain >> 0) & 0x01);
      digitalWrite(6, (gain >> 1) & 0x01);
      digitalWrite(7, (gain >> 2) & 0x01);
      break;
    case 2:
      digitalWrite(4, (gain >> 0) & 0x01);
      digitalWrite(3, (gain >> 1) & 0x01);
      digitalWrite(2, (gain >> 2) & 0x01);
      break;
    case 3:
      digitalWrite(8, (gain >> 0) & 0x01);
      digitalWrite(9, (gain >> 1) & 0x01);
      digitalWrite(10, (gain >> 2) & 0x01);
      break;
    case 4:
      digitalWrite(13, (gain >> 0) & 0x01);
      digitalWrite(12, (gain >> 1) & 0x01);
      digitalWrite(11, (gain >> 2) & 0x01);
      break;
  }
}

```

Figur (3). (a). Arduino IDE for PGA , (b) Save Gain and Set Gain Function Code

Results and Discussion

The proposed system is used to perform the implementation of a programmable hearing aid device controlled by application using Android smart phone via Bluetooth. The final hardware is experimented on 3 people, their results were presented and discussed. Audiograms of patients have been taken for experimentation to correct the hearing loss of patients using programmable hearing aid with smartphone application. Losses can be corrected by varying the gain factor of the particular frequency band of filter at which losses occur by using the application. The HA's device circuit was experimented on 3 patients with different (age, gender, degree of hearing loss).

1)Female- 60years old

- Type of hearing loss: Bilateral sensory HL
- Degree of hearing loss: (Right ear) mild to moderate and mild (Left ear)
- Occupation: House keeper
- Aided side : Left side

The (PGA) gain selection relation state with the number of pressing button that the patient do is shown in figure (4).

DIGITAL INPUTS			6910-2
G2	G1	G0	
0	0	0	0
0	0	1	-1
0	1	0	-2
0	1	1	-4
1	0	0	-8
1	0	1	-16
1	1	0	-32
1	1	1	-64

Figure (4). LT6910-2 gain selection relation state with the number of pressing button

With **500 Hz (30 dB) HL** ,the patient press four times until she get hearing and restore normal hearing with (20dB).

With **1000 Hz (30dB) HL**, the patient press five times until she gets hearing and restore normal hearing with (15dB).

With **2000 Hz (40dB) HL**, the patient press six times until she gets hearing and restore normal hearing with (10dB).

The unaided-aided of the female’s audiogram is shown in figure (5 (a)).

Male -32 years old

- Type of hearing loss: Bilateral sensory HL

- Degree of hearing loss: (Right ear) slight loss to mild and mild (Left ear)

- Occupation: Soldier

- Aided side : Right side

- Improvement: The same steps that have been mentioned in the first case are also will be followed in each next case .

With **500 Hz (25 dB) HL** ,the patient press three times until he gets hearing and restore normal hearing with (20dB).

With **1000 Hz (30dB) HL**, the patient press five times until he gets hearing and restore normal hearing with (15dB).

With **2000 Hz (30dB) HL**, the patient press five times until he gets hearing and restore normal hearing with (15dB).

The unaided-aided male’s audiogram is shown in figure (5(b))

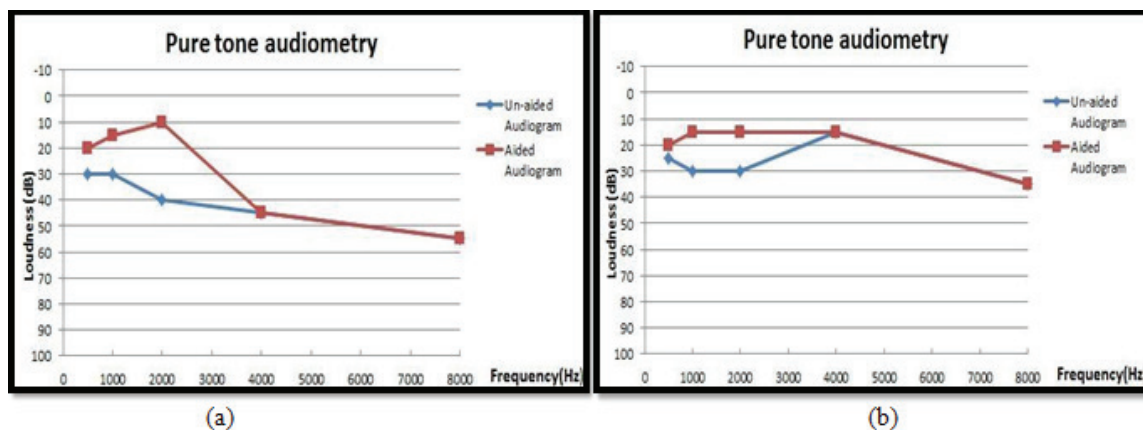


Figure (5). (a) The Unaided-Aided Female’s Audiogram, (b) The Unaided-Aided Male 1’s Audiogram

Conclusion

It can be seen clearly that a Smartphone’s application programmable Hearing aid (HA) will have a bright future. It should be continued and developed in the future as it has a huge potential to improve its performance, reliability and safety. The best part for using android is an open-source electronics platform and it is able to read an input and convert it into an output. Arduino is cheaper compared to other microcontrollers and it can run on windows, Macintosh OSX and Linux operating system. MIT App Inventor is used to create the system application which is an application to transform a complex language of text-based coding into a visual and drag-and-drop building block. Its performance is very friendly to use and can be altered by add, remove or replace block according to designer needs. A command is a block that specifies an action to be performed on the phone. Some commands require one or more input values to completely specify their action. The main advantage of our programmable hearing aid is tuning the HA according to the needs of the individual patient hearing impairment by the patient himself by the using the application and it can be much more accurate rather than the technique used in analogue hearing aid fitting. The presented programmable hearing aid system offers the high reliability, low-power operation and ease of use as well as affordable cost.

Ethical Clearance: The Research Ethical Committee at scientific research by ethical approval of both environmental and health and higher education and

scientific research ministries in Iraq

Conflict of Interest: The authors declare that they have no conflict of interest.

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The Effect of Exercises with the Inverse and Speed Play Method of Enduring the Performance and Some Functional Variables and Blood Components of Young Football Players

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Abstract

Studies which concerned with the human body physiology and the functional variables that occur as a result of effective athletic training methods have become an important and fundamental pillar which depend on direct training operations to achieve great accomplishments, the training process cannot achieve tangible results without depending on successful and effective training methods and ways to avoiding traditional work, which made it necessary for the coaches to search for the best of these methods that affect the work of the sports body's functional bodies positively, from these methods is reverse training, which represents a recent trend in the training field that uses various activities not related to the specialized activity and adopts training devices and tools that improve and develop physical efficiency and job indicators, In addition to adding them to the factors of pleasure, excitement, suspense and motivation in the practice direction, as well as the speed play method, which depends on the change in the speed of performance through running for various distances and in variable forms have a nature of training field, such as sandy land, plains, heights or distances with different speeds, which works positively to improve Aerobic and anaerobic capabilities, thereby improving the functional blood components.

Keywords: *Inverse, Enduring, Blood Components*

Introduction

The containing and current development in the field of sports training is one of the main factors that made sporting events work on a rapid pace towards progress in the great results level, and this is done through integrated sports preparation in various physical, skill, planning, psychological and mental aspects ⁽¹⁾. Therefore, studies concerned with the physiology of the human body and the functional and biochemical variables that occur as a result of effective and influential training have become one of the main pillars which depend on it in directing the training process to achieve the required success ⁽²⁾.

Achieving the tangible results in the training science does not take place without the adoption of training ways

and methods of modernity and development to move away from the traditional in training which allow to make a clear changes in the level of trainees, Therefore, the coaches should search for the best of these methods that affect the functional body sports equipment positively, One of these methods is counter-training and speed play, which represent modern trends in the field of preparation and training, as counter-training works to improve and develop physical efficiency and functional indicators through using a number of diverse activities that depend on many training methods and equipment, which is reflected in the physical and functional capabilities of the players, as well as increasing motivation, excitement and suspense in the direction of practice , multifaceted development, and it also contributes to reducing the risk of injury in the specialized activity⁽³⁾, the cross training includes different forms of exercises that are performed in the training unit itself or on training units within the schedule prepared for this purpose, For

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example, you can run , lift weights on the same day and swimming exercises on the next day, so the different diversity of these exercises allows us to use different parts of the body and also allows by using different and multiple exercises⁽⁴⁾. Also, “cross-training represents an organizational form of training methods and methods that depend on diversity in the practice of various activities and sports related to the specialized activity with a view to developing motor, physiological and skill capabilities through using the devices, tools and modern techniques in the field of training⁽⁵⁾, In addition to this, speed play training is used, which is a method that depends on the change in the performance speed by using running in various forms that are between slow and fast running and walking and running at full speed in various terrain areas ⁽⁶⁾, this method affects positively to improve the aerobic and anaerobic capabilities that reflected on the body’s systems and blood components, as it helps to “Strengthening muscle, tendon ligaments, increasing red blood corpuscles count and hemoglobin level ⁽⁷⁾. The nature of exercises used in both methods contributes to a number of changes in the functions of vital systems while increasing the player’s ability to continue performing in consistent manner with the competition nature and achieving the required results ⁽⁸⁾. Hence the importance of the research in identifying the effects type that will be caused by special exercises which applied in a cross-training method and play (change) quickly in endure performance and some functional indicators and blood components of young football players ⁽⁹⁾.

Methodology

The choice of the appropriate approach should compatible with the nature of the problem and contribute to finding solutions. The researchers used the

experimental approach (the two equivalent groups) with pre and posttests.

Population and Sample

The search population determined by the players of Wasit Governorate youth football clubs, which numbered (5) clubs and the total of players (96) players, the research sample was chosen in a random manner (lots) and was represented by Wasit club players and their number (18) players representing (18.75%) of the research population were divided into two equal groups by random method (odd numbers), As it represented the first experimental group that is trained in the inverse training method, while (marital numbers) represented the second experimental group that is trained in the speed play method.

Homogeneity of the Sample

Avoiding the factors which may affect in the experiment results and for the occurring variables of the players levels to be in accordance with the curricula prepared by the researchers, The homogeneity and parity process was performed in the variables of height, weight, training age, endure performance, maximum of oxygen consumption, vital capacity, hemoglobin as well as red blood corpuscles and platelets, all scales indicated that it achieves the moderate curve, as the ratio was between (± 3), indicates the good distribution of the sample members as well as the symmetry in endure performance and some functional indicators and blood components, as in Table (1).

Table (1)The individuals homogeneity of the research sample

Variables	Measure unit	Arithmetic mean A	Standard deviation	Mediator	torsion Coefficient
Length	CM	175.6	4.355	177	0.964
Weight	KG	72.16	2.6	71.8	0.415
Training age	year	2.5	0.729	2	2.05
age	year	17.55	1.63	17	1.01

Means of data collection

- Arab and foreign sources.
- World wide web.
- Test and scale.
- Statistical means.

Devices and used tools in the research

- HP laptop computer.
- Casio manual calculator, (1).
- (30) footballs.
- Tube to save blood, (20).
- A spyrometer for measuring vital capacity.
- Barriers and signs of different heights.
- Medical balls of different weights.

- Swimming pool.

- Stadium

- Iron terraces.

- (6) basket balls.

- (6) Hand balls.

Determination of blood components and physiological indicators

To determine the blood components and physiological indicators appropriate to the research procedures that researchers want to study, the researchers prepared a questionnaire that included blood components and physiological indicators, and it presented to a group of experts and specialists • to choose what suits the nature of the research problem, the researchers have the components and indicators that got the highest percentage of the experts 'choice, as in Table (2)

Table (2)Candidate tests for physical abilities

Variables	experts' number	approvals number	Square ka 2
red blood corpuscles	5	5	100%
White corpuscles		4	80%
Platelets		5	100%
hemoglobin		5	100%
PH		3	06%
the maximum of oxygen consumption		5	100%
vital capacity		5	100%
Endure performance		5	100%

Exploratory experiment

In order to identify the difficulties and problems facing the two researchers in conducting the tests, the researchers conducted an exploratory experiment on (6) players from outside the research sample on Saturday and Sunday, 3/18/18/2018, as the blood drawing process was done to identify the functional indicators at nine

o'clock in the morning on Wednesday 16/5/2018 in Al-Saeedi Lab and on the next day the process of testing the maximum consumption of oxygen and the vital capacity in Al-Karamah teaching Hospital and endure performance test was conducted at five o'clock from the same day, with the help of the Assistant Working Group ..

Pre-test

The researchers conducted the pretests of the research sample as follows, as the blood drawing process was done from the members of the two research groups at exactly ten o'clock in the morning on Tuesday 20/3/2018 in Al-Saeedi Lab and by the amount of (5 Cc) from each player and was saved in special tubes to be treated after to know the percentage of results in the blood components (Blood hemoglobin - platelets - red blood corpuscles - white blood corpuscles), on the following day, i.e. at nine in the morning on Wednesday, 3/21/2018, the process of measuring the

maximum consumption of relative oxygen, as well as the vital capacity in Al Karama Teaching Hospital in Wasit, was tested with a stationary bike test and a spy meter to measure the vital capacity, while a endure the performance test was conducted in the hour Sixth of the same day in the football stadium of Wasit Club.

Parity of the sample

After completing the tribal tests of the research sample, the parity process was performed in physiological variables, blood components, and endure performance. As shown in Table (3).

Table (3) Blood components, and endure performance

Variables	Experimental group1		Experimental group2		Calculated T value	Tabular T value	The differences indication
	A	S	A	S			
Endure performance	9.14	3.17	9.22	3.18	0.074	2.12	Not significant
The maximum consumption of oxygen	41.8	2.38	41.22	2.29	0.725		Not significant
Vital capacity	348.50	32.165	346.44	31.22	0.188		Not significant
blood Hemoglobin	14.11	0.78	14.16	0.96	0.15		Not significant
Platelets	206.75	53.20	209.65	53.65	0.052		Not significant
red blood corpuscles	5.65	0.34	5.59	0.29	0.6		Not significant
White corpuscles	6.60	1.64	6.38	2.01	0.564		Not significant

The main experience

The two researchers prepared a special exercise according to the inverse and speed play training method for the two research groups based on the results of the pre-test. As he began applying the vocabulary in the main experiment on Saturday, 24/3/2018 for the first

experimental group, which is trained in the inverse training method, and on Sunday, 25/3/2018 for the second experimental group, which trains according to the style of Speed play and on the Wasit football club stadium according to the following:

1- The duration of the training curriculum is (8) weeks.

2- The number of training units for each group (24) training units.

3- Training days for the first experimental group (Saturday - Monday - Wednesday) and for the second experimental group (Sunday - Tuesday - Thursday).

4- The time of one training unit is (90) minutes, and the total time of the training units is (2160) minutes (36 hours).

5- The main experiment was applied on Saturday 24/5/2018 for the first experimental group and on Sunday 25/5/2018 for the second experimental group and until Wednesday 23/5/2018 for the first experimental group and on Thursday 24/5/2018 for the second experimental group.

Post- tests

After completing the application of the training vocabulary of the two experimental groups, the researchers conducted the post tests and the researchers were keen to provide the same conditions which conducted to the pre-tests , As the blood drawing process was performed for the individuals of the research sample at ten o'clock on Saturday 26/5/2018 in Al-Sa' idy lab by using the same steps followed in pre- tests to measure blood variables (blood hemoglobin - platelets - red blood corpuscles - white blood corpuscles), At nine o'clock on the morning of Sunday 27/5/2018, the maximum consumption measure process of the relative oxygen and the vital capacity was measured by testing the stationary bike and spy meter in Al-Karamah Teaching Hospital in Wasit Governorate, while the endure the performance test was conducted at six o'clock in the same day and on Wasit football stadium.

Results

Presenting and discussing the results of the pre and posttests of the first experimental group.

Table (4) The pre and posttests in the hemoglobin of blood, platelets, red and white blood corpuscles

Variables	Pre test	Post test	P	P H	Calculated T value	Tabular T value	The differences indication	Evolution rate
Endure performance	9.14	11.88	2.74	0.69	3.97	2.30	significant	10.94%
The maximum consumption of relative oxygen	41.8	53.77	11.97	1.72	6.95		significant	28.63%
Vital capacity	348.5	495.81	146.31	8.215	17.81		significant	42.26%
Hemoglobin of blood	14.11	14.83	0.72	0.13	5.53		significant	5.10%
Platelets	206.75	224.15	17.4	2.27	7.66		significant	8.41%
red blood corpuscles	5.65	5.94	0.29	0.03	9.66		significant	5.13%
White corpuscles	6.60	7.12	0.52	0.07	7.42		significant	7.87%

Table (5) The results of the pre and posttests in the variables of blood hemoglobin

Variables	Pre test	Post test	P	P H	Calculated T value	Tabular T value	The differences indication	Evolution rate
Endure performance	9.22	11.48	2.28	0.53	4.30	2.30	significant	24.56%
The maximum consumption of relative oxygen	41.22	53.69	12.47	1.54	8.09		significant	30.25%
Vital capacity	346.44	418.75	72.31	6.88	10.51		significant	20.88%
blood Hemoglobin	14.16	14.84	0.68	0.12	5.66		significant	4.80%
Platelets	209.65	226.55	16.9	3.4	4.97		significant	8.06%
red blood corpuscles	5.59	5.98	0.39	0.04	9.75		significant	5.18%
White corpuscles	6.38	7.13	0.75	0.09	8.33		significant	11.75%

4- 3 Presenting and discussing the results of the posttest between the two experimental groups, between the results of endure the performance variables, the maximum consumption of relative oxygen, the vital capacity, hemoglobin, platelets, and red and white blood corpuscles in the two-post tests of the two experimental groups .

Table (6) Arithmetic mean, standard deviations, calculated and tabulated (T) value

Variables	Experimental group1		Experimental group2		Calculated T value	Tabular T value	Freedom degree	Significant level	The differences indication
	A	S	A	S					
Endure performance	11.88	2.92	11.48	2.39	0.38	2.12	16	0.05	Not significant
The maximum consumption of relative oxygen	53.77	11.890	53.69	11.38	0.02				Not significant
Vital capacity	495.81	114.66	418.75	111.63	1.99				Not significant
blood Hemoglobin	14.83	0.51	14.84	0.53	0.058				Not significant
Platelets	224.15	27.73	226.55	0.4	0.24				Not significant
red blood corpuscles	5.94	0.29	5.98	0.02	0.4				Not significant
White corpuscles	7.12	1.18	7.13	1.16	0.02				Not significant

Looking at the results of the post tests in Table (6) of the two experimental groups, we find in the endure the performance variable that the calculated (T) value of (0.38) is less than the (T) value of the table (2.12), and this indicates that there is no significant difference between the two groups in the post test, Although there is a clear moral difference between the pre and post tests for both groups, this clear the effect of the two training methods in developing endure performance, Where we find that cross training has a great positive impact on aerobic and anaerobic endurance as well as improving the level of muscle strength, flexibility and respiratory capacity ⁽¹⁰⁾ and this is what football effectiveness requires, as there is also a positive effect of the speed playing method in improving the aerobic and anaerobic capacity.

Conclusions

- Inverse and speed play training has an effective effect on functional variables and blood components related to research procedures.

