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CARE OF ELDERLY IN A DEVELOPING COUNTRY: A PAKISTANI PERSPECTIVE

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The world's older population is growing faster than the total population. In the 1950s, 1 in 12 persons were above 60 years of age while it is estimated that this figure will rise to 1 in every 5 persons by 2050.[1] The Industrialized countries had the advantage that they became affluent before their population aged, therefore they were able to foresee the impending issues and devised their policies and resources to manage this change. A clear example of this is the immigration policies of the developed world that grant citizenship to the younger age group much more leniently than the middle or old age groups.[2] In Pakistan, the economy is not in good shape and health care infrastructure is not meeting the needs of even the younger population. It is estimated that the elderly population, aged 60 and above, that was 12.5 million in 2015 will increase to 25 million by 2050. Care of elderly is not a priority that is reflected in the Global Age Watch Index, where Pakistan has the lowest pension-income coverage in the world and ranks 92nd among 94 countries.[3] It should therefore not be surprising that there is hardly any geriatric or psychogeriatric service available even in the tertiary care hospitals or academic departments. The College of Physicians and Surgeons of Pakistan also does not offer any fellowship in geriatric care.

The challenge is multipronged and multifaceted. However, in the care of the elderly, especially in a developing country like Pakistan perhaps the culture-religious domain should also be the part of the biopsychosocial model.[4] In old age, the disease and the body, both present challenges that may be very different from the young population. An example of the disease is urinary tract infection in the elderly that frequently presents with confusion and an example of change of body functions is the fact that renal functions gradually deteriorate and may decrease by 35% by age 65 and by 50% by age 80.[5] This could result in either the wrong treatment or toxicity due to poor excretion. Non-compliance is one of the most important reasons for treatment failure in the elderly population and several factors contribute to it, e.g., cognitive impairment, poor knowledge of the disease, poor knowledge of the medicine, socio-cultural beliefs about the allopathic medicines, and polypharmacy.[6] In this age group, multiple comorbidities are a rule than an exception, and the resultant treatment could have unusual and unexpected side effects due to poorly understood interactions of these medicines. Specialists in their field know the side effects of the individual medicines very well but may not have the same grasp on the potential side effects of these interactions. They, therefore, reassure that these are not the side effects of their prescription while the patients continue to suffer and the risk of non-compliance continues to grow. A health professional, not used to these realities, had minimal exposure and experience in the care of the elderly, keeps on changing the prescriptions, only to worsen the situation further. Psychologically, many times the elderly believe that their symptoms are part of their advancing age and many times caregivers mistakenly share this belief resulting in further complications and missed opportunities to halt the progression of the pathology. In the absence of state sponsored health care facilities or health insurance, the elderly are sometimes hesitant to make complaints about their symptoms so that they do not increase the burden of care on their loved ones and the money can be used for "more important and urgent needs" of the family. Sometimes the fear of hospitalization or institutionalization stops them from making complaints of ill health. To add to this difficult scenario, the question of who will or should be the care provider has its importance and implications.[7] In Pakistan, male members are the main breadwinners, and females mostly take or are assigned the responsibility of care. Due to social, cultural, and religious reasons, females may not be able to fulfill every need of the patients. Mothers, daughters, and daughter in laws may have conflicting opinions, and perceptions of the degree and nature of responsibility for the care of the elderly.

A relatively recent scenario of migration of young children abroad for better prospects has added a new dimension in the care of the elderly in Pakistan.

Although when asked about old homes, an overwhelming majority won't like to leave their parents at old homes same people agree that others in a similar situation have no other choice, exposing their hidden unease about the matter. Leaving their parents at big houses alone is as difficult as leaving them at old homes but socially and culturally is better accepted. The quality of care at the few old homes present in the country has no standardization and when the elderly are left alone in their own houses with servants and maids, they remain vulnerable to exploitation and abuse.[8] The guilt, some of the expatriates face stems from social, cultural, and religious beliefs that make it obligatory to provide their elderly the care they need. Otherwise, they will be considered to have not fulfilled their duty and could be answerable according to ingrained beliefs. Therefore, whenever they visit their parents, they want extensive medical checkups and investigative work up for their parents. Sometimes it is more to deal with their insecurities than for the real benefit of the elderly. As they are on vacation and have the time and financial resources, the elderly experience a very pleasant, relaxed, and desirable company and attention. Sometimes, this results in a comparison that results in frustration and misunderstanding not only between the elderly and the resident Pakistani care providers but also between the expatriates and the resident Pakistani care providers. The ultimate sufferers remain the elderly.

Although by and large, the elders are still respected and looked up for advice, yet the joint family system is melting down, where elders are supposed to be the joint responsibility of the whole family during times of crisis or illness. The financial hardships and pressures of achieving the elusive standards of life are breaking down. Hence the responsibility of care is increasingly narrowing down to own parents only. Children may have the financial resources, yet the social support that is an integral part of crises management is not of the same quality. Although the technological revolution has brought the world closer and, in many cases, has benefited the elderly to maintain some sort of connection, yet it cannot be a replacement for physical presence or contact. Furthermore, older people are not as proficient and skilled in using gadgets as the younger generation. To add to this are the problems related to the access and availability of the internet. The result is a further limitation of their ability to maintain social connectedness and increased risk of detachment.[9]

Religious beliefs shape and motivate the attitude and behavior of caregivers toward the elderly and provide social support and network to the lives of elderly in an otherwise dull and empty life, without adding any extra financial cost. The elderly sometimes take administrative responsibilities for the management of nearby mosques or other religious setups. This arrangement fulfills their need for purpose and usefulness in life and gives them a sense of contribution and religious satisfaction. In a way, it could be categorized as a rehabilitative process.[10] However, one must be cognizant that pushing or pulling those individuals towards religion who were not inclined towards religion in their earlier lives could be counterproductive.

Health care needs of the elderly require comprehensive multidisciplinary assessment by well-trained professionals in the field of geriatric medicine and psychogeriatrics. These needs are best understood and managed, if we formulate the care package in the context of a biopsychosocial and cultural-religious understanding of our society.

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NURSES' SHORTAGE AND CHALLENGES DURING INTERNSHIP: AN EMERGING ISSUE

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ABSTRACT

Nurses' contribution to the health care system is remarkable and as health care professionals they are doing more than their capacity within the limited resources as well as lack of facilitation. Their demand has been increased in the last decade due to the gross increase in the population of the world. The advancement in science and technology, high morbidity and mortality along shortage of nurses are affecting the internship process among nursing graduates. Certain challenges such as shortage of nurses, lack of rewards and job satisfaction, high turnover, and compromised competencies can be seen among nursing graduates. However, they still use some coping strategies to overcome these issues. Furthermore, proper internship programs and policies related to these problems may be helpful at the individual or organizational level depending upon the nature of the problem. In addition, a well-organized leadership may play a positive role in this regard.

Keywords: Nurses; Challenges; Internship.

INTRODUCTION

Nurses are the most important members of the health care team consisting of half of the human recourses around the world with a vital role in providing competency-based care to patients.[1] A study from Iran concludes that human recourses are the most common important aspect of the health system and nurses are considered as the backbone in this chain because of increased demand in the excellence of care as per international standards.[2] One of the reports from America in 2010 explored that the demand for nurses is more than the supply and approximately fifty million people will require health care in the current country.[3] Despite the highly demanded profession according to the World Health Organization (WHO) the human recourses in the nursing profession are lacking below the standards which are approximately 09 million by the year 2035, while in Pakistan approximately 60,000 nurses are needed in the current health care system.[4] In an advanced country like America the shortage of registered nurses will be 340,000 by the year 2020.[5] In addition, a study from Pakistan in 2018 found that the shortage of nurses is high in the country and the factors affecting job satisfaction among nurses are excessive work, poor support from healthcare professionals, way of training, surrounding and most commonly the salary package.[6]Furthermore, nurses are the most important person in the health care system with a vital role in providing quality of care to the patient, but their number is decreasing due to an increase in demands.[7]

Intern nurses are individuals who recently gets graduated from university and enrolled in the one-year internship program for clinical practice.[8] The main purpose of the internship program is to learn practical skills which relate to the leadership style of the supervisor in terms of communication and direction.[9] A successful internship program can fill the gap between the classroom and clinical practice leading to a "win-win" situation.[10] A study from Australia conducted in the year 2017 explains that the health care system around the world is extending into a complex one, which leads to problems among nursing graduates in different forms such as clinical, social, and emotional.[11] In addition, during the 12 months transition period of nursing graduates during their internship they are exposed to challenges such as increased workload, compromised level of knowledge, poor communication, high expectations, role change from student to staff, environment, lack of support, and bullying leading to decrease in quality of care as well as frustration among them.[12] Furthermore, the performance of nursing graduates affects their career, family, and even society.[13] The purpose of this narrative review was to identify the shortage along with challenges among nursing graduates during their internship.

METHODOLOGY

This narrative review focuses on the shortage of nurses and challenges among nursing graduates both nationally and internationally. Each subheading shows information about the current topic in detail.

Electronic databases such as Google Scholar, Google, and PubMed have been searched from October to December 2020. The key phrases are nurses' shortage, nursing graduates, challenges, and internship. The Boolean operators were nurses' shortage OR nursing graduates OR challenges OR internship; nurses' shortage AND nursing graduates AND challenges AND internship. Details of databases being searched are given in figure 1.

The papers included were (1) nurses' shortage (2) challenges among nursing graduates during internship (3) research articles (4) review articles (5) reports (6) in the English language (7) published after 2000. The exclusion can be noted as (1) studies other than nurses (2) Websites, Newspapers, Magazines, YouTube.

DISCUSSION

Nurses Shortage

The role of nurses is more vital than any other personnel in the health care team.[14] According to literature the deficiency of nurses is a global issue and will reach 590,000 by the year 2020 as per the European Commission.[15] The ratio of nurse to patient and nurse to doctor in Pakistan is 1:40 and 1:15 respectively.[16] In addition, Nurses shortage affects the quality of care at clinical practice which is approximately 44.3%.[17] Furthermore, multiple factors including lack of management, lack of new recruitment, and demographic aspects are responsible for the shortage and affecting the quality of care being provided to the patients.[18] Moreover, lack of skilled nurses in number affects both their profession and as well as patients' care, leading to poor job satisfaction. The above facts show that nursing graduates have certain challenges on different levels during their initial careers.

Challenges During Internship Among Nursing Graduates

Nursing Graduates have certain challenges in the modern world which are mainly individual and institutional. Many factors such as rewards, schedule of duties, way of dealing, chances of opportunities, motivation, working environment, and vision of the institution affect the performance of nursing graduates.[19] In addition, a study from America showed that nurses face challenges such as dealing with complex diseases, lack of clinical preceptors, being bullied by others, and anxiety due to task delegation along with advancement in care.[20] Furthermore, a study from Pakistan revealed that nurses

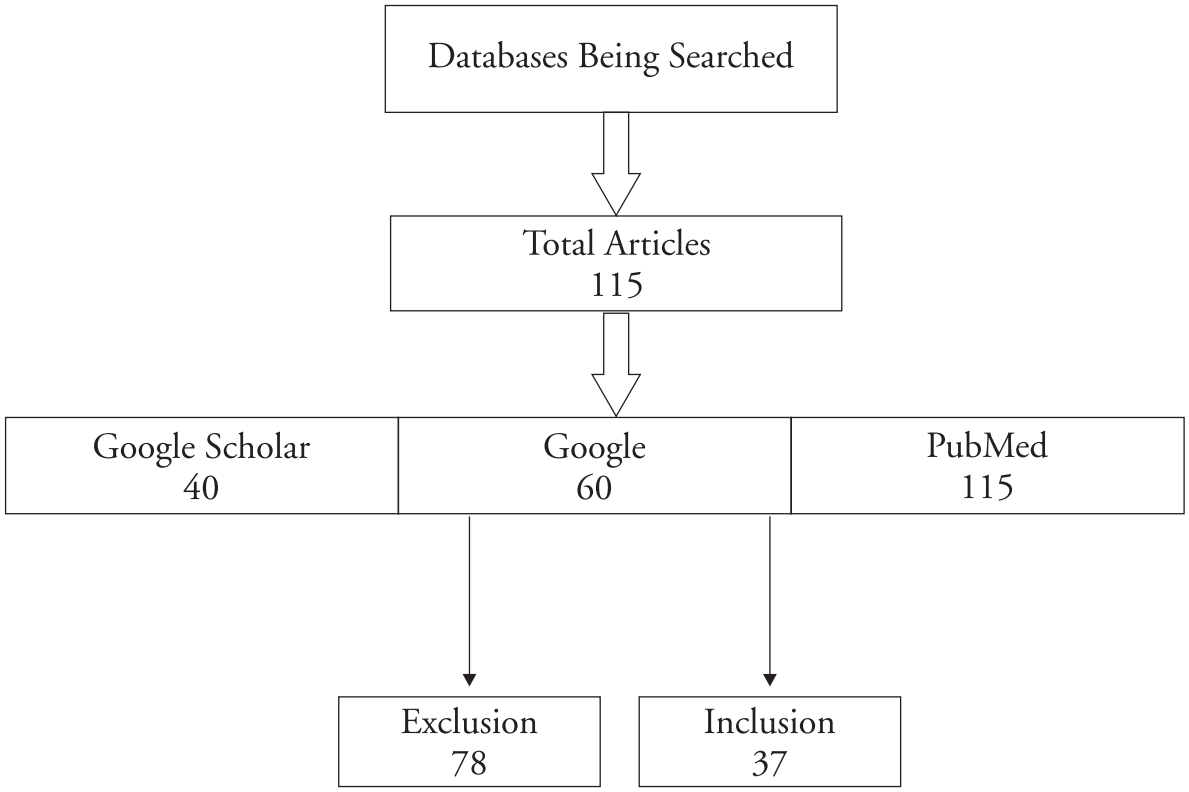

Figure 1: Search Strategy

face certain ethical challenges due to lack of co-operation by colleagues, poor nursing image, and improper facilities as well as policies for the patients, leading to tension in clinical practice.[21] This shows that nursing graduates are under pressure due to a lack of a proper internship program which leads to poor job satisfaction.

Lack of Job Satisfaction Among Nursing Graduates

Job satisfaction is the key to success for any profession and organization. According to statistics nursing graduates are less satisfied than other professionals in terms of their working environment leading to high turnover.[22] One of the studies from Pakistan found that approximately 86% of the nurses are not satisfied with their job.[23] A study from Yemen in 2019 found that nurses are more satisfied in private hospitals as compared to government system.[24] In addition, a study from Pakistan showed that the main reason for poor job satisfaction among nurses is sexual harassment, leading to high turnover and attendance.[25] Furthermore, violence among nurses during their clinical practice; physical 55.7% and mentally 82.1% leads to discontinuation of job.[26] Thus the lack of job satisfaction among nurses is high and causing an increased turnover.

Turnover Among Nursing Graduates

Switching jobs among nurses can be noted in recent years. As one of the studies from Brazil in 2010 showed that nursing graduates experiences reality shock while unable to apply their knowledge and skills as per standards.[27] Statistics showed that about 61% turnover is noted among nursing graduates during their internship process.[28] One of the studies from Indonesia in the year 2018 revealed that the rate of switching jobs among nurses ranges from 15-44% with the most common reasons such as individual factors, offers from other institutions, and poor environmental status.[29] Certain factors such as advancement in technology, high expectations of patients, nurse's turnover and transcultural care cause stress among nursing graduates in the form of confusion, confinement, and anxiety of unknown are affecting the performance of nursing graduates.[30] Collectively these factors are responsible for lack of confidence among nursing graduates.

Competencies Among Nursing Graduates

According to the literature nursing graduates are not prepared to deliver the quality of care independently as compared to other members of the health care team, there is an immediate need for improvement of the transition phase from classroom to clinical practice.[31] One of the studies from Africa conducted in 2016 revealed that nursing graduates is lacking competencies in performing skills in the clinical areas as per the demand of international standards.[32] A study from Pakistan in the year 2019 found that nursing graduates feels stress due to a lack of competency in performing basic nursing skills.[33] In addition, only 23% of nursing graduates have competency in basic skills due to a marked gap in academic education, which shows that they are not prepared to perform in a complex health care system.[34] Furthermore, there is an intense need for a proper orientation program for nursing graduates to improve job satisfaction, reduce turnover, increase competency and decrease the chance of human errors.[35] Moreover, certain coping strategies may help nurses to deal with professional challenges.

Coping Strategies Among Nursing Graduates

Coping involves handling difficult situations without the occurrence of conflict. The most common coping strategies which nursing graduates is using in their clinical challenges are creating a space for themselves and maintaining it with intelligence.[36] A study from Pakistan in 2018 showed that nursing is one of the emotional professions in which students use certain coping mechanisms such as self-confidence and a confident approach. Both academic and clinical instructors, nursing leadership, and administration should be involved in an internship program to make it useful while helping them in coping with the stress at clinical practice.[37] These coping strategies need implementation through proper policies at the institutional level.

CONCLUSION

The role of nurses in the health system is extremely important however, they encounter multiple challenges during their internship program leading to poor job satisfaction, high turnover, and decreased competency. Qualitative studies are required for an in-depth understanding of the concerned phenomena. Certain coping strategies can help up to some extent. Institutions and health authority needs to implement proper internship program which may be helpful to overcome these problems at the individual or organizational level.

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Author's Contribution

IA conceptualized the literature review and analyzed and drafted the manuscript. AS reviewed the literature and drafted the manuscript. Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflict of Interest

Authors declared no conflict of interest

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Data Sharing Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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ATTITUDE OF PREGNANT WOMEN IN CHOOSING THE TYPE OF DELIVERY: A QUALITATIVE STUDY

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ABSTRACT

Objective: To find out the attitude of women to the choice of type of delivery

Methodology: This qualitative study was conducted from June 2018 to July 2019 in Hamedan university of Medical Sciences. 12 pregnant women participated in this study. Data were analyzed with qualitative content analysis.

Results: We extracted two themes including "tendency toward vaginal delivery" with six categories: Lower rate of maternal and neonatal complications, Fear of cesarean section, Positive experiences of relatives, Maternal and neonatal benefits, improved techniques for enhancing the quality, Social and emotional support for mothers and "tendency toward cesarean section delivery" with five categories: Maternal complications of vaginal delivery, Concerns about inappropriate behavior of treatment team, Physical environment and equipment, Negative experiences of relatives, Concerns about different aspects of infant health.

Conclusion: Based on the results obtained from the findings of the study, the correct implementation of empowerment programs for maternity wards to reduce maternal and infant complications, improve the quality of maternity preparation classes, implement standard and appropriate pain relief techniques, improve social and psychological support for mothers And promoting respectful behaviors during the treatment of pregnant women with standard physical spaces and sufficient equipment can help pregnant women in choosing the type of delivery.

Keywords: Attitude; Vaginal delivery; Cesarean Section.

INTRODUCTION

Pregnancy and childbirth are natural physiological processes that are considered exciting and important events in the life of every woman and her family.[1] However, there is always a difference of opinions regarding the choice of delivery. One of the most important factors influencing the choice of delivery is the individual tendency towards the method of childbirth, which is influenced by several factors including the desire to experience natural childbirth, satisfactory earlier experiences, lack of concern for mother and child safety, faster recovery after childbirth and fear of anesthesia.[2] Norms and cultural values towards delivery also play a part in the decision-making of natural childbirth. The role of influential people in the family, such as the spouse, is very important in the decision-making process of choosing the method of delivery. Social studies show that friends, relatives, popular advice, and the media play a very influential role in choosing the type of delivery.[3] Demonstrating midwifery skills and professionalism, the ability to use appropriate technologies and maintain calmness, and instilling it in the mother is also very important in this regard.

Women who give birth naturally consider it as a natural phenomenon and a symbol of a woman's power. Vaginal delivery has numerous benefits, including cost-effectiveness, shorter hospital stays, less risk of infection, and bleeding.[4] Researchers acknowledge that vaginal delivery has a significant effect on maintaining women's physical and reproductive health, lowers physical complications, and leads to a more favorable emotional relationship between mother and infant.[5] However, when vaginal delivery is not safe for a mother or neonate, it is essential to have a cesarean section.[6]

Cesarean section is now regarded as the most common surgical technique, as well as one of the most prevalent midwifery procedures in the world. A cesarean section can save the lives of many mothers and newborns under specific circumstances.[7] The most common cause of the request for cesarean delivery by women worldwide is the fear of childbirth and our community is also facing the challenge in the rate of cesar-

ean delivery requested by mothers. According to studies conducted on child delivery centers in Tehran, 77% of cesarean section deliveries were carried on the mothers' requests or because of the fear of labor pain.[6] An increased incidence of complications of cesarean section in the mother, such as anesthesia, infection, abnormal bleeding during and after childbirth, as well as possible injuries to the baby such as respiratory problems and increased mortality are reported in Iran.[8] The actual rate of cesarean section in many countries is far higher than the rate recommended by the WHO (13-15%). For example, the rate of cesarean section in Iran is 53-63% which is very high as compared to the global standard rate.[9] According to a report published by the World Health Organization (WHO), cesarean section accounted for 40% of all deliveries in Iran, while it was predicted to account for only 13%.[10]

The process of choosing the type of delivery is one of the most important factors affecting women's health. Although numerous interventions have been conducted in the delivery preparation classes to promote the culture of vaginal delivery, there has been no desirable rate of increase in vaginal delivery. Since, Qualitative research has unique abilities to reflect the thinking, beliefs, and attitudes of people, and analyze their experiences in depth.[11] The findings of this research can provide a good insight into the reasons in identifying the potential barriers related to a specific type of childbirth and therefore this study aimed to investigate the reasons for a tendency toward cesarean section or vaginal birth in the city of Hamedan Medical University.

METHODOLOGY

This qualitative study was conducted from June 2018 to July 2019 at the Comprehensive Health Clinic of Hamedan University of Medical Sciences and the study was approved by the ethics review board of the university [Grant No, (IR.UMSHA.REC.1397.179)]. To observe ethical considerations, all participants were first explained about the purpose and method of the study. After the agreement, an informed consent form was obtained to participate in the study and they were given the necessary assurance that the information and audio files would remain anonymous and confidential.

