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# Health Advantages of Garlic

Mohsin Masud Jan

Editor

People have used garlic as food and medicine. In fact, eating garlic may have a number of health advantages. Garlic has powerful smell due to organic sulfur compound called Allicin.

Chronic non-communicable diseases, including cardiovascular diseases, chronic respiratory diseases, cancers, and diabetes, cause 41 million deaths annually. Glucose and lipids are crucial for energy, and their dysregulation can lead to atherosclerosis, diabetes, and fatty liver disease. Dyslipidemia, with high total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), triglycerides (TG), and low high-density lipoprotein cholesterol (HDL-C), is a major cardiovascular risk factor. Current treatments for metabolic diseases focus on symptom relief and have side effects. Garlic, rich in compounds like allicin, shows potential in regulating glucose and lipids. Further research is needed to understand its mechanisms, optimal dosage, and long-term effects.

According to a study, four databases- Embase, PubMed, Cochrane Library, and Web of Science were searched up to February 2024 using terms related to garlic, glucose, and lipid metabolism. Additional eligible trials were identified through manual searches, and the study adhered to the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020. Inclusion criteria were randomized clinical trials over two weeks, reporting outcomes like Hemoglobin A1c (HbA1c), fasting blood glucose (FBG), TC, HDL-C, LDL-C, and TG, involving adults aged 18 or older, with a placebo control group. Exclusions included non-garlic interventions, combined supplements, pregnant participants, non-clinical studies, and incomplete data.

Two researchers independently extracted data, including study details, sample size, demographics, and mean and standard deviation values for glucose and lipid indicators. Study quality was assessed using Cochrane Collaboration tools, evaluating bias risk factors.

Garlic significantly improved FBG, HbA1c, TC, LDL, and HDL levels but did not affect TG. Various forms of garlic, such as raw garlic, aged garlic extract, and garlic powder tablets, were effective. Despite some publication bias and variations in interventions, garlic's benefits on blood glucose and lipid profiles were evident.<sup>1</sup>

## Effects of garlic on cardiovascular diseases

Research also indicates that garlic can have a positive impact on your arteries and blood pressure. Garlic and its preparations have been widely recognized as agents for prevention and treatment of cardiovascular diseases.

The wealth of scientific literature supports the proposal that garlic consumption have significant effects on lowering blood pressure, prevention of atherosclerosis, reduction of serum cholesterol and triglyceride, inhibition of platelet aggregation, and increasing fibrinolytic activity (Chan et al, 2013)<sup>2</sup>. Both experimental and clinical studies on different garlic preparations demonstrate these favorable cardiovascular effects.

In another study, 200 mg of garlic powder was given three times daily, in addition to hydrochlorothiazide-triamterene baseline therapy, produced a mean reduction of systolic blood pressure by 10-11 mmHg and of diastolic blood pressure by 6-8 mmHg versus placebo. However, these data are insufficient to determine if garlic provides a therapeutic advantage versus placebo in terms of reducing the risk of cardiovascular morbidity in patients diagnosed with hypertension (Stabler et al, 2012)<sup>3</sup>.

Long term application of garlic and its preparations on experimental atherosclerosis induced by a high cholesterol diet, showed 50% reduction in atherosclerotic lesions, particularly in the aorta. Most of human studies on lipid lowering effects of garlic and garlic preparations described significant decrease in serum cholesterol and triglyceride (Gardner et al, 2001; Ziae et al, 2001)<sup>4,5</sup>. A meta-analysis including 39 primary trials of the effect of 2 months administration of garlic preparations on total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, and triglycerides was performed (Ried et al, 2013b)<sup>6</sup>. The results suggest garlic is effective in reduction of total serum cholesterol by  $17 \pm 6$  mg/dL and low-density lipoprotein cholesterol by  $9 \pm 6$  mg/dL in subjects with elevated total cholesterol levels ( $>200$  mg/dL). An 8% reduction in total serum cholesterol is of clinical relevance and is associated with a 38% reduction in risk of coronary events at 50 years of age. High-density lipoprotein cholesterol levels improved only slightly, and triglycerides were not influenced significantly. Garlic was highly tolerable in all trials and was associated with minimal side effects.

## Anti-tumor effect of garlic

Many in vitro and in vivo studies have suggested possible cancer-preventive effects of garlic preparations and their respective constituents. Garlic has been found to contain a large number of potent bioactive compounds with anticancer properties, largely allylsulfide derivatives. Different garlic derivatives have been reported to modulate an increasing number of molecular mechanisms in carcinogenesis, such as DNA adduct formation, mutagenesis, scavenging of

free radicals, cell proliferation and differentiation as well as angiogenesis. The growth rate of cancer cells is reduced by garlic, with cell cycle blockade that occurs in the G2/M phase (Capasso, 2013)<sup>7</sup>.

### Diabetes mellitus

Although experimental studies demonstrated a clear hypoglycemic effect of garlic, the effect of garlic on human blood glucose is still controversial. Many studies showed that garlic can reduce blood glucose level in diabetic animals. Garlic was effective in reduction of blood glucose in streptozotocin- as well as alloxan-induced diabetes mellitus in rats and mice (Ohaeri, 2001)<sup>8</sup>. Short term benefits of garlic on dyslipidemia in diabetic patients were shown (Ashraf et al, 2005)<sup>9</sup>. Garlic significantly reduced serum total cholesterol and LDL cholesterol and moderately raised HDL cholesterol as compared with placebo in diabetic patients (Ashraf et al, 2005)<sup>9</sup>. S-allyl cysteine, a bioactive component derived from garlic, restored erectile function in diabetic rats by preventing reactive oxygen species formation through modulation of NADPH oxidase subunit expression(Yang et al, 2013)<sup>10</sup>.

### Antifungal properties

Antifungal activity was first established in 1936 by Schmidt and Marquardt whilst working with epidermophyte cultures (Lemar KM, et al, 2002)<sup>11</sup>. Many fungi are sensitive to garlic, including *Candida* (Yousuf S, et al, 2011)<sup>12</sup>, *Torulopsis*, *Trichophyton*, *Cryptococcus*, *Aspergillus*, *Trichosporon*, and *Rhodotorula*. Garlic extracts have been shown to decrease the oxygen uptake, reduce the growth of the organism, inhibit the synthesis of lipids, proteins, and nucleic acids, and damage membranes.

### Antiviral properties

In comparison with the antibacterial action of garlic, very little work has been done to investigate its antiviral properties. The few studies have reported that garlic extract showed in vitro activity against influenza A and B, cytomegalovirus, rhinovirus, HIV, herpes simplex virus 1, herpes simplex virus 2, viral pneumonia, and rotavirus. Allicin, diallyl trisulfide and ajoene have all been shown to be active.

**Garlic Boosts Immune Function:** Compounds in garlic support the immune system's ability to combat pathogens. Alliin is a substance that is present in whole garlic. This compound transforms into allicin (with a c), the primary active component of garlic, when garlic is chewed or crushed. Sulphur is a component of allicin, which is what gives garlic its distinct flavour and aroma. However, because allicin is unstable, it quickly breaks down into other sulfur-containing substances that are thought to be the source of garlic's therapeutic benefits. When certain types of white blood cells in the body come into contact with viruses like those that cause the common cold or flu, these substances have been shown to enhance the body's response to fight the disease.

**Garlic Prevent Colds and Flu:** The ability of garlic to treat and prevent colds and the flu has been demonstrated. Garlic may shorten both the length of your illness and your risk of getting sick at all, according to studies. Additionally, it might make symptoms less severe. In one experiment, 146 healthy volunteers were given 3 months of either garlic supplements or a placebo. The risk of catching a cold was reduced by 63% in the garlic group. The length of time it took for each group to recover from a cold, however, was not significantly different. According to a different study, subjects who consumed 2.56 grammes of aged garlic extract daily during the cold and flu season had significantly fewer colds than those who received a placebo. Additionally, their colds were not as bad. If you frequently get the flu or a cold, eating garlic may help you experience fewer symptoms or even avoid getting sick at all. A review of the evidence, however, revealed that many of the studies looking into how garlic affects the common cold were of low quality. It's also unclear whether taking garlic regularly is necessary or whether it can be used as a temporary remedy when you first become ill.

### Effect of Garlic as an anti-inflammatory

Research has shown that garlic oil works as an anti-inflammatory. If you have sore and inflamed joints or muscles, rub them with garlic oil. The Arthritis Foundation even recommends it to help prevent cartilage damage from arthritis.

### Clears up skin

Garlic's antibacterial properties and antioxidants can clear up your skin by killing acne-causing bacteria. One study shows rubbing raw garlic over pimples can clear them away.

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# The Value of Serum Carcinoembryonic Antigen in the Diagnosis of Malignant Colonic Tumor and its Prognosis

Dina Saleh, Esraah Alharris and Thair Wali Ali

Carcinoembryonic Antigen in the Diagnosis of Malignant Colonic Tumor

## ABSTRACT

**Objective:** To assess the diagnostic value of serum carcinoembryonic antigen in the detection and prognosis of colorectal malignant epithelial tumors.

**Study Design:** Case-control study

**Place and Duration of Study:** This study was conducted at the Department of Pathology & Forensic Medicine, College of Medicine, University of Al-Qadisiyah, Iraq from 1<sup>st</sup> June 2023 to 31<sup>st</sup> December 2023.

**Methods:** Thirty-one patients with colorectal cancer and 36 controls. The serum level of carcinoembryonic antigens was collected from both groups. In addition, information about the age of the patients, sex of patients, tumor stage, and tumor grade was collected.

**Results:** Serum carcinoembryonic antigen levels were higher significantly in patients who have colorectal cancer patients in comparison to control (2.70 (2.20) vs. 1.85 (1.28) ng/ml, respectively). The cut-off value of serum carcinoembryonic antigen was >2.5 ng/ml with a sensitivity level of 58.1 %, a specificity level of 83.3 %, and an accuracy level of 73.1, with the area under the curve of 0.731 indicating a fair ability to differentiate.

**Conclusion:** Serum carcinoembryonic antigen is the fair marker to differentiate between colorectal carcinoma and healthy control, it has good specificity but poor sensitivity and has no significant correlation to age, sex, grade of disease, and stage of disease.