- The optimal choice of the training method has a major role in developing and improving the work of the athlete's body's functional devices and increasing the rate of development.

- The use of the two methods of inverse training and sped play has a positive role in the effectiveness of football for its contribution to developing the physical, functional and skill potential of young football players.

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Health Literacy Measurement Tool for Patients with Type 2 Diabetes Mellitus in Thailand

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Abstract

Background: The health literacy (HL) measurement tools have been various and not yet standardized.

Objectives: To investigate the properties of HL measurement tool for patients with type 2 diabetes mellitus (T2DM).

Methods: A cross-sectional study was conducted among 620 T2DM. Participants were interviewed about the 62 health literacy items in three domains: (a) reading medical terms; (b) numeracy test; and (c) decision making. The data were collected from January to April 2019. The reliability, discrimination, and difficulty are examined using the Kuder-Richardson Reliability Coefficient (KR-20), indices of discrimination and difficulty.

Results: The study found 49.8% aged older than 60 years, 80.2% had primary education level and 72.4% received no insulin injections. The properties of the HL measurement tool were (1) the reliability is excellent level for medical terms (KR-20 = 0.98) and good levels for both numeracy test and decision making (KR-20 = 0.72 and 0.79, respectively); (2) The index of discrimination are high for both medical terms and decision making ($r = 0.58 - 0.80$ and $0.48-0.55$, respectively) but low level for the numeracy test ($r = 0.02 - 0.43$); (3) The indices of difficulty are high level for medical terms and decision making ($p = 0.45 - 0.70$ and $0.73 - 0.76$, respectively) but low level for numeracy test ($p=0.02 - 0.64$).

Conclusions: The 62-item tool is considerably good to measure HL for patients with type 2 diabetes regarding its reliability, discrimination, and difficulty. However, the numeracy test should be more developed to the discrimination and difficulty.

Keywords: Health Literacy, Health Literacy Measurement Tool, Type 2 DM

Introduction

Health literacy (HL) is a substantial driver to build empowerment and increase individual capacity [1] and plays a very crucial role in self-management such as those patients with chronic diseases [2]. Previous studies revealed that HL has a negative association with physical inactivity, unhealthy food consumption, low body mass

index (BMI), and obesity [3]. Similarly, diabetic patients with sufficient functional HL can answer questions about the knowledge of diabetes correctly more than those with insufficient functional HL [4].

The HL measurement tools have been widely discussed [5] and not yet standardized. Moreover, HL measurement tools have been various. It is mostly used for functional HL measurement. In Thailand, the HL measurement tool was developed in 2015 by the Health Education Division, the Ministry of Public Health [6]. But there are still some limitations. Firstly, it has a low level of both reliability and index of discrimination especially in the critical HL domain (KR-20 = 0.49 and

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$r = 0.20-0.38$, respectively). Although the numeracy test for functional HL having a good level of reliability (KR-20 = 0.82) but the questions are designed by pairing the terms of physical examinations (blood pressure, blood glucose, BMI, etc) with several values of each term. This could only measure the memory ability of the patients. Lastly, the patient takes a long time to answer questions with an average of more than 30 minutes due to a high number of questions to measure functional HL even it had a good level of reliability (KR-20 = 0.98).

Thus, the properties of HL measurement tool were recently revised regards its reliability, discrimination, and difficulty to appropriately measure the HL for patients with type 2 diabetes.

Objectives

This study aimed to investigate the property of HL measurement tool for T2DM patients.

Materials & Methods

This cross-sectional study was conducted in Nakhon Ratchasima province, Thailand. this tool applies from HL measurement tool of the Health Education Division, Ministry of Public Health [6] to better measure HL about its reliability, discrimination, and difficulty. The revision of this tool had several steps including 1) reviewing previously published literature to consider the conceptual framework; 2) identifying substantial parameters that affect the HL of the patients including gender, age, marital status, educational attainment, duration of having diabetes; 3) improving the questions to ensure that there are precise and easily understandable; and 4) performing data collection.

The sample size was calculated by using the ratio of 1 question per 10 subjects [7], therefore, this study had 620 subjects for 62 questions in total. These subjects were from 8 health service centers including 4 from primary and secondary care levels equally. The consecutive sampling method [8] was conducted at these health service centers. The patients who met the inclusion criteria were selected considering the sequent orders of accessing health services.

Inclusion criteria

1. Patients with T2DM who are diagnosed by

physicians.

2. Age of 20 years or older.
3. Without mental disorders
4. Being able to read and write.

Exclusion criteria

1. Elderly aged 60 or older who extensively need care for their daily activities.
2. Dementia patients.

Questionnaire and measurements: The revised 62-item HL measurement tool composes of (1) There are 44 medical terms, which reduced from 66 items. The 22 terms were excluded due to its similarities to those 44 terms in terms of meanings, difficulty, and level of the index of discrimination, index of difficulty, and factor loadings altogether. (2) There were 14 items for the numeracy test, which translated from the Diabetes Numeracy Test (DNT) [9]. (3) There were four items of decision-making test.

Within the scoring system for all domains, the patient received 1 point when they are answering each question correctly and 0 points if they answered incorrectly. The value of the reliability greater than 0.80 is considered as a particularly good level [10, 11]. The index of discrimination (r) of 0.40 and higher is considered as a high level but less than 0.2 is as low level [12, 13]. The index of difficulty of between 0.2 and 0.80 is as good level [13].

Statistical analysis: Data from the subjects were collected between January and April 2019. Descriptive statistics including frequency, percentage mean and standard deviation were used to describe the study's results regarding gender, age, marital status, educational background, duration of diabetes, and insulin injection. The reliability (Kuder-Richardson reliability Coefficient; KR20), the indices of discrimination (r), and difficulty (p) were calculated.

Results

Patient characteristics: This study found 76.1% of the patients were females, 49.8% ($\bar{X} = 60.3$, $SD = 9.8$) aged more than 60 years, 79.7% were married, 80.2% had primary education level, 37.7% were those having

the duration of diabetes less than 6 years (\bar{X} =8.6 SD= 6.5), and 72.4% never have insulin injection. (not shown in table)

Reliability, Discrimination, Difficulty Indices

The reading medical term set 1 had very good level for the reliability (KR-20 = 0.98), high level for the index of discrimination (r = 0.59 - 0.74), and good level for the index of difficulty (p = 0.47 - 0.70) (Table 1).

Table 1 Reliability, Discrimination, and Difficulty of medical vocabulary set 1 (N=620)

Item	Index of discrimination (r)	Index of difficulty (p)
1. Value	0.62	0.56
2. Retina	0.61	0.68
3. Control	0.59	0.69
4. Jogging	0.74	0.52
5. Grape	0.63	0.68
6. Meditation	0.67	0.66
7. Hemodialysis	0.67	0.65
8. Candy	0.64	0.68
9. Teaspoon	0.68	0.65
10. Ophthalmologist	0.63	0.47
11. Paralysis	0.69	0.63
12. Bike	0.60	0.70
13. Drug allergy	0.59	0.69
14. Blood pressure	0.63	0.68
15. Evaluation	0.60	0.70
16. Kidney failure	0.66	0.63
17. Unconscious	0.63	0.68

Kuder-Richardson’s reliability Coefficient was 0.98 for the total scale.

The reading medical term set 2 had very good level for the reliability (KR-20 = 0.97), high level for the index of discrimination (r = 0.58 - 0.80), and good level for the index of difficulty (p = 0.45 - 0.70) (Table 2).

Table 2 Reliability, Discrimination, and Difficulty of medical vocabulary set 2 (N=620)

Item	Index of discrimination (r)	Index of difficulty(p)
1. Balance	0.67	0.63
2. Coffee spoon	0.61	0.61
3. Monosodium glutamate	0.58	0.70
4. Chest x-ray	0.80	0.52
5. Identification book	0.63	0.67
6. Body mass index	0.74	0.45
7. Foot pulse	0.75	0.57
8. Capillary	0.70	0.65
9. Palm oil	0.63	0.67
10. Chicken and shrimp soup	0.69	0.61
11. Skim milk	0.68	0.51
12. Complications	0.70	0.60
13. Consumer unit	0.68	0.65
14. Risk factors	0.70	0.64

Kuder-Richardson's reliability Coefficient was 0.97 for the total scale.

The reading medical term set 3 had a very good level for the reliability (Kr20 = 0.96), high level for the index of discrimination (r 0.62 - 0.80) and good/very good for the index of difficulty (p 0.45 - 0.65) (Table 3).

Table 3 Reliability, Discrimination, and Difficulty of medical vocabulary set 3 (N=620)

Item	Index of discrimination (r)	Index of difficulty(p)
1. Cholesterol level	0.74	0.45
2. Nutrition flag	0.70	0.57
3. Chocolate	0.80	0.52
4. Sodium	0.80	0.52
5. Crisis	0.78	0.49
6. Operating	0.69	0.64
7. Ischemic heart disease	0.67	0.63
8. Capillary in eyes	0.69	0.49
9. Protein in urine	0.72	0.62
10. Electrocardiogram	0.69	0.58
11. Blood concentration	0.73	0.54
12. Anticoagulants	0.73	0.58
13. Blood sugar after meals	0.62	0.65

Kuder-Richardson’s reliability Coefficient was 0.96 for the total scale.

The numeracy test had a good level for the reliability (KR-20 = 0.72), relatively low level of both the index of discrimination (r 0.02 – 0.43) and the index of difficulty (p 0.01 - 0.64) (Table 4).

Table 4 Reliability, Discrimination, and Difficulty of numeracy test (N=620)

Item	Index of discrimination (r)	Index of difficulty (p)
1	0.43	0.33
2	0.35	0.64
3	0.35	0.59
4	0.44	0.56
5	0.33	0.22
6	0.15	0.11
7	0.30	0.49
8	0.21	0.27
9	0.06	0.03
10	0.44	0.32
11	0.06	0.04
12	0.02	0.01
13	0.07	0.05
14	0.07	0.04

Kuder-Richardson’s reliability Coefficient was 0.72 for the total scale.

The decision-making test had a good level of reliability (KR-20 = 0.79), a high level of the index of discrimination (r 0.48 – 0.55), and a good level of the index of difficulty (p 0.73 - 0.76) (Table 5).

Table 5 Reliability, Discrimination, and Difficulty of decision (N=620)

Item	Index of discrimination (r)	Index of difficulty(p)
1	0.50	0.75
2	0.53	0.73
3	0.48	0.76
4	0.55	0.73

Kuder-Richardson’s reliability Coefficient was 0.79 for the total scale

Discussion

This study found that it was the first evidence on the improvement of the HL measurement tool in Thailand. Overall, this new 62-item tool is good and applicable regarding its reliability, discrimination, and difficulty as following discussed.

Reliability:

- 1) The total of 44 items using for measuring

functional HL is a very good level (KR-20 = 0.98, not shown on the table). All the medical term sets 1, 2, and 3 had very good levels. Moreover, this new tool is proven to be more efficient than the previous version. This is because it takes only 3-5 minutes to measure functional HL. Also, it is very applicable to measure HL among patients with T2DM in Thailand. Importantly, health professional uses the tool to evaluate the patient quickly and provide appropriate cares to the patients regarding their level of HL. Besides, care providers or health

professional can have more time to provide services for others who are in need. Our new tool is like the Rapid Estimate of Adult Literacy in Medicine (REALM). REALM is widely used to measure functional HL among the patients with T2DM to screen and identify patients considering their ability to read and pronounce medical terms. After that, supportive media and appropriate consultative approaches are needed to provide care for patients with low HL [14,15]. This is also like Medical Achievement Reading Test used to measure functional HL with 42 medical terms, within 3-5 minutes [16].

2) The numeracy test had a good level of reliability. This is different from DNT15 which had an excellent level.^[9] This is because the patients with T2DM in Thailand mostly had only a primary education level. So, they had low mathematic skills leading to low ability to answer questions.

3) The making decision test had the reliability at a good level, which was better than the previous version. This is because the questions were adjusted to be more understandable, so, the patients can answer questions correctly.

Discrimination

The medical terms had the index of discrimination at high levels. Moreover, the index of discrimination of the decision-making increases to a high level from the previous version ($r = 0.20 - 0.38$). But a quite low level for the numeracy test.

Difficulty

The medical terms had a good level of the index of difficulty. The index of difficulty of the decision making increased to a good level compared to the previous version. The numeracy test had a low level. This is because most of the T2DM were elderly and most had only a primary education level. These questions were probably too difficult to understand. They were less able to calculate some medical numbers about nutrition intake, exercise, blood glucose, and medication. Therefore, mathematical skills are required because these questions are quite complicated and difficult to understand. For example, they needed to calculate carbohydrate intake from daily food consumption and food packaging, food demand for a certain exercise, the use of strips for test

blood sugar because these were performed by the health professional. In general, blood samples from patients with T2DM in Thailand were collected about once a month while seeking care at health care centers to test the blood sugar levels by health staff/caregivers. This situation indicates that patients do not understand how to use the strips for blood sugar tests unlike in some countries. In some countries, this could be easier for patients to perform these by themselves. Similarly, in the case of the medication calculation, they are required to calculate the unit of insulin for injection and medical drug uses when the patients' blood level changes. Normally, the health professional is responsible to perform this process, adjust, and consider the unit of insulin and medical drug use. Therefore, the patients are unfamiliar with these domains. This supports the finding of this study that revealed only 27.6% of patients who had insulin injections. This is unlikely to other countries where the patients could adjust the unit of insulin and medical drug use by themselves.

Conclusions

The 62-item tool is considerably good to measure the HL for patients with T2DM regarding its reliability, discrimination, and difficulty. However, the numeracy test should be more developed to the discrimination and difficulty and more applicable in the Thai context.

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The Effect of Aloe vera Juice Before Meals on Fasting Blood Sugar (FBS) Level of T2DM Patients

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Abstract

Diabetes, especially type 2 diabetes mellitus (T2DM), the prevalence continues to increase, with the largest increase occurring in low and middle income countries. The active content of aloe vera functions as antioxidants, flavonoids, regulates body weight and antihyperglycemic, namely acemannan and glucomannan, which are included in the Liliaceae family and are succulent plants, shrubs, xerophytes commonly used to treat wound healing, microbial infections, skin diseases and inflammation. This study aims to analyze the effect of aloe vera juice before meals on fasting blood sugar levels in T2DM patients with an analytical study. Pre-post Test Control Group Design was used in the research design. The subjects were given aloe vera juice before lunch in the treatment group while the control group was given mineral water. Based on the results of statistical tests, there was a significance (p value = 0.022) in the aloe vera juice group and in the control group p value = 0.094. There is an effect of giving aloe vera juice to T2DM patients who are given lunch while there is no effect in the control group who is given mineral water. Further research on the effect of pre-meal aloe vera juice on cholesterol is recommended.

Keywords: *Aloe vera juice, before meals, fasting blood sugar*

Introduction

Metabolic disease due to increased blood sugar levels due to abnormal secretion insulin or insulin action or both is a sign of diabetes mellitus⁽¹⁻³⁾. Aloe vera leaf gel has therapeutic properties as an antidiabetic, immunomodulator, anti-inflammatory, antioxidant, wound healer, anti-cancer⁽⁴⁾.

Low and middle income countries are experiencing a significant increase in the prevalence of diabetes and in many developed countries the main cause of end-stage kidney disease is type 2 diabetes.⁽⁵⁾

Diabetes mellitus sufferers worldwide are now estimated to be around one in eleven adults with 90% having type 2 diabetes mellitus (T2DM)⁽³⁾. The interaction of genetic and metabolic factors such as gestational DM, family history of diabetes, is a risk of T2DM which was previously combined by age, obesity, smoking, lack of activity and an unhealthy diet⁽⁶⁾.

Modification of diet and physical exercise as non-pharmacological therapy to control glycemic levels based on recommendations from several international diabetes organizations^(3,6,7). Three basic principles of diet management for DM patients developed by the Indonesian Endocrinology Association (IEA), namely regular meal times, correct consumption of quantities and types⁽⁸⁾. However, most diabetic patients only reduce the frequency of eating and intake with a high glycemic index⁽⁹⁾.

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The Diabetes Prevention Program states that prevention of the onset of type 2 DM is more effective with lifestyle changes compared to the use of drugs⁽¹⁰⁾ such as metformin, thiazolidindion and acarbose which can only reduce risk by 31%⁽¹¹⁾. Functional food has sensory characteristics in the form of appearance, color, texture and taste that can be accepted by people and does not provide contra indications and side effects on the recommended number of uses for the metabolism of other nutrients⁽¹²⁾ with bioactive components that affect the body such as micronutrients, fiber, antioxidants, phytochemicals and prebiotics⁽¹³⁾.

Aloe vera species that are often used are aloe vera as a functional food including the Liliaceal family and more than 200 species worldwide with the common name Aloe barbadensis⁽¹⁴⁾ containing active ingredients such as fiber, vitamin, mineral and amino acid that play an important role in curing diseases^(15,16). The active antihyperglycemic ingredients in aloe vera are polysaccharides acemannan and glucomannan, glycoproteins, antioxidants, flavonoids and various vitamins and minerals⁽¹⁷⁾. Aloe vera extracts show preventive effects on insulin resistance and lipid-reducing effects^(18,19) and reduce macro and micro vascular risks such as eliminating nephropathy and diabetic retinopathy, healing diabetes wounds⁽²⁰⁻²³⁾.

Glucomannan has activity can inhibit the action of HMG Co-A reductase in lipid profile biosynthesis in cells and inhibits the action of Acyl Co-A Cholesterol Acyl Transferase (ACAT) so as to reduce the incidence of dyslipidemia⁽²⁴⁾. Aloe vera contains a large amount of antioxidants including flavonoids, alfa tocoferol, carotenoids, ascorbat acid and tannins separating nitric oxide, as seen in vitro studies of radioprotective effectiveness aloe vera gel⁽²⁵⁾.

Aloe vera can asc as a safe anti hyperglycemic and anti hipercholesterolemic for T2DM in clinical studies patient without significans effect for normal blood lipid kidney function⁽²⁶⁾. The water-soluble components of aloe vera can modulate mRNA expression via the glucose-4 transport pathway so that it can lower glucose.⁽²⁷⁾

Changes in lifestyle behavior by increasing fiber intake have the potential to reduce diabetes in the community⁽²⁸⁾ such as consuming fruits, green and yellow leafy vegetables that have high fiber content⁽²⁹⁾.

Based on the above background, the researchers formulated the problem in this study, namely analyzing the effect of aloe vera juice before meals on fasting blood sugar (FBS) levels in T2DM patients. The results of this study are expected to provide empirical evidence about the allegation that the effect of aloe vera juice before meals on reducing fasting blood sugar levels in T2DM patients and providing input to the public about one effective way to reduce fasting blood sugar levels in patients T2DM.

Methods

Analytical research with a randomized experimental study approach. Pre-post Test Control Group Design was used in the research design⁽³⁰⁾. The experimental design of outpatient T2DM patients at Sambas Hospital was given 300 ml aloe vera juice at 30 minutes before lunch for 14 days and the control group was given 300 ml mineral water 30 minutes before lunch. Measurement of fasting blood sugar levels was carried out before and after the study.

The population in this study is outpatients who have T2DM status without severe complications in Sambas Regional Hospital Sambas Regency, West Kalimantan Province with a large sample of 22 people.