All consenting pregnant women aged 15-45 years, in the gestational age of 30 weeks who have not received psychological counseling before enrolling in the study, and have attended childbirth preparation classes to prepare them for prenatal, antenatal, and postpartum care were included in the study. The exclusion criteria included the occurrence of preterm delivery and medical problems during the study and would be determined by participants. Semi-structured interviews were used to collect data.[12] Sampling continued until a complete understanding of the phenomenon was studied. The interview guide questions were as follows:

What is your view on the type of delivery?

What kind of delivery do you want to have at the moment?

What are the factors influencing your choice of delivery?

If the interviewees did not give enough explanations, more questions were asked to identify more details. All interviews were recorded with the permission of the participants and each interview session lasted about 30 to 45 minutes. After each session, the recorded version of the interviews was carefully transcribed on paper after listening several times. Data collection continued until information saturation was achieved. This means that in the interviews, new information was no longer provided by the participant.[13] Finally, 12 people participated in the study. The data were analyzed according to the method proposed by Graneheim and Lundman, based on the five steps for analyzing qualitative data.[14]

The written texts were read several times and the initial codes were extracted. After that, the related primary codes were merged. Based on the similarities, they formed classes, and finally, the themes were formed. In this way, the concepts hidden in the data were extracted. Data analysis was performed using MAXQDA-10 software. In this study, four aspects that included the accuracy and reliability of the data, the criteria of validity, verifiability, and reliability were used to examine the rigor of the study.[15] After compiling the initial codes, the participant's confirmation was ensured for the correctness of the codes and interpretations, and if the codes contradicted the participants' opinions, corrections were made. The control method was used by two faculty members and experts in the field of qualitative research and agreement was made on the selected codes and classification.

RESULTS

In this study, 12 pregnant women with a gestational age of 30 weeks and above were interviewed. According to the results, the social and economic status of the participants was at a moderate to high level (Table 1). After the initial coding, 489 primary codes were extracted. Then based on the similarities between the primary codes, the main codes were named. At this stage, 91 main codes were obtained. Similar main codes were merged and 22 subcategories were obtained. The process of merging and classifying continued, and the main categories and themes were formed. Finally, the codes and qualitative results were summarized into 11 categories and 2 themes (Table 2). Out of these two themes, the theme of Tendency to vaginal delivery consisted of 6 categories i.e., 1) Lower rate of maternal and neonatal complications in vaginal delivery; 2) Fear of cesarean section; 3) Positive experiences of relatives and other people in the community;

4) Maternal and neonatal benefits of vaginal delivery; 5) Improved techniques for enhancing the quality of vaginal delivery services, and 6) Social and emotional support for mothers.

The category of a lower rate of maternal and neonatal complications in vaginal delivery consisted of two subcategories, i.e., reduction of maternal complications and reduction of neonatal complications. Most of the participants preferred vaginal delivery due to the expected low level of maternal and neonatal complications. Their description of the choice is as follows,

"Generally, I want a vaginal delivery because I think it is a physiological process with fewer complications and with a shorter recovery time. Overall, I think it is better. I am tall and my mother had a history of normal birth record; considering the mentioned parameters, I think vaginal delivery is a better choice". (P-1, a 26 year old gravida III)

"*The Cesarean delivery has more side effects as compared with normal delivery. The Ampoule that is injected affects the brain, body, and backbone. However, normal birth is carried out under its pressure... I'm scared to have a baby who does not take breast milk. Breastfeeding is important for me. My sister-in-law had a cesarean section and everyone said that her baby did not take breast milk because she had a cesarean, and now the baby is weak and thin".* (P-2, a 21-year-old primigravida)

The reduction of neonatal complications in vaginal delivery: Many participants stated the low incidence of neonatal complications as a reason for preferring vaginal delivery over cesarean delivery *"I know that when a baby comes out of the vaginal canal, the pressure pushes out the amniotic fluid eaten by the baby. Hence, the baby has a more normal condition than those born in a cesarean section".* (P-12, a 26 year old primigravida)

The Category of Fear of cesarean section consisted of two subcategories, including fear of anesthesia for cesarean section and complications of cesarean surgery. The participants described their view as follows,

"Fear of repeating cesarean delivery and anesthesia during the Cesarean section is usually during the second and third delivery. The complications of anesthesia are another problem that can result in headache and backache". (P-4, 26 years old gravida II)

"Fear of complications of cesarean surgery includes the problems with lactation and postpartum hemorrhage because it is a kind of surgery. I'm afraid of surgery because several layers of my belly are torn". (P-3, 32 years old primigravida)

The category of Positive experiences of relatives and other people of vaginal delivery in the community consisted of two subcategories, i.e., positive experiences of previous deliveries and spouse's positive experiences of childbirth. The narrative of the participants regarding these two subcategories, respectively, is as follows

"It's great to use the experiences of other women. We had the chance to speak with some of the pregnant women who are experiencing their second or third childbirth. It is a very good experience and helps to change one's opinion". (P-3, 32 years old primigravida).

"A patient doesn't know whether to choose the cesarean section or vaginal delivery. However, since the sister of my husband had a good experience of vaginal delivery, my husband suggested vaginal delivery, though I think that cesarean section is more convenient". (P-4, 26 years old gravida II).

The Category of Maternal and neonatal benefits of vaginal delivery consisted of two subcategories, i.e., Emotional link between mother and neonate and more appropriate breastfeeding. The participants described that

"Vaginal delivery helps to accelerate the relationship between mother and child and patients can have more successful breastfeeding. In cesarean section, a mother may have a lot of pain and may prevent such a link, while in vaginal delivery it occurs more quickly". (P-5, 26 years old gravida III)

"The pregnant women can have more successful breastfeeding after vaginal delivery and the relationship between mother and child may form sooner. In cesarean section, the mother may experience more pain that can prevent such a link, while in vaginal delivery it occurs more quickly." (P-6, 23 years old primigravida)

"In case of cesarean section, breast milk is secreted more lately, and mother is not conscious enough to breastfeed properly". (P-4, 26 years old gravida II).

The category of Improved techniques for enhancing the quality of vaginal delivery services consisted of three subcategories, i.e., Improvements in labor pain relief techniques, childbirth preparation classes, and improvements in private spaces and equipment used for vaginal delivery. The participants opined the following,

"There are now new ways of easing the pain introduced". (P-4, 26 years old gravida II)

"A patient underwent spinal anesthesia and she was very satisfied. She said that her delivery finished sooner... Also. the childbirth preparation classes are great. They teach a lot of good things. I'm attending the classes both here and in the health center and I am very satisfied... Last year, I accompanied my sister-in-law and attended a delivery room in one of the neighboring cities, and it was very

beautiful. Her husband was allowed to accompany her, and my sister-in-law was very pleased. However, it is not the same here". (P-6, 23 years old primigravida)

"Both I and my husband attend these classes, and the information presented there helped us a lot". (P-2, 21 years old gravida II).

"Well, thank goodness, the conditions are better now and we hope to have an easier delivery. Delivery rooms and care services are better than before". (P-3, 32 years old primigravida).

The last category of theme 1 was Social and emotional support for mothers and it consisted of two subcategories, i.e., Increased level of publicity and more respectful services for pregnant women. The participants told that;

"It is very good policy to promote normal delivery everywhere. I had referred for a visit and there I received a card to attend the classes". (P-4, 26 years old gravida II).

"It is necessary to advertise more in the health centers for everyone, for husbands, for families. I visited here and became familiar with these classes. It was not much advertised in health centers". (P-6, 23 years old primigravida).

"The behavior at health services has improved a lot. They let the mother have an accompanying midwife that helps a lot... I was very stressed out two nights ago when I was referred to the emergency room, but a physician was there who helped and counseled me a lot". (P-3, 32 years old primigravida).

The second theme, "Tendency to cesarean delivery" consisted of 5 categories, i.e., 1) Maternal complications of vaginal delivery; 2) Concerns about inappropriate behavior of treatment team; 3) Physical environment and equipment; 4) Negative experiences of relatives and other people in the community, and 5) Concerns about different aspects of infant health.

The category of Maternal complications of vaginal delivery consisted of two subcategories, i.e., Complications of vaginal delivery and Pain of vaginal delivery. The Complications of vaginal delivery were considered too fearsome by the participants.

"I am scared that something bad will happen to my baby". (P-7, 34 years old gravida II).

"My husband is not in favor of vaginal delivery. He has heard something bad from people around? [What has he heard?] Being torn and other similar things. [Do you mean the genital area?] Yeah, I'm afraid to become ugly". (P-8 25 years old primigravida)

"The Pain of vaginal delivery is too much and the situation is kind of more dreadful". (P-4, 26 years old gravida II).

"People are more afraid of stitches and pain". (P-9, 27 years old primigravida).

The category of Concerns about inappropriate behavior of the treatment team in vaginal delivery consisted of two subcategories, i.e., Lack of respect for pregnant women and not respecting the privacy of mothers. The participants described that,

"The staff described that they are not afraid of troubles in hospitals but they do not like to hear the shouts and screams of delivering women". (P-4, 26 years old gravida II).

"I don't want to have a delivery in front of others. Once, I was hospitalized for preterm delivery, I did not like the idea of having no privacy". (P-10 28 years old primigravida).

The category of Physical environment and equipment consisted of a subcategory, i.e, Timeworn equipment. One of the participants expressed her concern that

"They say one thing in the class, but when we are referred there, we see something different. Our neighbor's daughter was having a delivery and they did not have a tool to stop bleeding". (P-7, 34 years old gravida II).

The category of Negative experiences of relatives and other people of vaginal birth in the community consisted of a subcategory, i.e., Mothers' negative view toward the repeat of bad experiences for their daughters. The participants described that

"My mother doesn't want me to have a vaginal delivery, because she had delivered with a lot of difficulties". (P-4, 26 years old gravida II)

The category of Concerns about different aspects of infant health in vaginal birth consisted of two subcategories, i.e., Lack of personnel and equipment for neonatal care and Concerns about infant physical health. The participants expressed their concern as follows,

"I'm afraid of vaginal delivery because my baby may not get enough oxygen and they may not know what to do... I always pray that nothing bad happens to my baby. I am afraid of bad events happening to my baby and students, who deal with us, do not know what to do during my vaginal delivery". (P-10, 28 years old Primigravida)

"My previous baby died before the age of forty days. Although I have no problem with vaginal delivery, I am worried about the safety of my baby. Some women said that their babies were blocked in the vaginal canal and couldn't breathe, so I'm scared". (P-11, 34 years old gravida III).)

Table 1: Demographics of participants in the qualitative research

Participant	Tendency to normal vaginal delivery	Age	Education	Employment status	Pregnancy age	Gravida	Number of miscarriages	History of attending childbirth preparation classes	Prenatal care
1	-	26	Bachelor	Employed	34	2	0	_	+
2	+	23	Bachelor	Housewife	32	1	0	_	+
3	+	26	Diploma	Housewife	38	1	0	+	+
4	-	34	Bachelor	Employed	33	2	0	+	+
5	-	28	Bachelor	Employed	30	1	0	+	+
6	-	27	Diploma	Housewife	32	1	0	+	+
7	+	26	Bachelor	Housewife	30	2	1	_	+
8	-	25	Bachelor	Employed	38	1	0	_	+
9	-	30	Bachelor	Housewife	32	1	0	_	+
10	+	26	Primary school	Employed	30	3	1	_	+
11	+	32	Diploma	Housewife	30	1	0	+	+
12	+	21	Bachelor	Housewife	31	2	0	+	+

+: presence, -: absence

Table 2: Subcategories, categories, and themes obtained in the qualitative part of the study

Theme	Main categories	Subcategories
Tendency to normal vaginal delivery	Lower rate of maternal and neonatal complications in normal vaginal delivery	Reduction of maternal complications in normal vaginal delivery
		Reduction of neonatal complications in normal vaginal delivery
	Fear of cesarean section	Fear of repeating cesarean delivery and anesthesia
		Fear of complications of cesarean surgery
	Positive experiences of relatives and other people of vaginal delivery in community	Positive experiences of previous deliveries
		Spouse's positive experiences of childbirth
	Maternal and neonatal benefits of normal vaginal delivery	More appropriate breastfeeding
		Emotional link between mother and neonate
	Improved techniques for enhancing the quality of vaginal delivery services	Improvements in labor pain relief techniques
		Childbirth preparation classes
		Improvements in private spaces and equipment used for normal vaginal delivery
	Social and emotional support for mothers in vaginal delivery	Increased level of publicity
		More respectful services for pregnant women
Tendency to cesarean section delivery	Maternal complications of normal vaginal delivery	Complications of normal vaginal delivery
		Pain of normal vaginal delivery
	Concerns about inappropriate behavior of treatment team in vaginal delivery	Lack of respect for pregnant women by medical staff in vaginal delivery
		Lack of respect for pregnant women during in vaginal delivery
	Physical environment and equipment	Timeworn equipment
	Negative experiences of relatives and other people of vaginal delivery in community	Mothers' negative view toward the repeat of bad experiences for their daughters in vaginal birth
	Concerns about different aspects of infant health in vaginal delivery	Lack of personnel and equipment for neonatal care in vaginal birth ward
		Concerns about infant physical health in vaginal birth

DISCUSSION

In this study, pregnant women's attitude toward choosing the type of delivery was classified into two themes, namely a tendency toward vaginal delivery and a tendency toward cesarean section delivery. Similar to our study, it was found in another study that children of women with a vaginal delivery benefit greatly from more favorable skin contact, are more likely to breastfeed better than other women, and have a higher cardiovascular respiratory stability for neonates.[16] Although researchers believe that cesarean section can prevent maternal and perinatal mortality, it also can result in short-term and long-term risks that can affect a mother and baby for many years beyond the current birth, affect the health of women and children, and have an impact on subsequent pregnancies.[17]

Rafiei et al conducted a meta-analysis and investigated the prevalence of cesarean section and its causes in Iran; the results showed that the average frequency of maternal complications such as muscle pain, headache, fever, and infection was higher in women undergoing cesarean section than in women with a vaginal delivery. The results of this study also showed that abnormal bleeding was more prevalent in vaginal delivery, while urinary incontinence was more common in the cesarean section group. In addition, muscle pain (45.1%) and headache (41%) were the most common complications of cesarean section for mothers. Furthermore, the mean hospital stay was 1.65 days for the vaginal delivery group and 3.3 days for the cesarean section group.[18] Somewhat similar concerns have been shared by the participants in our study.

A qualitative study by Long et al in 2018 showed the complexity and variety of women's experiences and their effects on making decisions and found that women's characteristics (age, height, behavior), internal concerns (deep fear of pain), priorities (child safety, perineal protection), relationship with others, and the exchange of everyday information about births in the community (family, friends, celebrities, popular culture, the internet) had influenced the personal preferences of women in choosing the type of delivery.[19] These findings are similar to the narratives given by the participants in our study.

Based on the statements of the participants of our study, the positive impact of prenatal education classes, communication with service providers, beauty and tranquility of private delivery rooms, and the possibility of the presence of an accompany were among the factors that reduced the negative views of pregnant women toward the health system, reduced the false beliefs of mothers, and enhanced their positive attitude toward vaginal delivery. These information sources highlight the importance and the power of communication between women and health care providers.[20] Munabi-Babigumira et al highlighted the role of skills, attitudes, and behavior of treatment team in an efficient work environment on the quality of care provided to mothers and infants, and noted that in the absence of a capable team and sufficient facilities the quality of maternal care would decrease, as it was reported that these issues prevented women to have a vaginal delivery.[21] This is quite similar to the views of participants in our study.

The findings of our study suggest that by increasing education and counseling during pregnancy about choosing the type of delivery, pregnant women will get acquainted with the different stages of childbirth, methods of analgesia, reduction of labor pain, benefits, and problems of vaginal delivery, and cesarean section. This leads to a reduction in anxiety levels, positive mental concepts of pregnant women, and more choice of vaginal delivery in these women.[22] Researchers have also noted the positive effects of effective delivery of analgesia methods in achieving better results for mothers.[23] The results of Sanders et al's study have also shown that preparing women for birth is an individual and psychological process that depends on understanding women's unique needs and is influenced by differences in cultural, religious, or spiritual contexts.[20] In line with the results of the present study, other studies have proven that a higher level of education, changing spouse's attitude toward protecting women in the delivery room, and providing privacy during delivery plays an important role in enhancing maternal health and have a positive impact on pregnancy outcomes. The results of a study showed that the shortage of equipment, medications, and supplies needed for the maternity ward not only affects mothers but also hurts the ability of maternity care providers to deliver quality services. Other studies have also addressed and highlighted the importance of equitable access to health services, access to empowered personnel, procurement and distribution of adequate equipment and medicines, and the establishment of a financing system to transform health systems into community-approved networks.[24,25] Many studies confirm that mothers' distrust in the agents involved in delivery and fear of labor pain is the most common stressors for women in the delivery room.[24,26] Moosavi et al showed that mothers with increased fear during pregnancy were vulnerable to the risk of the advent of childbirth and increased likelihood of intervention including increased cesarean section, medical and surgical interventions, and neonatal injury.[27]

In addition, men's involvement in emotional, social, and financial supports reduces maternal stress and helps women to feel safe and secure. Such involvement in maternal health issues can ultimately promote better relationships between couples and enhance maternal well-being.[28]

CONCLUSION

Based on the results from the findings of the study, empowerment programs are neede for maternity wards to reduce maternal and neonatal complications. Improvement in the quality of maternity preparation classes, implementation of standards, application of appropriate pain relief techniques, improvement of social and psychological support for mothers and promotion of respectful behaviours during the treatment of pregnant women can help pregnant women in appropriately choosing the type of delivery.

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Author's Contribution

SG designed & collected the data with drafting of the manuscript. SZM designed and reviewed the manuscript. KO collected the data for the manuscript. FK analysed the data with drafting of the manuscript. MRE collected data for the manuscript. Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflict of Interest

Authors declared no conflict of interest

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Data Sharing Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

COMPARISON OF DEXIBUPROFEN VERSUS IBUPROFEN AS AN ANTIPYRETIC IN FEBRILE CHILDREN- A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Objective: To compare the efficacy of dexibuprofen and ibuprofen for management of fever in febrile children.

Methodology: This randomized clinical trial was conducted at the Pediatric Department, Lady Reading Hospital, Peshawar-Pakistan from October 2019 to April 2020. A total 150 patients were randomly allocated into two arms (Group I; dexibuprofen and Group II; Ibuprofen) and were enrolled through non-probability consecutive sampling technique. Participants between the ages of 6 months and 12 years, with febrile illness were enrolled in this study. Data analysis was done using Stata version 14, independent samples t-test was applied to compare mean change in temperature between the groups at different stages.

Results: The mean age of the participants in the study was 2.84±1.655 years. The number of males were 107(71.33%) and females were 43(28.67%). There was no statistical difference in axillary temperature of participants in both groups before the intake of analgesics (p=0.527). The mean temperature after 4 hour of using dexibuprofen (100.14± 1.27 0F) was lower than ibuprofen (101.29±1.23 0F) with statistically significant difference (p<0.001).

Conclusion: Dexibuprofen and ibuprofen are both effective in control of febrile illness but mean reduction in temperature for dexibuprofen was statistically more significant than ibuprofen.

Keywords: Children; Dexibuprofen; Ibuprofen; Temperature.

INTRODUCTION

Children usually present with fever as the most prominent symptom of viral and bacterial diseases.[1] Fever is usually the main chief complaint of parents bringing their children for consultation.[2] Fever is symptoms occurring due to raise in body temperature which is recorded with thermometer. The most common cause of fever among children is respiratory tract infections.[3] Analgesics or antipyretics are from non-steroidal anti-inflammatory drugs and are commonly used to relieve fever among children.[4] In case of infection along with adequate antibiotics, antipyretics are routinely prescribed for symptomatic relieve of fever.[5] Paracetamol and iburprofen are commonly used analgesics for febrile children due to their overall safety profile, high efficacy and less cost.[6]

Ibuprofen has been improved by producing its racemic enantiomer called dexibuprofen. The less dose of Dexibuprofen can produce effective control of fever and pain as compared to ibuprofen.[7] A study was conducted on comparison of dexibuprofen and ibuprofen in the management of febrile children showed that after 4 hours intake of these drugs the mean body temperature in dexibuprofen (0.99°C ± 0.84) was lower statistically than ibuprofen (1.38°C ± 0.84) (p= 0.007).[8] However, another study reported that the mean difference in decrease of body temperature between these two drugs were not statistically significant.[9]

The rationale of this study is that no such study has been conducted in our local population. The current study will provide us the latest and updated information regarding efficacy of dexibuprofen versus ibuprofen in children with fever. This conclusive data will be helpful and can be used as baseline for further research work in the subject matter.

METHODOLOGY

This randomized clinical trial was conducted at Pediatric Department, Lady Reading Hospital, Peshawar-Pakistan from October 2019 to April 2020. Ethical approval was obtained from hospital ethical committee. After in depth explanation of the study to parents

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of the participants verbal informed consent was achieved. The total sample size was 150 (75 patients in each group) by taking anticipated population mean: 1.384 value of population mean: 0.99[4] Pooled standard deviation: 0.84, Power of study, 80%, Level of significance 5% . The sampling selection was done through non-probability consecutive technique.

The inclusion criteria were participant having age between 6 months and 12 years, either gender, Pakistani nationals (assessed on basis of parent's NIC) and having febrile illness. The operational definition of febrile illness was axillary temperature in range of 100.4°F to 106°F measured by thermometer by a pediatrician. The demographics of participants like age and genders were recorded. The participants were randomly allocated into two equal groups by computer generated random numbers. In group I dexibuprofen was used as an analgesic and in group II Ibuprofen. In group I 5mg kg-1 dexibuprofen (oral syrup four to six times a day) while in group II 10mg kg-1 ibuprofen (oral syrup four to six times a day) was provided. Baseline and after 4 hours, the axillary temperature was recorded from both groups. Bias and confounders were controlled by randomization and strictly following inclusion criteria.