**Key Words:** Serum, Carcinoembryonic antigen, Colorectal cancer, Malignant colonic tumor, Prognosis, Diagnosis

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## INTRODUCTION

Cancer of colorectal tissue is one of the most frequently encountered malignancies worldwide in adults, and around one to two million cases are diagnosed yearly.<sup>1</sup> It is regarded as the third most frequent malignancy and ranks fourth most frequent reason of cancer-associated mortality, with 700,000 mortalities rate each annum, being late in the list following cancers of lung tissue, hepatic tissue, and gastric region.<sup>2</sup> Concerning sex, this malignant tumor is the second most frequent malignancy in females and the third one in males.<sup>3</sup> The risk factors for colorectal carcinoma can be non-modifiable, such as increasing age.<sup>4</sup>

The usual predisposing factor is the presence of inflammatory bowel disease (Crohn's disease and

ulcerative colitis)<sup>5,6</sup> and a family history of colonic tumors or can be modifiable, such as dietary habits and lifestyle.<sup>7</sup>

The diagnosis of colorectal cancer is based on clinical presentation, imaging techniques and tissue diagnosis of biopsy, and detecting the pathognomonic histological changes in these tissue specimens.<sup>8</sup> However, the utilization of markers of tumors in cancer of the colon can aid in the diagnosis and can be utilized to predict therapeutic response and follow-up of patients in addition as a prognostic indicator.<sup>9</sup>

Freedman and Gold were the first to isolate Carcinoembryonic antigen (CEA) from tissues obtained from human malignant colonic tumors. CEA antigen is a fetal glycoprotein often postnatally not synthesized substantially.<sup>10</sup> This glycoprotein has a 200 kDa molecular weight and is naturally produced by the epithelium of endodermin the growing embryo and regulated by the oncogenes of the fetus. It is often not detected in serum following birth, but some amounts may persist in the colon's tissue. The antigen and associated genes (twenty-nine in number and 18 of them are expressed naturally) make up the family of CEA in humans and are found on chromosome 19q13.2.<sup>11</sup>

The CEA level increases in several malignant or non-malignant diseases.<sup>12</sup> The most frequent use of this marker as a diagnostic and prognostic indicator of

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colonic and rectal cancer.<sup>13,14</sup> Other malignant disorders that are associated with elevated CEA are medullary thyroid cancer, mucinous ovarian cancer, breast cancer, gastrointestinal, prostate, pancreas, and cervix.<sup>15</sup> Because the elevation of this serum marker is not specific to a particular type of malignant tumor, it has been used primarily in the follow-up of such tumors and not in the primary diagnosis.<sup>16</sup>

CEA is enrolled within the family of immunoglobulins known as CEA-related cell adhesion molecules (CEACaMs).<sup>17</sup> It is intimately included with various endothelial cell functions, such as proliferation, adhesion, and migration of cells both in vitro and in vivo.<sup>18</sup> It is located on the cell wall of natural cells, on the endoluminal side, and is believed to prevent programmed cell death and, therefore, is enrolled in the pathogenesis of tumors.<sup>12</sup>

Despite the availability of studies in several countries about the use of CEA as a diagnostic, prognostic biomarker and a predictor for relapse for colorectal malignancy, there is a lack of studies to examine the Iraqi population; this is important to ascertain the proper use of CEA in such Ethnic groups. The current research aimed to assess the value of carcinoembryonic antigen serum level in the detection and prognosis of colorectal malignant epithelial tumors in group of Iraqi patients.

## METHODS

The present case-control research was conducted in Diwaniyah Province, Iraq, in the Oncology Department of the Teaching Hospital from 1<sup>st</sup> June 2023 to 31<sup>st</sup> December 2023. A total of 31 patients with colorectal cancer and 36 healthy control subjects of comparable age range were included. The patients with colon cancer relapse or those treated with chemotherapy or radiotherapy were excluded from the study. Information about the age and sex of patients, tumor stage, and tumor grade was collected. Colonic cancer was confirmed by obtaining tissue samples from tumor masses, paraffin blocks were processed, and microscopical slides were stained with conventional hematoxylin and eosin stains and examined by two independent pathologists.

A sufficient amount of venous blood samples was taken from each patient and was sent to the central laboratory of the Teaching Hospital to measure serum CEA. Venous samples were also obtained from each control subject for the same purpose. The level of CEA was measured using a Biomrieux kit (North Carolina, USA) and the samples were inserted in VEDAS (lab equipment used to measure tumor marker level by ELFA; enzyme-linked fluorescent assay). Briefly, the serum was diluted and incubated with a solid phase receptacle, and then inserted into the machine. Then, the samples were incubated with ALP-labelled anti-CEA polyclonal antibodies (derived from goat). The

samples were washed thereafter to remove the unbound antibodies, followed by the final step of fluorescence detection after adding 4-methyl-umbellifliferone (the fluorescent material. The concentration of the tumor marker will be proportional to the fluorescence intensity measured at 450 nm.

Data were analyzed using SPSS-16. A comparison of the level of serum CEA between the control group and the patients' group was done using the Whitney U test. An unpaired *t*-test was used to see the variation in average age between patients and control categories. The association between categorical variables was based on a Chi-square test. The Spearman correlation test assessed the correlation between serum CEA and other variables. The point of significance was considered when the *p*-value was equal to or less than 0.05.

## RESULTS

There was no substantial variation in average age between control subjects and patients with colorectal carcinoma,  $60.31\pm8.73$  years versus  $59.32\pm11.00$  years (*p*=0.685). There was also no significant variation in the frequency distribution of individuals based on gender between study and control groups (*p*=0.605); however, the frequency of male patients was more than the frequency of females, 64.5% versus 35.5%, respectively, and the male to female ratio was 1.81:1 (Table 1).

According to stage patients were categorized into 2 (6.5%) as Stage I, 13 (41.9%) as Stage II, 7 (22.6%) as Stage III, and 9 (29.0%) as Stage IV. According to grade patients were categorized into 3 (9.7%) as grade I, 20 (64.5%) as grade II, and 8 (25.8%) as grade III (Table 2).

The median level in the patients' group was 2.70 (2.20) ng/ml and the range was 0.23-201.00 ng/ml; whereas the median level in the control group was 1.85 (1.28) ng/ml and the range was 0.50-7.20 ng/ml. Therefore, the serum level of CEA in patients with colorectal carcinoma was higher than that of the control category in a significant manner (*p*<0.001) [Table 3].

**Table No. 1: Demographic characteristics**

Characteristics	Patients group (n=31)	Control Group (n=36)	P value
<b>Age (years)</b>			
Mean±SD	59.32 ±11.00	60.31±8.73	0.685 <sup>I</sup>
Range	43-81	41-71	
<b>Sex</b>			
Male, <i>n</i> (%)	20 (64.5%)	21 (58.3%)	0.605 <sup>C</sup>
Female, <i>n</i> (%)	11 (35.5%)	15 (41.7%)	

**C:** Chi-square test; **SD:** standard deviation; **n:** number of cases; **I:** independent samples *t*-test

Table No.2: Pathological characteristics of patients

Characteristics	No.	%
<b>Stage</b>		
I	2	6.5
II	13	41.9
III	7	22.6
IV	9	29.0
<b>Grade</b>		
I	3	9.7
II	20	64.5
III	8	25.8

Table No. 3: Comparison of serum level of carcinoembryonic antigen between patients with colorectal cancer and control group

Characteristics	Patients group (n=31)	Control Group (n=36)	P value
<b>CEA (ng/ml)</b>			
Median (IQR)	2.70 (2.20)	1.85 (1.28)	<0.001M***
Range	0.23 - 201.00	0.50 - 7.20	

IQR: interquartile range; M: Mann Whitney U test;  
\*\*\*significant at  $p \leq 0.001$

Table No. 4: The characteristics of ROC curve analysis

Cutoff	> 2.5 ng/ml
AUC	0.731
95 % CI	0.608 to 0.832
p-value	< 0.001
Sensitivity %	58.1
Specificity %	83.3
Accuracy %	73.1

AUC: area under curve; CI: confidence interval

Table No. 5: Correlations of serum CEA to other patients' characteristics

Characteristic	<i>r</i>	<i>P</i>
Age	-0.232	0.209
Gender	-0.057	0.763
Stage	-0.048	0.797
Grade	-0.255	0.166

Figure 1 and Table 4 show receiver operating characteristic (ROC) curve analysis to detect the cutoff value of carcinoembryonic antigen serum level that can segregate between colorectal cancer cases and control cases. The cutoff value was >2.5 ng/ml, with a sensitivity level of 58.1 %, a specificity level of 83.3 %, and an accuracy level of 73.1%. There has been no substantial correlation between serum CEA and other clinicopathological characteristics of patients with colorectal carcinoma (Table 5).

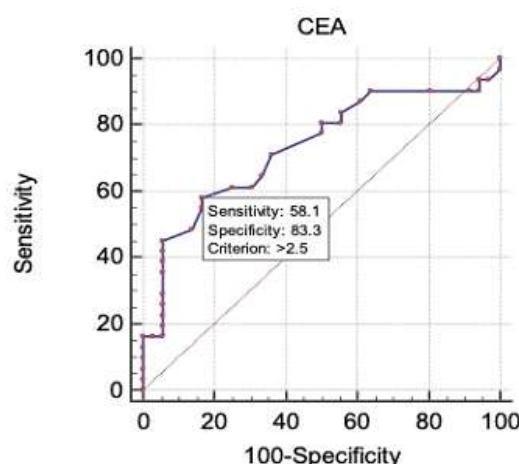


Figure No. 1: "Receiver operating characteristic (ROC)" curve analysis to detect the carcinoembryonic antigen serum level between colorectal cancer and control cases

## DISCUSSION

The current study was planned and conducted to see the value of CEA as an aid tool in detecting colorectal carcinoma and its association with prognostic parameters of this malignant tumor, such as stage and grade of the disease. We found significant variation in the serum level of CEA between patients and control subjects, and the level was higher in patients than in the control group. We also found a cutoff value of >2.5 ng to segregate cases from control subjects, but the sensitivity was poor (58.1%). In addition, we find that serum CEA in patients with colorectal carcinoma had no significant correlation to the age of the patient, gender of the patient, stage of disease, and grade of disease.

Therefore, we can suggest that serum CEA above 2.5 ng/ml is important in detecting colorectal cancer in patients with high clinical suspicion; this may be related to tumor mass burden, and the level may not reflect the true prognosis of patients with such malignant tumors, especially if we notice the wide variation in serum levels ranging from 0.23 to 201.00 ng/ml.

In previous Iraqi studies<sup>19-21</sup>, serum CEA was evaluated in subjects with colon malignancy. In the research of Al-Saadi et al<sup>19</sup>, there was no significant link between serum CEA and the stage of disease, and this observation is consistent with our observation. In the study of Mahmood et al<sup>20</sup>, there was a significant deviation in average serum CEA between controls and patients, and they found that a cutoff value of >2.65 ng/ml carries 100% sensitivity, which is far more than that reported in our study; they found a significant correlation between stage of disease and serum CEA level in clear contradiction to our observation. In the study of AL-Rubaiawi et al<sup>21</sup>, there was no significant link between serum CEA and the stage of disease, and this observation is consistent with our observation.

Patients with colon malignancy who underwent surgical removal and treatment that is adjuvant benefit from the powerful predictive biomarker CEA.<sup>22-24</sup> When colorectal cancer is first diagnosed, elevated CEA levels of >5 g/L are linked to a poor prognosis.<sup>25,26</sup> After surgery, however, stabilization of increased CEA levels is not linked to a bad prognosis. Therefore, routine CEA screening before surgical therapy is not advised, and post-surgical detection is typically more helpful for prognostication and recurrence detection within one year of operation. In the follow-up after colorectal surgery (FACS) trial, it was discovered that following up with a CEA concentration in patients with colon cancer following initial therapy is useful for identifying cancer reappearance that may be managed with the intention of curing them.<sup>27</sup> National recommendations for colorectal cancer in Europe and North America also support measuring CEA in post-surgical care.<sup>28</sup> Serial measurement of CEA is advised before treatment begins; then, every three months during active treatment to evaluate the effectiveness of resection and systemic therapy (chemotherapy/radiotherapy).<sup>29,30</sup>

## CONCLUSION

Serum CEA is a fair marker to differentiate between colorectal carcinoma and healthy control, it has good specificity but poor sensitivity and has no significant correlation to age, sex, grade of disease, and stage of disease.