The selection of research subjects is simple random sampling⁽³⁰⁾. Subjects are taken randomly without ignoring the conditions that have been determined, so that the overall design can be referred to as Purposive Random Sampling, which is a combination of the use of purposive techniques and Simple Random Sampling.

Data analysis was carried out on the effect of giving aloe vera juice to T2DM outpatients by comparing before and after treatment in the experimental group. Differences in average fasting blood sugar levels in each group were tested by different tests (Paired t test).

The hypothesis in this study are “There is an effect of giving aloe vera juice before meals to reduce fasting blood sugar levels in T2DM patients”.

Results

Characteristics of respondents are shown in Table 1. There were 11 respondents in each treatment group and control group who met the criteria. The results showed as many as 7 respondents (63.6%) each in the treatment and control group were female. A total of 7 respondents (63.6%) in the treatment group and 8 respondents

(72.7%) in the control group aged 46-55 years, had work as a government employees as many as 5 respondents (45.5%) in the treatment group and as housewives as many as 5 respondents (45.5%) in the control group, have a college education background of 5 respondents (45.5%) in each treatment group and control group and have a BMI with a range between 18.5- 24.9 as many as 8 respondents (72.7%) in each treatment group and control group.

Table 1. Characteristics of Respondents

Characteristics of Respondents	Treatment		Control	
	Frequency	Percent (%)	Frequency	Percent (%)
Gender				
- Male	4	36,4	4	36,4
- Female	7	63,6	7	63,6
Age				
- 20-45 years old	2	18,2	1	9,1
- 46-55 years old	7	63,6	8	72,7
- > 55 years old	2	18,2	2	18,2
Occupation				
- Housewife	4	36,4	5	45,4
- The farmer	1	9,1	1	9,1
- Honorary	1	9,1	-	-
- Government employees	5	45,4	4	36,4
- Entrepreneur	-	-	1	9,1
Education				
- Primary School	3	27,3	3	27,3
- Junior High School	2	18,2	2	18,2
- Senior High School	1	9,1	1	9,1
- University	5	45,4	5	45,4
BMI (Body Mass Index)				
- 18,5-24,9	8	72,7	8	72,7
- 25-29,9	3	27,3	3	27,3

The results of the examination of fasting blood sugar (FBS) of respondents before and after receiving treatment and in the control group can be seen in Table 2.

Table 2. FBS values of the treatment and control groups

FBS	Treatment		Control	
	Before	After	Before	After
N	11	11	11	11
Mean	204,54	168,54	162,27	199,00
Std. Deviasi	80,39	46,45	34,29	70,47
Minimum	107,00	100,00	115,00	100,00
Maksimum	307,00	254,00	221,00	291,00

The average value of inspection of FBS before treatment is 204.54 with the lowest value of 107.0 and the highest of 307.0. While after treatment the average value of FBS of 168.54 with the lowest value of 100.0 and the highest value of 254.0. In the control group the average value of examination of FBS before being given mineral water was 162.27 with the lowest value of 115.0 and the highest of 221.0. While after treatment the average value of FBS is 199.0 with the lowest value of 100.0 and the highest value of 291.0.

The analysis used was the parametric Paired Sample T Test because the variable data in the treatment group and the control group were normally distributed. The results of the analysis are shown in Table 3.

Table 3. Paired Samples Statistics Treatment and Control Groups

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Blood Sugar Before Juice - Blood Sugar After Juice	36,00	44,27	13,35	6,26	65,741	2,70	10	,022
Blood Sugar Before Given Mineral Water - Blood Sugar After Given Mineral Water	-36,73	65,84	19,855	-80,96	7,50	-1,85	10	,094

The significance value of 0.022 is smaller than 0.05, which means that there is a significant change in FBS between before treatment and after treatment in study respondents who received aloe vera juice before meals.

In the control group the significance value of 0.094 is greater than 0.05 which means that there is no

significant change in FBS between before treatment and after treatment.

Discussion

Before joining the program, we conducted nutrition counseling to respondents and in general they suffered

from DM and were treated for outpatient treatment. Respondents can prepare their own food according to the dietary recommendations given and some respondents have an incorrect perception of their diet. They limit rice and sugary foods and reduce the frequency of eating, but still consume other sources of carbohydrates during their snack time. This causes their FBS levels not to decline even some have increased after the program, especially in the control group.

According to Imai and Kajiyama⁽³¹⁾ that consuming vegetables 7 minutes by chewing 20 times before consuming rice can reduce postprandial blood glucose levels and insulin levels compared to vegetable consumption after rice.

Research conducted by Shukla *et al*⁽³²⁾ states that consumption of protein and vegetables before carbohydrates can reduce postprandial glucose levels by 28.6%, 36.7% and 16.8% at 30, 60 and 120 minutes compared to consumption carbohydrate first.

The this study are same with the research of Dwipajati⁽³³⁾ and Nagoro⁽³⁴⁾, who stated that consumption of bananas with a low GI before eating can reduce levels of FBS \pm 9 mg / dl in T2DM patients and in healthy people with obesity FBS \pm 2.5 mg / dl.

Consumption of fruit fiber can reduce 35% of blood glucose levels ⁽³⁵⁾, consuming protein and vegetables first before carbohydrates for 3 days can reduce levels of PPG (Postprandial Glucose) 34.7 mg / dl and increase insulin levels in T2DM patients⁽³²⁾ and can reduce levels of PPG 32.42 mg / dl in T2DM patients with overweight⁽³⁶⁾.

Conclusion

In this study shows that there is an effect of giving aloe vera juice in T2DM patients given before meals on FBS levels. The interim order of carbohydrate and fiber consumption during meals has a significant impact on FBS levels.

Recommendation

Limitations of this study include small sample sizes and unclear generalizations for foods with different macronutrient compositions and populations including T1DM and prediabetes.

Recommended for further research on the effect of aloe vera juice before meals on cholesterol.

Conflict of Interest: There is no conflict of interest in this study.

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Ethical Clearance: Taken from Health Research Ethics Committee Sebelas Maret University (No. 020/UN27.06.6.1/KEPK/EC/2020)

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Knowledge and Acceptability of Human Papilloma Virus Vaccine among Health Colleges' Students at King Abdul Aziz University, Jeddah Saudi Arabia, 2018 (A Cross-Sectional Study)

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Abstract

Background: Three types of HPV vaccine were introduced, and they were effective against HPV infection, their efficacy reached 98%. Worldwide, many studies have explored the level of knowledge and acceptability scores of the HPV vaccine. **Objectives:** To measure knowledge and acceptability and their predictors toward HPV vaccination among the final year of health college students at King Abdul-Aziz University in Jeddah, Saudi Arabia, in 2018. **Methods:** A cross-sectional study with a self-administered, well-structured questionnaire involving 300 students from the final year of male and female health colleges (Medicine, Dentistry, Pharmacology, Medical Technology, and Nursing) at King Abdul-Aziz University in Jeddah, Saudi Arabia, in 2018. **Results:** This study showed 34.00% good knowledge and 76.00% high acceptability among health college students. A low level of knowledge about the HPV vaccine among Saudi students (32.80%) in comparison with non-Saudis (66.70%) ($P \leq 0.05$). The acceptability of the HPV vaccine was higher in females (80.80%) and was statistically significant ($P \leq 0.05$). The logistic regression analysis showed that good knowledge level was independently associated with nationality and awareness about the possibility of preventing cervical cancer, while the acceptability level was independently associated with the good knowledge score. **Conclusion:** poor level of knowledge and a high acceptability toward the HPV vaccine offered us a strong push forward to provide the HPV vaccine to the community.

Keywords: *knowledge, acceptability, human papilloma virus vaccine, cervical cancer.*

Introduction

Human papillomavirus (HPV) is a DNA virus that accounts for more than 170 of known genotypes⁽¹⁾. It is a sexually transmitted infection typically spread through skin-to-skin contact⁽²⁾.

Worldwide, cervical cancer is one of the major causes of death among female genital cancers⁽³⁾. In 2018, the World Health Organization (WHO) ranked cervical cancer as the second most common cancer affecting women in the low developed countries. According to the Information Center on HPV and Cancer 2019, cervical cancer was ranked as the ninth most frequent cancer affecting childbearing women between 15–44 years of age in Saudi Arabia. Annually, 316 new cases of cancer

are diagnosed, and 158 deaths are reported⁽⁴⁾.

Cervical cancer cases significantly decreased among women who received at least one dose of the vaccine from 53.6% to 28.4% after the introduction of the vaccine against HPV infection in the United States (US) from 2008–2012 in contrast to non-vaccinated women (57.1% to 28.4%)⁽⁵⁾.

Worldwide, 71 countries had introduced an HPV vaccine (Gardasil) by 31 March 2017 to their national immunization program for girls, and 11 countries had done the same for boys. Three vaccines are currently available and these distinct vaccines protect against two HPV strains (bivalent), four HPV strains (quadrivalent),

or nine HPV strains (nine-valent) and were approved by the US Food and Drug Administration (US FDA) in Osman 2009 (6), 2007, and 2014, respectively (7). The HPV vaccine is administered intramuscularly in two or three doses and is safe for both males and females from 9–26 years of age (8). The vaccine is recommended in immunocompromised patients who are susceptible to acquiring the infection (9). The efficacy of the quadrivalent HPV vaccine in the prevention of cervical intraepithelial neoplasia (CIN2+) is 98.2% (10). The high level of antibodies produced against specific types of quadrivalent vaccine and bivalent vaccine HPV types persists for a minimum of eight or nine years, respectively (11,12) and at least five years for the nine-valent vaccine. There were no cases of death reported (13).

Worldwide, many studies have explored the knowledge and acceptability of the HPV vaccine. In February 2016, a cross-sectional study was conducted among undergraduate female medical students at Jimma University in Addis Ababa, Ethiopia. The study showed that more than half of the participants (56.2%) had poor knowledge about the HPV vaccine, and a low level of acceptability to receive the vaccine for themselves (49.4%) (14). In Saudi Arabia, a cross-sectional study was conducted in 2014 among 1400 medical students in the health colleges at Princess Nora Bint Abdul Rahman University; the study showed poor overall knowledge about the HPV vaccine equal to 95.5 % (15). The knowledge score was associated with different colleges in a Nigerian study (16) and associated with marital status in Malaysian study (17), and finally associated with level of awareness about the HPV infection in a Chinese study (18). On the other hand, the acceptability score among health college students was associated with different health colleges in a Nigerian study (16), by Olumide et al. the acceptability score was associated with level

of awareness about the HPV infection and knowledge about the preventable nature of cervical cancer (19), and finally by Adejuyigba et al. showed that acceptability score was associated with good knowledge score (20).

Materials and Method

Study Design Setting and Population:

This was an analytical, cross-sectional study conducted among health college students during a 12-months to measure their knowledge and acceptability toward the HPV vaccine at King Abdul-Aziz University in Jeddah, Saudi Arabia.

• Inclusion criteria:

- o Both gender male and female.
- o Final-year students from different health colleges (Medicine, Dentistry, Pharmacology, Medical Technology, and Nursing) at King Abdul-Aziz University in Jeddah, Saudi Arabia in 2018.
- o Saudi and Non-Saudi Students.
- o Married and Non-Married
- No identifiable information was collected, and all participants provided informed consent prior to answering the questionnaires.

• The Sample Size:

The sample size was calculated using the sample size equation. The previous prevalence of knowledge & acceptability of the vaccine was reported as 78% by a study conducted in China by Fu et al. in 2015 among medical students (21), and the significance level was $\alpha=0.05$.

$$n = \frac{Z^2_{1-\alpha/2} P(1-P)}{d^2}$$

$$n = (3.841) \times 0.785 \times (0.22) / (0.0025)$$

n = Minimum Sample Size. $Z^2_{1-\alpha/2}$ Value = Is standard normal variate at 5%, type 1 error [P < 0.05] is 1.96. p = The expected proportion in a population based on previous studies or pilot studies. d = The absolute error or precision – Must be decided by the researcher.

A pilot study of 10% of the sample was conducted for the reliability analysis and to test the applicability of the questionnaire and the accessibility of the study sample.

Sampling Technique:

The survey was conducted based on sample size of 300 medical students. At the beginning the data collected from the following college: Medicine college which contained 347 both sex students, Dentistry college contained 191 both sex students, College of Nursing contained 113 female students, college of Pharmacology which contained 164 both sex students and lastly college of Medical Technology 42 both sex students. The total number of health college students equaled 857, by the proportional allocation percentage which was carried out from each health college included in

the study and the breakdown for it as following; college of Medicine (40.4%) equal to 121 participants, college of Dentistry (22.3%) equal to 67 participants, college of Nursing (13.2%) equal to 39 participants, college of Pharmacology (19.14%) equal to 58 participants, college of Medical Technology (4.90%) equal to 15 participants.

We selected the sample using a systematic random technique by choosing the students from administration lists (name lists) from each college included in the study. We collected the questionnaires and checked for any missing data.

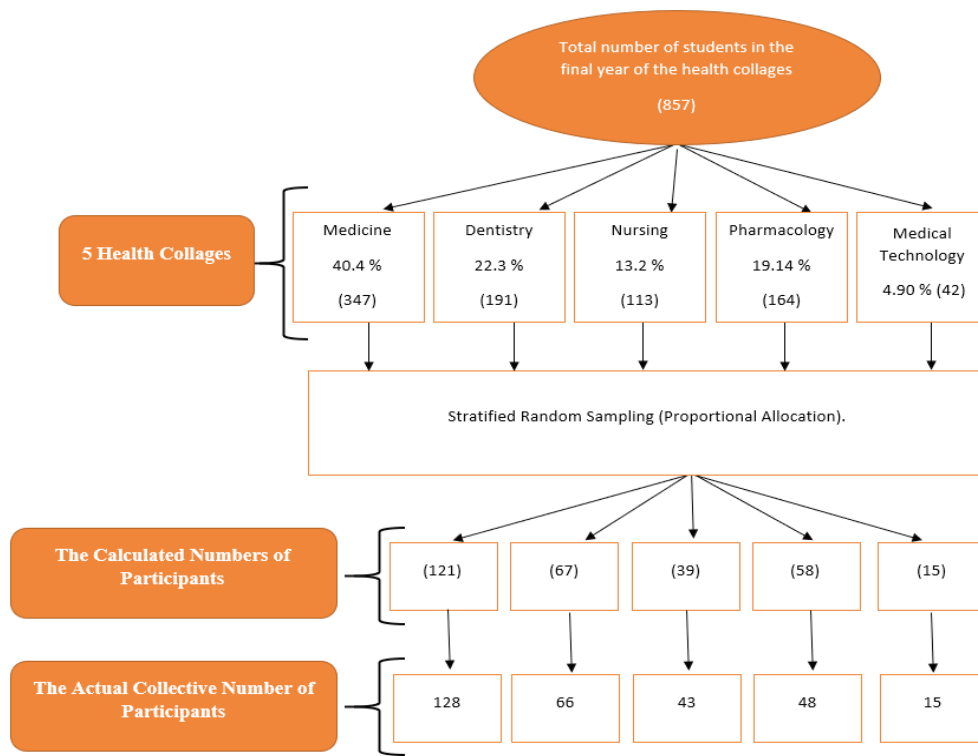


Figure (1): Sampling Technique:

Research Instrument:

This study used a self-administered, well-structured, closed-ended questionnaire for data collection. The questionnaire was reviewed and validated by three experts (two community medicine and one obstetrics and gynecology consultants) and was modified according to the experts’ opinions. It was developed using three previously validated and published questionnaires by Pandey et al. 2012⁽²²⁾, Fu et al. 2014⁽²¹⁾, and Al-Shaikh et al. 2014⁽¹⁵⁾.

It was with four sections: 1- Sociodemographic questions included 11 question e.g. their age, gender, college, marital status. 2- Knowledge about HPV infection which include 17 questions, e.g. respondents were asked if they had previously heard about HPV infection, 3- Knowledge about the HPV vaccine which included 23 questions e.g. if they had ever heard about the HPV vaccine to prevent cervical cancer in females. 4 - HPV vaccine acceptability which included 11 questions about the students’ willingness to receive the vaccine or to recommend it to their future patients or family.

Twenty-three questions were asked to measure the participants' HPV vaccine knowledge, so the total scores ranged from 0–23. A composite score in percentage was then derived by dividing everyone's score by 23 and then multiplying it by 100. According to Geneti et al. (2016), 50% used as a cut of point to divided our sample into 2 groups (good knowledge group and poor knowledge group) (14). The acceptability score was measured using a Likert-type scoring system, which was categorized into three levels of agree, disagree, and neutral. Any acceptability score above 50% was considered high, while scores below 50% represented a low acceptability level (14).

Data Entry and Data Analysis

The data were coded, entered, and analyzed using the Statistical Package for the Social Sciences (SPSS) software, 22. Qualitative variables were presented using frequencies and percentages, while quantitative variables were shown as the mean and standard deviation. A Chi-squared test was used to and P-values < 0.05 were considered statistically significant. A logistic regression analysis was used to assess the strength of associations.

Results

According to the participants' knowledge scores, they were categorized in the **table (1)** into two groups; (66.0%) had a poor knowledge score, while (34.0%) had good knowledge score. Non-Saudis demonstrated a significantly higher knowledge score regarding the HPV vaccine than Saudis (66.7% versus 32.3%, respectively; $P \leq 0.05$). Distribution by college specialty showed that medical students' score was the highest percentage (46.1%), followed by nursing (32.6%), dentistry (27.3%), and pharmacology students (22.9%).

The participants were assigned to one of two groups based on their acceptability scores: Of the total participants, 228 (76%) had a high acceptability score, while 72 (24%) had a low score. Based on the acceptance scores, females had a greater percentage of acceptance than males (80.8% versus 69.5% respectively), and the difference was statistically significant ($P \leq 0.05$). Also, there was a significant difference in the acceptability between different specialties ($P \leq 0.05$); the highest percentage of acceptance was observed among nursing students (83.7%), followed by medical (81.3%) and

dentistry (74.2%) students. Moreover, the present study showed that as the knowledge increased, the acceptability also increased ($P \leq 0.05$).

Of the 64% of respondents who had a family member or friend diagnosed with cervical cancer chose the "yes" answer and illustrated a high acceptability level toward the HPV vaccine in comparison to the 45.5% of them who showed a low level of acceptability toward the vaccine ($P \leq 0.05$). Regarding the attitude of the participants about the ability of the HPV infection to cause cervical cancer in females, 82.60% of the participants who answered "agree" demonstrated a higher level of acceptability toward the vaccine in comparison to the 17.40% who showed a low level of acceptability toward the vaccine ($P \leq 0.05$). Participants with a high knowledge score about the HPV vaccine demonstrated a high level of acceptability toward receiving the HPV vaccine (95.1%) in comparison to the 4.9% who showed a low level of acceptability toward the vaccine ($P \leq 0.05$).

Table (2) contained the binary logistic regression, which demonstrated the predictors of knowledge and acceptability level about the HPV vaccine. Good knowledge about the HPV vaccine was independently associated with the participant's knowledge about the information that cervical cancer can be a preventable disease. Participants who answered "yes" were 4.19 times more likely to have a good knowledge level about the HPV vaccine than participants who chose the answer "do not know" (OR = 4.19 [95% CI = 1.97, 8.88]). Followed the participant's nationality, with non-Saudis being 3.99 times more likely to have a good knowledge level in comparison with Saudi students (OR = 3.99 [95% CI = 1.22, 13.00]). It also showed that the knowledge level was a strong predictor for vaccine acceptability, the participants with a high knowledge score about the HPV vaccine were 7.66 times more likely to have a high acceptability toward the vaccine in comparison to poor knowledge score participants (OR = 7.66 [95% CI = 2.83, 20.76]).