Microsoft excel sheet 2016 was used to record the data and was then imported to Stata 14 for analysis. Qualitative data like gender and age groups was presented as frequencies and percentages. Mean and SD were computed for continuous data like age and axillary temperature. Outcome variable (axillary temperature) was compared among the two groups by using two samples independent t-test under two sided hypothesis at P≤0.05 significant level. The results were stratified among genders to see effect modifiers using post stratification two samples independent t test

RESULTS

The mean age was 2.84±1.655 years with range from 1 to 8 years. The males were 107(71.33%) and females were 43(28.67%). Table No 1 shows that there was no difference in axillary temperature of participants in both groups before the intake of analgesics (p=0.527). The mean temperature after 4 hour using dexibuprofen (100.14± 1.27 0F) was lower than ibuprofen (101.29±1.23 0F). The difference were highly statistically significant (p<0.001). (Table No 1). Similarly in both males (p=0.0081) and females (p<0.001) the mean temperature after 4 hour in dexibuprofen group was lower than ibuprofen statistically. (Table No 2)

DISCUSSION

Myriad of literature are available on comparison of antipyretic efficacy of various analgesics.[10]

This randomized controlled trial was aimed to compare the antipyretic effect of ibuprofen and dexibuprofen in a sample of Peshawar population. Our findings showed that both dexibuprofen and ibuprofen are effective in control of febrile illness but mean reduction in temperature for dexibuprofen was statistically more than ibuprofen among under 12 years children.

The dexibuprofen is modified innovative drug having better efficacy due to better pharmakonetics than ibuprofen theoretically.[11] Theoretical claims are the phrased hypotheses which should be judged by evidence based research. Randomized clinical trials are considered the good source of evidence if performed correctly.[12] We conducted this randomized clinical trial to answer the question whether dexibuprofen is more effective than ibuprofen or not. Our results showed that dexibuprofen is more effective in reducing body temperature than ibuprofen statistically though no clinical difference as observed in their efficacies.

An RCT was conducted on Korean population on comparison of efficacy and safety of dexibuprofen compared with ibuprofen in febrile children due to upper respiratory tract infection. Their results showed that the mean difference in decrease of body temperature between these two drugs were not statistically significant.[9] These results are different from our study. The difference can due to genetic and environmental factors.

Table 1: Comparison of Baseline Temperature Between Ibuprofen and Dexibuprofen

Group		Mean ± SD	95% CI	P-Value*
Baseline	Ibuprofen	103.04±1.21	-0.401, 0.37	0.5270
	Dexibuprofen	103.05±1.19		
After 4 hour	Ibuprofen	101.29±1.23	0.74, 1.55	<0.001
	Dexibuprofen	100.14± 1.27		

*Independent samples t test

Table 2: Comparison of After Temperature Between Ibuprofen and Dexibuprofen Stratified By Gender

Gender	Group	Mean ±SD	95% CI	P-Value*
Male	Ibuprofen	101.21±1.41	0.21, 1.99	0.0081
	Dexibuprofen	100.13± 1.27		
Female	Ibuprofen	101.33±1.15	0.71, 1.62	<0.001
	Dexibuprofen	100.72± 1.31		

*Independent samples t test

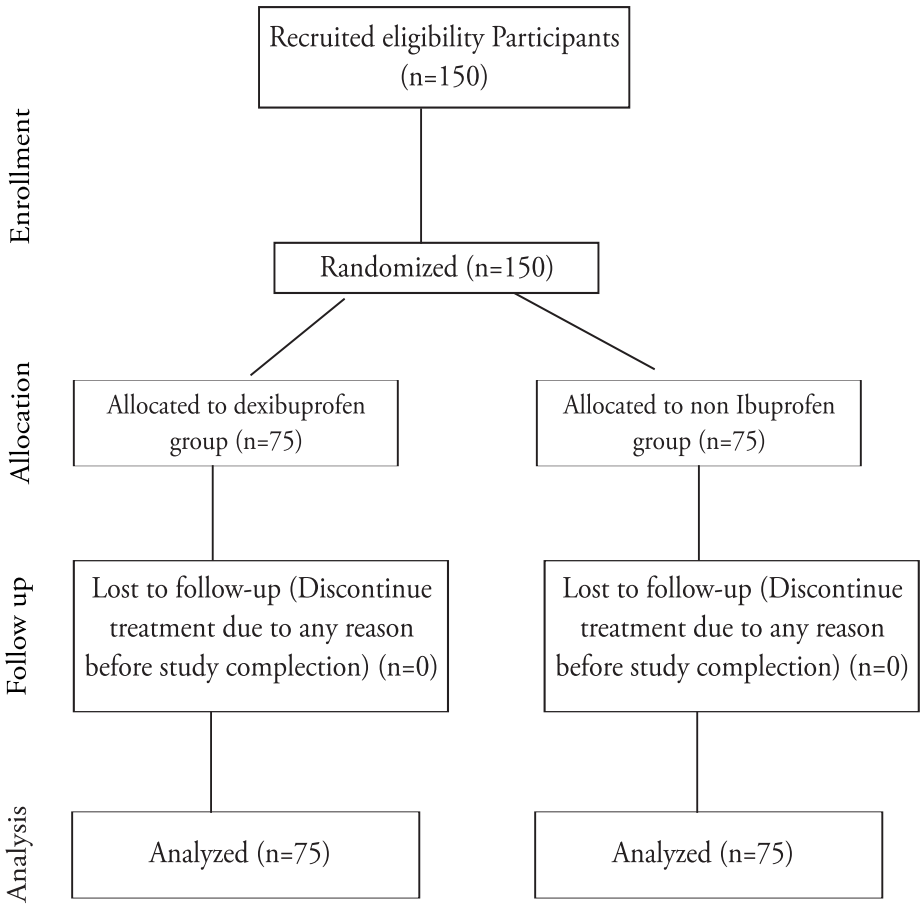

Figure 1: A CONSORT Diagram Showing the Flow of Participants Through Each Stage of the Trial

Another study was conducted on comparison of dexibuprofen and ibuprofen in the management of febrile children. Their results showed that 4 hours after the intake these drugs the mean body temperature in dexibuprofen (0.99°C ± 0.84) was lower than ibuprofen (1.38°C ± 0.84) statistically (p= 0.007).[8] These results are in consistent with our study.

CONCLUSION

Both dexibuprofen and ibuprofen are effective in control of febrile illness but mean reduction in temperature for dexibuprofen was statistically more than ibuprofen among under 12 years children.

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Author's Contribution

A designed the study, collected the data and drafted the manuscript. WKK collected the data and drafted the manuscript. AM collected & analyzed the data and drafted the manuscript. Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflict of Interest

Authors declared no conflict of interest

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Data Sharing Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

NURSING STUDENTS' EXPERIENCE OF RECEIVING FEEDBACK IN CLINICAL LEARNING: A QUALITATIVE STUDY

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ABSTRACT

Objectives: To explore nursing students' understanding of feedback, its timing and implementation in clinical learning with assessment of their perceived impact on performance due to feedback and barrier recognition.

Methodology: This qualitative phenomenological study was conducted in College of Nursing, Allama Iqbal Medical College, Lahore and College of Nursing, Nishtar Medical University, Multan. Nursing students at level of bachelor were recruited using purposive sampling until data saturation. Data was collected through in-depth interviews of 28 participants. It was tape-recorded, transcribed and analyzed through thematic analysis framework method with inductive and deductive approach.

Results: Eight themes were derived, namely; students' understanding of feedback, feedback practices, categories of feedback provided, styles and occurrence of feedback, Components of feedback, effects of feedback on learners' performance, perceived barriers to feedback practice, and areas for improvement in clinical supervision.

Conclusion: Study revealed that in clinical setting infrequent and irregular feedback is provided to student which is not according to set criteria of evaluation of skills in clinical settings. Instructors focus on specific behaviours and are biased. Improper feedback and barriers to feedback hinder students' learning.

Key words: Feedback; Clinical learning; Practice.

INTRODUCTION

Effective feedback is one of the responsibilities of clinical nursing instructors in order to enhance student's clinical performance in theory and clinical practice[1].It is observed that the suggestions and information given by the teachers through verbal, nonverbal or written format have impact on learners' performance[2]. On the other hand, feedback causes distress and low self-esteem in the learners, when it is not clear, concise and self-explanatory. So, it should be positive, goal directed and according to standardized criteria[3]. Generally, three types of feedback are recommended such as oral, written or combined. However, it is evident that students learn better when oral and written feedbacks are used simultaneously. Moreover, face to face or individual conference is more effective for treating the errors in learners' performance[4].

Feedback, for effective performance can be given on spot, weekly, monthly and upon completion of tasks. Furthermore, if it is participative, supportive, systematic and non-threatening then it will be helpful in developing self-confidence, self-realization, effective interpersonal communication, time management and decision making skills in learners[5]. Feedback is one of the important elements for students' learning in clinical involvement, which enables nurse trainees to serve securely, precisely and mercifully in human clinical settings. For this purpose, trainee nurses require sufficient support, supervision and watchful arrangement by the instructors to pick up the greatest advantages from the learning environment[6]. Despite so many advantages, feedback is a time-consuming activity and it requires establishment of an educational culture and training of supervisors[7]. Furthermore, for students, it should focus on specific areas in a positive way. These areas require appreciation and improvement through respectable manners and confidentiality. Although positive feedback enhances students' morals and performance, supportive clinical practice situation is still mandatory[8]. A study revealed that the students perceived feedback as a positive activity and constructive feedback motivated them to learn more effectively in clinical setting[9]. Similarly, another study explored that students wanted feedback soon after completion of assigned task as they felt it more effective in the entire process of learning[10]. Constructive feedback enhanced and directed students' performance, while criticism hindered their learning. Moreover, it is desired that feedback providers

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should stress on increasing learners' comfort in learning situation[11].

Furthermore, a large number of barriers may influence effective feedback practices such as ineffective communication between teachers and students, incompetent teachers, non-supportive clinical learning environment, inappropriate time and theory-practice gap etc[12]. So, instructors should be aware of innovative techniques for more effective clinical teaching. Meanwhile, teachers are required to regularly upgrade their knowledge and skills on the latest drifts in clinical practice. They must design a series of related events or processes that leave sustainable impact on students and organization, and also provide a framework to remove theory practice gap[13]. Hence structured feedback is essential to correct learner's mistakes and to develop new strategies to improve students' performance in learning process. Since, teaching learning theories developed by different educational theorists like Hull, Guthrie, Thorndike and Skinner, focused on the role of reinforcement in motivating the individual to behave in certain ways, but no structured feedback system has been formally developed and provided to learners yet. Moreover, the researcher of the current study being a nursing instructor observed that hardly any of the guidelines were being used for assessing student's performance for the purpose of improvement. Therefore, researcher wants to touch this area with an intention to explore nursing students' point of view about feedback i.e. how they perceive it, what are current practices, how it should be improved and what factors have impact on it?

Theoretical framework:

System theory, proposed by Ludwing Von Bartalanffy in 1940, was used as theoretical framework in current study. According to general systems theory, the relationship between feedback and learning is unavoidable component to bring about the change in teaching and learning process as shown in Figure 1. So the study was aimed to to explore nursing students' understanding of feedback, to identify how and when feedback takes place in clinical learning, to assess students' perceived impact of feedback on performance and to recognize barriers in current feedback practices during clinical learning.

METHODOLOGY

Qualitative phenomenological study was conducted in College of Nursing, Allama Iqbal Medical College, Lahore and College of Nursing, Nishtar Medical University, Multan. After approval from Institutional Review Board (IRB) of the university, institutional permission was taken from concerned administrative authority. Students of B.Sc. Nursing (3rd Year and 4th Year) were recruited using purposive sampling until data saturation, when no new information was identified by the participants. Failure students undergoing for supplementary examination were excluded. After introduction, researcher explained the purpose and procedure of data collection. Written informed consent was attained, and then direct face-to-face in depth interviews of 28 participants were conducted using an interview guide. Sample size was large enough for qualitative study, as study was conducted in two different setups, and students had variety of experiences to share, so data saturation started around 25 participants. Researcher added 3 more participants to avoid losing any information. Interviews with the participants were conducted to collect the data. Interviews were conducted in Urdu language with proper confidentiality and privacy, and the participants had the right to withdraw at any time. The interviews were recorded with the permission of the participants. Qualitative data obtained during interview was analysed using thematic analysis framework method with inductive approach. Six-phase guide by Braun and Clarke (2006) was used, which was very helpful for conducting this kind of analysis.

Each participant was given an identity document (ID) number. Interview Recordings were transcribed and translated by the researcher manually, and reviewed by the experts in English language. Written transcripts were read and re-read to get familiarity with the data, common words and phrases were highlighted as meaning units, these units were coded and grouped together to generate themes and subthemes. Then, the researcher discussed all transcripts with co-authors to ensure that selected themes and subthemes were representative of the data. Then themes were defined and written down verbatim.

To analyse the findings in context of theoretical framework used in study, deductive analysis method was used. In deductive analysis method, predetermined codes generated in inducted analysis were categorised according to relevance with the concepts of general system theory and then these codes were presented in theoretical framework.

RESULTS

Twenty-eight students of 3rd year and 4th year B.Sc. Nursing with age range of 18-22 years were the participants in the study. After inductive thematic analysis of qualitative data, eight themes emerged from the participants' responses which are described below.

Theme 1; Students' understanding of feedback

The participants explained well the term feedback, as all of them perceived it as a two-way process where their activities were observed by clinical teachers. This was validated when learners defined feedback as an analysis of work by supervisor which is done in clinical areas.

"I think feedback is a process in which supervisor judge our work and evaluate deficiencies and tell us how to correct. It is a task of supervisor to give feedback" (ID14)

Theme 2; Feedback Practices

According to participant's point of view, the current feedback practices should be goal oriented and according to set criteria. Respondents perceived feedback practices are objectives focused, but commonly mistakes oriented. Participants professed that it is a behaviour modification tool, as stated,

"feedback is usually conducted against the set standards although it is used as a fault findings practice in which the teachers just focused on our mistakes." (ID21)

Theme 3; Categories of feedback provided.

The participants identified multiple types of feedback provided to them in their clinical learning, but according to them, verbal feedback usually occurs during clinical assignment to ensure performance accuracy. However, verbal feedback is also strengthened by written, they stated. Besides this, some other forms of feedback were also conveyed by the participants. According to them, positive feedback is offered in recognition of students' good performance and the negative one on poor performance. Two of the study participants mentioned that,

"Positive feedback enhances my morals and motivates me for better performance while negative hurts my feelings, ultimately leading to mistakes or even spoil my interest in clinical practice". (ID5, ID11)

Theme 4; Styles and Occurrence of feedback

Under this theme, the participants reported how and when they are provided with feedback. They reported that their performance is graded as poor, average, good and excellent, they also expressed that tasks are clearly defined when these are given to students and the feedback is most often provided at the end of each task they perform. Participants perceived that feedback which is provided at the end of year is not very productive for performance upgradation.

"We are just rated as poor, average, satisfactory or good and usually supervisors don't directly observe us. They just give feedback at the end of year. So don't put much in my learning" (ID19)

Theme 5; Components of feedback

The participants reported that they are observed and communicated for performance, discipline and punctuality and their relationships with staff and peers in clinical learning. The findings showed that almost all the components of feedback were equally recorded, but mostly importance was given to personal relationships, and favourite students were ranked high in feedback. As participants told,

"Teachers give us feedback on our skill performance, uniform, discipline etc. but I observe that they discriminate among favourite students and other students". (ID04, ID09)

Theme 6; Effects of feedback on learner performance

On exploring the impact of feedback on learners' performance, the participants acknowledged that it enhances attention in clinical learning, updates students about their progress, and communicates with the learner for observed learning needs for clinical perfection. It encourages learner to take part in proper learning actions and also plays an important role in professional development. While participants also explored that negative feedback provided in negative way hinders student's learning.

"Feedback helps in repairing our faults and is beneficial for professional development and clinical skills perfection." (ID10, ID24)

"It demoralizes the students when they receive continuously negative feedback so negative feedback should be given with positive attitude". (ID03, ID11)

Theme 7; Perceived Barriers to feedback practice

Participants conveyed a list of barriers, faced by them, in the entire process of feedback in students' clinical area. The study participants identified lack of up to date knowledge of ward staff and theory practice gap as barriers which create obstacles in their learning, and consequently effect productive feedback process. Insufficient number of clinical instructors and non-supportive behaviour of ward staff are also one of the identified barriers as reported by the participants.

"We are not provided feedback regularly and effectively due to many reasons, sometimes instructors are not available, sometimes they don't have time to observe, some instructors even don't know how to give feedback." (ID04, ID12)

Theme 8; Areas for improvement in clinical supervision

The participants recommended that current feedback practices can be improved by correlating theory with practice, by improving education and refining staff skills, by developing positive attitude and ensuring conducive learning environment. According to participant's point of view, clinical training permits nursing students to take direct experience from the live nursing situation,

to exercise the hands-on practice, to learn about general nursing routines, and to acquire the responsibilities of the nurse that is essential for becoming a registered nurse, so they must be provided with positive feedback and conducive learning environment.

"Teachers should be trained for effective feedback practices and they should also be kept updated by training and continuous nursing education. They should be trained for providing feedback by workshop." (ID09, ID21)

"Staff nurses who are supervising students in clinical should also update their skills according to advance standards" (ID1, ID16).

DISCUSSION

This study explored that all students had the clear concept of feedback and its purpose in the clinical learning e.g. to interact with students, directly supervise them and rectify their mistakes by clinical teachers. Findings are in line with previous exploratory study.[9] Similarly, findings suggest that students perceive that feedback should be an important element of educational and clinical activity in order to attain predetermined objectives, meet standards, identify errors and ensure correction in student's performance, but they perceive, it is used only as fault finding activity and negative criticism tool, as supported by previous study[14].

Findings suggested that verbal and written feedbacks usually occur during performing any clinical assignment which improves efficiency. These results are also matching with the study 'verbal feedback promotes students' ability to accurately perform a given activity when supported with written.[15] Furthermore, findings explored that positive feedback enhances student's abilities while negative and biased hinders student's capacity to learn. Results are also supported by literature.[8,9]

Findings of current study communicated that the instructors use traditional feedback methods and provide mostly at the end of every assignment and rate students' performance as poor, good, very good and sometime excellent. On the other hand, some of the students reported, it is not clear enough which is contrary to the previous studies that mentioned regular feedback provided during or soon after any of assigned task can be more helpful to prepare students as a best practitioner nurses in future[16].

In present study, performance, discipline, punctuality and relationship with staff and peers were perceived as important components in the feedback system, which are also the components of standard criteria of feedback practices.[17] Current study showed that instructors focus on overall performance rather than focusing on skills performance.

Findings suggested that participants acknowledged that feedback provided in positive way enhances attention in clinical

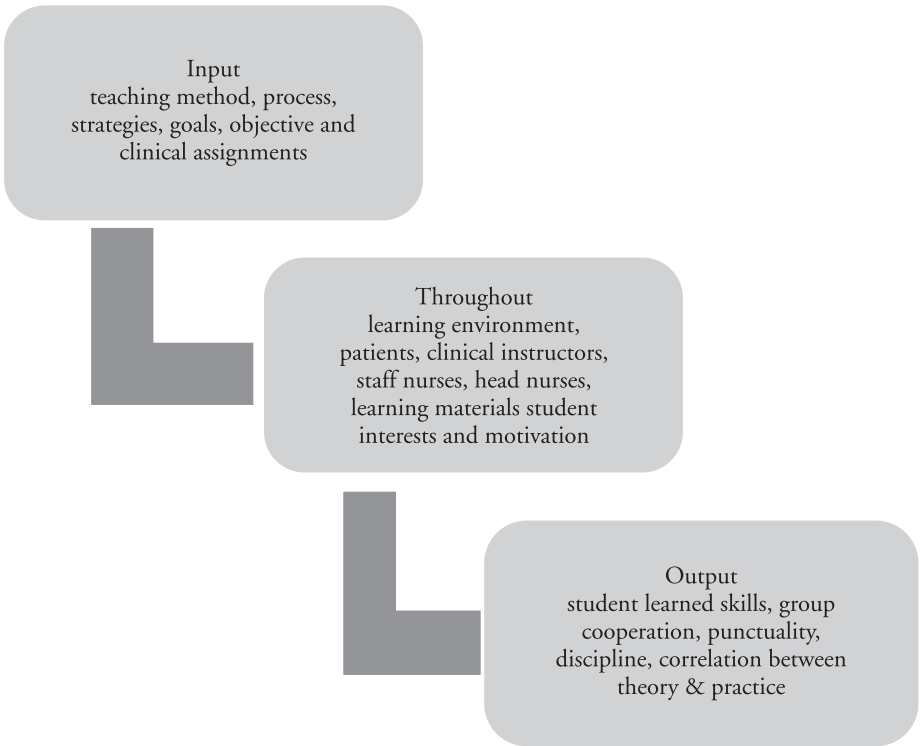

Figure 1: The Relationship Between Feedback and Learning

learning, helps in repairing faults, update about their progress, and motivates them for further hands-on practice improvement. Results of this study aligned with previous studies which mentioned that feedback performed properly, can lasts a major impact on the learner's efficiency and growth as well as retention in workplace[18].

Students proposed that inadequate number of clinical instructors/supervisors, lack of training and education, unfavourable ward learning environment and insufficient time, shortage of clinical resources and overcrowded wardsare perceived as barriers. These findings of our study are in line with previous study which explored that these barriers prevent them and supervisors to ensure positive and productive feedback[19].