**Limitations of the study:** We would like to mention, the first limitation is that the study was conducted in a short time in Diwaniyah Province, the second is that there is no follow-up for that patient's serum level of CEA, third is that we need to look further for other tumor marker expression in tumor cells in addition to the normal colon tissue near the tumor mass. Additional studies are needed to show the expression of CEA in colon cancer patients all around Iraq, with follow-up for at least 5 years so we can assess the response of the patient to colon cancer therapy and predict the ratio of relapse using serum CEA level.

### Author's Contribution:

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

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Original Article

# A Study of the Relation Between Hypothyroidism and Serum Anti-Mullerian Hormone in Infertile Women

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Essa AL-Obaidi

Hypothyroidism  
and Serum Anti-  
Mullerian  
Hormone in  
Infertile Women

## ABSTRACT

**Objective:** To identify the correlation between hypothyroidism and serum anti-Mullerian hormone in infertile women.

**Study Design:** Pre-experimental study

**Place and Duration of Study:** This study was conducted at the Department of Obstetrics and Gynecology, Pediatric and Maternity Teaching Hospital, Iraq Adiwaniyah Province from 2<sup>nd</sup> January 2023 to 15<sup>th</sup> January 2024.

**Methods:** Eighty women diagnosed with infertility were enrolled.

**Results:** The AMH levels were significantly lower in the adults with euthyroid. The AMH levels tended to be lower in subclinical hypothyroidism, although the differences were not significant. The AMH levels and hypothyroidism were significantly correlation while there is appositive relationship between level of AMH and age of women less than 30 years.

**Conclusion:** A causal relationship between the infertile women's AMH levels and genetically determined thyroid function.

**Key Words:** Hypothyroidism, Serum anti-Mullerian hormone, Infertile

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## INTRODUCTION

Hypothyroidism, characterized by inadequate thyroid hormone production, has been implicated in female infertility. Conversely, serum anti-Mullerian hormone (AMH) levels are considered a crucial marker of ovarian reserve, impacting fertility. Thyroid dysfunction, particularly hypothyroidism, may adversely affect reproductive outcomes in women.<sup>1</sup> The importance of AMH as a predictor of ovarian reserve and fertility potential. Thus, exploring the relationship between hypothyroidism and serum AMH levels in infertile women is essential for understanding the intricate interplay between thyroid function and ovarian health.<sup>2</sup>

The incapacity of a couple to conceive after a year (for women under 35) or six months (for women over 35) of consistent, unprotected sexual activity is known as

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infertility.<sup>3</sup> Infertility impacts around 8-12% of couples globally. The prevalence ranges from 3.8% to 16.8% in India. The female reproductive axis may be impacted by thyroid dysfunction and autoimmune thyroiditis, which are recognized risk factors for anovulation, irregular menstruation, subfertility, polycystic ovarian disease (PCOD), and recurrent miscarriages.<sup>4</sup>

Among the most prevalent illnesses affecting women in the reproductive age range are thyroid dysfunctions. Oocytes have thyroid hormone receptors, which suggest that thyroid hormones may affect ovarian activities. It is commonly known that women with hypothyroidism have longer menstrual cycles, which might result in infertility due to changes in peripheral estrogen metabolism, hyperprolactinemia, and aberrant gonadotropin-releasing hormone release.<sup>5</sup>

Adverse effects on fertility in women who are reproductive age are associated with thyroid dysfunction and autoimmune. The link between thyroid hormone and anti-mullerian hormone (AMH), a biomarker of "ovarian age," is unknown, but it may be impacted by compromised thyroid function.<sup>6</sup>

A dimeric glycoprotein, Anti-Müllerian Hormone (AMH) is a member of the Transforming Growth Factor-beta (TGF- $\beta$ ) super-family. Tissue differentiation and growth are impacted by AMH. Pre-antral and tiny antral follicles' granulosa cells generate antral fluid hormone (AMH).<sup>7</sup> Female ovarian reserve is assessed using serum AMH values, which are also a useful indicator of ovarian reserve.<sup>8</sup> Age tends to cause a decline in AMH concentration. The link

between elevated blood TSH levels and reduced ovarian reserve is supported by several studies.

Thyroid autoimmune diseases have been seen in 12%–33% of patients with premature ovarian failure, according to earlier research.<sup>9</sup> Thus, ovarian reserves may be reduced in infertile patients with autoimmune thyroid disorders. In this instance, thyroid autoimmunity may impact AMH concentrations regardless of the age of the female, if it has an impact on follicular growth and development.<sup>10</sup> Granulosa cells of prenatal and tiny antral follicles produce anti-Mullerian hormone, a dimeric glycoprotein that is a part of transforming growth factor-beta (TGFB). The amount of the remaining follicular pool is correlated with the quantity of tiny antral follicles.<sup>11</sup>

The current study's goal was to identify the correlation between the measurements of AMH content with infertility and hypothyroidism.

## METHODS

The pre-experimental study was enrolled 80 women diagnosed with infertility. The work has been carried out at “Department of Obstetrics & Gynecology” in the Pediatric and Maternity Teaching Hospital in Iraq, Adiwaniyah Province during the time interval spanning the 2<sup>nd</sup> January 2023 to 15<sup>th</sup> January 2024. The women with infertility, their age was in the range of 18–35 years were included. Those women with pregnancy who refuse to participate were excluded. The approval of this research was issued by the committee dealing with ethical approval in “University of Al-Qadisiyah/ College of Medicine. Information was collected. The data was entered and analyzed through SPSS-25. The contrast of rates was done using a chi-square test and P<0.05 was considered as significant.

## RESULTS

Correlation between age and AMH level in women with infertility and reflect that there is low AMH level in women with age less than 30 years (Table 1). There is correlation between high level of FSH as a hypothyroidism and AMH level in women with infertility (Table 2).

**Table No. 1: Correlations between age and AMH account**

Age (years)	AMH	
	2.2-6.8 ng/ml	<2.2 ng/ml
< 30	44 (55%)	21 (26.3%)
> 30	4 (5%)	11 (13.7%)
P value	0.032	

**Table No. 2: Correlation between hypothyroidism and AMH count**

Thyroid function	AMH	
	Normal	Low
Euthyroid	44	21
Hypothyroidism	4	11
P value	0.004	

## DISCUSSION

One of the most important things to know about fertility assessment is the relationship between the age of women with hypothyroidism and infertility and their AMH levels. In our investigation, we found that, in contrast to the 11 women over 30 years old, 21 women under 30 years old had low AMH levels. This implies that, in comparison to their older counterparts, younger women with hypothyroidism may be more susceptible to decreased ovarian reserve, as shown by lower AMH levels.

As an illustration of the age-related differences in AMH levels among women with thyroid dysfunction, Smith et al<sup>12</sup> looked at the relationship between hypothyroidism and AMH levels in infertile women undergoing ART evaluation. Their research, like ours, demonstrated how crucial it is to take age into account when interpreting AMH levels in relation to infertility brought on by thyroid dysfunction. Disagree with the study that explains the relationship between serum anti-Mullerian hormone levels and thyroid dysfunction in women who report with infertility. The findings of that study indicate that the age of the women did not appear to have an impact on the prevalence of thyroid disease or infertility.

Understanding the relationship between anti-Mullerian hormone (AMH) levels and hypothyroidism is one topic of focus. Eleven of the eighty participants in the research had low AMH levels and hypothyroidism. Low AMH levels in this study point to a possible link between hypothyroidism and diminished ovarian reserve. Our study's findings about the relationship between hypothyroidism and low AMH levels are consistent with those of other studies. Research by Raffone et al<sup>1</sup> and Unuane et al<sup>14</sup> have also brought attention to the effects of thyroid disease, specifically hypothyroidism, on women's ability to conceive and reproduce. These findings lend more credence to the theory that thyroid function affects ovarian health and function.

Furthermore, our results corroborate those of Grynneup et al<sup>13</sup>, who highlighted the necessity of additional research into the relationship between thyroid function and ovarian reserve in women who are infertile. We add to the increasing body of research that links thyroid dysfunction to decreased ovarian reserve and fertility by proving a connection between hypothyroidism and low AMH levels in our study cohort.

Adding to the conversation with earlier research, our results are consistent with the information offered by Kim et al<sup>2</sup> about the prognostic usefulness of AMH in determining ovarian reserve and potential for conception. Kim et al<sup>2</sup> also concentrated on AMH as a stand-alone marker, our study expands on this knowledge by investigating the potential interactions between AMH levels and hypothyroidism, a prevalent endocrine disease, in determining reproductive outcomes.

Furthermore, as recommended by Unuane et al<sup>14</sup>, our study highlights the usefulness of incorporating thyroid function measurement into the assessment and treatment of female infertility. Our findings highlight the significance of a holistic approach to fertility testing that takes into account both ovarian and endocrine parameters, by highlighting hypothyroidism as a potential contributor to lower ovarian reserve, as shown by low AMH levels.<sup>15</sup>

## CONCLUSION

A significant connection between the indications of infertility in women and thyroid function were seen.

### Limitation

1. The number of thyroid antibody-positive cases is particularly low in the short sample size. Later on, the study will be extended even more to conduct a thorough analysis of any potential relevance.
2. More research is needed to determine the association between the length of impaired thyroid function and infertility. Further research is necessary to examine the molecular mechanisms that underlie the reduced ovarian reserve observed in women diagnosed with thyroid disorders.

### Author's Contribution:

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Original Article

# The Role of Gliclazide on Galectin-3 Expression in Individuals with Left Ventricular Diastolic Dysfunction and Type 2 Diabetes Mellitus

Tharaa Thaer A. Alaziz and Bassim I. Mohammad

Gliclazide on  
Galectin-3 with  
LVDD and  
Diabetes

## ABSTRACT

**Objective:** To investigate the role of the antidiabetic medication gliclazide on the galectin-3 expression, a biomarker associated with cardiac fibrosis and diastolic dysfunction, in those suffering from diastolic dysfunction of the left ventricle and type 2 diabetes.

**Study Design:** Cross-section study

**Place and Duration of Study:** This study was conducted at the Al-Diwaniyah Teaching Hospital in Diwaniyah, Iraq from 1<sup>st</sup> February 2023 to 31<sup>st</sup> December 2023.

**Methods:** A total of 62 patients with type 2 diabetes mellitus and left ventricular diastolic dysfunction were enrolled. Two groups were divided; one for gliclazide therapy and the other for control. Gliclazide group was given standard treatment for type 2 diabetes mellitus plus gliclazide while the control group received standard treatment alone.

**Results:** Galectin-3 expression was measured at baseline of treatment using quantitative real-time polymerase chain reaction (qRT-PCR). The results showed that gliclazide treatment significantly increase in galectin-3 expression relative to the group under control. Galectin-3 levels have decreased levels correlated with improvements in left ventricular diastolic dysfunction parameters, including left ventricular filling pressure and diastolic function. Additionally, gliclazide treatment was associated with improved glycemic control, as evidenced by reduced HbA1c levels.