Discussion

In the present study, a higher percentage of students were non-married (92.00%), while only (8.00%) were married. Comparable results were found in another study from Ethiopia, in 2016, The study showed a higher percentage of unmarried participants (97.5%), while

only 2.5% were married (14).

The good knowledge score demonstrated 34% in comparison to 66% of poor knowledge score among the studied participants. The high acceptability score reached (76.00%) in comparison to 24.00% of low acceptability score among the studied participants. In contrast, another study showed (60.4%) of rejection toward the vaccine than (39.6%) of acceptance of it (20).

In the current study good knowledge scores predominantly belonged to students of the faculty of Medicine (46.10%). A different study was conducted in Benin City, Nigeria, that study showed higher good knowledge among students of the Faculty of Medicine (35.8%), Dentistry (9.3%) (16). In the current study, married students had a higher level of good knowledge (45.8%) than single students (33%). In contrast, a study conducted in Malaysia 2010 showed that single participants had a higher good knowledge (41.5%) than married and divorced students (23.2% and 22.2%, respectively) (17). Only 36.4% of the participants in the current study who were informed about HPV infections demonstrated good knowledge about the HPV vaccine ($P \leq 0.05$), while 76.5% of the participants in a Chinese study 2014 had heard about HPV infection (18).

The acceptability rate was higher in the current study among students in the faculty of Medicine (81.3%), followed by the faculty of Nursing (83.7%). In agreement with the current study, another study in Nigeria 2016 the acceptability was higher among students in the Faculty of Dentistry (100%) followed by students of Faculty of Medicine (99.3%) (16). In the current study, 80.00% of the participants who were aware about the HPV infection demonstrated a high acceptability for the HPV vaccine ($P \leq 0.05$). In contrast, another study in Nigeria in 2015 showed that 71.2% of the participants who had heard about HPV infection having high acceptability toward the HPV ($P \leq 0.05$) (19). In the running study, 81.9% of the participants who knew that cervical cancer can be a preventable disease had a high acceptability toward the HPV vaccine. In comparison with Olumide et al.'s 2015 study, showed that 75% of the participants who knew about the preventable nature of cervical cancer had a high acceptability toward the HPV vaccine (19). In the present

study, 95.1% of good knowledge score participants had a high acceptability toward the HPV vaccine ($P \leq 0.05$). In agreement with the current study, another study showed that 55.9% of participants who had a full knowledge score demonstrated a high acceptability toward the HPV vaccine ($P = 0.008$) (20).

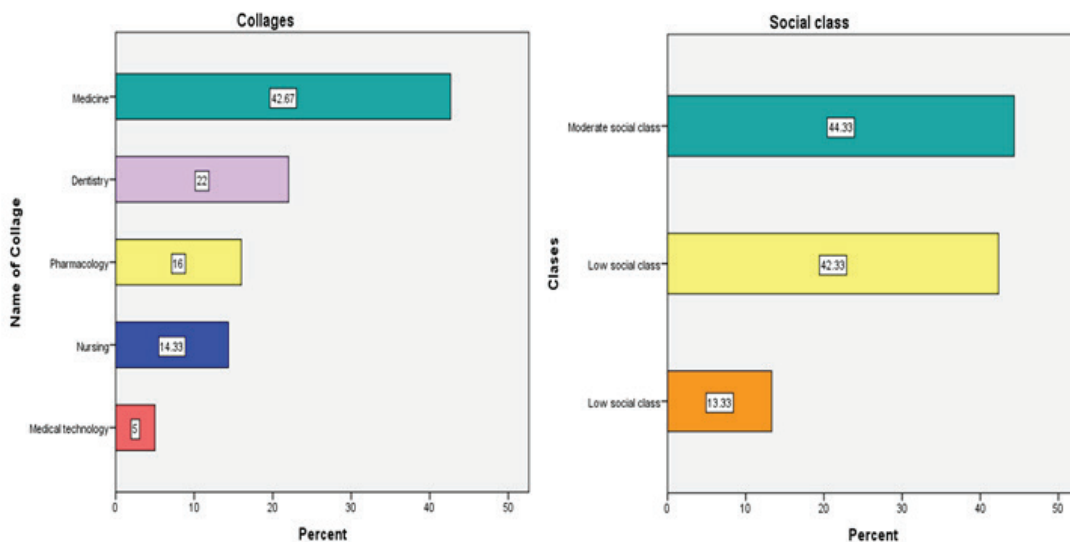
The present study showed significant difference between the desire to receive the HPV vaccine between male and female participants (69.5% and 80.8%, respectively) ($P \leq 0.05$). In parallel, a study in India in 2012 demonstrated that 79.4% of the female students were more willing to receive the HPV vaccine than males 53% ($P < 0.00$) (22).

The logistic regression analysis demonstrated that the highest predictor for good HPV vaccine knowledge was the participant's knowledge about the information that cervical cancer could be a preventable disease ($R = 4.19$ [95% CI = 1.97, 8.88]) followed by being non-Saudis having a greater likelihood for having a good knowledge level about the vaccine (OR = 3.99 [95% CI = 1.22, 13.00]). In contrast, a study conducted in China 2014 demonstrated that being female increased the likelihood of having good knowledge about the vaccine compared to male participants (OR = 1.39 [95% CI = 1.11, 1.75]). (18). Cervical cancer is a female cancer, so women pay attention about it.

The logistic regression analysis in the study revealed that the highest predictor of the participants high acceptability toward the HPV vaccine was the good knowledge score (OR = 7.66 [95% CI = 2.83, 20.76]). In comparison, Chinese study in 2014 showed the acceptability toward the HPV vaccine was independently associated with the knowledge score of the participants and having good knowledge score was 2.46 greater of having high acceptability than poor knowledge score (OR = 2.46 [95% CI = 1.54, 3.93]). (23)

Conclusion

The current study illustrated that 34% of the final year undergraduate health college students at King Abdul-Aziz University had a good knowledge level about the HPV vaccine and 76% had a high level of acceptability toward the HPV vaccine.



Graph (2): The descriptive data of the studied sample.

Table (1): Factors affecting the knowledge and acceptability level of the studied participants about the Human Papilloma Virus (HPV) vaccine.

Variables	Poor knowledge 198 (66%)		Good knowledge 102 (34%)		Significant test	Low acceptance 72 (24.0%)		High acceptance 228 (76.0%)		Significant test
	No.	%	No.	%	P. Value	No.	%	No.	%	P. Value
Gender:										
Male	86	67.20%	42	32.80%	0.81	39	30.50%	89	69.50%	0.03*
Female	112	65.10%	60	34.90%		33	19.20%	139	80.80%	
Nationality:										
Saudi	193	67.70%	92	32.30%	0.01*	68	23.90%	217	76.10%	0.76
Non-Saudi	5	33.30%	10	66.70%		4	26.70%	11	73.30%	
Marital Status:										
Married	13	54.20%	11	45.80%	0.26	5	20.80%	19	79.20%	0.80
Not Married	185	67.00%	91	33.00%		67	24.30%	209	75.70%	
Residence:										

Cont... Table (1): Factors affecting the knowledge and acceptability level of the studied participants about the Human Papilloma Virus (HPV) vaccine.

Medicine	69	53.90%	59	46.10%	0.00*	24	18.80%	104	81.30%	0.04*
Dentistry	48	72.70%	18	27.30%		17	25.80%	49	74.20%	
Nursing	29	67.40%	14	32.60%		7	16.30%	36	83.70%	
Pharmacology	37	77.10%	11	22.90%		18	37.50%	30	62.50%	
Medical Technology	15	100%	0	0.00%		6	40.00%	9	60.00%	
Awareness about the HPV infection										
Yes	175	63.60%	100	36.40%	0.01*	55	20.00%	220	80.00%	0.00*
No	15	88.20%	2	11.80%		13	76.50%	4	23.50%	
Do Not know	8	100.00%	0	0.00%		4	50.00%	4	50.00%	
The preventable nature of cervical cancer										
Yes	103	54.80%	85	45.20%	0.00*	34	18.10%	154	81.90%	0.01*
No	19	76.0%	6	24.00%		7	28.00%	18	72.00%	
Do not know	76	87.40%	11	12.60%		31	35.60%	56	64.40%	
A Family Member or Friend of the participant was Diagnosed with Cancer Cervix										
Yes	9	81.80%	2	18.20%	0.23	5	45.50%	6	54.50%	0.02*
No	162	64.00%	91	36.00%		53	20.90%	200	79.10%	
Do not know	27	75.00%	9	25.00%		14	38.90%	22	61.10%	
Attitude toward HPV infection in causing cervical cancer in females										
Agree	124	58.20%	89	41.80%	0.00*	37	17.40%	176	82.60%	0.00*
Disagree	21	80.80%	5	19.20%		11	42.30%	15	57.70%	
Neutral	53	86.90%	8	13.10%		24	39.30%	37	60.70%	
Knowledge Score:										
Good Knowledge (<11.6)	-----					5	4.90%	97	95.1%	0.00*
Poor Knowledge (0-11.50)	-----					67	33.80%	131	66.20%	

Table (2): logistic Regression analysis of the independent factors affecting knowledge and acceptability level about the Human Papilloma Virus (HPV) vaccine among the studied participants.

Predictor	Knowledge Level					Acceptability Level					
	Category	OR	95%	CI	P-value	Category	OR	95%	CI	P-value	
Gender	-----					Female	1.31				
						Male	REF	0.67	2.57		0.43
Nationality	Non-Saudi	3.99	1.22	13.00	0.02	-----					
College	Pharmacology	REF			0.93	Medical Technology	REF			0.74	
	Dentistry	0.94	0.44	1.98	0.87	Medicine	2.03	0.52	7.97	0.31	
	Nursing	0.70	0.32	1.53	0.37	Dentistry	2.11	0.60	7.38	0.24	
	Medicine	0.82	0.34	2.01	0.66	Nursing	1.96	0.49	7.89	0.34	
	Medical Technology	NC	NC	NC	0.99	Pharmacology	1.43	0.43	4.77	0.56	
Awareness about HPV Infection	Yes	REF			0.63	Do not know	REF			0.01	
	No	0.44	0.09	2.29	0.33	Yes	1.85	0.38	9.02	0.45	
	Do not Know	NC	NC	NC	0.99	No	0.20	0.03	1.45	0.11	
Attitude towards HPV infection in causing cervical cancer in female	Disagree	REF			0.08	Disagree	REF			0.33	
	Agree	2.12	0.68	6.62	0.19	Agree	2.02	0.71	5.78	0.19	
	Neutral	0.83	0.22	3.08	0.78	Neutral	1.29	0.43	3.86	0.65	
The preventable nature of cervical cancer	Do not know	REF	-	-	0.01	Do not Know	REF			0.95	
	Yes	4.19	1.97	8.88	0.00	Yes	1.12	0.54	2.31	0.76	
	No	2.23	0.67	7.43	0.19	No	1.05	0.35	3.17	0.93	

Conflict of Interest: Nil

Source of Funding: Researcher

Ethical Clearance: The research project was approved by the ethical committee at King Abdul-Aziz University in Jeddah, Saudi Arabia.

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Workplace Violence Against Healthcare Workers at Ministry of Health Hospitals, Holy Makkah City, Saudi Arabia, 2019: A Cross-Sectional Study

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Abstract

Background: Workplace violence affected most of the healthcare workers in almost all the specialties, departments and in most categories of health facilities.

The objectives: to estimate the prevalence of the workplace violence against health care workers and to determine the different risk factors which can causing this workplace violence against health care workers in one year in Makkah city at the Ministry of Health Hospitals between April and July 2018.

Material and Method: It's a cross-sectional study conducted at Al-Noor specialist hospital, King Abdul-Aziz Hospital (KAH), Hera'a general hospital at Makkah holy city on 450 of healthcare workers included doctors and nurses who worked in emergency, critical care, inpatient and outpatient departments by using a validated questionnaire in English (Workplace Violence in the Health Sector Country Case Studies, Research Instruments, 2003) constructed by (ILO, ICN, WHO, and PSI).

Conclusion: More than half of the participants (52%) exposed to workplace violence. Type of department, work shift and the marital status were the most contributing factors of workplace violence.

Keywords: Workplace violence, doctors, nurses, healthcare workers, violence, abuse.

Introduction

Working as a healthcare practitioner in the healthcare sector is the leading cause of occupational hazards.⁽¹⁻³⁾ From 2002–2013, 75% of violence occurred in healthcare settings.^(4,5) However, workplace violence (WPV) has become a global problem, and its true extent is unknown.

Workplace violence is a difficult concept to define because there is no standard definition, and it is based on conceptual aspects, methods, type of healthcare sector, or/and the culture in which WPV exists.⁽⁶⁻⁸⁾ In 2002, the International Labour Office (ILO), International Council of Nurses (ICN), WHO, and Public Services International (PSI) defined WPV as, "Incidents where staff are abused, threatened, or attacked in circumstances

related to their work, including commuting to and from work and involving an explicit or implicit challenge to their safety, well-being, or health."⁽⁹⁾

Numerous worldwide studies have considered WPV. A 2013 study in the United Arab Emirates on 1,077 nurses reported a prevalence of WPV of 24%,⁽¹⁰⁾ while the majority of physicians (86.4%) were exposed to at least one type of violence in Turkey in 2015.⁽¹¹⁾ The prevalence of WPV against HCWs in the KSA is like that reported globally. However, only a few studies were conducted on WPV against all HCWs and primarily focused on Riyadh.⁽¹²⁻¹⁴⁾ Recently, a study was conducted in Abha city, KSA (2020) to determine the prevalence, types, and correlates of physical and verbal abuse among 164 medical staff working in emergency departments. It was found that 17% of them had been

exposed to physical violence, and 50% of them had experienced psychological violence. ⁽¹⁵⁾

Generally, there is a need to understand the risk factors associated with WPV in order to identify suitable development and enforcement solutions. Many risk factors increase the risk of WPV occurring against HCWs and they are either relating to HCWs as age, gender, job category, marital status, and/or related to the work environment such as type of healthcare facility, type of department, work shift and reporting procedure.

WPV is a serious problem and has a negative impact on the well-being of HCWs and healthcare economics and has a psychological impact that includes dissatisfaction, low productivity, turnover, absenteeism and a reduction in the quality of the healthcare service provided to the patients.

The prevalence of WPV has been assessed in several studies, but the actual rate is unknown. Nevertheless, Middle East countries have not paid too much attention to this phenomenon. Research on WPV in the healthcare setting is particularly limited in the KSA. This limitation creates a gap in the literature and prohibits an understanding of this issue.

There is a lack of such studies in the KSA, among HCWs particularly in Mecca, which is the holy city in the KSA that is visited by millions of pilgrims annually. In addition, this study will guide healthcare organizations to address this problem with qualified team members in order to evaluate the environment and atmosphere of HCWs in the healthcare setting.

Methodology

Study Design:

An analytical cross-sectional design was applied and conducted over 12 months, into the prevalence of different forms of WPV against 450 HCWs (doctors and nurses) and related risk factors.

Study area and setting:

The current study was conducted in three governmental hospitals were under MOH, selected according to geographical location and its bed capacity: Hera'a General Hospital, King Abdul-Aziz Hospital (KAH) and Al-Noor Specialist Hospital.

Study population:

The target populations included doctors and nurses who were working in critical care units, the emergency department, inpatient department and outpatient clinics.

Sample Size:

The sample size calculated by using the cross-sectional study equation. The following equation was used to calculate the sample size: $SS = \frac{Z^2 \cdot p \cdot (1-p)}{d^2}$ ⁽¹⁶⁾ The sample size calculated was 379 and it was increased to 450.

Sample technique:

Figure 1 showed the sample technique of study sample.

Exposure: The various demographic characteristics (age, gender, and marital status...etc) of HCWs and other work-related characteristics (number of years' work experience...etc).

Outcome: workplace violence against health care workers (doctors, nurses).

The inclusion criteria :

1. Doctors and nurses
2. Saudi and non-Saudi.
3. Male and female.
4. Able to speak and read English.
5. Work experience more than one year.

The exclusion criteria :

1. Students, trainees and interns.
2. Work experience less than one year.
3. Participants in a pilot study.

Research Tool:

1- Interview with each participant by using validated an English version of the **Workplace Violence in the Health Sector Country Case Studies, Research Instruments, 2003** survey.

2- Some of the questions were modified to suit the Saudi culture.

Data Collection:

The data collection was conducted having received Intramural Research Program institutional research board (IRB) committee approval. Verbal consent was obtained from each participant after ensuring that the research objectives and the questionnaire survey were fully understood. The data were collected over four months.

The collected data were kept as a soft copy on a researcher computer and only accessed by authorized authors for research purposes.

Data Analysis

The participants' names were coded and anonymously entered and analyzed using Statistical Packages for Social Sciences (SPSS) version 22. The categorical data were presented as numbers and percentages. The chi-square test was used to evaluate the qualitative variables. P-value of 0.05 denoted statistical significance. Logistic regression analysis was used to determine the association between the independent factors and the dependent factor (exposure to WPV).

The Result

Table 1 showed the socio-demographic data of the studied sample. Related to gender, the study participants were predominantly men (66% of men vs. 34% of women). While approximately half of the participants were non-Saudis. The majority of the participants' age were 31 – 40 years old (40.7%)

Moreover, two thirds of the subjects were married (66.2%). forty-two percent of the respondents had a bachelor's degree.

Table 2 presented the participants' work-related characteristics. Considered to the hospitals, 45% of the HCWs worked at Al-Noor Specialist Hospital, and the remainder were equally distributed in another hospitals. However, the result of the participants' distribution in the departments was around 25% of the participants worked in each department. In view of the professional category, many the HCWs (67%) were nurses

Over half (54.7%) of the participants worked in shifts time. Moreover, one third of the participants had worked for ≤ 5 years. However, nearly all of the respondents had interactions with patients. While 66.9 % of the participants routinely engaged in direct physical contact with patients. Approximately three-quarters of the participants (72.4%) stated that procedures for reporting WPV existed at their current workplace.

Figure 2 illustrated the participants' view regarding the existence of specific measures related to workplace violence in the studied hospital.

Table 3 showed the prevalence of workplace violence among healthcare workers who participated in the present study. The overall prevalence of exposure to workplace violence was (52%).

Table 4 demonstrated the bivariate analysis for HCWs characteristics in relation to their exposure to workplace violence. Based on the results, 45.7% of the participants aged 31-40 years were exposed to the violence. Saudi participants were slightly more likely to be exposed to WPV than their non-Saudi. Also, the participants who worked in emergency and inpatient departments were most frequently exposed to the violence (32.5%,26.5%, respectively). However, more than half of the assaulted participants were married (62%). The participants who had physical contacted with patients (71.8%) were frequently exposed to WPV. Anyhow, 40% of HCWs reported that a reporting procedure was in place for WPV. Anyhow all the previous factors were statistical significance ($P \leq 0.05$).