Findings of the study explored that, students suggested that, to improve feedback practices a standardized assessment tool or strategies should be used and appropriate number of ward supervisors and clinical instructors should be trained with sound professional and technological knowledge and skills to provide proper feedback.[20,21] In addition, feedback should be provided with respectful manners and a comprehensive written feedback should be augmented by faculty development to ensure meaningful use.[11]

CONCLUSION

Study revealed that current feedback practices in clinical are infrequent. Irregular feedback is provided to students which is not according to set criteria of evaluation of skills in clinical settings. Instructors focus on specific behaviours and are biased. Improper feedback and barriers to feedback hinder students' learning. Well informed, timely and constructive feedback positively influences learners' performance. Furthermore, nursing tutors should be trained through workshops.

RECOMMENDATIONS

Current study recommends the periodic training of clinical teachers on feedback practices and development of standardized assessment tool or strategies for assessing students' performance. The study is expected to be helpful to the Pakistan Nursing Council, Policy Makers, Various Universities involved in nursing education, Academician, and Educators enduring to upgrade the faculty in learning process and the students at large.

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Author's Contribution

NS conception and design of study, statistical analysis & interpretation of data with manuscript drafting. SM conception and design of study, statistical analysis & drafting of the manuscript. SF drafting with critical revision of manuscript and final approval. MG analysed data for the manuscript. Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflict of Interest

Authors declared no conflict of interest

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None

Data Sharing Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

COMPARISON OF EFFICACY OF BOTULINUM INJECTION WITH SURGICAL RELEASE IN CEREBRAL PALSY CHILDREN WITH FOOT EQUINUS

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ABSTRACT

Objective: To compare the efficacy of surgical release and Botulinum Toxin injections for treating foot equinus in Cerebral Palsy (CP) patients.

Methodology: This Quasi-experimental study was conducted in the Orthopedic Department, Khyber Teaching Hospital (KTH) Peshawar-Pakistan. The study enrolled 60 patients from 1st March 2018 to 1st June 2019 via non-probability consecutive sampling. All diagnosed cases of CP with equinus foot of either gender and age between 4-18 years with no previous surgery or botulinum injections and no joint deformity were included; while all patients with myasthenia gravis, neuromuscular junction disease, use of aminoglycoside, and those with discontinued physiotherapy were excluded. The patients were distributed into two equal groups, group A (botulinum group) and group B (surgery group). The outcome of the interventions in each group was measured based on improvement in Gross Motor Function Measure-66 (GMFM-66). Data was analysed using SPSS v.21.0, descriptive and analytical analysis was conducted where needed.

Results: The mean age of patients was 11.47±4.01 years with male to female ratio of 1.22:1. The right and left foot distribution among the patients was 31 (52%) and 29 (48%) respectively. Botulinum type A (BTX-A) injection resulted in improvement of GMFM-66 score in 27 (90%) patients in group A while the surgical release was effective in 20 (66.7%) patients in group B in terms of improvement in GMFM-66 score.

Conclusion: The study concluded that Botulinum Toxin has much better effectiveness as compared to surgical release in treatment of foot equinus among CP patients.

Key Words: Efficacy; Botulinum Toxin; Surgical Release; Equinus; Cerebral Palsy.

INTRODUCTION

Cerebral Palsy (CP) has an incidence of 1.5-3 cases per 1000 live births and is one of the most common causes of physical disability in humans.[1] CP is defined as a disorder of posture and movement that appears at an early age. It is not caused by degenerative or progressive disease of the brain and is secondary to dysfunction or lesion of the central nervous system. CP is most prevalent in premature children and represents around 65% of all cases.[2] Equinus is a common deformity in cerebral palsy patients and is defined as the inability to dorsiflex the foot above the plantigrade, with the knee extended and the hindfoot in a neutral position.[3] Equinus is caused by triceps surae contracture. It has a direct impact on the gait and standing ability of the patient.[4] Its treatment options consist of non-operative modalities like physical therapy, stretching the contracted tissue with serial casting, botulinum toxin injection, brace management, and finally, and triceps surae lengthening.[5]

Equinus surgery is aimed to produce a plantigrade foot and improve standing function and gait but there is a danger of overcorrection to hyper dorsiflexion causing progressive crouch. Recurrence is very common after surgical treatment and the outcomes of the surgical intervention have been extensively reported.[5] On the other hand, Botulinum toxin is a neurotoxin protein produced by the bacterium Clostridium botulinum.[6, 7] Botulinum toxin A (BTX-A) is considered an effective and safe therapy for children with cerebral palsy (CP).[8] BTX-A injections were found effective for spastic equinus in cerebral palsy in 64% of cases and the remaining cases were reported as poor responders.[9] Equinus is the most common ambulatory problem in CP and produces an inefficient and unstable gait pattern. It can progress to permanent deformities of the foot requiring surgical intervention if not managed at an early stage. Early intervention can allow children to maximize func-

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tional mobility and regain or maintain a full range of motion (ROM). In addition, these interventions help prevent contracture and delay surgical intervention.[10]

Several studies demonstrate the effectiveness of BTX-A injections and surgical treatment in achieving these goals.[11] However, no particular local data in the subject area is available from a tertiary care hospital of the Peshawar. So, this is designed to compare the efficacy of surgical release and Botulinum Toxin for the treatment of foot equinus in cerebral palsy patients.

METHODOLOGY

This quasi-experimental study was conducted in the Orthopedic Department, Khyber Teaching Hospital Peshawar-Pakistan from 1st March 2018 to 1st June 2019. Patients of both gender and aged between 4-18 years with diagnosed Cerebral Palsy (CP) and equinus foot irrespective of the degree of equinus, with no previous surgery or botulinum injection, and no joint deformity were included in the study. All those Patients with myasthenia gravis, neuromuscular junction disease, use of aminoglycoside, and those who discontinued physiotherapy were excluded from the study. Total of 60 patients were included in the study and were distributed equally into 2 groups. Group A consisted of patients that received Botulinum Toxin injections while patients treated surgically were included in group B.

This study was conducted after approval from the ethical committee of the hospital. All patients presented to the emergency department or were admitted through Out Patient Department, meeting the inclusion criteria were included in the study and were followed by informed consent. All the patients underwent a detailed history and clinical examination including the Silfverskiold test followed by routine lab investigations. The patients were treated under the supervision of seniors who were fellows of CPSP and have more than 5 years of experience as consultant Orthopedics. Patients were assessed in terms of GMFM-66 score at baseline i.e., before either intervention and at 1.5, 3, and 6 months intervals.

For group A, 100U of botox toxin type A were diluted in 1 ml normal saline achieving a concentration of 10U/0.1ml. Under sterile conditions, patients were injected with 4U/kg BTX-A (with a maximum dosage of 200U) with half of the dose injected on the medial side of gastrocnemius while the other half on the lateral side. For group B we did percutaneous Achilles tendon lengthening using Hoke's three incision techniques in which after identifying the Achilles, it is cut part way through using a small incision. The first incision is made near the insertion of the tendon and it cuts through the skin and half of the tendon usually the medial half. The second incision is made 1-2 cm above the first in the same way as the first but on the lateral half. A third incision is made 1-2 cm from the second incision and is used for releasing the inner half of the tendon followed by gentle pressure applied to the foot to allow the sliding of the fibers over each other in the cut areas and the Achilles tendon is lengthened gently. Finally, the incisions are stitched. The patient is immobilized with the ankle joint in a neutral position.

Data were analyzed using SPSS v.21.0. Mean and standard deviation was used for quantitative data. Frequency and percentages were used for qualitative data. Shapiro Wilk's test was done to find the normality of the data. T-test was applied to measure the difference in efficacy between the two groups keeping P-Value < 0.05 as significant.

RESULTS

This study included a total of 60 patients with a mean age of 11.47 years ± 4.01 SD. The basic demographics of the study are mentioned in (Table No 1).

Postintervention effectiveness in group A showed an improvement of GMFM-66 score in 27(90%) patients while 3(10%) patients have no improvement. Group B showed an improved score in 20 (66%) patients while no improvement in 10(34%). The details of improvement in GMFM-66 score at the baseline and a follow up of 1.5, 3, and 6 months is shown in (Table No 2)

DISCUSSION

Cerebral palsy (CP) is the most common cause of physical disability in children, affecting 1 of 400 children.[10] It has a multitude of motor disorders like paresis, spasticity, in-

Table 1: Basic Demographics of the Study

Mean Age of Patients			
	Group A	Group B	Overall mean age
Male	11.03 ± 4.02 years	11.63 ± 4.06 years	11.47 ± 4.01 years
Distribution of patients based on gender			
	Group A	Group B	Total
Male	17 (56%)	16 (53%)	33 (55%)
Female	13 (44%)	14 (47%)	27 (45%)
Male to female ration	1.3:1	1.1:1	1.22:1
Distribution of patients based on side involvement			
	Group A	Group B	Total
Right	20 (66%)	11 (63%)	31 (52%)
Left	10 (34%)	19 (37%)	29 (48%)

Table 2: Stratification of in Terms of Gmfm-66 Score

Distribution based on GMFM-66 score			
	Improvement in GMFM score	No Improvement in GMFM score	p-value
Group A Botulinum Toxin group	27 (90%)	3 (10%)	0.029
Group B Surgery Group	20 (66%)	10 (34%)	
Details of improvement in GMFM- 66 Score			
	Group A	Group B	
	Mean±SD	Mean±SD	
Pre-injection (Baseline)	71.51±13.44	68.54±10.88	
Post-injection 1.5 month	72.53±13.54	69.03±11.06	
Post-injection 3 months	74.44±13.31	70.14±11.98	
Post-injection 6 months	77.45±13.53	70.93±12.09	
Change (1.5 month)	1.02±2.99	0.49±2.45	
Change (3 month)	1.91±3.27	1.11±3.26	
Change (6 month)	3.01±3.49	0.79±3.10	

coordination, and dystonia. Lower limb spasticity causes a problem in walking in 80% of these children.[11] Clostridium botulinum produces a potent neurotoxin called Botulinum toxin.[12]

This quasi-experimental study demonstrated the efficacy of botulinum toxin for the treatment of CP-related equinus gait in terms of improvement in GMFM-66 score. The parameters of gait that are related to spasticities of the gastrocnemius and soleus muscle complex, like ankle position and gait pattern, showed significant improvement with botulinum toxin (BTX-A). the pattern of improvement of gait from baseline was followed for 6 months and found was statistically significant. As demonstrated by a previous double-blinded trial, this study also confirms the improvement in ambulation in patients with the BTX-A injections when compared with a placebo.[13]

In addition to improvement in ankle position and gait pattern, botox toxin also caused improvement in knee position thus improving knee recurvatum during gait. Even though upper leg muscles are more important for the position of the knee during gait, spasticity of gastrocnemius can contribute to knee recurvation as well.[14, 15] In fact, we can achieve a normal foot contact by knee recurvatum when we have a persistent equinus of the ankle. Thus if we decrease the position of the equinus foot, knee recurvatum can be made less evident with the passage of time.

A slight improvement in the position of the hindfoot was also noted during foot strike. Improvement in the position of the foot is a significant finding because due to BTX-A administration the muscles controlling the ankle and foot may become more balanced. A single BTX-A injection had a lasting effect of an average of 3 to 6 months, which was in accordance with other studies of focal dystonia.[16, 17]

The GMFM-66 is an adequate scale for assessing function in children of cerebral palsy.[18] Compared to the patients treated surgically, we noted a clinically significant improvement in patients after BTX-A injection in terms of GMFM-66. In the BTX-A group, the GMFM-66 score improved from 71.51 to 77.45 with a total change of 5.94 at the 6 month follow up while in the surgery group it improved from 68.54 to 70.93 with a total change of 2.39 at 6 months follow up.

After the administration of BTX-A injection, we did not notice any differences in improvement in GMFM-66 in hemiplegic versus diplegic children. GMFM score has rarely been used as an outcome measure in studies even though it is a recommended tool for assessing motor performance in cerebral palsy patients.[19, 20]

Boyd and Graham reported a significant functional improvement in a subset of 2-4-year-old CP patients that lasted for more than 18 months after the administration of BTX-A.[21] The dose of BTX-A be tailored according to the need of the patient because the duration of the therapy and its effect depends on the factors like the physiology of the muscle before injection including endurance, spasticity, and power, delivering the toxin into the target muscle(s); extensibility of connective tissue and joint range of motion.

Due to developmental changes in the pattern of gait and maturational changes of the musculature it is difficult to predict the long-term success of surgical intervention to improve ambulation. If performed in early childhood the recurrence rate of equinus in children is very high.[22] The necessity for surgery can be delayed by decreasing muscle spasticity with BTX-A injections thus providing time for gait patterns muscles to mature.

Richardson states that BTX-A injection provides a favorable opportunity for making changes in muscle function, length, pattern of movement, and also in antagonist motor control.[23] BTX-A provides the necessary active and passive stretch for longitudinal muscle growth. Although the literature is deficient concerning muscle growth in CP children, Eames et al noted an increase in length of gastrocnemius after BTX-A injection.[24] BTX-A causes a decrease in focal muscle spasticity which provides an opportunity for children to strengthen and learn the use of opposing muscles via occupational and physical rehabilitation.

In this trial, BTX-A injection caused an improvement in the gait of children having equinus deformity and this improvement was maintained over 6 months period of follow-up. The outcome of our trial suggests and also supports the idea that reduction of excessive foot and ankle tone with BTX-A may improve gait and can be a first-line therapeutic option in the treatment of equinus foot deformity due to cerebral palsy.

A key limitation of this study is that the data was collected from a single institution, even though we included the data from different surgical teams, the generalizability of our results becomes limited.

CONCLUSION

The study shows that Botulinum toxin is more efficacious, can be easily administered as an outpatient procedure and causes more improvement in walking among patients with equinus foot due to cerebral palsy.

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Author's Contribution

KI designed, analyzed the data, and drafted the study. MK designed, analyzed the data, and drafted the study. MU collected & analyzed the data with drafted the study. IA collected the data with drafted the study. Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflict of Interest

Authors declared no conflict of interest

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None

Data Sharing Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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ROLE OF POVIDONE-IODINE-SOAKED GAUZE IN PREVENTING INFECTIOUS COMPLICATIONS FOLLOWING TRANS RECTAL DIGITAL GUIDED PROSTATE BIOPSY

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ABSTRACT

Objective: To identify the role of povidone iodine-soaked gauze following transrectal digital guided prostate biopsy in the prevention of infectious complications.

Methodology: This prospective comparative study was conducted in the urology department of Lady Reading Hospital including 201 patients. Patients who had indications for prostate biopsy, including an elevated prostate-specific antigen (PSA) or abnormal prostatic nodule on digital rectal findings were included. Patients were distributed into two groups by the closed envelop method. Group, I (n=101) received a povidone-iodine-soaked gauze intrarectally along with xylocaine lubricant for 5 minutes just before biopsy, while group 2 (n=100) did not receive povidone-soaked gauze. The transrectal digital guided prostate biopsy guided method was used in this study. The rectal swab was taken before using povidone-soaked gauze and after doing biopsy in both groups The bacterial colonies were counted in swabs before using povidone-soaked gauze and after biopsy using biopsy Mueller-Hinton agar medium.

Results: The mean age of group 1 was 64 years (range, 39–80) and group 2 was 61.7 years (range, 35–82). The average PSA values were 7.3 ng/ml and 8.34 ng/ml in groups 1 and 2, respectively. The rate of infectious complications in group1 was 0.9% (n=1) whereas in group 2 was 10% (n=10). A single-use of povidone-soaked rectal gauze significantly lowered the risk of infectious complications $P<0.05$. There was a 99.9% decrease in the mean number of colony-forming units after rectal preparation.

Conclusion: Findings concluded that using povidone iodine-soaked gauze before doing digital guided prostate biopsy is a significant method to minimize complications.

Key Words: Transrectal ultrasonography; Prostate biopsy; Povidone-iodine; Sepsis

INTRODUCTION

Prostate biopsy is a gold standard test for the detection of prostate cancer.[1] It is reported that prostate cancer is the second most prevalent malignancy after lung cancer in 2018, accounting for more than 1276100 new cases and 358900 deaths (3.8% of all cancer deaths) globally.[2,3] The rate of prostatic biopsy techniques has dramatically increased after the introduction of prostate-specific antigen (PSA). PSA is a vital parameter in the diagnosis of prostate carcinoma [1]. Nowadays Transrectal ultrasound (TRUS) guided biopsy is the standard protocol for the precise mapping of the suspicious hypoechoic lesions in the prostate. Previously six-core biopsy was in fashion but to increase the sensitivity of TRUS guided biopsy twelve core biopsy is recommended now a days[4]. A previous study reported that rectal cleansing with povidone-iodine before the transrectal ultrasound-guided prostate biopsy was safe[5]. Due to economic constraints, our institute is not having the facility of TRUS, that's why Digital guided prostate biopsy is still in practice in our setup. Digital guided prostate biopsy is a safe procedure not requiring specific and complicated preoperative preparations but still one can come across minor as well as major complications like urosepsis[6]. One of the disastrous complications encountered after trans rectal prostate biopsy are the pathologies having infectious etiology prostatitis, epididymitis, prostatic abscess, sepsis eventually leading to death[7].

The most common practice by urologists in most of the Khyber Pakhtunkhwa institutions is to administer antibiotics prophylactically to minimize the infection chances after biopsy, but despite these protocols still, the chances of infection persist. That's why to reduce infectious complications a bowel preparatory technique in the form of rectal scrubbing has been in use. How-

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ever, the effects of rectal scrubbing are not established as per recent guidelines up till yet. Literature about povidone-iodine-soaked gauze in preventing infectious complications after a Transrectal digital guided prostate biopsy is lacking in Pakistan. This study is the first in our setting to the best of our knowledge. Therefore, this study was conducted to determine the role of povidone iodine-soaked gauze following transrectal digital guided prostate biopsy in the prevention of infectious complications.

METHODOLOGY

This prospective comparative study was conducted in the Urology department of Lady Reading Hospital Pakistan from January 2014 to January 2018 including 201 patients. The study was approved by the ethical review board of the selected hospital vide notification number [(10-1/LRH/ MTI)]. Patients of any gender with indications for prostate biopsy, abnormal prostatic nodule on digital rectal findings, and an elevated PSA were enrolled in this study.

A single dose of 1gm intravenous 3rd generation cephalosporin (Ceftriaxone) was administered to all the patients just before biopsy in combination with oral ciprofloxacin (500 mg BD) on the morning of the procedure, then followed by 5 days post-procedure in both groups. All (n=201) patients were distributed into two groups by the closed envelop method. Group, I received a povidone-iodine-soaked gauze intrarectally along with xylocaine lubricant for 5 minutes just before biopsy, while group 2 did not receive povidone-soaked gauze. All patients were informed a consent form shall be signed by all of them prior to the procedure for biopsy. Transrectal digital guided Trucut prostate biopsies were performed after applying 2.5% topical lidocaine gel using a 16-gauge Trucut spring-loaded needle in an operation theatre by an experienced urologist. From both, groups 4 core prostatic biopsy was obtained. At one-week follow-up, Patients were assessed for post-biopsy complications which were recorded on computerized proforma. Due to the non-availability of Transrectal ultrasonography (TRUS) in our region, we used TRUS digital guided method in this study.

The classification of infectious complications was sepsis-free fever and sepsis. Sepsis was characterized as two or more of the following infection-related conditions: body temperature < 36 or > 38, heart rate more than 100 beats/minute, breathing rate equal to or more than 20 breaths/minute, and WBC counts >10 000 cells or < 4000 cells[7]. A body temperature of more than 38 ^{o}C was considered as fever. Other complications like haematospermia, hematuria, and perineal discomfort/pain were also evaluated.

For the determination of the bactericidal properties of povidone-iodine gauze, bacterial colonies were counted in the rectum which was obtained by the insertion of the gauze before the rectal swab and after biopsy. Colonies were counted by dilution of agar. Rectal swabs were diluted and immersed in sterile saline before being put to the Mueller-Hinton agar medium in sections. The bacterial colonies counts were determined after the entire night of incubation. The final data was analyzed using Statistical Package for Social Sciences (SPSS) software, version 22 (IBM Corp. USA). To determine the significance t-test was applied.

RESULTS

The mean age of group 1 was 64±5 years (range, 39–80), while group 2 was 61.7±8 years (range, 35–82). The average PSA level in groups 1 and 2 was 7.3±1.5ng/mL and 8.34±1 ng/mL respectively. Demographic and complications data of the enrolled subjects are presented in table 1. There was no substantial difference between Groups 1 and 2 in terms of statistical demographic results.

In the no rectal preparation group (group 2) 10 cases (10%) developed infectious complications and whereas only 1 patient (0.9%) in group 1 got infected. Out of 10 infectious complications in the no rectal preparation group (group 2), 8 subjects had fever without any septic element and two patients got septic. One patient from group 1 complained of feverish sensation, which resolved with a stat dose of two tablets of Panadol orally. Hematuria developed in 15 (14.8%) patients in group 1 and 10 (10%) in group 2. In group1 9.9% of cases presented with rectal bleeding whereas 8% in group 2. No transfusion or intervention is required to manage these noninfectious complications as shown in table 1.

A single-use of povidone-soaked rectal gauze significantly lowered the risk of infectious complications $P<0.05$.

This study revealed that the bacterial colony count before the rectal preparation was in the range of 2.19×105 to, 7.5×105 but decreased to less than 3x101 after biopsy. After rectal scrub by povidone, a significantly decreased by 99.9% in the mean number of colony-forming units was observed. The data show that the bacterial count decreases when the povidone gauze is inserted. The use of povidone statistically lowered the colony count as shown in table 2.

