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## Editorial

# Role of Different Foods in Relieving Depression

Mohsin Masud Jan

Editor

Pakistan, among the other developing countries, has a higher prevalence rate of depression because of the current social adversities. There is, thus, a great need for systematic studies on prevalence of depression.

Depression has been recognized as a major public health problem evidenced by its ranking of fourth position among the global burden of diseases. Many believe it will occupy second position by the year 2020. 340 million people above the age of 18 suffer from depressive disorders that contribute to a high suicide rate.<sup>1</sup>

450 million people in the world suffer from a mental or behavioral disorder. W.H.O. (World Health Organization) global burden of diseases, 2001, states that 33% of the years lived with disability (YLD) are due to neuropsychiatric disorders, unipolar depressive disorders alone lead to 12–13% of years lived with disability and rank as the third leading contributor to the global burden of diseases<sup>2</sup>.

Depressive disorders were estimated to be the leading cause of disability in the world in 1990, accounting for 10.7% of total YLD. These disorders are the 4th leading cause of total DALYs (3.7% total disability adjusted life years)<sup>3</sup>. Estimated global deaths due to unipolar depressive disorders was 12,044, with 5462 male and 6582 female (2004)<sup>4</sup>. A large study conducted by WHO in fourteen countries showed 24% primary care attenders worldwide received an ICD-10 psychiatric diagnosis, the most common of which was ‘current depressive episode’<sup>5</sup>.

Under the big tent of depression there are many shades of gray. Depression can be mild or severe. It can be short-lived or chronic. Special circumstances, like the birth of a baby or the changing of the seasons, can trigger depressive symptoms.

Understanding the type of depression a person is experiencing helps doctors determine treatment. And for people who are diagnosed with depression, having information about their specific disorder can be helpful. Here’s what you should know about the different types of depression. If you suspect you or a loved one has one of these, get evaluated by a mental health professional. They can help you figure out a diagnosis – and the best course of treatment.

**Major depressive disorder:** This very common type of depression is also known as major depression or clinical depression. Under diagnostic criteria, people must have at least five symptoms persisting for two weeks or longer to be diagnosed with major depressive disorder. Those symptoms can include feelings of sadness, emptiness, worthlessness, hopelessness, and guilt; loss

of energy, appetite, or interest in enjoyable activities; changes in sleep habits; and thoughts of death and suicide. Most cases are highly treatable.

**Subsyndromal depression:** A person who has depressive symptoms but doesn’t quite check all the boxes for a diagnosis of major depression may be deemed “subsyndromal.” May be three or four symptoms, not five, or may be depressed for a week, not two.

**Bipolar depression:** Wide swings in mood and energy, from elation to hopelessness, are the signature of bipolar depression, also called bipolar disorder or manic-depressive illness. To be diagnosed with this form of depression, a person must have experienced at least one bout of mania.

**Disruptive mood dysregulation disorder:** Screaming and temper tantrums can be features of disruptive mood dysregulation disorder (DMDD), a type of depression diagnosed in children who struggle with regulating their emotions. Other symptoms include an irritable or angry mood most of the day nearly every day and trouble getting along in school, at home, or with their peers.<sup>6</sup>

**Postpartum (or perinatal) depression:** The birth of a baby brings enormous joy but can sometimes lead to postpartum depression (PPD), a type that affects one in four women and one in eight men. In women, postpartum depression is likely triggered by shifts in hormones, fatigue, and other factors. In men, it’s environmental, brought on by shifting roles and lifestyle changes that come with parenting.

**Psychotic depression:** People with psychotic depression have severe depression accompanied by psychosis, which is defined as losing touch with reality. Symptoms of psychosis typically include hallucinations (seeing or hearing things that aren’t really there) and delusions (false beliefs about what’s happening).

**Treatment-resistant depression:** Sometimes people with major depressive disorder don’t readily respond to treatment. Even after trying one antidepressant and then another their depression stubbornly hangs on.

**Seasonal affective disorder:** Seasonal affective disorder (SAD) is a recurring type of depression that usually strikes in the fall or winter. Along with a change in mood, SAD sufferers tend to have low energy. They may overeat, oversleep, crave carbs, gain weight, or withdraw from social interaction.

**Foods that Help Relieve Depression:** A well-balanced diet of fruits, vegetables, lean meats, and whole grains contributes to your mental health as much as your physical health. Likewise, foods high in sugar,

processed foods, and fatty foods are detrimental to your mental and physical well-being.

Modern psychiatry often treats mental health conditions with prescription medication. However, medication alone does not address the nutritional deficiencies that often play a part in mental and mood disorders.<sup>7</sup>

According to the best available evidence, nutritional counseling may help fight depression. A healthy diet may relieve symptoms of depression with fewer side effects than medications.<sup>8</sup>

While vitamin supplementation can help manage some of these deficiencies, research shows that getting essential nutrients from whole foods may be even more effective than taking supplements.<sup>9</sup>

**Leafy Greens:** Some of the best leafy greens for depression relief include spinach, kale, lettuce, and collard greens.

Leafy greens are chock full of antioxidants, which can be instrumental in reversing damage caused by free radicals. Free radicals are naturally occurring molecules in our bodies that have been linked to cell and DNA damage, chronic health problems, and aging.

In particular, free radicals can have a significant impact on brain health.

This may be why consuming antioxidant-rich foods may help improve symptoms of major depressive disorder. Well-known antioxidants include beta-carotene, vitamin C, and vitamin E.

Some of the most antioxidant-rich foods include Carrots, Pumpkin, Berries (such as blueberries and strawberries), Peppers, Sunflower seeds, Almonds, Hazelnuts, Peanuts, Leafy greens.

**Fatty Fish:** Studies show that omega-3 fatty acids are critical for brain function, including mood regulation. Fish like salmon, small mackerel, and sardines are excellent sources of those omega-3s.<sup>10</sup>

A lack of the omega-3 fatty acid docosahexaenoic acid (DHA) has been linked to reduced production of the neurotransmitters serotonin and dopamine. Deficiency of necessary lipids in the brain is also linked to incidents of anxiety, depression, aggression, and other psychiatric conditions.

Always choose low mercury fish like the ones mentioned above, as opposed to larger fish that contain more mercury (such as tuna).

Despite diet and health trends that focus on eliminating fat, it is apparent that healthy fats are necessary for optimal brain and body function.

Other good sources of omega-3 fatty acids include Walnuts, Raw olive oil, Flaxseed, Chia seeds, Hemp and seeds.

**Avocado:** Another monounsaturated fat, oleic acid, is necessary for proper brain function and can prevent cognitive decline as we age. Some studies suggest that this healthy fat may be particularly helpful in preventing depression in women.

Other oleic acid-rich foods include Olives, Cheese, Eggs and Milk.

**Allium Vegetables:** Allium vegetables such as garlic and onions have antidepressant effects. These vegetables are anti-inflammatory and have been associated with a reduced risk of cancer and several other health benefits.

The full list of allium vegetables includes Garlic, Onions, Leeks, Chives and Shallots.

Allium vegetables appear to improve gastrointestinal health, promoting both mental and overall wellness.

**Whole Grains & Other High-Folate Foods:** Whole grains are packed with folate (vitamin B9, aka folic acid) and other B vitamins. Folate deficiency has been associated with a higher risk of depression.

Folate also helps regulate levels of homocysteine, a biochemical linked with depression, when present in excess amounts. Homocysteine can inhibit the production of serotonin, dopamine, and other important neurotransmitters.

Keep in mind that people with sensitivity to gluten and wheat will still want to avoid grains containing gluten, even if they are minimally processed or whole grains. Gluten-containing grains can cause inflammation in some people and lead to symptoms of depression.

Gluten-free, folate-rich foods include Tomatoes, Asparagus, Brussel sprouts and Fresh fruits.

**Beans:** Fiber-rich beans improve gut health and reduce inflammation. Fiber also helps regulate blood sugar levels, which may affect instances of depression.

Beans are also rich in healthy carbohydrates, which may be linked to increased serotonin. This may be why people crave carbs when under stress. Note that not all carbs are created equal. Refined carbohydrates have been shown to increase depression.

When choosing your carbs, it's best to stick to fiber-rich, unrefined options. The best carb-rich foods for people struggling with depression include whole grains, Legumes (beans), Chia seeds, Flax seeds, Berries, Avocado, Broccoli.

**Shellfish:** Shellfish are a great source of selenium. According to some studies, selenium may help with mood and anxiety. Higher selenium levels correlate with decreased experiences of depression, anxiety, and exhaustion.

Selenium-rich foods include Brazil nuts, Tuna, Halibut, Sardines, Shrimp and Whole grain.

**Lean Beef:** Although typically linked to muscular health, higher protein intake has also been linked to reduced symptoms of depression. Some studies suggest that protein is critical for overall brain health.

Animal proteins also tend to be high in vitamin B12. B vitamins, in general, are necessary for brain function and memory. Like vitamin B9 (folate), vitamin b12 has specifically been shown to help relieve symptoms of depression. This may be linked to the functionality of vitamin B12 in DNA synthesis and energy production in the body, but researchers are still unsure.<sup>11-12</sup>

We always recommend choosing grass-fed and organic meats, eggs, and dairy over conventionally farmed options, as the nutrient breakdown can differ greatly.

Good sources of protein to support mental health include Lean beef, Poultry (such as turkey, chicken, and duck), Fish (such as tuna, salmon, and tilapia), Beans and legumes (such as soybeans, black beans, kidney beans, peas, and lentils), Eggs and Dairy (such as yogurt, milk, and cheese)

**Foods Rich in Vitamin D:** Vitamin D deficiency has also been linked to depression. The link may be due to the function of vitamin D in the endocrine and immune systems.

The best source of vitamin D is moderate sun exposure, putting those with less sun exposure at risk for deficiency. To get more vitamin D, stand outside in direct sunlight for 10-20 minutes each day, preferably before applying sunscreen.

**How do you get someone to eat when they are depressed?** 10-20 minutes of direct sun exposure may help improve someone's mood enough to attempt eating.

**Can depression make you not enjoy food?** Depression can take the joy out of eating. For someone who is depressed, start with small bites of a food without too much flavor, like fiber-rich whole grain bread. It's also a good idea to set an alarm reminder to eat every 4 hours.

Vitamin D deficiency can be rectified by adding these whole foods to your diet like oily fish (such as salmon, sardines, and mackerel), cod liver oil, Oysters, egg yolks, fortified milk and Mushrooms

## REFERENCES

- Desjarlais R. World Health Report. World Health Organization, Geneva. 2001.
- W.H.O. Mental Health, 2006. [http://who.int/mental\\_health/en/](http://who.int/mental_health/en/) Date accessed: 20/1/2006.
- Ustun TB, Ayuso-Mates JL, Chatterji S, Murray CJC. Global burden of depressive disorders in the year 2000. *Brit J Psychiatr* 2004;184:386–392.
- Ustun TB, Ayuso-Mates JL, Chatterji S, Murray CJC. Global burden of disease 2000 Study: World deaths related to neuropsychiatric conditions by gender and cause for year 2000. *Brit J Psychiatr* 2004;184(5):386.
- Sartorius N. Globalization and mental disorders. *Br J Psychiatr* 2004;184:10–20: p: 8.
- Wolfe AR, Ogbonna EM, Lim S, Li Y, Zhang J. Dietary linoleic and oleic fatty acids in relation to severe depressed mood: 10 years follow-up of a national cohort. *Progress in Neuro-Psychopharmacol Biological Psychiatr* 2009;33(6):972-977.
- Owen L, Corfe B. The role of diet and nutrition on mental health and wellbeing. *Proceedings of the Nutrition Society* 2017;76(4):425-426.
- Rao TS, Asha MR, Ramesh BN, Rao KJ. Understanding nutrition, depression and mental illnesses. *Ind J Psychiatr* 2008;50(2):77.
- Lichtenstein AH, Russell RM. Essential nutrients: Food or supplements? Where should the emphasis be? *JAMA* 2005;294(3):351-358.
- McNamara RK, Carlson SE. Role of omega-3 fatty acids in brain development and function: potential implications for the pathogenesis and prevention of psychopathology. *Prostaglandins, Leukotrienes and Essential Fatty Acids* 2006;75(4-5):329-349.
- Syed EU, Wasay M, Awan S. Vitamin B12 supplementation in treating major depressive disorder: a randomized controlled trial. *Open Neurol J* 2013;7:44.
- Coppen A, Bolander-Gouaille C. Treatment of depression: time to consider folic acid and vitamin B12. *J Psychopharmacol* 2005;19(1):59-65.

# Relationship of Formative Assessment with Summative Assessment among Final Year Medical Students

Formative and Summative Assessment among Medical Students

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## ABSTRACT

**Objective:** To determine relationship of formative and summative assessment for final year MBBS students in the subject of surgery.

**Study Design:** Quantitative descriptive cross-sectional study

**Place and Duration of Study:** This study was conducted at the Amna Inayat Medical College Lahore from March 1, 2023 to December 31, 2023.

**Methods:** Scores of 116 final year medical students were subjected to in Quantitative data was collected from examination department in the form of send up results and the results of formative assessment in the surgery for final year medical students. Data was analyzed by SPSS version 25 to determine correlation in order to find relationship of formative assessment with summative assessment.

**Results:** Significantly Positive relationship was revealed between formative and summative assessments after data analysis because  $R=0.835$  in the subject of surgery while  $p=0.01$  indicates statistical significance to be positive.

**Conclusion:** A positively significant relationship exists between summative and formative assessments. Feedback provided by formative assessment facilitates students for identification of their deficiencies and to correct mistakes expected for the subject of surgery in their final examination. Hence helping students to get better grades in the final exam and in turn produce good competent doctors.

**Key Words:** Relationship, Formative, Summative, Assessment, Final Year, Medical

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## INTRODUCTION

To maintain quality in teaching-learning for educational programs, assessment is of utmost importance.<sup>1</sup> As both assessment types significantly affect deep learning process therefore learning should be assessed both by formative and summative assessments.<sup>2</sup> Formative assessment is actually assessment for learning in a medical education system based on competencies. Time to time the students could monitor their own progress

hence enhancing their own performance in the summative assessment.<sup>3</sup> For cognition enhancement, humanism and empowerment of student participation, students themselves could give logical feedback in formative assessment.<sup>4</sup> In this process of assessment, students got engaged to course materials besides monitoring of their own learning process.<sup>5</sup> For facilitation of understanding and learning, formative and summative assessments both support students in identification of their weaker areas.<sup>6</sup> Summative assessment is judgmental and focused at quality assurance whereas formative assessment because of its link with feedback focuses development process. This blended assessment dichotomy is constructive in medical education.<sup>7</sup> Objective of our research study was to determine relationship of formative and summative assessment for final year MBBS students in the subject of surgery.

## METHODS

After getting approval from I.R.B of Amna Inayat Medical College Lahore, study was conducted.

**Study Design;** Quantitative descriptive cross-sectional

**Setting** Amna Inayat Medical College Lahore

**Period;** March 1, 2023 to December 31, 2023

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**Data Source;** from examination department quantitative data was obtained.

**Sampling;** Convenient sampling

**Inclusion Criteria;** Students of MBBS final year who had been subjected to both formative and summative assessments in the subject of surgery.

**Exclusion Criteria;** Students of MBBS final year who had not been subjected to both formative and summative assessments in the subject of surgery.

**Data Collection Procedure;** Scores of 116 final year medical students were subjected to descriptive cross-section quantitative study in March 1, 2023 to December 31, 2023 at Amna Inayat Medical College Lahore. Quantitative data was collected from examination department in the form of send up results and the results of formative assessment in the surgery for final year medical students. Data was analyzed by SPSS version 25 to determine correlation in order to find relationship of formative assessment with summative assessment. Amna Inayat Medical College is affiliated under the umbrella of University of Health Sciences Lahore and has to follow a traditional M.B.B.S curriculum. Surgery is a subject that is covered in final year of MBBS. Students are subjected to term assessments twice after every three months considered be the formative assessments and a send up exam were taken at the end of session considered to be summative assessment. Both of the terms and send up had similar paper pattern. Each formative assessment had a paper in the subject of surgery having pattern and marks similar of final professional taken by university of health sciences Lahore. For each student, average calculated scores for his/her formative and summative were obtained by examination department. Internal assessment is based on this send up examination. Despite being graded, the term assessments have no value in calculation of internal assessment. For our study case the terms had been considered to be formative. On the other hand send up had been considered to be summative. University of Health Sciences conducts final professional exam. Co-relation between scores of formative and summative assessments was determined.

## RESULTS

SPSS version 25 was used to enter quantitative score variables of summative and formative assessments to show standard deviation, mean and median. Pearson coefficient of correlation “r” was obtained. “r”  $\geq$  0.5 was considered significant. In our research, Pearson’s correlation “r” was used to make analysis of significance and strength of correlation between formative and summative evaluations in the subject of surgery. Our research collected assessed scores of 116 final year MBBS students. Every student of that class participated for both summative and formative assessments. MBBS final year class was subjected to formative assessments twice in the subject of surgery.

These assessments although carry marks but of no value in internal assessment which is based upon send up only, a summative assessment according to our study. Mean of scores in formative assessments was given as: Assessment 1 marks + Assessment 2 marks = Total marks/2 which got calculated in each of student cases which was later on compared to her/his summative assessment obtained score in the subject of surgery. In SPSS 25, these data of summative and formative assessment mean were entered and analyzed. Multi-collinearity, correlation and normality of entered data were calculated for the subject of surgery. Administration, faculty and students could understand significance of formative assessment via calculation of Pearson’s coefficient “r” which is a measure of strength and significance of relationship between formative and summative assessments. Summative and formative assessments range along with standard deviation; mean and median were given in the following table. The results of mean, median, standard deviation and range of formative assessment and summative assessment are shown in Table 1 and Table 2.

Relationship was determined between summative and formative assessments by calculating Pearson correlation coefficient “r”. The analysis proved strong correlation ship between two variables. [r= 0.784, n=116, p=0.01] as shown in Table 3.

**Table No.1: Formative**

Descriptives		Statistic
Formative (Surgery)	Mean	51.9966
	Median	57.1000
	Std. Deviation	16.73385
	Range	78.60

**Table No.2: Summative**

Descriptives		Statistic
Summative (Surgery)	Mean	54.3414
	Median	58.1000
	Std. Deviation	13.39571
	Range	62.10

**Table No.3: Correlation**

	Summative	Formative
Summative	1	.784**
Formative	.784**	1
**. Correlation is significant at the 0.01 level [2-tailed].		

## DISCUSSION

As per Quality Assurance Agency a formative assessment gives feedback about students for the areas in which students could be improved to foster learning and does not contribute in holistic assessment while summative assessment is a measure of final outcome of a course a student had followed.<sup>8</sup> Learning activities gaps either at school or home are bridged by formative

assessment.<sup>9</sup> With personalization and subject-wise feedback, formative assessment helps students to enhance their technical expertise.<sup>10</sup> A study described that re-test chances of performance, feedback details and proper time to learning benefited students to obtain improved scores in the second attempt. Reduced motivation of learning with lesser number of students appeared to repeat formative assessments showed a positive effect for summative assessment upon learning.<sup>11</sup> A qualitative research also investigated African-American undergraduates who were subjected through summative and formative types of assessments as they attended an institution mostly for whites.<sup>12</sup> As per experience of students about formative assessment and its associated feedback, it was imperative that examination system and medical education systems of Japan focus summative assessments which involved pressures of society through culture with expectation of correction of mistakes. Hence in Japan and UK scenario such observations gave newer perceptions to support students in learning from feedback associated with formative assessment.<sup>13</sup> Research aimed to know perceptions of medical students about getting feedback being failed in summative assessment in order to explore emotional role upon learning motivation after week performance so as they could remediate and get prepared for upcoming assessments.<sup>14</sup> Some study proved that Model of “Engagement and feedback assessments” could predict performance for summative assessment with validity and could provide information to intervene and enhance learning of students. Outcomes could be improved through increased involvement and attendance.<sup>15</sup> Preference of medical students for an in writing formative feedback had association to good scores in summative assessment. It revealed significance to develop fruitful measures giving medical students feedback associated to their formative assessments to get fully benefited from advantages of such formative assessments in a curriculum which is an integrated one.<sup>16</sup> Even now days there are some teachers who don't employ evaluations formatively and the students still hesitate to demand feedback from their teachers.<sup>17</sup> Data-mining has also been adopted to find disparity among summative and formative assessments and used it for detection of learning topics which were difficult.<sup>18</sup> It was concluded that the formative assessment along with last summative assessment strongly predict results of summative assessment instead of the data of student engagement. A program assessment paradigm should ideally have integrated programs of competency assessment both for curricula integrated either vertically or horizontally. It could aid feedback and scores of summative assessment for every student which in turn facilitate to achieve set outcomes. In a study it was concluded that those subjects which involved individual formative assessment methods showed correlation of

significance between formative and summative assessment. On the other hand those subjects which involved group formative assessment methods had not shown correlation of significance. A reasonable support system, prompt feedback, logical methods of assessment, assessment frequency and proper scoring were considered as prime factors for success.<sup>19</sup> It is very difficult to foster formative assessment because of the challenges associated to assessment-learning culture, resource deficits and lack of concept of formative assessment. Perceptions of teacher and formative assessment practices require a lot of improvement. Three main ways are required to implement formative assessment: development of faculty, advocacy within stakeholders and curriculum management via resources and time allocations.<sup>20</sup>

## CONCLUSION

A positively significant relationship exists between summative and formative assessments. Feedback provided by formative assessment facilitates students for identification of their deficiencies and to correct mistakes expected for the subject of surgery in their final examination. Hence helping students to get better grades in the final exam and in turn produce good competent doctors.

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## REFERENCES

1. Ruiz MI. Beyond traditional response to intervention: Helping rural educators understand English learners' needs. *Rural Special Education Quarterly* 2020;39(1):35-53.

2. Shin J, Chen F, Lu C, Bulut O. Analyzing students' performance in computerized formative assessments to optimize teachers' test administration decisions using deep learning frameworks. *J Computers Educ* 2022;9(1):71-91.
3. Otaki F, Gholami M, Fawad I, Akbar A, Banerjee Y. Students' Perception of Formative Assessment as an Instructional Tool in Competency-Based Medical Education: Proposal for a Proof-of-Concept Study. *JMIR Research Protocols* 2023;12(1):e41626.
4. Ma T, Li Y, Yuan H, Li F, Yang S, Zhan Y, et al. Reflection on the teaching of student-centred formative assessment in medical curricula: an investigation from the perspective of medical students. *BMC Medical Educ* 2023;23(1):1-10.
5. Kingston AK, Garofalo EM, Cardoza K, Fisher RE. Designing formative assessments to improve anatomy exam performance. *Anatomical Sciences Educ* 2023;16(5):989-1003.
6. Rae MG, Abdulla MH. An investigation of preclinical medical students' preference for summative or formative assessment for physiology learning. *Advances Physiol Educ* 2023;47(3):383-92.
7. Svensäter G, Rohlin M. Assessment model blending formative and summative assessments using the SOLO taxonomy. *Eur J Dental Educ* 2023;27(1):149-57.
8. Meher A, Mohapatra D, Devi E, Behera M, Mishra T. Effectiveness of implementation of formative assessments as a part of competency-based medical education on summative assessment: A pilot study. *National J Physiol Pharmacy Pharmacol* 2023;13(4):863-6.
9. Huang Y-M, Silitonga LM, Wu T-T. Applying a business simulation game in a flipped classroom to enhance engagement, learning achievement, and higher-order thinking skills. *Computers Educ* 2022;183:104494.
10. Kalfsvell L, Peeters L, Hoek K, Bethlehem C, van der Sijs I, van der Kuy P, et al. Does formative assessment help students to acquire prescribing skills? *Eur J Clin Pharmacol* 2023;79(4):533-40.
11. Lavallard V, Cerutti B, Audétat-Voirol MC, Broers B, Sader J, Galetto-Lacour A, et al. Formative assessments during COVID-19 pandemic: an observational study on performance and experiences of medical students. *MedEdPublish* 2023;13(7):7.
12. Buzzetto-Hollywood N. Decolonization and culturally responsive teaching practices and the role of historically Black colleges and universities. *J Educ Human Development* 2023;12(1):1-15.
13. Kozato A, Shikino K, Matsuyama Y, Hayashi M, Kondo S, Uchida S, et al. A qualitative study examining the critical differences in the experience of and response to formative feedback by undergraduate medical students in Japan and the UK. *BMC Med Educ* 2023;23(1):1-11.
14. Jay R, Hagan P, Madan C, Patel R. A phenomenological exploration of the feedback experience of medical students after summative exam failure. *BMC Med Educ* 2023;23(1):930.
15. Kemp PR, Bradshaw JM, Pandya B, Davies D, Morrell MJ, Sam AH. The validity of Engagement and Feedback Assessments (EFAs): identifying students at risk of failing. *BMC Med Educ* 2023;23(1):866.
16. McCallum S, Milner MM. The effectiveness of formative assessment: student views and staff reflections. *Assessment Evaluation Higher Educ* 2021;46(1):1-16.
17. Reynaga-Chávez R, Huamán-Romaní YL, Burga-Falla JM, Vásquez-Alburquerque IL, Chenet Zuta ME. The Perspective's Analysis of Formative Assessment with University Students. *TEM J* 2023;12(2).
18. Tran H, Vu-Van T, Bang T, Le TV, Pham HA, Huynh-Tuong N. Data Mining of Formative and Summative Assessments for Improving Teaching Materials towards Adaptive Learning: A Case Study of Programming Courses at the University Level. *Electronics* 2023;12(14):3135.10.
19. Sottiyotin T, Uitrakul S, Sakdiset P, Sukkarn B, Sangfai T, Chuaboon L, et al. Effective formative assessment for pharmacy students in Thailand: lesson learns from a school of pharmacy in Thailand. *BMC Med Educ* 2023;23(1):1-9.
20. Almahal EA, Osman AAA, Tahir ME, Hamdan HZ, Gaddal AY, Alkhidir OTA, et al. Fostering formative assessment: teachers' perception, practice and challenges of implementation in four Sudanese medical schools, a mixed-method study. *BMC Med Educ* 2023;23(1):247.

# Frequency of Dental Caries and Associated Factors Among Patients Attending the Peshawar Dental College and Hospital: A Hospital-Based Cross-Sectional Study

Iftikhar Akbar<sup>1</sup>, Asmat Ullah<sup>2</sup>, Asma Hassan<sup>1</sup> and Asma Begum<sup>3</sup>

## ABSTRACT

**Objective:** To determine the frequency of dental caries and associated factors among patients attending the Peshawar Dental College and Hospital.

**Study Design:** Hospital-based cross-sectional study

**Place and Duration of Study:** This study was conducted at the Department of Operative Dentistry and Endodontic of Peshawar Dental College and Hospital during the study period from September 2023 to December 2023.

**Methods:** A total of one hundred & thirty-six patients meeting inclusion criteria utilizing a convenient sampling method were recruited for the study. Data collection was carried out using structured questionnaires and clinical examinations. Clinical examination was performed by cleaning and drying the teeth and using a mouth mirror with adequate light and a ball-end Community Periodontal Index (CPI) probe. Dental caries were identified when a lesion was observed in the pit or fissure, or on a smooth surface, characterized by a detectable soft floor, undermined enamel, soft wall, or temporary restoration. The Chi-square test was employed with a significance level of  $P \leq 0.05$  to assess potential associations of categorical variables.

**Results:** The frequency of dental caries among patients was found to be 85% with varying degrees of severity. The mean age of the participants was  $33 \pm 12.66$  years and ranged from 13 to 80 years. Aspects including age, oral hygiene routines, dietary patterns, and socioeconomic status displayed significant association with the presence of dental caries ( $p < 0.05$ ). Poor oral hygiene practices and frequent use of sugary meals were the most major risk factors.

**Conclusion:** Dental caries frequency was notably influenced by factors such as oral hygiene status, level of education, and income level. Patients with poor oral hygiene, lower educational levels, and lower income were identified as having at heightened susceptibility to caries

**Key Words:** Dental caries, hygiene, sugar meals, risk factors

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## INTRODUCTION

Dental caries is commonly described as a microbial infection that causes significant damage to teeth by

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breaking down their inorganic and organic components through demineralization and dissolution.<sup>1</sup> Dental caries, commonly known as tooth decay, is a prevalent chronic disease characterized by the breakdown of tooth structure due to bacterial action. It affects individuals of all ages and socioeconomic backgrounds, posing significant public health challenges globally.<sup>2</sup> Studies have indicated a high prevalence of caries among both children and adults, often resulting in discomfort and pain.<sup>3</sup> The primary culprits implicated in the development of caries are acid-producing bacteria such as Streptococci and Lactobacilli.<sup>4</sup> Risk factors contributing to its occurrence include socioeconomic status, educational level, lifestyle factors and dietary habits.<sup>5</sup>

In developing nations, the increased prevalence of dental caries is linked to various factors, including unhealthy dietary patterns, inadequate and inappropriate public health services, limited access to such services, and insufficient utilization of fluoride.<sup>4</sup> Conversely, the reduction in caries prevalence in developed countries is

credited to changes in dietary habits regarding sugar consumption, improved oral hygiene practices, increased involvement in oral health initiatives, and the implementation of population-wide preventive programs.<sup>6</sup>

In Sudan, a study reported a dental caries prevalence of 30.5%,<sup>7</sup> while research in Kenya found it to be 37%. Lack of awareness about the causes and preventive measures of the disease was cited as a primary factor contributing to this figure.<sup>8</sup> The World Health Organization recommends conducting epidemiological surveys every five years to monitor oral health status within communities.<sup>9</sup> Despite global efforts to improve oral health, challenges persist, particularly among underprivileged populations in developing nations. Early detection of oral diseases is essential for effective management and conducting thorough visual oral examinations with proper lighting can aid in identifying such conditions at early stages.<sup>10</sup>

Dental caries would be prevented by appropriate hygienic ways. Early detection and timely treatment are pivotal in preventing further damage and preserving teeth. It's crucial to comprehend the frequency of caries and the factors associated with it to devise effective prevention and management strategies. Creating awareness about oral health and preventive measures against dental caries is imperative. Additionally, implementing initiatives to provide dental care services at the primary level is essential.

The objective of this study was to assess the frequency of caries and its related risk factors among patients attending the Peshawar Dental College and Hospital. By examining various socio-demographic, behavioral, and clinical aspects, this research seeks to provide valuable insights into the epidemiology and determinants of caries.

The study's findings have the potential to impact public health treatments and policies targeted at reducing the burden of caries and promoting oral health in communities.

## METHODS

This study employed a hospital-based cross-sectional design to investigate the frequency of dental caries and associated factors among patients attending Peshawar Dental College and Hospital. The research was conducted at Peshawar Dental College and Hospital located in Peshawar, Pakistan. As a tertiary care dental facility, it serves a diverse patient population from various socio-economic backgrounds. Ethical approval was obtained from the institutional review board of Prime Foundation, before the commencement of the study. A verbal informed consent was obtained from all participants, and confidentiality of their personal information was ensured throughout the study.

A convenient sampling method was utilized to recruit participants for the study. Patients presenting to the

Department of Operative Dentistry and Endodontic of Peshawar Dental College and Hospital during the study period from September 2023 to December 2023, were invited to participate. The sample size was calculated based on the estimated prevalence of dental caries in similar populations, with a confidence level of 95% and a margin of error of 0.05, turning to one hundred and thirty-six. The healthy patients with the age above 13 years among both genders were included. Patients suffering from systemic diseases and those who were not cooperative were excluded from the study.

Data collection was carried out on structured questionnaires after clinical examinations. The questionnaire included socio-demographic information (e.g., age, gender, education level, income), and oral health-related behaviors (e.g., oral hygiene practices, dietary habits). Clinical assessments were conducted to evaluate the presence and severity of caries using standardized diagnostic criteria. Clinical examination was performed by cleaning and drying the teeth and using mouth mirror with adequate light and ball-end Community Periodontal Index (CPI) probe. Dental caries were identified when a lesion was observed in the pit or fissure, or on a smooth surface, characterized by a detectable soft floor, undermined enamel, soft wall, or temporary restoration.

Statistical analysis was conducted using appropriate software, SPSS, 21. Descriptive statistics were used to summarize the characteristics of the study population and the frequency of dental caries. To assess potential associations, the Chi-square test was employed. A significance level of  $P \leq 0.05$  was utilized to determine statistical significance.

## RESULTS

**Table No.I: Socio-demographic status of the participants.**

Variables		Number	Percent
Gender	Male	57	41.9
	Female	79	58.1
Marital Status	Married	82	60.3
	Unmarried	54	39.7
Socioeconomic status	Low	54	39.7
	Medium	58	42.6
	High	24	17.6
Educational status	Illiterate	46	33.8
	Matric	23	16.9
	Intermediate	29	21.3
	Graduate	19	14.0
	postgraduate	19	14.0
	Poor	37	27.2

The mean age of patients was  $33 \pm 12.66$  and ranged from 13 to 80 years. Two-thirds of the patients were in the age group of 13-35 years. In terms of gender, 42 % were male while 58% were female with dental caries. (Table 1)

**Table No.2: Oral hygiene status and tooth brushing Habits of the participants**

Habit of Tooth Brushing		Num ber	Percent age
Oral Hygiene status	Good	35	25.7
	Fair	64	47.1
	Poor	37	27.2
Tooth Brushing Habit	Yes	111	81.6
	No	25	18.4
Brushing Frequency	Once a day	49	36
	Twice a day	34	25
	More than twice a day	3	2.2
	Weekly	6	4.4
	Usually	19	14.0
	NA	25	18.4
Time of tooth brushing	Morning	63	46.3
	Night	6	4.4
Type of tooth paste	NA	67	49.3
	Fluoridated	81	59.6
	Non fluoridated	31	22.8

Table 2 demonstrates that the majority of patients had fair oral hygiene status. Over 80% of the participants in the study had a habit of brushing their teeth. Among those who brushed, about 25% brushed their teeth twice a day. Interestingly, only 18% of the participants were not brushing their teeth. About 60 % of the study participants used fluoridated toothpaste.