Table 5 conducted the multivariate logistic regression analysis to assess the association between HCW-related risk factors and the odds of their exposure to WPV. The type of department was shown to be strongly associated with exposure to WPV. Participants who worked in the emergency department were 3.5 times more likely to be exposed to WPV (OR of 3.27, 95% CI: 1.99–6.20) compared to those who worked in a critical care department. In addition, HCWs worked-in an inpatient department were at in a greater risk (1.8 times higher) of being exposed to WPV compared to the reference group (95% CI=1.05 – 3.16).

Moreover, HCWs who worked in shifts were evaluated in terms of their potential for exposure to

WPV, and the odds of this occurring were found to be considerably higher (OR of 1.9, 95% CI: 1.15–3.23) than those who were not worked in shifts. In addition, the analysis showed that the marital state of HCWs associated with the extent of their exposure to WPV. The risk of exposure to WPV was thought to be 1.6 times higher for unmarried HCWs compared to married HCWs (OR of 1.64, 95% CI: 1.07–2.52).

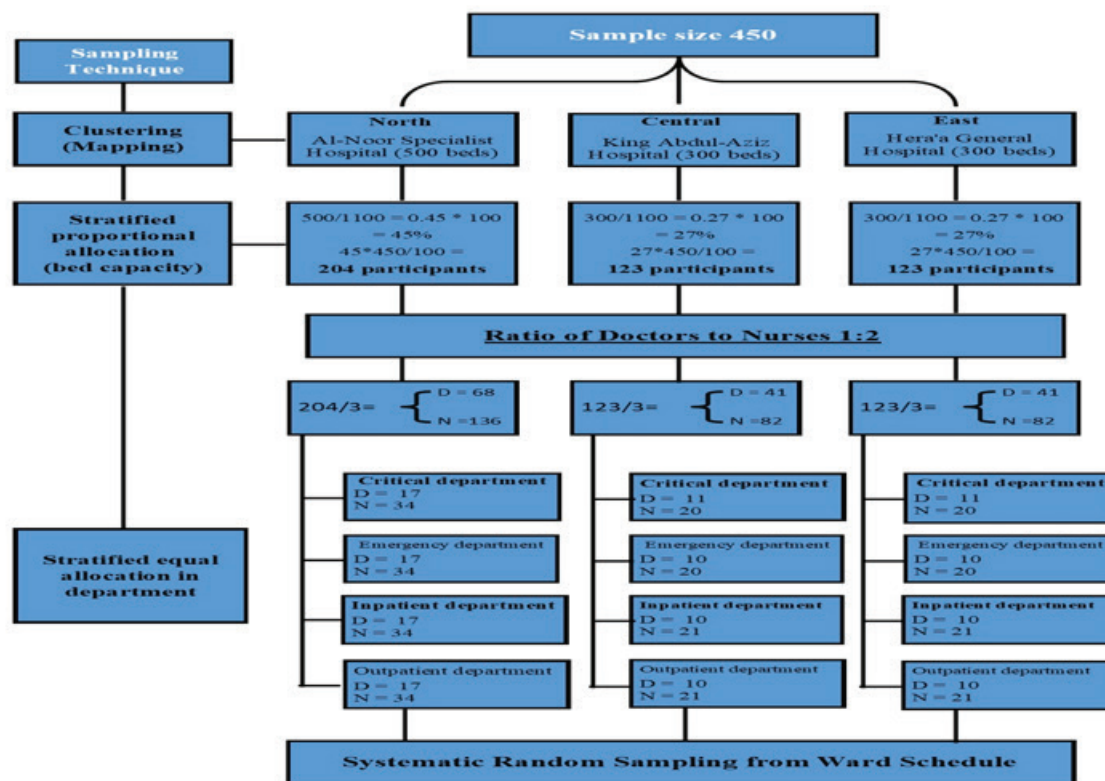


Figure 1 : Flow Chart of Sampling Technique.

Table 1: Socio Demographic Data of the Studied Sample at Ministry of health Hospitals in Holy Makkah City, 2018. (N=450)

Socio Demographic Data	N (%)
Gender	
· Male	297 (66%)
· Female	153 (34%)
Nationality	
· Saudi	215 (47.8%)
· Non-Saudi	235 (52.2%)
Age group in years	
· 20 – 30 years	141 (31.3%)
· 31 – 40 years	183 (40.7%)
· >40 years	126 (28.0%)

Cont... Table 1: Socio Demographic Data of the Studied Sample at Ministry of health Hospitals in Holy Makkah City, 2018. (N=450)

Marital Status	
· Unmarried	149 (33.1%)
· Married	301 (66.9%)
Educational level	
· Diploma	123 (27.3%)
· Bachelor	188 (41.8%)
· Postgraduate	139 (30.9%)

Table 2: Participants' Work Characteristics at Ministry of health Hospitals in Holy Makkah City, 2018. (N=450)

Work Characteristics	N (%)
Hospital	
· King Abdulaziz Hospital	123 (27.3%)
· Hiraah Hospital	123 (27.3%)
· Al Noor Hospital	204 (45.4%)
Department	
· Emergency room	111 (24.7%)
· Inpatient department	113 (25.1%)
· Outpatient clinic	113 (25.1%)
· Critical care department	113 (25.1%)
Professional Category	
· Physician	150 (33.3%)
· Nurse	300 (66.7%)
Working in Shift	
· No	204 (45.3%)
· Yes	246 (54.7%)
Years of Experience	
· ≤5 years	143 (31.8%)
· 6 – 10 years	128 (28.4%)
· 11 – 15 years	90 (20%)
· >15 years	89 (19.8%)
Interact with Patients/Clients During Work	
· No	9 (2%)
· Yes	441 (98%)
Routinely Direct Physical Contact with Patients/Clients	
· No	149 (33.1%)
· Yes	301 (66.9%)

Cont... Table 2: Participants' Work Characteristics at Ministry of health Hospitals in Holy Makkah City, 2018. (N=450)

Type of Patients with Most Frequently the Healthcare Workers Working With	
· Female patients	54 (12%)
· Male patients	43 (9.6%)
· Mix male and female patients	353 (78.4%)
Types of the patients were Mostly Handled by Healthcare Workers	
· Adult	406 (90.2%)
· Elderly	393 (87.3%)
· Adolescent	324 (72%)
· Pregnant Women	191 (42.4%)
· Children	178 (39.6%)
· Infants	81 (18%)
· Newborn	75 (16.7%)
Presence of the Procedures for the Reporting of Violence in the studied Workplace	
· No	208 (46.2%)
· Yes	242 (53.8%)
If Yes, Types of People Who Encourage to Reporting the Violence** (n=242)	
· Colleague	127(52.5%)
· Organization	40 (16.5%)
· Employer	34 (14%)
· Quality	31(12.8%)
· Family/friend	8 (3.3%)
· Union (directorate of health affairs)	2 (.8%)

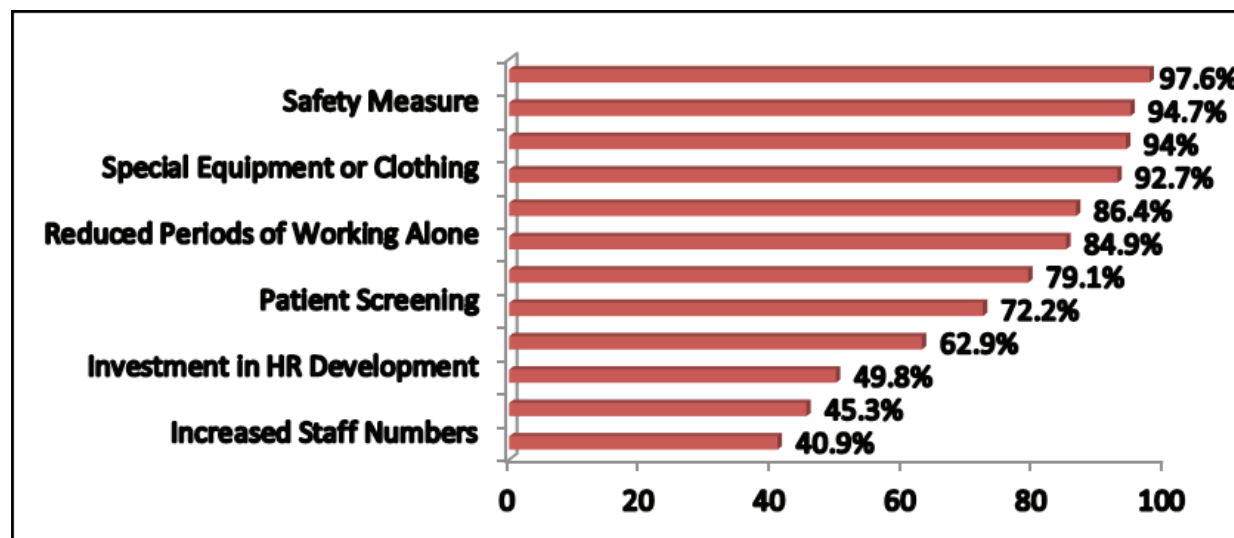


Figure 2: The Participants View Regarding to Existence of Specific Measures related to workplace violence in the Studied Hospitals.

Table 3: Prevalence of the Workplace Violence Among the Studied sample at Governmental Hospitals in Holy Makkah City, 2018. (N=450)

Workplace Violence	N (%)
Studied Health Care Workers	
· Violence Exposed	234 (52%)
· Violence Non-exposed	216 (48%)

Table 4: The Healthcare Workers characteristics related to Workplace Violence Among the Studied Sample at Ministry of health Hospitals in Holy Makkah City, 2018. (n=450)

The Factors	Exposed(n=234) N (%)	Non-exposed(n=216) N (%)	P-value Chi- square
Age Group in Years			
· 20 – 30 years	71 (30.3%)	70 (32.4%)	0.04 * (6.10)
· 31 – 40 years	107 (45.7%)	76 (35.2%)	
· >40 years	56 (24%)	70 (32.4%)	
Gender			
· Male	159 (67.9%)	138 (63.9%)	0.36 (0.82)
· Female	75 (32.1%)	78 (36.1%)	
Nationality			
· Saudi	123 (52.6%)	92 (42.6%)	0.03 * (4.47)
· Non-Saudi	111 (47.4%)	124 (57.4%)	
Hospital			
· King Abdulaziz Hospital	69 (29.5%)	54 (25.0%)	0.29 (2.47)
· Hira Hospital	57 (24.4%)	66 (30.6%)	
· Al Noor Hospital	108 (46.2%)	96 (44.4%)	
Department			
· Emergency department	76 (32.5%)	35 (16.2%)	0.0 * (22.41)
· Inpatient department	62 (26.5%)	51 (23.6%)	
· Outpatient clinic	53 (22.6%)	60 (27.8%)	
· Critical care department	43 (18.4%)	70 (32.4%)	
Educational Level			
· Diploma	65 (27.8%)	58 (26.9%)	0.67 (0.78)
· Bachelor	101 (43.2%)	87 (40.3%)	
· Post graduate	68 (29.1%)	71 (32.9%)	

Cont... Table 4: The Healthcare Workers characteristics related to Workplace Violence Among the Studied Sample at Ministry of health Hospitals in Holy Makkah City, 2018. (n=450)

Marital Status			
Unmarried	88 (37.6%)	61 (28.2%)	0.03 * (4.44)
Married	146 (62.4%)	155 (71.8%)	
Professional Title			
Physician	75 (32.1%)	75 (34.7%)	0.54 (.36)
Nurse	159 (67.9%)	141 (65.3%)	
Years of Experience			
≤5 years	76 (32.5%)	67 (31.0%)	0.74 (.11)
>5 years	158 (67.5%)	149 (69.0%)	
Working in shift			
No	111(24.7%)	93(20.7%)	0.39 (.87)
Yes	123 (27.3%)	123 (27.3%)	
Physical Contact with Patients/Clients			
No	66 (28.2%)	83 (38.4%)	0.02 * (5.29)
Yes	168 (71.8%)	133 (61.6%)	
Presence of a procedure for the reporting of violence			
No	51 (11.3%)	73 (16.2%)	0.00 * (8.10)
Yes	183 (40.7 %)	143 (31.8%)	

Table 5: Multivariate Analysis for predictor the Risk Factors of Workplace Violence Among Studied sample at Ministry of health Hospitals in Holy Makkah City, 2018. (N=450)

Exposure Factors	Odds Ratio (OR)	95% confidence interval (CI)	P-value
Department			
Critical Care Unit	Ref		
Inpatient department	1.83	1.05 – 3.16	0.03
Outpatient clinic	1.36	0.69 – 2.67	0.36
Emergency room	3.52	1.99 – 6.20	0.00
Work shift			
No	Ref		0.01
Yes	1.93	1.15 – 3.23	
Marital status			
Married	Ref		0.02
Un married	1.64	1.07-2.52	
Physical Contact with Patients			
No	Ref		0.01
Yes	0.54	.32 - .90	
Presence of a procedure for the reporting of violence			
No	Ref		0.01
Yes	.566	.36 - .88	

Discussion

Half of the HCWs in the current study (52%) had been exposed to WPV. Similarly, a study performed in Abha City, KSA, carried out in 2018, reported that 57.5% of HCWs had experienced WPV, and another in Ethiopia in 2019 documented that 58.2% of the 553 HCWs evaluated had encountered WPV.⁽¹³⁾

Both higher and lower WPV have been recorded in national and international studies, when compared to the present study. In a 2012 study in Palestine, the rate of WPV against physicians and nurses in the 12 months prior was found to be 80%, which was considerably higher than in the current study.⁽¹⁷⁾ A similarly high figure (90%) reflected violence against HCWs in a study in the KSA in 2016.⁽⁸⁾ This city is located in the far north of KSA, and this finding could be explained by the numerous Bedouin inhabitants with tribal bias who may not have been as adherent to following the rules as other populations.

A study in Riyadh, Saudi Arabia in 2016, reported a prevalence of WPV of 45.6% among HCWs in family medicine centers.⁽⁷⁾ The reasons for different rates of WPV can be attributed to several factors, the most important of which are the type of hospital and the implementation of strict laws and regulations, as well as environmental factors, such as security measures and the type of patient in each hospital.

Certain factors were shown to be associated with WPV in the current study. **Related to the department**, HCWs worked in the emergency department were a greater extent than others who worked in other departments, with statistically significant differences. However, this might have been because the emergency department initially receives all types of cases, and HCWs in this department are the first healthcare professionals' group to receive critical cases. A study conducted in northwest Ethiopia 2019 confirmed the same result and found that the HCWs who worked in the emergency department were four times more likely to be exposed to WPV than the HCWs who worked in outpatient clinic.⁽¹⁸⁾

There was association between HCWs who **worked in shifts** and WPV, with significantly higher odds (OR = 1.9) of being exposed to WPV. In Spain, a similar

finding to that in the current study was reported; HCWs who worked in shifts were 2.6 times more likely to be exposed to WPV than those who didn't assign in shifts.⁽¹⁹⁾

However, **marital status** was seen to correlate with exposure to WPV in the current study. Dissimilar to the current study finding in this regard, the reviewed studies found that the marital status of HCWs was not significantly correlated with exposure to WPV.^(15, 11, 21)

However, 71.8% of HCWs who had **contacted physically** with the patients were exposed to the violence, and there was a statistically significant difference. The result of significantly in a study in china 2017 was consistent with the result of the present study.⁽²²⁾

Regarding to the **reporting procedure**, seventy-two of the participants in the current study claimed that there was a procedure for reporting WPV, whereas 67.3 % of abused HCWs reported the violent action. Various published papers have documented a similar finding to that of the current study.^(7,11, 23)

Conclusion

The present study determined the prevalence and identified the risk factors for WPV in governmental hospitals in Holy Makkah City. HCWs (doctors, nurses) reported that the violence was common. More than half of them were exposed to workplace violence. The type of department, work shift and marital status were identified as having the highest relation with exposure to WPV. The implementing of strict policy for WPV and strategies that ensure the safety of healthcare providers is needed to decrease the prevalence of WPV in the KSA.

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Sedation During Non-invasive Ventilation and its Association with Intubation Rate and Intensive Care Units Stay among Adult Patients at King Abdulaziz Medical City

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Abstract

Background: Non-invasive ventilation (NIV) is a procedure of providing the patient, positive pressure ventilation without the use of artificial airway. Some patients may require minimum sedation for patient comfort. However, there are few studies examined the effect of using sedation with NIV. This study aimed to examine the prevalence of using sedation during NIV.

Methods: A cross-sectional study was carried out at King Abdulaziz Medical City (KAMC) from 2016-2018 using data from an electronic medical record of patients who received NIV in ICUs. We collected demographic data, type of NIV, comorbidity, and type of sedation. We studied the outcome of intubation rate, length of ICUs stays and mortality for patients who received sedation during NIV.

Results: Total of 110 adult patients were included in this study, with a median age of 70 years (IQR 63-78 years), and 53% were female patients. Most patients had COPD as a cause of ICU admission (31%). Among this population, only six patients, 5.45% received sedation during NIV in which the majority received Dexmedetomidine. Intubation rate was 12% among all patients, 33% of them received sedation. The median of the length of stay for the sedated patient was 7.5 (IQR 7-18).

Conclusions: Using sedation during NIV is not a common practice for patients admitted in ICU. Using sedation during NIV did not have a significant effect on reducing intubation rate or ICU stay.

Keywords: Non-invasive Ventilation , Intubation Rate , Intensive Care Units

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Introduction

Non-invasive ventilation (NIV) is a procedure of providing the patient, positive pressure ventilation without the use of artificial airway like an endotracheal tube⁽¹⁾. NIV has two main types Continuous Positive Airway Pressure (CPAP) and Bi-level Positive Airway Pressure (BiPAP)⁽²⁾. Besides, NIV indicted for patients

who had acute respiratory failure, cardiogenic pulmonary oedema, and exacerbation of Chronic Obstructive Pulmonary Disease (COPD)⁽²⁾. Since artificial airways are not required for using of NIV, a fewer complication is associated with NIV comparing to invasive ventilation. Even though there are some disadvantages of using NIV such as nasal bridge ulceration and discomfort due to the mask⁽²⁾.

NIV is useful for many cases, but only a few patients could tolerate this procedure due to the discomfort of using this type of ventilation. Therefore, some studies found that using sedation during NIV technique should be considered to reduce the percentage of NIV failure and comfort the patient during NIV⁽³⁻¹³⁾. Some studies reported that NIV was challenging to apply in the Intensive Care Unit (ICU) because of patient agitation⁽⁴⁻⁶⁾. Those studies reported that, patients who use dexmedetomidine had much better outcome in term of discharge from ICU compared to those who did not use sedating⁽⁶⁻⁷⁾. Other studies showed dexmedetomidine affects the length of the ICU hospitalization and the duration of mechanical ventilation⁽⁸⁻⁹⁾. As a result, the patients who were given Dexmedetomidine have shown a remarkably decreased failure percentage of NIV, which reduced the need for intubation and eased the weaning from mechanical ventilation. On the other hand, Conti et al. showed that improving the tolerance and mitigate the discomfort of the patients undergoing NIV could be achieved with continuous infusion of Sufentanil as a single sedative agent, and obtaining a preferred level of awake sedation, without direct effect related to respiratory drive, respiratory rate, blood gas, minute volume, and hemodynamics⁽¹⁰⁾. Although some studies reported side effect of using such sedation and the need of close monitoring for those patients, the use of sedation to reduce the requirement of intubation and increase patient comfort is sensible to achieve the complete success of this ventilation⁽¹¹⁻¹⁴⁾.

Due to the daily use of NIV in ICUs, the outcome of this research will help in guiding health care providers. This research aimed to investigate the association of using sedation during NIV with intubation rate and ICUs length of stay. It is anticipated that the finding of such research would help to support the role of using sedation with the adult patients who were receiving NIV.