DISCUSSION

In this study, a single use of povidone-soaked rectal gauze significantly lowered the risk of infectious complications. After the rectal preparation, there was a 99.9% decrease in the mean number of colony-forming units. hematuria and rectal bleeding complications were also observed. According to the previous studies, one of the most common complications was perineal pain which was noticed in more than 65% of patients and the frequency is still on the increasing side due to an increase in the

Table 1: Patients demographic details (n=201)

Variables	Group 1	Group 2	T-Test
Patients number	101	100	
Mean age (years)	64±5	61.7±8	
Average PSA (ng/mL)	7.35±1.5	8.24±1	P=0.231
Prostate cancer diagnosis	42 (40.6%)	16 (16%)	
Infective complications			
Sepsis	0	2 (2%)	
Sepsis-free fever	1 (0.9%)	8 (8%)	P=0.02
Other complications			
Hematuria	15 (14.8%)	10 (10%)	P=0.289
Rectal bleeding	10 (9.9%)	8 (8%)	P=0.25

Table 2: Colony counts before insertion of povidone-iodine-soaked gauze and after biopsy

	Colony counts before povidone-iodine soaked gauze	Colony counts after povidone-iodine soaked gauze
1	2.19×105	5×102
2	1.93×104	≤3×101
3	1.09×104	≤3×101
4	7×103	≤3.6×101
5	7.2×105	≤3×101
6	7.5×105	≤3×101

number of biopsy chunks[8,9]. Furthermore, hematuria, local pain, haematospermia, dysuria, and rectal bleeding complications were also reported in previously published literature. Hematuria after a biopsy has been reported in up to 60% of cases whereas the frequency of haematospermia is also more or less equal to hematuria about 64%[10]. Rectal bleeding is also one of the common complications reported in 75% of patients and very rarely 1% of patients suffer from massive rectal bleeding requiring blood transfusions up to 5 pints [11]. Rectal bleeding heals by itself in the majority of patients and is not bothersome. Unlike rectal bleeding and hematuria, haematospermia has a transient harmful effect on sexual activity. A short-term worsening of symptoms of the lower urinary tract has been described in 6 to 25% of patients with a reported incidence of 0.4% urinary retention cases [12-15]. A small number of patients also complain of the transient erectile dysfunction which reverses by itself after 1-3 months without any medication[16].

Infection is one of the adverse complications represented by prostatitis, epididymitis, Prostatic abscess, and sepsis. Antibiotic prophylaxis is defined as the administration of antibiotics before contamination by surgical incision has occurred and is given to prevent infection. The usage of prophylactic antibiotics is a standard of care to minimize infectious complications [17-20]. Ciprofloxacin is the drug of choice for the long long-term because of its broad-spectrum activity and high concentration in prostatic tissue. The Resistance to ciprofloxacin is on rising because of excessive prescriptions which ca urinary tract infections, which is a quite alarming situation for healthcare professionals, to tackle this intervention it is recommended to use multidrug prophylaxis. [21]. The fever is associated with lower urinary tract and septicemia were reported 3-10% and 5% respectively in patients after prostatic biopsy. Despite consensus on prophylactic administration of antibiotics, regimen duration, timings, and administration route are still debatable. Ciprofloxacin at a dosage of 100 mg BID for 3 days was the minimum effective dose for the treatment of uncomplicated urinary tract infection.

Although the incidence is low but still the possibility of infectious complications is there despite prophylactic antibiotic administration. For this reason, some urologists use a rectal cleansing enema to reduce the chances of infection. Anastasiadis et al. reported that chances of bacterial infection can be lessened by a pre-biopsy administration of an enema. They highlighted that about 4% of patients presented with bacteremia had an enema before biopsy as compared to 28% of patients who didn't have a pre-biopsy enema. This study provides a solid base for use of rectal enema scrub before the prostatic biopsy. While searching international literature it is evident that a minority of patients for example 1.1-1.4% require hospitalization secondary to sepsis whereas in our study 2% required hospitalization in the non-rectal prepared group and none of the patients developed sepsis in the rectal prepared group[22].

Even with the use of prophylactic antibiotics, there is the possibility of getting infection chances are there–which can be reduced by using a povidone-iodine rectal swab preoperatively. When Povidone-iodine rectal prophylaxis was combined along with the use of antibiotics as compared to the only use of antibiotics significant difference was there with combination therapy.[23] Povidone-iodine is commonly used in surgical and allied fields due to its broad-spectrum antimicrobial activity and anti-inflammatory activity. Povidone-iodine is used in different concentrations as an antiseptic solution. Jordan et al. reported a 97% decrease in the colonies after using the povidone-iodine rectal swab whereas in our study the result was even more significant with a 99% decrease in colonies[24]. Borghesi et al. determined that parenteral use of piperacillin with a povidone-iodine enema which is a method of de-

livery of liquids through rectum significantly decreases the complication caused by bacterial infections.[25] A meta-analysis of eight studies reported by Walker et al. showed a significant drop in the incidence of bacteriuria and sepsis after prostatic biopsy[23].

Microbial growth of bacteria in colonies was counted in the rectum collected from rectal swabs before and after povidone-iodine injection and biopsy to investigate the antibacterial effects of povidone-iodine. Bacterial colony counts were reported to be significantly lower following the prostate assay when compared to counts before rectal preparation. These local antiseptic treatments appear to be one of the least expensive ways to reduce the occurrence of infection problems. Our study also indicated that using a povidone-iodine rectal swab to prevent infective consequences is a dependable, cost-effective, and trusted strategy.

An ultrasound-guided prostate biopsy is a gold standard, well-tolerated and one of the most common procedures used as a diagnostic tool for prostate cancer, but due to scarce financial resources, trust digital guided prostate biopsy is utilized as a diagnostic tool in all tertiary care hospitals of Khyber Pakhtunkhwa. Although we do not come across complications most of the time yet it's not a harmless procedure. Secondly, the strength of our study is that comparison has been done between two groups and large sample size, but on the other hand weakness is that randomization was lacking in our study.

LIMITATION

Firstly, an ultrasound-guided prostate biopsy is a gold standard, well-tolerated, and one of the most common procedures used as a diagnostic tool for prostate cancer, but due to scarce financial resources, Trust digital guided prostate biopsy is utilized as a diagnostic tool in all tertiary care hospitals of Khyber Pakhtunkhwa. Although we do not come across complications most of the time yet it's not a harmless procedure. Secondly, the strength of our study is that comparison has been done between two groups and large sample size, but on the other hand weakness is that randomization was lacking in our study.

CONCLUSION

The current study concluded that rectal preparation using a povidone-iodine soaked rectal gauze for 5 minutes is an effective and cheap method in controlling and minimizing the complications of the infection significantly. Thus, due to its effectiveness in managing rectal bacterial colony-forming units, we suggest povidone-iodine rectal swab preparation before prostate biopsy. Further multi-institutional and longitudinal studies are needed to explore and validate the role of povidone iodine-soaked gauze in various health care settings and special populations.

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Author's Contribution

KF and MA conceived the idea, designed the study and wrote initial manuscript. KF, MA and NM reviewed the draft critically, carried out corrections and supervised the whole study. Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflict of Interest

Authors declared no conflict of interest

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Data Sharing Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

COMPARISON BETWEEN FLUORESCENT MICROSCOPY AND DUPLEX PCR TO DETECT MYCOBACTERIUM BOVIS AND MYCOBACTERIUM TUBERCULOSIS IN TUBERCULOSIS SUSPECTED PATIENTS

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ABSTRACT

Objective: The aim of this study was to compare the gold-standard fluorescent microscopy as a diagnostic technique with the PCR test, an advance molecular technique.

Methodology: A total of 200 suspected pulmonary and extra-pulmonary samples were taken and stored for analysis in Quetta city. Samples were tested for Mycobacterium tuberculosis and Mycobacterium bovis by both the gold standard fluorescent microscopy (auramine-O FM) and molecular technique duplex PCR. By duplex PCR, Mycobacterium tuberculosis's 245bp sequence and Mycobacterium bovis's 500bp sequence was detected by using specific primers.

Results: Among 200 pulmonary and extra-pulmonary samples, fluorescent microscopy detected 31 positive cases, while PCR detected 60 and 2 positive cases for Mycobacterium tuberculosis and Mycobacterium bovis respectively. The PCR analysis showed 28% of male patients and 32% female patients as positive for M. tuberculosis. Moreover, about52/164 pulmonary samples and 8/36 Extra-pulmonary samples were detected to be positive by PCR analysis.

Conclusion: The PCR results were more accurate, rapid, sensitive and specie specific for detection of tuberculosis showing 60 positive cases for Mycobacterium tuberculosis and 2 positives for Mycobacterium bovis with a significant p-value. On the other hand, FM detected Mycobacterium tuberculosis with comparatively lower sensitivity with only 31 positive cases and had failed to distinguish between species.

Keywords: Fluorescent microscopy; Duplex PCR; Mycobacterium bovis; Mycobacterium tuberculosis.

INTRODUCTION

Since prehistoric times Tuberculosis existed and was observed in Egyptian mummies and Hippocrates described it as "Phthisis" 2000 years ago. In history TB has proved itself as a deadly disease and hence termed as "white plaque" because of the fact that one in seven deaths was due to tuberculosis at the first half of 20th Century.[1] It is a highly contagious and is caused by Mycobacterium tuberculosis Complex (MTB-Complex) and most of the cases are due to the specie Mycobacterium tuberculosis.[2] Mycobacterium tuberculosis is aerobic, non- motile and rod- shaped bacilli. Its cell wall possesses waxy cuticle which makes it highly resistant to many antibiotics, disinfectants and Gram staining. It is termed acid fast due to the fact that conventional staining procedures are unable to stain, hence, heat is required to perforate the cell wall and allow the 5% acid alcohol to stain making it unable to decolorize.[3] TB spreads via infected people coughing, talking or sneezing adjacent to anon-infected person.[4] Extra-pulmonary as well as pulmonary TB can be caused by Mycobacterium tuberculosis specie, whereas Mycobacterium bovis which is known for its zoonotic approach typically causes BTB bovine tuberculosis (BTB). M.bovisis also capable of causing TB of Extra-pulmonary and pulmonary origin. The signs and symptoms of Extra–Pulmonary TB varies and depend upon the organ involved, whereas, that of the Pulmonary TB includes the classical symptoms of TB including blood-tinged or dry sputum, fever, weight- loss, chest congestion and night sweats.[5] Mycobacterium tuberculosis mostly attacks host's lungs but is capable of attacking body parts apart from the respiratory system.[6]

TB is second most deadly disease affecting one-third of the global population.[7] As per WHO estimate in the year 2015, the death rate was 1.4 million and

new infection rate was 10.4 million. In the same year the death toll of HIV co-infected with TB was 0.4 million. Although death rate decreased in the year 2000 to 2015 up to 22% but still TB continues to be amongst the top 10 deadly diseases in the world.[8] About 80% of the global TB cases are reported in 22 countries which labels them as high burden countries (HBCs). If we see globally, Pakistan stands 5th amongst these 22 HBCs.[9] The Pashtun belt consisting of specific areas of Afghanistan, Pakistan and neighboring region of Iran has different TB incidence rate from the rest of the world's statistics with females acquiring infection twice commonly than males.[10]

Diagnosis of TB in initial stages is important in term of controlling disease. In order to detect TB infection, different approaches are used; for instance, the initial diagnostic of symptoms, culturing, sputum smear microscopy, tuberculin skin test (TST) and histopathology.[11] Culture method is considered as gold standard for detection. However, this procedure is time consuming and slow as mycobacterium takes six to eight weeks to multiply. In comparison, microscopic method is rapid and low cost but provides low accuracy and specificity for the detection of dead and alive bacteria.[12] The aim of this study was to compare the gold-standard microscopy technique with that of the PCR for the incidence as well as prevalence of Bovine tuberculosis.

METHODOLOGY

In the present prospective study, 200 sputum samples of susceptible patients visiting the Out Patient Department of Fatima Jinnah General and Chest Hospital (FJGCH) with chronic signs of cough, night sweat, fever, weight loss as well as appetite were collected for the study. The sputum samples were stored in wide-open sterile bottles and packed in clean plastic bags & labeled with differentiated IDs. The patients who were on medication were eliminated from research. Before sampling patients were aware of research and approval from ethical review was taken from Sardar Bahadur Khan Women's University board. The initial steps like sample collection, staining (auramine-O), microscopy (fluorescent) heat killing and DNA extraction steps were performed in FJGC and other steps (PCR and Gel Electrophoresis) were performed in Center for Advanced Studies in Vaccinology and Biotechnology (CASVAB), University of Baluchistan, Quetta.

The gold Standard microscopy technique was used to process sample along with PCR diagnosis method. Proper lab safety protocols were followed since suspected sputum sample may contain TB aerosols and can result in infection of tuberculosis by inhaling. Sample were processed using N-acetyl-L-cysteine (NALC), Sodium hydroxide (NaOH) solutions to eliminate contamination & collect TB cells from sample by centrifugation using CDC standard recommended procedure.

Two sets of primers were used in duplex PCR. First sets of primers (INS1: 5'-CGTGAGGGCATCGAGGTGGC-3' and INS2:5'-GCGTAGGCGTCGGTGACAAA-3') were used to detect Mycobacterium tuberculosis and 2nd sets of primers (JB21: TCGTCCGCTGATGCAAGTGC andJB22: CGTCCGCTGACCTCAAGAAAG) were used for Mycobacterium bovis[13,14]. All 200 samples for MTB with 245 bp sequence were amplified using automated applied biosystem thermo-cycler with primer INS1 and INS2. For PCR, total 25µlmixture was prepared in safety cabinet to avoid any type of contamination that hinder PCR process. Likewise, 200 samples were run with primers JB21 and JB 22 for extension of Mycobacterium bovis500bp sequence. Reaction mixtures of volume25µl was prepared with positive and negative controls used in the reaction. The fluorescent microscopy was performed using the Kent & Kubica (1985) recommended protocol for preparing auramine-O stain slides and its analysis.

RESULTS

In the present study, among 200 total patients, 99 (49.5%) were females and 101(50.2%) were male patients. The patients with age ranging between 1 to 80 years old were included. Among them Mycobacterium tuberculosis susceptibility was noted higher in age range of 41-60 years that is 38%and lowest among aged 1-20 years (14%). Other frequencies recorded were24.5% in 61-80 years old and 23.5% in 21-40 aged patients.

Among 200 pulmonary (sputum and BAL) and extra-pulmonary (ascitic fluid, CSF, gastric lavage, pleural fluid, puss and tissue) samples were collected as given in Figure No.1. Fluorescent microscopy detected 31 positives among 200 but could not be differentiated on specie level and no case of Mycobacterium bovis were detected on FM (Figure No. 2). On the other hand, PCR detected 60 positives for Mycobacterium tuberculosis and 2 positives for Mycobacterium bovis, one each of male and female patients with a significant p-value of 0.001(Figure No. 3& Table No. 1).

Out of 101 male patients, 28(27.7%) patients were positive for M. tuberculosis, whereas among 99 female patients, 32(32.3%) patients were positive for M. tuberculosis on PCR. Analysis clearly showed that frequency of female patients (32.3%) to male patients (27.7%) was visibly high and P-value of 0.471 was noted that is non-significant. Pulmonary and extra-pulmonary samples were collected in which 52/164 pulmonary samples were PCR positive and other 112 were negative. Whereas about 8/36 extra-pulmonary samples were detected PCR positive and other 28 were found negative. The P-value is 0.261 which is non-significant as given in Table No. 2.

Table 1: Comparison of Fluorescent Microscopy Versus PCR Showing Prevalence of Both Species; Mycobacterium Tuberculosis and Mycobacterium Bovis

Technique	Mycobacterium tuberculosis		Mycobacterium bovis		X^2	P-value
	Positive	Negative	Positive	Negative		
FM	31	169	0	0	82.353	0.001
PCR	60	140	2	198		

Table 2: Distribution of Pulmonary and Extra Pulmonary Samples on PCR

Sample Type	PCR		X^2	P-value
	Positive	Negative		
Pulmonary	52(32%)	112(68%)	1.265	0.261
Extra Pulmonary	8(22.2%)	28(77.8%)		

Table 3: Age-Wise Prevalence of Mycobacterium Tuberculosis on PCR.

Age Groups	PCR		X^2	P. Value
	Negative	Positive		
1 – 20	19 (67.9%)	9(32.1%)	0.990	0.112
21 – 40	33(70.2%)	14(29.8%)		
41 – 60	53(69.7%)	23(30.3%)		
61 – 80	35(71.4%)	14(28.6%)		

The prevalence of Mycobacterium tuberculosis was found different in various age groups, but results indicated that age group 1-20 years was the most affected with 32% cases positive on PCR (Table No. 3) with a P-value 0.990, which is non-significant.

DISCUSSION

The effective and timely management of tuberculosis as well as its prevention can only be achieved through the use of new approaches to detect the presence of Mycobacterium in sputum samples. Thus, the scientists have targeted the mycobacterial DNA identification through real-time PCR in the specimens being studied[15]. Beside this, the routine conventional methods for detection of mycobacterial species depends on microscopic examination of the smears along with culture but have drawback of lack of sensitivity and required prolonged duration[16].

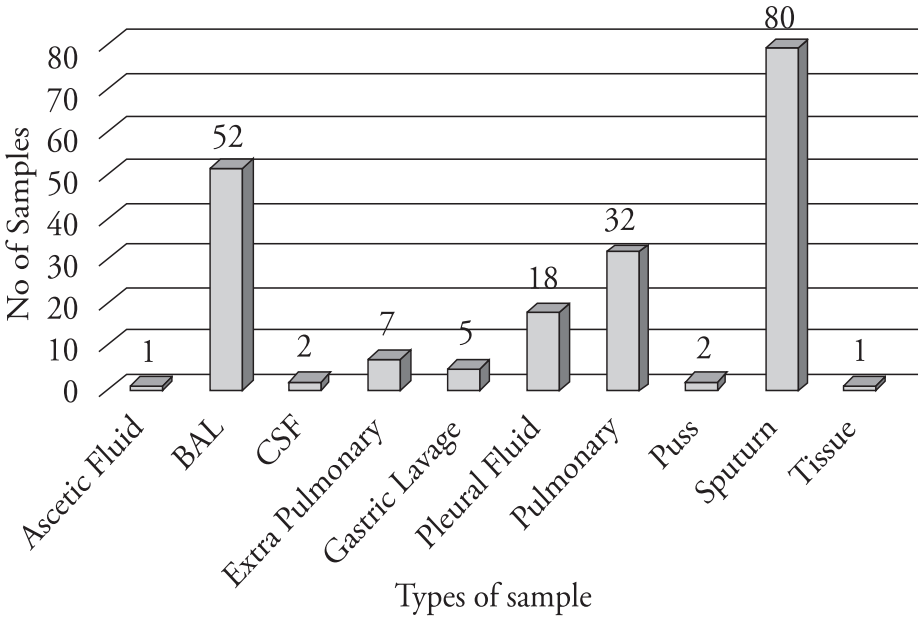

Figure 1: Graph Showing the Percentage of Different Sample Types of the Suspected Tb Patients

Because of low sensitivity of microscopy technique, Pakistan does not practice this technique in proper diagnosis. Because, if patient is not diagnosed on time then infection may spread to surrounding population and can affect other healthy individuals. To lower this risk, rapid, specific and sensitive techniques are mandatory in laboratories. This study aims for detection of rapid, accurate, specie-specific (like BTB) technique. Molecular techniques make specie-specific identification possible. Larger number of smear negative cases creates doubts and can be resolved by steadfast molecular technique like PCR.

First line drugs for treating MTB are not effective on Bovine TB. The present study

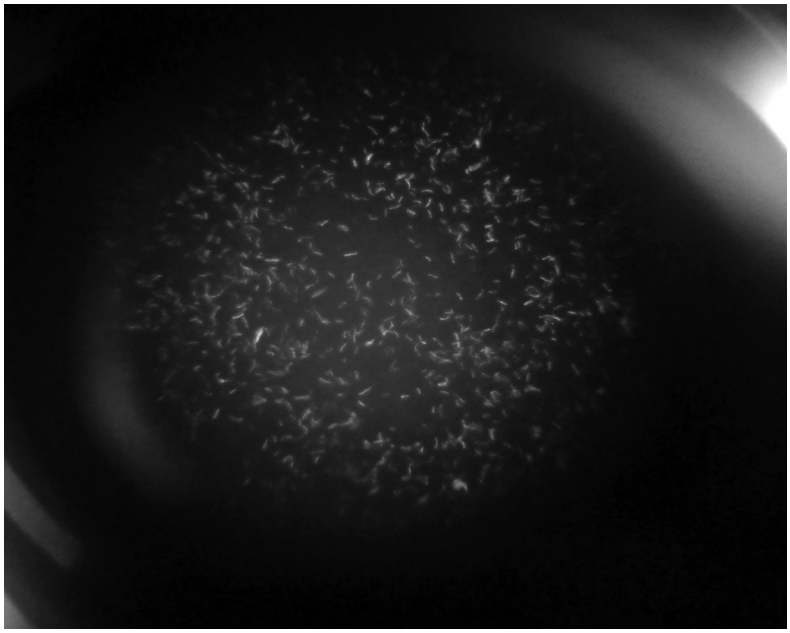

Figure 2: Fluorescence Microscopy of Afb Via Auramine-O Dye.
Fluorescent smear microscopy: The specimen on microscopic slide stained with auramine-O fluorochrome dye and visualized under dark field microscope with 40X objective showing positively for Mycobacterium tuberculosis AFB and graded as 3+ positive results.