**Conclusion:** Gliclazide may have no beneficial effect on left ventricular diastolic dysfunction in patients with type 2 diabetes mellitus by modulating galectin-3 expression. The upregulation of galectin-3 may contribute to the deterioration in diastolic function observed with gliclazide treatment. It is necessary to do additional research to clarify the underlying mechanisms and validate these findings in a larger patient group.

**Key Words:** Gliclazide, Metformin, Left ventricular diastolic dysfunction, Type 2 diabetes mellitus, Galectin-3

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## INTRODUCTION

Myocardial fibrosis (MF) is highly correlated with increased left ventricular (LV) chamber stiffness and reduced LV relaxation, which result in left ventricular diastolic dysfunction (LVDD). Heart failure with preserved ejection fraction, or HFpEF, is thought to have its precursor in LVDD.

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Adverse myocardial remodeling brought on by MF at the late stage of LVDD results in HFpEF. Reversing the poor left ventricular diastolic function (LVDF) in patients with HFpEF is challenging. Adverse cardiac events, such as newly acquired myocardial ischemia, arrhythmia, myocardial infarction (MI), angina pectoris, and heart failure (HF), are linked to higher all-cause mortality when LVDF is low.<sup>1</sup>

Chronic metabolic disease known as diabetes mellitus (DM) is typified by ongoing hyperglycemia. It could be brought on by decreased insulin secretion, resistance to insulin's peripheral effects, or both. Together with other metabolic abnormalities in individuals with diabetes mellitus, persistent hyperglycemia can harm multiple organ systems, resulting in the development of debilitating and potentially fatal health complications. Microvascular complications, such as retinopathy, nephropathy, and neuropathy, are the most common, while macrovascular complications raise the risk of cardiovascular diseases by two to four times.<sup>2</sup>

Type 1 diabetes, Type 2 diabetes, and gestational diabetes are the most prevalent types of the disease. The hallmarks of type 2 diabetes (T2DM) are insulin resistance and a relative lack of insulin production.<sup>3</sup> Secondary diabetes and monogenic diabetes are two more, less prevalent forms of the disease.<sup>2</sup>

A1c  $\geq 6.5\%$ , fasting glucose  $\geq 126$  mg/dL, glucose of  $\geq 200$  mg/dL two hours after a 75 gm glucose load, or random glucose  $\geq 200$  mg/dL with symptoms, all support the diagnosis and can be verified by a follow-up or second test.<sup>4</sup>

Atherosclerotic cardiovascular disease (ASCVD) is linked to diabetes mellitus (DM), and reducing risk requires statin use, blood pressure medication, regular exercise, and quitting smoking. Although it varies greatly, people with T2DM have an overall 15% higher excess death rate. About 4.4% of adult diabetics in the US have vision-threatening diabetic retinopathy, compared to 1% of those with end-stage renal disease. These days, vascular complications can be effectively managed to reduce morbidity and mortality. Pharmacotherapy for hyperglycemia, as well as ACE/ARB therapy for controlling blood pressure, lowering LDL cholesterol, and secondary prevention with aspirin, cans all help.<sup>2,6</sup>

The  $\beta$ -galactoside-binding lectins are known as galectins. Nearly all forms of cardiovascular illness have been linked to elevated serum galectin-3 levels, and patient predictive research on this protein's significance for various clinical outcomes has been done in great detail. The fibrosis and inflammatory biomarker galectin-3 has been linked to the onset and development of heart failure (HF) and has the potential to predict higher rates of morbidity and death. Increased expression levels of galectin-3 have been linked to mortality in both acute and chronic heart failure.<sup>5</sup>

This paper aims to investigate the effect of gliclazide, an oral sulfonylurea, on LVDD in T2DM patients by targeting galectin-3 and compare it with the standard treatment metformin.

## METHODS

The Al-Diwaniyah Teaching Hospital in Diwaniyah, Iraq, served as the site of this cross-sectional study for the period 1<sup>st</sup> February 2023 to 31<sup>st</sup> December 2023. The patients diagnosed with T2DM and LVDD, aged between 45 and 65 years, 36 of the participants were female and 26 of them male who are receiving standard care for diabetes management. The patients were divided into two groups at random: the gliclazide group and the metformin group. The gliclazide group received gliclazide as an add-on therapy to their existing antidiabetic regimen, while the metformin group continued their standard treatment taking gliclazide 90mg and gliclazide + metformine (90/1000) for at least six months. All patients have T2DM, HbA1C (6.5-9), age 45-65 years, onset of diseases  $>3$  years and

onset of current therapy at least 6month were included. Patients having HbA1C  $>9$ , renal impairment (eGFR  $<30$  ml/min/1.73m<sup>2</sup> of body surface area) or diaylasis, hepatic impairment, pregnancy, overt heart failure, EF which is less than 50 and psychiatric patients were excluded.

Baseline demographic characteristics, clinical data, assessment of body mass index (weight of the patients included in the study is measured by electronic scale in kg. The height is measured by height scale in m<sup>2</sup>). The blood samples with 1 ml were collected from the patients that were aspirated from antecubital vein was placed in 1 ml EDTA tube, which is then kept cold until the moment of DNA extraction. Galectin-3 levels were measured at baseline in the beginning RNA extraction then RNA concentration measurement by Quantus™ Fluorometer (Promega, USA) Subsequently, the whole RNA was converted to cDNA by utilizing the ADDBio (Korea) kit. by adding H2O (6 $\mu$ l) to Reverse transcriptase (RT) Add two times as much cDNA (20 $\mu$ l), dNTPs (4 $\mu$ l), random oligos hexamer (2 $\mu$ l), and RNA (8 $\mu$ l) to the script; the total amount is 40 $\mu$ l. The expression of Galectin-3 gene was measured using the comparative Ct method ( $\Delta\Delta Ct$ ), normalized to the control group level when GAPDH mRNA transcript levels were present. This was accomplished in accordance with the suggestion made by Schmidtgen and Livak.<sup>7</sup> Increasing the strength of the Galectin-3 gene was carried out using the following primers employed by Papaspyridonos et al.<sup>8</sup>

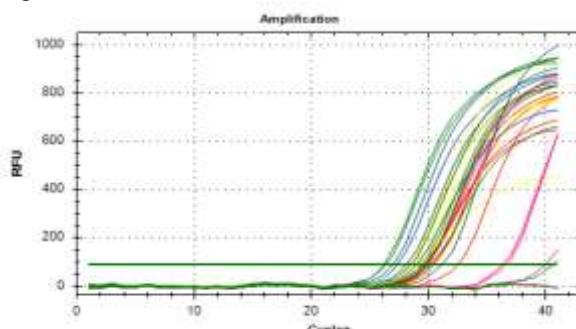
Gene of Interest (Galectin-3) Sequence (5'->3') Gal3-Forward Template strand (5'.....3') TGCAGT-GAATGATGCTCACTTG and Gal3-Reverse the template strand CAGAAATTCCCAGTTGCTGATT. Housekeeping gene (HKG) or internal reference gene; human glyceraldehyde 3-phosphate dehydrogenase Sequence (5'->3') GAPDH-F template strand CAGAACATCATCCCTGCCTCTA and GAPDH-R Template strand (5'.....3') CCAGTGAGCTTCCC-GTTCA. Preparing Reverse Transcriptase PCR Quantitatively (RT-qPCR) The RT-qPCR amplification was first accomplished with AddScript RT-qPCR Syber master (AddBio, Korea). The reaction consisted of adding H2O (4  $\mu$ l) to AddScript RT-qPCR (10  $\mu$ l), as well as Forward and Reverse primers (0.05 pmol/20  $\mu$ l and 2  $\mu$ l, respectively), cDNA (2  $\mu$ l), and a total of 20  $\mu$ l. Normalization of RT-qPCR data: Transcript levels were adjusted to those of using the delta-delta Ct technique. GAPDHmRNA<sup>7</sup>, wherein the subsequent formula was utilized:  $2-\Delta\Delta Ct = [((\text{internal control-CT gene of interest}) \text{ sample A} - (\text{internal control-CT gene of interest}) \text{ sample B})]$ . Note that sample A refers to a single group and sample B refers to a different specific group. The graph pad prizim software-8.4.3 was applied to the analysis of data. Each set of data was displayed as mean #standard deviation (SD).and a difference with

P values less than 0.05 were regarded as statistically significant.

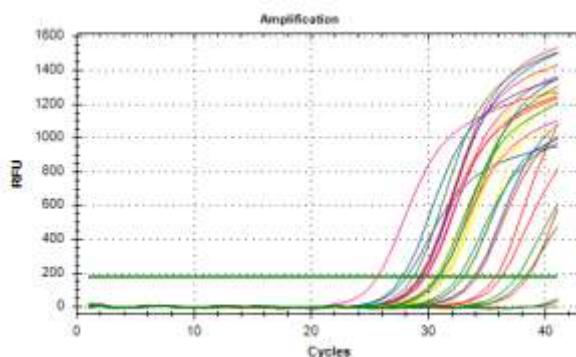
## RESULTS

After the intervention period, there is a statistical difference between the two groups. The gliclazide group exhibited a significant rise in galectin-3 levels when compared to the metformin group ( $p$  less than 0.0001). Significantly different ( $P < 0.05$ ), as shown in table 1 and 2. Mean for metformin 1.541 and 13.96 for Gliclazide with Standard deviation for metformin is 1.596 and 2.788 for gliclazide. As shown the successful amplification curves with corresponding crossing threshold (CT) as the number of cycles with the round forming unit (RFU) (Figs.1-2).

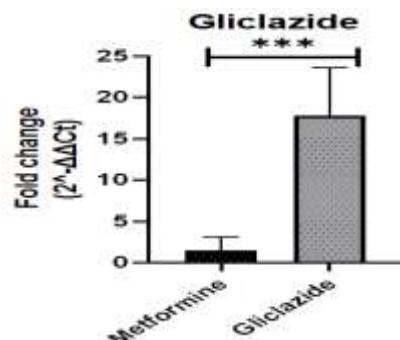
This demonstrates a notable increase in Galectin-3 expression in the gliclazide treated group ( $P < 0.0001$ ) in comparison with metformine treatment. This was analyzed by Graph pad prizim software (version 8.4.3). Descriptive statistics in the galectin-3 expression in gliclazide and metformine treated groups (Fig. 3). Patients taking metformin has lower effect on heart grading than those taking Gliclazide (Table 1). The results show variations in patients taking metformin has higher effect in relation to RBS, sex and age, than those taking Gliclazide while Gliclazide patients grouping has higher effect in relation to BMI (Table 2).