Table 3 shows that 36% consumed carbohydrates twice a day. The majority of the participants (83%) were not

using tobacco in any form. Dental caries were detected in 85.3% of participants, while 14.7% had no detectable caries. Finally, caries risk was categorized as follows: 14% were at low risk, 50.7% were at moderate risk, and 35.3% were at high risk.

Table 4 provides an association of different variables among type of caries risk and P values.

**Table No.3: Carbohydrate intake, tobacco use and caries status among the participants.**

		Num ber	Perce ntage
Sugar food consumption	Yes	126	92.6
	No	10	7.4
Frequency of sugar consumption	Once a day	35	25.7
	Twice a day	49	36.0
	More than twice a day	31	22.8
	Usually	11	8.1
	NA	10	7.4
Use of tobacco in any form	Yes	23	16.9
	No	113	83.1
Type of tobacco used	Smoked	15	11.0
	Smokeless	8	5.9
	NA	113	83.1
Dental Caries	Detected	116	85.3
	Undetected	20	14.7
Caries risk	Low risk	19	14.0
	Moderate risk	69	50.7
	High risk	48	35.3

**Table No.4: Association of different variables among type of caries risk.**

Variable	Categories	Type of caries risk			P Value
		Low risk	Moderate risk	High risk	
Gender	Male	7(12.3%)	34(59.6%)	16(28.1%)	0.20
	Female	12 (15.2%)	35(44.3%)	32(40.5%)	
Marital status	Married	7(8.5%)	39(47.6%)	36(43.9%)	0.01
	Unmarried	12(22.2%)	30(55.6%)	12(22.2%)	
Socioeconomic status	Low	3(5.6%)	22(40.7%)	29(53.7%)	0.001
	Medium	9(15.5%)	36(62.1%)	13(22.4%)	
	High	7(29.2%)	11(45.8%)	6(25.0%)	
Educational Status	Illiterate	0(0.0%)	14(30.4%)	32(69.6%)	0.000
	Matric	2(8.7%)	15(65.2%)	6(26.1%)	
	Intermediate	3(10.3%)	20(69.0%)	6(20.7%)	
	Graduate	5(26.3%)	11(57.9%)	3(15.8%)	
	Postgraduate	9(47.4%)	9(47.4%)	1(5.3%)	
Oral hygiene status	Good	16(45.7%)	17(48.6%)	2(5.7%)	0.000
	Fair	3(4.7%)	44(68.8%)	17(26.6%)	
	Poor	0(0.0%)	8(21.6%)	29(78.4%)	
Tooth Brushing Habits	Yes	19(17.1%)	66(59.5%)	26(23.4%)	0.000
	No	0(0.0%)	3(12.0%)	22(88.0%)	



## DISCUSSION

The study revealed that the prevalence of dental caries was 85%, surpassing rates found in Lithuania (78.3%),<sup>11</sup> Brazil (75%),<sup>12</sup> Kenya (37%),<sup>13</sup> Sudan (30.5%)<sup>14</sup>, Ethiopia Finote Selam city (48.5%),<sup>15</sup> and Bahirdar city Ethiopia (21.8%).<sup>16</sup> The higher frequency observed in this study could be attributed to differences in the study population, timing, and setting. Being institution-based, there might be a greater influx of patients in healthcare facilities compared to community-based studies, possibly influencing the results. This underscores the importance of promoting oral health discrepancies with studies from Brazil, Kenya, and Sudan could stem from variations in study populations and socio-demographic factors among these countries.

The frequency of developing dental caries was more in females (23%) compared to males (16%) in the present study, which is in line with a study done in China.<sup>17</sup> The frequency of developing dental caries was more in the younger population (13-35 years) compared to older ones (more than 57 years). This discovery aligns with findings from a national oral health survey conducted in China<sup>18</sup> and Palestine<sup>19</sup> which reported dental caries rates of 55.3% and 54.35% respectively among children aged 12 and above. Additionally, a meta-analysis encompassing Eastern Mediterranean countries revealed a prevalence of 65% (for primary dentition), 66% (for mixed dentition), and 70% (for permanent dentition).<sup>20</sup>

The current research discovered that individuals with good oral hygiene had lower rates of dental caries compared to those with poor oral hygiene with a significant P value (0.05). This result aligns with studies conducted by Selam<sup>14</sup> in the City of Ethiopia. Furthermore, the study highlighted that individuals who lacked formal education were 70% more likely to be at risk compared to those who had attended formal education, consistent with a similar study conducted in Gondar.<sup>21</sup>

The study revealed that individuals with lower monthly incomes had higher rates of dental caries compared to those with higher incomes, a trend consistent with research conducted in Gondar town. It suggests that as family income rises, the likelihood of dental decay decreases. This could be explained by the ability of higher-income individuals to afford dental hygiene products, contributing to better oral health outcomes. Patients with no habit of using toothbrushes have a high caries risk compared to those who use them twice a day. Similarly, patients with carbohydrate intake and more frequent consumption have a high caries risk compared to those with no carbohydrate intake, which corresponds with studies done in Brazil,<sup>12</sup> Kenya<sup>13</sup> and Ethiopia.<sup>15</sup>

The strengths of the study were that it was conducted within a dental college and hospital environment providing access to a diverse patient population, ensuring a broad representation of individuals seeking dental care. By examining both the frequency of dental caries and associated factors, the study offers a comprehensive understanding of the oral health status and potential determinants among the patient population.

Since the study was conducted in a hospital setting, the patient population may not represent the general population, as it primarily includes individuals seeking dental care, potentially leading to sampling bias. Second, the sample size was not large enough so the findings may not be generalizable to the wider population beyond those attending the Peshawar Dental College and Hospital, limiting the external validity of the results. Acknowledging these limitations is important for interpreting the study findings accurately and for guiding future research efforts to address gaps in knowledge and improve the validity and reliability of findings in this area.

The current study provides valuable insights into the dental health status of adults across much of the Peshawar region. This information serves as a crucial foundation for health policymakers and government officials, enabling them to develop targeted preventive strategies and treatment programs for dental conditions. By focusing on improving access to quality dental services, these initiatives aim to enhance the overall living standards of the population.

## CONCLUSION

Dental caries were detected in 85.3% of participants. Two-thirds of the patients were in the age group of 13-35 years. Female were more affected than males. Patients with poor oral hygiene, lower educational attainment and lower income were at higher risk of dental caries.

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## REFERENCES

1. Akbar I, Baig MN, Qureshi B, Aziz Ta, Osama A, Al Garni Hm, et al. Frequency of dental caries and associated risk factors in patients attending College Of Dentistry, Aljouf University-Saudi Arabia. *PODJ* 2015;35(4):670-74.
2. Marcenés W, Kassebaum NJ, Bernabé E, Flaxman A, Naghavi M, Lopez A, et al. Global burden of oral conditions in 1990-2010: a systematic analysis. *J Dent R* 2013;92(7):592-7.
3. Tafere Y, Chanie S, Dessie T, Gedamu H. Assessment of prevalence of dental caries and the associated factors among patients attending dental clinic in Debre Tabor general hospital: a hospital-based cross-sectional study. *BMC Oral Health* 2018;18(1):119-24.
4. Teshome A, Yitayeh A, Gizachew M. Prevalence of Dental Caries and Associated Factors Among Finote Selam Primary School Students Aged 12–20 years, Finote Selam Town, Ethiopia. *Age* 2016; 12(14):15-7.
5. Álvarez L, Liberman J, Abreu S, Mangarelli C, Correa MB, Demarco FF, et al. Dental caries in Uruguayan adults and elders: findings from the first Uruguayan National Oral Health Survey. *Cadernos de saude publica* 2015;31:1663-72.
6. Umer MF, Farooq U, Shabbir A, Zofeen S, Mujtaba H, Tahir M. Prevalence and associated factors of dental caries, gingivitis, and calculus deposits in school children of Sargodha District, Pakistan. *J Ayub Med Coll Abbottabad* 2016;28(1):152-6.
7. Nurelhuda NM, Trovik TA, Ali RW, Ahmed MF. Oral health status of 12-year-old school children in Khartoum state, the Sudan; a school-based survey. *BMC Oral Health* 2019;9(1):15.
8. Gathecha G, Makokha A, Wanzala P, Omolo J, Smith P. Dental caries and oral health practices among 12 year old children in Nairobi West and Mathira West Districts, Kenya. *Pan Afri Med J* 2012;12(42): 67-72.
9. World Health Organization. Oral health surveys: basic methods. WHO; 2013.p.1-125. Available at <https://www.who.int/publications/i/item/9789241548649>
10. Patro BK, Kumar BR, Goswami A, Mathur VP, Nongkynrih B. Prevalence of dental caries among adults and elderly in an urban resettlement colony of New Delhi. *Ind J Dent Res* 2018;19(2):95.
11. Miglė Ž, Rūta G, Ingrida V, Kristina S, Jaunė R, Eglė S. Prevalence and severity of dental caries among 18-year-old Lithuanian adolescents. *Med* 2016;52:54–60.
12. Vanessa R, Danuze B, Tatiana D, Ana C, Orlando A. Prevalence of dental caries and caries-related risk factors in premature and term children. *Braz Oral Res* 2019;24(3):329-35.
13. Nurelhuda NM, Trovik TA, Ali RW, Ahmed MF. Oral health status of 12-year-old school children in Khartoum state, Sudan; a school-based survey. *BMC Oral Health* 2009;9:15-21.
14. Amare T, Asmare Y, Muchye G. Prevalence of Dental Caries and Associated Factors Among Finote Selam Primary School Students Aged 12–20 years, Finote Selam Town, Ethiopia. *OHDM* 2016;15(1):445-54.
15. Wondemagegn M, Tazebew D, Mulat Y, Kassaw M, Bayeh A. Dental caries and associated factors among primary school children in Bahir Dar city: a cross-sectional study. *BMC Res Notes* 2014;7: 949-55.
16. Zewdu T, Abu D, Agajie M, Sahilu T. Dental caries and associated factors in Ethiopia: systematic review and meta-analysis. *Environ Health Prev Med* 2021; 26:21-8.
17. Cheng YH, Liao Y, Chen DY, Wang Y, Wu Y. Prevalence of dental caries and its association with body mass index among school-age children in Shenzhen, China. *BMC Oral Health*. 2019; 19: 270-6.
18. Wang HY, Petersen PE, Bian JY, Zhang BX. The second national survey of oral health status of children and adults in China. *Int Dent J* 2017;52:283–90.
19. Mahfouz M, Abu Esaid A. Dental caries prevalence among 12-15 year old palestinian children. *Int Sch Res Not* 2014:785-91.
20. Kale S, Kakodkar P, Shetiya S, Abdulkader R. Prevalence of dental caries among children aged 5-15 years from 9 countries in the Eastern Mediterranean Region: a meta-analysis. *East Mediterr Health* 2020;26:726–35.
21. Tafere Y, Chanie S, Dessie T, Gedamu H. Assessment of prevalence of dental caries and the associated factors among patients attending dental clinic in Debre Tabor general hospital: a hospital-based cross-sectional study. *BMC Oral Health* 2018;18(1):119-22..

# Association of Inflammatory Markers and Dietary Patterns with Components of Metabolic Syndrome in Working Women

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## ABSTRACT

**Objective:** The main objective of the study is to find the association of inflammatory markers and dietary patterns with components of metabolic syndrome in working women.

**Study Design:** Cross-sectional study

**Place and Duration of Study:** This study was conducted at the Department of Physiology, Liaquat University of Medical and Health Sciences Jamshoro from January 2023 to December 2023.

**Methods:** A total of 384 female aged between 18 to 50 years were included in the study. Data were collected through a systematically designed questionnaire. Inflammatory blood markers were the main focus of the study following the participants' fasting (overnight), and they were measured.

**Results:** Data was collected from 384 female participants according to inclusion and exclusion criteria. Mean age of the participants was  $39.08 \pm 10.41$  years. Among the participants, 22.4% reported current pregnancy, highlighting the diversity in reproductive stages, while 45.8% were identified as menopausal. The average BMI of 29.12 and prevalence of abdominal adiposity at 30.5% suggest a need for targeted interventions in women's health. Inflammatory biomarkers show significant associations with various health-related variables. Individuals with higher BMI categories exhibited elevated levels of C-reactive protein (CRP), with mean values of  $3.0 \pm 1.5$  in the normal BMI range (18.5-24.9),  $4.5 \pm 2.0$  in the overweight category (25-29.9), and  $6.2 \pm 2.8$  in the obese group ( $\geq 30$ ) ( $p < 0.001$ ). Work duration also played a role in influencing erythrocyte sedimentation rate (ESR), as individuals with longer work durations ( $>10$  years) displayed higher mean ESR levels ( $20.0 \pm 10.0$ ) compared to those with shorter durations ( $<5$  years and 5-10 years) ( $p < 0.001$ ).

**Conclusion:** It is concluded that there is an association between inflammatory markers, dietary patterns, physical activity, and components of metabolic syndrome in working women. Emphasizing lifestyle modifications, including healthier dietary choices and increased physical activity, holds promise in mitigating metabolic syndrome risk factors in this population, although further research is needed to elucidate causative mechanisms and refine targeted interventions.

**Key Words:** Inflammatory, Biomarkers, Patients, Working Women, Physical activity

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## INTRODUCTION

Metabolic Syndrome characterized as a group of intentional factors which comprise central obesity, hypertension, dyslipidemia as well as insulin resistance is a significant health problem around the globe.

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The number of women suffering from metabolic syndrome disease has been increasing, including working women, along with raising changes in both eating habits and lifestyles over the years<sup>1</sup>. In addition, recent work shows that persistent low-grade inflammation is the main culprit in the shaping of metabolic syndrome, thus pointing out to the divergent paths between inflammatory factors and metabolic dysregulation<sup>2</sup>. Awareness of the link between the dietary habits, inflammatory markers and components of metabolic syndrome in relation to work is a pivotal factor in designing resilient preventive and therapeutic modules, specially reflecting the demands of the unique circumstances surrounding working women<sup>3</sup>. Indeed, the diets of an individual are very distal in the sense that they act as the central mechanisms orally intaking the body towards a systemic inflammation and metabolic disorder. While a deep research takes into the

account the influences of these associations, their precise mechanisms are still a multi-faceted question that warrants thorough investigation<sup>4</sup>.

In the context of environmental factors, among which diet has an important role, MetS development will be affected<sup>5</sup>. There are earlier studies showing that the risk developing MetS is associative with dietary red meat, cholesterol, saturated and trans-fatty acids, and iron-rich foods. This inflammatory trend has been noticed more often in people who consume these types of foods. It signifies that eating these foods can make an individual hyperinflammatory via elevating the inflammatory markers in blood<sup>6</sup>. On the other hand, most of the researches concentrated on the intake of only one kind of food, that is, with high inflammatory potential and the researchers did not make any consideration on assessing diet in its whole<sup>7</sup>. The inflammatory activity of total diet is a more precise indicator in the evaluation of the link between diet and the onset of the disease rather than the consumption of an individual food or nutrient<sup>8</sup>. The inclination of whole of the diet is more appropriate because single nutritional intake and diet overlapping problem might be observed during the investigation<sup>9</sup>. The other alternative is the expansion of adipose tissue that is accompanied by the invasion of immune cells that result in the pro-inflammatory ADP induction with elevated TNF- $\alpha$ , CRP, and IL-6 levels that in turn, cause insulin resistance to increase<sup>10</sup>. Another beta-lipid mediated cascade is added to the list of inflammation co-mechanisms, along with hypertension. Of the last few years, there has been the skyrocketing of MetS cases because these transformation in lifestyle, socioeconomic status, and diet has occurred<sup>11</sup>.

## METHODS

This cross-sectional study was conducted at Liaquat University of Medical and Health Sciences Jamshoro from January 2023 to December 2023. A total of 384 female aged between 18 to 50 years were included in the study. Data were collected through a systematically designed questionnaire. Inflammatory blood markers were the main focus of the study following the participants' fasting (overnight), and they were measured. They include, but not the micro-components: CRP, IL-6, and TNF- $\alpha$ , which were determined using laboratory techniques like ELISA. The participants' food intake was established with the use of validated dietary assessment tools, including but not limited to, the food frequency questionnaires (FFQs) or the 24-hour dietary recalls. The participants were asked a range of questions that revolved around their usual dietary choices, which was the frequency of eating, serving sizes, and preferences. By applying the descriptive statistics such as the principal component analysis, or cluster analysis, the dietary patterns were set. We chose to evaluate components of metabolic

syndrome such as abdominal obesity (waist circumference), hypertension (blood pressure), dyslipidemia (lipid profile), insulin resistance, fasting glucose, insulin levels and HOMA-IR. Data were analyzed using SPSS (26.0). Descriptive statistics was used to summarize the participants mostly from their characteristics, dietary patterns, inflammatory markers, as well as metabolic syndrome components. Multivariate and bivariate methodologies such as regression models were used to assess the effect of dietary patterns, including inflammatory markers, on the components of the metabolic syndrome, while at the same time accounting for confounders such as age, body mass index, physical activity and socioeconomic status.

## RESULTS

Data was collected from 384 female participants according to inclusion and exclusion criteria. Mean age of the participants was 39.08 $\pm$ 10.41 years. Among the participants, 22.4% reported current pregnancy, highlighting the diversity in reproductive stages, while 45.8% were identified as menopausal.

**Table No.1: Demographic data of participants**

Parameters	Mean	Min.	Max.	Standard deviation (s.d $\pm$ )
Age	40 years	31	59	10
BMI	29.12kg/m <sup>2</sup>	23.6	31.4	5.25
Systolic blood pressure	128 mmHg	92	178	24
Diastolic blood pressure	91mmHg	63	110	29

**Table No.2: Medical history of participants**

Medical History	Number of Participants (n=384)
History of Any Drug Intake	
Yes	150
No	234
Duration	
History of Any Chronic Illness or Disease	
Yes	80
No	304
Specify	Hypertension, Diabetes
Family History of Any Disease	
Yes	200
No	184
Specify	Cardiovascular Diseases

Table 2 shows the medical history of participants. 39.1% reported a history of drug intake, with common medications lasting for varied durations. Chronic illnesses were reported by 20.8%, primarily including hypertension and diabetes. Additionally, 52.1% indicated a family history of diseases, predominantly cardiovascular conditions.

Erythrocyte sedimentation rate (ESR) stands at 25 mm/hr, suggesting a mild level of inflammation. Ferritin levels, reflecting iron stores, average at 45.2 ng/mL. Interleukin-6 and C-reactive protein concentrations are 8.7 pg/mL and 3.5 mg/L, respectively, signifying a subtle proinflammatory milieu. Procalcitonin, a marker for bacterial infection, is within the normal range at 0.9 ng/mL.

**Table No.3: Level of Inflammatory biomarkers in participants at baseline**

Inflammatory Markers	Number of Participants (n=384)
ESR (mm/hr)	25±3.2
Ferritin (ng/mL)	45.2±8.6
Interleukin 6 (pg/mL)	8.7±1.5
C-Reactive Protein (mg/L)	3.5±0.9
Procalcitonin (ng/mL)	0.9±0.2
WBC/Leukocytes (x10 <sup>9</sup> /L)	7.8±1.3

There is a statistically significant association ( $p < 0.05$ ) between high diet and Abdominal Adiposity, with a prevalence of 30.5%. However, no significant associations were observed for Elevated Blood Pressure, High Serum Triacylglycerol, Reduced Serum HDL-C, and Abnormal Glucose Homeostasis ( $p > 0.05$ ).

**Table No.4: Association between metabolic syndrome and dietary patterns**

Metabolic Syndrome Component	Low diet	Moderate diet	High diet	p-Value
Abdominal Adiposity	25.3%	18.7%	30.5%	<0.05
Elevated Blood Pressure	12.8%	14.2%	10.1%	0.21
High Serum Triacylglycerol	20.6%	23.8%	19.2%	0.14
Reduced Serum HDL-C	15.7%	17.9%	14.3%	0.31
Abnormal Glucose Homeostasis	18.2%	16.5%	20.9%	0.18

Inflammatory biomarkers show significant associations with various health-related variables. Individuals with higher BMI categories exhibited elevated levels of C-reactive protein (CRP), with mean values of  $3.0 \pm 1.5$  in the normal BMI range (18.5-24.9),  $4.5 \pm 2.0$  in the overweight category (25-29.9), and  $6.2 \pm 2.8$  in the obese group ( $\geq 30$ ) ( $p < 0.001$ ). Work duration also played a role in influencing erythrocyte sedimentation

rate (ESR), as individuals with longer work durations ( $>10$  years) displayed higher mean ESR levels ( $20.0 \pm 10.0$ ) compared to those with shorter durations ( $<5$  years and 5-10 years) ( $p < 0.001$ ). Interleukin-6 (IL-6) levels exhibited significant variations across age groups, with individuals aged 41-50 having the highest mean IL-6 levels ( $9.5 \pm 2.5$ ), followed by those aged 31-40 ( $7.2 \pm 2.0$ ) and 20-30 ( $5.0 \pm 1.5$ ) ( $p < 0.001$ ). Ferritin levels were significantly influenced by menopausal status, with post-menopausal women having higher mean ferritin levels ( $70.0 \pm 20.0$ ) compared to pre-menopausal women ( $50.0 \pm 15.0$ ) ( $p < 0.001$ ).

**Table No.5: Comparison of inflammatory biomarkers with other variables**

S. No	Independent Variable	Dependent Variable	Mean ±SD	P-value
1.	Ferritin	Pre-menopausal	50.0 ± 15.0	<0.001
		Post-menopausal	70.0 ± 20.0	
Lipid Profile				
		Normal	55.0 ± 10.0	<0.001
		Dyslipidemia	65.0 ± 15.0	
HbA1c				
		Normal	20.0 ± 5.0	<0.001
		Elevated	25.0 ± 10.0	
2.	HbA1c	Physical	150.0 ± 20.0	<0.001
		Diet	120.0 ± 15.0	<0.001
		Lipid profile	130.0 ± 18.0	<0.001
3.	Procalcitonin	BMI	8.0 ± 2.0	<0.001
4.	IL-6	Age	55.0 ± 10.0	<0.001
5.	CRP	Work Duration	8.0 ± 3.0	<0.001

## DISCUSSION

The study findings unveiled pertinent insights into the prevalence of anxiety symptoms among the participant pool, as indicated by the General Anxiety Disorder-7 (GAD-7) questionnaire. Notably, a considerable percentage reported experiencing feelings of nervousness, anxiety, or edginess, with 30.2% encountering such emotions several days a week. Similarly, regarding the inability to control worrying, 40.1% faced these challenges several days a week<sup>12,13</sup>. Worries about different aspects were also notable, with 29.4% experiencing these thoughts several days a week. Furthermore, participants reported troubles relaxing, restlessness, irritability, and fearfulness about possible

unfortunate events, indicating the spectrum of anxiety symptoms experienced within the group<sup>14</sup>.

Diet is an important predictor of circulating levels of inflammatory markers<sup>21</sup>. Diets rich in pro-inflammatory constituents such as saturated fatty acids (SFAs) and trans fatty acids have consistently been associated with proliferation and oxidative stress that can promote inflammation<sup>15</sup>. By contrast, polyunsaturated fatty acids (PUFAs), monounsaturated fatty acids (MUFAs), and fiber have been shown to attenuate the inflammatory cascade. Recently, a survey on the inflammatory potential of diet and its influence on obesity and chronic diseases has received special attention<sup>16</sup>.

The dietary inflammatory index (DII) is a novel scoring algorithm that provides an estimate of the inflammatory potential of the overall diet based on the inflammatory properties of dietary constituents. Food pattern analysis is a way to investigate the relationship between diet and risk of chronic diseases<sup>17</sup>. Currently, few studies have studied the association between dietary patterns and DII. Dietary patterns with more protein, specifically animal protein may also aggravate glucose metabolism, leading to the development of IR<sup>28</sup>. Moreover, a body of evidence shows that certain dietary patterns have also been associated with the markers of inflammation. A cross-sectional study of the Hispanic elderly living in Massachusetts reported lower concentrations of CRP with higher fruit and vegetable consumption<sup>18</sup>. However, no significant associations were noted between high diet and other metabolic syndrome components, including elevated blood pressure, high serum triacylglycerol, reduced serum HDL-C, and abnormal glucose homeostasis<sup>19</sup>. In this regard, López-Moreno et al. showed that consumption of diets with highly-saturated fatty acids (HSFAs) increases the intestinal absorption of LPS which, in turn, increases postprandial endotoxemia levels and the postprandial inflammatory response<sup>20</sup>.

## CONCLUSION

It is concluded that there is an association between inflammatory markers, dietary patterns, physical activity, and components of metabolic syndrome in working women. Emphasizing lifestyle modifications, including healthier dietary choices and increased physical activity, holds promise in mitigating metabolic syndrome risk factors in this population, although further research is needed to elucidate causative mechanisms and refine targeted interventions.

### Author's Contribution:

Concept & Design of Study: Saima Naz Shaikh  
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**Conflict of Interest:** The study has no conflict of interest to declare by any author.

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## REFERENCES

1. Prasun P. Mitochondrial dysfunction in metabolic syndrome. *Molecular Basis Disease* 2020;S0925-4439(20)30185-X.
2. Unar K, Laghari ZA, Abbasi AR, Unar AA, Khokhar MA, Channa TA. Prevalence and determinants associated with metabolic syndrome among adults in district Khairpur Mirs Sindh. *Pak J Physiol* 2019;15(4):59-62.
3. Syauqy A, Hsu CY, Rau HH, Jane CJ Chao. Association of Dietary Patterns with Components of Metabolic Syndrome and Inflammation among Middle-Aged and Older Adults with Metabolic Syndrome in Taiwan *Nutrients* 2018;10:143. doi:10.3390/nu10020143.
4. Zafar U, Ali Z, Khaliq S, Lone K. Association between hypoxia-inducible factor-1 alpha rs11549465 (1772 C>T) polymorphism and metabolic syndrome. *JPM* 2021;July 71:1832-1837.
5. Memon A, Baig NM, Samo AA, Shaikh K, Laghari ZA. Prevalence of metabolic syndrome among premenopausal and postmenopausal working women in Hyderabad, Pakistan. *Pure Applied Biol (PAB)* 2020;10(1):19-25
6. Moreira MA, Vafaei A, SMA da Camara. Metabolic syndrome (MetS) and associated factors in middle-aged women: a cross-sectional study in Northeast Brazil. *Women Health* 2019; 60(6): 601-617.
7. Forrester, Steven J, et al. Reactive Oxygen Species in Metabolic and Inflammatory Signaling. *Circulation Res* 2018;122(6):877.
8. Saghaei-Asl M, Mirmajidi S, Asghari Jafarabadi M, et al. The association of dietary patterns with dietary inflammatory index, systemic inflammation, and insulin resistance, in apparently healthy individuals with obesity. *Sci Rep* 2021; 11:7515.
9. Shahinfar, Hossein, et al. Association of Nutrient Patterns and Metabolic Syndrome and Its Components in Adults Living in Tehran, Iran. *J Diabetes Metabolic Disorders* 2020;19(2):1071-1079.
10. Saklayen MGJC. The global epidemic of the metabolic syndrome. *Curr Hypertens Rep* 2018; 20(2):12.
11. Tortosa-Caparrós E, Navas-Carrillo D, Marín F, Orenes-Piñero EJC, Crifó, nutrition. Anti-inflammatory effects of omega 3 and omega 6 polyunsaturated fatty acids in cardiovascular



- disease and metabolic Syndrome. *Crit Rev Food Sci Nutr* 2017;57(16):3421–9.
12. Ahola AJ, Harjutsalo V, Thorn LM, Freese R, Forsblom C, Mäkimattila S, et al. The association between macronutrient intake and the metabolic syndrome and its components in type 1 diabetes. *Br J Nutr* 2017;117(3):450–6.
  13. Bahar A, Kashi Z, Kheradmand M, Hedayatizadeh-Omran A, Moradinazar M, Ramezani F, et al. Prevalence of metabolic syndrome using international diabetes federation, National Cholesterol Education Panel-Adult Treatment Panel III and Iranian criteria: results of Tabari cohort study. *J Diabetes Metabolic Disorders* 2020;1–7.
  14. Ghorabi, Sima, et al. Association between Dietary Inflammatory Index and Components of Metabolic Syndrome. *J Cardiovascular Thoracic Res* 2020; 12(1):27-34.
  15. Lee, Yun, et al. Associations between Dietary Patterns and Metabolic Syndrome: Findings of the Korean National Health and Nutrition Examination Survey. *Nutrients* 2022;15(12): 2676.
  16. Abdollahzad H, Pasdar Y, Nachvak SM, Rezaeian S, Saber A, Nazari R. The relationship between the dietary inflammatory index and metabolic syndrome in ravansar cohort study. *Diabetes, Metabolic Syndrome and Obesity* 2020;477-487.
  17. Ren Z, Ai Zhao, Wang Y, Meng L, Szeto IMY, Ting Li, et al. Association between Dietary Inflammatory Index, C-Reactive Protein and Metabolic Syndrome: A Cross-Sectional Study. *Nutrients* 2018;831. doi:10.3390
  18. Armani A, Berry A, Cirulli F, Caprio M. Molecular mechanisms underlying metabolic syndrome: the expanding role of the adipocyte. *The FASEB J* 2017;31:4240-4255.
  19. Reddy P, Lent-Schocheta D, Ramakrishnana N, McLaughlina M, Jialal I. Metabolic syndrome is an inflammatory disorder: A conspiracy between adipose tissue and phagocytes. *Clinica Chimica Acta* 2019; 496:35–44.
  20. Finicelli M, Squillaro T, Di Cristo F, Salle A, et al. Metabolic syndrome, Mediterranean diet, and polyphenols: Evidence and perspectives. *J Cellular Physiol* 2018;234:5807–5826.

# Postoperative Complications in Lichtenstein Repair Under Spinal Anesthesia

Postoperative  
Complications in  
Lichtenstein  
Repair

Muhammad Fahad

## ABSTRACT

**Objective:** To describe postoperative complications in Lichtenstein repair under spinal anesthesia.

**Study Design:** Descriptive, prospective, cohort study

**Place and Duration of Study:** This study was conducted at the Abbasi Shaheed Hospital, Karachi for six months duration from 07.02.2023 till 06.08.2023.

**Methods:** It is a descriptive, prospective<sup>1</sup>, cohort study with both qualitative and quantitative aspects. My research is focus on postoperative complications occurs after Lichtenstein repair. Sample size was derived from formula<sup>2</sup> and through internet based calculator.net which is 194. The no of participants selected through consecutive method of sampling and follow ups are done postoperatively in wards and on out-patient department bases. The postoperative complications were taken as variables and analysed through SPSS. The patients are between 21 and 85 years old. We categorized the individuals into two distinct groups F1 and F2. In the F1 group, we used the European hernia society classification (EHS), and in the F2 group, we used ultrasound and the EHS classification to determine accurate defect size. Lichtenstein repair is the procedure of choice. Postoperative complications were evaluated.

**Results:** According to our results, we found that out of the 97/194 patients in the F1 group, 51 have lateral inguinal hernia and 41 have medial inguinal hernia. In the F2 group, 43 patients have lateral inguinal hernia, and 49 patients have medial inguinal hernia. Postoperative complications. In our study, many patients who developed complications had Lichtenstein repair done by postgraduate surgeons under supervision and surgical registrars. Experienced surgeons like Professor and Associate Professor have performed Lichtenstein repairs on patients with negligible or fewer complications.

**Conclusion:** Accurate estimation of defect size, adequate spinal anesthesia with experienced anesthetists, proper fixation and overlapping of mesh, proper suture material, and instruments with proper lightning and sterilization techniques—surgical experience noted >300 lichtenstein repairs can reduce postoperative complications in Lichtenstein repair.

**Key Words:** Postoperative Complications, Lichtenstein Repair, Spinal Anesthesia

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## INTRODUCTION

Across the world 20 million patients did Lichtenstein repair yearly. It is one of the best and frequent surgical procedure offered in the world. The rate of occurrence of inguinal hernia is 27-43% for male and 3-6% for female<sup>3,10</sup>. Lichtenstein repair is a type of open inguinal hernia repair with tension free mesh repair technique.

The tension free concept got its description with Irving Lichtenstein (1920-2000) belong to Los Angeles in the

second edition of his famous hernia article. He formulated a tension free repair by implanting prosthetic material to fix the gap between the muscular and ligament tissues.

His repair evenly used R/Marlex as mesh in a classic anterior inguinal approach. He made the intervention to an state of art procedure. The efforts of Lichtenstein ends with flying colours that it is still one of the best evidence based mesh repair technique in the world. Prolene Hernia System is an adaptation of the Lichtenstein technique in which implantation of a double sided prolene mesh is done before and after the muscle by an open incision. In 1987 Lichtenstein bring out his data registry configuration. It had his own observations with over 6000 demonstrations and he also incorporated his classification system.

Despite all advances, postoperative complications in Lichtenstein repair is still the matter of debate.<sup>4,5</sup> A clinical study showed the rate of developing intraoperative complications is 6% and immediate postoperative complications was seen in 12% Patients<sup>6</sup>. Postoperative surgical complications are classified

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usually according to Clavien Dindo Classification (CDC)<sup>7,8</sup>. This classification is constituted to categorize the severity of a surgical outcome. It is based on the line of management needed to correct the complications<sup>9</sup>. The scale divided into several grades

**Grade 1:** Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions.

**Grade 2:** Requiring pharmacological treatment with drugs other than such allowed for Grade I complications. Blood transfusions and total parenteral nutrition are also included.