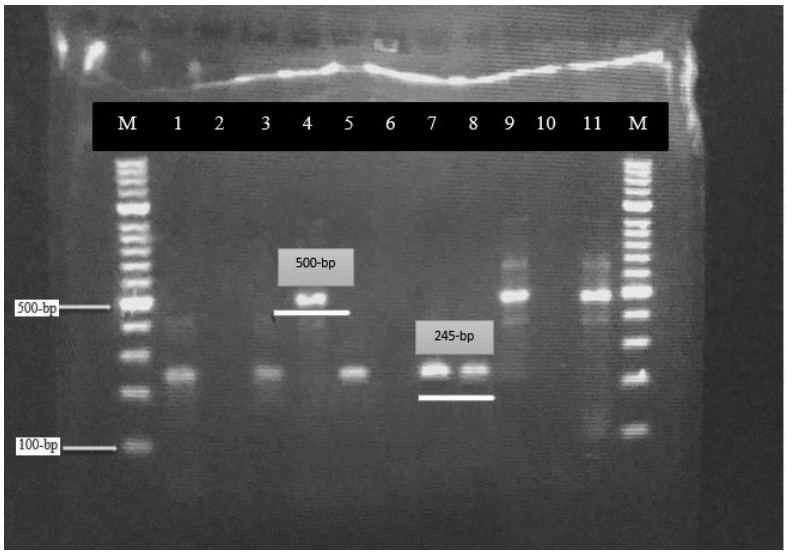

Figure 3: PCR Analysis for Mycobacterium Tuberculosis (245bp) and Mycobacterium Bovis (500bp) Detection.
Lanes M: 1Kb marker, Lane 1, 11: Positive control (245bp left and 500bp right), Lane 2, 10: Negative control(500bp right and 245bp left); Lane 4 and 9 positive for Mycobacterium bovis; Lane3,5,7 and 8 positive for Mycobacterium tuberculosis and Lane6 negative for Mycobacterium tuberculosis amplification.

aims for rapid identification M. Bovisin order for the cure to be possible timely. The results revealed that the infection rate of M. Bovis is 1% in humans in pulmonary samples as only two such cases (one male and a female patients) were seen in the present study.

In this study, the results of microscopy (florescence) and molecular technique (PCR) were analyzed. Its how's clear difference between these techniques, where the analysis via PCR showed30% positive and FM showed15.5% positives. Other studies also show the better compatibility of PCR results over microscopy[17,18]. PCR detection of MTB and M. Bovis is based on specific sequence extension based on primers INS and JB respectively. The highly significant statistical difference between FM and PCR was noticed ($P<0.005$).

According to Mostaza et al. (2007), 17% smear negative cases of TB were transmitted and showed great human heath damage, and 14.5% negative microscopy results were later confirmed positive when run via PCR[19]. In 2007, Oberoi and Aggarwal observed 60% negative microscopy results[20] due to which the control of TB had been a challenge, and much accurate methods had to be adopted.

The present study also indicated the prevalence of TB disease in females (32.3%) in comparison to males (27.7%). Similarly, few of the other studies which were conducted in Pakistan have shown similar findings[21,22]. This may be due to inadequate access of health facilities available to females and their low acquaintance to outdoor. Results are opposite in Russia, where TB prevalence is high in males as compared to females[23,24]. The reasons behind might be due to high smoking rate and frequent male gatherings compared to females.

The prevalence of tuberculosis was also observed in distinguished age groups and

high prevalence was noted in age group 1-20 i.e. 32.1% and secondly 41 to 60 years age group i.e. 30.3%. That might be due to lower preventive measures adopted by younger population or the exposure is frequent to infectious persons. The high risk of TB prevalence in comparatively high age groups (i.e.,20-40 years) is reported in other studies[25,26]. This factor affects economic development where TB is endemic, and it may upsurge due to crowding, malnourishment, family histories and poor socio- economic status.

CONCLUSION

The PCR results were more accurate, rapid, sensitive and specie specific for detection of tuberculosis with 60 positive cases to Mycobacterium tuberculosis and 2 positive to Mycobacterium bovis with a significant P-value. On the other hand, FM detected Mycobacterium tuberculosis with comparatively lower sensitivity with only 31 positive cases and failed to distinguish between species.

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Author's Contribution

ST conception and design of study, statistical analysis & interpretation of data. AR data acquisition and manuscript writing and editing. NT conception and design of study, statistical analysis & interpretation of data. MAK & MS drafting and critical revision of manuscript and final approval of manuscript. Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflict of Interest

Authors declared no conflict of interest

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None

Data Sharing Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

CLINICAL AND LABORATORY CHARACTERISTICS AND OUTCOME OF COVID-19 PATIENTS ADMITTED TO THE ISOLATION WARD OF A PUBLIC SECTOR HOSPITAL

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ABSTRACT

Objective: To evaluate the clinical and laboratory presentation and outcome of COVID-19 patients admitted to a public sector hospital in Pakistan.

Methodology: This is a retrospective, cross sectional chart review of COVID-19 patients admitted to Dr. Ruth K.M Pfau Civil Hospital Karachi Isolation Ward from 28th February till May 28th 2020.

Results: Out of 306 admitted patients, 216 (70%) tested SARS CoV-2 positive of whom median age was 45. COVID-19 was asymptomatic in 35 (16.2%), non-severe in 112 (51.9%), severe in 55 (25.5%) and critical in 14 (6.5%) patients. Severe/critical as compared to asymptomatic/non-severe disease was associated with co-morbidities (37 [53.6%] vs 35 [23.8%], p value <0.001), shortness of breath (50 [72.5%] vs 34 [23.1%], p value <0.001). Median [IQR] values demonstrated lower oxygen saturation (90 [87-92] vs 97 [97-98], p value <0.001) and lower absolute lymphocyte counts (1.3×109/L [0.9-1.82] vs 1.7×109/L [1.1-2.2], p value <0.001) with higher neutrophil to lymphocytic ratio (5.2 [3.3-8.4] vs 2.5 [1.6-3.7], p value <0.001), lactate dehydrogenase level (360U/L [271-566] vs 296U/L [207-377], p value <0.001), C-reactive protein (89mg/L [36-179] vs 19mg/L [0.9-91], p value <0.001) and ferritin level (580mg/L [331-1021] vs 341mg/L [163-679], p value <0.001). Of 216 patients, 2 (0.9%) died in the ward, whereas 13 (6%) were shifted to ICU of whom 12 died. Overall mortality was 14 (6.5%).

Conclusion: In COVID-19 patients admitted to a public sector hospital, severe disease was associated with co-morbidities and elevated inflammatory markers. Mortality was very high in those that required ICU care.

Key Words: COVID-19; Hospital; Management; Pakistan.

INTRODUCTION

COVID-19 cases were first diagnosed in December 2019 in China and SARS CoV-2 coronavirus pandemic was declared in March 2020.[1] Worldwide, over 142 million cases and 3 million deaths had been recorded one year later by April 2021.[2] The first case in Pakistan was in the province of Sindh and was diagnosed on February 26th 2020 during the first wave of coronavirus which peaked in June. A second wave of COVID-19 became evident in November 2020. In the following year, by February 2021, a third wave was already underway in the provinces of Khyber Pakhtunkhwa and Punjab and by April 2021, over 750,000 cases and more than 16,000 deaths had been recorded in Pakistan.[2]

Pakistan is a country with a population of approximately 224 million with only 4% of the population above 60 years of age. The young population in Pakistan could be a contributing factor to the less devastating impact of coronavirus so far. There is limited data of the clinical characteristics of COVID-19 in Pakistan. A recent study from Karachi describes 299 patients with severe and critical COVID-19 that were admitted to a public sector hospital during the peak months of the first wave.[3] Our study, however, covers the initial months of the first wave of coronavirus in patients presenting across the COVID-19 clinical spectrum. A similar study of 100 patients during the first wave of coronavirus has also been reported from Pakistan.[4] Our study provides an opportunity to describe our experience at a public sector hospital when faced with this new and formidable challenge at a time of heightened fear and anxiety. It describes the clinical and laboratory characteristics, management and outcome of these patients.

METHODOLOGY

This is a retrospective, cross sectional descriptive study of patients who presented to Dr. Ruth KM Pfau Civil Hospital Karachi (CHK) in relation to COVID-19,

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and were admitted to the Isolation Ward. CHK is a tertiary care public sector hospital providing care free of cost and is also a teaching hospital affiliated with the Dow University of Health Sciences.

The study spans a 3 month period commencing with the first admission (who was also the second reported case in the province of Sindh) to the 18 bedded Isolation Ward on February 28th 2020 till May 28th 2020. Subsequently, within the premises of CHK, the COVID-19 outpatient clinic, triage center and a testing facility for PCR for SARS CoV-2 were established and were fully functional within four weeks by March 2020. In April 2020, a building within CHK with a capacity of 50 beds was designated as an additional COVID-19 Isolation facility and a 12 bedded COVID-19 medical ICU with negative pressure was readied for patients.

In order to assess the number of patients that presented to the CHK COVID-19 triage center during the initial stages of the epidemic, data was obtained from the registration counter electronic data and also tallied with the hand written COVID-19 Register. The number of PCR tests performed by the Central Laboratory of CHK during the study period was obtained from the computerized data of the IT department. Initially, when it was still early days of COVID-19 and containment protocols were not mature and well defined, we admitted all patients with suspected or confirmed COVID-19.

Those that were confirmed COVID-19 remained admitted until they tested negative for SARS CoV-2 coronavirus by PCR. When home isolation was allowed by the Sindh Government in April, we allowed clinically stable patients to go home after testing, and only those requiring hospitalization were admitted.

Our study inclusion criteria were all patients admitted to the COVID-19 Isolation ward. We however excluded admitted patients that had been initially treated at outside healthcare facilities or were stepped down to the Isolation Ward after initial admission to COVID-19 Medical ICU at the hospital.

Medical records of all admissions to the two Isolation Wards were reviewed. Data sheets for all admissions that met the inclusion criteria were filled. For those that had a confirmed diagnosis of COVID-19, we documented the demographics, clinical presentation, laboratory and radiological data, management and outcome. Those that tested negative, and were found to have an alternate diagnosis, were analyzed as non-COVID-19 admissions and data sheet was filled for demographics and diagnoses.

Disease classification of COVID-19 for study purposes was according to the NIH National Guidelines of December 2020.[5] Asymptomatic COVID-19 was described as patients having no symptoms. Non-severe was described for patients with oxygen saturation of $\geq$ 94% and respiratory rate of $\leq$ 25 breaths/minute. Severe was described as oxygen saturation of $<$ 94% or respiratory rate $\geq$ 25 breaths/minute. Critical disease was when presence of respiratory compromise severe enough to require non-invasive ventilation (NIV) or mechanical ventilation (MV). During the study period, COVID-19 patients had been managed in accordance with the earlier national guidelines of April 2020.[6] Primary outcome studied was discharge or death.

Data was entered on the IBM SPSS version 24. Continuous variables were expressed as medians, interquartile ranges. Student t test was used for continuous data and categorical data was presented as frequency and percentages. To see the association, we used the Chi-squared test or Fischer's exact as appropriate for categorical variables. Significance was set at α less than or equal to 0.05.

Approval for the study was obtained from the Institutional Review Board of Dow University of Health Sciences (IRB-1790/DUHS/approval/2021/).

RESULTS

During the study period, 5405 patients presented to the COVID-19 triage center of the government hospital. Its Central Laboratory performed 8083 PCR tests of which 1879 (23%) were positive for SARS CoV- 2 coronavirus. During the three month study period, 306 patients who met the study inclusion criteria were admitted to the two Isolation Wards. Of 306, 216 (70%) were SARS CoV-2 positive and 90 (30%) tested negative.

Of 216 confirmed COVID-19 patients, the median age was 45 (IQR 31-55) with a range of 13-90 years, 166 (76.9%) were males. 14 (6.4%) patients were health care workers. 72 (33.3%) patients had one or more co-morbidities with diabetes mellitus and hypertension most commonly reported in 43 (19.9%) and 40 (18.5%) respectively. (Table No 1)

At presentation, the median duration of symptoms since onset was 5 (IQR 1.2-7) days. Most frequently reported symptoms were fever in 130 (60.2%), cough in 106 (49.1%) and shortness of breath in 84 (38.9%). COVID was categorized at presentation as asymptomatic in 35 (16.2%), non-severe in 112 (51.9%), severe in 55 (25.5%) and critical in 14(6.5%)

At presentation, in 216, median absolute lymphocyte count (ALC) was 1.7×10^9/L (IQR 1.1-2.2) with a median neutrophil lymphocyte ratio (NLR) of 3.0 (IQR 1.8-5.3), median C-reactive protein was 9.8 mg/L (IQR 0.9-91), median lactate dehydrogenase was 296 U/L (IQR 203-307). Chest X-rays were available in 208 of whom 76 (36.5%) had bilateral infiltrates. Oxygen therapy was required in

69 (31.9%) patients. (Table No 1)

Comparison between COVID-19 patients with severe/critical and asymptomatic/non-severe is shown in Table No 2. Severe/critical disease was associated with the presence of co-morbidities (37 [53.6%] vs 35 [23.8%], p value: <0.001), shortness of breath (50 [72.5%] vs 34 [23.1], p value: <0.001), lower median [IQR] oxygen saturation (90 [87-92] vs 97 [97-98], p value: <0.001), lower median [IQR] absolute lymphocyte counts (1.3×10^9/L [0.9-1.82] vs 1.7×10^9/L [1.1-2.2], p value: <0.001), higher median [IQR] neutrophil to lymphocytic ratio (5.2 [3.3-8.4] vs 2.5 [1.6-3.7], p value: <0.001), higher median [IQR] lactate dehydrogenase level (360U/L [271-566] vs 296U/L [207-377], p value: <0.001), higher median [IQR] C-reactive protein (89mg/L [36-179] vs 19mg/L [0.9-91], p value: <0.001) and higher median [IQR] ferritin level (580mg/L [331-1021] vs 341mg/L [163-679], p value: <0.001). Significantly more patients with severe/critical COVID-19 had bilateral infiltrates on chest X-ray at presentation (54 [78%] vs 22 [15.7%], p value: <0.001).

Table 1: Characteristics and Outcome of Patients with Covid-19 Admitted to A Public Sector Hospital Isolation Ward (N=216)

Demographics	n (%)
Age (Median-IQR)	45(31-55)
Male	166(76.9)
Female	50(23.5)
Admitted from	
COVID-19 Outpatient Clinic/Triage	164(75.90)
Outside healthcare facility	26(12.1)
Intra-hospital transfer	18(8.3)
Field Epidemiology and Laboratory Training Program(FELTP)	4(1.9)
Emergency Room	4(1.9)
Occupation	
Healthcare worker	14(6.4)
Travel and Contact History	
International and domestic travel within 21 Days	29(13.4)
Contact history with known or suspected COVID-19	47(21.8)
Co-morbidities	
None	
Diabetes Mellitus	43(19.9)
Hypertension	40(18.5)
Ischemic Heart diseases	8(3.7)
COPD	3(1.4)
Chronic Kidney Diseases	2(0.9)
Days Since Onset of Symptoms at Presentation (Median-IQR) n=181	5(1.2-7)
Symptoms	
Asymptomatic	35(16)
Fever	130(60.2)
Cough	106(49.1)
Shortness of breath	84(38.9)
Sore throat	16(7.4)
Rhinorrhea	16(7.4)
Diarrhea	6(2.8)
Headache	9(4.2)
Nausea and vomiting	6(2.8)
Altered level of consciousness	3(1.40)
Myalgia	19(8.8)
Disease Category at Presentation	
Asymptomatic	35(16.2)

Out of 216 patients, 81 (37.5%) had a documented negative PCR, considered recovered, and discharged after a median stay of 14 (IQR 10-18) days whereas 82 (37.9%) were discharged to complete isolation at home without repeat PCR testing. Two died in the ward, and 13 were transferred to ICU of whom 12 (92%) died. Of 216, overall mortality was 14 (6.5%) patients with all deaths occurring in patients with severe and critical disease (p value: <0.001). The overall median duration of hospitalization was 6 (IQR 2-13) days.

There were 90 admissions to the Isolation Ward that subsequently were reported to be SARS 2 PCR negative. Most (75 %) of these patients who turned out to be PCR negative were admitted during the first four weeks of the opening of the Isolation ward. Of 90, on further evaluation, 88 patients were found to not fit the case definition for suspected or probable COVID-19 and were counseled and discharged. However, two were highly suspicious for COVID-19 and retained and managed as such. Median age was 32 years, and two-thirds (67.8%) were male. Diagnoses included upper respiratory tract infection in 65 (72.2%). Median duration of stay in the Isolation Ward of SARS 2 PCR negative patients was 1 (IQR 1-2) days. (Table No 3)

DISCUSSION

Our study has shown that a public sector

Non-severe	112(51.9)
Severe	55(25.5)
Critical	14(6.5)
Laboratory Findings at Admission (Median- IQR)	
Absolute Lymphocyte Count (ALC) (109/L)	1.7(1.1-2.2)
Neutrophil Lymphocyte Count Ratio (NLR)	3.0(1.8-5.3)
Total Leukocyte Count (TLC) (109/L)	7.4(5.6-10.2)
Hemoglobin(g/L)	13.2(11.9-14.3)
Platelets(109/L)	223(166-301)
C-Reactive Protein (CRP) (mg/L) n=141	19.8(0.9-91)
Lactate Dehydrogenase(LDH) (U/L) n=136	296(203-307)
Ferritin (mg/L) n=140	341(163-679)
Chest X-ray findings (n=208)	
Clear	106(51)
Bilateral Infiltrates	76(36.5)
Unilateral Infiltrates	24(11.5)
Pleural effusion	2(0.96)
Management	
Oxygen (nasal cannula/face mask/non-rebreather)	69(31.9)
Antibiotics	89(41.2)
Hydroxychloroquine	100(46.3)
Steroids	60(27.8)
Enoxaparin	39(18.1)
Outcome	
Recovered with negative PCR (test based strategy for de-isolation)	81(37.5)
Discharged to home isolation (without negative PCR documentation)	82(37.9)
Transferred to another healthcare facility for isolation	21(9.7)
Left against medical advice	17(7.9)
Died in ward	2(0.9)
Transferred to ICU	13(6.0)
Died in ICU	12 (92%)
Overall mortality	14 (6.5%)

hospital with limited resources had established the full spectrum of COVID-19 facilities within 4 weeks of the first patient admission. Indeed the global pandemic of COVID-19 has been an enormous test of governments worldwide due to high pressure on health systems and increased demand for essential medical supplies. [7] A study from a public sector hospital in Lahore, province of Punjab, describes how it prepared for COVID-19, and despite limited resources, established systems and policies, with the conclusion that all is possible in the public sector if there is political will.[8]

Our study highlights that almost one-third of admitted patients tested negative for COVID-19 and who, on further evaluation, were considered to have an alternative diagnosis. This is a reflection of panic and fear in both the public and healthcare workers at the time. Heightened anxiety in the general public is well exemplified by a young girl admitted to the Isolation Ward when brought by her parents for "cough that developed after shaking hands with a foreign tourist'. Similarly, there was a tendency for doctors to over-diagnose COVID-19, sometimes delaying the diagnosis and management of patients with alternative, often serious, conditions. Indeed, the pandemic has taken a toll on patients without COVID-19.[9] Anxiety amongst healthcare workers remained at high levels throughout the span of this study with not enough support afforded by the institution.[10] Mental health and psychosocial considerations must be addressed.[10,11]

The median age of COVID-19 inpatients was 45 years which is much lower than those reported from other studies including the study of 299 patients with severe disease from Pakistan in which the median age was 60 years.[3] This is because over two-thirds of our patients were asymptomatic or with non-severe disease which is found in younger patients. A study from Pakistan of 100 patients in the first wave of COVID-19 reported an average age of 52 years.[4]

Three-fourths were male as has been shown in numerous studies reporting male predominance in COVID-19.[12] Risk factors for severe disease included the presence of co-morbidities.[4] Shortness of breath is a clinical indicator of severe disease. Elevated inflammatory markers were also significantly elevated in severe disease in our study as has been demonstrated in many studies including a meta-analysis comprising 3962 patients.[13]

In early 2020, hydroxychloroquine was considered effective in COVID-19, and supplies were expeditiously secured by the hospital. Initially our patients received hydroxychloroquine but it was stopped once studies did not support its efficacy. In a randomized controlled trial among patients hospitalized with COVID-19, those who received hydroxychloroquine did not have a lower incidence of death at 28 days than those who received usual care.[14] We gave steroids to most patients requiring oxygen, and the Recovery Trial has demonstrated a significant mortality benefit in such patients.[15] Over half of our patients received antibiotics but studies now do not support antibiotics as part of standard

Table 2: Comparison of Severe/Critical Covid-19 with Asymptomatic/Non-Severe Covid-19 In 216 Patients Admitted to the Isolation Ward

Variables	Severe /Critical 69(31.9%) n (%)	Asymptomatic /Non-Severe 147(68%) n (%)	p-value
<60 Years of age	52(75.4)	121(82.3)	0.156
≥60 years of age	17(26.4)	26(17.7)	
Male	50(72.5)	116(78.90)	0.190
Female	19(27.5)	31(21.50)	
Co-morbidities	37(53.6)	35(23.8)	<0.001
Diabetes Mellitus	24(34.8)	19(12.9)	<0.001
Hypertension	17(34.8)	23(15.6)	0.083
Fever	50(72.5)	80(54.4)	0.008
Cough	42(60.9)	64(43.5)	0.013
Shortness of breath	50(72.5)	34(23.1)	<0.001
Altered Level Of Consciousness	3(4.3)	0(0.0)	0.032
Laboratory Values On Day Of Admission (Median-IQR)			
Oxygen saturation	90(87-92)	97(97-98)	<0.001
Absolute Lymphocyte Count (ALC)(109/L)	1.3(0.9-1.82)	1.7(1.1-2.2)	<0.001
Neutrophil Lymphocyte Ratio(NLR)	5.2(3.3-8.4)	2.5(1.6-3.7)	<0.001
C-Reactive Protein(CRP) (mg/L) n=141	89(36-179)	19(0.9-91)	<0.001
Lactate Dehydrogenase(LDH) (U/L)n=136	360(271-566)	296(207-377)	<0.001
Ferritin(mg/L)n=140	580(331-1021)	341(163-679)	<0.001
Total Leukocyte Count (TLC) (109/L)	9.3(5.7-12.4)	7.4(5.6-10.2)	0.007
Hemoglobin(g/L)	12(11.1-14.1)	13(11.9-14.3)	0.15
Platelets(109/L)	215(167-273)	223(166-301)	0.614
Chest X-ray Findings n=208			
Clear	1(1.5)	105(75.0)	<0.001
Bilateral Infiltrates	54(78)	22(15.7)	
Unilateral Infiltrates	12(17.6)	12(8.5)	
Outcome			
Recovered (with negative PCR)	27(39.1)	54(36.7)	<0.001
Home isolation	17(24.6)	65 (44.2)	
Transferred To Another Healthcare Facility For Isolation	1(1.4)	20(13.6)	
Transferred To ICU	13(18.8)	0(0.0)	
Left Against Medical Advice	9(13.0)	8(5.4)	
Died (in ward and ICU)	14(20)	0(0.0)	

care and should be reserved for secondary bacterial infection.[16]

There was no mortality in patients that presented with non-severe disease in our study. Overall mortality in our study was 6.5% which is higher than 3.77% reported from Wuhan, [17] but lower than reported from Pakistan where 22% was reported in a similar population, as well as 37.7% in severe cases. [3,4] We found a very high mortality in those patients that required ICU care, as is reported from Pakistan and worldwide.[3,18]

Limitations of our study include that it is retrospective with missing information. Moreover, management guidelines were changing even during the short study duration so that comparison between modalities of treatment cannot be done. We do not have follow-up of patients who were discharged on isolation recommendations and therefore cannot comment on their final outcome.