**Figure No. 1: Amplification curve of the tested samples for expression of gene of interest (Galectin-3) in the gliclazide group**



**Figure No. 2: Amplification curve of the tested samples for expression of gene of interest (Galectin-3) in the metformine group**



**Figure No. 3: Gene expression of Galectin-3 in the Gliclazide**

**Table No.1: Demonstrate Ranks of metformin and gliclazide (n=62)**

Drug	No.	Mean Rank	Sum of Ranks
Metformin	30	37.00	1110.0
Gliclazide	32	26.34	843.0

**Table No.2: Demonstrate Group statistics of age, sex,BMI and RBS**

Variable	Drug	Mean $\pm$ SD
Age	Metformin	59.70 $\pm$ 10.87
	Gliclazide	50.56 $\pm$ 13.48
Sex	Metformin	1.63 $\pm$ 0.49
	Gliclazide	1.53 $\pm$ 0.507
BMI	Metformin	29.58 $\pm$ 4.97
	Gliclazide	31.67 $\pm$ 5.94
RBS (md/dl)	Metformin	198.60 $\pm$ 91.85
	Gliclazide	181.81 $\pm$ 80.99

## DISCUSSION

In the present study metformin treatment showed significantly higher reduction in Gal-3 concentration indicate its potential as an adjunct therapy targeting LVDD compared to Gliclazide therapy in addition to standard of care group. Other study reported same findings on other treatments done by Ates et al.<sup>9</sup> The use of simvastatin reduced TBARS levels. By suppressing the effects of ROS and upregulating antioxidant enzymes, which block free radicals, simvastatin may prevent the production of oxidants.<sup>6</sup>

The majority of inflammatory cells produce galectin-3, and the degree of this expression varies in response to both internal and external stimuli. The acute inflammatory response involves several processes that are significantly influenced by galectin-3, including neutrophil adhesion and activation<sup>10</sup>, monocyte or macrophage chemoattraction<sup>11</sup>, and opsonization of apoptotic neutrophils. Streptococcus pneumoniae membrane fraction treatment was demonstrated to cause alveolar macrophages to produce Galectin-3.<sup>12</sup> Henderson and Sethi<sup>13</sup> discovered that Galectin-3 was stimulated to be expressed and released upon macrophage activation via IL-4 and IL-13. The current

investigation found that rats treated with lipopolysaccharide (LPS) had higher levels of Galectin-3 expression in their alveolar macrophages. But in rats given LPS, injections of simvastatin reduced its expression. Their immune response patterns resembled those of the control group. Simvastatin thereby alleviated the acute inflammatory alterations that took place in the animals' lungs after receiving an LPS injection.

In several investigations, researchers demonstrated that Galectin-3 increased vascular inflammation by causing macrophages to express pro-inflammatory products.<sup>11</sup> Additionally, it may regulate inflammation through a variety of methods. The increased survival of inflammatory cells caused by the production of Galectin-3 may also worsen inflammation.<sup>14</sup> The lung tissue's bronchial epithelium and pneumocytes both showed an increase in Galectin-3 immuno re-activities in the LPS group. When statins were administered during mouse atherosclerosis, both the amount of plaque macrophages and plaque alectin-3 expression were decreased.<sup>15</sup> Prior simvastatin dosing reduced the densities and quantity of immunoreactive Galectin-3 in lung tissue's bronchial epithelium and pneumocytes.

This paper found that simvastatin administration protected against septic ALI. In ALI, lowering the levels of galectin-3 might work as an internal compensatory anti-inflammatory strategy. Other study by Sygitowicz et al.<sup>16</sup> The sulphated or acetylated heparin derivatives known as heparin-based inhibitors represent a relatively novel and appealing class of galectin-3 inhibitors. Studies conducted in vitro have shown that they are selective for galectin-3 and non-cytotoxic (i.e., they do not block galectin-1, -4, or -8). Experimental in vivo experiments using nude mice showed that chemicals produced by galectin-3 markedly reduced human melanoma and colonic cancer cells' ability to metastasize to the lungs. The substances also appeared to be prospective therapeutic agents despite having no discernible anti-thrombotic action.<sup>17</sup>

Regarding gliclazide, its primary mechanism of action is to stimulate insulin secretion from pancreatic beta cells, thereby reducing blood glucose levels. It primarily acts by binding to the pancreatic beta cells' sulfonylurea receptors, which causes the ATP-sensitive potassium channels to close, the cell membrane to depolarize, and then calcium to influx, which causes the release of insulin. As for the specific interaction between gliclazide and galectin-3, the available literature is limited. While gliclazide's primary role is to control blood glucose levels in patients with type 2 DM, some studies have suggested that sulfonylureas may have pleiotropic effects beyond glycemic control. For example, sulfonylureas have been reported to have potential anti-inflammatory and antioxidant properties, which could have implications for cardiovascular diseases.<sup>18</sup>

In the context of LVDD, there is limited direct evidence on the effects of gliclazide specifically on galectin-3 levels or LVDD outcomes. The majority of studies on gliclazide have focused on its glycemic control effects and its impact on cardiovascular outcomes in patients with diabetes.

## CONCLUSION

Gliclazide, through its effect on Galectin-3, may have no any beneficial impact on LVDD in patients with T2DM. The increase in galectin-3 levels indicates it has no potential as an adjunct therapy targeting LVDD. To confirm these results and investigate the further implications, more research with bigger sample sizes and longer follow-up times is required underlying mechanisms in more detail.

### Author's Contribution:

Concept & Design of Study: Tharaa Thaer A. Alaziz, Bassim I. Mohammad

Drafting: Tharaa Thaer A. Alaziz, Bassim I. Mohammad

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Revisiting Critically: Tharaa Thaer A. Alaziz, Bassim I. Mohammad

Final Approval of version: By all above authors

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

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Original Article

# The Impact of Duration of Type 2 Diabetes Mellitus on Retina and Overall Eye Health in Pakistan's Population

Muhammad Junaid, Fawad Ahmed, Zia-ur-Rehman, Irfan Ali and Sana Naz

Diabetes Mellitus on Retina and Overall Eye Health

## ABSTRACT

**Objective:** With reference to the study conducted in Pakistan, the following hypotheses were postulated with the view to establish relationship between the longevity of T2DM and retina health; moreover, to establish factors that affects its progression over time.

**Study Design:** Cross-sectional study

**Place and Duration of Study:** This study was conducted at the Mehboob Charity Vision International Eye and General Hospital in Mansehra from May 2023 to January 2024.

**Methods:** This study examines 420 diabetic patients from Mehboob Charity Vision International Eye and General Hospital in Mansehra, Pakistan, diagnosed with type 2 diabetes for at least five years. The sample was diverse, representing both genders and ethnic backgrounds, and was selected using a simple random sampling procedure.

**Results:** A study conducted on 3865 patients with diabetes, focusing on their demographics, sociodemographic, and diabetes-related data. The majority of participants were male and female, with a majority residing in rural areas. The majority of patients had Type 2 diabetes, with 90.75% (n=380) having the condition. The study revealed varying familial contexts, with 31.90% (n=134) having no diabetes history and 8.58% (n=36) having a family history from both parents. The majority of patients had uncontrolled blood sugar levels and hypertension. The duration of diabetes was found to be between 1-5 years, with most diagnosed within the last 1-5 years. Discomfort levels decreased with diabetes duration, and mild non-proliferative diabetic retinopathy (NPDR) and proliferative diabetic retinopathy (PDR) cases decreased. The study suggests a potential decline in visual acuity functions in later years, particularly in terms of perception of light, hand movement, and counting figures. Hence, suggesting the higher complications in first 10 years of diabetic duration.

**Conclusion:** Diabetes duration is a threat to eyes as the 1-10 years group complained of more complications. Because diabetic retinopathy and cataracts relate to long-term glucose control, sustained measures are necessary to prevent or cure the illnesses.

**Key Words:** T2DM, eye health, retina, diabetic retinopathy, glycemic control, blindness, HTN.

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## INTRODUCTION

T2DM is a multifaceted disorder that develops from multiple factors of risk such as; the unhealthy habits of physical inactivity, eating habits that lead to obesity, genetics, age, race and ethnic factors.

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PCOS, conditions associated with insulin resistance and other diseases and previous history of gestational diabetes also increases the risk<sup>1</sup>. Diabetes has acute compounding effects such as diabetic ketoacidosis, hypoglycemia, and hyperglycemia that largely contribute to the severe and fatal complications in diabetes<sup>2</sup>. Chronic complications are, hepatitis, myositis and muscle weakness, osteoporosis and arthritis, diabetic retinopathy, renal complications, diabetes neuropathy, diabetic foot, and increased susceptibility to infections<sup>3</sup>.

Diabetes mellitus is still a threat to the global population; it is the 10th leading cause of death that claims over one million lives per year<sup>4</sup>. Diabetes prevalence has also been published by the International Diabetes Federation; 537 million people out of the population of people aged 20-79 years, have the disease<sup>5</sup>. This research proposal focuses on examining the effects of T2DM lasting on retina and the eye health of the population in Pakistan.

## METHODS

This is a hospital-based cross-sectional study that investigates a sample of 420 diabetic patients suffering from type 2 DM who attended Mehboob Charity Vision International Eye and General Hospital, Mansehra, Pakistan between May 2023-January 2024.

**Source Population:** The source population of this study was all diabetic patients from Mehboob Charity Vision International Eye and General Hospital, Mansehra, Pakistan.

**Study Population:** T2DM patients who are 40 years and above duration of disease for at least 5 years. Regarding the participants, they were both male and female, and of different ethnic origin.

**Sampling Procedure:** In the study, a technique of random sampling was applied in such a way that the likelihood of choosing a participant was equal.

### Inclusion and Exclusion Criteria

**Inclusion Criteria:** Suffers from T2DM for not less than 5 years. They are equal to or more than 40 years of age. Compliant to give an informed consent

**Exclusion Criteria:** So diagnosed with any other form of diabetes. Excluding participants who have other diseases that can harm the eyes other than diabetes. Incapable of giving informed consent.

### Operational Definitions:

**Diabetic Retinopathy:** An eye condition that can cause vision loss and blindness in people with diabetes, affecting blood vessels in the retina (National Eye Institute 2019).

**Visual Acuity:** A measure of vision clarity, typically assessed using the Snellen chart, expressed as a Snellen fraction (e.g., 20/20).

**Visual Impairment:** A condition where eyesight is significantly affected, ranging from mild to severe.

**Blindness:** Visual acuity worse than 3/60.

**Statistical Analysis:** Microsoft Excel was used to enter the data, and SPSS Software version 20.0 was used to clean and transport the data for analysis. Descriptive statistics, in particular the mean and standard deviation, were used to describe continuous data. Frequencies and percentages were used to describe categorical variables. It was estimated how common DR was overall, confirmed or diagnosed by an eye exam. Gender and age-specific reports on DR prevalence are also provided. The descriptive statistics about effect of duration of diabetes in years on complications related to eye health are the major focus of study.

**Data Collection and Quality Control Procedure:** It was crucial to devise a systematic questionnaire; therefore, the board of the institution approved the recruitment process. Subjects were required to be aged 40 years and above, and have diabetes for not less than 5 years. The Clinical assessments were done by an Optometrist and two Ophthalmologists. A one-day training was provided to data collectors to ensure data

quality. 420 patients met the inclusion criteria, and 3445 did not meet the outcome measure. The interview and examination were done after participants provided signed informed consent.

## RESULTS

Among the 3865 patients who reported to the Outpatient Department (OPD) for eye examinations, 420 met the inclusion criteria for study. The participants' sociodemographic and diabetes related data is summarized in table 1.