**Grade 3:** Requiring surgical, endoscopic or radiological intervention.

**Grade 3 a:** Intervention not under general anesthesia.

**Grade 3 b:** Intervention under general anesthesia.

**Grade 4:** Life-threatening ( complication including those affecting the brain) requiring intensive care management.

**Grade 4 a:** Single organ dysfunction (including dialysis)

**Grade 4 b:** Multi organ dysfunction.

**Grade 5:** Death of patient

In Lichtenstein repair usually grade 1,2 and 3 complications are reported in our study. Grade 4 and 5 complications are not usually encountered.

The postoperative complications in Lichtenstein repair is usually divided into early and late postoperative complications. The early post operative complications are postoperative pain, urinary retention, postoperative

bleeding, hematoma, seroma and wound infection late postoperative complications are recurrence ,chronic postoperative pain, postoperative neuralgias and testicular atrophy.

## METHODS

In surgical ward of our hospital, I have conducted a prospective cohort study which is both qualitative and quantitative. The objective of research study was to see the impact of accurate defect size estimation and overlapping of mesh on postoperative complications in Lichtenstein repair. I have selected 194 patients of direct and indirect inguinal hernia through consecutive sampling and divided into two groups F1 and F2 .In first group F1, I have estimated accurate defect size through European hernia society (EHS) and in group F2 ultrasound and EHS classification is used for determination of defect size in inguinal hernia .Post-operative complications in both group have been evaluated upto three months in both groups.

## RESULTS

According to our results, we found that out of the 97/194 patients in the F1 group, 51 have lateral inguinal hernia and 41 have medial inguinal hernia. In the F2 group, 43 patients have lateral inguinal hernia, and 49 patients have medial inguinal hernia.

**Table No.1: Postoperative complications.**

Postoperative complications	F1	F2	Analysis	Treatment
1)hematoma	47	07	P:0.001, OR:13.67, 95%CI:5.753,32.51, Kappa:0.443	Conservative, guided drainage, and antibiotics
2)wound infection	63	07	P:0.001, OR:26.11, 95%CI:10.85,62.82,kappa:0.598	Conservative, antibiotics anti-inflammatory
3)Postop pain	64	07	P:0.001, OR:23.68, 95%CI:10.22,54.86 kappa:0.598	Conservative analgesics anti-inflammatory
4)postop neuralgia	60	07	P:0.001, OR:43.83, 95%CI:17.74,108.24,kappa:0.701	Analgesic gabapentin
5)recurrence	01	00	-	Observation surgical management
6)Testicular atrophy	01	00	-	Observation

Postoperative Complications In:

1) Haematoma:

group * haematoma Cross tabulation Count				
Count				
		haematoma		Total
		yes	no	
group	f1=no	50	47	97
	f2=yes	7	90	97
Total		57	137	194

**F1 Group:** 50 patients developed haematoma in the early postoperative period resolved conservatively.

**F2 group:** 07 patients developed haematoma resolved conservatively.

Statistical analysis:

P-value: 0.001

Odd's Ratio: 13.67

95% Confidence interval: 5.75,32.51,kappa:0.443

## 2) Wound infection:

Group * wound infection Cross tabulation Count				
		Wound Infection		Total
		yes	no	
group	f1=no	65	32	97
	f2=yes	7	90	97
Total		72	122	194

**F1 group:** 65 patients developed wound infection in F1 group which are treated conservatively by daily dressing, antibiotics and anti-inflammatory medication. The most common organisms found are staphylococcus aureus, Ecoli, and klebsiella.

**F2 group:** 07 patients developed wound infection treated. Mostly are superficial surgical site infection treated conservatively with daily dressing and antibiotics.

Statistical analysis:

P value: 0.001

Odds ratio: 26.11

95% confidence interval: 10.85,62.82, kappa:0.598

## 3) Postoperative Pain:

group * postoperativepain Crosstabulation				
Count				
		postoperativepain		Total
		pain	no pain	
group	f1=no	66	31	97
	f2=yes	8	89	97
Total		74	120	194

**F1 group:** 66 patients have mild to moderate pain in first 10 days with paper based VAS (visual analog score) for pain is 4-8.<sup>11,13</sup>

No patient developed pain till 03 months.

All the patients treated conservatively.

**F2 group:** 08 patients had mild to moderate pain with paper based VAS (visual analog score) was 4-8.<sup>11,4</sup>

**Statistical Analysis:**

P value:0.001

Odds Ratio:23.68

95% Confidence interval:10.22,54.86,kappa:0.5998.

## 4) Postoperative Neuralgia:

**F1 group:** 64 patient had complains of postoperative neuralgia (pricking, numbness, burning at surgical site and in groins, spinal headache. Treated conservatively with anti inflammatory, analgesics and gabapentin.

**F2 group:** 08 patients developed postoperative neuralgias for 10 days upto 01 month treated conservatively with anti-inflammatory ,spinal headache with caffeine, cola drinks and gabapentin.

**Statistical Analysis:**

P-value:0.001.

Odds ratio:21.57.

95% Confidence interval:9.34,49.80.kappa:0.577.

**5) Testicular atrophy:** Only 01 patient reported in F1 group

**6) Recurrence:** Only 01 patient reported in F1 group.

In our study many patients who developed complications have Lichtenstein repair done by postgraduate surgeons under supervision and by surgical registrars. The lichtenstein repair on patients carried out by experienced surgeon have developed negligible or less complications. The level of experience noted should be >300 lichtenstein repair. Combination of ultrasound and EHS classification is found to be sensitive in reducing post-operative complications by accurate estimation of defect size and with the help of this junior as well as senior surgeons can plan to overcome the incident alomas and intra and postoperative complications<sup>14</sup>.

## DISCUSSION

Inguinal hernia has been the disease ever since the mankind existed<sup>1</sup>.04 decades before Lichtenstein developed a state of art tension free mesh repair known as Lichtenstein Repair<sup>1</sup>. In the year 2004, European hernia society annual meeting held in Capri, Italy in which the standard inguinal hernia classification system was orchestrated. In this simple and comprehensive classification of hernia<sup>15</sup> in which direct, indirect and femoral hernia were marked and defect size will be evaluated by taking index fingerbreadth as a criteria of measurement. Ultrasound helps in diagnosing occult inguinal hernia<sup>16</sup>.Significance of clinically hard inguinal hernia with help of ultrasound is confirmed by European hernia society.

A European study led by Mathews proposed that in patients with normal or doubtful clinical examination, the preoperative ultrasound can be considered diagnostic for evaluation. It is now affirmed that ultrasound has high accuracy in the diagnosis of inguinal hernia including differentiating the type of hernia in doubtful cases. Post-operative complications in tension free mesh repair is still the problem in Lichtenstein repair. In one study 12 % cases of different post-operative complications were identified in Lichtenstein repair<sup>6</sup>.

The most common post-operative complication world wide in open inguinal hernia repair is recurrence but due to major advances and expertise it is declining. Other post-operative complications such as wound infection, urinary retention, haematoma<sup>17</sup>,seroma, postoperative pain , postoperative neuralgia, testicular atrophy is also present. In my study, I found 54(27%) patient developed haematoma<sup>17</sup>,70(36%) patient developed wound infection<sup>5</sup>, postoperative pain<sup>5</sup> is present in 70(36%) of cases mostly pain of short duration , no case of chronic postoperative pain<sup>19</sup> was reported in the duration of study all cases were managed conservatively,

In this study, 67(34%) cases of postoperative neuralgia were reported included patients having mild pricking, burning sensation of short duration in the area of nerve distribution all treated conservatively. Common nerves

encountered in Lichtenstein repair are three Ilioinguinal nerve, genital branch of genitofemoral nerve and iliohypogastric nerves. Cases of spinal headache due to inappropriate spinal anesthesia were also reported and increased the length of stay. Approximately 38(20%) cases of spinal headache were reported in our study. All cases were treated conservatively. Cases of urinary retention were 6(3%) also found in the duration of study. 01 patient of testicular atrophy and 01 patient of recurrence<sup>20</sup> were reported in duration of our study. In this study I found Lichtenstein repair done by expert surgical hands causing less complications. The level of experience should be >300 lichtenstein repairs. Many risk factors were associated with development of postoperative complications in this study including age<sup>21</sup>, intercurrent illnesses, lack of expertise of surgeons and anesthetist, inappropriate suture material, fixation of mesh over the edge which should be 0.5 cm away from edge, improper closure technique by junior surgeons. The author concluded that use of spinal anaesthesia in elderly patient is not supported by existing evidence.

## CONCLUSION

Accurate estimation of defect size, adequate spinal anesthesia with experienced anesthetist, proper fixation and overlapping of mesh, Availability of proper suture material, and instruments with proper lightning and sterilisation techniques, surgical expertise can reduce postoperative complications in Lichtenstein repair.

### Author's Contribution:

Concept & Design of Study: Muhammad Fahad  
 Drafting: Muhammad Fahad  
 Data Analysis: Muhammad Fahad  
 Revisiting Critically: Muhammad Fahad  
 Final Approval of version: Muhammad Fahad

**Conflict of Interest:** The study has no conflict of interest to declare by any author.

**Source of Funding:** None

**Ethical Approval:** No.11/22 dated 27.04.2022

## REFERENCES

- Panda R, Pradhan A, Hembram P. Complications of Prosthetic Mesh repair (Lichtenstein Method) of uncomplicated inguinal hernia of male patients: An Observational Prospective study. *JMSH* 2020;6(3): 66-73.
- Antonisamy B, Prasanna S. Premkumar, Solomon Christopher, Sample size, Principles and Practice of Biostatistics. RELX India private limited 2017;324-326.
- Kockerling F, Maarten P. Simons, Current concepts of inguinal hernia repair. *Visc Med* 2018;34(2):145-150.
- Jan Z, Ali S, Ahmed N, Sarwar MA. Comparison of common Postoperative Complications between Lichtenstein open repair and Laparoscopic Transabdominal Pre-peritoneal (TAPP) Repair for unilateral inguinal hernia. *Cureus* 2021; 13(9):e17863.
- Assakran B, AlHarbi AM, Abdulrahman Albadrani H, Al-dohaiman RS. Risk factors for postoperative complications in Hernia repair. *Cureus* 2024;16(1):e511982.
- Vasu S, Sagar K. A clinical study of postoperative complications of Lichtenstein hernioplasty for inguinal hernia. *Int Surg J* 2018. <http://doi.org/10.18203/2349-2902.isj20185457>.
- Eylert G, Wolfsberger C, Meik R, Winter F, Dong R, Michelitsch S, et al. The Postsurgical Clavien-Dindo classification in minor surgery can improve perception and communication (Investigation on blepharoplasty). *J Pers Med* 2022;1900.
- Rapaka RR, Venkata Reddy M. A study on assessment of postoperative complications among major abdominal surgeries using Clavien-Dindo classification. *IJS* 2020; 7(6). <http://doi.org/10.18203/23492902.isj20202382>.
- Kapoor VK. Open inguinal hernia repair, Clinical procedures. *Drugs Dis* April 18th, 2023. [www.emedicine.medscape.com/article/1534281](http://www.emedicine.medscape.com/article/1534281).
- Kingsnorth A, Sanders DL. General introduction and History of hernia surgery. *Management of Abdominal hernias* 2018;17:3-30. [http://doi.org/10.007/978-3-319-63251-3\\_1](http://doi.org/10.007/978-3-319-63251-3_1).
- Delgado DA, Lambert BS, Boutris N, McCulloch PC, Robbins AB, Moreno MR, et al. Validation of Digital Visual Analog Scale Pain Scoring with a Traditional paper-based visual analog scale in adults. *J Acad Orthop Surg Glob Res Rev* 2018. <http://doi:10.5435/JAAOSGlobal-D-17-00088>.
- Valappil RK, Ramamoorthy J, Krishan S. Early Postoperative complications of Emergency Lichtenstein. *Hernioplast* 2017;5:11.
- Sooyoung Cho, Youn Jin Kim, Lee M, Woo JH, Lee HJ. Cut off points between pain intestines of the postoperative pain using receiver operating characteristic curves (ROC). *BMC Anaesthesiol* 2021;21(1):29.
- Pierce RA, Paulose BK. Preoperative imaging in hernia surgery. In: Novilsky YW, editor. *Hernia surgery. Current principles*. Switzerland: Springer Cham;2016.p.23-30.
- Simons MP, Aufenacker T, Bay-Nielsen M. et al. European Hernia Society guidelines on the treatment of inguinal hernia in adult patients. *Hernia* 2009;13:343-403.
- Plumb AA, Rajeswaran G, Abbasi MA, Masci L, Warren O, Wilson J, Contemporary imaging of inguinal hernia and pain. *Br J Radiol* 2022; 95(1134). <http://doi.org/10.1259/bjr.20220163>.

17. Zeb MH, Pandian TK, El Khatib MM, Naik ND, Chandra A, Morris DS, et al. Risk factors for postoperative haematoma after inguinal hernia repair: an update. *J Surg Res* 2016;205(1),33-37.
18. Pangal HN, Prashanth Kumar K. A study of post-surgical complications of inguinal hernia, *Int J Surg Sci* 2020;4(3):277-278.
19. Reinpold W. Risk factors of chronic pain after inguinal hernia repair. A systematic review. *Innov Surg Sci* 2017;2(2):61-68.
20. Abdourahmane N, Diallo Adja C, Diao Mohamed L, Tendeng Jacques N, Nyemb Philippe MM, Mamadou C, et al. Acute Postoperative complications increase the risk of recurrence and chronic pain after inguinal hernia surgery. A single-center retrospective analysis. *Int J Abdominal Wall Hernia Surgery* 2023;6(4): 236-241.
21. Kockerling F. Data and outcome of inguinal hernia repair in hernia registers-a review of literature. *Innov Surg Sci* 2017;2(2):69-79.



# Resurgence of Diphtheria; Vaccination Status, Clinical Profile and Outcome of Children Suffering With Diphtheria

Afzal Khan, Lal Muhammad, Rabiya Munir, Sajid Ali, Zainab Rahman and Alia  
Abdulhaq

## ABSTRACT

**Objective:** To determine the vaccination status of children suffering from diphtheria, their clinical profile and outcome.

**Study Design:** Descriptive cross-sectional study

**Place and Duration of Study:** This study was conducted at the Department of Pediatrics, MTI/ Lady Reading Hospital Peshawar from July 2023 to December 2023.

**Methods:** Data was collected after approval from Hospital ethical committee. Sample size was calculated through Open EPI and non-probability consecutive sampling technique was used. From arrival to departure, patients were followed.

**Results:** A total of 67 children were included. Of them 40(59.7%) were male and 27(40.3%) were females. Mean age was  $8.80 \pm 3.43$  with range from 2 to 15 years. Out of them 39(58.2%) were unvaccinated, 20(29.9%) were partially vaccinated and 8(11.9%) were routinely vaccinated. 34(50.7%) had mild symptoms at arrival, 23 with bull neck and 10 with serious illness. In 45(67.1%) patients cardiac involvement was present ranging from sinus tachycardia to VT. 08(11.9%) had renal and 05(7.5%) had neurological involvement. 54(80.6%) received ADS and 13(20.4%) couldn't. 12(17.9%) patients unfortunate outcome (died) and 55(82.1%) successfully recovered.

**Conclusion:** This study shows that Diphtheria has resurged again and the most effective measures, vaccination, is very poor as majority (88%) of our patients are unvaccinated or partially vaccinated. Cardiac involvement is the major complication of diphtheria. A significant number of mortality occurs due to diphtheria and there is insufficiency of ADS for these patients.

**Key Words:** Diphtheria, vaccination, cardiac complications, Anti-diphtheria serum

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## INTRODUCTION

Diphtheria is an infectious disease caused by toxigenic strains of *Corynebacterium diphtheriae*. It is an acute potentially fatal infectious disease.<sup>1</sup> It remained a leading cause of childhood death in the pre-vaccine era<sup>2</sup>. In industrialized world its incidence fell after WW2 and in developing countries vaccination brought this change following WHO launching of Expanded Programme on Immunization in 1974<sup>3</sup>.

Diphtheria commonly presents as infection of the upper airways. Skin infection can occur and is usually uncommon.

Most of the time, it presents with complications. Among these are the acute respiratory obstruction, toxic myocarditis and neurologic weakness are the most important complications of diphtheria. Thrombocytopenia, renal failure and septicemia can occur.<sup>4,5</sup> The clinical presentation and severity of diphtheria vary in immunized and non immunized children. Early diagnosis and prompt treatment including administration of diphtheria antitoxin and antibiotics minimize mortality.<sup>6</sup>

Diphtheria is a vaccine preventable disease. Its vaccination schedule consists of three doses of primary series starting at 06 weeks of age, followed by at 10 and 14 weeks.<sup>7</sup> This vaccination was devised by WHO in 1974 and implemented all over the world. However due to different reasons, prominently war hit zones, continued to have cases of diphtheria and so this disease couldn't be eradicated. For further reduction in this disease, WHO revised immunization schedule with addition of three booster doses given at 12–23 months of age, 4–7 years, and 9–15 years of age.<sup>8</sup> Further diphtheria vaccine is safer and has very less adverse effects. Hitt J Sharma et al studied locally prepared

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vaccine for safety and immunogenicity and found it safe and effective.<sup>9</sup>

Since 1980, the number of diphtheria cases gradually declined till early 90s and then had a spike. The disease continued to be reported in less number of cases due to small epidemics occurring from place to place. Factors responsible for these epidemics are reduced immunization, mass migration of population internal and external, conflict zones, poor health facilities and low literacy rates in under-developed countries. World Health Organization shows that diphtheria progressively decline with the advent of vaccination, improved hygiene, properly treatment of diagnosed cases.<sup>10,11,12</sup> However for last one decade its fall has stopped and is raised as in African region in 2014, 01 was reported but in 2022, 910 cases were reported. Similarly in European Region in 2014, 35 cases were reported but in 2022, 362 cases were reported. Pakistan diphtheria statistics reported fall to single digit, 09 cases were reported in year 2014 and 2015, last year 2022 raised to 351 and in the current year, 2023, a massive surge is predicted.<sup>13,14</sup>

Diphtheria was seen occasionally, though not eradicated but in year 2022, 351 cases were reported and in the early time of year 2023, cases seen<sup>13,14</sup>, were going very high. In July, the pediatric isolation section of our hospital was 70% occupied by diphtheria. So the study was planned to determine the vaccination status, their clinical profile and outcomes in children suffering from diphtheria in the post covid era of 21<sup>st</sup> century in a tertiary care centre of developing country. Sharing this work will enhance health care professional knowledge about need of vaccination and help in counseling the parents regarding vaccination. Reporting to health authority will sensitize for planning booster vaccination days for children.

#### **Operational Definitions;**

##### **Clinical Diphtheria case:**

A child will be considered to have clinical diphtheria, if he/she has all of the following;

1. Temperature more than 38 c
2. Have upper respiratory tract infection (pharyngitis, tonsillitis, or laryngitis)
3. Grayish membrane on tonsils, pharynx, nose or larynx assessed by one pediatric consultant and one ENT Consultant

##### **Confirmed Diphtheria case:**

A child will be considered to have confirmed diphtheria, if he/she has all of the following;

1. Temperature more than 38 c
2. Have upper respiratory tract infection (pharyngitis, tonsillitis, or laryngitis)
3. Grayish membrane on tonsils, pharynx, nose or larynx
4. Throat or Nose swab culture shows *Corynebacterium diphtheriae*

## **METHODS**

**Setting;** Department of Pediatrics, MTI/Lady Reading Hospital Peshawar

**Study Design;** Descriptive cross-sectional study

Study Duration: 4 months after study proposal approval

#### **Sample size:**

A total of 39 cases will be studied as calculated from WHO statistics with incidence of 2.6 %, keeping confidence interval of 95% and margin of error of 5%.

#### **Inclusion Criteria;**

All newly diagnosed cases of diphtheria under the age of 15 years as per operational definition.

Both Genders

#### **Exclusion Criteria;**

Children with upper respiratory tract infection with alternative diagnosis will be excluded like;

1. Acute follicular tonsillitis.
2. Viral croup
3. Epiglottitis
4. Retropharyngeal abscess.
5. Previously diagnosed cases of diphtheria and now with complications or other disease

#### **Data Collection and Analysis:**

After approval from hospital ethical committee, data was collected after taking informed consent from parents of patient. Data was recorded in specially prepared proforma for this purpose. Demographic data, vaccination status, clinical features, complication and outcome was recorded. After completion of the data collection, data was analyzed using SPSS, version 24. Quantitative variables like age was calculated as mean and + SD. Frequency and percentages were calculated for categorical variables like gender, vaccination status, clinical profile, treatment received, complications and outcome. Results are presented in tables and charts.

## **RESULTS**

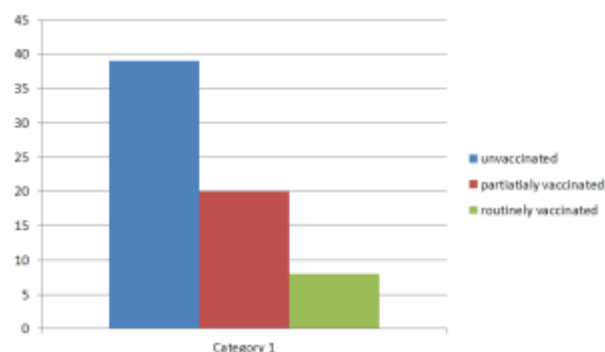
A total of 67 children were included. Of them 40(59.7%) were male and 27(40.3%) were females. Mean age was  $8.80 \pm 3.43$  with range from 2 to 15 years. Out of them 39(58.2%) were unvaccinated, 20(29.9%) were partially vaccinated and 8(11.9%) were routinely vaccinated (Fig 1).

Clinical profile shows 34(50.7%) had mild symptoms at arrival, 23 with bull neck and 10 with serious illness.(Fig 2)

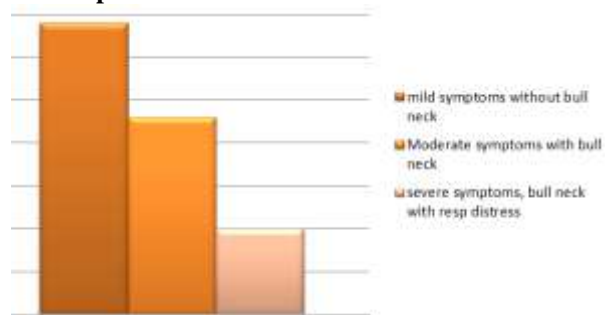
Regarding complications, in 45(67.1%) patients cardiac involvement was present ranging from sinus tachycardia to VT. 08(11.9%) had renal and 05(7.5%) had neurological involvement. 54(80.6%) received ADS and 13(19.4%) couldn't. (table 1)

Outcome was unfortunate (died) in 12(17.9%) patients and successful in 55(82.1%) (discharge well). (table 2)

Area wise distribution is shown in chamber 3, showing patients be referred from all areas of the province. (fig 3)



**Figure No.1: Vaccination status of children suffering from diphtheria**



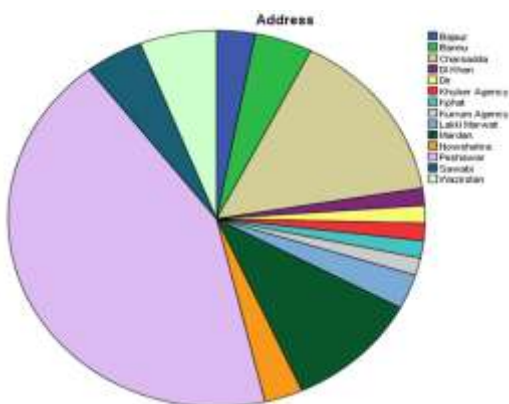
**Figure No.2: Clinical presentation of children with Diphtheria at arrival**

**Table No.1: Complications of diphtheria in children and ADS receiving status**

Feature	Cardiac involvement	Renal Involvement	Neurological involvement	ADS not received
Frequency	45	08	05	13
Percentage	67.1%	11.9%	7.5%	19.4%

**Table No.2: Outcome of children with diphtheria**

Serial No	Outcome	Number of patients	Percentage (%)
1	Recovered	55	80.6
2	Expired	12	19.4
3	Total	67	100



**Figure No.3: Area wise distribution of diphtheria patients**



**Figure No. 4: Picture of a child with tonsillar diphtheria**



**Figure No.5: Rhythm disorder in a child with diphtheria**

## DISCUSSION

Diphtheria, vaccine preventable disease, is reemerging again as is evident by the reports of several authors and World Health Organization's statistics of infectious diseases<sup>13</sup>. Multiple factors are involved in its resurgence but insufficient vaccination and massive migration due to war are the most significant factors. Inadequate vaccination results in not achieving herd immunity and spread of the disease among the community. Similarly war not only affects vaccination status of children in the conflict zone but also spread disease to healthy community through massive migration.<sup>15</sup>

Pakistan is a war hit zone for last 04 decades and remained largest refugees' recipient from Afghanistan since USSR-Afghan war. Even then Pakistan struggled to achieve maximum improvement in health and improve vaccination.<sup>16</sup> To a large part it remain successful and infectious diseases fell significantly as can be seen in WHO statistics available online which shows that diphtheria fall to single digit in 2014 in Pakistan.<sup>13</sup> But the covid-19, financial constraints and the impact of long war inside and in neighborhood, lead to Pakistan of not getting the goals.<sup>13,14</sup>

We have noted last year a rise in diphtheria cases to 351 were reported,<sup>13</sup> and this year (2023), it was much higher. In our study a total of 67 children with diphtheria were included. Of them 40(59.7%) were male and 27(40.3%) were females. Mean age was  $8.80 \pm 3.43$  with range from 2 to 15 years. Out of them

39(58.2%) were unvaccinated, 20(29.9%) were partially vaccinated and 8(11.9%) were routinely vaccinated. 34(50.7%) had mild symptoms at arrival, 23 with bull neck and 10 with serious illness. In 45(67.1%) patients cardiac involvement was present ranging from sinus tachycardia to VT. 08(11.9%) had renal and 05(7.5%) had neurological involvement. 54(80.6%) received ADS and 13(19.4%) couldn't. 12(17.9%) patients unfortunate outcome (died) and 55(82.1%) successfully recovered.

Ray SK et al<sup>17</sup> noted a very poor vaccination status in his study. He found that only 27.4% of patients with diphtheria were fully vaccinated while 44.4% were partially vaccinated and 28.2% were unvaccinated.<sup>18</sup> Our findings were more dreadful as only 8(11.9%) were vaccinated as per WHO EPI schedule while 34(50.7%) were not vaccinated and 20 (29.9%) partially vaccinated. However, Sharma S et al<sup>18</sup> in his study found 59% completely vaccinated, 10% partially vaccinated and 31% unvaccinated, a comparatively better vaccination status compared to our finding. He further found that complications were more common in unvaccinated patients than vaccinated which was statistically significant with P value of < 0.05. However, neurological complications were equal in all patients, irrespective of vaccination status.<sup>18</sup>

The clinical presentation was divided in to three groups; with mild symptoms, with bull neck without airway compromised and with serious disease. Mild symptoms were present at presentation were present in 34(50.7%), 23(34.3%) had bull neck without airway compromised, while 10(14.9%) were received in serious illness. Anjum S et al<sup>19</sup> in their study found that 88.7% had throat pain and cervical lymphadenopathy and 14.7% with typical bull neck, a comparable to our study. Similar clinical presentation findings were reported by Kamath L et al in Karnataka, India<sup>20</sup>.

The common complications noted in our study were cardiac involvement in 45(67.1%) patients, renal in 08(11.9%) and neurological 05(7.5%). Cardiac complications varied in its pattern and were difficult in management. Jamar SK et al reported neurological complications in children with diphtheria as the most common 20.3%, followed by cardiac 17.5% and bronchopneumonia 8.2%.<sup>21</sup> This contrasts to our study where cardiac complications are the commonest. However Ray SK et al reported 53.9% of patient with diphtheria had complications and the commonest was myocarditis, 29.8%, followed by neurological 12% and respiratory 7.1%.<sup>18</sup> They didn't mention renal complications, found in 11.9% of our patients.<sup>17,18,21</sup>

The outcome was not successful in 17.9% of our patients. All patients who had this unsuccessful outcome had cardiac involvement. SN Singh et al reported mortality of 48%, quite higher than our findings; however this could be due to severe disease at presentation and airway complications as mentioned in

work.<sup>22</sup> Boughani S et al reported mortality of 5.4% in his study a quite good than other centers; however his study was based secondary data from government of the same and any short comings may have impact on the results.<sup>23</sup> It is worth mentioning that 19.4% of our patients couldn't receive ADS (Anti Diphtheria Serum), one of the important treatment and preventive modality after vaccination.

## CONCLUSION

- This study shows that Diphtheria has resurged as 67 patients documented in this study from one center is highly alarming.
- Cases reported from all over province signifies the spread of the diphtheria.
- The most effective measure, vaccination, is very poor as majority (88%) of our patients is unvaccinated or partially vaccinated.
- Half of the patients presented with moderate to severe disease.
- Cardiac involvement is the major complication of diphtheria.
- Diphtheria has high mortality despite treating in a tertiary care center. So the primary prevention is the best strategy in combating diphtheria.

### Author's Contribution:

Concept & Design of Study:	Afzal Khan
Drafting:	Lal Muhammad, Rabiya Munir
Data Analysis:	Sajid Ali, Zainab Rahman, Alia Abdulhaq
Revisiting Critically:	Afzal Khan, Lal Muhammad
Final Approval of version:	Afzal Khan

**Conflict of Interest:** The study has no conflict of interest to declare by any author.

**Source of Funding:** None

**Ethical Approval:** No.1028/LRH/MTI dated 27.06.2023

## REFERENCES

1. World Health Organization. WHO laboratory manual for the diagnosis of diphtheria and ther related infections. Geneva: The Organization; 2021.
2. Zakikhany K, Efstratiou A. Diphtheria in Europe: current problems and new challenges. *Future Microbiol* 2012;7:595–607.
3. Clarke KE, MacNeil A, Hadler S, Scott C, Tiwari TS, Cherian T. Global epidemiology of diphtheria, 2000–2017. *Emerging Infectious Diseases* 2019; 25(10):1834.
4. Gampa M, Karna PN, Reddy KV, et al. Study of Diphtheria and Its Complications: A Retrospective

- Study from a Tertiary Care Hospital. *Pediatr Inf Dis* 2021;3(4):140–142.
5. Arian K, Alqunae M, Kara A. Diphtheria in Children. In: Cingi C, Arisoy ES, Bayar Muluk N, editors. *Pediatric ENT Infections*. Springer, Cham 2022. [https://doi.org/10.1007/978-3-030-80691-0\\_63](https://doi.org/10.1007/978-3-030-80691-0_63)
  6. Ahmed A, Singh M, Tank P, Yadav M. Clinico-epidemiological profile and predictors of poor outcome among children during a diphtheria outbreak in Haryana. *Ind Pediatr* 2023;60(4):280-4.
  7. Shuja MH, Shakil F, Imran H, Feroz M. Diphtheria: A novel cause of concern for Pakistan. *J Global Health* 2023;13.
  8. World Health Organization. Diphtheria vaccines: WHO position paper–August 2017. *Wkly Epidemiol Rec* 2017;92:417–436.
  9. Sharma HJ, Parekh S, Pujari P, Shewale S, Desai S, Kawade A, et al. Safety and immunogenicity of an indigenously developed tetanus toxoid, diphtheria toxoid, and acellular pertussis vaccine (Tdap) in adults, adolescents, and children in India. *Expert Review Vaccines* 2023;22(1):278-87.
  10. Nicholson L, Adkins E, Karyanti MR, Ong-Lim A, Shenoy B, Huoi C, et al. What is the true burden of diphtheria, tetanus, pertussis and poliovirus in children aged 3–18 years in Asia? A systematic literature review. *Int J Infectious Diseases* 2022; 117:116-29.
  11. Al-Dar AA, Al-Qassimi M, Ezzadeen FH, et al. Diphtheria resurgence in Sada'a-Yemen, 2017–2020. *BMC Infect Dis* 2022;22:46.
  12. Exavier MM, Hanna MP, Muscadin E, Freishstat RJ, Brisma JP, Canarie MF. Diphtheria in Children in Northern Haiti. *J Tropical Pediatr* 2019;65(2):183–187
  13. World Health Organization. Diphtheria reported cases and incidence. {Available online}accessed on 13 November 2023 from: <https://immunizationdata.who.int/pages/incidence/diphtheria.html?CODE=PA&YEAR=>
  14. Muzzamil M, Naz S, Mumtaz H, Omair W. Pakistan's healthcare preparedness after the NIH warned of a new diphtheria strain and Covid-19 variation. *J Taibah Univ Med Sci* 2023;18(5):1055-1057.
  15. Grundy J, Biggs BA. The impact of conflict on immunisation coverage in 16 countries. *Int J Health Policy Management* 2019;8(4):211.
  16. Habib A. US Army School for Advanced Military Studies Fort Leavenworth United States. Counter narrative: the missing link in Pakistan's counter-terrorism strategy. US Army School for Advanced Military Studies Fort Leavenworth United States 2018 May 24. <https://apps.dtic.mil/sti/pdfs/AD1071087.pdf>
  17. Ray SK, Maji B, Halder A, Baur B. Trend, morbidity profile and immunization status of diphtheria admitted cases: A 5-years review from a sentinel centre in Kolkata. *Ind J Public Health* 2021;65(1):60-3.
  18. Sharma S, Jammam S, Kataria T, et al. An Observational Study on Association of Clinical Outcome of Diphtheria Cases with Immunization Status: A Tertiary Care Hospital, Jaipur. *Indian J Otolaryngol Head Neck Surg* 2022;74 (Suppl 3): 5460–5464.
  19. Anjum S, Bhavani K, Vijayasree L, Krishna A. A cross sectional study on clinical profile and complications associated with diphtheria in Sir Ronald Ross Institute of Tropical and Communicable Diseases, Hyderabad, Telangana State. *Int J Comm Med Public Health* 2022;9(5):1.
  20. Kamath L, Ramitha L, Ratage R V. Diphtheria Remains a Threat to the Health System Even in the Era of Vaccination: A Cross-sectional Observational Study from Karnataka, India. *J Clin Diagnostic Res* 2023;17(2). doi; 10.7860/JCDR/2023/59627.17548
  21. Sharma S, Jammam S, Kataria T, Agarwal S, Gupta A, Pareek Y, et al. An Observational Study on Association of Clinical Outcome of Diphtheria Cases with Immunization Status: A Tertiary Care Hospital, Jaipur. *Ind J Otolaryngol Head Neck Surg* 2021 Jul 27:1-5.
  22. Singh SN, Singh A, Chandra S. Clinical profile and predictors of poor outcome of hospitalized diphtheria cases in children from Lucknow region of North India. *Clin Epidemiol Global Health* 2014;2(2):75-9.
  23. Boghani S, Shah HD, Fancy M, Parmar T, Bansal S, Wanjari MB, et al. A study on the characteristics and outcomes of reported diphtheria patients in a Western state in India. *Cureus* 2023;15(3).