Methodology

This was a cross-sectional retrospective study conducted at King Abdulaziz Medical City in Riyadh KAMC during 2016 to 2018. We included all patients who have been admitted to ICU and required NIV. we excluded all adult patients who admitted to the medical wards head injury patients, patients with liver problems and patients who are older than 90 years. For each patient we search the medical file to collect information on demographic data (age, weight and height), the reason for admission, the use of sedation, type and dose of sedation, and the outcomes. Also, we collected information of the time of admission in ICU in which we utilize this to calculate the length of stay was calculated from admission day and discharge day. NIV duration was calculated from the starting hour of usage to the end of the therapy session, and the settings of NIV were obtained from the medical records. Sedation duration usage and type of sedation were collected from the starting day of sedation until the end of sedation session. Blood gas tests were obtained before using NIV and sedation (if used), and after using NIV and sedation. Intubation rates and death rates were obtained for the outcomes of using sedation with NIV therapy.

Data management and Analysis Plan:

The data had been collected and entered in Microsoft Excel, which has been transferred to SPSS afterwards for further analysis. We have used the Unpaired T-test for the continuous variables and Chi-Square for the categorical variables.

Results

From 2016 to 2018, 110 patients received NIV, of these 6 (5.45%) patient were given sedation to control agitation and discomfort during NIV, mostly were admitted due to COPD, or Pneumonia. Table 1 shows, baseline characteristics, 104 patients were not receive sedation (while only 6 patients were use sedation during NIV. COPD was the common diagnosis for the admission (31%), followed by pneumonia (20%). 10% of all study population had been died.

Five patients were using Dexmedetomidine; two of them (33.3%) showed a significant NIV success, and three of them (50%) died. And only one patient received Fentanyl that showed acceptable tolerance and

successful NIV therapy. Table 3 shows blood gas analysis which was conducted from all 110 patients, the patients who receive sedation (n=6) show improving hypercapnia compared to non-sedated patient (n=104). Using sedation did not show the effective result in reducing the length of stay in ICUs which has a mean of 10 days compared to patients who did not receive sedation with a median of 7.5 (IQR 7-18).

Table 1: the demographic characteristics of the study population of all patients and for patients who and who did not receive sedation during the non-invasive ventilation.

Variables	All patients N=110 N (%)	Patients who not receive sedation N=104 N (%)	Patients who receive sedation N=6 N (%)
Gender			
Female	52(47)	51(49)	1(16)
Male	58(52)	53(51)	5(83)
Age in years (median, IQR)	70(63-78)	69.5(63-78)	75.5(68-80)
Body Mass Index			
Underweight	7(6)	7(6)	-
Normal	23(20)	22(21)	1(16)
Overweight	19(17)	18(17)	1(16)
Obese	61(55)	57(54)	4(66)
Admission diagnosis			
COPD	35(31)	34(32)	1(16)
Pneumonia	22(20)	19(18)	3(50)
Bronchiectasis	9(8)	9(7)	-
Other respiratory condition	17(15)	16(15)	1(16)
Cardiovascular disease	20(18)	20(19)	-
Other condition	7(6)	6(5)	1(16)
Type of NIV			
BiPAP	99(90)	93(89)	6(100)
CPAP	11(10)	11(10)	-

Table 2: The blood gas parameter of all patients before and after non-invasive ventilation(NIV) and before and after using sedation.

Parameter	All patients		Patients who receive sedation	
	Before NIV Mean(SD)	After NIV Mean(SD)	Before sedation Mean (SD)	After sedation Mean(SD)
pH	7.23 (.670)	7.35 (.078)	7.38 (.051)	7.40 (.04195)
PaCO ₂	64.48 (23.338)	59.44 (23.332)	50.30 (11.596)	46.750 (10.083)
PaO ₂	60.30 (26.435)	75.01 (28.467)	62.05 (30.816)	102.283 (37.99)
HCO ₃	30.72 (9.421)	31.15 (8.756)	28.88 (5.940)	28.783 (7.7360)

Discussion

110 patients were included in this study that used NIV in ICUs and ER at KAMC. Only six (5.45%) patients were on a minimal dose of sedation with NIV to control agitation and discomfort. Most of our sample size used NIV due to COPD exacerbation.

Regarding those who were on sedation with NIV, three of them (50%) had pneumonia as a principal admission diagnosis. In this study, the most sedative drug used for those patients was Dexmedetomidine, and only one patient received Fentanyl. Moreover, two of those patients were intubated due to NIV failure, and three of them died after using sedation with NIV. Subsequently, the same patients who were intubated had passed away, and the third patient died due to family refusal for intubation. As a result, we must be aware that using sedation during NIV could lead to NIV failure, which eventually leads to intubation or increase in the mortality rate. Also, using sedation did not show the effective result to reducing the length of stay in ICUs which has a mean of 10 days compared to patients who did not receive sedation with a median of 7.5 (IQR 7-18).

In this study, we examined that using sedation during NIV did not have a substantial impact on increasing the rate of NIV success. Previous studies have shown the ability of Dexmedetomidine to improve NIV tolerance

and improve compliance, which may reduce ICU length of stay⁽⁴⁾, and sedation is safe and beneficial for those who were receiving NIV⁽¹¹⁾. In contrast, there is one research has shown that using sedation during NIV did not improve the patient comfort or NIV success⁽⁵⁾. In our study, five patients were using Dexmedetomidine; two of them (33.3%) showed a significant NIV success, and three of them (50%) died. Regarding that, only one patient received Fentanyl that showed acceptable tolerance and successful NIV therapy. In that matter, there are not many studies that show the efficacy of Fentanyl during NIV in comparison to Dexmedetomidine during NIV.

In this study, patients who were under sedation during NIV therapy resulted in a small sample size in comparison to the patients who were under no sedation. However, the outcome differences between patients who were under sedation and patients who did not receive any sedation can be informative in the management of NIV therapy with sedatives. The blood gas result shows a great improvement on the CO₂ level with the patient who received sedation during NIV rather than the patient using NIV without minimal sedation. Generally, physicians choose intubation with mechanical ventilation when NIV is not effective. For this reason, two of those who received sedation with NIV therapy were intubated due to NIV ineffectiveness. The two patients who died after being intubated were diagnosed with pneumonia

as the main reason for admission to ICU. In addition to that, pneumonia has shown 50% of the total patients who received sedation (three patients). This could provide evidence in the association of sedation with failure NIV therapy and patients who were diagnosed with pneumonia.

Our study had a few limitations. First, our sample size was small to distinguish significant differences. Moreover, most of the patients who received NIV were in ward areas; therefore, we were not able to compare the use of sedation with NIV adequately. Regardless, we had been able to show the practical use of sedation during NIV treatment. Second, in this study, the use of sedation sometime was to prepare to intubation than to calm the patient, in one case the patient was sedated to intubate, and the family refused to intubate, resulting in the death of the patient. Third, our study orchestrated in a single institution, which is both advantage and disadvantage, the institution was experienced in the use of NIV treatment; however, the practice of using sedation with NIV is not common in the region. Despite previous studies recommendation.

Our study suggested that the use of a minimum dose of sedation during NIV minimize the length of stay in ICU and reduce the intubation rate. However, we must be fully aware of the risk of mortality and hypercapnia⁽¹³⁾, although it might not be connected with the use of sedation itself, the possibility is present. Moreover, readers should take consideration of the limitless of the use of sedation in the region; therefore, our study should encourage the use of sedation to improve the synchrony of NIV therapy.

Conclusion

Based on our study the use of minimal sedation with patients on NIV therapy has shown no significant effect on preventing intubation and reduce the ICU length of stay evidenced by high mortality rate with patients who received the sedation. Also, using sedation during NIV to control the agitation and improve patient-ventilator asynchrony was not a common practice on our institution so, we recommend further similar study with larger sample size to be conducted in the local region to identify the effect of sedation on patients with NIV.

Ethical Clearance- The study was approved by the Research Ethics Committee of King Abdulla International Medical Research Center (KAIMRC), protocol number (SP18/225/R).

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Conflict of Interest: The authors declare that they have no conflict of interest

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The effect of Hyaluronic Acid as an Adjunct after Scaling and Root Planning in the Treatment of Chronic Periodontitis

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Abstract

The aim of this study is to evaluate the effect of the subgingival application of 0.8% hyaluronic acid (HA) gel as an adjunct to scaling and root planing (SRP) in the treatment of chronic periodontitis. Twenty patients with chronic periodontitis were recruited to participate in a study and divided to Group 1 (G1) treated with 8% hyaluronic acid gel as an adjunctive to scaling and root planning (HARP) and Group 2 (G 2) treated with scaling and root planning only. Plaque index (PL.I) Gingival index (G.I) and bleeding on probing (B.O.P) were evaluated pretreatment (baseline) (1st visits), one week (2nd visits), and 4 weeks (3rd visit) post-treatment. Subgingival plaque sample were taken for microbiologic analysis at baseline and 4 weeks post-treatment. Intragroup comparison result between visits for Group 1 showed that there was highly significant different for BOP, CFU, and no significant different for PLI and GI between 2nd and 3rd visit. For G 2, there was highly significant different for GI and significant for PLI and BOP, and non-significant different CFU, between 2nd and 3rd visit. Intergroup comparison for clinical parameter and bacteriological result between visits Showed that there was highly significant different in 1st visit for PLI, BOP and CFU in 3rd visit. It can be conclude that the local application of hyaluronic acid gel (0.8%) in conjunction with scaling and root planning have a beneficial effect on clinical periodontal parameter and may prevent recolonization of periodontal pathogens in patients with chronic periodontitis

Key words: *Chronic periodontitis; hyaluronic acid; root planning; microbiology.*

Introduction

Chronic periodontitis is an inflammatory and infectious diseases of all tissues supporting structure of the teeth, leading to the progressive destruction of deep periodontal tissues. They are irreversible and are accompanied by apical migration of the junctional epithelium along the root, leading to the appearance of periodontal pockets and gingival recessions ⁽¹⁾. The effective methods of treating periodontitis are Scaling and Root Planning (SRP)⁽²⁾, which is the first-line treatment for periodontitis and stopping the inflammatory process through destabilizing and removing the subgingival pathogenic biofilm and restoring an environment compatible with periodontal health ⁽³⁾. Gontiya and Galgali indicated that subgingival application of chemotherapeutic agents may be used as an adjunct to nonsurgical therapy because SRP is technically

demanding and is not always efficient in eradicating all periodontal pathogens and in lessening inflammation ⁽⁴⁾. Hyaluronan is one of the chemotherapeutic agents that used in treatment of periodontal diseases ⁽⁵⁾. Hyaluronan, anon-sulfated glycosaminoglycan, is widely distributed throughout connective tissue and epithelial and neural tissues. It is a critical component of the extracellular matrix and contributes significantly to tissue hydrodynamics and cell migration and proliferation. Hyaluronan is also produced by fibroblasts in the presence of endotoxin; it cause inhibition of tissue destruction and facilitates healing so it plays an important anti-inflammatory role ^(6,7). It has already been used in the treatment of the inflammatory process in various domains such as orthopedics, dermatology and ophthalmology. In dentistry, it played a role in treatment of the temporomandibular joint disorders, and more

recently it used in the treatment of periodontal disease due to its anti-inflammatory, anti-oedematous and anti-bacterial effects⁽⁸⁾. The topical and systemic application of HA offers a lot of benefit effects in the regulation of the host response because it's non-toxic, biocompatible, and it has numerous biochemical and physio-chemical features⁽⁹⁾. The aim of the present study was to evaluate the effect of a hyaluronan gel used in adjunct with SRP clinically and bacteriologically in the treatment of chronic periodontitis.

Material and Method

Twenty patients aged 35 to 50 years who attending the Department of Periodontics at the College of Dentistry, University of Baghdad were recruited for the study. all the patients should not had history of any systemic diseases., periodontal therapy including scaling or root planning, anti-inflammatory or antimicrobial therapy was taken within the previous 3 months and non-smokers. All the patients have chronic periodontics not less than 4 periodontal sites with pocket depth of 4mm or greater, radiographic evidence of bone loss and have at least 20 teeth. The subjects gave their written informed consent to participate in the study. The patients were divided into two groups according to type the treatment as following

- Group 1 (G1): ten patients were treated with 8% hyaluronic acid gel as an adjunct to scaling and root planning by applying of 0.5 ml of HA to the base of the pocket.

- Group 2 (G2): ten patients were treated with SRP only.

Before baseline examination, full mouth supragingival scaling was done and oral hygiene instructions was given, concerning instruction in

the modified Bass technique of brushing and the use of appropriate interdental cleaning aids. The following clinical periodontal parameters was recorded respectively: Plaque index⁽¹⁰⁾, gingival index⁽¹¹⁾ and bleeding on probing. Bacterial Sample was carried out after recording of clinical periodontal parameters. The site dried with air blast and cotton, isolated with cotton rolls to avoid contamination saliva. Subgingival plaque from periodontal pocket was excavated by gracey curette without touching adjacent tissue. The bacterial sample was suspended in 1 ml sterile thioglycolate solution in 5 ml. screw cupped bottle by vigorously agitating the tip of the instrument in the solution, and then incubated for 24 hours until evidence of growth is noted as shown by turbidity of the broth. Subcultures on blood agar solid media supplied with selective materials in the plates then plates were transported into an anaerobic jar with anaerobic gas pack incubated anaerobically for 72 hours. After incubation the total number of colony forming units (CFU) per sample was determined. The clinical parameters and bacterial samples were recorded at day 0 (baseline 1st visit) prior to treatment and were repeated after one week (2nd V), and 4 week (3^{ed} V) after treatment. During this period reinforcement of plaque control and any additional instruction were given to maintain good oral hygiene during the study period. For statistical Analysis Mean, Median, Mann –Whitney U test, Z test and Kruskal test were used, level of significant was 0.05.

Result

The Clinical periodontal parameters (which included PLI and G.I) and Bacteriological examination (CFU) was reduced in 3rd visit in compared to 1st visit for both groups as shown in Table

Table 1: Descriptive analysis of PLI , G.I and CFU of both groups in deferent time interval

	Variables	Visits	Median	Mean	S.D.	Min.	Max.
G 1	PLI	1st	1.11	1.08	0.61	0.81	1.44
		2nd	0.58	0.64	0.23	0.36	1.12
		3rd	0.48	0.56	0.24	0.27	0.92
	GI	1st	1.05	1.02	0.21	0.75	1.43
		2nd	0.47	0.53	0.33	0.15	1.15
		3rd	0.58	0.52	0.18	0.22	0.71
	CFU	1st	138	149.60	38.78	103	214
		2nd	125	130.20	23.45	92	168
		3rd	99.5	103.80	26.67	76	164
G 2	PLI	1st	0.735	0.77	0.08	0.71	0.95
		2nd	0.625	0.65	0.09	0.56	0.84
		3rd	0.575	0.58	0.06	0.5	0.65
	GI	1st	0.835	0.81	0.10	0.66	0.97
		2nd	0.645	0.67	0.09	0.61	0.88
		3rd	0.585	0.59	0.04	0.53	0.67
	CFU	1st	162.5	163.20	62.67	73	244
		2nd	154	160.00	51.15	98	250
		3rd	166.5	163.20	56.30	88	277

Also The % of Bop (score 1) in the 3rd visit was reduced in compared to 1st visit for both groups as shown able (2).

Table 2: Percentage of BOP in both groups at deferent time interval.

	Visits	%
G1	1st	74.95
	2nd	29.47
	3rd	22.79
G 2	1st	74.45
	2nd	30.47
	3rd	24.80

Intragroup comparison for clinical parameter and bacteriological result between visits for G1 was showed in table (3).

The result showed that there was highly significant different for PLI, GI, BOP and significant different for CFU between 1st and 3rd visit.

Table 3: Intragroup comparison for clinical parameter and bacteriological result for group 1 between visits using Wilcoxon signed ranks test.

Variables		1st vs. 2nd	1st vs. 3rd	2nd vs. 3rd
PLI	Z-test	-2.507	-2.814	-1.586
	p-value	0.012 (S)	0.005 (HS)	0.113
GI	Z-test	-2.405	-2.814	-0.256
	p-value	0.016 (S)	0.005 (HS)	0.798
BOP	Z-test	-2.803	-2.803	-2.803
	p-value	0.005 (HS)	0.005 (HS)	0.005 (HS)
CFU	Z-test	-1.734	-2.550	-2.803
	p-value	0.083	0.011 (S)	0.005 (HS)

Intragroup comparison for clinical parameter and bacteriological result between visits for G 2 was showed in table (4).

There was highly significant different for PLI, GI and BOP and no significant in CFU between 1st visit and 3rd visit

Table4: Intragroup Comparison between the visits using Wilcoxon signed ranks test for (G 2).

Variables		1st vs. 2nd	1st vs. 3rd	2nd vs. 3rd
PLI	Z-test	-2.809	-2.814	-1.992
	p-value	0.005 (HS)	0.005 (HS)	0.046 (S)
GI	Z-test	-2.609	-2.809	-2.814
	p-value	0.009 (HS)	0.005 (HS)	0.005 (HS)
BOP	Z-test	-2.803	-2.803	-2.395
	p-value	0.005 (HS)	0.005 (HS)	0.017 (S)
CFU	Z-test	-0.765	-0.153	-0.255
	p-value	0.444	0.878	0.798

Intergroup comparison for clinical parameter and bacteriological result between visits was showed in table (5)

It was found that's there was highly significant different in 1st visit for PLI, while BOP and CFU in 3rd visit

Table5: Intergroup Comparison between groups using Kruskal-Wallis H test.

Variables	Visits	HARP	RP	Comparison		
		Mean	Mean	X2	d.f.	p-value
PLI	1st	1.08	0.77	17.081	2	0.000 (HS)
	2nd	0.64	0.65	0.668	2	0.716
	3rd	0.56	0.58	2.358	2	0.308
GI	1st	1.02	0.81	4.242	2	0.120
	2nd	0.53	0.67	2.908	2	0.234
	3rd	0.52	0.59	1.266	2	0.531
BOP	1st	74.95	74.45	0.375	2	0.829
	2nd	29.47	30.47	9.511	2	0.514
	3rd	22.79	24.80	1.329	2	0.009 (HS)
CFU	1st	149.60	163.20	0.194	2	0.908
	2nd	130.20	160.00	1.251	2	0.535
	3rd	103.80	163.20	8.734	2	0.003 (HS)

Discussion

The result showed that there was significant reduction in all clinical parameters for all groups. The inter comparison groups showed that there was significant difference in Bop at deferent time interval when compare G1 and G2 .This observation is in concert with previous reports who found that HA could be used as an adjunct to mechanical therapy, it can accelerate tissue healing because it has anti-inflammatory and anti- edematous properties⁽¹²⁾. Al-Shammari found that

The local application of 0.8% hyaluronan gel with SRP have a positive effect on periodontal health in chronic periodontitis patients after 6 and 12 weeks⁽¹³⁾. Johannsen *et al* ⁽¹⁴⁾, Gontiya, Galgali ⁽¹⁵⁾ and Polepalle *et al* ⁽¹⁶⁾ who found a significant improvement in all clinical gingival parameters following subgingival application of a 0.8% HA gel in addition to root debridement (SRP). This beneficial effect of HA on gingival inflammation is also observed by Pilloni *et al* ⁽¹⁷⁾ when used as an adjunct to mechanical home plaque control. Also this observation is in concert with previous reports who found that the

improvement gingival health after the supragingival application of various hyaluronan formulations in subjects with gingivitis⁽¹⁸⁾. The result of this study Disagree with Xu *et al*⁽¹⁹⁾, who investigated the effect of a subgingivally administrated hyaluronan gel in combination with SRP, found no differences between the hyaluronan and control groups relative to BOP and PLI. The improvement in periodontal parameter was more noticeable in the test group in comparison to the control group, suggesting a positive effect of HA on wound healing. HA has numerous roles in the initial inflammatory stages, such as improved inflammatory cell infiltration into the inflammatory site, in order to speed up the gingival immune response. HA has a role in migration and adherence of polymorphonuclear leukocytes and macrophages at the inflamed site, and phagocytosis and destruction of microbial pathogens. So HA directly prevents proliferation of anaerobic pathogenic bacteria. It also indirectly acts to moderate inflammation and stabilize the granulation tissue by preventing degradation of the extracellular matrix (ECM) proteins by enzymes-protease of inflamed cells⁽⁸⁾. Because its complex interactions with the extracellular matrix and its components, HA is a candidate for use in the restoration of periodontal integrity. Hyaluronan administration to periodontal wound sites could achieve comparable beneficial effects in periodontal tissue regeneration and periodontal disease treatment⁽⁷⁾.