Among the 420 participants, the age distribution showed that 0.61% (n=3) were aged 1-20, 4.90% (n=20) were 21-40, 47.23% (n=199) were 41-60, and 46.01% (n=193) were 61 and above. Gender-wise, 44.1% (n=185) were males and 55.8% (n=235) were females. Most participants resided in rural areas (69.32%, n=291), with 19.01% (n=79) from urban areas, and 11.65% (n=50) unspecified. The study reported 90.75% (n=380) with Type 2 diabetes and 9.20% (n=39) with Type 1 diabetes. Family history revealed 31.90% (n=134) had no diabetes history, 23.92% (n=100) had a paternal history, 35.58% (n=149) had a maternal history, and 8.58% (n=36) had both. BMI distribution showed 28.83% (n=121) normal, 60.73% (n=255) overweight, and 10.42% (n=44) obese. Most patients (73.01%, n=305) had uncontrolled blood sugar levels, while 14.2% (n=60) had normal levels. Additionally, 46.03% (n=193) had hypertension, while 53.97% (n=225) did not.

**Table No.1: Sociodemographic and Disease-Related Characteristics of Participants**

Variables	Categories	%
Age (Years)	1-20	0.61%
	21-40	4.90%
	41-60	47.23%
	61 and above	46.01%
Sex	Male	44.1%
	Female	55.8%
Place of Residence	Rural	69.32%
	Urban	19.01%
	Nill	11.65%
Type of Diabetes	Type 1	9.20%
	Type 2	90.75%
Family History	No Family History	31.90%
	Father	23.92%
	Mother	35.58%
	Both	8.58%
BMI	Normal	28.83%
	Overweight	60.73%
	Obesity	10.42%
Glycemic Control	Normal	14.2%
	Un-controlled	73.01%
Hypertension	Yes	46.03%
	No	53.97%

**Table No.2: Education and Occupation Related Data of participants.**

Employment Status	Employed	39.26%
	Unemployed	60.73%
Education	No Fromal Education	80.95%
	Primary-Middle	0.00%
	Secondary	3.17%
	Higher	1.78%
	Graduate	14.28%
Occupation	Housewife	41.71%
	Driver	1.84%
	Teacher	2.45%
	Jobless	7.97%
	Other	7.97%

**Table No.3: Duration of Diabetes and DR Complications**

Variables	Categories	Frequency %
Duration of Diabetes	1-5	21.47%
	6-10	24.53%
	11-15	15.95%
	16-20	9.00%
	21-25	6.13%
	25 and above	1.22%
Examination Frequency at Hospital (For Retinal Diseases)	1 <sup>st</sup>	39.87%
	2 <sup>nd</sup>	12.88%
	3 <sup>rd</sup>	7.36%
	Already Diagnosed	33.74%
Visual Acuity	6/60 or Less	R=11.65% L=14.11%
	6/38 To 6/19	R=31.28% L=28.22%
	6/15 To 6/6	R=51.53% L=47.85%
Cataracts	Posterior Sub Capsular	14.72%
	Lenticular Changes	19.01%
	Senile Mature	3.06%
	Cortical Cataract	0.00%
	Nuclear Sclerosis	0.00%
Fundus	Normal	53.96%
	Mild NDPR	9.52%
	Moderate NDPR	6.34%
	Severe NDPR	0%
	PDR	6.34%

Table 3 is offering insights into the duration of diabetes and associated complications. The temporal aspects of diagnosis of diabetes are depicted by the duration of diabetes which showed that majority had been diagnosed within the last 1-5 years (21.47%, n=90), followed by 6-10 years (24.53%, n=103), 11-15 years (15.95%, n=67), 16-20 years (9.00%, n=38), 21-25 years (6.13%, n=26), and 25 years and above (1.22%, n=5).

Examining the examination frequency at the hospital for retinal diseases, 39.87% (n=167) attended their first examination, 12.88% (n=54) their second, 7.36% (n=31) their third, and 33.74% (n=141) had already

been diagnosed. Visual acuity was assessed based on Snellen chart reading. For visual acuity of 6/60 or less, the right eye (R) had 11.65%, and the left eye (L) had 14.11%. For visual acuity between 6/38 to 6/19, R was at 31.28%, and L was at 28.22%. For visual acuity between 6/15 to 6/6, R was at 51.53%, and L was at 47.85%. As far as cataracts is concerned, 14.72% (n=62) presented with posterior sub-capsular cataracts, 19.01% (n=79) with lenticular changes, 3.06% (n=13) with senile mature cataracts, 0.00% with cortical cataracts, and 0.00% with nuclear sclerosis. 3.96% (n=226) exhibited a normal fundus, 9.52% (n=40) had mild non-proliferative diabetic retinopathy (NDPR), 6.34% (n=27) had moderate NDPR, and 6.34% (n=27) had proliferative diabetic retinopathy (PDR)<sup>7</sup>.

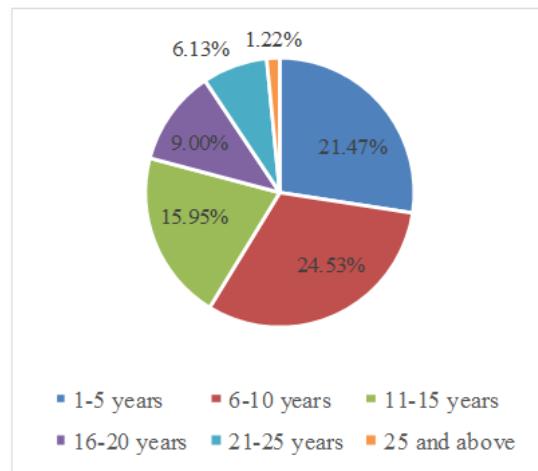
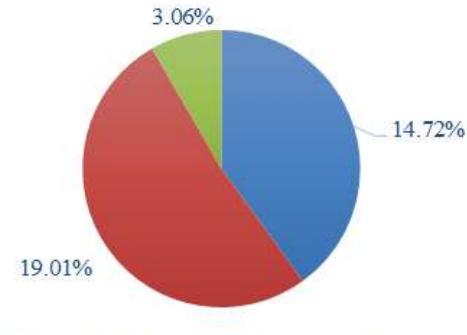
**Figure No.1: Distribution of Respondents according to duration of diabetic years****Figure No.2: Prevalence of Cataracts Complications In Diabetics**

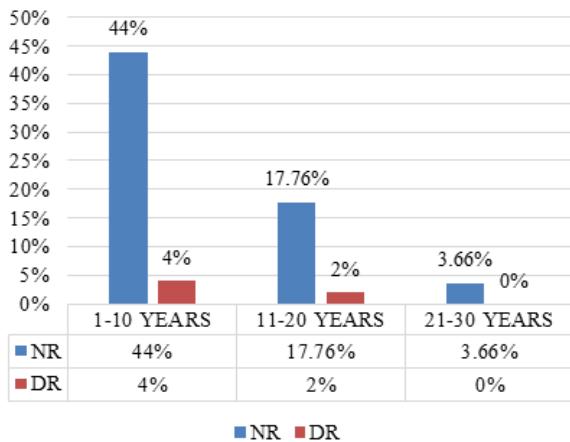
Table 4 depicts the effect of duration of diabetes on the outcomes related to diabetic retinopathy.

44% (n=185) of participants had a normal retina in first 10 years. Specifically, 17.76% (n=74) had been living with diabetes for 1-10 years, and 3.66% (n=15) for 11-20 years. Diabetic retina was present in 4% (n=17) of participants with duration of diabetes 1-10 years and

2% (n=8) in 11-20 years group. Discomfort levels have reported to decrease as 8% (n=34) reported mild discomfort, 16.2% (n=68) reported severe discomfort and 28.4% (n=119) reported disturbance while in duration of 1-10 years.

**Table No.4: Classification of DR Complications according to Duration of Diabetes**

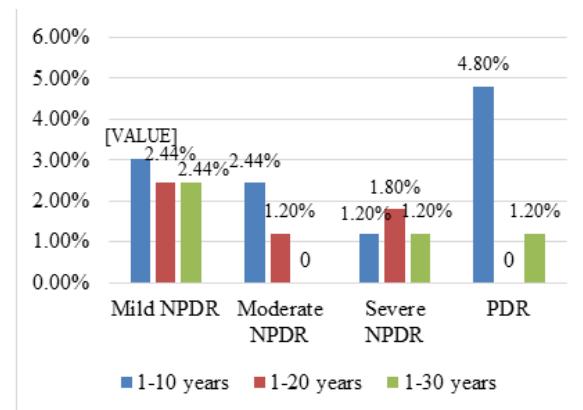
Duration (Years)	Yrs. (1-10)	Yrs. (11-20)	Yrs. (21-30)
Normal retina	44%	17.76%	3.66%
Diabetic Retina	4%	2%	0%
Discomfort Level			
Mid Discomfort	8%	4.9%	0%
Severe enough to stop Work and take rest	16.2%	8.3%	2.5%
Normal	7.5%	1.2%	0.6%
Disturbs work	28.4%	12.3%	5.6%
Complications			
Mild NPDR	3.04%	2.44%	2.44%
Moderate NPDR	2.44%	1.2%	-
Severe NPDR	1.2%	1.8%	1.2%
PDR	4.8%	-	1.2%
PSC Cataract	21.5%	11.1%	3.68%
Lenticular Changes (Cataract)	2.56%	11.05%	6.8%
Senile Mature Cataract	14%	1.2%	3.06%
VA Perception of Light PL	4%	0%	0%
VA Hand Movement HM	2%	0%	0%
VA Counting Figures CF	8%	0%	0%



**Figure No.3: Prevalence of Normal and Diabetic Retina**

Mild NPDR has reported to decrease in successive years as 3.04% (n=13) in Yrs(1-10), 2.44% (n=10) in Yrs(11-20), 2.44% (n=10) in Yrs(21-30) showed its presence. Similarly moderate NPDR data showed same trend: 2.44% (n=10) in Yrs(1-10), 1.2% (n=5) in Yrs(11-20), no cases in Yrs(21-30). In first 10 years 1.2% (n=5) reported severe NPDR, 1.8% (n=8) in duration of 11-20 years and 1.2% (n=5) in duration of 21-30 years. PDR cases were reported in 4.8% (n=20)

in duration of 1-10 years and 1.2% (n=5) in duration of 21-30 years.



**Figure No.4: NPDR and PDR prevalence**

## DISCUSSION

The demographic and selected health data of the participants are also described in the study, where greater than 40 years are the most represented and largest proportion. 1% (n=185) male participation and 55 among the females. 8% (n=235) though mostly females were involved in the study, the majority 69. 32 % (n=291) of them hailed from rural areas. BMI data showed 60. Regarding the weight status, 73% (n=255) were overweight which is consistent with WHO estimate for Pakistan<sup>8</sup>. Diabetic patients suffering from uncontrolled blood sugar was 73 per cent. 28% (n= 2025), similarly to earlier research<sup>9</sup>. Hypertension affected 46. Out of the participants, 03% (n=193) reported the level of participation as appropriate, which is in parity with<sup>6</sup>.

Patient had diabetes of different durations; 21. (n=90) with diabetes duration of 1-5 years, 24. It was 53% (n=103) for 6-10 years, which was followed by a gradual decrease in the proportion for higher years of involvement<sup>10</sup>. Initial examinations in hospitals contributed to 39. 87% (n = 167) to have experienced at least one of the negative occurrences described and 63% (n = 120) for the second visit. Specifically, on the Snellen chart used to assess the level of visual acuity, performances were also varied<sup>11</sup>. Cataract types included 14. : 72% (n = 62) of the patients had the posterior subcapsular form; 19. 01% (n=79) patients showed lenticular changes<sup>12</sup>.