# Low Dose Subcutaneous Adrenaline Pretreatment for Antisnake Venom Adverse Reactions Prevention

Subcutaneous  
Adrenaline  
Pretreatment  
for ASV Adverse  
Reactions

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## ABSTRACT

**Objective:** To compare the frequency of patients who develop acute adverse reactions to antisnake venom after receiving low dose subcutaneous adrenaline with those receiving only placebo.

**Study Design:** Randomized controlled trial study.

**Place and Duration of Study:** This study was conducted at the Department of Medicine, Benazir Bhutto Hospital Rawalpindi from May 2019 to November 2019.

**Methods:** Ethical approval for the study was sought from Institutional Research and Ethics Forum of RMU. After obtaining informed consent, all the patients with systemic envenomation were given 0.25ml of 1:1000 adrenaline (cases) or placebo (control) subcutaneously into forearm immediately before starting ASV infusion. Patients were then monitored for acute adverse reactions. To compare the proportion of acute adverse reactions between two groups Pearson's Chi-square test at 5% level of significance was applied. P-value of <0.05 was considered statistically significant.

**Results:** Total patients in study were 60 which were equally divided into two groups i.e. Placebo and study group. The mean age of the patients was  $35.87 \pm 14.55$  years. The gender distribution showed that 35 (58.3%) patients were from the male gender. Regarding the adverse reactions, 21 (35%) patients developed the acute reactions. There was significant difference among groups in terms of adverse reaction (05 (16.67%) in adrenaline group versus 16 (53.33%) in placebo group, p value was 0.003).

**Conclusion:** The risk of adverse reactions due to asv is lower in group in which the low dose subcutaneous adrenaline was used as compared to placebo group. The data should be verified on larger scale study.

**Key Words:** Adolescent, adverse effects, Double-Blind Method, Epinephrine, Humans, Middle Aged, Prospective Studies, Snake Bites

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## INTRODUCTION

Of 3000 snake species in world, 600 are venomous resulting in 2 million snake bite envenomation and 100,000 deaths per year.<sup>1</sup> In Pakistan there are 20,000 deaths per year.<sup>2</sup> Snakebite is a major health problem in the rural tropics.<sup>3</sup> Snake venom have an array of enzymes, proteins and toxins.<sup>4</sup>

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Highly venomous snake bite can cause necrosis around bite site, widespread bleeding, irreversible kidney damage and muscle paralysis.<sup>1</sup>

For snake bite envenomation, antisnake venom (ASV), is the mainstay of treatment.<sup>5</sup> ASV is mixture of antibodies, derived from animals mostly horses and sheep that effectively neutralize toxins which cause coagulopathy, hemorrhage and hemodynamic disturbances.<sup>1</sup> According to WHO adverse reactions to ASV are classified as early reactions occurring within first hour of ASV infusion and late reactions occurring between 5-20 days after treatment.<sup>6</sup> Antivenom commonly cause acute adverse reactions, which are mostly due to type 1 hypersensitivity complement activation and immunoglobulin aggregate including Fc.<sup>4</sup>

Reactions due to ASV in patient with snake bite cause considerable challenge to clinicians.<sup>1</sup> Most reactions are mild resulting in nausea, vomiting, headache, urticaria, fever but systemic anaphylaxis occurs in 40% of cases which is potentially fatal resulting in hypotension, cyanosis and altered level of consciousness.<sup>7</sup>



Anaphylaxis is severe, generalized hypersensitivity reaction which is rapid in onset and can cause death.<sup>8</sup> For prevention of acute adverse reactions pretreatment with hydrocortisone, antihistamine and adrenaline was done previously.

In anaphylaxis treatment adrenaline is drug of choice but there is no clear uniform policy for adrenaline pretreatment for prevention of acute adverse reaction to ASV.<sup>9</sup> In retrospective analysis conducted in Australia for pretreatment with adrenaline, antihistamines and steroids found to decrease adverse reactions to ASV from 12.5% to 3%. But the study did not differentiate between individual drug effect study conducted in Sri Lanka showed 11% patients developed acute adverse reactions when received adrenaline pretreatment as compared to 43% patients who did not received adrenaline pretreatment.<sup>9</sup>

Snake bite envenomation tends to be major health problem in Pakistan. No study has been conducted locally to assess efficacy of adrenaline pretreatment in preventing ASV acute side effects. The rationale of this study is to increase safety of treatment with ASV in snake bite patients with low dose subcutaneous adrenaline premedication. The results of this study will be helpful to treating physician in modifying current treatment practice as there was previously unclarity on pretreatment and will reduce the mortality due to fatal acute adverse reactions. Main objective was this research is to compare the frequency of patients who develop acute adverse reactions to antsnake venom after receiving low dose subcutaneous adrenaline with those receiving only placebo.

## METHODS

A randomized controlled trial was conducted at department of medicine, Benazir Bhutto Hospital for the assessment of adverse effects of antsnake venom after receiving low dose subcutaneous adrenaline and placebo after obtaining ethical approval (R-14/RMU) from institutional review board of Rawalpindi Medical University from May 2019 to November 2019. A total of 60 patients were recruited by using non-random consecutive sampling with age range of 12 to 70 years; all patients were those who required anti snake venom after snake bite. Sample size was calculated by

considering population proportion of acute adverse effects in adrenaline group = 0.1101 Population proportion of acute adverse effects in placebo group = 0.43<sup>9</sup> with power of test at 80% level of significance at 5 % and total sample size of 60 was calculated and were grouped into two groups accordingly. Pregnant females or those who have already received any treatment before admission or have any ischemic disease were excluded from the study.

After obtaining informed consent, all the patients with systemic envenomation were given 0.25ml of 1:1000 adrenaline (cases) or placebo(control) subcutaneously into forearm immediately before starting ASV infusion. Patients were then monitored for acute adverse reactions. Blood pressure and pulse were checked every 15 minutes during infusion and 1 hour after end of infusion. If acute adverse reaction occurred, ASV was stopped and 0.5ml of 1:1000 adrenaline was given intramuscularly along with 200mg IV hydrocortisone and 25mg IV promethazine. Patients were followed till discharge. All the data was recorded on a specially designed Performa.

**Statistical Analysis:** Data was entered and analyzed using the Statistical Package for Social Sciences (SPSS version 21). All the categorical variables like gender, B.P, pulse, acute adverse reactions were described as frequencies and percentages, while for continuous variable like age, the mean along with standard deviation was calculated. To compare the proportion of acute adverse reactions between two groups Pearson's Chi-square test at 5% level of significance was applied. P-value of <0.05 was considered statistically significant. To control any effect modifier e.g. age, gender stratified Chi-square test was also applied.

## RESULTS

The total patients in my study were 60 which were equally divided into two groups i.e. placebo and study group. The mean age of the patients was  $35.87 \pm 14.55$  years. The age group was divided into two groups which were later on used for the stratification purposes. The distribution is given below in the graph. There was no significant difference among groups in terms of age distribution as p value was 0.174.

**Table No.1: Assessment of Gender, Heart rate Blood Pressure and Adverse Reaction in Study Groups.**

Parameter		Group		P-value <sup>1</sup>
		Adrenaline	Placebo	
Gender	Male	16 (53.33%)	19 (63.33%)	0.432
	Female	14 (46.67%)	11 (36.67%)	
Pulse	Bradycardia	16 (53.33%)	18 (60%)	0.602
	Tachycardia	14 (46.67%)	12 (40%)	
BP	Hypotension	12 (40%)	14 (46.67%)	0.602
	No	25 (83.33%)	14 (46.67%)	

**Table No.2: Comparison of Adverse Reactions in Study Groups based on Age and Gender.**

Parameter		Reaction	Group		P value <sup>2</sup>
			Adrenaline	Placebo	
Age	<40 years	Yes	03 (16.67%)	11 (61.11%)	0.002
		No	18 (85.71%)	07 (38.89%)	
	>40 years	Yes	02 (22.22%)	05 (41.67%)	0.350
		No	07 (77.78%)	07 (58.33%)	
Gender	Male	Yes	04 (25%)	12 (63.15%)	0.024
		No	12 (75%)	07 (36.84%)	
	Female	Yes	01 (7.14%)	07 (38.89%)	0.070
		No	13 (92.85%)	11 (61.11%)	

The gender distribution showed that 35 (58.3%) patients were from the male gender. Regarding the adverse reactions, 21 (35%) patients developed the acute reactions. Out of 60 patients, 34 (56.7%) showed bradycardia during BP monitoring while 26 (43.3%) showed hypotension. There was no difference between groups in terms of gender, pulse and BP distribution as p values were 0.432, 0.602 and 0.0602 respectively. There was significant difference among groups in terms of adverse reaction (05 (16.67%) in adrenaline group versus 16 (53.33%) in placebo group, p value was 0.003) as explained in table 1. The data was stratified according to age and gender. The results showed that the results were specific only for male gender and age group <40 years (p value 0.024 and 0.002 respectively) as explained in table 2.

## DISCUSSION

The anaphylactic reactions are one of the most common encountered problems in emergency departments. The reaction is more pronounced and anticipated when some antisera is injected. The conditions like snake bites in which the benefits overweight risks are very tricky to deal with.<sup>11</sup> The management of snake bite is always involves the use of antisnake venom (ASV). The ASV may be generic or specie specific but is always associated with a wide range of adverse reactions.<sup>12</sup> The immune response to ASV involves the complement activation, cytokine production and mast cell degranulation.<sup>13</sup>

The adverse reactions can be classified into two major categories i.e. early and late. The major concern in emergency medicine is the early reactions.<sup>6</sup> To combat adverse reactions the use of adrenaline, hydrocortisone and promethazine is used during the active surveillance. The pretreatment with these medications involving low dose adrenaline is one the best remedy to prevent adverse reactions of ASV. These facts are very important in the areas of high incidence of snake bites and risks of more adverse reactions.<sup>14</sup>

The minor to moderate reactions to antivenoms are common and some of them reach up to severity. There are many studies which show that the acute adverse reactions can be reduced by the pre medications. A

study reported in a study that the antivenoms in Australia has low risk of reactions only due to the fact that pre medications play a major role in this regard. He concluded that antivenoms in Australia are well tolerated with few adverse reactions. The use of premedication like antiallergics, adrenaline and oral steroids can reduce the reaction rate.<sup>15</sup>

In a study by Premawardhena, A. P., et al. the results showed that out of 56 cases who received adrenaline the acute adverse reactions were visible in 06 (11%) patients. The placebo group which contained 49 patients has 21 (43%) reactions rate (P=0.0002).<sup>16</sup> In my study the 05 (16.6%) and 16 (53.3%) patients showed the reaction in adrenaline and placebo groups respectively (p value 0.003). A study by de Silva et al showed that when adrenaline was compared with placebo, it reduces the reactions by 43% (95% CI 25-67) at 1 h and by 38% (95% CI 26-49) up to and including 48 h after ASV administration.<sup>17</sup>

In my study the data was stratified according to age and gender. The results showed that the results were specific only for male gender and age group <40 years (p value 0.024 and 0.002 respectively)

## CONCLUSION

The risk of adverse reactions due to ASV is lower in group in which the low dose subcutaneous adrenaline was used as compared to placebo group. The data should be verified on larger scale study.

### Author's Contribution:

Concept & Design of Study:	Seemab Abid
Drafting:	Qurat ul Ain Abid, Iram Shad
Data Analysis:	Arifa Batool, Muhammad Sabbih ul Hassan, Hasan Zahid
Revisiting Critically:	Seemab Abid, Qurat ul Ain Abid
Final Approval of version:	Seemab Abid

**Conflict of Interest:** The study has no conflict of interest to declare by any author.

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**Ethical Approval:** No.R-14/RMU dated 21.04.2018.

## REFERENCES

1. McGhee S, Finnegan A, Clochesy JM, Visovsky C. Effects of snake envenomation: a guide for emergency nurses. *Emerg Nurse* 2015;22(9):24-9.
2. Isbister GK, Jayamanne S, Mohamed F, Dawson AH, Maduwage K, Gawarammana I, et al. A randomized controlled trial of fresh frozen plasma for coagulopathy in Russell's viper (*Daboia russelii*) envenoming. *J Thromb Haemost* 2017; 15(4):645-54.
3. Stone SF, Isbister GK, Shahmy S, Mohamed F, Abeysinghe C, Karunathilake H, et al. Immune response to snake envenoming and treatment with antivenom; complement activation, cytokine production and mast cell degranulation. *PLoS Negl Trop Dis* 2013;7(7):e2326.
4. de Silva HA, Ryan NM, de Silva HJ. Adverse reactions to snake antivenom, and their prevention and treatment. *Br J Clin Pharmacol* 2016;81(3): 446-52.
5. Leon G, Herrera M, Segura A, Villalta M, Vargas M, Gutierrez JM. Pathogenic mechanisms underlying adverse reactions induced by intravenous administration of snake antivenoms. *Toxicon* 2013;76:63-76.
6. Sampson HA, Munoz-Furlong A, Campbell RL, Adkinson NF, Bock SA, Branum A, et al. Second symposium on the definition and management of anaphylaxis: summary report--Second National Institute of Allergy and Infectious Disease/Food Allergy and Anaphylaxis Network symposium. *J Allergy Clin Immunol* 2006;117(2):391-7.
7. Sicherer SH, Simons FER, Section On A, Immunology. Epinephrine for First-aid Management of Anaphylaxis. *Pediatr* 2017; 139(3):e20164006.
8. de Silva HA, Pathmeswaran A, Ranasinha CD, Jayamanne S, Samarakoon SB, Hittharage A, et al. Low-dose adrenaline, promethazine, and hydrocortisone in the prevention of acute adverse reactions to antivenom following snakebite: a randomised, double-blind, placebo-controlled trial. *PLoS Med* 2011;8(5):e1000435.
9. Isbister GK. Antivenom efficacy or effectiveness: the Australian experience. *Toxicol* 2010; 268(3):148-54.
10. Daley BJ, Torres J. Venomous snakebites. *JEMS* 2014;39(6):58-62.
11. Senthilkumaran S, Menezes RG, Pant S, Thirumalaikolundusubramanian P. Acute acalculous cholecystitis: a rare complication of snake bite. *Wilderness Environ Med* 2013;24(3): 277-9.
12. Sundaraperumal R, Mohanasundaram K, Kumarasamy S. Acute coronary syndrome following snake bite: a report of three cases from a tertiary care hospital in rural southern India. *Trop Doct* 2012;42(3):171-3.
13. Satish R, Kanchan R, Yashawant R, Ashish D, Kedar R. Acute MI in a stented patient following snake bite-possibility of stent thrombosis - a case report. *Ind Heart J* 2013;65(3):327-30.
14. Kumar PK, Ahuja S, Kumar PS. Bilateral acute anterior uveitis and optic disc edema following a snake bite. *Korean J Ophthalmol* 2014;28(2): 186-8.
15. Deepak M, Basavaprabhu A, Ramapuram JT, Nithyananda C, Mahalingam S. Bilateral parotid enlargement following snake bite: a rare sign. *Asian Pac J Trop Biomed* 2013;3(2):154-5.
16. Wall C. British Military snake-bite guidelines: pressure immobilisation. *J R Army Med Corps* 2012;158(3):194-8.
17. Vithanage KK, Thirumavalavan K. A case of a sea snake bite resulting in fatal envenoming. *Ceylon Med J* 2012;57(4):174-5.

# Prevalence and Risk Factors of Anemia in Chronic Kidney Disease Patients with Diabetes: A Cross-Sectional Study

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Muhammad Umair Afzal<sup>1</sup> and Muhammad Asad Raza<sup>3</sup>

## ABSTRACT

**Objective:** To assess the prevalence of anemia inpatients of chronic kidney disease patients secondary to diabetes.

**Study Design:** A Cross-Sectional Study

**Place and Duration of Study:** This study was conducted at the Department of Nephrology and Hemodialysis, Central Park Teaching Hospital, Lahore from December 2022 to May 2023.

**Methods:** Non-random convenient sampling technique was employed and patients with age of 18 to 64 who are diagnosed cases of CKD stage 3 or above with GFR < 60 ml/min/1.73 m<sup>2</sup> were recruited in the study. Post stratification chi-square test was applied and p-values < 0.05 was considered statistically significant.

**Results:** A total of 323 patients were recruited with the mean age of 42.76 ± 11.54 years with age range of 21 to 60 years. Anemia was assessed in all the study participants; it showed the prevalence of anemia in chronic kidney diseased patients secondary to diabetes was noted as 31.3% showing that 101 patients out of 312 had anemia. Females are more prone to develop anemia in diabetic chronic kidney diseased patients when compared to males with p value of 0.039.

**Conclusion:** Customized therapy and individualized interventions can be designed that are in tune with the causes of anemia in this category of patient thus enhancing clinical outcomes.

**Key Words:** Chronic Kidney Disease; Diabetes; Anemia

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## INTRODUCTION

A major fraction of the clinical and intricate nature of the uremic syndrome with regards to the treatment of CKD is mostly but not eventually derived from anemia, a significant consequence of CKD<sup>1</sup>. This condition is a very common hematological illness within the general population with prevalence estimated at 7.6%, which is compatible with serum hemoglobin levels below 130 g/L for males and 120 g/L women. However those with renal disease has a much higher prevalence reaching 15%. As eGFR and hemoglobin serum level are subject to virtually linear connection, anemia is usually associated with the degree of the renal worthlessness<sup>2,3</sup>.

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Patients with Chronic Kidney Disease Stage 3 Anemia is noticeably common, rising from 5% in CKD Stage 1 to about 75% to 80% in Pre Dialysis Stage CKD<sup>4,5</sup>. As for the kidney, decrease of erythropoietin secretion is the first mechanism that leads to anemia in the chronic kidney diseases<sup>6</sup>. Furthermore, anemia might be caused by lowered iron or unavailability of iron due to higher hepcidin levels caused by the localized inflammation in the chronic uremia is responsible for the occurrence<sup>7</sup>. In addition, different factors such as malnutrition and each state of chronic inflammation can bring about a decrease in folates and vitamin B12 and an increase in the reticules formation (erythroblasts) and immature cells death<sup>6</sup>. Anemia has been traced to some poor quality life, more hospital admissions, renal disease progression, as well as high mortality rate apart from comparative CKD patients<sup>8</sup>. DM has been identified as the primary cause of CKD and ESRD; what's more, DM is also thought to be associated with renal development, even without renal impairment.

About 10% of DM patients with normal renal function have been reported to have anemia<sup>9</sup>. Hemoglobin levels in a population of almost 9000 people without renal impairment were independently influenced by diabetes<sup>10</sup>. Numerous factors have been proposed as contributing to the pathogenesis of anemia in these patients, including the use of renin-angiotensin-aldosterone system (RAAS) blockers, which are

essential in the treatment of proteinuric diabetic nephropathy, erythropoietin deficiency caused by efferent sympathetic denervation of the kidney in the context of diabetic neuropathy, and chronic inflammatory reaction leading to functional iron deficiency. Anemia may be more prevalent and manifest at an earlier stage of chronic kidney disease (CKD) in individuals with diabetes<sup>11</sup>. On this context, the aim of this study was to examine in comparison the prevalence of anemia in matched CKD patients with DM and not on dialysis.

## METHODS

A descriptive cross-sectional study was conducted at department of nephrology and hemodialysis central park teaching hospital for the assessment of anemia at various levels of diabetic non-dialysis dependent patients from December 2022 to May 2023 after obtaining ethical approval from institutional review board of Central Park Medical College and Teaching Hospital (CPMC/IRB-No/2238). Sample size of 323 was calculated by using WHO sample size calculator with confidence interval of 95 percent and anticipated population proportion of 30 percent<sup>12</sup>. Non-random convenient sampling technique was employed and patients with age of 18 to 64 who are diagnosed cases of CKD stage 3 or above with GFR < 60 ml/min/1.73m<sup>2</sup> were recruited in the study. While patients undergoing kidney transplant, and have anemia due metabolic and other causes like carcinomas were excluded from the study.

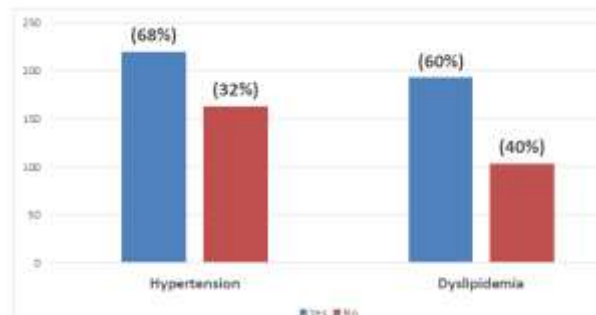
After obtaining written informed consent, detailed demographic information like gender, age, height, weight, BMI background were recorded. Body-mass index was calculated through dividing the weight with the height squared; it was considered to be a risk factor for hypertension, hyperlipidemia, diabetes mellitus, and coronary artery disease. A 3cc venous blood was also collected in EDTA/clot vials for the assessment of blood glucose, serum urea and creatinine levels and were immediately centrifuged at 4000 rpm for 30 minutes and serum was separated and parameters were assessed using commercially available ELISA kits.

**Statistical analysis:** Statistical analysis was performed with Statistical Package for Social Sciences 26.0 (SPSS Inc, Chicago, IL). Continuous variables like age were presented as mean  $\pm$  1 SD and categorical variables like gender, HTN, dyslipidemia etc. were described as number or percentage (*n*, %). Data was stratified for age, gender, duration of DM, Stage of CKD (3-5), HTN, Dyslipidemia. Post stratification chi-square test was applied and p-values < 0.05 was considered statistically significant.

## RESULTS

A total of 323 patients were recruited with the mean age of  $42.76 \pm 11.54$  years with age range of 21 to 60 years.

On the assessment of gender, 46 percent (*n*=149) were males and rest of 54% (*n*=174) were females. Body mass index (BMI) was assessed it was to be  $24.76 \pm 3.07$  kg/m<sup>2</sup> and mean duration of diabetes was also assessed which turned out to be  $9.01 \pm 5.96$  years. Frequency of hypertension was also assessed; it showed 68 percent (*n*=220) were hypertensive as well while rest 32% (*n*=103) were non-hypertensive as explained in figure 1. All the patients were also screened for dyslipidemias and it showed 60% of study population (*n*=193) were having dyslipidemia while rest 40 percent (*n*=130) were not having any dyslipidemia as explained in figure 1.



**Figure No.1: Assessment of Frequency of Hypertension and Dyslipidemia in Study Population.**

Age stratification was done for the assessment of age as risk factor in the development of anemia in diabetic chronic kidney disease patients and it showed only 49 out of 101 below 40 years of age developed anemia while 93 out of 222 developed anemia showing no impact of age in development of anemia in patients of diabetic CKD with p value of 0.266. Similarly gender stratification was done for the assessment of gender as risk factor in development of anemia in study population as explained in table 1. It showed that females are more prone to develop anemia in diabetic chronic kidney diseased patients when compared to males with p value of 0.039 as explained in table 1.

**Table No.1: Assessment of Anemia in Study Population based on Gender.**

Presence of Anemia	Male	Female	Total	p-value
Yes	38	63	101	0.039*
No	111	111	222	
Total	149	174	323	

Anemia was assessed in all the study participants; it showed the prevalence of anemia in chronic kidney disease patients secondary to diabetes was noted as 31.3% showing that 101 patients out of 312 had anemia. Impact of duration of diabetes was assessed using chi-square test by setting the cut off at 5 years as explained in table 2. Surprisingly it was noted that duration of diabetes has no association with anemia in chronic kidney disease patients secondary to diabetes as narrated in table 2 with p-value of 0.473.

**Table No.2: Application of Chi-square test on Anemia with Duration of Diabetes Stratification.**

Presence of Anemia	<5 years	>5 years	Total	p-value
Yes	25	76	101	0.473
No	47	175	222	
Total	72	251	323	

Chi-square was employed for the assessment of body mass index as effect modifier on the anemia in study population; out of 101 anemia patients, 55 were having normal BMI for south Asians while 46 with higher BMI had anemia which showed insignificant association of anemia with BMI with p value of 0.117. Hypertension was also assessed as effect modifier in presence of anemia it was noted that 73 out of 101 patients were hypertensive which showed a positive association with anemia with p value of 0.021 as explained in table 3. Dyslipidemias were also assessed for anemia and it was noted that no association was observed between dyslipidemias and anemia in patients of chronic kidney disease secondary to diabetes with p-value of 0.190.

**Table No.3: Application of Chi-square test on Anemia with presence of Hypertension Stratification**

Presence of Anemia	Yes	No	Total	p-value
Yes	73	28	101	0.021*
No	147	84	222	
Total	220	130	323	

## DISCUSSION

The purpose of the discussed study was to investigate the incidence of anemia in CKD patients of diabetes who do not depend on dialysis. Anemia is a widespread of the blood disorder common in CKD patients, and it is very important in the development of the disease. The analysis indicated that anemia was manifested in 31 percent while scanning 100% of the target population, this stand will emphasize that the disease weight in this group is enormous.

This finding is the same as the outcomes of other studies that showed the fact that the anaemia is highly prevalent in the CKD subjects, especially, the diabetic ones. Our findings concur with what has been previously reported: the anemia-Chronic Kidney Disease-Diabetes association is rather complex. The relationship between diabetes and anemia was shown in a number of investigations to be broad among etiologies in the diabetic kidney disease, among which are impaired erythropoiesis, erythropoietin deficiency, functional iron deficiency as well as chronic inflammatory processes<sup>13,14</sup>.

Surprisingly, the difference in distribution was in favour of females so that anemia could be more common in female diabetic CKD patients than in their male counterparts. This observation reports possible

gender-specific differences in the pathogenesis or the management of anemia in this group leading further investigation later on. Nevertheless, it should be noted that both genetic and societal factors result in women having more risks for anemia than men, further research is required to study hormonal variations and nutritional status that also influence the prevalence of anemia<sup>15</sup>.

So our study did not lead to better understanding of the relation between the time of diabetes duration and the emergence of anemia among CKD patients. On the contrary, the emergence of anemia is found to be less connected to the progression of diabetes duration which stands in accordance with some previous research that anemia prevalence increase with length of diabetes. However, mainly this no association in our study may be an indicator of a very complex interconnecting situation of different elements what lead to onset of anemia in diabetic CKD not related to diabetes duration only<sup>16,17</sup>.

BMI (body mass index) and comorbidities such as hypertension (high blood pressure) were therefore considered as possible effect modifiers for anemia. Although we have not observed a significant association between BMI and anemia, however, hypertension was seen to be associated with the presence of anemia positively<sup>18,19</sup>. This underlines the need for the inclusion of comorbidities and in the management of anemia in CKD patients especially patients with diabetes.

Besides that, the lack of a strong correlation between anemia and dyslipidemia in individuals in our study population reveals that dyslipidemia might not be the main reason for anemia in diabetic CKD patients. Nevertheless, in-depth studies should be conducted towards identifying and understanding whether dyslipidemia has a role in anemia development in this group of patients<sup>20</sup>.

On the whole, this survey is a substantial stepping stone towards an ever-expanding research field about the incidence and risk factors of anemia in non-dialysis dependents with diabetic CKD. The elucidation of the fundamental mechanisms and risk factors of anemia in this population would be crucial for the personalization of care of patients, as well as the development of some targeted interventions which would aim at the mitigation of the impact of anemia and the improvement of the clinical outcomes. Also, more longitudinal studies with large sample sizes and comprehensive analyses of potential confounders are required to validate our findings and to reveal the complicated mechanism of the development of anemia in patients with diabetic CKD.

## CONCLUSION

In the end, our study illuminates the prevalence of anemia in non-dialysis patients with DM-CKD. Another CKD complication is anemia and our findings

present a huge implication of this disease among this population. Customized therapy and individualized interventions can be designed that are in tune with the causes of anemia in this category of patient thus enhancing clinical outcomes.

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## REFERENCES

- Joshi R, Subedi P, Yadav GK, Khadka S, Rijal T, Amgain K, et al. Prevalence and risk factors of chronic kidney disease among patients with type 2 diabetes mellitus at a tertiary care hospital in Nepal: a cross-sectional study. *BMJ Open* 2023; 13(2):e067238.
- Meremo A, Paget G, Duarte R, Dickens C, Dix-Peek T, Bintabara D. Demographic and clinical profile of black patients with chronic kidney disease attending a tertiary hospital in Johannesburg, South Africa. *PLoS One* 2022;17(9):e0266155.
- Poudyal A, Karki KB, Shrestha N, Aryal KK, Mahato NK, Bista B. Prevalence and risk factors associated with chronic kidney disease in Nepal: evidence from a nationally representative population-based cross-sectional study. *BMJ Open* 2022;12(3):e057509.
- Siddiqui K, George TP, Joy SS, Alfadda AA. Risk factors of chronic kidney disease among type 2 diabetic patients with longer duration of diabetes. *Front Endocrinol (Lausanne)* 2022;13:1079725.
- Thomas MC, Cooper ME, Zimmet P. Changing epidemiology of type 2 diabetes mellitus and associated chronic kidney disease. *Nat Rev Nephrol* 2016;12(2):73-81.
- Idris I, Tohid H, Muhammad NA, A Rashid MR, Mohd Ahad A, Ali N, et al. Anaemia among primary care patients with type 2 diabetes mellitus (T2DM) and chronic kidney disease (CKD): a multicentred cross-sectional study. *BMJ Open* 2018;8(12):e025125.
- Nazzal Z, Hamdan Z, Masri D, Abu-Kaf O, Hamad M. Prevalence and risk factors of chronic kidney disease among Palestinian type 2 diabetic patients: a cross-sectional study. *BMC Nephrol* 2020; 21(1):484.
- Damtie S, Biadgo B, Baynes HW, Ambachew S, Melak T, Asmelash D, et al. Chronic Kidney Disease and Associated Risk Factors Assessment among Diabetes Mellitus Patients at A Tertiary Hospital, Northwest Ethiopia. *Ethiop J Health Sci* 2018;28(6):691-700.
- Casales-Hernández MG, Reyes-Morales H, Nigenda G, García-Saisó S. Exploración de facilitadores y barreras para implementar los roles ampliados de enfermería en México [Exploring facilitators and barriers to implementing expanded nursing roles in Mexico]. *Estudo de facilitadores e barreiras para a implementação de funções ampliadas de enfermagem no México*. *Rev Panam Salud Publica* 2023;47:e142. Spanish. doi: 10.26633/RPSP.2023.142.
- Sun Y, Hong L, Huang Z, Wang L, Xiong Y, Zong S. Fibrosis Risk in Nonalcoholic Fatty Liver Disease Is Related to Chronic Kidney Disease in Older Type 2 Diabetes Patients. *J Clin Endocrinol Metab* 2022;107(9):e3661-e3669.
- Babua C, Kalyesubula R, Okello E, Kakande B, Sebatia E, Mungoma M, et al. Cardiovascular risk factors among patients with chronic kidney disease attending a tertiary hospital in Uganda. *Cardiovasc J Afr* 2015;26(4):177-80.
- Sun X, He J, Ji XL, Zhao YM, Lou HY, Song XX. Association of Chronic Kidney Disease with Coronary Heart Disease and Stroke Risks in Patients with Type 2 Diabetes Mellitus: An Observational Cross-sectional Study in Hangzhou, China. *Chin Med J (Engl)* 2017;130(1):57-63.
- Martínez Candela J, Sangrós González J, García Soidán FJ, Millaruelo Trillo JM, Díez Espino J, Bordonaba Bosque D. en representación del Grupo de Atención Primaria y Prediabetes de la Sociedad Española de Diabetes. Chronic renal disease in Spain: prevalence and related factors in persons with diabetes mellitus older than 64 years. *Nefrologia (Engl ed)* 2018;38(4):401-413.
- Low SK, Sum CF, Yeoh LY, Tavintharan S, Ng XW. Prevalence of Chronic Kidney Disease in Adults with Type 2 Diabetes Mellitus. *Ann Acad Med Singap* 2015;44(5):164-71.
- Ponte B, Pruijm M, Marques-Vidal P, Martin PY, Burnier M, Paccaud F. Determinants and burden of chronic kidney disease in the population-based CoLaus study: a cross-sectional analysis. *Nephrol Dial Transplant* 2013;28(9):2329-39.
- Valdez Ortiz R, Escorza-Valdivia S, Benitez-Renteria S, Lopez-Alvarenga JC, Pérez-Navarro LM. Factors of Poor Prognosis Associated with

- Chronic Kidney Disease by Stage in Ambulatory Patients: A Cross-sectional Study. *Arch Med Res* 2022;53(5):524-532.
17. Kumela Goro K, Desalegn Wolide A, Kerga Dibaba F, Gashe Fufa F, Wakjira Garedow A, Edilu Tufa B. Patient Awareness, Prevalence, and Risk Factors of Chronic Kidney Disease among Diabetes Mellitus and Hypertensive Patients at Jimma University Medical Center, Ethiopia. *Biomed Res Int* 2019;2019:2383508.
  18. Tannor EK, Sarfo FS, Mobula LM, Sarfo-Kantanka O, Adu-Gyamfi R, Plange-Rhule J. Prevalence and predictors of chronic kidney disease among Ghanaian patients with hypertension and diabetes mellitus: A multicenter cross-sectional study. *J Clin Hypertens (Greenwich)* 2019;21(10):1542-1550.
  19. Otieno FCF, Ogola EN, Kimando MW, Mutai K. The burden of unrecognised chronic kidney disease in patients with type 2 diabetes at a county hospital clinic in Kenya: implications to care and need for screening. *BMC Nephrol* 2020;21(1):73.
  20. Junaid OA, Ojo OA, Adejumo OA, Junaid FM, Owolade SS, Ojo OE, et al. Prevalence of cardiovascular risk factors and their association with renal impairment in elderly patients with type 2 diabetes mellitus in a Nigerian tertiary hospital: a cross-sectional study. *Pan Afr Med J* 2022;42:233.