CONCLUSION

During the first wave of COVID-19 in Pakistan, patients across the clinical spectrum of the disease were admitted to the Isolation Ward of a public sector hospital. A male predominance was demonstrated. Severe disease was associated with the presence of co-morbidities, elevated neutrophil-to-lymphocyte ratios and high inflammatory markers. Mortality was very high in those that required ICU care.

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Table 3: Characteristics Of 90 Patients Admitted To The Covid-19 Isolation Ward That Tested Negative For Pcr Sars-Cov 2

Demographics	n(%)
Age (Median-IQR)	32(24-45)
Male	61(67.8)
Female	29(32.2)
Occupation	
Health Care Workers	4(4.4)
Discharge Diagnosis	
Upper Respiratory Tract Infection	65(72.2)
Community Acquired Pneumonia	10(11.1)
COVID Related Anxiety/Hyperventilation	7(7.8)
Highly Suspected COVID/False Negative PCR	2(2.2)
Other Diagnoses	6(6.7)
Hospital Stay (Median IQR) days	1(1-2)

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Author's Contribution

SI designed, collected, interpreted the data, and drafted the manuscript. AKD designed and reviewed the manuscript. SM collected the data, and drafted the manuscript. FB collected the data, and drafted the manuscript. SB designed and reviewed & drafted the manuscript. Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflict of Interest

Authors declared no conflict of interest

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None

Data Sharing Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

BULLYING, VICTIMIZATION, AND REJECTION SENSITIVITY IN ADOLESCENTS: MEDIATING ROLE OF SELF-REGULATION

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ABSTRACT

Objective: To explore the mediating role of self-regulation in bullying, victimization as related with rejection sensitivity among adolescents.

Methodology: This cross-sectional research was conducted at the Department of Psychology, University of Gujrat after taking approval from Advanced Studies and Research Board. In first phase, Self-Regulation Questionnaire (SRQ) and Rejection Sensitivity Questionnaire (RSQ) were translated into Urdu language by forward-backward translation method after taking permission from their respective authors. For pilot-testing, these scales were administered on 130 students and scales were found to be reliable with α=0.83 and α=0.85 respectively. In second phase, Urdu version of Adolescent Peer Relations Instrument (ARRI) by Parada, SRQ, and RSQ were administered to a sample of 608 college students. Stratified Random Sampling technique was use to collect the data. The data was analyzed in AMOS-21.

Results: The study reported male as 330, and female as 278, age range between 16 to 19 years with mean of 17.60±0.83 years. The model fit indices of chi-square/df =2.2 ($p<0.001$), Goodness of fit (GFI)=0.94, Adjusted goodness of fit (AGFI)=0.91, Comparative fit index (CFI)=0.904, Incremental fit index (IFI)=0.906, Tucker Lewis index (TLI)= 0.88 and Root Mean Square Error of Approximation (RMSEA)=0.046 were in the acceptable limits. Structure Equation Model in AMOS-21 showed significant mediating role of self-regulation with bullying, victimization and rejection sensitivity among adolescents.

Conclusion: Self-regulation has fully and significantly mediated the association of both bullying and victimization with the level of sensitivity for rejection in adolescents.

Keywords: Adolescents; Bullying; Peer relationship; Rejection sensitivity; Self-control

INTRODUCTION

We have witnessed self-regulation has served as a hallmark for promoting well-being in adolescents. Similarly, high emotional pitch due to hormonal changes in adolescence needs regulatory monitoring particularly in relation to their chums. But problematic relationships with peers, a critical issue in adolescence, might hamper their mental health by escalating element of rejection sensitivity in their personality makeup. In Pakistan, 50.5% were bullied and 42.6% were victimized[1], indicating high prevalence of concerned issue in children, yet went unexplored in college adolescents. Therefore, the present study has explored the interaction of bully, victimization, and rejection sensitivity with mediation of self-regulation. Conceptual definitions of the variables under study are indispensable to delve further into these variables. Self-regulation can be defined as a controlling one's own behavior, emotions and thoughts that produce positive result in ways acceptable for achievement of determined aims and objectives.[2] Bullying is the use of force and hatred to cause harm or control another through physical aggression (hitting, kicking) and verbal aggression (insults, racial or sexual harassment, threats). Whereas, victimization referred to the act of singling out someone by manipulation of social relationships to hurt him or her.[3] Rejection sensitivity is defined as an individual's proneness to rejection. It is a reactive response to disapproval received from others.[4] This rejection sensitivity, unmonitored by self-control, could lead to low self-esteem, and poor academic performance in students, which could in turn effect their education, but also impedes their career aspirations and opportunities, abating their cognitive processing ability and mental health.[5]

The Peer Socialization Model[6] empirically supported in adolescents assumes that peer rejection is the promoter for increased aggressive behaviour over time in individuals who are rejected by their peers and they are more likely to behave aggressively toward others. Since aggression is precursor of combat behaviours,

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implications suggest these adolescents are prone for getting caught up in a vicious cycle of bullying and victimization while interacting with peers. Thus, there is a significant association between perceived fighting and harassing incidences with sensitivity to rejection from chums in adolescence.[7-9] Here premises of Cognitive-Affective Processing System (CAPS)[10] posit about a protective strategy of regulating one's emotions and cognitions arising as a result of perceived dejection during experiences of fights. Self-Regulation is a cognitive-affective unit embedded in an individual that operates to shrink the deteriorating effects of rejection sensitivity[11] on personalities of adolescents.

Thus, combining Peer Socialization Model and Cognitive-Affective Processing System into a theoretical framework, the aim of the present is to explore the missing link among bullying, victimization, self-regulation and rejection sensitivity in adolescents. The findings would be beneficial for practicing psychologists, and clinical psychologists to work not only for counseling provision of adolescents with bullying problems, but also to address community intervention for psychoeducation parents, teachers, and health professionals to interact with more self-regulatory enhancing strategies while interacting with adolescents. Nevertheless, the aims and objectives for conducting the present study are to investigate self-regulation as a significant mediator between bullying and rejection sensitivity among adolescents. In addition, to view the former role with victimization and rejection sensitivity among adolescents.

METHODOLOGY

This cross-sectional research was carried out in two phases and three standardized instruments were applied in the present study. To measure self-regulation of adolescents, Self-Regulation Questionnaire (SRQ)[12] was used. It consisted of 22 items with very unlikely=1, unlikely=2, neutral=3, likely=4 and very likely=5 response categories. The reverse scoring was of Item number 5, 11, 17 and 22. SRQ is divided into four subscales 1) Plan; 2) Monitor; 3) Control; 4) Reflect. The first subscale Plan consists of 5 items, Monitor consists of 6 items, Control consists of 6 items and the Reflect subscale consists of 5 items. The original reliability of self-regulation questionnaire was 0.89. To measure rejection sensitivity in adolescents, Rejection Sensitivity Questionnaire (RSQ)[13] was used. It consisted of 18 items with Very unlikely/very unconcerned=1, to very likely/very concerned =6 response categories. The original reliability of rejection sensitivity scale was 0.84. To measure bullying and victimization experiences of adolescents, Adolescent Peer Relationship Instrument (APRI)[14] was used. It consisted of 36 items with Never = 1, Sometimes=2, Once or twice a week =3, Once a week =4, several a week=5 and Everyday=6 response categories. The peer relationship questionnaire divided into two sections A measured bullying and section B measured victimization. In section A was three subscales verbal, physical and social. The verbal subscale consists of 6 items, physical consist of 6 items and social also consist of 6 items. Section B also divided in to three subscale verbal, social and physical. The verbal consist of 6 items, social consist of 6 items and physical also consist of 6 items. The original reliability of peer relationship questionnaire ranged between 0.83 to 0.92 for all subscales.

In first phase, SRQ[12] and RSQ[13] were translated into Urdu language by forward-backward translation method and were found reliable[14]. In second phase, Urdu versions of ARRI[15], SRQ[14], and RSQ[14] were administered to a sample of 608 college students of 1st and 2nd years (Male=330, and Female=278), age range between 16 to 19 years (M=17.60, SD=0.83). Stratified Random Sampling technique was use to collect the data in two steps. First step comprised of making two strata of colleges based on being classified in private and public educational domains and then two colleges in Sarai Alamgir from each strata were selected through random sampling technique from list of colleges obtained from District Office Gujrat. In second step, sampling frame was obtained from the administration of the colleges for 1st year and 2nd year students. College students of 1st and 2nd year were selected because previous researches have been conducted to explore phenomenon of bullying and victimization in school children and university early adults in Pakistan[16-17], neglecting the late adolescent developmental stage studying in colleges of Pakistan. Since every college had different number of students in each class, sample size was determined by using Yumane formula[18] where sample size is equal to total population divided by sum of one with multiple of population size into margin of error constant (0.05). The students were selected by proportional random sampling technique. Inclusion criteria focused on age above 15 years and below 20 years adolescents who is enrolled in first or second year of college. The students studying in school or university were excluded from the present study. This age group was selected because this is the time period where emotions are at their peak and requires significant attention for better performances in various spheres of life[19]. Advanced Studies and Research Board, University of Gujrat approved the research protocol and the data was obtained between January to May, 2019 at Department of Psychology. After sorting the permission from the Principal of the college along with the class teacher of 1st and 2nd years, data was filled out by the students that comprised of written informed consent, demographic sheet and Urdu versions of SRQ, APRI, and RSQ. Confirmatory Factor Analysis was carried out in AMOS-26 to explore the mediating role of self-regulation for bullying, victimization, and rejection sensitivity in adolesc

RESULTS

45.7% females and 54.3% males within the age range 16 to 19 years (Mage=17.6; SD=0.83) studying in 1st (53.1%) and 2nd (46.9%) year of the either government (54.8%) or private (45.2%) colleges were approached with the permission of the teacher, and principal. 68.9% were studying arts and 31.1% opted for science. Majority (65.8%) lived in joint family system, in rural areas (70.6%) of Sara-i-Alamgir.

Confirmatory Factor Analysis (CFA) has yielded model fit summary with significant CMIN/DF value of 2.38 in acceptable range, showing structural relationship among bullying, victimization, rejection sensitivity, with self-regulation. The values of model fit indices such as GFI, AGFI, CFI, IFI, TLI, and RMSEA are 0.92, 0.902, 0.87, 0.885, 0.850, and 0.048 respectively (Table 1). Though the values of GFI, AGFI, and RMSEA are in acceptable range, yet to increase values of CFI, IFI, and TLI, three items (13, 15, and 17) with low load factor loading were removed from the RSQ, yielding acceptable GFI, AGFI, CFI, IFI, TLI, and RMSEA with 0,94, 0.91, 0.904, 0.906, 0.88, and 0.046 values (Table 2). Results of Structure Equation Model in AMOS-21 showed significant mediating role of self-regulation with bullying, victimization and rejection sensitivity among adolescents. Figure 3 of structure equation model confirms the hypothetical model of the study.

DISCUSSION

The structure equation model fit indices confirmed two hypotheses of the study, posited as 'Self-regulation will significantly mediate the relationship between bullying and rejection sensitivity among adolescents'. And 'Self-regulation will significantly mediate the relationship between victimization and rejection sensitivity among adolescents'. The findings of the present study have highlighted a significant association among the study variables of bullying, victimization, rejection sensitivity and self-regulation in children, adolescents and even adults. Consistent results were found in previous researches. Seventy seven school going children were studied in USA for their emotional self-regulation competencies and experiences of bullying and victimization. Mediational role of emotion self-regulation was found empirically significant for bully-victims as compared to no bully-victim group of children.[20] Transformation from childhood to adulthood in a longitudinal study, people with high rejection sensitivity, exhibited low self-regulation.[21] This served as a plausible sign of explaining self-regulation as playing role to effect rejection sensitivity in college adolescents in our results. Therefore, the findings of the present study in Pakistan implied that intervention plans aimed at enhancing self-regulatory mechanisms to effectively buffer rejection sensitivity should be planned and executed at college level to minimize harmful after effects of bullying in adulthood.

Adolescents with heightened interpersonal rejection sensitivity influenced their peer bullying and victimization[22] and in Pakistan, 120 school going children between age range 9 to 13 years, results indicated significant correlation of rejection sensitivity with bully and fight.[23] However, this relationship between bullying and rejection sensitivity can be reduced by the operative mechanisms of self-regulatory strategies as

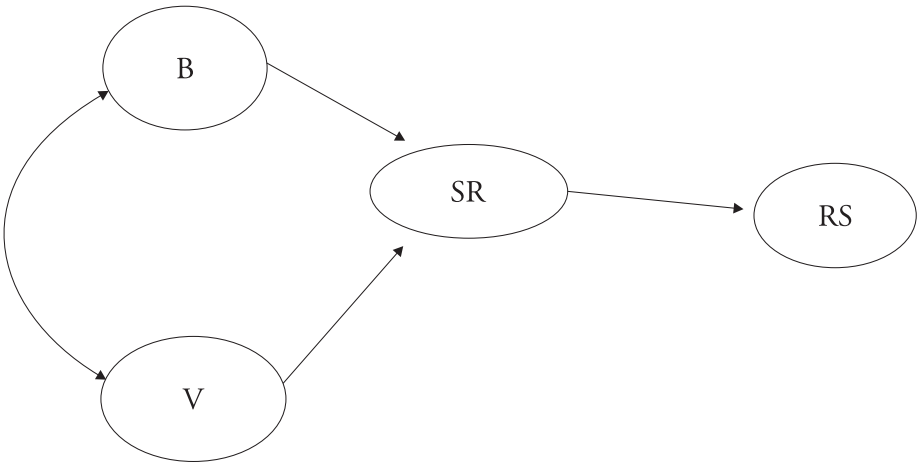

Figure 1: Structure Equation Model For Bullying, Victimization And Rejection Sensitivity: Self-Regulation As Mediator

Table 1: Model Fit Summary for Variables of the Study Without any Item Deletion (N=608)

χ2	CMIN/DF	p	GFI	AGFI	CFI	IFI	TLI	RMSEA
502.539	2.38	<0.001	.925	.902	.877	.885	.850	.048

GFI Goodness of fit, AGFI Adjusted goodness of fit, CFI Comparative fit index, IFI Incremental fit index, TLI Tucker Lewis index, RMSEA Root Mean Square Error of Approximation.

Table 2: Model Fit Summary for Variables of the Study After Deleting Three Items in Rejection Sensitivity Questionnaire (N=608)

χ2	CMIN/DF	p	GFI	AGFI	CFI	IFI	TLI	RMSEA
502.539	2.2	<0.001	.94	.91	.904	.906	.88	.046

GFI Goodness of fit, AGFI Adjusted goodness of fit, CFI Comparative fit index, IFI Incremental fit index, TLI Tucker Lewis index, RMSEA Root Mean Square Error of Approximation.

in the present findings, the latter has played a role of a mediator. Similar findings have been observed in the research study conducted in China where 631 adolescents with mean age 10.52 years in China were taken under investigation and results signified association of low victimization with high self-regulatory skills.[24] Contrasting results of another study in USA on a group of 206 adolescents with mean age = 10.13 years showed that with experiences of relational victimization by peers, they exhibited dysfunctional social-cognitive processes and intensified emotion dysregulation[25] and high depression-anxiety symptoms.[26] Thus, in the light of the contradictory results of the former studies such as bullied children with exhibited low socio-cognitive skill, the vice versa findings of the present study indicate mediating role of self-regulation between bullying and victimization with rejection sensitivity has been found to be strengthened. Since university youth in Pakistan has showed enhanced academic self-efficacy due to high self-regulatory strategies,[27] the mediating position of self-regulation in bullying-victimization syndrome and rejection sensitivity implied that by enhancing emotional and cognitive regulatory mechanisms of the self, sensitivity to occurrence of negative effects of bullying and victimization are minimized. Thus, counseling intervention aimed at enhancement of self-regulation on one hand and reduction of bullying on other hand for the students enrolled in school, colleges, and universities in Pakistan is advisable strategy to be carried out in future.

The sample of the present study was only restricted on the college students. Therefore it is suggested for future research to approach university as well as school level students. The sample was only restricted on the adolescents from age range 16 to 19 years old. Therefore it is recommended to approach adults as well. Adolescents from colleges of Sara-i-Alamgir only were approached. Therefore it is suggested for future research pursuit to incorporate different colleges from varying cities so as to provide comprehensive understanding of the construct under study. In addition to the present variables, individuals' personality traits and parental interactions should be studied while exploring these issues.

CONCLUSION

Self-regulation has fully and significantly mediated the association of both bullying and victimization with the level of sensitivity for rejection in adolescents. Therefore, the implications of the present study have highlighted the implementation of counselling intervention for enhancement of self-regulatory coping strategies in adolescents to handle peer relations effectively. The findings have pointed out target areas to launch workshops in colleges aimed at reduction of bullying, enhancing self-regulation, and development of the wellbeing in adolescents experiencing peer victimization in Pakistan.

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Author's Contribution

SS conceptualized, analysed the data. SB did data collection and wrote the manuscript. Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflict of Interest

Authors declared no conflict of interest

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Data Sharing Statement

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FREQUENCY AND PATTERN OF SUBSTANCE MISUSE IN PATIENTS WITH SCHIZOPHRENIA

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ABSTRACT

Objective: To determine the frequency and pattern of substance misuse in patients with schizophrenia

Methodology: A total of 425 patients with schizophrenia, as per International Classification of Diseases Research criteria version 10 (ICD-10), were included in this cross sectional study from Sarhad Hospital for Psychiatric Diseases Peshawar from September 2020 to February 2021. Patients Information was gathered through a semi-structured questionnaire. Frequency and percentage for categorical variables while mean and standard deviation for continuous variables were calculated using SPSS version 24.

Results: Out of 425, 84.9% are males while 15.1% are females. Mean ages of onset of schizophrenia and substance misuse are 21.97±6 years and 17.99±7 years respectively. Age of onset of schizophrenia and substance misuse in males is 21.97±6.01 years and 17.99±7.06 years while in females it is 24.12±8.07 years and 19.45 ±4.42 years respectively. Life time history for any substance misuse is 69.6%, tobacco 68.2% and non-tobacco substances 41.2%, cannabinoids 40.8%, opioids 5.2%, stimulants 5.7%, sedative hypnotics 2.6% and other substances 0.2%. 54.4% started substance misuse before the onset of schizophrenia while 12.5% started after the onset of schizophrenia. 65.9% are still (presently) misusing any substance, 65.4% are still misusing tobacco while 26.1% are still misusing non-tobacco substance. Substance misuse was more among uneducated, single and male patients.

Conclusion: Substance misuse is quiet common among schizophrenic patients and its onset usually precedes the onset of schizophrenia. Onset of schizophrenia and substance misuse is earlier in males as compare to females. Moreover frequency of substance misuse is lower in female patients, those who are educated and those who are married and vice versa.