With regard to DR trends, there was a significant difference by the diabetes duration<sup>13</sup>. The discomfort levels reduced in frequency and where patients had expressed mild discomfort in the first week, the respective score reduced from 8% (34) to 28. 4% of the patients (n=119) reported disturbance during the first 10 years. Mild NPDR and PDR cases are evaluated separately, and both of them reduced over time: while mild NPDR fell from 3. 04% (n=13) to 2. 44% (n=10),

and PDR from 4. 8% (n=20) to 1. 2% (n=5). Again, there was a change with PSC cataract frequency reducing, but the lenticular changes increasing with the duration of the disease.

The study showed a reduced vision after the first 10 years of diabetes but no perception of light, hand movement or counting figures in the 11-20- and 21-30-years' duration groups. This points to the possibility of the absence or even the stabilization of these complications with long term diabetes. In accordance with the literature, the current study demonstrates that both poor glycemic control and a longer duration of diabetes harm the eyes<sup>14</sup>.

## CONCLUSION

The findings point a high prevalence of overweight, high blood pressure and raised fasting blood sugar comparable to the national and international trends. The importance of the duration of the disease on the eyesight A description of the trends of eye complications according to the duration of the disease showing a trend of a higher frequency of complications among those who have been diabetic for 1-10 years<sup>15</sup>. The discoveries stress how longer time management of glucose is essential since signs like the diabetic retinopathy and cataracts prove it<sup>16</sup>. Thus, the given findings are valuable for policy makers and healthcare workers and stress the necessity of developing specific prevention measures to reduce the negative impact of diabetes on vision in the context of Pakistani population<sup>17</sup>.

### Author's Contribution:

Concept & Design of Study: Muhammad Junaid, Fawad Ahmed  
 Drafting: Fawad Ahmed, Zia-ur-Rehman  
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 Final Approval of version: By all above authors

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

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# Antibiotic Sensitivity and Resistance Patterns of Common Microbes among Burn Patients at Ayub Teaching Hospital, Abbottabad

Firdous Khan, Abdullah Mahmood and Saad Iqbal

Antibiotic Sensitivity and Resistance Among Burn Patients

## ABSTRACT

**Objective:** To determine the most frequently occurring microbes in burn infections, along with their antibiotic sensitivity and resistance profile and to revise treatment protocols accordingly.

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

**Place and Duration of Study:** This study was conducted at the Department of Plastic Surgery & Burns, Ayub Teaching Hospital Abbottabad from 1<sup>st</sup> January 2024 to 30<sup>th</sup> June 2024.

**Methods:** This descriptive cross-sectional study included 97 patients with burn injuries having a Total Burn Surface Area (TBSA) greater than 10% and who had not been previously treated. Data were collected using a non-probability consecutive sampling technique after obtaining informed consent. Microbial analysis was performed and data were analyzed. Pearson chi-square test was applied and P value  $\leq 0.05$  was considered significant.

**Results:** Mean age of patients was 33.3 years. Out of 97 patients, majority of cases were seen in females (58.8%). Methicillin Resistant Staphylococcus Aureus (MRSA) and Pseudomonas Aeruginosa were the most commonly isolated organisms (34% and 30.90%) respectively. Linezolid (68%) and Meropenem (58%) are the most sensitive antibiotics while Amoxicillin-Clavulanic acid and Erythromycin carries the highest resistance rate i.e. 93.8% for both.

**Conclusion:** There is a rising concern of multidrug resistant organisms especially Pseudomonas Aeruginosa and MRSA. Several antibiotics like Piperacillin, Tazobactum, and Meropenem are becoming more and more resistant. Some drugs like Linezolid and Vancomycin still have better efficacies but they should be used cautiously.

**Key Words:** Burn injury, Sensitivity, Multidrug resistant organisms

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## INTRODUCTION

Burn injury is one of the most devastating forms of injury that leads to grave outcomes. It carries a significantly high mortality and morbidity due to post burn infections<sup>1</sup>. An estimated 120,000 deaths occur annually due to burns. More than half of these deaths are reported from Southeastern Asia and low to middle income countries<sup>2</sup>. The causes of burns can be thermal, electrical, chemical, radiation or contact<sup>3</sup>, irrespective of the cause; all burn injuries damage the largest organ of body i.e. skin.

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Skin is responsible for thermoregulation, hemostasis, sensations and also acts as a primary immunological barrier<sup>4</sup>. Once burn injury occurs, it damages the skin and increases the susceptibility to infections due to loss of primary barrier as well as local inflammatory response<sup>5</sup>. Burn wounds release large amounts of exudates which are protein rich; it acts as a medium which favors bacterial growth<sup>6</sup>. Burn wounds remain sterile for about first 48 hours, after that the damaged skin starts getting colonized by pathogens. Majority of these come from patient's normal flora from gastrointestinal and respiratory tracts and the rest are acquired from the environment. If not treated promptly, patient can develop uncontrolled sepsis which leads to increased mortality<sup>7</sup>.

Diagnosis of infection is made on the basis of physical examination, vital signs (temperature, pulse rate) and infection biomarkers (TLC count and CRP)<sup>8</sup>. Major cause of gram positive infections is Staphylococcus Aureus. In normal individuals, Staphylococcus aureus does not cause infection but in burn patients, it causes opportunistic infections due to compromised immunity and lack of skin barrier. Among gram negatives,

Pseudomonas Aeruginosa is the leading causative organism<sup>9</sup>.

In developing countries like Pakistan, late presentations, overburdened hospitals, inappropriate use of antibiotics and lack of practice of performing cultures is leading to an increase in antibiotic resistance which makes it difficult to effectively treat burn infections which increases mortality and morbidity<sup>10</sup>.

## METHODS

This descriptive, cross sectional study was conducted at the Department of Plastic Surgery & Burns, Ayub Teaching Hospital Abbottabad from 1<sup>st</sup> January 2024 to 30<sup>th</sup> June 2024. Ethical approval was taken. Patients of burn injury with Total Burn Surface Area (TBSA) greater than 10% who have not been treated previously in any other hospital were included irrespective of age or cause of burn. Based on these criteria, data was collected by non-probability consecutive sampling method after taking informed consent from 97 patients. Samples from wound sites were taken using sterile swabs under aseptic conditions. Swabs were immediately sent to microbiologic laboratory where they have been inoculated on Blood and MacConkey agar. Microbes were identified using gram staining, morphological features and certain biochemical tests, after 24 to 48 hours of incubation at 37 degree Celsius. Antibiotic sensitivity patterns have been identified by Kirby-Bauer Disk Diffusion method. Data was analyzed using data analysis software SPSS v.27. Quantitative variables were described in terms of mean and standard deviation while qualitative variables were analyzed using Pearson chi square test and results were deemed significant for a P value of  $\leq 0.05$ .

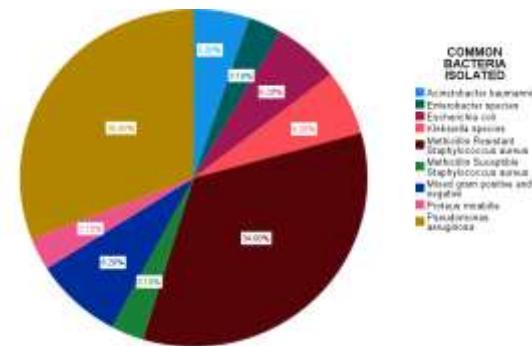
## RESULTS

Out of the total 97 cases, majority of burn injuries were seen in females (n=57) as compared to males (n=40).

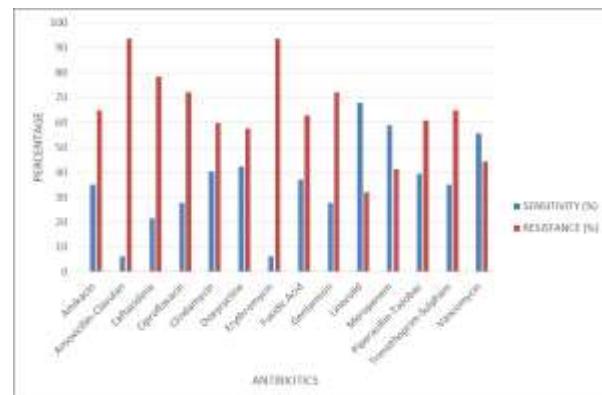
**Table No.1: Socio- demographic characteristics.**

Total Burn Patients (N=97)			
		Frequency (n)	Percentage
Gender	Male	40	41.2 %
	Female	57	58.8 %
Cause of burn Injury	Scald	31	32.0%
	Flame	57	58.8%
	Electric	09	9.2%
Degree of burn	First degree	15	15.5%
	Second degree	59	60.8%
	Third Degree	23	23.7%
Gender Relationship with Cause of Burn P value <0.001	Male	Scald	23
		Flame	9
		Electric	8
	Female	Scald	8
		Flame	48
		Electric	1

Mean age of patients were 33.3 years. Most common cause of burn was flame burn which accounted for (58.8%) followed by scald (32%) and electric (9.2%). Second degree burns were more prevalent (60.8%) as compared to first degree (15.5%) and third degree (23.7%). In females, most burns were due to flame injury while in males mostly scald injury was the cause (P value <0.001). Our results are described in the following tables & figures.



**Figure No.1: Percentages of Common Bacterial isolates.**



**Figure No.2: Sensitivity and resistance of individual antibiotics**

Table No.2: Antibiotic sensitivity and resistance patterns of common burn wound isolates.