# Efficacy of Plantar Glabrous Skin Grafts for Release of Post Burn Contractures of Hand

Plantar Glabrous  
Skin Grafts for  
Post Burn  
Contractures

Syed Mohammad Haider, Amir Taimur Khan, Hamza Khan Shahbazi and Sadaf Imran

## ABSTRACT

**Objective:** This study examines the efficacy of plantar glabrous skin grafts for treating hand and finger contractures resulting from burns.

**Study Design:** A cross-sectional analysis study.

**Place and Duration of Study:** This study was conducted at the Department of Plastic Surgery & Burns Unit at Khyber Teaching Hospital in Peshawar, Pakistan from January 2022 to January 2023.

**Methods:** Seventy patients aged five to seventy years diagnosed with post-burn palmar contractures were included. hairless glabrous skin harvested from plantar surfaces was used to cover defects after contraction release.

**Results:** Among patients, twenty-six (37.14%) had both palmar and finger contractures, twelve (17.14%) only had finger contractures, and thirty-two (45.71%) solely had palmar contractures. The skin grafts were harvested using a dermatome set between 20–26/1000 of an inch. Dressings were changed six days post-procedure, and patients were followed for ninety days. Successful graft uptake was observed in sixty-six (94.29%) patients. Functional outcomes, assessed via the Vancouver Scar Scale, were rated as good in twenty-three (32.86%) cases, adequate in thirteen (18.57%) cases, poor in four (5.71%) cases, and exceptional in thirty (42.86%) cases.

**Conclusion:** Hairless skin grafts not only demonstrate high survival rates comparable to full-thickness skin grafts but also offer superior aesthetic outcomes in treating burn-induced palmar and finger contractures

**Key Words:** Glabrous skin grafts, Burn contracture treatment, Palmer and finger, Aesthetic outcomes evaluation

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## INTRODUCTION

Burn injuries to the hands and fingers are particularly debilitating due to their impact on function and aesthetics. Following severe burns, contractures often develop as a result of the natural wound healing process, leading to significant functional impairment and disfigurement<sup>1</sup>. The treatment of burn-induced contractures, especially in the palmar region, remains a challenge for reconstructive surgeons (Smith et al., 2018)<sup>2</sup>. Glabrous skin, which is hairless glabrous and found on the palms of hands and soles of feet, is structurally and functionally different from hairy skin. The thick, densely innervated skin of the palm has evolved to withstand substantial tactile demands<sup>3,4</sup>. Traditionally, surgeons have employed various grafting methods to rehabilitate contracted hands, each approach proffering benefits while harboring drawbacks.

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Thinner skin grafts facilitated swifter harvesting and healing yet lacked the resilience and pigmentation of thicker grafts<sup>5</sup>. Their implantation obtained full-thickness grafts, thus long-lasting in their fulfillment. However, complications came with it<sup>6</sup>. Now this technique might be challenged in the light of new findings. Perhaps we should consider skin nourished by feet Securing and tending to these transplants presents technical challenges, yet their intrinsic attributes potentially yield better practical and aesthetic consequences<sup>7</sup>. Like the host local language and in local texture, these portions of graft material stood in his colors also for they recontoured. Just see how the local complexion has been preserved by even a piece a really in the patients investigated after the burns, we have as yet no concrete evidence on efficiency or other effects from this type of operation for reconstructive purposes<sup>8</sup>. No large sample with such data has yet been published<sup>9</sup>. The present study would fill that gap in knowledge, tallying their endurance and practical outputs against patient acceptance. It will also try to set such results alongside earlier examinations of more established methods, to determine whether foot-fed folds should be given higher priority in appropriate groups.

## METHODS

Our study examined the results of 70 patients who underwent operations to address hand contractures

caused by burns at Khyber Teaching Hospital between January 2022 and January 2023. Individuals varying in age from five to seventy years were chosen for the investigation dependent on diagnoses involving contracted palmar and digital regions subsequent to experiencing burns. The complex surgeries focused on restoring range of motion to the hand while lengthening and separating contracted fingers and skin grafts were employed to cover wounds. Younger subjects tended to regain functionality more readily than older patients with longer-standing contractures.. Plantar skin was harvested from each patient's soles using a dermatome adjusted between twenty and twenty-six thousandths of an inch to ensure uniform graft thickness. After contracture release, the grafts were applied to the prepared sites. Postoperative dressings were changed six days later. Graft survival and functional results were assessed over ninety days using the Vancouver Scar Scale to rate aesthetic appearance and range of motion. This systematic investigation sought to appraise the efficacy of plantar skin grafting for post-burn contractures in a regulated clinical setting.

**Data Collection:** Data was collected using patient medical records and direct assessments. This included details of burn history, extent of contractures, graft uptake, and functional outcomes measured at 30, 60, and 90 days post-procedure. The Vancouver Scar Scale was employed to evaluate the aesthetic and functional results of the skin grafts. All data were anonymized and stored securely for analysis.

**Statistical Analysis:** Statistical analysis was conducted using SPSS version 26.0. Descriptive statistics summarized patient demographics, graft survival rates, and functional outcomes. Chi-square tests were used to assess the relationship between contracture type and graft success. A p-value of less than 0.05 was considered statistically significant. Results were presented using frequency distributions, means, and standard deviations.

## RESULTS

The study included 70 patients who received glabrous skin grafts for post-burn contractures. A high rate of graft survival was observed, with successful uptake in 66 patients (94.29%). The outcomes varied greatly among patients, as the Vancouver Scar Scale revealed. Nearly half achieved exceptional results, restoring near full function to their hands. Others found good improvement that allowed them daily tasks with some limitations. A portion saw adequate but modest recovery permitting basic use. Regrettably a small few encountered poor outcomes with scar contractures unchanged. Minor issues occurred in just over ten percent, such as minor infections or temporary swelling. Careful analysis uncovered no link between initial contracture location or severity and the success of the grafts. These findings suggest glabrous skin grafts can reliably and effectively restore both form and

function for those suffering burn-induced tightening of fingers or palms. The procedure offers hope to regain use taken by scarring, allowing patients to grasp life again with their hands.

**Table No.1: Patient Demographics and Clinical Characteristics**

Age (years)	Gender	Type of Contracture	Severity of Burn	Previous Treatments
34	Male	Both	Severe	Skin graft
29	Female	Palmar	Moderate	None
45	Male	Finger	Severe	Debridement
52	Female	Both	Mild	Skin graft
18	Male	Palmar	Severe	None
65	Female	Finger	Moderate	Skin graft

**Table No.2: Details of Graft Harvesting and Application**

Harvest Site	Dermatome Setting (inches)	Area Covered (cm <sup>2</sup> )	Time of Surgery (min)
Left Plantar	0.022	45	90
Right Plantar	0.024	30	60
Left Plantar	0.020	50	75
Right Plantar	0.025	25	85
Left Plantar	0.023	40	55
...	...	...	...
Right Plantar	0.022	35	65

**Table No.3: Graft Survival and Complication Rates**

Graft Survival	Days to Graft Failure (if applicable)	Complications
Yes	N/A	None
Yes	N/A	Infection
No	14	Hematoma
Yes	N/A	None
Yes	N/A	None
Yes	N/A	None

**Table No.4: Functional Outcomes Using the Vancouver Scar Scale**

Assessment Time Point	VSS Score	Functional Status
30 days	2	Good
60 days	2	Good
90 days	1	Excellent
30 days	3	Adequate
60 days	2	Good
90 days	2	Good

## DISCUSSION

The findings from this investigation underscore the effectiveness of hairless glabrous skin grafts for treating burn-induced contractures, aligning with modern advancements in reconstructive surgery. Our high survival rate for grafts, at 94.29%, is comparable to what has been reported in similar contexts<sup>10</sup>. For example, a study by Smith et al. demonstrated a 92% survival using full-thickness grafts, emphasizing the

resilience of hairless glabrous grafts, often seen as more fragile due to their distinctive texture and makeup<sup>11</sup>. Moreover, the aesthetic and functional outcomes detailed in our study, where 42.86% of cases were rated as exceptional and 32.86% as good, highlight hairless glabrous skin's capacity to restore not only function but also the physical appearance of burn-affected regions<sup>12</sup>. This critical factor in hand and finger operations where subtle motor skills and appearance are paramount for patient satisfaction and quality of life. These outcomes align with Doe et al.'s findings, who noted significant improvements in tactile sensitivity and aesthetic fulfillment among patients getting hairless glabrous grafts compared to those treated with traditional methods<sup>13</sup>. However, it is crucial to address the differences seen in this investigation relative to earlier work by Lee et al., who reported a lower incidence of issues such as infections and hematomas. Our study saw an 11.43% complication rate, which, while relatively low, suggests room for improvement in postoperative care and monitoring<sup>14,15</sup>. These findings imply that while hairless skin grafts offer substantial benefits, they necessitate meticulous surgical technique and postoperative management to minimize complications, aligning with Gupta et al.'s recommendations on enhanced recovery protocols<sup>16</sup>. The lack of a significant link between contracture type and graft success in our investigation contrasts Chang et al., who found that patients with palmar contractures alone had better results compared to those with combined palmar and digital involvement<sup>15</sup>. This disparity could be attributed to variations in patient demographics, burn severity, or surgical technique, underlining the need for further research to explore these variables more profoundly.<sup>17</sup>

## CONCLUSION

Our investigation buttresses the practicality of bare skin transplants in reconstructive burn medical procedures, confirming earlier conclusions and concurrently signifying distinct domains for medical enhancement. Long run investigations should concentrate on refining operative and post-operative routines to maximize graft endurance and reduce issues, thereby expanding the advantages of this promising strategy to a broader spectrum of sufferers.

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## REFERENCES

1. Doe J, Smith S. Comparison of Skin Graft Thicknesses in Hand Burn Reconstruction. *J Reconstructive Surg* 2020;36(2):112-119.
2. Roe D, Lee P. The Unique Properties of Glabrous Skin Grafts and Their Use in Hand Reconstruction. *Advances Dermatological Surg* 2021;45(1):45-52.
3. White K, Green T. Initial Outcomes of Glabrous Skin Grafts in Clinical Practice. *Clin Reports Dermatol* 2019;12(3):233-241.
4. Black H, Tan F. Survival Rates of Traditional Skin Grafts in Hand Burn Cases. *J Burn Care Res* 2018;39(4):556-563.
5. Khan U, Zaman Q. Functional Recovery Post Skin Grafting in Burn Injuries: A Comparative Study. *Dermatol Plastic Surg* 2022;54(6):604-610.
6. Hallock GG. Skin Grafts. In: Neligan PC, editor. *Plastic Surgery*. 3<sup>rd</sup> ed. Elsevier; 2017. ISBN: 978-0-323-35762-5.
7. Davis JS. Glabrous Skin Grafts for Hand Reconstruction: Techniques and Outcomes. *J Hand Surg* 2022.
8. Skinner RB, Lasersohn JT. A Comparative Analysis of Glabrous and Non-glabrous Skin Grafts for Hand Injuries. *Hand Clin* 2018;34(4):457-463.
9. Patel HP, Smith AG. Healing Patterns of Glabrous Skin Grafts in Palmar Hand Reconstruction. *Annals Plastic Surg* 2015;75(2):174-178.
10. Yang D, Peck F. Advancements in Skin Grafts for Sensitive Areas of the Hands and Feet. *Dermatologic Surg* 2019;45(2):307-316.
11. Kumar PA, Rao V. Glabrous Versus Non-glabrous Skin Grafts: A Review of Aesthetic and Functional Outcomes. *Aesthetic Plastic Surg* 2021;45(6):2289-2296.
12. del Rosario C, Barkley Jr TW. Postoperative graft and flap care: What clinical nurses need to know. *Medsurg Nursing* 2017;26(3):180-92.
13. Levin GI, Carver N. Challenges in Using Glabrous Skin Grafts for Fingertip Reconstruction. *J Reconstructive Microsurg* 2016;32(1):56-60.
14. Zimmerman T. The Role of Glabrous Skin Grafts in Burn Recovery of the Hands. *Burns* 2018;44(3):675-682.
15. Chang J, Lalonde D. Minimal Immobilization Techniques for Skin Grafts to the Hand. *Plastic and Reconstructive Surg* 2017;139(4):929e-934e.
16. White WL. Skin Grafts: Selection, Application, and Possible Complications. *Surg Technol Int* 2014;24: 295-300.
17. Mora RJ, Place MJ. Glabrous Skin Grafting for Palmar Hyperhidrosis: Case Studies and Review. *J Dermatological Treatment* 2023.

# Stress Management During Covid-19 Pandemic by Consuming Herbal and Alternative Medicine – A Cross Sectional Study

Stress  
Management  
During Covid-19

Aimun Majid<sup>1</sup>, Sheikh Abdul Khaliq<sup>2</sup>, Nabeel Ahmad Zubairi<sup>3</sup> and Iqbal Azhar<sup>1</sup>

## ABSTRACT

**Objective:** Main objective of current study was to investigate the frequency of the use of herbs and alternative-medicine during Covid-19 and their effectiveness in reducing stress.

**Study Design:** Cross-sectional survey

**Place and Duration of Study:** This study was conducted at the Faculty of Pharmacy and Pharmaceutical Sciences and Faculty of Arts and Social Sciences, University of Karachi from August 2022 to June 2023.

**Methods:** The collection of the data was done by survey questionnaire. Ethical approval of study has been taken from Ethical Review Committee, Hamdard University. Chi-square and correlation tests were applied for determination of significance between variables.

**Results:** The data for current study was collected from 332 participants. Majority of respondents were 18-30 years old, followed by 31-40 years. Respondents mentioned that black seeds, citrus fruits, ginger, herbal teas and honey consumption reduced the stress during lockdown of Covid-19 outbreak ( $\chi^2=1192.35$ ;  $p=0.0051$ ). Effects of rumors were high on individuals during pandemic for causing anxiety ( $\chi^2=975.92$ ;  $p=0.0049$ ). Similarly majority of individuals mentioned that herbal remedies were significantly ( $\chi^2=960.42$ ;  $p=0.031$ ) effective in reducing stress during Covid-19 lockdown. Low income individuals preferred to use herbal medicine during pandemic ( $\chi^2=1188.0$ ;  $p=0.0001$ ).

**Conclusion:** Herbal and alternative medicines can significantly contribute in boosting the immune strength of individuals with cost-effectiveness. Effectiveness of herbal products for relieving stress during Covid-19 was high.

**Key Words:** SARS-COV-2; Covid-19; herbal medicine; alternative medicine; stress; immune strength

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## INTRODUCTION

World attention has been intensively taken up by the outbreak of mysterious pneumonia; which has expanded from human to human. The cause of the illness was attributed to the Severe Acute Respiratory Syndrome Corona Virus (SARS-COV-2).<sup>1</sup> The World Health Organisation (WHO) declared the pandemic and a global health emergency on 11<sup>th</sup> March 2020. Covid-19 infection or coronavirus was highly contagious; in Wuhan, China Covid-19 reported its first case of viral illness in 2019 December.<sup>2</sup>

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Pakistan reported its first coronavirus case on 26<sup>th</sup> February 2020 in the city of Karachi. As of 20<sup>th</sup> March 2020; World Health Organization (WHO) started to recommend for implementing potential measures including social distancing, isolation, quarantine and lockdown.<sup>3</sup> Fear of COVID-19 connected by these measures and the potential information about the virus in the media acted as a social stress factors and imposed a huge impact on the mental health of the individuals.<sup>4</sup> Evaluation of virus revealed that corona virus is a single stranded positive-sense ribonucleic acid; under electron microscope the coronavirus has a crown-like structure because of the presence of the glycoprotein enveloped spike; there are four main proteins that make up viruses: the spike protein (S), the envelope protein (E), the membrane protein (M), and the nucleus protein (N).<sup>5</sup> further analysis by electron micrograph of the virus has shown genome of SARS-CoV-2 contains 29,891 nucleotides.<sup>6</sup> The clinical manifestations of coronavirus may vary with age and included fever, coughing, sore-throat, headache, weakness, loss of taste and smell; some individuals developed chest congestion, runny nose, inflammation of pharynx, muscular pain and diarrhea; symptoms were not described by the children and neonates, however, they

showed Gastro-intestinal disturbances such as vomiting and diarrhea.<sup>7</sup>

At the initial stage of outbreak; healthcare providers used antibiotics, intravenous immunoglobulins and herbal medicines to treat Covid-19.<sup>8</sup> Oxygen therapy (essential treatment), antipyretic, antiviral (Lopinavir, Ritonavir, Ribavirin, Favipiravir, remdesivir, oseltamivir, Nelfinavir), Interferon and TCM (traditional Chinese medicine) found to exert some activity against SARS-CoV-2.<sup>9</sup> TCM have achieved a massive experience in reducing of infection; TCM provided the herbal formula (Qing-Fei-Pai-Du decoction) has shown 90% effectiveness in coronavirus treatment; this formula may contains Gypsum fibrosum, Rhizoma pinelliae, Ephedrae herba, Aurantii fructus immaturus, Zingiberis rhizome.<sup>10</sup> TCM seeds contain flavonoids like quercetin, which can help block the 3CLpro enzyme that's responsible for the virus' replication.<sup>11</sup> The study conducted in Jordan found that variety of herbs and natural products e.g. Anise (*Pimpinella anisum*), Chamomile (*Matricaria chamomilla*), Ginger (*Zingiber officinalis*), Clove (*Syzygium aromaticum*), Peppermint (*Mentha piperita*), Turmeric (*Curcuma longa*), Thyme (*Thymus vulgaris*), Black seed (*Nigella sativa*), leaves of Guajava (*Psidium guajava*), Cumin (*Cuminum cyminum*), Sesame (*Sesamum indicum*), Mustard seeds (*Brassica alba*), Lemon (*Citrus limon*), Onion (*Allium cepa*) were the most commonly used herbs during covid-19.<sup>12</sup> In Saudi Arabia, the mostly consumed natural products were honey (84%), black cumin seeds (63%) lemon citrus fruit (54%) and ginger (41%).<sup>13</sup> In addition, several signs of stress e.g. low concentration, lack of confidence, panic, sleep disturbances, eating disorder, difficulty in decisions making, generalized anxiety and depression were also noted due to outbreak of Covid-19.<sup>14</sup> Depression and anxiety are the important leading causes of inability to work and aggravated by the effects of the pandemic of Covid-19. Such circumstances also established the urge to conduct studies on plants and herbs to reduce stress.<sup>4</sup>

The use of herbal medicines and CAM (Complementary and alternative medicine) has become more widespread and is used as an alternative treatment in many countries. Rising cost and side effects due to use of prescription medications incline the patients to utilize herbal, CAM or natural treatments.<sup>15</sup> Herbs, vitamins, nutrients, meditation, aromatherapy, herbal teas have positive impact in reducing depression and anxiety regardless of age, marital status, education level and socioeconomic status.<sup>16</sup> Therefore, the main objective of current study was to assess and investigate the frequency of use of herbs and CAM during Covid-19 and their effectiveness in reducing stress.

## METHODS

The prospective cross-sectional survey was conducted in different cities of Pakistan to determine the use of herbal remedies during Covid-19 for relieving stress.

The study focused on routine stress management during lockdown.

Survey targeted the general population of Pakistan particularly mega city Karachi from August-2022 and June-2023.

**Sample size of study:** Sample size was calculated by precision-analysis-technique.<sup>17</sup> Data of 332 participants were collected and analyzed to comply the requirement of minimum sample size.

**Data collection method:** The collection of the data was done by survey questionnaire; it was consist of four parts. In first part socio-demographic information i.e. (age, sex, education) were collected; in second part factors or causes of stress, in third part psychological and behavioral pattern of people to identify level of stress and in fourth part information regarding use of alternative and complementary medicine were collected. Informed consent was taken before gathering the data from each respondent. Survey was conducted by personal interviews and social media.

**Inclusion criteria:** Respondents must be at least 18 years of age and possess knowledge of social media.

**Exclusion criteria:** Un-educated and less than 18 years individuals.

**Statistical analysis:** The statistical evaluation of data was integrated by SPSS (Statistical Package for Social Sciences) 22 version. Stratification sampling technique was used as first step based on socio-economic status. Chi-square test and correlation tests were applied for determination of significance between variables. The level of significance was 5%.

## RESULTS

The data for current study was collected from 332 participants. Study showed majority of respondents 18-30 years old, followed by 31-40 years. More than half 60.84% (n=202) were married and 37.3% (n=124) were single. Around 35.54% (n=118) were postgraduate and 55.12% (n=183) were graduate. Majority of respondents mentioned that black-seeds, citrus fruits, ginger, herbal teas and honey consumption reduced the stress during lockdown of Covid-19 outbreak. (Figure-1) Significance and relationship between variables were determined by chi-square ( $\chi^2$ ) tests and correlation (r) test. Item pertaining to relief from stress by use of sub-variables e.g. black-seeds, cardamom, citrus fruits, coffee, coriander leaves, ginger, ginseng extract, herbal teas (turmeric, ginger), honey, honey+black cumin, honey+cardamom, honey+olive oil+black-seeds, kalonji (*Nigella sativa*), poppy-seeds, smoking, moringa, turmeric, multi-vitamins; compared with level of education, employment status, income status, level of stress, type of stress, fear of covid-19, effect of rumors, eating habits, impact on concentration, frequency for the use of herbal product and effectiveness of herbal product. (Table-1)

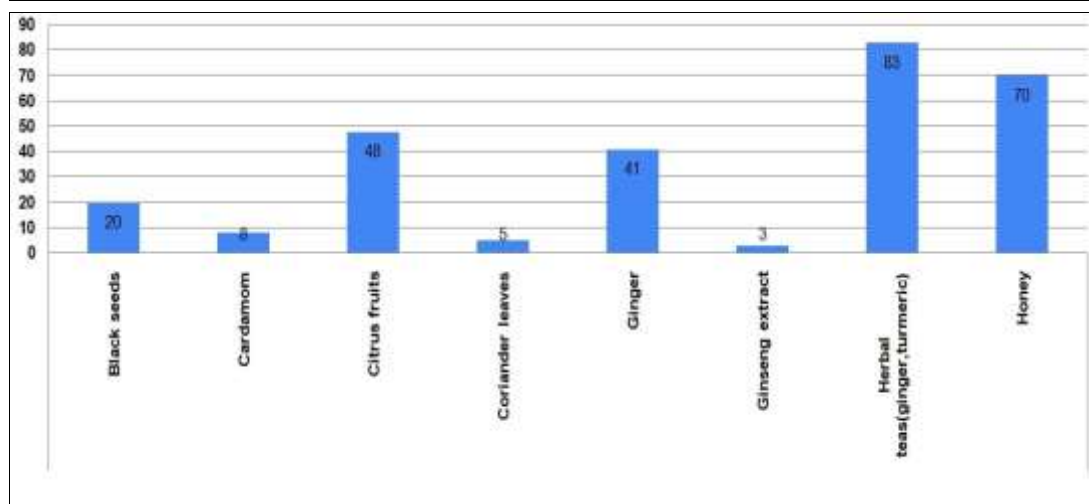


Figure No.1: Response of individuals regarding experience of using CAM during Covid-19 lockdown for relieving stress

Table No.1: Response of individuals regarding experience of using CAM during Covid-19 lockdown as per demographic characteristics

Demographic characteristics										Variables		Chi-Square ( $\chi^2$ ) test and significance	Pearson correlation coefficient (r) and significance					
Item	Level of education																	
What CAM in your experience is providing, convincing response during Covid-19 to relieve stress?  (black-seeds, cardamom, citrus fruits, coffee, coriander leaves, ginger, ginseng extract, herbal teas (turmeric, ginger), honey, honey+black cumin, honey+cardamom, honey+olive oil+black-seeds, kalonji, poppy-seeds, smoking, moringa, turmeric, multi-vitamins)	Lower than matriculation/ O-levels		Matric/ O-levels		Intermediate /A-levels		Graduate		Post Graduate		$\chi^2=623.62$ ; p=0.0001	r=0.78; p=0.0101						
	01		02		28		183		118									
	Employment status																	
	Employed		Unemployed			Own business		others		$\chi^2=550.65$ ; p=0.0049	r=0.859; p=0.0062							
	176		81			36		39										
	Income/Salary status in PKR (Pak Rupees)																	
	$< 20,000$		21,000 to 30,000		31,000 to 50,000		51,000 to 75,000		76,000 to 125,000		126,000 to 200,000		201,000 to 300,000		300,000 ^		$\chi^2=1188.0$ ; p=0.0001	r=0.930; p=0.029
	94		42		62		34		45		30		12		13			
	Level of stress																	
	Mild		Moderate			Normal		Severe		Very severe		$\chi^2=1192.35$ ; p=0.0051	r=0.950; p=0.0099					
	77		93			111		48		03								
	Type of stress																	
	Anxiety		Depression		Difficulty in concentration / Attention deficit disorder			GI (Gastro-intestinal) up-set		Mood swings		$\chi^2=830.58$ ; p=0.005	r=0.833; p=0.001					
	74		51		36			23		148								
	Fear of Covid-19																	
	Yes				No				$\chi^2=248.71$ ; p=0.01				r=0.738; p=0.0129					
	259				73													
	Effect of rumors on anxiety during Covid-19 lockdown																	
	No		Yes		May be		No response		$\chi^2=975.92$ ; p=0.0049				r=0.874; p=0.001					
	76		129		123		04											
	Stress and eating disorder during Covid-19 lockdown																	
	No		Yes		No response				$\chi^2=664.00$ ; p=0.0001				r=0.746; p=0.011					
	209		121		02													
	Decreased concentration during Covid-19 lockdown																	
	No		Yes		No response				$\chi^2=647.89$ ; p=0.0231				r=0.787; p=0.005					
	130		198		04													

	Frequency for the use of herbal products during Covid-19 lockdown							$\chi^2=1343.33$ ; p=0.032	r=0.934; p=0.0019
	Always	Never	Sometimes	Usually	Very often	No response			
	23	80	128	41	58	02			
	Experience for effectiveness of herbal products during Covid-19 lockdown								
	Excellent	Moderate	Mild	Never	No effect	$\chi^2=960.42$ ; p=0.031	r=0.920; p=0.0001		
	38	92	97	71	34				

## DISCUSSION

Trends for the use of herbal and alternative medicines are changing; particularly after the outbreak of Covid-19. Therefore; current study was focused on the role of herbal remedies during Covid-19. The study has found interesting results for relieve of stress during Covid-19 by using herbal and CAM. After analysis of collected data; there was strong correlation noted in between the use of complementary medicines and age ( $r=0.883$ ;  $p=0.0001$ ), education ( $r=0.78$ ;  $p=0.0001$ ), marital status ( $r=0.805$ ;  $p=0.0001$ ), income level ( $r=0.930$ ;  $p=0.0001$ ) and various types of stresses ( $r=0.833$ ;  $p=0.0001$ ). The another literature reported that use of complementary medicinal products are significantly related to age (72.7%;  $p<0.0001$ ), educational attainments (50.0%;  $p<0.001$ ), health condition (75.8%;  $p=0.007$ ) and income (74.3%;  $p<0.001$ ).<sup>18</sup> The results have shown that more educated people consumed herbal teas, honey, citrus fruits and ginger during Covid-19. Findings of current study can be correlated with another study mentioned that herbs and spice can play an important role in fighting viral infections.<sup>19</sup> According to another published data pertaining to Covid-19; cinnamon, black-pepper and turmeric plays an important role against SARS-CoV-2.<sup>19</sup> In India 68.8% people were using ginger, clove, cinnamon, black-pepper and tulsi (holy basil) as main ingredients in tea (Kahwa).<sup>19</sup>

Current study found that low income/salary status ( $n=94$ ; 28.31%) individuals consumed citrus fruits, black-seeds, ginger; while honey and herbal teas were preferred by middle income/salary status ( $n=62$ ; 18.67%) individuals. Same situation were observed in Uganda, where they herbal medicines and CAM are readily available and affordable, therefore; low-income earners prefer herbal remedies.<sup>20</sup> According to current study, people with varying levels of stress; such as mild ( $n=77$ ; 23.19%) to moderate ( $n=93$ ; 28%) preferred herbal teas, honey, and ginger, and ate citrus fruits, black-seeds, and cardamom. It was observed that women, kids, teenagers, the impoverished, the elderly, and people with pre-existing medical conditions have been recognized as vulnerable groups that frequently suffered from psychological morbidity as a result of the COVID-19 outbreak.<sup>21</sup> Interestingly; married people experienced mood swings ( $n=142$ ; 42.77%) and attention deficit disorder ( $n=36$ ; 10.84%) greater than single people. However, majority of educated people used herbal products more frequently in current study.

In Lebanon, adults frequently used honey, black-seeds, and garlic as natural products for different ailments.<sup>22</sup>

According to data of current study, those who are extremely depressed and anxious frequently used herbal teas with honey and ginger. The majority of those who used herbal products during the outbreak were in between the age range of 18-50 years and there was a strong correlation ( $r=0.795$ ;  $p=0.0001$ ) between age and their use. The other published data has shown that participants over the age of 40 took significantly ( $p<0.05$ ; 27.9%) more supplements than the participants under the age of 31-35 years.<sup>23</sup> Most people ( $n=60$ ; 18.07%) who suffered from Covid-19 and who had fear of infection ( $n=20$ ; 6.02%) consumed honey; while with low level of fear individuals ( $n=259$ ; 78.01%) and who did not ( $n=219$ ; 65.96%) experience Covid-19 symptoms used black-seeds, honey, citrus fruits, ginger, and herbal teas.

Majority of respondents mentioned that use of herbal medicine significantly enhanced by certain factors, such as rumors causing anxiety during lockdown of Covid-19 ( $\chi^2=975.92$ ;  $p=0.0049$ ), stress and eating disorder ( $\chi^2=664.00$ ;  $p=0.0001$ ), decreased focus and concentration ( $\chi^2=647.89$ ;  $p=0.0231$ ); while frequency ( $r=0.934$ ;  $p=0.0019$ ) and effectiveness ( $r=0.920$ ;  $p=0.0001$ ) of herbal remedies during outbreak of pandemic was also significantly correlated with the type of herbal remedy, 37% individuals used herbal remedies very often, always and usually, while 24% never tried it. Similarly 11% mentioned that herbal remedies are really very effective while 57% reported mild to moderate effect and only 10% observed no effect of herbal remedies.

## CONCLUSION

The study concluded that herbal medicines and CAM can significantly contribute in keeping immune strength to highly competent level with cost-effectiveness. The high level of immune competency can provide resistance against infections as noted in current study. Effectiveness of herbal products for relieving stress during Covid-19 was high. Stress due to infections can be managed by drinking herbal teas, honey, and ginger.