The result showed that there was significant reduction of anaerobic bacterial count for G1, For G2 there was initial reduction for bacterial count and then count of bacteria increase after 4 week. This agreement with Zijng *et al*⁽²⁰⁾, who conducted that after the initial reduction of total bacterial load in periodontal pocket followed by increased again in weeks and months after treatment and this may result of more intention paid to oral hygiene by patient before entering the study .

This result showed that HA had antibacterial effect and this in agreement with many studies^(21,14,16). HA seemed to be able to stabilize these low counts for a longer period and prevent the early regrowth of these bacterial species. In addition, Eick *et al*⁽²²⁾ concluded that HA stabilizes low rates of periodontal microbial flora, and prevents the re-growth of certain bacteria . Palak D Batavia **found** that there was reduction of organisms from slightly positive (+) to undetected (-) after topically

and intrasulcularly application of HA⁽²³⁾. This study is compatible with Xu *et al*⁽¹⁹⁾ who concluded that HA was applied once a week in vivo, and no influence was seen on the counts of periodontopathogenic bacteria. High molecular-weight HA gel reduces cell proliferation in gingival epithelial cells, fibroblasts and lymphocytes, decrease the inflammatory process, and improves periodontal lesions in patients with chronic periodontitis⁽²⁴⁾.

Conclusion

The local application of hyaluronic acid gel have beneficial effect on periodontal health, also have antibacterial effects on periodontal pathogenic bacteria as an adjunct to SRP.

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Health and non-Health College Students' Perception of Scaling Insurance

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Abstract

To investigate the awareness and improvement requirements of this study was conducted on college students who were the beginnings of adulthood and who were subject to scaling health insurance. Subjects were divided into health and non-health college students to investigate the perception of whether or not to apply scaling health insurance, payroll costs, and the number of benefits. In addition, this study was conducted to provide basic data for the long-term scaling health insurance business to become a social system for improving the quality of life of the people

The subjects of this study were to have health and non-health college students respond to the questionnaire from October 10th to October 23rd, 2019 by using the self-assessment writing method and the total of 341 questionnaire was analyzed as the final subject. Cross-analysis was used to verify the difference in perception of the presence or absence of scaling to the general characteristics of the study subjects, and t-test was used to verify the difference in the recognition score for the detailed criteria of scaling insurance. The significance level of the collected data was verified at $p < 0.05$.

Recognition of scaling benefits was high in 32.5% of health and 25.7% of non-health college students and the awareness of detail was low in all items. In the improvement requirements, the highest response from both health and non-health sectors were that to increase the number of scaling which is covered in dental insurance in south Korea more than once per year. Looking at the needs of health-related and non-health related college students for the scaling health insurance benefit project, 16.2% of respondents wished to increase the number of times applied per year, 11.7% needed business promotion, 11.2% answered it should included the stain removal (colorants), 9.2% wished age-reduced relief for the business, 6.6% for the cost adjustment in the health-related college student.

To raise awareness about scaling salary among college students, it is necessary to recognize the importance of oral health through education and promotion on scaling. In order to raise awareness about scaling insurance among college students, it is necessary to recognize the importance of oral health through education and promotion of scaling. Through this study, it is thought that the scaling health insurance reimbursement project will contribute to the improvement of oral health of the people and furthermore to a healthy life. In the future, the government should continue to develop policies to promote oral health by collecting thoughts and opinions of college students and others as well.

Key words: *scaling, college students, awareness*

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Introduction

In modern society, as the level of education, income increases and aging, interest in social welfare increases, and the need for medical quality and services is increasing as well¹⁾. Currently, South Korea's national

health insurance system is implemented, and it is making efforts to pursue a healthy life for the people by providing and environment where all people can receive medical benefits without a burden. However, the National Health Insurance System provides medical care centering on serious diseases such as cancer or those requiring hospitalization, and has not been greatly benefited in the dental field where there is little need for hospitalization or severe diseases²⁾. The oral cavity is the first step in the digestive system, and maintaining healthy teeth and healthy periodontal tissue is an essential element in leading a high-quality life, and the importance of oral health is increasing³⁾. The most common oral diseases are dental caries and periodontal diseases, especially periodontal diseases are a serious oral disease with a high incidence among Korean adults. Periodontal disease is often treated after the alveolar bone is destroyed and the tooth is shaken because there are almost no subjective symptoms at the early stage. Once the alveolar bone is destroyed, it is impossible to regenerate it, so it is very important to find and prevent it early. A typical method for preventing periodontal disease is proper brushing and scaling. Proper brushing is important, but it is necessary to remove the major causes of periodontal diseases such as dental hygiene membrane, plaque, and calculus which are difficult to remove by only brushing by performing regular scaling managed by experts⁴⁾.

However, health insurance was applied to scaling only in the case of periodontal disease from July 2001, and in the case of removal of calculus accompanied by gum treatment or surgery, most people were able to receive scaling by paying a high amount⁵⁾. Accordingly, the Ministry of Health and Welfare induces regular scaling of the public by extending the application of scaling health insurance once a year to health insurance subscribers and insured persons over the age of 20 from July 1st, 2013, so that they can receive a scale of approximately 14,000 won per clinic. As a result, it is possible to prevent periodontal disease and to save time and economic costs through treatment of periodontal disease⁶⁾.

However, despite the application of scaling health insurance, gingivitis and periodontal disease were ranked first in the outpatient status by multi-incident ranking by disease subclass according to the health insurance review and evaluation statistics released

in the third quarter of 2019⁷⁾. Recently, it has been reported that periodontal disease can be related to cause heart diseases, cerebrovascular diseases, and coronary artery disease. Thus, measures for periodontal disease management is urgent⁸⁾.

Therefore, this study was conducted on college students who were the beginnings of adulthood and who were subject to scaling health insurance. Subjects were divided into health and non-health college students to investigate the perception of whether or not to apply scaling health insurance, payroll costs, and the number of benefits. In addition, this study was conducted to provide basic data for the long-term scaling health insurance business to become a social system for improving the quality of life of the people.

Material and Methods

Research Subject

From October 10th to October 23rd, 2019, college students in their 20s were randomly selected. The purpose of the study was described, and subjects with voluntary consent were asked to respond to the questionnaire by themselves using the self-assessment method, and 341 persons except for unfaithful responses were taken as final subjects and collected and analyzed.

Research Method and evaluation

This study used a questionnaire to find out the perceptions of health-related and non-health related college students about the scaling health insurance benefit project. The collection of data was conducted by distributing the Naver Form (mobile) questionnaire or paper questionnaire to the survey subjects, and the collected data were analyzed using the SPSS (Statistical Package for the Social Science) 24.0 program.

The frequency and percentage were calculated by conducting a frequency analysis to find out the general characteristics of the study subjects, the recognition degree for scaling insurance, the recognition route, and the recognition timing and the detailed criteria for scaling insurance.

Cross-analysis was used to verify the difference in perception of the presence or absence of scaling to the general characteristics of the study subjects, and t-test

was used to verify the difference in the recognition score for the detailed criteria of scaling insurance.

The significance level of the collected data was verified at $p < 0.05$.

Research Results

Shows the general characteristics of the study

subjects. In the case of gender, the proportion of women was 16.1% for men and 83.9% for women. In the case of majors, there were 57.8% of health related college students and 42.2% of the non-health related college students (Table 1.)

Table 1: General characteristics of study subjects

Sort		Frequency (No.)	Percentage(%)
Gender	Men	55	16.1
	Women	286	83.9
Majors	Health related	197	57.8
	Non-health related	144	42.2
Total		341	100

1.1. Recognition degree, recognition path, and recognition period according to majors in the scaling health insurance benefit business shows the recognition rate, recognition route, and recognition time according to the majors of the scaling health insurance benefit program. Among the health-related college students, about 66.5% of respondents answered “do not know” and 33.5% of respondents answered “know” about the scaling health insurance benefit project. As for the recognition route, “being informed” was the highest with 12.2%, ‘via an expert when visiting the hospital’ was 9.1%, ‘via the internet’ was 5.1%, and ‘via media’ was 4.6%. As for the recognition period, ‘after one month of project implementation’ was 16.8%, ‘within one-month project’ was 7.6%, ‘before project implementation’ was 5.1%, and ‘after six months of project implementation’

was followed by 4.1%.

Among the non-health related college students, about 74.3% of respondents answered “do not know” and 25.7% of respondents answered “know” about the scaling health insurance benefit project. As for the recognition route, ‘being informed around’ and ‘via an expert when visiting a hospital’ was the highest at 9.0%, ‘via the internet’ was 5.6%, ‘via media’ was 2.1% and ‘via education’ was followed by 0%. As for the recognition period, ‘after one month of project implementation’ was 15.3%, ‘after six months of project implementation’ was 4.2%, ‘before project implementation’ was 3.5%, and ‘within one month of project implementation’ was followed by 2.8%(Table 2).

Table 2: Health and non-health related college students’ perception of scaling insurance and the route of recognition and period

Sort		Health related		Non-health related	
		Freq. (No.)	Percentage (%)	Freq. (No.)	Percentage (%)
Awareness	Know	66	33.5	37	25.7
	Do not know	131	66.5	107	74.3
Recognition Route	Via media (TV, Radio, Newspaper)	9	4.6	3	2.1
	Via internet	10	5.1	8	5.6
	Being informed (Family, Neighbor, Friends, meeting, etc.)	24	12.2	13	9.0
	via an expert (Doctor, Dental hygienist) when visiting a hospital	18	9.1	13	9.0
	Via education (Special lecture)	5	2.5	0	0.0
	Did not know	131	66.5	107	74.3
Recognition period	Before project implementation	10	5.1	5	3.5
	Within one month of project implementation	15	7.6	4	2.8
	After one month of project implementation	33	16.8	22	15.3
	After six months of project implementation	8	4.1	6	4.2
	Did not know	131	66.5	107	74.3
Total		197	100	144	100

1.2. Perceptions of detailed criteria for scaling insurance by health and non-health students

shows the awareness of the detailed criteria of scaling insurance for health and non-health college students.

Among the health-related college students, 22.8% answered ‘Applicable criteria are over 20 years old’, 20.3% for ‘Number of times that scaling health insurance can be applied for one year’, 19.3% for ‘Expenses to be paid by patients after applying scaling health insurance’, 8.6% for ‘the procedure that is not included

in the insurance’, and 7.6% for ‘when the scaling health insurance was renewed’.

Among the non-health related college students, 20.8% answered ‘Number of times that scaling health insurance can be applied for one year’, 17.4% for ‘Applicable criteria are over 20 years old’, 17.4% for ‘Expenses to be paid by patients after applying scaling health insurance’, 9.7% for ‘the procedure that is not included in the insurance’, and 6.3% for ‘when the scaling health insurance was renewed’ (Table 3).

<Table 3> Perceptions of detailed criteria for scaling insurance by health and non-health college students

Questions		Health related		Non-health related	
		Freq. (No.)	Percentage (%)	Freq. (No.)	Percentage (%)
1	The number of times applicable for one year is one time	40	20.3	30	20.8
2	Applicable criteria are over 20 years old	45	22.8	25	17.4
3	Personnel expenses is around 14,000 won	38	19.3	25	17.4
4	July to be renewed every year	15	7.6	9	6.3
5	Removal of tooth colorants is not covered	17	8.6	14	9.7

Recognition score for detailed criteria of scaling insurance according to the general characteristics of the study subjects

4 shows the recognition scores for the detailed criteria for scaling insurance according to the gender of the study subjects. Out of 5 points, men scored 0.91 points, women scored 0.83 points, and the recognitions scores for the detailed criteria for scaling insurance according to major fields were 0.87 points in the health-related students and 0.81 points in the non-health related students (Table 4).

<Table 4> Recognition score for detailed criteria of scaling insurance according to the general characteristics of the study subjects

Sort		Mean	Standard Deviation	p-value*
Gender	Men	0.91	0.21	0.479
	Women	0.84	0.09	
Majors	Health-related	0.87	0.11	0.305
	Non-health related	0.81	0.12	

*By independent sample t-test

Research on subjects' demand for improvement on the benefits of scaling health insurance shows the demand for improvement of the study subjects' scaling health insurance benefits.

In the health-related students, 16.2% answered 'number of applications per year', 11.7% for 'business promotion', 11.2% for 'add stain removal', 10.7% for 'addition of oral care education', 9.2% for 'age

restriction on insurance', and 6.6% for 'cost adjustment' were followed.

In the non-health related students, 12.5% answered 'number of applications per year', 11.8% for 'age restriction on insurance', 11.1% for 'add stain removal', 8.3% for 'cost adjustment', and 'business promotion', and 6.9% for 'add oral management education' were followed. (Table 5).

<Table 5> Subjects' demand for improvement on the benefits of scaling health insurance (Unit: No. (%))

	Health-related	Non-health related
Age restrictions for insurance	18(9.2)	17(11.8)
Cost adjustment	13(6.6)	12(8.3)
Number of times applied per year (once a year)	32(16.2)	18(12.5)
Add oral management education	21(10.7)	10(6.9)
Include stain removal	22(11.2)	16(11.1)
Business promotion	23(11.7)	12(8.3)
No response	113(59.4)	80(55.6)

Consideration

As a college student, it is necessary to establish proper health care habits and take responsibility for health physically, mentally, and socially. However, indifferent behaviors and attitudes can be the cause, making it difficult to form good health habits⁹⁾. At this time, correct health care habits can be linked to the elderly which can affect oral health¹⁰⁾, and social attention is needed to ensure that correct health care habits are formed in college⁹⁾.

Therefore, this study identified differences in the perceptions between health and non-health students to determine how much college students in their 20s perceived the scaling health insurance benefit business and it was conducted to improve the importance and necessity of scaling, oral health concerns, and to provide basic data on oral health policy, as a way for preventive

scaling health insurance benefits to maintain oral health.

First of all, the survey subjects' awareness of scaling is within the health insurance was as follows: 66 out of 197 students (33.5%) in health-related students, and 37 out of 144 (25.7%) in non-health related students answered 'know'. The cognitive rate was lower than 55.3% of Lee¹¹⁾, 65.2% of Lee¹²⁾, 71.0% of Joo¹³⁾. This is considered to have been low due to lack of interest shortly after becoming a college student in adulthood, after six year of health insurance benefits were applied to scaling. The route for students to learn about the insurance coverage for scaling was the highest at 12.2% when they came to know from their acquaintances, followed by 9.1% when they visited a dentist or dental hygienist during a hospital visit. The route for non-health related students learn about the insurance coverage for scaling was 9.0% when they learned from their acquaintances and through dentist and dental hygienists

when visiting hospitals. This is thought to be a lack of a path to recognize health insurance for scaling due to the limited broadcasting and terrestrial media on oral health education for college students in early adulthood, where periodontal disease prevention is important.

According to the result of examining the perception of the detailed criteria of the scaling health insurance, the recognition rate was low with 20.3% of the health-related students and 20.8% of the non-health related students. In the case of the question about the criteria for the coverage of scaling health insurance, the recognition rate was low with 22.8% for health-related students and 17.4% for non-health related students. The recognition rate when asked about the cost to patients after applying scaling health insurance was 19.3% in health-related students and 17.4% in the non-health related students. In the studies of Lee and Lee¹⁴), the number of applications was 54%, the amount of application was 62.8%, and the application age was 47.5%, which was higher than this study. In order to raise the awareness of the detailed standards, it is considered that it is necessary to prepare a method that not only recognizes the fact of salary for scaling, but also delivers the details of the standards.

The recognition scores for the detailed criteria for scaling insurance of health and non-health related students were out of 5 points and scored 0.88 and 0.81 respectively. Although the degree or recognition was not significantly different, the health-related students was slightly higher than the non-health related students.

For health-related students, the requirements to improve scaling health insurance benefits was the highest in 14.7% for the number received per year, 11.7% in the business promotion, 11.2% in the opinion that it would also include removing stains (colorants), 10.7% in the including oral management education, 9.2% in the age limit of insurance, and 6.6% in the cost control. The non-health related students' requirement for improvement in scaling health insurance benefits was the highest in 12.5% of the number received per year, 11.8% in the age limit of insurance, 11.1% in the include removing stains (colorants), 8.3% in the cost control and business promotion, and 6.9% in the including oral management education. Both health and non-health related students had the highest change in the number of times they were applied once a year in scaling. According to the results

of studies by Lee¹¹), and Joo¹³), scaling 'time to fit' was twice a year, more than once per year which is currently in effect. It is considered that the frequency of scaling required by experts varies depending on the subject's oral hygiene status or oral hygiene management ability.

The purpose of this study was to provide basic data on health insurance benefits by comparing the recognition and its scores of health and non-health related students after three years of scaling health insurance benefits that has been implemented. Although, in this study, the gender of respondents who answered the questionnaire was 55 men and 286 women, and it was difficult to generalize the results because women were more than 4 times larger than men. In addition, as less than one-third of respondents said they knew about scaling insurance coverage, the proportion of non-responses to the questionnaire was high, so there were many errors to be generalized. However, this study is meaningful in that it aims to provide a basis for improvement and revitalization of future project by grasping the awareness and improvement requirements of scaling benefits for health and non-health students. In the future research, it is necessary to further refine the questionnaire, and continuous research should be conducted for the development and stable settlement of the scaling benefit project.

Conclusions

This study investigated the recognition, its scores, and improvement requirements of health and non-health college students about the preventive scaling health insurance reimbursement project implemented since July 2013. The study was conducted from October 10th, 2019 to October 23rd, 2019 for health and non-health college students.

In order to objectively judge how well the health and non-health college students know about the detailed criteria as well as whether they are implemented, the questionnaire was presented in the form of a question about the detailed standards, and the research method for the results is analyzed by frequency.

1. Regarding the fact that preventive scaling is possible with health insurance through the scaling health insurance reimbursement project, in the group of health-related college students, 32.5% answered that they

'know' and 67.5% answered 'do not know'. As for non-health related college students, 25.7% answered 'know' and 74.3% answered 'do not know'.