Key words: Substance misuse; Schizophrenia; Frequency

INTRODUCTION

Schizophrenia is a lifelong major psychiatric illness with heterogeneous etiology characterized by positive and negative symptoms as well as behavioral disorganization and cognitive symptoms. About 0.5% population are effected by schizophrenia worldwide during their life time with annual incidence of about 0.16 to 1.00 per 1000 population.[1] Other than the prominent genetic factors, a range of environmental factors including substance misuse have been identified as possible etiological factors for schizophrenia.[2] Substance misuse causes poor prognosis, is an established fact. But however whether substance misuse plays a causal role in schizophrenia is controversial. However there is evidence that cannabis increases the risk of schizophrenia.[1,3] Similarly tobacco and stimulants etc. are also risk factors for development of signs and symptoms similar to schizophrenia.[1,4] Age of onset of schizophrenia is earlier in those who are misusing substances. This fact is more related with cannabis but also to some degree to use of stimulants such as amphetamine, cocaine, and ecstasy.[5,6] Cannabis use appears to be an independent risk factor for the development of persistent psychotic disorders, particularly in those at genetic risk for developing schizophrenia and those who previously experienced psychotic symptoms.[3,6]

The life time prevalence of substance abuse in general population in different countries varies from 16% to 42%. While The estimated lifetime prevalence of any substance misuse in schizophrenia is 47%.[1] In two large German samples of schizophrenic patients, the life time prevalence estimate for substance abuse were found to be 21.8% and 42.9%, with 3 months prevalence rates being 21.3% and 29%.[3] According to a study the frequencies of substance misuse in schizophrenic patients were as; alcohol # 47%, cannabis # 42%, stimulants # 25%, Hallucinogens # 18%, sedatives # 7%. Substance misuse is more common in

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males than females in each group of drugs particularly alcohol and cannabis.[7] According to meta-analysis, the prevalence of any substance use disorder was 41.7%, followed by illicit drugs (27.5%); cannabis (26.2%), alcohol (24.3%) and stimulant use (7.3%). Meta-analysis showed the pooled variance of any substance use disorder in males with schizophrenia was 48% which was significantly higher than that for females with schizophrenia.[8]

The incidence rate of cannabis-induced psychosis increased steadily from 2.8 per 100,000 people yearly in 2006 to 6.1 per 100,000 people yearly in 2016. There was a corresponding increase in dual diagnosis with schizophrenia and cannabis use disorder, but a decrease in alcohol-induced psychosis. The data showed no trend in the other substance-induced psychosis. This increase in cannabis-induced psychosis may be due to the increase in the concentration of THC in cannabis, and the increase in cannabis use. The change in diagnostic practice does not appear to explain the increase in incidence of cannabis-induced psychosis.[9]

According to Kaplan and Sadock, the life time prevalence of any substance misuse in patients with schizophrenia is greater than 50%. Schizophrenia is considered to affect the neural circuit mediating drug reward, leading to an increased vulnerability to addiction. Moreover abnormalities in the hippocampal formation and frontal cortex associated with schizophrenia effect, the reinforcing effects of drug reward and reduce inhibitory control over drug-seeking behavior.[10] Up to 90% patients of schizophrenia may be dependent on nicotine. This increased prevalence of nicotine in patients with schizophrenia is due to abnormality in nicotine receptors which in turn affect glutamatergic and dopaminergic pathways in mesolimbic system. Nicotine may improve some cognitive impairments and parkinsonism in schizophrenia which also leads to frequent usage of tobacco by such patients.[10,11] Comorbid substance misuse is not only associated with increased burden of positive symptoms but also increases risk of suicide and depression, frequent admission to hospital, poor compliance and poorer social and occupational outcome.[8] Most patients with schizophrenia abuses illicit drugs. This comorbidity is on one hand due to overlap of biological genetic susceptibility[10,12] but on another hand may be due to drugs that are used to treat schizophrenia. Because these drugs may produce negative symptoms or enhance the euphoric response to abuse drugs. Acute medication with neuroleptics seems to decrease effect of abused drugs. However their chronic use may enhance their reinforcing properties.[12] Similarly those Individuals who have a stronger genetic predisposition to schizophrenia are more likely to initiate cannabis use, use cannabis more regularly, and consume more cannabis over their lifetime.[12]

Although similar studies have been conducted in hospitals of district Peshawar but they are either too old or have insufficient sample size. Moreover in this study, other than frequency we wanted to find out pattern of substance misuse in term of age of onset of substance misuse versus age of onset of schizophrenia that had not been studied before in hospitals of this geographical area. In pattern of substance misuse we tried to answer questions regarding what percent of patients had started substance misuse before the onset of schizophrenia and vice versa.

METHODOLOGY

This descriptive cross sectional study was carried out in Sarhad Hospital for Psychiatric diseases, Peshawar from September 2020 to February 2021. A total of 425 patients were enrolled through convenience sampling technique. Sample size was calculated while considering life time frequency of substance misuse as 50% and that is 385 plus 40 for any expected loss. All patients who met ICD10 criteria for schizophrenia, diagnosed by qualified psychiatrist were included. Information regarding demographic variables like age, sex, education and marital status etc. and disease related characteristics like age of onset of schizophrenia and substance misuse, any history of substance misuse in past and presently etc. were gathered through Questionnaires from patient, accompanying medical records, attendant and hospital record if any. Substance misuse was defined per ICD10 criteria as maladaptive patterns of substance use that impair health in broad sense (physically, psychologically and or socially). And the pattern of use has persisted for at least past one month. The life time history of any substance misuse was defined as the proportion of individuals in the sample that at some point in their whole life (up to the time of assessment) have qualified for the diagnoses of substance misuse at least once. By the pattern of substance misuse in this study we mean what percent of patients have started substance before the onset of schizophrenia and vice versa. Mean and standard deviation for continuous data while frequency and percentage for categorical data was calculated using SPSS version 24. Informed consent from each patient and where not valid due to lack of insight then from guardian was taken. Confidentiality was maintained by using OPD No instead of patient name. NOC was obtained from Head of institution before starting data collection.

RESULTS

In this study, the mean current ages for male and female patients were 33.91±10.76 and 34.12±11.03 respectively. The means of age of onset of schizophrenia and substance misuse in males are 21.97±6.01years and 17.99±7.06 years, while among females these are 24.12±8.07 years and 19.45±4.42 years respectively. Out of 425 patients, 52% have no education

Table 1: Demographic details of the samples (n=425)

Variable		Frequency	Percent
Education	Uneducated	221	52 %
	Educated	204	48%
Gender	Male	361	84.9%
	Female	64	15.1%
Marital status	Married	211	49.6%
	Single	214	50.4%

Table 2: Life time history of misuse of different groups of Substances (n=425)

S.No	Substance	Frequency	Percent
01	Any substance	296	69.6%
02	Tobacco	290	68.2%
03	Non-tobacco	175	41.2%
04	Cannabinoid	174	40.8%
05	Volatile solvents	1	0.2%
06	Stimulants	25	5.7%
07	Opioids	22	5.2%
08	Alcohol	13	3.1%
09	Sedatives hypnotics	11	2.6%
100	Other substances	1	0.2%

Table 3: Onset of substance misuse vs. onset of Schizophrenia (n=425)

Variable	Frequency	Percent
Substance misuse started before the onset of schizophrenia	231	54.4
Substance misuse started after the onset of schizophrenia	53	12.5
Onset of substance misuse was during first reported clinical symptoms of schizophrenia	11	2.6
No history of any substance misuse	130	30.5

and 48% have some education at least up to primary level. Marital status and gender wise distribution is given in table 1. 69.6% patients were having the life time history of substance misuse while life time history of misuse for individual group of substances is given in table 2. Further details of the study are given in table 3.

DISCUSSION

In this study the frequency of still/presently misuse of different groups of substances was according to the finding of Barnes et al.[6] It was also noted that these frequency of still misusing any substance, tobacco and non-tobacco substance were higher among males as well those who were uneducated as vice versa. However the frequency of non-tobacco substance is higher among those who are single as compare to those who are married. So we can conclude that possibly marriage provides protection against only non-tobacco substances while education and female gender provides protection against all groups of substances. Tobacco misuse was almost equal between married and unmarried patients. This fact may be due to the reason that tobacco misuse is socially more acceptable as compare to non-tobacco substances.

In our study the life time history of substance misuse among schizophrenic patients was 69.6%, while that of tobacco and non-tobacco substances was 68.2% and 41.2% respectively. Similar studies conducted in Europe, UK and USA had also concluded that life time history of tobacco misuse was 70% while that of non-tobacco misuse was up to 50%.[6,7,9] Similar to these studies, in our study too tobacco is at the top to be misused. The increased frequency of tobacco might be due to the fact that tobacco is cheap, more easily available, and socially more acceptable and has positive impact on thalamic functions including improvement in sensory gating and hence improved cognitions. Moreover among non-tobacco substances, cannabinoid is at the top to be misused by schizophrenic patients as compare to alcohol contrary to western countries where alcohol is at the tope to be misused after tobacco misuse.[9-11] This again may be due to the fact that cannabis is easily available and socially more acceptable as compare to alcohol in our set up as compare to west. Another reason may be that cannabis induces positive symptoms in chronic schizophrenic patients, which alleviates the negative symptoms and hence apparent improvement in social interactions.[11]

The onset of substance misuse precedes the onset of schizophrenia both males and females. 54.5% reported that they had started substance misuse before the onset of schizophrenia while 12.5% started substance misuse after the onset of schizophrenia. In males the mean age of onset of schizophrenia was 2.15 years while that of substance misuse was 1.46 years earlier as compare to females. Earlier studies had almost similar results.[13,14] The early onset of substance misuse as compare to schizophrenia in most cases may be due to the overlap of biological genetic susceptibility of both disorders. And the later onset in females may be due to the protective role of possibly female sex hormones.[10,12]

CONCLUSION

Substance misuse is quiet common among schizophrenic patients and its onset usually precedes the onset of schizophre-

nia. Onset of schizophrenia and substance misuse is earlier in males as compare to females. Moreover frequency of substance misuse is lower in female patients, those who are educated and those who are married and vice versa.

RECOMMENDATIONS

In future analytical studies should be performed while urine/blood screening test for illicit substances should be done to confirm or exclude claim of any currently/presently misuse of any substance and larger sample should be taken from community instead of hospital, particularly for calculation and comparison of age of onset of schizophrenia versus age of onset of substance misuse.

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Author's Contribution

MS conceived the idea, planned the study, confirmed the diagnosis in each case, drafted and analyzed the data and manuscript. AA helped in data collection. MA helped in data collection, entry of data into SPSS software and analysis of data. Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflict of Interest

Authors declared no conflict of interest

Grant Support and Financial Disclosure

None

Data Sharing Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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THE OUTCOME OF PALLIATIVE STENTING IN CYANOTIC CONGENITAL HEART DISEASES

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ABSTRACT

Objective: To determine the outcome of palliative stenting in children with cyanotic congenital heart diseases.

Methodology: From February 2018 to October 2020, the Department of Paediatric Cardiology at Lady Reading Hospital in Peshawar conducted a cross-sectional study on patients who underwent right ventricular outflow tract blocked Blalock Taussig shunt stenting or patent ductus arteriosus stenting for cyanotic congenital heart disease. The patients' information was gathered using a pre-formatted proforma. Pre- and post-procedure oxygen saturations were recorded for 48 hours. The favorable outcome was defined as an increase in oxygen saturation of at least 15%.

Results: The mean age of the sample (n=49) was 20±29 months. The etiology was Pulmonary Atresia (PA) with Patent ductus arteriosus (PDA) in 23 patients, followed by blocked Blalock Taussig Shunt (BT-Shunt) in 9 patients. The number of patients who underwent PDA stenting was 32, 9 patients had stenting of blocked BT-Shunt and 8 patients had RVOT stenting. The mean pre-intervention oxygen saturation was 43% ±8.9% and the mean post-intervention oxygen saturation was 81% ±5.3%. The number of patients who died was 2, one patient for RVOT stenting died on the table due to cyanotic spell while other post-PDA stenting died because of stent thrombosis.

Conclusion: RVOT, Patent Ductus arteriosus, and blocked Blalock Taussig shunt stenting was found effective in increasing oxygen saturation in children with cyanotic PDA.

Key Words: Right Ventricular Outflow Tract; Patent Ductus Arteriosus; Palliative Stenting; Blalock Taussig Shunt

INTRODUCTION

Children with patent ductus arteriosus, who have duct-dependent pulmonary blood flow may require an early emphasis on palliative surgery to sustain or establish a constant source of pulmonary blood flow until a more suitable surgical procedure can be performed.[1] Transposition of the ductus arteriosus, simple valvular obstructive diseases such as critical pulmonary stenosis, and complex obstructive diseases such as Tetralogy of Fallot or pulmonary atresia with an intact ventricular septum are examples of cyanotic congenital heart diseases that can be managed with interventional treatments.[2] The most frequent type of cyanotic congenital cardiac disease is the Tetralogy of Fallot (TOF), which affects 3 out of every 10,000 children and accounts for 7% to 10% of all cardiovascular diseases.[3] The degree of right ventricular outflow tract (RVOT) obstruction detected at birth or shortly thereafter determines the initial presentation of the patient with Tetralogy of Fallot (TOF)..[4] In case of severe cyanosis where corrective surgery is not possible, palliative BT shunt, RVOT stenting, and if PDA is present, PDA stenting is performed.[5]In patients with Pulmonary Atresia and Critical pulmonic stenosis where PDA is present, PDA stenting is a non-invasive and effective mean of palliative treatment.[6]For a wide range of cyanotic congenital heart disease most commonly Modified BT shunt is performed which is an invasive palliative treatment option. Morbidity and mortality as a potential of BT shunt are known.[7] PDA stenting is introduced as an alternative for BT Shunt in 1992.[8] Many studies have been published on safety complications and the efficacy of Stenting.[9-11] This study was conducted to share the experience of stenting in various forms of cyanotic cardiovascular disease, as studies are limited and there is only one government sector facility in the province of Khyber Pakhtunkhwa providing cardiac interventions in pediatric patients.

METHODOLOGY

From February 2018 to October 2020, a total of 49 individuals were enrolled in this cross-sectional study at the Department of Paediatric Cardiology at Lady Reading Hospital in Peshawar.

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Patients with cyanotic congenital heart disease who received right ventricular outflow tract obstructed BT shunt stenting or patent ductus arteriosus stenting were included in the study, regardless of age or gender. Patients' clinical information, echocardiographic results, and radiologic data were collected on prefabricated proforma. Oxygen saturations were measured before the surgery. A consultant pediatric cardiologist performed the procedures. All procedures were performed while the patient was sedated. For recognized issues, the availability of emergency medications was ensured before the procedure. Post-procedure oxygen saturations were recorded for 48 hours. The favorable outcome was defined as an increase in oxygen saturation of at least 15%. SPSS version 22 was used to analyze the data. Descriptive statistics such as mean SD were computed for numerical data, whereas frequency and % were computed for categorical variables.

RESULTS

The total number of patients was 49, 29 were males, and 20 patients were female shown in table 1. The age of the patients ranged from 9 days to 12 years with a mean age of 20 months ±29 months. The etiology was Pulmonary Atresia with PDA in 23 patients, Tetralogy of Fallot (TOF) in 8, Tetralogy of Fallot with Patent ductus arteriosus in 7, blocked BT-Shunt in 9 and 1patient each of Transposition of great arteries with pulmonary stenosis/ patent ductus arteriosus and severe pulmonary stenosis with patent ductus arteriosus as shown in table 2 and bar graph 1. 32 patients underwent PDA stenting, 9 patients had stenting of blocked BT-Shunt and 8 patients had RVOT stenting and the mean pre-intervention oxygen saturations were 43% ± 8.9% and the mean post-intervention oxygen saturations were 81% ±5.3%, with the improvement of 47 patients (95.9%). Two patients (4.1%) died one due to a Cyanotic spell during the procedure and the other with PDA stent thrombosis on the first post-procedure day. Patients' oxygen saturations were observed for 48 hrs after the procedure in the ward and labeled as a positive outcome after documenting an oxygen saturation difference of more than 15%. A common complication after the procedure was fever due to contrast use and was relieved with symptomatic care. 2 patients had an infection at the cannulation site which resolved with antibiotics therapy.

DISCUSSION

Maintaining optimal pulmonary blood flow in most cyanotic patent ductus arteriosus is mandatory for survival and further palliative or corrective repair. Our study was conducted on all patients with different forms of cyanotic congenital heart diseases who underwent stenting of either patent ductus arteriosus, right ventricle outflow tract, or blocked Blalock Taussig Shunts. In our study, 49 patients were included who underwent palliative stenting out of which 47 patients had a positive outcome in the form of improved oxygen saturation. Out of 49 patients 2 patients died, one patient for RVOT stenting died on the table due to cyanotic spell while another post PDA stenting died because of stent thrombosis. In our study, a total of 32 patients underwent PDA stenting out of which 1 patient (3.1%) died during a hospital stay due to Stent thrombosis and 31 patients (96.9%) had positive outcomes while in a study by Glatz et al[12] conducted on 106 patients reported death in 7 patients (6.6%) and 12 patients (11.3%) required re-intervention for cyanosis. Most of the procedures in our study were planned for patients with cyanosis, this difference in outcome was probably because many cases reported by Glatz et al[12] were unplanned interventions for cyanosis. In another study conducted by Alwi et al [5,] 143 patients who underwent PDA stenting reported no procedural death, 2 patients (1.3%) had early hospital deaths owing to low cardiac output

Table 1: Type of cyanotic congenital heart disease.

Type of congenital heart disease	No of Patients	Positive Outcome	Death
Pulmonary Atresia with PDA	23	22 (96.9%)	1 (3.1%)
Tetralogy of Fallot	8	7 (87.5%)	1 (12.5%)
Tetralogy of Fallot with PDA	7	7 (100%)	0
Blocked BT-Shunt	9	9 (100%)	0
TGA with pulmonary stenosis and PDA	1	1 (100%)	0
Severe pulmonary stenosis with PDA	1	1 (100%)	0

Table 2: Type of stenting done.

Type of procedure stented	No of patients
PDA stenting	32
Blocked BT-Shunt Stenting	9
RVOT Stenting	8

syndrome. In our study, 8 patients underwent RVOT stenting out of which 7 patients (87.5%) had a positive outcome and 1 patient (12.5%) with TOF and cyanotic spell died on the procedure table, while a study conducted by Quandt et al[13] reported 76 patients who underwent RVOT stenting documented 1 procedural death and one emergency surgery while 74 patients had a positive outcome. Another study conducted by Sandoval et al[14] reported that 42 infants who underwent RVOT stenting were 100% successful. In our study, 9 patients had Blocked BT Shunt stenting with 100% results while a study conducted by Moszura et al[15] reported 22 of 23 (96%) successful re-cannulation of Blocked BT Shunt.

Local studies are deficient and data from local hospitals are mostly not published. Our study differs from other international studies as we have included all modalities of stenting rather than individual types.

LIMITATION

The limitation of our study is the small sample size and single-center data. More studies with bigger sample size and data from multiple centers are needed to be published to establish the safety and efficacy of stenting in patients with cyanotic congenital heart diseases.

CONCLUSION

Right ventricular outflow tract, patent ductus arteriosus, and blocked Blalock-Taussig shunt stenting were found effective in increasing oxygen saturation in children with cyanotic congenital heart diseases.

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Author's Contribution

AK conceived the idea, designed the study and supervised the project. IH wrote the manuscript. SI analyzed the data and kept liaison among the authors. YR, TA, AM, AA and ZR helped in data collection, reviewed the draft critically and carried out subsequent changes. All authors contributed significantly to the submitted manuscript.

Conflict of Interest

Authors declared no conflict of interest

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None

Data Sharing Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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❑ Acknowledgments

List all contributors who do not meet the criteria for authorship, such as a person who provided purely technical help, writing assistance, or a department chair who provided only general support. Financial and material support should also be acknowledged. Groups of persons who have contributed materially to the paper but whose contributions do not justify authorship may be listed under a heading such as "clinical investigators" or "participating investigators," and their function or contribution should be described for example, "served as scientific advisors," "critically reviewed the study proposal," "collected data," or "provided and cared for study patients." Because readers may infer their endorsement of the data and conclusions, all persons must have given written permission to be acknowledged.

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Standard journal article

Upto 6 authors: Irfan M, Abdullah AS, Sethi MR, Saleem U, Zeeshan MF, Haq NU. Assessment of personality disorders in students appearing for medical school entrance examination. J Pak Med Assoc. 2018;68(12):1763-8.

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No author given

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(Note: Previous Vancouver style incorrectly had a comma rather than a semicolon between the publisher and the date.)

Personal author(s)

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Norman IJ, Redfern SJ, editors. Mental health care for elderly people. New York: Churchill Livingstone; 1996.

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Computer file

Hemodynamics III: the ups and downs of hemodynamics [computer program]. Version 2.2. Orlando (FL): Computerized Educational Systems; 1993.

❑ Tables and Figures/ Illustrations

Tables and figures/ illustration should be self-explanatory and numbered in the order of their mention in the text. Provide a brief title for each. Type each double-spaced on a separate page. Abbreviations should be defined in a double-spaced footnote at the

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A systematic review paper should have a structured abstract of no more than 250 words using headlines as Objective, Data Sources, Study Selection, Data Extraction, Data Synthesis and Conclusions and with 3-10 key words for indexing.

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Data Sources: Present data sources used, including any time restriction.

Study Selection: Describe criteria to select studies for detailed review. Specify methods used, as blinded review, consensus, multiple reviewers.

Data Extraction: Describe how extraction was made, including assessment of quality and validity.

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Conclusion: Give a clear statement of the conclusions made, its generalisability and limitations.

The Introduction of the paper could be similar to an original report, but without any longer literature survey, only reviewing shortly previous structural reviews and stating the reason and aim of the present review.

The Methodology section may have subheadings corresponding to the Abstract (Data Sources, Study Selection, Data Extraction) and should include clearly defined and reported inclusion and exclusion criteria, and specification of databases and other formal register, conference proceedings, reference lists and trial authors, which are used as sources. The full search strategy should be given so that it is easy to reproduce. If it is considered too long to be published in the article, an electronic document as an Appendix may be the alternative. The stages of selection usually include several steps, each undertaken by at least two independent researchers (identified in the Methods). There will be an initial selection from titles/abstracts to select the articles to be examined in full. The full articles should be re-screened against the selection criteria. The articles fulfilling the criteria should be subjected to quality assessment. Summarize in a flow chart with the number of articles selected and reasons for rejection at each stage.

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Length of paper: The total length of the text should usually not be more than 5000 words (corresponding to 8-9 printed pages) and in addition tables and the reference list. The reference list should be comprehensive and will therefore often be rather long. However, in the printed version of a review paper normally or more than 100 references will be accepted. If needed and without an upper limit, additional references may be published only electronically with a link to such an Appendix given in the original version of the paper.

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A narrative (educational) review should have an unstructured Abstract which should not exceed 250 words, summarizing the current status of the knowledge about the topic reviewed followed by 3-10 key words for indexing.

The introduction should provide a background to a review which focuses on relevant literature published over the last few years that has advanced our understanding of the issue under consideration. The headlines in the review have to be chosen according to the need of that particular review.

There is usually no methology section. However proper Research strategy should be

given. Give a detailed strategy for inclusion of article in the review. Details of the database searched and the time period for which it was searched should be stated.

The discussion section could be structured along the lines for an original report. At the end of discussion, limitations of the study and key message may be given.

Conclusions of the article highlighting the problems, or areas for future research may be included.

Word count should be between 2000 and 5000 words with upto 5 tables and upto 3 figures/ illustrations and upto 100 references.

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Case Reports should be limited to three type: 1) written pages, including an unstructured abstract, 2 a short introduction; and 3) details of the case report followed by discussion and 6 to 10 references. Relevant documentary proof including pictures of the case (with the consent of the patient) or investigations like radiological or histopathological evidence should be submitted along with the manuscript.

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