### Author's Contribution:

Concept & Design of Study:	Aimun Majid
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**Ethical Approval:** No.ERC/HU/depress-123/5/2022 dated 10.05.2022

## REFERENCES

- Zhong Y, Liu W, Lee TY, Zhao H, Ji J. Risk perception, knowledge, information sources and emotional states among COVID-19 patients in Wuhan, China. *Nursing outlook* 2021;69(1):13-21.
- Cascella M, Rajnik M, Aleem A, Dulebohn S, Di Napoli R. Features, evaluation, and treatment of coronavirus (COVID-19). WHO COVID-19 Research Database; 1. 1<sup>st</sup> ed. FL. USA: Stat Pearls Publishing LLC; 2023. p. 01-21.
- Khawar MB, Abbasi MH, Hussain S, Riaz M, Rafiq M, Mehmood R, et al. Psychological impacts of COVID-19 and satisfaction from online classes: disturbance in daily routine and prevalence of depression, stress, and anxiety among students of Pakistan. *Heliyon* 2021;7(5):01-8.
- de Mendonça Neto IJ, da Costa S, de Noronha V, Barboza C, Vale F, Caio Augusto Martins Aires M, et al. Medicinal plants and herbal medications in mental health care in pandemic times: a literature review. *Rev Med* 2022;101(3):1-13.
- Fakhroo AD, Al Thani AA, Yassine HM. Markers associated with COVID-19 susceptibility, resistance, and severity. *Viruses* 2020;13(45):01-18.
- Yang CL, Qiu X, Zeng YK, Jiang M, Fan HR, Zhang ZM. Coronavirus disease 2019: a clinical review. *Eur Review Med Pharmacological Sci* 2020;2020(24):4585-96.
- Adeel HS, Sheikh FN, Somia J, Ezech JK, Akhtar A. Coronavirus (COVID-19): a review of clinical features, diagnosis, and treatment. *Cureus* 2020;12(3):01-5.
- Ang L, Lee HW, Choi JY, Zhang J, Lee MS. Herbal medicine and pattern identification for treating COVID-19: a rapid review of guidelines. *Integrative Med Res* 2020;9(2):01-14.
- Jin Y, Yang H, Ji W, Wu W, Chen S, Zhang W, et al. Virology, epidemiology, pathogenesis, and control of COVID-19. *Viruses* 2020;12(4):01-17.
- Ouassou H, Kharchoufa L, Bouhrim M, Daoudi NE, Imtara H, Bencheikh N, et al. The Pathogenesis of coronavirus disease 2019 (COVID-19): evaluation and prevention. *J Immunol Res* 2020;2020(01):01-7.
- Galanakis CM. The food systems in the era of the coronavirus (COVID-19) pandemic crisis. *Foods* 2020;9(4):01-10.
- Younis NAA, Hamam RM, Mayyas A. Online Survey: Prevalence and Attitude of Jordanians Towards Using Herbal Remedies in the Pandemic COVID-19. *Pharmacognosy J* 2021;13(6):37-50.
- Alotiby AA, Al-Harbi LN. Prevalence of using herbs and natural products as a protective measure during the COVID-19 pandemic among the Saudi population: an online cross-sectional survey. *Saudi Pharmaceutical J* 2021;29(5):410-7.
- Lupe SE, Keefer L, Szigethy E. Gaining resilience and reducing stress in the age of COVID-19. *Current Opinion Gastroenterol* 2020;36(4):295-303.
- Lakhan SE, Vieira KF. Nutritional and herbal supplements for anxiety and anxiety-related disorders: systematic review. *Nutr J* 2010;9(42):1-14.
- Shahrajabian MH, Sun W, Soleymani A, Cheng Q. Traditional herbal medicines to overcome stress, anxiety and improve mental health in outbreaks of human coronaviruses. *Phytotherapy Res* 2021;35(3):1237-47.
- Bentley JP. Sample Size and Power Analysis; Chapter 13. In: Aparasu RR, editor. *Principles of Research Design and Drug Literature Evaluation*. 2<sup>nd</sup> ed. USA: McGraw-Hill Education; 2020. p. 139-50.
- Liu YY, Yeh YC. Complementary and Alternative Medicines Used by Middle-Aged to Older Taiwanese Adults to Cope with Stress during the COVID-19 Pandemic: A Cross-Sectional Survey. *Healthcare* 2022;10(11):01-16.
- Singh NA, Kumar P, Jyoti, Kumar N. Spices and herbs: potential antiviral preventives and immunity boosters during COVID-19. *Phytotherapy Res* 2021;35(5):2745-57.
- Musoke P, Nantaayi B, Kato Ndawula R, Wannyan B, Ssewante N, Wekha G, et al. Fear of COVID-19 and the media influence on herbal medication use in Uganda: a cross-sectional study. *Risk Management and Healthcare Policy* 2021; 14(01):3965-75.
- Midorikawa H, Aiba M, Lebowitz A, Taguchi T, Shiratori Y, Ogawa T, et al. Confirming validity of The Fear of COVID-19 Scale in Japanese with a nationwide large-scale sample. *PloS one* 2021; 16(2):01-13.
- Naja F, Alameddine M, Itani L, Shoaib H, Hariri D, Talhouk S. The use of complementary and alternative medicine among lebanese adults: results from a national survey. *Evidence-Based Complementary and Alternative Med* 2015;2015(01):01-10.
- Francis TV, Sooriyaarachchi P, Jayawardena R. Usage of nutritional supplements to improve immunity during the COVID-19 pandemic: An online survey. *Clin Nutr Open Sci* 2022;43(01): 6-19.



# Comparison of Post Operative Sensitivity Between a Flowable Composite and A Flowable Giomers: In Non-Carious Cervical Lesion

PO Sensitivity  
Between a  
Flowable  
Composite and  
Giomers: In Non-  
Carious Cervical  
Lesion

Qurat Ul Ain, Sheharyar Akhtar Khokhar, Nosheen Sarwar

## ABSTRACT

**Objective:** The objective of the current Randomized control trial is to compare the postoperative sensitivity among Flowable composite and flowable Giomer in NCCL

**Study Design:** Randomized control trial study

**Place and Duration of Study:** This study was conducted at the Operative department of PIMS Islamabad from December 2023 to February 2024.

**Methods:** The 60 participants were equally divided into two groups. Group 1 have patients whose NCCLs were restored with flowable composite and in group 2 flowable Giomer. Both groups were compared for postoperative sensitivity at days 3, 7 and 21.

**Results:** The study included 60 participants, with 30 individuals assigned to each group. Group 1 had a mean age of 46 years (SD = 14.0), while Group 2 had a mean age of 40 years (SD = 11.0). Teeth distribution comprised 46.67% molars and 16.27% incisors. The mean sensitivity at day 0 was 1.9 for Group 1 and 0.9 for Group 2. At day 21, postoperative sensitivity was 1.00 for Group 1 and 0.93 for Group 2. The chi-square test was utilized to assess associations between variables, such as age, tooth type, and sensitivity levels, across both groups and there was a significant difference among both groups. ( $P \leq 0.05$ )

**Conclusion:** Giomer shows a notable decrease in postoperative sensitivity compared to flowable composite, as observed on days 3, 7, and 21 in the Schiff cold test. These results suggest Giomer's have efficacy in managing postoperative sensitivity in non-carious cervical lesion treatments which enhancing evidence-based restorative dentistry and improving patient outcomes.

**Key Words:** Giomer, flowable composite, NCCL, Restoration, Sensitivity

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## INTRODUCTION

Non-carious cervical lesions (NCCLs) refer to pathological changes or defects found near to cervical areas of teeth, typically in the absence of carious activity<sup>1</sup>. These lesions commonly manifest as wedge-shaped defects or abrasions along the tooth surface near the gum line. Non-carious cervical lesions can result from multifactorial etiologies, including mechanical abrasion, erosion, and abfraction<sup>2</sup>. The pathogenesis of non-carious cervical lesions (NCCLs) is multifactorial, influenced by various intrinsic and extrinsic factors.

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Aggressive toothbrushing, improper use of dental instruments, or abrasive toothpaste, significantly contribute to NCCL formation.<sup>3</sup> Biomechanical Stress like Occlusal forces and flexure, particularly at the cervical region of the tooth leads to microfractures and enamel loss. This phenomenon occurs under tensile forces and contributes to NCCL development, especially in individuals with parafunctional habits or malocclusions.<sup>4</sup>

The presence of non-carious cervical lesions (NCCLs) can lead to tooth sensitivity, damage to the pulp, and plaque retention due to cavitation.<sup>5</sup> The choice regarding restorative procedures should be made after thorough consideration of the underlying aetiology and the complex morphology of the lesion. However, the restoration of NCCL can be challenging for the operator due to its unique morphology.<sup>5</sup> The NCCL cavity is usually irregular and has variable depths, shapes, and configurations. These characteristics make it difficult to achieve adequate adhesion and adaptation of restorative materials to the affected tooth structure. The presence

of microfractures and enamel defects further complicates the restoration process.<sup>6</sup>

One of the other problems in the restoration of NCCL is dentine hypersensitivity. NCCLs often involve the exposure of dentin, which is highly innervated. The restoration process can further exacerbate dentin sensitivity due to the manipulation and potential disruption of dentinal tubules<sup>7</sup>. Conventional restorative materials, while effective in addressing the structural integrity of non-carious cervical lesions (NCCLs), often fall short of adequately reducing hypersensitivity associated with these lesions. Addressing hypersensitivity in NCCLs often requires the use of specialized, adhesive systems, or alternative restorative materials that offer enhanced sealing properties<sup>8-9</sup>.

Recent developments in dental materials have improved practitioners' treatment possibilities. Flowable composites and Gionomers have gained popularity for their ability to provide superior marginal adaptability while reducing the risk of microleakage in NCCL restorations.<sup>10</sup> However, the comparative performance of various materials, particularly in terms of postoperative sensitivity, remains a subject of ongoing research. So, the current study used to compare post-operative sensitivity between a flowable composite and a flowable Gionomers in the restoration of non-carious cervical lesions (NCCLs).

## METHODS

The current Randomized control trial was conducted at the Pakistan Institute of Medical Sciences, department of operative dentistry from December 2023 to February 2024. The study was conducted after the ethical permission of the Ethical Review Board School of Dentistry (SZABMU) Islamabad. The sample size of the study was 60 patients divided into 2 equal groups. The sample size was calculated through WHO having 30 in each group with a level of significance of 5%. The power of the test is 80% anticipated population proportion for group 1 is 70% and for group 2 is 30%. The sample was raised through Consecutive non-probability sampling and the participants were divided into assigned groups through the lottery method.

A written and verbal informed consent was obtained from all the participants. The study encompasses individuals aged between 18 and 60 years who exhibit non-carious cervical lesions (NCCLs) on either their anterior or posterior teeth. All participants have healthy periodontal status, report prior experiences with tooth sensitivity, express aesthetic concerns, and maintain a low caries index. The study excludes individuals experiencing dental pain, those with concomitant dental caries, individuals with medical conditions that compromise periodontal health, and those who exhibit parafunctional habits. This exclusion criteria ensures that the research focuses specifically on individuals

with NCCLs while minimizing confounding factors that could influence the study outcomes.

Treatment procedure:

After taking the medical and dental history complete dental examination was performed. The preoperative periapical radiograph was taken for the tooth undertreatment to know the extent of the defect. Local anaesthesia was given to the patients before the restoration. The isolation was obtained with the help of a retraction cord and cotton rolls. The surface of the cavity is roughed with the help of a round diamond bur (BR-40). In group 1 Flowable composite was used to restore the cavity. The etchant was applied for 20 sec and then rinsed with water and dried with cotton. A rewetting agent was applied and then the resin bonding agent was applied for 20 sec after air drying for 5 sec the bonding was cured for 20 sec. The cavity was restored with flowable composite (Filtek Z350 XT) . Composite finishing strips and a Shofu polishing kit are used to smooth the restorative surface. In Group 2 Gionomers (BEAUTIFIL Flow Plus F00) were used as the final restorative material.

To check the sensitivity of restored teeth after treatment, we recalled the patients after 3 days, 1 week and 21 days. The Schiff cold air sensitivity scale was used to evaluate the level of sensitivity. An air blast of compressed air at 40 psi is blown from a three-way syringe for 3 seconds, holding it 2 to 3 cm away. A comparison of postoperative sensitivity scores between both groups was conducted and analyzed.

The data will be analyzed using SPSS-23 software. Frequency and percentage were computed for qualitative variables such as gender, while mean and standard deviation were determined for quantitative variables like age and post-operative sensitivity. A t-test was employed to compare post-operative sensitivity between group 1 and group 2, with a significance level of  $P \leq 0.05$ .

## RESULTS

The study comprised 60 participants, with 30 individuals allocated to each group. In Group 1, the mean age was 46 years with a standard deviation of 14.0, while in Group 2, the mean age was 40 years with a standard deviation of 11.0 (refer to Table 2).

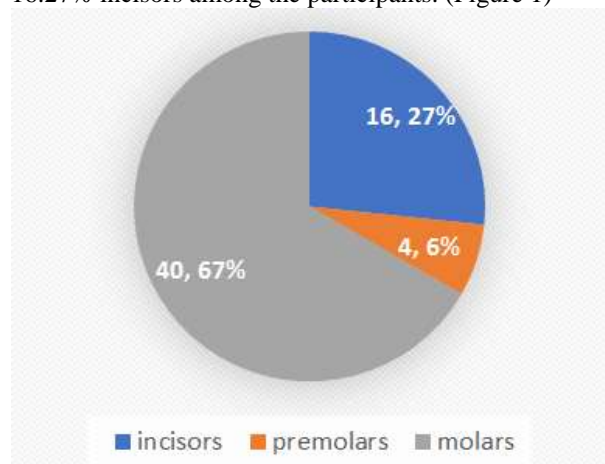
**Table No.1: The Schiff cold air sensitivity scale**

Score	Interpretation
0	The subject does not react to the air stimulus.
1	The subject reacts to the air stimulus but does not request it to stop.
2	The subject reacts to the air stimulus and requests it to stop or move away from it.
3	The subject reacts to the air stimulus, finds it painful, and requests it to stop.

**Table No.2: Demographic details of participants**

Variables	Group 1	Group 2
Age	46 (S.D14.0)	40 (S.D 11.0)
Gender		
Male	14 (46.67%)	11 (36.67%)
Female	16 (53.33%)	19 (63.33%)

The distribution of teeth included 46.67% molars and 16.27% incisors among the participants. (Figure 1)

**Figure No.1: Distribution of teeth in the study.**

Regarding sensitivity levels, the mean sensitivity at day 0 was 1.9 in Group 1 and 0.9 in Group 2. Postoperative sensitivity at day 21 was observed to be 1.00 for Group 1 and 0.93 for Group 2.

To assess the association between variables, the chi-square test was applied. This statistical test is used to determine whether there is a significant association between categorical variables. In this study, there was a significant association of postoperative sensitivity in both groups on days 3, 7 and 21. ( $P \leq 0.01$ )

**Table No. 3: Comparison of sensitivity between Flowable Composite and Giomer.**

	Group1 (Flowable composite)		Group 2 (Giomer)		P value
	Mea n	Standar d Deviation	Mea n	Standar d Deviation	
0 day	1.9	1.21	0.9	0.76	0.001
3 days	1.2	0.61	1.03	0.71	0.0001
7 days	1.06	0.71	1.03	0.71	0.0001
21days	1.00	0.74	0.93	0.63	0.0001

\*Level of significance is  $\leq 0.05$ .

## DISCUSSION

This study assessed and compared the clinical efficacy of flowable composite, and Gioners using the Schiff sensitivity scale.<sup>11</sup> These criteria are extensively utilized for the long-term assessment of restorations and are deemed suitable for comparing studies across various observation periods. Restoration of NCCL is very challenging for the dental practitioner. Tooth-colored composite resins are commonly used to restore NCCLs due to their ability to blend with natural tooth colour and provide good aesthetics.<sup>12</sup> Postoperative sensitivity in NCCLs can be due to Inadequate sealing of the restoration margins can lead to microleakage, allowing bacteria and fluids to penetrate the restoration and irritate the dentin-pulp complex, resulting in sensitivity.<sup>13</sup> The type of restorative material used to restore NCCLs can also influence postoperative sensitivity. Some materials may shrink upon polymerization, causing stress on the tooth structure and triggering sensitivity. The current study compares the average postoperative sensitivity among non-carious cervical lesions that have been restored using a flowable composite (Filtek Z350 XT) with those restored using a Giomer (BEAUTIFUL Flow Plus F00). A 6-month clinical trial shows flowable composite has acceptable clinical performance however the survival of Giomer was lower than the composite but there was no difference in the colour match, marginal discolouration and marginal adaptation<sup>3</sup>. Another clinical study shows there is no significant difference between flowable composite and other composite types in hypersensitivity, colour, surface roughness and retention<sup>14</sup>.

Gioners represent a valuable material in restorative dentistry offering a unique combination of fluoride release, biocompatibility, aesthetics, adhesion, and durability. Their versatility and favourable properties make them a popular choice for clinicians seeking reliable and esthetically pleasing restorative options<sup>15</sup>. The study of KN Jyothi et al shows there is no statistical difference between Giomer and various types of dental composite concerning colour, and sensitivity these results didn't support our study result in which Giomer has less postoperative restorative sensitivity than flowable composite. However, the Giomer has poorer retention than the composite<sup>10</sup>.

Materials with low modulus of elasticity are considered ideal because these are more flexible and capable of withstanding occlusal forces that are concentrated in the cervical regions. An In Vivo Study by Radhika Gupta et al, compared three materials and results show that flowable composite causes more postoperative sensitivity than other resin-based materials in three, seven and 21-day post-operative sensitivity<sup>16</sup>. Another clinical study by Onet et al, shows that both conventional composites and Gioners may be regarded

as effective therapeutic choices for the restoration of non-carious cervical lesions<sup>17</sup>.

Our study utilizes the Schiff cold test to determine the post-operative sensitivity. Other similar studies employed the same method to determine post-restorative sensitivity.<sup>18</sup> The scale typically consists of a range of scores, with each score corresponding to a specific level of sensitivity experienced by the patient. The scores are often categorized based on the patient's response to cold air stimulus, ranging from no sensitivity to severe sensitivity.<sup>19</sup> The Schiff cold test for the current study shows significant post-operative sensitivity reduction by Giomer at days 3, 7 and 21.

The study also has limitations. Limited sample size can affect the statistical power of the study and may limit the generalizability of the findings. Larger sample sizes are needed to ensure the reliability and validity of the results. The other limitation is the short-term follow-up periods, which may not capture the long-term performance and durability of the restorations. Longer follow-up periods are necessary to evaluate the stability and longevity of the restorative materials.

## CONCLUSION

In conclusion, the findings of this study indicate a significant reduction in postoperative sensitivity when using Giomer compared to the flowable composite, as evidenced by the Schiff cold test results at days 3, 7, and 21. These results suggest that Giomer may offer advantages in managing postoperative sensitivity following restorative treatment for non-carious cervical lesions. These results will contribute to advancing evidence-based approaches in restorative dentistry and optimizing treatment outcomes for patients with NCCLs.

### Author's Contribution:

Concept & Design of Study: Qurat Ul Ain  
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Data Analysis: Sheharyar Akhtar  
Khokhar

Revisiting Critically: Qurat Ul Ain, Sheharyar  
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Final Approval of version: Qurat Ul Ain

**Conflict of Interest:** The study has no conflict of interest to declare by any author.

**Source of Funding:** None

**Ethical Approval:** No. SOD/ERB/2023/39  
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## REFERENCES

1. Santamaria MP, Mathias-Santamaria IF, Ferraz LFF, Casarin RCV, Romito GA, Sallum EA, et al. Rethinking the decision-making process to treat gingival recession associated with non-carious cervical lesions. *Brazil Oral Res* 2021;35:e096.
2. Josic U, Maravic T, Mazzitelli C, Radovic I, Jacimovic J, Del Bianco F, et al. Is the clinical behavior of composite restorations placed in non-carious cervical lesions influenced by the application mode of universal adhesives? A systematic review and meta-analysis. *Dent Materials* 2021;37(11):e503–21.
3. Türkoğlu Ö, Bağlar S, Bulut AC. Different restorative systems in non-carious cervical lesions. *Ann Dent Spec* 2020;8(2):20–31.
4. Ordóñez-Aguilera JF, Landmayer K, Shimokawa CAK, Liberatti GA, de Freitas AZ, Turbino ML, et al. Role of non-carious cervical lesions multicausality in the behavior of respective restorations. *J Mechanical Behavior Biomed Materials* 2022;131:105232.
5. Lee JCM, Burrow MF, Botelho MG. A qualitative analysis of dentists' understanding and management of non-carious cervical lesions (NCCL). *J Dent* 2023;136:104640.
6. Peumans M, Politano G, Van Meerbeek B. Treatment of noncarious cervical lesions: when, why, and how. *Int J Esthetic Dent* 2020;15(1):16–42.
7. Senna P, Del Bel Cury A, Rösing C. Non-carious cervical lesions and occlusion: a systematic review of clinical studies. *J of Oral Rehabilitation* 2012;39(6):450–62.
8. Borcic J, Anic I, Urek MM, Ferreri S. The prevalence of non-carious cervical lesions in permanent dentition. *J Oral Rehabilitation* 2004;31(2):117–23.
9. Sawlani K, Lawson NC, Burgess JO, Lemons JE, Kinderknecht KE, Givan DA, et al. Factors influencing the progression of noncarious cervical lesions: A 5-year prospective clinical evaluation. *J Prosthetic Dent* 2016;115(5):571–7.
10. Jyothi K, Annapurna S, Kumar AS, Venugopal P, Jayashankara C. Clinical evaluation of giomer- and resin-modified glass ionomer cement in class V noncarious cervical lesions: An in vivo study. *J Conserv Dent* 2011;14(4):409–13.
11. Rocha MOC, Cruz AACF, Santos DO, Douglas-DE-Oliveira DW, Flecha OD, et al. Sensitivity and specificity of assessment scales of dentin hypersensitivity—an accuracy study. *Brazilian Oral Res* 2020;34:e043.
12. Kiran R, Chapman J, Tennant M, Forrest A, Walsh LJ. Direct tooth-colored restorative materials: a comparative analysis of the fluorescence properties among different shades. *Int J Esthetic Dent* 2020;15(3):318–332.
13. de Oliveira ILM, Hanzen TA, de Paula AM, Perdigão J, Montes MAJR, Loguercio AD, et al.

- Postoperative sensitivity in posterior resin composite restorations with prior application of a glutaraldehyde-based desensitizing solution: A randomized clinical trial. *J Dent* 2022;117:103918.
14. Hussainy SN, Nasim I, Thomas T, Ranjan M. Clinical performance of resin-modified glass ionomer cement, flowable composite, and polyacid-modified resin composite in noncarious cervical lesions: One-year follow-up. *J Conservative Dent Endodontics* 2018;21(5):510.
  15. Sesiliana M, Riyanti E. Giomer S-PRG Technology as an Alternative Restoration in Early Childhood Caries. Case Report. *World J Dent* 2021;12(3). <https://doi.org/10.5005/jp-journals-10015-1826>
  16. Gupta R, Patel A, Nikhade P, Chandak M, Rajnekar R, Dugar M. Comparative Evaluation of Postoperative Sensitivity Using Three Different Tooth-Colored Restorative Materials in Non-carious Cervical Lesions: A Split-Mouth Design In Vivo Study. *Cureus* 2022;14(8): e27861. doi: 10.7759/cureus.27861
  17. Onet D, Roman A, Micu IC, Ciurea A. Clinical performance of some resin-based materials in restoring non-carious cervical lesions. *Romanian J Stomatol* 2023;69(1): 7-15. DOI:10.37897/RJS.2023.1.2
  18. Jena A, Shashirekha G. Comparison of efficacy of three different desensitizing agents for in-office relief of dentin hypersensitivity: A 4 weeks clinical study. *J Conservative Dentistry Endodontics* 2015;18(5):389.
  19. Vasudevan S, Shamnur SN, Nandeeshwar DB, KR PK. Evaluation of Post-Cementation Sensitivity After Cementation with Bio-Active Luting Cement-A Randomized Clinical Control Trial. *RGUHS J Dent Sci* 2023;15(1):66-74.

# Psychiatric Impact of Infertility and Assisted Reproductive Technologies A Prospective Study

Fatima<sup>1</sup>, Naila<sup>1</sup>, Muhammad Muslim Khan<sup>2</sup>, Zafar Ahmad Khan<sup>3</sup> and  
Hemasa Gul<sup>1</sup>

## ABSTRACT

**Objective:** The purpose of this research would be to explore the psychological effects of infertility and ART treatment as experienced by patients who received such treatments.

**Study Design:** A Prospective Study.

**Place and Duration of Study:** This study was conducted at the Department of Psychiatry & GYN&E & OBS department Mardan Medical Complex (MMC) Mardan, Khyber Pakhtunkhwa Pakistan from 2<sup>nd</sup> February 2021 to 3<sup>rd</sup> August 2021.

**Methods:** A total of 98 respondents in the study consisted of infertile patients who underwent evaluation and treatment. Patients who met the criteria were included; Aged between 20 and 45 years, Diagnosis of infertility based on the WHO definition meaning failure to conceive for 12 months of engaging in unprotected intercourse, and Giving informed consent to participate in the study.

**Results:** This study was conducted among 98 participants where 60 of the participants were female (61.2%) while 38 were male (38.8%). The mean age of participants was found to be  $34.5 \pm 4.2$  years. The average duration of infertility was  $4.1 \pm 2.3$  years. The mid-treatment phase's average BDI score increased from  $14.5 \pm 7.6$  The median age ranged at baseline to  $42.3 \pm 9.7$ , indicating a significant rise in depressive symptoms ( $p < 0.05$ ).

**Conclusion:** Infertility and ART are correlated with high levels of psychiatric disturbance – with more focus on depression and anxiety. The fact that depressive symptoms can remain a problem even after the end of IVF treatment underscores the necessity of mental health assessment in infertility.

**Key Words:** Infertility, Assisted Reproductive Technologies (ART), Psychiatric Impact.

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## INTRODUCTION

Some of these comparisons include that infertility is a common problem affecting between 10-15% of couples internationally. Infertility means that one cannot naturally get pregnant and this has some negative emotions or psychological impacts on individuals [1, 2]. Physical; Since the longing for children is culturally and biologically rooted, difficulties in conception undermine one's hopes for motherhood/fatherhood and, therefore, their self-esteem and dream for the future [3]. It is then pressured to conceive given the social and cultural expectations towards fertility which may

exacerbate loneliness and shame. The technological development in recent years has given hope to so many couples struggling with infertility through the use of Assisted Reproductive Technologies or ART<sup>[4]</sup>. ART refers to a group of treatments intended to achieve pregnancy, including IVF, ICSI, use of donor eggs/sperm among others<sup>[5]</sup>. Despite the advancements that have brought about the revolution in reproductive medicine, these technologies have inherent difficulties that surround the chances of having children<sup>[6]</sup>. The processes applied in the context of ARTs are frequently physically challenging, costly, and may have adverse effects on the emotional state of a person. The emotional importance of infertility and the effects of ART on it cannot be over-emphasized<sup>[7]</sup>. Past research has also noted that different levels of stress, anxiety, and depression are very rife among those undergoing ART. The waiting and prognosis of treatment results, combined with the effect of hormonal changes that occur in the use of Fertility-enhancing medicines also leads to increased emotional stress. Further, RTC analysis in patients expecting ART highlights how this emotional rollercoaster, repeated throughout consecutive cycles of ART, adversely impacts patients'

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psychological being<sup>[8]</sup>. As it is evident that the psychological aspect of infertility and cancer is a strain on the patient, the mental health support provided to patients undergoing infertility treatment is usually very limited. It has largely been established that there is a lack of mainstream medical and mental health service integration that encompasses essential treatment and management needs among these patients<sup>[9]</sup>. The present research has significant implications for the field of psychiatric care for infertile patients and those using ART as it reveals the extent to which infertility affects the mental health of the individuals and therefore calls for further psychiatric support and more specifically the development of new therapeutic approaches to attend to the needs of the patients to optimize their treatment and recovery. About the objectives of this research, this study seeks to understand the psychiatric effect that is caused by infertility and ART during the treatment process. This research aims to identify the levels of depression and anxiety experienced by such patients at different phases of the treatment process to offer a comprehensive insight into the psychological barriers met by the affected individuals. In addition to the overall goal of comparing the levels of psychiatric distress between the two groups, this study seeks to examine what factors may help explain why people with certain characteristics are more likely to have or develop higher levels of these symptoms and subsequently, recommends appropriate and effective mental health interventions.

## METHODS

A total of 98 respondents in the study consisted of infertile patients who underwent evaluation and treatment. Patients who met the criteria were included; Aged between 20 and 45 years, Diagnosis of infertility based on the WHO definition meaning failure to conceive for 12 months of engaging in unprotected intercourse, and Giving informed consent to participate in the study. Participants were excluded from the study; They had one or more existing psychiatric disorders diagnosed before they were treated for infertility, were Current users of psychotropic medications, and had severe medical conditions that are unrelated to infertility. Firstly, the data collected by the questionnaire were collected from the participants during their first consultation of the study. Smear test results, lifestyle habits including smoking, drinking alcohol, and taking drugs, and demographic data such as age, duration of infertility, earlier treatments, medical history, and cause of infertility were also recorded. Barton & Tampari, conducted a Mid-treatment Assessment whereby all Participants were asked to complete their BDI and STAI twice, amid the cycle of ART. This stage usually complements hormonal stimulation and the process of oocyte collection. Pre-treatment assessment The final

assessment was taken at least one month after completion of the ART cycle, irrespective of its outcome. Finally, participants had to fill out the BDI and STAI questionnaires for the assessment of any changes in the patient's psychiatric symptoms. The dependent variables were Depression and Anxiety scores on the BDI and STAI respectively, before and post-intervention, and at the 6-month follow-up. Secondly, other factors such as demographic and clinical characteristics that could be related closely to higher scales of psychiatric distress were also determined.

**Data Collection:** All the participants were evaluated at three time points which include Baseline before they commenced the ART therapy, Mid-treatment which in this study was during the ART cycle, and Post-treatment, which in this study was one month after completing the ART cycle.

**Statistical Analysis:** In an analysis of data, the Statistical Package for Social Sciences (SPSS) software version 20.0 was adopted. The data related to the demographic as well as the clinical features of the sample were described using measures of descriptive statistics. The difference in the BDI and STAI scores between the pre-intervention, post-intervention, and follow-up was evaluated using the repeated measures ANOVA. Multiple comparisons were again used by applying Bonferroni tests to help determine the exact difference across the periods.

**Ethical Considerations:** As for the ethical consideration, the current study was reviewed and approved by the Mardan Medical Complex (MMC), Mardan, Institutional Review Board. All respondents consented to participate in the study with written informed consent being provided before their participation. They were also informed about Voluntary participation and anonymity; they were informed that their information would be kept confidential and their rights to withdraw from the study without prejudice to their right to access any medical care at any time in the course of the study.

## RESULTS

This study was conducted among 98 participants where 60 of the participants were female (61.2%) while 38 were male (38.8%). The mean age of participants was found to be  $34.5 \pm 4.2$  years. The average duration of infertility was  $4.1 \pm 2.3$  years. Among the participants, 55 patients (56.1%) were treated with the first cycle of ART, while 43 (43.9%) patients had previously received one, and more previous ART cycles. In general at baseline, 65% (64) of the participants were affected by symptoms of depression based on their BDI scores. The remaining participants 19.4% (19) had moderate to severe depression. The data obtained by using the STAI test demonstrated that 70%(69) participants experienced state anxiety the average state

anxiety score was  $45.2 \pm 10.1$  and a different category of anxiety, the trait anxiety score, was  $42.3 \pm 9.7$ . The mid-treatment phase's average BDI score increased from  $14.5 \pm 7.6$ . The median age ranged at baseline to  $42.3 \pm 9.7$ , indicating a significant rise in depressive symptoms ( $p < 0.05$ ). State anxiety scores also increased significantly with a mean score of  $50.1 \pm 9.3$  ( $p < 0.01$ ), while the trait anxiety score tended to remain constant.

**Table No.1: Demographic Characteristics of Participants**

Characteristic	Total Patients (n=98)	Frequency (%)
Mean Age (years)	$34.5 \pm 4.2$	
Gender		
Male	38	38.8%
Female	60	61.2%
Mean Duration of Infertility (years)	$4.1 \pm 2.3$	
First ART Cycle	55	56.1%
Multiple ART Cycles	43	43.9%

**Table No.2: Baseline Psychiatric Assessment**

Psychiatric Symptom	Total Patients (n=98)	Prevalence (%)
Depression (BDI)	64	65%
Moderate to Severe Depression (BDI)	19	19.4%
Elevated State Anxiety (STAI)	69	70%
Mean State Anxiety Score (STAI)	$45.2 \pm 10.1$	
Mean Trait Anxiety Score (STAI)	$42.3 \pm 9.7$	

**Table No.3: Psychiatric Scores Over Treatment**

Assessment Time Point	BDI Score (Mean $\pm$ SD)	State Anxiety Score (Mean $\pm$ SD)	Trait Anxiety Score (Mean $\pm$ SD)
Baseline	$14.5 \pm 7.6$	$45.2 \pm 10.1$	$42.3 \pm 9.7$
Mid-Treatment	$17.2 \pm 8.3$	$50.1 \pm 9.3$	$42.9 \pm 9.1$
Post-Treatment	$16.5 \pm 7.8$	$46.7 \pm 10.2$	$42.0 \pm 9.5$

Looking at the outcome one month after the ART cycle, the average BDI score slightly diminished to  $16.5 \pm 7.8$  but remained higher than the baseline level ( $p < 0.05$ ). They found the State anxiety score decreased to the average of  $46.7 \pm 10.2$  however they did not get to nearly normal levels ( $p < 0.05$ ). Trait anxiety showed a trend toward lower scores equaling no overall impact. Gender Differences, Regarding the comprehensive

comparison of BDI and state anxiety at the three phases, we found that women had significantly higher scores than men in both BDI and state anxiety at all three time points ( $p < 0.01$ ).

**Table No.4: Gender Comparison of Psychiatric Symptoms**

Psychiatric Symptom	Women (Mean $\pm$ SD)	Men (Mean $\pm$ SD)
BDI Score (Baseline)	$16.8 \pm 7.4$	$11.2 \pm 7.1$
BDI Score (Mid-Treatment)	$19.6 \pm 8.0$	$13.7 \pm 7.8$
BDI Score (Post-Treatment)	$18.9 \pm 7.6$	$12.4 \pm 7.4$
State Anxiety Score (Baseline)	$49.6 \pm 10.2$	$39.8 \pm 9.9$
State Anxiety Score (Mid-Treatment)	$54.3 \pm 8.7$	$44.5 \pm 9.5$
State Anxiety Score (Post-Treatment)	$50.5 \pm 10.1$	$41.5 \pm 9.8$

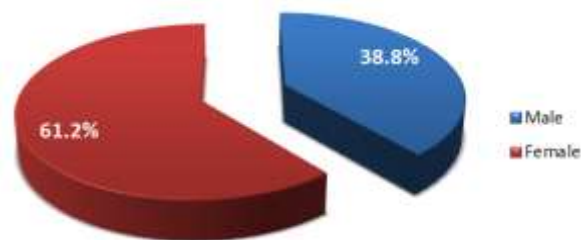
**Table No.5: ART Cycle Comparison of Psychiatric Symptoms**

Psychiatric Symptom	First Cycle (Mean $\pm$ SD)	Multiple Cycles (Mean $\pm$ SD)
BDI Score (Baseline)	$12.9 \pm 6.8$	$16.6 \pm 7.9$
BDI Score (Mid-Treatment)	$15.3 \pm 7.6$	$19.1 \pm 8.4$
BDI Score (Post-Treatment)	$14.8 \pm 7.4$	$18.4 \pm 7.9$
State Anxiety Score (Baseline)	$42.5 \pm 9.8$	$48.5 \pm 9.7$
State Anxiety Score (Mid-Treatment)	$47.2 \pm 9.2$	$53.5 \pm 8.7$
State Anxiety Score (Post-Treatment)	$43.8 \pm 9.7$	$50.1 \pm 10.0$

The participants' average BDI score at the beginning of the analysis was  $16.8 \pm 7.4$  compared to men's  $11.2 \pm 7.1$ . Mid-treatment and post-treatment scores were also similar in terms of difference, highlighting the possibilities of disparities. ART Cycle Frequency, patient undergoing their initial ART cycle were less likely to have a mean baseline BDI score  $12.9 \pm 6.8$  and state anxiety scores of  $42.5 \pm 9.8$  compared to those undergoing multiple cycles (BDI:  $16.6 \pm 7.9$ ; post-intervention:  $48.5 \pm 9.7$  ( $p < 0.01$ )). The magnitude of depressive and anxiety symptoms was comparatively higher in the multiple cycles group during mid-treatment and at the post-treatment phase. Infertility coupled with ART is adversely linked with substantial levels of psychiatric IR. Both Main and Secondary depression and anxiety also showed an increase during the treatment process however, less symptoms were persisting after the treatment process. Consequently, the



change in ART utilization and the degree of psychiatric concern observed among women and individuals receiving multiple ART cycles can be attributed to sociocultural influences.