2. Recognition routes were highest among health-related college students by 12.2% through acquaintances, followed by 9.1% through experts when visiting hospital, and 5.1% through internet. In the case of non-health related college students, the highest level was 9.0% when they were informed by experts and through their acquaintances, followed by 5.6% through internet. (Non-response rate was too high)

3. As for the degree of awareness of the details of the scaling health insurance reimbursement project, the criteria applied to health college students accounted 22.8% for the applicable standards, followed by 20.3% for the number of times that scaling health insurance could be applied for one year, 19.3% for the out-of-pocket costs, 8.6% for the procedures that are not included in health insurance, and only 7.6% were aware of the question of when scaling health insurance was renewed, indicating that the recognition was low.

For non-health related college students, the number of times that scaling health insurance can be applied for one year was 20.8%, the applicable standards and the cost of copayment accounted for 17.4%. 9.7% thought that scaling is not included in the health insurance and only 6.3% of respondents were aware of the question of when scaling health insurance was renewed. (Non-response rate was too high)

4. Recognition scores for the detailed criteria for scaling health insurance were 5 out of 5, with a health-related student of 0.87 points and a non-health related student of 0.81 points showing that although the degree of recognition was not significantly different, the health-related college student was slightly higher than the non-health college student.

5. Looking at the needs of health-related and non-health related college students for the scaling health insurance benefit project, 16.2% of respondents wished to increase the number of times applied per year, 11.7% needed business promotion, 11.2% answered it should include the stain removal (colorants), 9.2% wished age-reduced relief for the business, 6.6% for the cost adjustment in the health-related college student.

In the case of the non-health related student, 12.5% of respondents wished to increase the number of times applied per year, 1.8% of age-reduced relief for business, 11.1% of stain removal should be included in the insurance, 8.3% for both business promotion is necessary and the cost adjustment needed. It was found that the demand for improvement in the number of times per year was high in both sectors.

In order to raise awareness about scaling insurance among college students, it is necessary to recognize the importance of oral health through education and promotion of scaling. Through this study, it is thought that the scaling health insurance reimbursement project will contribute to the improvement of oral health of the people and furthermore to a healthy life. In the future, the government should continue to develop policies to promote oral health by collecting thoughts and opinions of college students and others as well.

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Food Habit and Risk of Pre Diabetes and Type2 Diabetes among the Meiteis of Manipur, India

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Abstract

Background: The eating pattern and types of food consumption are associated with the risk of type 2 diabetes. The present study aims at finding out the association between the types of food consumption and prevalence of type 2 diabetes among the Meiteis of Manipur, India.

Methods: A total of randomly selected 1026 Meitei subjects which include both sexes (25 to 65 yrs.) from Five valley districts of Manipur were tested for fasting blood glucose levels using AccuCheck Active Glucometer. Each and individual was personally interviewed for dietary assessment.

Result: Among the studied population, the most commonly consumed food items for breakfast is deep fry pooris (20.66%), while 46.39% go for an early meal skipping their breakfast though no significant difference is observed between breakfast eaters and non-eaters. Considering the meals, though consumption of mixed white rice was found higher (51.4%) than the consumption of Meitei indigenous white rice (48.6%), the prevalence of pre-diabetic 40.5% and diabetic 16.0% was found significantly higher among the Meitei indigenous white rice eaters.

Conclusion: There is an increased risk of pre-diabetic and diabetic. Therefore, it is recommended that people should eat mixed white rice to reduce the risk of type 2 diabetes.

Keywords: Breakfast, White rice, Lifestyle, Food habit, Meitei, Diabetes

Introduction

The most common lifestyle disease is type 2 diabetes mellitus (DM), which is multifactorial that results to malfunctioning of many organs in man. Diabetes Mellitus is defined as a metabolic syndrome characterized by chronic hyper glycemia due to disturbances of fats, carbohydrate, and protein metabolism that are associated with absolute or relative deficiencies in insulin secretion, insulin action, or both¹. Western dietary pattern is

characterized by increased consumption of red meat, processed meat, French fries, high-fat dairy products, refined grains, and sweets and desserts. These patterns are associated with T2D risk². The proportion of people who reported regularly consuming breakfast has been decreasing over the past decades among children, adolescents and adults as many of them started skipping breakfast^{3,4}. In a recent cross-sectional study among the US adults, consumption of ready-to-eat cereal breakfast was associated with a better cardio metabolic risk profile than was with the consumption of other types of breakfast⁵. A study reported that skipping breakfast is associated with obesity and an increased risk of type 2 diabetes⁶.

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Risk of Type 2 Diabetes:

There are several risk factors triggering type 2

diabetes, both genetic and environmental factors like physical activity, obesity status, dietary habit, age, alcohol consumption and smoking etc. In today's world diet plays a vital role in causing type 2 diabetes. An unbalanced dietary habit with readily available prepared food or pack food leads to physically inactiveness and overweight.

Diet is a significant risk factor for diabetes. Diet, consisting of higher and inadequate fat intake, higher carbohydrate, but lower protein intake promotes the onset and increases the susceptibility to diabetes, cardiovascular disease, and other associated diseases. Higher dietary fat intake is associated with insulin resistance and obesity. Reduced fibre consumption and an increase in the consumption of refined carbohydrates are associated with an increased risk of developing T2D⁷. A prospective study found that regular consumption of white rice is associated with an increased risk of T2DM, whereas replacement of white rice by brown rice or other whole grains is associated with a lower risk⁸.

Rice is widely cultivated and consumed especially by the Asian population. Rice which is now grown worldwide, provides food for more than half of the world's population, particularly those living in some of the most populous countries, such as India, China, and Japan. Higher consumption of white rice is significantly associated with increased risk of type 2 diabetes, particularly in Asian (Chinese and Japanese) populations^{9,10,11}. A significant positive relation between white rice consumption and risk of diabetes was observed among two cohorts of Chinese and Japanese women^{10,11}. White rice is the highest contributor to dietary glycaemic load for all the populations that consume rice as a staple food^{10,11}.

Furthermore, white rice has a higher glycemic index (GI) compared to brown rice and other whole grains¹². Starchy foods such as boiled white potatoes, French fries, and white rice are high in glycemic index¹³. High glycemic Index diets have been observed to have co-relation with an elevated risk of T2DM in several prospective cohort studies^{11,14}. The Middle East is estimated to have the highest relative increase in the prevalence of T2DM by 2030¹⁵. Rice has low in fibre and has a high glycemic index, meaning it can increase blood sugar levels very rapidly¹⁶.

Based on the findings of the earlier researchers who had worked on different parts of the globe, it is reported that food habit more particular types of food consumed has a correlation with the incidence of T2DM. Steered by these findings, the present study aims at examining if there is any correlation between the types of food consumed and type 2 diabetes among the Meiteis of Manipur.

The Meiteis who are the subjects of the present study is the dominant caste group found distributed in 5 (five) valley districts of Manipur - one of the small states of the North-Eastern Indian Union situated on the Indian-Myanmar border. Considering what the various writers said about the possible origin of the Meiteis of Manipur, the researchers traced the origin of the Meiteis to have a connection with Aryan, Mon Kmer and Tai, Tibeto-Burman and Naga-Kuki^{17,18}.

The staple food of Meitei is white rice; they consume it at least twice a day as a practice. The Meitei people do not have the habit of eating heavy breakfast; they therefore solely depend on white rice in the form of meals for their daily consumption.

Since there is high consumption of white rice among the Meitei people, the present study hypothesized that there must be a high prevalence of pre-diabetic and type 2 diabetes among the Meitei of Manipur.

The Meiteis of Manipur consumes different types of food. Irrespective of different districts, they have common food consumption; those people who used to eat regular breakfast prefer to have deep fry poori, bread, biscuit, milk, etc. The Meiteis distributed in different districts of Manipur have the same food habit. Unlike mainland India and Western countries, people of Manipur don't have the habit of consuming heavy breakfast which can last till afternoon. With the quantity of food consumed, the risk of different lifestyle diseases also differs. White rice is a food that cannot be replaced by any other food among the Meiteis of Manipur.

Most of the Meitei people of Manipur consume mixed rice (local Manipuri indigenous white rice mixed with imported rice from other states popularly known as superfine rice. There are quite a number of local varieties of white rice with a different local name but with a common name '*Chak athotpa*' meaning soft rice widely

cultivated all over the valleys and hills of Manipur. This indigenous white rice has high starch content and aromatic flavour. They are tastier and costlier than the non-sticky white rice. On the other hand, the non-sticky white rice commonly known as superfine rice (mostly imported) they are rarely cultivated in the Valleys of Manipur. These white rice can be of two varieties, sticky white rice with high starch content and non-sticky white rice with very low starch content. All the types of superfine white rice are mostly imported from outside (other states of India) and are non-sticky and contain little starch. Therefore, in the present study, the consumption of different kinds of white rice is carefully examined and recorded during the data collection. The Meiteis of Manipur, eat three different varieties of white rice, i.e. either only *Chak Athotpa*, or only superfine rice or both mixed. But in general, most of them consume either *Chak Athotpa* or mixed white rice. Therefore, in the present study, subjects belonging to these two categories are considered.

Materials and Methods

In this present study altogether, 1026 participants comprising of 517 males and 509 females, age ranging

between 25 to 65 years representing the five valley districts viz. Imphal East, Imphal West, Thoubal, Kakching and Bishnupur districts (table 1) were recruited by using multi-stage random sampling technique.

The fasting blood glucose level was recorded with the help of Accu Check Active Glucometer for all the participants. A set of close-ended structured questions relating to their dietary habits such as food items for breakfast, types of white rice consumed and frequency of consumption were administered to them. Meiteis do not have the habit of having heavy breakfast, but mainly depend on rice consumption. All the participants in the present study consume rice twice a day, one at morning as morning meal and second at night as dinner. None of the participants skipped rice consumption for a day or either of the meal. None of them substitutes rice with either roti, chappati or any other food item. None of them replaces white rice with black rice. Hence, the study was conducted purely only on white rice consumption and breakfast items among the Meiteis of Manipur. Since the present work is based on qualitative data, chi-square goodness of fit has been applied to check if there is any significant difference.

Table 1: District wise Distribution of Sample

Population	Imphal East	Imphal West	Thoubal	Kakching	Bishnupur	Total
Male	98	100	103	107	109	517
Female	109	100	98	99	103	509
Total	207 (20.18%)	200 (19.50%)	201 (19.60%)	206 (20.08%)	212 (20.66%)	1026

Source: Authors data

Survey period-2019

Results and Discussion

The most common food items eaten by the Meiteis of Manipur at the time of morning breakfast are deep fry roti or poori, bread, biscuit, plain milk, and tea. Only a few families among the studied population eat fruits,

eggs, noodles, etc. Some of the subjects eat mixed food item; hence they were over-counted, resulting in 1051 persons instead of the actual sample size of 1026, (table 2). The type of food pattern was noted after an in-depth interview and cross-questioning the regularity.

Table 2: Food Items Consumed at Breakfast time

Type of Food	Frequency	Percentage
Deep fry Poori	212	20.17
Bread	155	14.75
Biscuit	109	10.36
Not Specified (mixed)	44	4.19
Milk	27	2.57
Fruits	22	2.09
Bread + Egg	6	0.58
Skipped	476	45.29
Total	1051	100

Source: Authors data

Survey Period-2019

Among the studied population, irrespective of age and sex, the most commonly consumed food item of breakfast is deep fry poori (20.17%) combined with some vegetables stir fry or gravy food. It is readily available in most of the tea stalls and hotels elsewhere in the localities and market. They are also tasty that blends a perfect combination. Hence, people prefer to consume it more than any other menu. The high incidence of Pre Diabetic individuals was found among those who eat deep fry poori (38.68%) in their breakfast as compared to other food items. There is a high incidence of Type 2 Diabetes among those people who take milk (29.62%) regularly. Though there is variation in the rate of Pre Diabetic and Type 2 Diabetes with different food item consumed in breakfast, it does not show any statistically significant difference ($\chi^2=10.625$, $df= 14$, $p<0.122$, table 3). Therefore, different food items consumed as

breakfast does not play a vital role in developing Type 2 Diabetes among the Meiteis of Manipur. At the same time, though the findings of the present work reveal some difference in the frequency percent distribution among the participants who are regular breakfast eater and those who skipped their breakfast, there is no statistically significant difference in the prevalence of diabetes, ($\chi^2=2.6723$, $df= 8$, $p< 0.262$, table 4). The main reason for this finding may be that people of Manipur do not eat heavy breakfast like those in mainland India and other countries. Consuming two slice of bread or two pieces of fried poori daily does not have any impact for resulting in the incidence of diabetes, unlike those in other places, countries, where they consume heavy breakfast, which includes bread, butter, milk, egg, sausage, etc. at one time.

Table 3: Type of Food and Incidence of Pre-diabetes and Type 2 Diabetes among the Meiteis of Manipur Valley

Food item	Blood Glucose levels						Total	
	Normal		Pre-diabetes		Diabetes			
	f	%	f	%	f	%	f	%
Deep fry Poori	103	48.58	82	38.68	27	12.74	212	100
Bread	75	48.39	52	33.55	28	18.06	155	100
Biscuit	65	59.63	32	29.36	12	11.01	109	100
Not Specified	20	45.45	13	29.55	11	25.00	44	100
Milk	11	40.74	8	29.63	8	29.62	27	100
Fruits	9	40.9	11	50.1	2	9.0	22	100
Bread + Egg	6	100	0	0	0	0	6	100
Skipped	259	54.41	163	34.24	54	11.35	476	100
Total	548		361		142		1051	

$\chi^2=10.625$, $df= 14$, $p<0.122$

(Survey period- 2019)

Table 4: Prevalence of Pre Diabetes and Diabetes among Breakfast Eater and Skipper Meiteis of Manipur Valley

Consumption Pattern	Blood Glucose levels						Total	
	Normal		Pre-diabetic		Diabetic			
	f	%	f	%	f	%	f	%
Eat Breakfast (53.60%)	277	50.37	194	35.27	79	14.36	550	100
Skipped (476%)	259	54.42	163	34.24	54	11.34	476	100
Total	536 (52.34%)		357 (34.80%)		133 (12.96%)		1026	

$\chi^2=2.6723$, $df= 8$, $p< 0.262$

(Survey period- 2019)

The eating pattern and types of food consumption are associated with the risk of Type 2 Diabetes. Rice is widely cultivated all over Manipur and all over Asia. White rice being the staple food of Meiteis, all the Meitei people of Manipur consume white rice. Despite that they also consume white rice of different varieties having different flavours. These include white rice landrace cultivated or as well as imported from other states.

A significant positive association between white rice consumption and risk of diabetes was observed among two cohorts of Chinese and Japanese women^{10,11}. White rice is the primary contributor to dietary glycaemic load for populations that consume rice as a staple food^{10,11}. Higher consumption of white rice is associated with a

significantly increased risk of type 2 diabetes, especially in Asian (Chinese and Japanese) populations^{9,10,11}.

White rice being the staple food of Meiteis all the Meitei population of Manipur valley consume white rice, despite that they also consume different varieties and flavours of white rice, these include white landrace rice as well as imported from other states. Among the studied population of 1026 participants, 51.4% consume mixed white rice, while 48.6% consume only Meitei indigenous white rice. Though the consumption of mixed white rice was found higher, the prevalence of pre-diabetic 40.5% and diabetic 16.0% was found significantly higher among the people who consume only Meitei indigenous white rice than

Table 5: Type of Rice Consumption and Risk of Pre Diabetic and Type 2 Diabetes among the Meiteis of Manipur Valley

Type of Rice	Blood Glucose levels						Total	
	Normal		Pre diabetic		Diabetic			
	f	%	f	%	f	%	f	%
Meitei white rice (51.4%)	217	43.5	202	40.5	80	16.0	499	100
Mixed (48.6%)	319	60.5	155	29.4	53	10.1	527	100
Total	536 (52.34%)		357 (34.80%)		133 (12.96%)		1026	

$\chi^2=30.338, df= 2, p< 0.000$

(Survey period- 2019)

their counterparts (pre-diabetic 29.4% and diabetic 10.1%) thus revealing a statistically significant difference ($\chi^2=30.338, df= 2, p< 0.000$, table 5). Diet is a significant risk factor for diabetes. Diet, consisting of higher and inadequate fat intake, higher carbohydrate, but lower protein intake promotes the onset of diabetes. It increases the susceptibility to diabetes such as cardiovascular disease, Type 2 Diabetes, Hypertension and other associated disorders.

As Revealed from these findings, there is increased risk of developing both pre diabetes and type 2 diabetes among those who consumed only Meitei indigenous white rice. The given figure (fig. 1) clearly indicated that

pre diabetic and type 2 diabetes upswing for the category who consumed only Meitei indigenous white rice. The present work has also shown a statistically significant increase in risk of pre diabetic and diabetic. The figure also shows that those who consume mixed white rice (sticky and non-sticky) are more in number than those who consume only Meitei indigenous white rice. But the risk of pre diabetic and diabetic is observed higher among those who consume only Meitei Cheng.

Summary

The people of Manipur, irrespective of urban or rural residing, they do not have the habit of taking

regular breakfast. Most of them prefer for early meals for a day instead of taking breakfast. Out of the total of 1026 subjects, 46.39% skipped their breakfast and go for an early meal. The main reason why most of the Meiteis of Manipur skipped their breakfast is that, from the early days and till today, rice is the staple food, and eating a heavy early morning meal is the common practice. The present study shows that there is an increase in risk on both pre-diabetic and type 2 diabetes among those who consumed only Meitei indigenous white rice or *Chak Athotpa*. It is observed that pre-diabetic and Type 2 diabetes upswing for the category who consumed only Meitei indigenous white rice. The present study has therefore shown a statistically significant increase in the risk of pre-diabetic and diabetic among those who consume Meitei indigenous white rice than those who consume mixed white rice even though those who consume mixed white rice (sticky and non-sticky) are more in number than those who consume only Meitei indigenous white rice or *Chak Athotpa*. Many earlier studies have also revealed that white rice consumption has the higher risk of getting pre-diabetic and diabetic. However, replacing of white rice consumption by black rice or other non-sticky white rice is practically not possible for Meitei population as they have been adapted to their cultural practice of eating indigenous white rice. So it is highly recommended to consume mixed white rice (that is blending of two different varieties of rice sticky rice and non-sticky rice) for avoiding the risk of getting pre-diabetic and diabetes.

Conclusion

Type 2 diabetes is a lifestyle disease which can be easily triggered by unconcerned routine and habit of the people. Keeping aside genetic factors it can be led by different environmental factors like sedentary lifestyle, types of food habit, etc. Based on the findings of the present study, it can be concluded that there is no significant relationship between those who consume regular breakfast, and those who skipped breakfast among the Meiteis of Manipur valleys far as type 2 diabetes is concerned. In Manipur, since there is no habit of consuming substantial breakfast, the present work could not find any significant difference among those who eat different breakfast food items. Even if there are some differences in frequency percent of consumption of various food items like deep fry poori, bread, biscuit,

etc. among the Meiteis of Manipur Valley concerning type 2 diabetes, they are statistically insignificant. As regards the consumption of Mixed white rice and Meitei indigenous white rice and its association with type 2 diabetes in the said population, it is observed that there is a higher risk of getting pre-diabetic and diabetic among those who consume Meitei indigenous white rice than those mixed white rice eaters even though the numbers of mixed white rice eaters are more than the Meitei indigenous rice eaters.

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