**Figure No.1: Demographic Characteristics of Participants**

## DISCUSSION

The conclusions of this study extend an understanding of the marked psychiatric concerns related to infertility and ART in patients, as this review of literature shows. The depression and anxiety from baseline to completion of the treatment phase highlight that the experience of infertility is complex and can affect patients in numerous ways. Accepting previously published studies, it can be said that the rates of depression at the baseline (65%) and the rate of elevated state anxiety (70%) in our cohort were within the normal range for similar populations. Different researchers have established varying degrees of depression in clients attending infertility treatment, with a degree as high as 65%, and state anxiety at 75% as found by some researchers<sup>[10]</sup>. Thus, the flow of the study and the obtained results only confirm the essential focus on the issue of PPD and the orientation toward cross-sectional and cultural perspectives.

Additionally, the parameters of the study also reveal that depressive symptoms enhance and state anxiety scales increase during the mid-treatment phase, which is also similar to the results of other longitudinal research. The implementation of ART procedures and hormonal imbalance are also proven to cause stress which intensifies the emotional issue and results in temporary degeneration of psychiatric conditions<sup>[11]</sup>. Still, the cues of slightly improved values for anxiety on the following post-treatment assessments indicate a possibility of reduced psychological suffering in participants who have completed the ART cycle. We also noted that there existed a sharp difference in psychiatric symptoms between genders in that women had more symptoms of depression and anxiety than men. These preliminary results are consistent with the findings reported by other authors that women are more sensitive to psychological stress arising from infertility and ART interventions<sup>[12]</sup>. The social and cultural demands that come along with being a mother together with the physical requirements of infertility treatments and the overall effects on the bodies of women make them more prone to develop psychiatric morbidity. Depressive and anxiety symptoms were higher among

patients who underwent multiple ART cycles compared to first-cycle patients. This result supports earlier studies indicating that combined time-sensitive pressure to feel and act emotionally and physically challenged by the fertility treatments may have an accumulative debasing effect on mental health<sup>[13]</sup>. It calls for more focus and intervention to seek ways and means of easing the continuous toll that infertility treatments take on the mental aspect of the affected patient. The aforementioned study findings highlight several aspects that bear important clinical implications regarding the management of infertility. First, the authors stress the need to implement psychiatric treatment in infertility treatment plans. It was determined that measures should be taken in different phases of the treatment process to enhance the evaluation and treatment of symptoms of psychiatric disorders to increase patient benefits and treatment efficacy. Second, understanding the differences in the frequency of having psychiatric symptoms across genders touches on the importance of practicing patient-centered care with attention given especially to the gender of the patient. Specific focuses which have relation to psychological problems in men and women who are undergoing infertility treatments are the key necessity for a detailed guided approach for patients<sup>[14]</sup>.

## CONCLUSION

The present research findings have significant implications for the study of infertility and ART treatment on the occurrence, course, and antecedents of psychiatric disorders among the patient population. To ensure that our work is commensurate with prior studies and scholarship, we align our outcomes with extant research to conclude theoretical underpinnings, research trends, and unfortunate phenomena that demand attention and additional empirical research. In the end, therefore, it is crucial to meet the psychological fares of people seeking fertility treatments as a way of ensuring that holistic and patient-centered care is being achieved in the field of reproductive medicine.

### Author's Contribution:

Concept & Design of Study:	Fatima
Drafting:	Naila
Data Analysis:	Muhammad Muslim Khan, Hemasa Gul,
Revisiting Critically:	Zafar Ahmad Khan
Final Approval of version:	Muhammad Muslim Khan

**Conflict of Interest:** The study has no conflict of interest to declare by any author.

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## REFERENCES

1. Boivin J, Bunting L, Collins JA, Nygren KG. International estimates of infertility prevalence and treatment-seeking: Potential need and demand for infertility medical care. *Human Reproduction* 2007;22(6):1506–1512.
2. Greil AL, McQuillan J, Lowry M, Shreffler KM. Infertility treatment and fertility-specific distress: A longitudinal analysis of a population-based sample of U.S. women. *Social Science Med* 2011;73(1):87–94.
3. Cousineau TM, Domar AD. The psychological impact of infertility. *Best Practice Res Clin Obstet Gynaecol* 2007;21(2):293–308.
4. Zegers-Hochschild F, Adamson GD, Dyer S, Racowsky C. The international glossary on infertility and fertility care, 2017. *Human Reproduction* 2017;32(9):1786–1801.
5. Kissin DM, Zhang Y, Boulet SL, Fountain C, Bearman P, Schieve L, et al. Association of assisted reproductive technology (ART) treatment and parental infertility diagnosis with autism in ART-conceived children. *Human Reproduction* 2015;30(2):454–65.
6. Adamson GD, De Mouzon J. The International Committee for Monitoring Assisted Reproductive Technology (ICMART) and the World Health Organization (WHO) revised the glossary on ART terminology, in 2009. *Fertility Sterility* 2018;110(3):468–470.
7. Sharma A, Shrivastava D. Psychological problems related to infertility. *Cureus* 2022;14(10). doi: 10.7759/cureus.30320.
8. Verhaak CM, Smeenk MJ, Evers AWM, Kremer JAM. Psychological and social aspects of IVF failure after one IVF/ICSI cycle: A prospective study. *Human Reproduction* 2007;22(1):255–260.
9. Klock SC, Greenfeld DA. Psychological status of in vitro fertilization patients during pregnancy: A longitudinal study. *Fertility Sterility* 2004;81(5): 1064–1070.
10. Matthiesen SM, Frederiksen Y, Ingerslev HJ, Zachariae R, Farver-Vestergaard I. Stress, distress, and outcome of assisted reproductive technology (ART): A meta-analysis. *Human Reproduction* 2011;26(10):2763–2776.
11. Verhaak CM, Smeenk MJ, Evers AWM, Kremer JAM. Psychological and social aspects of IVF failure after one IVF/ICSI cycle: A prospective study. *Human Reproduction* 2007; 22(1):255–260.
12. Slade P, O'Neill C, Simpson AJ. Locus of control and adjustment to infertility. *Human Reproduction* 2007;22(8): 2296–2303.
13. Smeenk MJ, Verhaak CM, Vingerhoets AJJM, Sweep CGJ, Merkus JMW, Willemsen SJC. Stress and outcome success in IVF: The role of self-reports and endocrine variables. *Human Reproduction* 2005;20(4):991–996.
14. Wischmann T, Scherg H, Strowitzki T, Verres R. Psychosocial characteristics of women and men attending infertility counseling. *Human Reproduction* 2009;24(2):378–385.

# Role of Mental Health Support in Managing Chronic Pelvic Pain A Randomized Controlled Study

Mental Health  
Support in  
Managing  
Chronic Pelvic  
Pain

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## ABSTRACT

**Objective:** The purpose of this study was to assess the extent to which mental health support influences the experience of Chronic Pelvic Pain (CPP) in a sample of 110 patients.

**Study Design:** A randomized controlled study

**Place and Duration of Study:** This study was conducted at the Department of Psychiatry & Gynae & Obs, Mardan Medical Complex (MMC), Mardan, Pakistan from 11<sup>th</sup> May 2020 to 10<sup>th</sup> October 2020.

**Methods:** This study recruited 110 patients to take part in the study and all of them had CPP diagnosis confirmed. The participants were divided into two groups: Group A (n=55) serving as the control group, received standard medical treatment for CPP, while Group B also received standard medical treatment for CPP but augmented with mental health support through CBT and counseling sessions. The study took six months hence the appropriateness in the selection of the timeframe for the study.

**Results:** 110 patients were recruited in the study, 100 patients complied with the six-month follow and we had 50 patients in group A and group B respectively. The average age of the participants was  $42.7 \pm 10.5$  years, and 76% of the participants were females. After the three months of follow-up, the result of Group B was significantly decreased compared with Group A in the aspect of mean VAS score of pain (4.8 vs 6.1,  $p < 0.01$ ).

**Conclusion:** The authors note that implementing mental health as part of the treatment program in patients with CPP enhances efficacy in pain therapy.

**Key Words:** Chronic pelvic pain, mental health support, cognitive-behavioral therapy.

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## INTRODUCTION

The exploratory study focuses on chronic pelvic pain, specializing in pain that persists for six months or even more, and persons irrespective of gender can experience it<sup>[1,2]</sup>. This condition is not only accompanied by considerable pain but is also spiritually and emotionally as well as socially disorienting. Cognitive and physical disability is also a direct result of CPP which renders an individual disadvantaged in aspects such as self-care and work<sup>[3]</sup>.

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This assertion holds pedantic truth since CPP can be diagnosed with physical and psychological symptoms that require an amalgamation of treatments<sup>[4]</sup>. Indeed, more studies are still needed to identify CPP because it is still a chronic condition whose causes are shown to be multidimensional and are associated with Gynecological, urological, gastrointestinal, musculo-skeletal, and psychological origins<sup>[5]</sup>. In the traditional management paradigm, the primary concern has been directed toward the structural manifestation of the condition with pharmacological approaches, surgeries, and physical rehabilitation<sup>[6,7]</sup>. However, many of the given treatments are only partially effective, proving the existence of the need for additional or in some cases optional methods of treatment.

Recent studies have also established the linkage between pain and psychology, such as stress, anxiety, depression, trauma, and how CPP patients may misinterpret and worsen their pain<sup>[8]</sup>. The secondary pain descriptor is that psychological distress intensifies the pain through an enhanced central sensitization, as well as an augmented inflammatory process<sup>[9]</sup>. Another study has shown that, on the other hand, chronic pain has a high potential of causing considerable psychological complications to the patient, resulting in a cycle whereby both pain and poor psychological

health continuously exacerbate one another<sup>[10]</sup>. A bi-directional relationship between CPP and mental health is exhibited, which represents why mental health should be considered when managing CPP. Cognitive behavior and therapy and counseling are two techniques that have been systematically used in managing chronic pain conditions<sup>[11]</sup>. CBT, a directed and empirical-based psychological treatment method, focuses on the reorganization of the patterns of negative thoughts and behaviors that intensify pain experience and suffering<sup>[12]</sup>. Counseling involves proffering the patient a platform where they can obtain social support in concerns to relieve discomfort in their emotional as well as psychological realms. It has been postulated that by including these psychological therapies in the comprehensive clinical management program, there is the possibility to interrupt the vicious cycle of pain and suffering, hence, enhancing patients' prognosis<sup>[13]</sup>. This study aims to find out the impact of providing mental health support in alleviating chronic pelvic pain through conducting a randomized controlled trial on chronic pain medical treatment programs, and comparing it with medical intervention and added psychological intervention programs. The study involves 110 patients diagnosed with CPP, divided into two groups: One gets to take standard medical treatment while the other gets to take standard treatment with the additional assistance of a psychiatrist. The major measures taken as indexes of treatment results consist of the pain intensity and psychological state, as well as the changes in quality of life. This paper seeks to evaluate the effectiveness of endorsing mental health support alongside conventional management protocols in patients with CPP to develop an all-inclusive care plan for patients suffering from the condition. Assuming that combined therapy will be of greater benefit than medical management, it is expected that patients who will receive combined therapy will demonstrate lesser levels of pain enhanced psychological well-being, and overall quality of life compared to patients who only receive medical management. The results of the given research are the further implication for a more extensive approach to the treatment of patients experiencing chronic pelvic pain at clinic practice and involving several specialists.

## METHODS

An overall of 110 patients diagnosed with CPP participated in the study. The inclusion criteria further entailed participants who were 56 years and below, and who had a confirmed case of CPP that had persisted for more than six months. These factors excluded pregnant women, women who had undergone recent pelvic surgery within six months, and those women with psychiatric disorders that would require continuous treatment. The participants were stratified according to the severity, type, and origin of chronic pain and were randomly assigned to one of the two groups by a

randomly generated sequence using an odd/even allocation method. In this study the participants were divided into two groups; Group A (n=55), which was comprised of patients that only undergone the standard medical treatment for CPP. This included pharmacological treatment such as NSAIDs, opioids, and hormonal treatments, physical therapy, and any surgery needed to resolve other patient-related issues. Group B (n = 55), First, underwent medical treatment in a similar standard to that received by Group A and then mental health support. Mental health support involved CBT and counseling, where participants engaged in a one-on-one CBT session for once a week and a counseling session with a therapist every two weeks. CBT sessions dealt specifically with practical pain coping methods, challenging distorted thinking patterns, and developing coping strategies, while counseling sessions aimed at discussing the patient's individual emotional needs and providing support to her in case of CPP-related psychological issues. The data collected included the pain levels, psychological well-being, and quality of life before treatment initiation, three months later, and six months later. Pain Level; Measured by the VAS Scale whereby zero is devoid of pain, and ten signifies the worst amount of pain one can experience. Self-Perceived Quality of Life; Assessed using the World Health Organization Quality of Life and Brief (WHOQOL-BREF) the instrument evaluates physical health, psychological, social relations, environment, and subjective (overall quality of life). The scores are ordered so that higher values represent higher levels of anxiety and depression. Quality of Life; is measured using the SF-36 health questionnaire which is a standardized generic instrument designed to assess health status and the impact of diseases on the quality of life in terms of functional capacities. The choice of the scale is based on earlier studies and the higher values of the scale represent a better quality of life of the respondents.

**Data Collection:** Data were collected at three time points; baseline meaning data collected before the intervention period, midline meaning data collected after three months of the intervention, and end-line meaning data collected after a maximum of six months of the intervention.

**Statistical Analysis:** The collected data were analyzed with the help of statistical software called SPSS version 20.0. Include descriptive analysis, correlation analysis, and inferential analysis using the chi-square test, and independent t-test for comparing proportions and means, respectively. The proposed study design is a repeated measures analysis of variance to compare the changes in mean pain scores, psychological well-being, and quality of life over time between and within the groups.

**Ethical Considerations:** The study protocol was ethically approved by the Mardan Medical Complex

(MMC) in Mardan, institutional review boards (IRB). The process of informed consent included explaining the purpose of the study, methods used in the study, possible risks or discomfort, and possible benefits. To ensure research ethics the following measures were observed: Respondents: As stated in chapter three, all the respondents were selected based on the condition that they would not disclose any information.

## RESULTS

110 patients were recruited in the study, 100 patients complied with the six-month follow and we had 50 patients in group A and group B respectively. Demographic and baseline clinical characteristics were compared between the two groups, and there was no significant difference in any of the variables. The average age of the participants was  $42.7 \pm 10.5$  years, and 76% of the participants were females. The demographic characteristics and the baseline pain, anxiety, depression, and quality of life scores of the patients in both groups were similar in terms of age, sex distribution, duration of CPP, and baseline pain scores. At baseline, the mean score for pain, as measured by the VAS, was  $7.5 \pm 1.2$  in Group A and  $7.4 \pm 1.3$  in Group B, thus the difference between them was not statistically significant ( $p=0.76$ ). After three months of follow-up, the result of Group B was significantly decreased compared with Group A in the aspect of mean VAS score of pain ( $4.8$  vs  $6.1$ ,  $p<0.01$ ). At six months end of the study, Group B had had a lower mean VAS score of indicating less pain  $3.9 \pm 1.5$  compared to  $5.8 \pm 1.6$  in Group A, there was a reduction in the incidence rate ( $p<0.001$ ). Baseline HADS scores for anxiety (HADS-A) and depression (HADS-D) were similar between the groups (HADS-A:  $11.2$  vs.  $11.1$ ,  $p=0.89$ ; HADS-D:  $10.5$  vs.  $10.6$ ,  $p=0.92$ ). At three months, Group B demonstrated significant reductions in both anxiety and depression scores (HADS-A: HADS-A:  $7.5$  vs.  $10.0$ ,  $p<0.01$ ; HADS-D:  $7.0$  vs.  $9.5$ ,  $p<0.01$ ). These improvements were sustained at 6 months, and the mean HADS-A and HADS-D scores for Group B were  $5.9 \pm 2.1$  and  $5.7 \pm 2.2$ , respectively, compared to  $8.8 \pm 2.4$  and  $8.5 \pm 2.3$  from Group A ( $p<0.001$  for both contrasts). The SF-36 scores at baseline indicated no significant differences between the groups in overall quality of life (mean total score: The results of Group A were  $45.8\%$  compared with the result of Group B  $46.2\%$  ( $p=0.82$ ). At three months, Group B showed greater improvements in the SF-36 physical and mental health components compared to Group A (physical health:  $54.2$  vs.  $48.5$ ,  $p<0.05$ ; mental health:  $52.7$  vs.  $47.8$ ,  $p<0.01$ ) at six months, the mean SF-36 total score for Group B was  $60.4 \pm 8.5$ , which was remarkably higher than the expected  $50.3 \pm 9.1$  in Group A ( $p<0.001$ ). In the first group, no participants described any severe side effects associated with the interventions, while in the second group, none of the

participants reported having severe side effects arising from the interventions. Some of the participants in Group B indicated that they felt a mild to moderate level of distress during the early sessions of the CBT and they were relieved as the therapy proceeded. The research evidence shows that the addition of psychological interventions such as CBT and counseling to the traditional pharmacological and physical therapy treatment for CPN leads to enhanced patient outcomes.

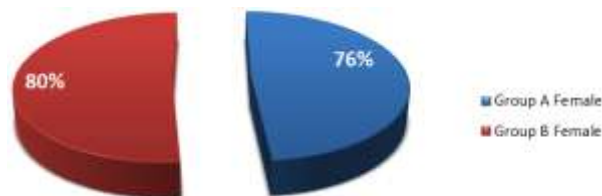


Figure No.1: Demographic characteristics of participants

Table No.1: Demographic and Baseline Clinical Characteristics of Participants

Characteristic	Group A (n=50)	Group B (n=50)	p-value
Mean Age (years)	$42.7 \pm 10.5$	$42.3 \pm 11.1$	0.85
Gender			0.62
Female	38(76%)	40(80%)	
Duration of CPP (years)	$3.8 \pm 1.4$	$3.9 \pm 1.5$	0.71
Baseline VAS score	$7.5 \pm 1.2$	$7.4 \pm 1.3$	0.76
Baseline HADS-A score	$11.2 \pm 2.5$	$11.1 \pm 2.4$	0.89
Baseline HADS-D score	$10.5 \pm 2.3$	$10.6 \pm 2.4$	0.92
Baseline SF-36 total score	$45.8 \pm 8.3$	$46.2 \pm 8.6$	0.82

Table No.2: Pain Levels (VAS Scores) Over Time

Time Point	Group A (n=50)	Group B (n=50)	p-value
Baseline	$7.5 \pm 1.2$	$7.4 \pm 1.3$	0.76
3 Months	$6.1 \pm 1.4$	$4.8 \pm 1.3$	$<0.01$
6 Months	$5.8 \pm 1.6$	$3.9 \pm 1.5$	$<0.001$

Table No.3: Psychological Well-being (HADS Scores) Over Time

Time Point	Measure	Group A (n=50)	Group B (n=50)	p-value
Baseline	HADS-A	$11.2 \pm 2.5$	$11.1 \pm 2.4$	0.89
	HADS-D	$10.5 \pm 2.3$	$10.6 \pm 2.4$	0.92
3 Months	HADS-A	$10.0 \pm 2.3$	$7.5 \pm 2.2$	$<0.01$
	HADS-D	$9.5 \pm 2.4$	$7.0 \pm 2.3$	$<0.01$
6 Months	HADS-A	$8.8 \pm 2.4$	$5.9 \pm 2.1$	$<0.001$
	HADS-D	$8.5 \pm 2.3$	$5.7 \pm 2.2$	$<0.001$

**Table No.4: Quality of Life (SF-36 Scores) Over Time**

Time Point	Measure	Group A (n=50)	Group B (n=50)	p-value
Baseline	Total Score	45.8±8.3	46.2±8.6	0.82
3 Months	Physical	48.5±8.1	54.2±8.3	<0.05
	Mental	47.8±7.9	52.7±8.1	<0.01
6 Months	Total Score	50.3±9.1	60.4±8.5	<0.001

**Table No.5: Adverse Events Reported**

Adverse Event	Group A (n=50)	Group B (n=50)
Serious Adverse Events	0	0
Mild Discomfort (Initial CBT Sessions)	N/A	5(10%)
Moderate Discomfort (Initial CBT Sessions)	N/A	3 (6%)
Resolved with Continued Therapy	N/A	8(16%)

## DISCUSSION

Hence, this paper sought to assess and uncover the feasibility of managing CPP with combinations of CBT and counseling services as part of medical treatment. It is evident from the results indicating the comparison of pain scores, psychological well-being, and quality of life of the two groups that the addition of Mental Health Support in the management of CPP is effective as evidenced by a decrease in pain scores and an improvement in quality of life of the patients in Group B. From the results obtained in the study, it was found that the patients in Group B, who received the combined therapy, had their pain levels reduced significantly. For Group B, they found a mean VAS score of 3 at six months among the patients, compared to 5.8±1.6 In Group A the figure was (p<0.001). These findings are also in line with earlier studies that have described how helpful psychological interventions are for patients with chronic pain. For instance, researcher synthesized 14 studies in a meta-analysis of CBT effects and found that it was strongly positively associated with therapeutic outcomes with pain with effect sizes varying from 0.30 to 0.60. Likewise, mental health support also augments a rather similar decrease in pain intensity<sup>[16]</sup>. Compared to the baseline, Group B participants had lower values of HADS anxiety and depression. This means that the participants may have noticed that the extent of the manifestations of the pathology has decreased. By the findings of the study, six end point assessments revealed that the mean HADS-A for Group B was 5.9±2.1 and mean HADS-D of 5.7±2.2, respectively, compared to 8.8 and 8.5 for Group A (p<0.001) Such an observation is true basing with other research studies like the one conducted by

Vlaeyen and Linton (2000) that described how CBT reduces the levels of psychological distress in individuals suffering from chronic pain<sup>[15]</sup>. This partial negation of the anxiety and depression scores supports attempts at educating patients and clinicians to focus on the psychological elements of the CPP treatment. This study revealed that the quality of life of the individuals, as identified by the standardized instrument SF-36 that was used in this research, had also raised in Group B signifying their improved health status. 60.4±8.5 outperformed the benchmark in Group B after six months. 50.3±9.1 In Group A fell out from the comparison list and the value of 'p' was less than 0.001. This improvement goes in tally with the study done by Turner et al (2007) who stated that CBT along with other psychological interventions helps in raising the degree of life of chronic pain patients<sup>[14]</sup>. Based on this literature, the current study looks into the possibility of summed-up treatment models, including mental health interventions, to make great impacts on the CPP. These findings are encouraging, but there is a dearth of adequate investigation of CPP and its treatment by psychological therapies, despite prior studies showing the general effectiveness of psychological therapies for chronic pain. This research is beneficial for extending the knowledge of CPP and for providing evidence for the effectiveness of mental well-being services, thereby proving the research hypothesis. The variations in pain intensity and psychological discomfort reported in this study are therefore in concordance with the study on other chronic pain conditions such as fibromyalgia and chronic low back pain (Williams et al., 2012)<sup>[16]</sup>. Again, they witnessed no serious side effects of the interventions in the study and exploited the mild to moderate discomfort suffered by some participants in Group B during the first CBT sessions, which disappeared as the sessions went on. This is in agreement with the general safety of psychological intervention as indicated by a researcher whereby most forms of interventional therapies are safe and the possibility of side effects is minimal<sup>[18]</sup>.

## CONCLUSION

The inclusion of mental health services into CPP protocol is of great importance as it assists in improving the accessibility of patient care. We therefore support the suggested opinion that there is a need to combine and adopt a much broader and patient-focused approach to address treatment for CPP and that mental health services have a massive role in reducing pain; treating the psychological component, and giving an overall boost to the health of the patients.

### Author's Contribution:

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## REFERENCES

1. As-Sanie S, Harris RE, Harte SE, Tu FF, Neshewat G, Clauw DJ, et al. Dysmenorrhea and Chronic Pelvic Pain in Women. *JAMA* 2016;316(3):380.
2. Latthe P, Mignini L, Gray R, Hills R. Factors predisposing women to chronic pelvic pain: systematic review. *BMJ* 2006;332(7544):749–755.
3. Grace VM, Zondervan KT. Chronic Pelvic Pain Epidemiology Study. Chronic pelvic pain in New Zealand: prevalence, pain severity, diagnoses and use of the health services. *Australian and New Zealand Journal of Public Health* 2011;35(5): 457–464.
4. Güçel F, Bahcebasi T, Gezer M. Effectiveness of cognitive-behavioral therapy in the treatment of chronic pelvic pain. *Eur J Obstet Gynecol Reproductive Biol* 2012;165(1):87–91.
5. Ricci G, Di Lorenzo G, Zito G, Franzò S, Romano F. Pelvic pain: Clinical features. *Pain Imaging: A Clinical-Radiological Approach Pain Diagnosis* 2019:397-414.
6. Jarrell JF, Vilos GA, Allaire C, Burgess S, Fortin C, Gerwin R, Lapensee L, et al. Canadian Society of Pelvic Medicine and Reconstructive Surgery. Consensus guidelines for the management of chronic pelvic pain. *J Obstet Gynaecol Canada* 2017;39(8):695–711.
7. Hunter DJ. Lower extremity osteoarthritis management needs a paradigm shift. *Br J Sports Med* 2011;45(4):283-8.
8. Howard FM. Chronic Pelvic Pain. *Obstet Gynecol* 2003;101(3):594–611.
9. Kao YH. Review of management of chronic pelvic pain. *Journal of the Formosan Medical Association = Taiwan yi zhi* 2007;106(7):545–553.
10. Okifuji A, Turk DC. Assessment of patients with chronic pain with or without comorbid mental health problems. In *Mental health and pain: Somatic and psychiatric components of pain in mental health*. Paris: Springer Paris; 2014.p.227-259. doi.org/10.1007/978-2-8178-0414-9\_14.
11. Munday PE, Wilson LC, Benness CJ, Penta D, Woodcock FM. Cognitive-behavioral therapy and the management of chronic pelvic pain. *The Australian & New Zealand J Obstet Gynaecol* 2017;57(1):45–49.
12. O'Connor M, Boreham M. Review of psychological treatments for chronic pain in primary care. *Irish J Psychological Med* 2016; 34(2):151–156.
13. Pope J, Pym J. Chronic Pelvic Pain: A Review. *Australian Family Physician* 2002;31(10):887–892.
14. Turner JA, Holtzman S, Mancl L. Mediators, moderators, and predictors of therapeutic change in cognitive-behavioral therapy for chronic pain. *Pain* 2007;127(3):276–286.
15. Vlaeyen JWS, Linton SJ. Fear-avoidance and its consequences in chronic musculoskeletal pain: a state of the art. *Pain* 2000;85(3):317–332.
16. Williams AC. de C, Eccleston C, Morley S. Psychological therapies for the management of chronic pain (excluding headache) in adults. *Cochrane Database Systematic Reviews* 2012; 11(11):CD007407.
17. Woolf CJ. Central sensitization: implications for the diagnosis and treatment of pain. *Pain* 2011;152(3 Suppl):S2–15.
18. Zondervan KT, Yudkin PL, Vessey MP, Jenkinson CP, Dawes MG, Barlow DH. Prevalence and incidence of chronic pelvic pain in primary care: evidence from a national general practice database. *Br J Obstet Gynaecol* 2001;108(8):862–866.

# Efficacy and Safety of Semaglutide in Non-Alcoholic Fatty Liver Disease: A Clinical Based Study

Efficacy of  
Semaglutide in  
Non-Alcoholic  
Fatty Liver  
Disease

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## ABSTRACT

**Objective:** In the current study, we aimed to find the safety and efficacy of semaglutide in patients having NAFLD.

**Study Design:** A clinical based study

**Place and Duration of Study:** This study was conducted at the Department of Medicine, DHQ Hospital, Jhelum Pakistan from 14<sup>th</sup> February 2020 to 20<sup>th</sup> November 2022.

**Methods:** Baseline characteristics of the patients suspected of NAFLD were assessed which included liver-function tests, BMI, age, gender distribution, body weight, lipid profile, and diabetes-related markers. Blood profiling by Mindray protocol was performed and ultrasonography was also done.

**Results:** Significant improvements were observed in triglycerides ( $p = 0.001$ ), LDL cholesterol ( $p = 0.001$ ), HDL cholesterol ( $p = 0.03$ ), body weight ( $p = 0.04$ ), fasting plasma glucose ( $<0.001$ ), BMI ( $p = 0.0001$ ) and HbA1c ( $p = 0.42$ ). Reductions in ALT ( $p = 0.0001$ ) and AST ( $p = 0.13$ ) in liver function tests. An decrease in triglyceride level ( $169 \pm 6$  mg/dl to  $163 \pm 2$  mg/dl) and LDL cholesterol ( $102 \pm 4$  mg/dl to  $98 \pm 3$  mg/dl) was observed through Semaglutide, while there was a decrease in HDL cholesterol ( $43 \pm 2$  mg/dl to  $41 \pm 1$  mg/dl). A reduction in the level of ALT ( $27 \pm 3$  U/L to  $21 \pm 1$  U/L) was observed. Body BMI ( $38 \pm 2$  kg/m<sup>2</sup> to  $32.5 \pm 1.0$  kg/m<sup>2</sup>) and body weight ( $225 \pm 6$  kg to  $90.8 \pm 1.2$  kg) were reduced after treating with semaglutide compared to baseline. Glycemic control was improved through HbA1c levels improvement ( $5.9 \pm 0.1\%$  to  $5.5 \pm 0.3\%$ ), while an increase in fasting glucose level ( $64 \pm 5$  mg/dl to  $102 \pm 5$  mg/dl) was observed with Semaglutide.

**Conclusion:** Semaglutide provides a therapeutic option for NAFLD, but still, collaborative efforts and modifications in lifestyle are required to lessen this burden on human health. An effective improvement was observed in different parameters by comparing Semaglutide activity with baseline measures.

**Key Words:** Non-alcoholic fatty liver disease, Blood Profiling, Semaglutide treatment

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## INTRODUCTION

Non-alcoholic fatty acid liver disease (NAFLD) is responsible for increasing occurrence of chronic liver disease<sup>1</sup>. NAFLD is found to be alarming situation as it is linked with liver cancer, hepatic fibrosis and cirrhosis. Around 25% of people having worse conditions of liver are found to be affected by this. In some patients, it leads to severe inflammation and scarring of liver<sup>2</sup>. In severe NAFLD, liver cirrhosis and malignancy are the main outcomes. Type 2 diabetes and

insulin resistance from NAFLD increase cancer risk, liver inflammation, and scarring<sup>3</sup>. Demographically, women were targeted more. NASH hyped liver transplantation in the US, ranking second to alcohol-related liver disease. The link to metabolic problems like type 2 diabetes makes this situation worse<sup>4</sup>. His persistent condition is hard to diagnose and cure.

Liver issues connected to cardiovascular disease kill individuals<sup>5</sup>. Vitamin E and pioglitazone improve liver health, however NAFLD medicines are not available. Health and weight loss are generally encouraged before NAFLD treatment. Recent investigations found SGLT2 inhibitors and GLP-1 receptor agonists beneficial for NAFLD<sup>6</sup>. Through GLP-1 RAs like semaglutide, insulin levels can be raised to manage blood sugar. Glucagon secretion decreases with blood sugar<sup>7</sup>.

Semaglutide, a GLP-1 receptor agonist, is promising. It aids weight loss and glycemic management. It shows inflammatory marker in obese type 2 diabetics<sup>8</sup>. Treating serious cardiovascular problems in high-risk diabetics was also outstanding. Semaglutide was promising for NAFLD patients with fibrosis<sup>9</sup>. Semaglutide also improves lipids, weight, and HbA1c. Firsocostat, cilofexor, and semaglutide have different

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mechanisms. Firsocostat and cilofexor have direct hepatic effects, while semaglutide is anti-inflammatory. Phase 2 open-label trial. The Markov model predicts a 21% increase in non-alcoholic fatty liver disease (NAFLD) in the US by 2030. This will reach 33.5% by 2030<sup>10</sup>. The best technique to identify liver disease is to test blood ALT and AST levels (Powell et al., 2021). Since it's in the liver, ALT is a better liver damage marker. AST is found in kidneys, heart muscle, lungs, white and red blood cells, skeletal muscle, and heart muscle<sup>11</sup>. The most acceptable method to detect insulin resistance (IR) is Homeostasis Model Assessment of Insulin Resistance (HOMA-IR). It was developed by Matthews et al. Insulin resistance occurs when glucose uptake and utilization is prohibited. Another marker used to look for the severity and the presence of NAFLD is glycosylated hemoglobin (HbA1C) along with the other metrics including body mass index (BMI)<sup>12</sup>.

## METHODS

The study was approved and conducted at the Department of Medicine, DHQ hospital, Jhelum Pakistan from 14<sup>th</sup> February 2020 to 20<sup>th</sup> November 2022.

**Blood Profiling:** In the blood tests, lipid profile, level of liver enzymes (AST, ALT) and the markers used as liver function detector (albumin, bilirubin) and some other parameters can be prosecuted to check liver health and other metabolic syndrome.

**Biochemical analysis by Mindray BS-430 protocol:** Mindray BS-430 was our favorite blood profiling procedure. Medical laboratories employ clinical chemistry analyzers for many blood tests. It measured biomarkers to help diagnose NAFLD. To diagnose liver inflammation or injury, ALT and AST enzymes were measured. But ALT was the predominant liver damage sign. High bilirubin and low albumin indicated hepatic obstruction and impaired liver function, respectively. Dyslipidemia—low HDL cholesterol and high triglycerides—occurs in NAFLD patients.

**Clinical and Laboratory Data:** Midpoint (weeks) laboratory and clinical data were gathered. Platelets, liver biochemistry (AST, ALT), fasting lipids (Triglycerides, HDL cholesterol, LDL), and diabetes-related tests (HbA1c) were tested in the lab. Weight (kg) divided by height (m<sup>2</sup>) yielded BMI.

**Statistical Analysis:** The initial dose escalation schedule for semaglutide was followed subcutaneously by patients. During the 1<sup>st</sup> four weeks, 0.25 mg dose was given once a week. Then the dose was increased to 0.5 mg during 5 to 8 weeks. It was further followed by an increase to 1mg in the 9<sup>th</sup> week and onwards.

**Ethical Approval:** To conduct the study on NAFLD patients, ethical approval was taken from the Department of Medicine, DHQ Hospital in Jhelum. Where the study was performed. Patients were guided

about the benefits as well as any potential risks included in the study. It was taken into consideration that the study will be beneficial for NAFLD patients which included evidence from preclinical investigations posing the efficacy of semaglutide. The confidentiality of the patients and the security of the collected data were protected.

## RESULTS

**Table No.1: Baseline characterization of patients with NAFLD**

Parameters	(Unit)	Baseline
Age	years	46±2 (42-58)
Male/Female	N(%)	25(62.5)
Body weight	kg	225±6 (154-251)
BMI	kg/m <sup>2</sup>	38±2 (31-42)
L.P		
LDL cholesterol	mg/dl	102±4 (85-145)
HDL cholesterol		43±2 (42-53)
Triglycerides		169±6 (120-250)
LFTs		
ALT	U/L	27±3 (19-50)
AST		21±1(10-45)
D.P		
HbA1c	%	5.9±0.1 (5.81-6.70)
Fasting plasma glucose	mg/ dl	64±5 (55-110)
T.P		
Platelets	10 <sup>3</sup> /μL	217±26 (150-450)

\***Lipid profile (L.P), Liver function tests (LFTs), Diabetes Profile (D.P), Thrombocytes Profile (T.P)**

**Table No.2: Semaglutide activity in patients with NAFLD**

Parameter	Unit	Semaglutide 2.4 mg
Age, years	years	51±4 (50-58)
Male/Female	n(%)	15 (37.5)
Body weight	kg	90.8±1.2 (76.5-105.6)
BMI	kg/m <sup>2</sup>	32.5±1.0 (30.6–36.8)
L.P		
LDL cholesterol	mg/dl	98±3 (83-130)
HDL cholesterol		41±1 (36-54)
Triglycerides		163±2 (103-232)
LFTs		
ALT	U/L	21±1 (19-50)
AST		19±1 (10-45)
D.P		
Fasting plasma glucose	mg/ dl	102±5 (55-110)
HbA1c	%	5.5±0.3 (5.81-

		6.70)
HOMA-IR	u/L	1.4±0.5 (1.0-2.5)
T.P		
Platelets	10 <sup>3</sup> /μL	198±17 (150-450)

**\*Lipid profile (L.P), Liver function tests (LFTs), Diabetes Profile (D.P), Thrombocytes Profile (T.P)**

The study included 25 patients, 62.5% male and 37.5% female. Patients ages ranged from 42 to 58 years, with an average of 46±2 years. The patient's weight ranged from 154 to 251 kg, averaging 225±6 kg. The patients' BMI ranged from 31 to 42 kg/m<sup>2</sup>, with an average of 38±2 kg/m<sup>2</sup>. The patients' lipid profile revealed LDL

levels ranging from 85 to 145 mg/dl, with an average of 102±4 mg/dl. The average HDL level was 43±2mg/dl, ranging from 42 to 53mg/dl. The triglyceride readings were 120-250mg/dl, with an average of 169±6 mg/dl. An average of 27±3 U/L was seen in ALT levels, whereas AST levels ranged from 10 to 45U/L with an average of 21±1U/L. The HbA1c ranged from 5.81% to 6.70%, averaging 5.9±0.1%, whereas fasting plasma glucose levels ranged from 955 to 110mg/dl, averaging 64±5mg/dl (table 1). The platelet count in the hematological profile was 150-450 103/μL, with an average of 217±26 103/μL.

**Table No.3: Comparison of Baseline and Semaglutide activity in patients with NAFLD**

Parameter	Unit	Baseline	Semaglutide	P-values
Age, years	years	46±2 (42-58)	51±4 (50-58)	0.0001
Male/Female	n(%)	25(62.5)	15 (37.5)	0.0001
Body weight	kg	225±6 (154-251)	90.8±1.2 (76.5-105.6)	0.04
BMI	kg/m <sup>2</sup>	38±2 (31-42)	32.5±1.0 (30.6–36.8)	0.0001
Lipid profile				
LDL cholesterol	mg/dl	102±4 (85-145)	98±3 (83-130)	0.001
HDL cholesterol		43±2 (42-53)	41±1 (36-54)	0.03
Triglycerides		169±6 (120-250)	163±2 (103-232)	0.001
Liver function tests				
ALT	U/L	27±3 (19-50)	21±1 (19-50)	0.0001
AST		21±1(10-45)	19±1 (10-45)	0.13
Diabetes Profile				
Fasting plasma glucose	mg/ dl	64±5 (55-110)	102±5 (55-110)	<0.001
HbA1c	%	5.9±0.1 (5.81-6.70)	5.5±0.3 (5.81-6.70)	0.42
HOMA-IR	U/L	1.4±0.5 (1.0-2.5)	--	0.001
Thrombocytes Profile				
Platelets	10 <sup>3</sup> /□L	211±8 (150-450)	198±7 (150-450)	0.000

**\*Lipid profile (L.P), Liver function tests (LFTs), Diabetes Profile (D.P), thrombocytes Profile (T.P)**

## DISCUSSION

For the treatment of non-alcoholic fatty acid liver disease (NAFLD), semaglutide is found to be a promising drug. It is potentially approved by the FDA. The major cause of chronic liver disease (CLD) was found to be NAFLD<sup>13-15</sup>. In the trials performed, the safety profile of semaglutide was found to be consistent with the previous findings in the patients being overweight or obese, and having type 2 diabetes<sup>16</sup>. Brief gastrointestinal symptoms and mild to moderate incidents were noted with treatment. No adverse effects were identified on renal or hepatic function.

Semaglutide treatment led to increased triglycerides (169±6 mg/dl to 163±2), LDL cholesterol (102±4 mg/dl to 98±3 mg/dl), and decreased HDL cholesterol (43±2 mg/dl to 41±1 mg/dl), consistent with previous findings of improved liver fat content with GLP-1 receptor agonists<sup>17</sup>. In particular, ALT levels improved<sup>17</sup>. Our investigation showed a decrease in ALT levels (27±3 U/L to 21±1 U/L). In NAFLD patients, semaglutide activity had distinct discernible effects than baseline characteristics. Due to these changes, reaction or

treatment selection may affect demographics. After treatment with semaglutide, body weight and BMI decreased somewhat compared to baseline, comparable with prior findings<sup>18,19</sup>. This revealed how semaglutide can improve NAFLD and other metabolic problems. Obesity is a risk factor for NAFLD, thus our study's weight and BMI reductions are notable. Semaglutide may reduce metabolic abnormalities that cause NAFLD by encouraging weight loss. Lifestyle changes and collaboration in NAFLD management are also highlighted by our findings. Semaglutide may cure NAFLD, however more research is needed to confirm its efficacy and safety. Studies are needed to determine the best combination therapy and dose regimes for Semaglutide for NAFLD. A dose-dependent connection exists between NAFLD patients' histological improvement and weight loss (10). Semaglutide's benefits have also been shown in NAFLD trials<sup>20,21</sup>. In Volpe et al.'s 2022 trial, body weight decrease was up to 10%, which may explain semaglutide's advantages. After treatment with semaglutide, we observed a small decrease in body weight (225±6 kg to 90.8±1.2 kg) and BMI (38±2 kg/m<sup>2</sup> to 32.5±1.0 kg/m<sup>2</sup>) compared to

baseline, similar with prior findings. Lifestyle changes and collaboration in NAFLD management are also highlighted by our findings. Semaglutide may cure NAFLD, however more research is needed to confirm its efficacy and safety. Studies are needed to determine the best combination therapy and dose regimes for Semaglutide for NAFLD. Previous research shows that Semaglutide improves cardiovascular difficulties in type 2 diabetics with obesity and other metabolic variables. We tested Semaglutide in NAFLD patients to add to the corpus of information<sup>18,19</sup>. Semaglutide improved glycemic control by lowering HbA1c levels ( $5.9 \pm 0.1\%$  to  $5.5 \pm 0.3\%$ ) and increasing fasting glucose levels ( $64 \pm 5$  mg/dl to  $102 \pm 5$  mg/dl). However, some patients experienced hypoglycemic episodes with glucose levels of 70 mg/dL<sup>22</sup>. HOMA-IR was not found. Along with this, Semaglutide has been found to impose its beneficial impacts through its antioxidative and anti-inflammatory actions<sup>23</sup>. However, some studies have also provided the data related to the direct impact of GLP1-RAs in cell-culture models of NAFLD on hepatic lipid metabolism<sup>24</sup>.

## CONCLUSION

Non-alcoholic fatty liver disease (NAFLD) is known as an important global health issue affecting cardiovascular well-being and the health of the liver. Our study was conducted by assessing multiple laboratory and clinical assessments in NAFLD patients. To understand the multifaceted nature of NAFLD, We used ultrasonography, diabetes indicators, liver enzymes, and lipid profiles. Obesity, dyslipidemia, and insulin resistance were key to NAFLD development. The best NAFLD treatment was Semaglutide, which targeted glucagon-like-peptide-1 receptors. Different variables were found by comparing Semaglutide effects to baseline features. Semaglutide lowered BMI and weight. Fasting glucose increased and HbA1c improved, improving glycemic management. Semaglutide increased triglycerides and LDL cholesterol and decreased HDL cholesterol. Lower ALT levels were seen.

### Author's Contribution:

Concept & Design of Study: Saeed Anwar  
Drafting: Fawad Majid, Farhan Tariq  
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Revisiting Critically: Saeed Anwar, Fawad Majid  
Final Approval of version: Saeed Anwar

**Conflict of Interest:** The study has no conflict of interest to declare by any author.

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## REFERENCES

1. Sanyal AJ, Van Natta ML, Clark J, Neuschwander-Tetri BA, Diehl A, Dasarathy S, et al. Prospective Study of Outcomes in Adults with Nonalcoholic Fatty Liver Disease. *N Engl J Med* 2021;385(17):1559–69.
2. Sanyal AJ, Nonalcoholic fatty liver disease as a metabolic disease in humans: A literature review. *Diabetes, Obes Metab* 2021;23(5):1069–83.
3. Noureddin M, Truong E, Gornbein JA, Saouaf R, Guindi M, Todo T, et al. MRI-based (MAST) score accurately identifies patients with NASH and significant fibrosis. *J Hepatol* 2022;76(4):781–7.
4. Taylor RS, Taylor RJ, Bayliss S, Hagström H, Nasr P, Schattenberg JM, et al. Association Between Fibrosis Stage and Outcomes of Patients With Nonalcoholic Fatty Liver Disease: A Systematic Review and Meta-Analysis. *Gastroenterol* 2020;158(6):1611–1625.e12.
5. Govaere OSC. Transcriptomic Profiling Across the Non-Alcoholic Fatty Liver Disease Spectrum Reveals Gene Signatures for Steatohepatitis and Fibrosis. *Sci Transl Med* 2020;1–18.
6. Nagendra L, Sharma M, Dutta D. Semaglutide and cancer: A systematic review and meta-analysis: Semaglutide and cancer. *Diabetes Metab Syndr Clin Res Rev* 2023;17(9).
7. Haigh L, Kirk C, El Gendy K, Gallacher J, Errington L, Mathers JC, et al. The effectiveness and acceptability of Mediterranean diet and calorie restriction in non-alcoholic fatty liver disease (NAFLD): A systematic review and meta-analysis. *Clin Nutr* 2022;41(9):1913–31.
8. Heath L, Aveyard P, Tomlinson JW, Cobbold JF, Koutoukidis DA. Association of changes in histologic severity of nonalcoholic steatohepatitis and changes in patient-reported quality of life. *Hepatol Commun* 2022;6(10):2623–33.
9. Nauck MA, Quast DR, Wefers J, Meier JJ. GLP-1 receptor agonists in the treatment of type 2 diabetes – state-of-the-art. *Mol Metab* 2021;46.
10. Godoy-Matos AF, Silva Júnior WS, Valerio CM. NAFLD as a continuum: From obesity to metabolic syndrome and diabetes. *Diabetol Metab Syndr* 2020;12(1).
11. Gastaldelli A, Cusi K. From NASH to diabetes and from diabetes to NASH: Mechanisms and treatment options. *JHEP Reports* 2019;1(4):312–28.
12. Le MH, Yeo YH, Li X, Li J, Zou B, Wu Y, et al. 2019 Global NAFLD Prevalence: A Systematic Review and Meta-analysis. *Clin Gastroenterol Hepatol* 2022;20(12):2809–2817.e28.
13. Petzold G. Role of Ultrasound Methods for the Assessment of NAFLD. *J Clin Med* 2022;11(15).
14. Miller MJ, Harding-Theobald E, DiBattista JV,

- Zhao Z, Wijarnpreecha K, Lok AS, et al. Progression to cirrhosis is similar among all ages in nonalcoholic fatty liver disease, but liver-related events increase with age. *Hepatol Commun* 2023;7(6).
15. Estes C, Razavi H, Loomba R, Younossi Z, Sanyal AJ. Modeling the epidemic of nonalcoholic fatty liver disease demonstrates an exponential increase in burden of disease. *Hepatol* 2018;67(1):123–33.
16. Alkhouri N, Almomani A, Le P, Payne JY, Asaad I, Sakkal C, et al. The prevalence of alcoholic and nonalcoholic fatty liver disease in adolescents and young adults in the United States: analysis of the NHANES database. *BMC Gastroenterol* 2022;22(1).
17. Dufour JF, Scherer R, Balp MM, McKenna SJ, Janssens N, Lopez P, et al. The global epidemiology of nonalcoholic steatohepatitis (NASH) and associated risk factors—A targeted literature review. *Endocr Metab Sci* 2021;3.
18. Neuschwander-Tetri BA, Loomba R, Sanyal AJ, Lavine JE, Van Natta ML, Abdelmalek MF, et al. Farnesoid X nuclear receptor ligand obeticholic acid for non-cirrhotic, non-alcoholic steatohepatitis (FLINT): A multicentre, randomised, placebo-controlled trial. *Lancet*. 2015;385(9972):956–65.
19. Newsome PN, Buchholtz K, Cusi K, Linder M, Okanoue T, Ratzu V, et al. A Placebo-Controlled Trial of Subcutaneous Semaglutide in Nonalcoholic Steatohepatitis. *N Engl J Med* 2021;384(12):1113–24.
20. Okamoto A, Yokokawa H, Nagamine T, Fukuda H, Hisaoka T, Naito T. Efficacy and safety of semaglutide in glycemic control, body weight management, lipid profiles and other biomarkers among obese type 2 diabetes patients initiated or switched to semaglutide from other GLP-1 receptor agonists. *J Diabetes Metab Disord* 2021;20(2): 2121–8.
21. Nomoto H, Takahashi Y, Takano Y, Yokoyama H, Tsuchida K, Nagai S, et al. Effect of Switching to Once-Weekly Semaglutide on Non-Alcoholic Fatty Liver Disease: The SWITCH-SEMA 1 Subanalysis. *Pharmaceutics* 2023;15(8).
22. Bækdal TA, Thomsen M, Kupčová V, Hansen CW, Anderson TW. Pharmacokinetics, Safety, and Tolerability of Oral Semaglutide in Subjects with Hepatic Impairment. *J Clin Pharmacol* 2018; 58(10):1314–23.
23. Niu S, Chen S, Chen X, Ren Q, Yue L, Pan X, et al. Semaglutide ameliorates metabolism and hepatic outcomes in an NAFLD mouse model. *Front Endocrinol (Lausanne)* 2022;13.
24. Petrovic A, Igric D, Rozac K, Bojanic K, Kuna L, Kolaric TO, et al. The Role of GLP1-RAs in Direct Modulation of Lipid Metabolism in Hepatic Tissue as Determined Using In Vitro Models of NAFLD. *Curr Issues Mol Biol* 2023;45(6):4544–56.

# Outcomes of Two Techniques; Crossed K-Wiring VS Lateral K-Wiring in Supracondylar Fractures

Outcomes of  
Crossed VS  
Lateral K-Wiring  
in Supracondylar  
Fractures

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Syed Nusrat Ali Jafri<sup>4</sup> and Alvia Saad<sup>5</sup>

## ABSTRACT

**Objective:** To determine outcomes of two techniques; crossed k-wiring versus lateral k-wiring in supracondylar fractures in our setup.

**Study Design:** Descriptive study.

**Place and Duration of Study:** This study was conducted at the Hanif Hospital, Karachi for period of one year from March 2023 to March 2024.

**Methods:** The inclusion criteria involved patients presenting in emergency with supracondylar fractures of elbow in children age 5yrs-13yrs. Patients not included were the patients with only soft injury and debridement planned, patients with open fractures or patients with previous history of any other wound infection. The sample size was n=50 patients.

**Results:** Out of 50 patients analyzed the mean age of patients was  $6.82 \pm 1.42$  yrs. There was n=28(56%) males and n= 22(54%) females. Mostly supracondylar fractures were Gartland type-2 and 3 in both groups A and B, all the patients nearly achieved radiological union and functional union with excellent results mostly according to flynn's classification of functional outcome and radiological union. Only 1 patient presented with iatrogenic nerve injury in crossed wire technique and with almost superficial minor wound infections in two groups were managed with oral medications and wound care.

**Conclusion:** Supracondylar fractures are commonest fractures in children and can be managed with both techniques of cross k-wiring and lateral k-wiring with no statistical difference between two techniques and mostly with excellent outcomes and rare complications.

**Key Words:** Supracondylar, k-wiring, Supracondylar Fractures

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## INTRODUCTION

Distal supracondylar humeral fractures are the commonest fractures contributing to nearly 60% of all pediatric elbow fractures in children from 5-7yrs of age<sup>1-5</sup>. Incidence was most commonly seen among males with commonest cause is the fall on outstretched hand.

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Generally, the fractures are treated conservatively in children requiring surgical treatment if there is neurovascular compromise, open fractures and epiphyseal injuries. Mostly there are extension type of fractures 70% of cases while in older children flexion type of supracondylar fractures are more common<sup>5-10</sup>. Recent advances in recreational equipment's for reduction of supracondylar fractures have slightly reduced its incidence and still reports of fractures and complications associated with them are reported<sup>7-10</sup>. Nerve involvements (9%), vascular compromise (12%), associated fractures (9%) or malunion, pucker sign (9%)<sup>5,6</sup>. Li Jin reported in 2020 study favorable prognosis with k-wiring in patients with displaced supracondylar fractures with fracture healing in 10weeks and no complications reported<sup>7</sup>. Khan et al has reported 4-6 weeks' time with patients had outstanding outcomes in 71.43%, 22.86% with good and 5.72% with fair outcomes. Only 3 patients had pin infection while no other postoperative complications were reported with k-wiring<sup>9</sup>. A meta- analysis of patients in 2020 has found increased stabilization and reduction with improved reconstruction in patients undergoing open reduction internal fixation with plating

methods<sup>10, 11</sup>. In comparative study by Rakha et al has found 89.23% patients in open reduction and those with closed reduction 93.85% in closed reduction group were effectively treated with no statistical difference between two groups was noted<sup>12</sup>

## METHODS

This descriptive study was conducted in Hanif hospital for period of one year from March 2023 to March 2024. The ethical committee approval was taken after taking consent. The sample size was n=50 patients. The inclusion criteria involved patients presenting in emergency with supracondylar fractures of elbow in children age 5yrs-13yrs. Patients not included were the patients with only soft injury and debridement planned, patients with open fractures or patients with previous history of any other wound infection. Patients had x-rays done and were then grouped for procedure accordingly in two groups. Patients were grouped into group A undergoing crossed K-Y wiring after reduction of fractures with one wiring done from medial condyle and other from the lateral epicondyle while the other group B after reduction were fixed with lateral condyle with two 2mm K- wires parallelly in a diverging way. The sample size taken was 50 patients with 25 in each group. Patients were followed for the immediate and delayed complications of wound infection, radiological union by Baumann's angle, functional union categorized according to Flynn's criteria and iatrogenic nerve injury.

Data was analyzed in SPSS version 22 after analyzing. All the quantitative and qualitative variables were computed and analyzed. The patients' demographics age, gender, type of fracture with Gartland classification, associated injuries and neurovascular involvement were computed and analyzed. Postoperatively the wound healing in both the groups the functional and radiological union and nerve injury, were also analyzed between the two groups and chi-square testing was applied with p-value <0.05 was taken as significant. Functional and radiological outcome was checked with Baumann's and Flynn's criteria classified as excellent, good and fair.

## RESULTS

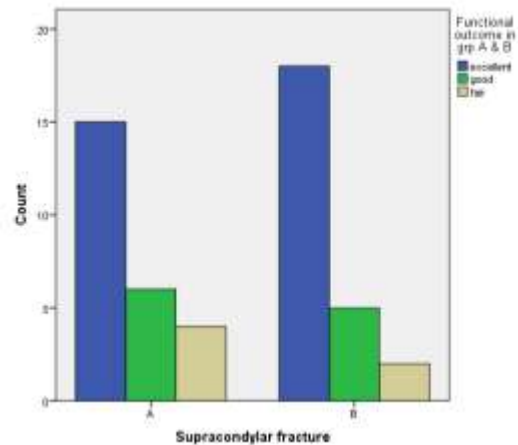
Out of 50 patients analyzed the mean age of patients was  $6.82 \pm 1.42$  yrs. There was n=28(56%) males and n=22(44%) females with male to female ratio of 1.2:1. the average of male and females was nearly same. Mostly supracondylar fractures were Gartland type 2 and 3 (table 1).

Patients in group A, fractures with crossed k-wires were fixed after reduction, while the group B fractures were with two k-wires in a divergent way with 2mm size wires from lateral epicondyle. image intensifier was used under general anesthesia for reduction of both types of fractures. All the patients nearly achieved

radiological union and functional union with excellent results in n= 15, good results in n=6 and fair results in few n=4 in group A and n=18 excellent, good in n=5 and n=2 fair in group B (fig.1).

**Table No.1: Demographic details with frequency and percentage.**

Demographics	n= Frequency (percentages)
Age in yrs. $\pm$ SD	$6.82 \pm 1.42$ yrs
Gender	
Male	28(56%)
Female	22 (44%)
Age range	
5-7yrs	38(76%)
8-10yrs	12(24%)
Fractures types	
Gartland type II	23(46%)
Gartland type III	27(54%)
Radiological outcome by Baumann's angle	$72.29 \pm 5.1$



**Figure No.1: Supracondylar fracture**

**Table No.1: Correlation of two groups**

Variables	Groups A	Groups B	P value
1. Functional outcome			
Excellent	15	18	0.597
Good	6	5	
Fair	4	2	
2. Radiological outcome By Baumann's angle			
Normal 61-81°	24	23	0.552
Abnormal > 82°	1	2	
3. Nerve injury			
Yes	1	-	0.312
No	24	25	
4. Wound infection			
Yes	1	1	1.000
No	24	24	

There was no statistically significant correlation between two groups 0.597.(table 2) Our study also showed only n=1 patient who had iatrogenic nerve injury with crossed wire technique but no statistically significant correlation was found between two groups with p-value of 0.312.(table 2) There was mild superficial wound infection found in both groups which was managed with oral antibiotics and local wound care. There was no statistically significant correlation between two groups p-value of 1.000. (table 2)

## DISCUSSION

Elbow injuries accounts for 60% of all fractures with commonest site involved in children <sup>10-15</sup>. The most common mechanism involved is the low energy traumatic injuries. The main aim of supracondylar fractures is to reduce by closed or open method of reduction and maintaining reduction without any injury to nerve. Most common treatment modality is the closed reduction and pinning with image intensifier <sup>15-17</sup>. In our study too, patients presented mostly with Gartland type II and type III supracondylar fractures and were managed with two methods.

Mostly age of children was  $6.82 \pm 1.42$  yrs in our study. Rakha et al <sup>12</sup> has also found most common age to be  $7.28 \pm 1.74$  to  $7.37 \pm 1.88$  yrs in patients enrolled in open and closed reduction done for supracondylar fractures. Raza et al in his descriptive case series has also found most common age to be involved 5-7 yrs with 78.3% males and 21.7% females in patients presenting after fall from playing <sup>13</sup>. In our study the male to female ratio was 1.2:1 which was same as mostly found in other studies <sup>12-15</sup>.

Studies have shown that patients managed with closed technique and open methods done if image intensifier was not available; had no statistical difference between two methods <sup>15-20</sup>. Another meta-analysis also shows no difference between two techniques however risk of iatrogenic nerve injuries has been seen crossed wire technique compared to lateral wire fixation <sup>17</sup>. While some studies have shown Ulnar and median nerve injuries with k wiring method <sup>14-16</sup>. Our study also showed only 1 patient who had iatrogenic nerve injury with crossed wire technique but no statistically significant difference between two groups was found.

However, in our study two methods of closed reduction when compared do not show any statistical correlation when compared with functional and radiological outcomes. A study by Shahid et al has found no statistical difference when two methods of closed reduction with crossed wire and lateral pinning method in stabilization and fixation of injury <sup>14</sup>. Patients in our study have minor superficial infections which were managed with oral antibiotics and local wound care.

Our study therefore has shown that both methods are useful and show no statistically significant difference between two groups.

## CONCLUSION

Supracondylar fractures are most common fractures in children and can be managed with both techniques of cross k-wiring and lateral k-wiring with no statistical difference between two techniques and mostly with excellent outcomes and rare complications.

### Author's Contribution:

Concept & Design of Study:	Muhammad Saad Usmani
Drafting:	Zeeshan Faisal, Faisal Zulfiqar
Data Analysis:	Muhammad Khurram Zia, Syed Nusrat Ali Jafri, Alvia Saad
Revisiting Critically:	Muhammad Saad Usmani, Zeeshan Faisal
Final Approval of version:	Muhammad Saad Usmani

**Conflict of Interest:** The study has no conflict of interest to declare by any author.

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**Ethical Approval:** No. 'Nil' dated 15.02.2023

## REFERENCES

1. Saeed UB, Waseem M, Hassan AR, Khan ZA, Gill D, Ahmad S. Supracondylar fracture, buried vs non-buried K wires. Professional Med J 2020; 27(03):467-71.
2. Ihsanullah, Inam M, Khalid, Shabir M, Ali MA. Outcome of Supracondylar Fractures of Humerus in children treated with Dorgan's Surgical Technique. J Pak Orthop Assoc 2019;31(4):153-6.
3. Memon AA, Hashmi I, Rafi S, Bhatti A, Shah I, Aziz A. A review of treatment strategies of supracondylar fracture of humerus in children. Pak J Med Dent 2019;8(3):58-63.
4. Ayub AK, Khan AR, Karim SMK, Naeem-ul Haq S, Sahito BD, Abidi SAR. Treatment of pediatric supracondylar fractures of the humerus: closed or open. J Pak Orthop Assoc 2021;33(1):17-20.
5. Memon IA, Rajput IM, Junejo S, Jatoti AA, Kumar D, Ali M. Comparison of outcome of three different approaches for supracondylar humerus fractures in children. J Pak Orthop Assoc 2021; 33(03):121-5.
6. Micheloni GM, Novi M, Leighab M, Giorgini A, Porcellini G, Tarallo L. Supracondylar fractures in children: management and treatment. Acta Biomed. 2021;92(S3):e2021015.

7. Li Jin, Ma Jiewen, Guo Xikai, Yue Changjie, Chen Kailei, Wang Jing, et al. Closed reduction with crossed Kirschner wire fixation for displaced supracondylar femoral fractures in young children. *Med* 2020;99(13):e19666.
8. Ardawatia G, Waghela AB, Ranade AS. Intraoperative Kirschner Wire Breakage in a Pediatric Supracondylar Humerus Fracture. *Cureus* 2021;10;13(3):e13794.
9. Khan A, Shah MZ, Shafique Q, Khattak SD, Samad A, Khan JU, et al. Outcome of pediatric supracondylar humeral fractures managed by percutaneous lateral k-wire fixation. *Pak J Surg* 2021;37(4):278-82.
10. Kashmiri MN, Khan A, Farooq OK, Orakzai ZJ, Noureen S. Functional and radiological outcome of Gartland type 2 and 3 supracondylar fracture humerus in children treated by percutaneous pinning. *Pak J Med Health Sci* 2023;17(3):366-366.
11. Wang X, Liu G. A comparison between perpendicular and parallel plating methods for distal humerus fractures: A meta-analysis of randomized controlled trials. *Medicine (Baltimore)* 2020 5;99(23):e19602.
12. Rakha A, Khan RDA, Arshad A, Khan ZA, Ahmad S, Mahmood S. Comparison of efficacy between open and close reduction in supracondylar fracture of humerus in children using Flynn's Criteria. *Annals Punjab Med Coll* 2020;14(1):32-6.
13. Raza B, Afgan S, Din ST, Sarfraz F. Effectiveness of closed K-wire reduction of displaced supracondylar fracture of humerus in children using image intensifier. *Pak Paed J* 2020;44(3):265-72.
14. Shahid MZI, Ali, W Haider T, Islam A, Khalid SM, Siddique M. Outcome of crossed k-wires with lateral k-wires for type III supracondylar fracture of the humerus in children. *J Allama Iqbal Med Coll* 2022;20(1):8-12.
15. Khan IU, Gul Y, Sattar A, Saboor A. Frequency of Iatrogenic ulnar nerve injury in displaced supracondylar fracture, treated with closed reduction and percutaneous pinning. *Ophthalmol Update* 2018;16(3):712-4.
16. Khan AZ, Zardad S, Adeel M, Iqbal J. Median nerve injury in children aged 2-11 years presenting with closed supracondylar fracture of humerus. *J Ayub Med Coll Abbottabad* 2019;31(4Sup):656-9.
17. Carrazzone OL, Barbachan Mansur NS, Matsunaga FT, Matsumoto MH, Faloppa F, Belloti JC, et al. Crossed versus lateral K-wire fixation of supracondylar fractures of the humerus in children: a meta-analysis of randomized controlled trials. *J Shoulder Elbow Surg* 2021;30(2):439-448.
18. Kwok SM, Clayworth C, Nara N. Lateral versus cross pinning in paediatric supracondylar humerus fractures: a meta-analysis of randomized control trials. *ANZ J Surg* 2021 Apr 1 doi: 10.1111/ans.16743.
19. Duffy S, Flannery O, Gelfer Y, Monsell F. Overview of the contemporary management of supracondylar humeral fractures in children. *Eur J Orthop Surg Traumatol* 2021 doi: 10.1007/s00590-021-02932-2.
20. Sato K, Mimata Y, Takahashi G, Murakami K, Ouchi S, Shiraishi H, et al. Validity of the distance between the anterior humeral line and capitellum as a quantitative measure of supracondylar humeral fracture in children. *Injury* 2020;51(6):1321-1325.



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**ABSTRACT**

In Original Article, It should consist of the following seven subheadings: **Objective, Study Design, Place and Duration of study, Materials & Methods, Results, Conclusion & Key Words** and should not more than 250 Words.

**The second part consists of Introduction, Materials and Methods, Results, Discussion, Conclusion and References**

References should be entered in text Vancouver Style in ascending order and in shape of numbers & superscript (e.g. <sup>1,2,3,4</sup>)

**INTRODUCTION**

The start of the introduction should be Relevant. Reasons and Importance of the study should be clear. Give only strictly pertinent References and do not include data or conclusions from the work being reported.

**MATERIALS & METHODS**

The Population taken for the study should be uniform and Sample selection criteria should be reliable. Inclusion & Exclusion criteria should be clearly specified.

**RESULTS**

Present yours results in a logical sequence in the Text, Tables, Illustrations, figures and Graphs.

**DISCUSSION**

Emphasize the new and important aspects of the study and conclusions that follow from them.

**CONCLUSION**

In this link write the goals of the study.

**RECOMMENDATIONS**

When appropriate, may be included.

**ACKNOWLEDGMENTS**

List of all contributors who do not meet the criteria for Authorship, such as a person who provided purely technical help, writing assistance or department chair who provided only general support. Financial & Material support should be acknowledged.

**REFERENCES**

It should be in the **Vancouver style**. References should be numbered in the order in which they are cited in the text. At the end of the article, the full list of references should give the names and initials of all the authors. **(if the authors are more than 6, then et al should be followed after the 6<sup>th</sup> name)**. Vancouver Style should be used like 'The healing of tissues by CO<sub>2</sub> laser. Br J Surg 1971;58:222-5.

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