		Pseudomonas aeruginosa	MRSA	Klebsiella species	Acinetobacter baumannii	Escherichia coli	Enterobacter species	Mixed growth	Proteus mirabilis	MSSA	P Value
		n=30	n=33	n=6	n=5	n=6	n=3	n=8	n=3	n=3	
Amoxicillin-Clavulanic acid	Sensitivity	0.0%	9.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%	0.000
	Resistance	100.0%	90.9%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	0.0%	
Piperacillin-Tazobactam	Sensitivity	43.3%	27.3%	50.0%	60.0%	0.0%	100.0%	12.5%	100.0%	100.0%	0.003
	Resistance	56.7%	72.7%	50.0%	40.0%	100.0%	0.0%	87.5%	0.0%	0.0%	
Ceftazidime	Sensitivity	30.0%	9.1%	50.0%	0.0%	0.0%	0.0%	0.0%	100.0%	100.0%	0.000
	Resistance	70.0%	90.9%	50.0%	100.0%	100.0%	100.0%	100.0%	0.0%	0.0%	
Meropenem	Sensitivity	56.7%	45.5%	100.0%	60.0%	50.0%	100.0%	50.0%	100.0%	100.0%	0.098
	Resistance	43.3%	54.5%	0.0%	40.0%	50.0%	0.0%	50.0%	0.0%	0.0%	
Vancomycin	Sensitivity	40.0%	90.9%	50.0%	60.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.000
	Resistance	60.0%	9.1%	50.0%	40.0%	100.0%	0.0%	100.0%	100.0%	0.0%	
Amikacin	Sensitivity	50.0%	0.0%	50.0%	100.0%	0.0%	100.0%	100.0%	0.0%	0.0%	0.000
	Resistance	50.0%	100.0%	50.0%	0.0%	100.0%	0.0%	0.0%	100.0%	100.0%	
Gentamicin	Sensitivity	50.0%	0.0%	50.0%	100.0%	0.0%	0.0%	50.0%	0.0%	0.0%	0.000
	Resistance	50.0%	100.0%	50.0%	0.0%	100.0%	100.0%	50.0%	100.0%	100.0%	
Erythromycin	Sensitivity	10.0%	9.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.901
	Resistance	90.0%	90.9%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	
Doxycycline	Sensitivity	20.0%	54.5%	50.0%	100.0%	50.0%	100.0%	0.0%	0.0%	100.0%	0.000
	Resistance	80.0%	45.5%	50.0%	0.0%	50.0%	0.0%	100.0%	100.0%	0.0%	
Ciprofloxacin	Sensitivity	40.0%	18.2%	50.0%	0.0%	0.0%	0.0%	37.5%	100.0%	0.0%	0.011
	Resistance	60.0%	81.8%	50.0%	100.0%	100.0%	100.0%	62.5%	0.0%	100.0%	
Trimethoprim-Sulphamethoxazole	Sensitivity	10.0%	45.5%	50.0%	0.0%	50.0%	100.0%	12.5%	100.0%	100.0%	0.000
	Resistance	90.0%	54.5%	50.0%	100.0%	50.0%	0.0%	87.5%	0.0%	0.0%	
Clindamycin	Sensitivity	50.0%	45.5%	0.0%	60.0%	0.0%	100.0%	0.0%	100.0%	100.0%	0.001
	Resistance	50.0%	54.5%	100.0%	40.0%	100.0%	0.0%	100.0%	0.0%	0.0%	
Linezolid	Sensitivity	80.0%	100.0%	50.0%	60.0%	0.0%	0.0%	0.0%	0.0%	100.0%	0.000
	Resistance	20.0%	0.0%	50.0%	40.0%	100.0%	100.0%	100.0%	100.0%	0.0%	
Fusidic Acid	Sensitivity	60.0%	27.3%	0.0%	60.0%	0.0%	100.0%	0.0%	0.0%	100.0%	0.000
	Resistance	40.0%	72.7%	100.0%	40.0%	100.0%	0.0%	100.0%	100.0%	0.0%	

## DISCUSSION

Burn wound infections present a difficult clinical challenge, due to their complex microbiological profiles and evolving antibiotic resistance. This study aimed to determine the common pathogens isolated from burn wounds and their respective antibiotic resistance and sensitivity profiles. By comparing our findings with existing literature, we can better understand the present issues surrounding burn wound infections and devise strategies to address them. Our study identified that gender difference exists in burn injuries with a higher incidence among females (58.8%) compared to males (41.2%) (Table1). This finding contrasts with previous studies such as the one reported by Chaudhary et al.<sup>11</sup> which observed a higher prevalence of burns in males (55%) compared to females (45%). However, gender based variations can be present among populations of different areas. Various factors can contribute to this aspect, for example housing conditions, occupational

risks, psychosocial factors, access to medical facilities, availability of safety equipment etc.

The mean age of burn patients in our study was 33.3 years, which is nearly consistent with the age distribution reported by Gu et al. who found a mean age of 37 years<sup>12</sup>. Regarding the causes of burn injuries, we found that flames were the predominant cause (58.8%), followed by scalds (32%) and electric burns (9.2%). This distribution is similar with findings from another study<sup>13</sup>. Ji S et al. provided a consensus in 2023 after analyzing burn cases for a period of 10 years and agreed that second degree burns were most common type of burns in clinical practice<sup>14</sup> which is similar to what we observed in our patients. When gender-specific analysis of burn injuries was done, we came across the fact that females experienced a higher incidence of flame burns (84.2%) compared to males (22.5%) which was similar to results of another study<sup>15</sup>. This is logical to think that a female is more vulnerable to flame burns because of house hold exposures to gas and fire appliances. All these findings show that most

demographic characteristics of our study align with broader trends observed worldwide among burn patients.

We identified Methicillin- Resistant Staphylococcus Aureus (MRSA) is the most common pathogen in burn wound infections accounting for 34% of isolates. *Pseudomonas Aeruginosa* was the second most common pathogen representing 30.9% of the isolates. These findings are consistent with a study by El Hamzaoui N et al. which also identified *Staphylococcus aureus* is the most common pathogen (33.85%) followed by *Pseudomonas* occurring in 18.46%<sup>16</sup>. This indicates that MRSA and *Pseudomonas Aeruginosa* are the main contributors in burn infections and they need to be addressed properly. We observed a concerning trend in our study related to *Pseudomonas Aeruginosa*. A study was conducted on burn wound isolates back in 2020 in our unit; at that time *Pseudomonas Aeruginosa* was found to be the lowest isolate (7%)<sup>17</sup>. However, our 2024 data reveals that *Pseudomonas Aeruginosa* is the second most common isolate (30.9%). This fourfold increase in *Pseudomonas* over a period of just four years is an alarming sign and it indicates towards increased resistance or adaptability of *Pseudomonas* in the burn wound environment, raising concerns about its potential impact on patient mortality and morbidity.

When sensitivity and resistance patterns of *Pseudomonas Aeruginosa* were analyzed, they demonstrated only 56.7% sensitivity to Meropenem, a drastic decline from the 97.62% sensitivity reported by Shukla et al.<sup>18</sup>. Similarly, sensitivity to Piperacillin-Tazobactum was 43.3% in our study compared to 90.48% in Shukla's research. This dramatic difference in sensitivity of two antibiotics demonstrates that prevalence of multidrug resistant organisms is more in our setup. Linezolid and Vancomycin exhibited sensitivities of 100% and 90.9% respectively, against MRSA. These results are consistent with a study conducted in a Burn unit in Peshawar which reported Linezolid sensitivity at 97% and Vancomycin at 98%<sup>19</sup>. This suggests that Linezolid and Vancomycin are still an effective option to treat MRSA in our region for burn injuries. High sensitivities of these drugs do not imply that we start using them indiscriminately. It is crucial that these antibiotics should be used more cautiously because in a few more years to come these might be the only resort to treat MRSA. Mantal and Das reported that Piperacillin-Tazobactum was the most sensitive antibiotic followed by Imipenem<sup>20</sup> but in our setting, we identified that Linezolid was the most potent antibiotic followed by Meropenem. When data for most resistant antibiotics was drafted, it revealed Amoxicillin-Clavulanic acid and Erythromycin carried 93.8% resistance rate which was highest among all antibiotics tested. This finding is particularly concerning because we use Amoxicillin-Clavulanic acid as a first line empiric drug for all burn patients

being admitted to our unit. These results warrant a change in empiric therapy to decrease the incidence of multidrug resistant organisms and improve patient outcome.

## CONCLUSION

In summary, our study points out several important problems in treating burn wound infections. There is a growing concern about the bacteria *Pseudomonas Aeruginosa* and its increasing resistance to major antibiotics like Meropenem and Piperacillin-Tazobactum which needs urgent attention. Although Linezolid and Vancomycin seem to work well, they should be used carefully to prevent the development of resistance. The high resistance rates of Amoxicillin-Clavulanic Acid show that we need to update our treatment protocols.

**Limitations:** There are several limitations to our study which include:

1. Insufficient testing of antibiotics due to limited availability of antibiotic discs commercially thus only a finite number of discs are being used which does not provide a complete picture of resistance patterns.
2. If one drug from a class is sensitive other drugs of that class are not being tested, ideally 3 to 4 drugs from each class should be tested to determine other variables like cross resistance of drugs across a genera and individual efficacies.

## Recommendations:

1. We recommend that future researches should test a wide variety of antibiotics to assess the resistance patterns more accurately. At least, 3 antibiotics from a class should be tested to determine individual efficacies and cross resistance among drugs.
2. Periodic culture and sensitivities should be carried out to keep an eye on changing trends over the time. This will not only improve literature and guide clinical decisions but also improve patient outcome.

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# E-learning Self-Perceived Readiness Among Dental Students: A Multi-Institution Study

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## ABSTRACT

**Objective:** This study aimed to evaluate dental students' perceived readiness for e-learning in low and middle-income countries, employing the Online Learning Readiness Scale (OLRS).

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

**Place and Duration of Study:** This study was conducted at the College of Dentistry, King Faisal University Al-Ahsa, Saudi Arabia, from March and August 2023.

**Methods:** An electronic survey was conducted among dental students in six countries: Egypt, India, Nigeria, Pakistan, Saudi Arabia, and Sudan. Convenience and snowball sampling techniques were employed to recruit the participants and disseminate the survey links through collaborative networks.

**Results:** This study included 665 dental students; 59.4% were female and 73.4% were younger students. Most participants (74%) were enrolled in public institutions, with 54.4% categorized as senior students. The highest average score for the agreement was 52.9% in online communication self-efficacy. Saudi Arabia scored highest across all constructs, while Sudan recorded the lowest, primarily due to insufficient institutional support. Notably, computer/internet self-efficacy demonstrated significant correlations with all other constructs, while the motivation for learning correlated significantly with self-directed learning and online communication self-efficacy.

**Conclusion:** The findings underscored the importance of assessing dental students' perceived readiness for e-learning, which emerges as a crucial factor in ensuring the efficacy of educational processes. While overall readiness was evident among dental students, variations were observed across demographic factors such as age, gender, study level, and institutional type. The disparity in readiness levels highlights the necessity for tailored approaches to support e-learning initiatives, particularly in regions with limited institutional resources.

**Key Words:** e-Learning, Dental students, readiness, Dental education, online, OLRS

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## INTRODUCTION

Online or electronic learning (e-learning) has revolutionised higher education. E-learning is 'an educational method that facilitates learning by applying

information technology and communication, providing an opportunity for learners to access all the required education programs'<sup>1</sup>. In practice, e-learning offers many adaptable models or designs, from enhanced or adjunct models to blended e-learning models and fully online models<sup>2</sup>. The effectiveness of e-learning is not a fixed concept but is contingent on certain levels of technical training and motivation among dental students and educators<sup>3</sup>. Full implementation necessitates measuring students' e-learning readiness, which involves assessing their confidence in using various technologies and computer-mediated devices for online learning, particularly the Internet<sup>4</sup>.

COVID-19 has posed a significant challenge to dental education. It forced institutes to completely overhaul their teaching methods and focus more on online teaching<sup>5</sup>.

Researchers have developed a readiness scale for e-learning Smith et al<sup>6</sup> found two primary factors that predicted student success: self-management of learning and comfort with e-learning.

Later, Hung, Chou<sup>7</sup> developed and validated the Online Learning Readiness Scale (OLRS), a multidimensional

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instrument for assessing students' readiness. The (OLRS) assesses five domains. Self-directed learning (SDL); Motivation for learning (MFL); Computer/internet self-efficacy (CIS); Learner's control (LC); Online communication self-efficacy (OCS)<sup>8</sup>.

Researchers in education have widely recognized the OLRS, which is often used to measure the online learning readiness of higher education students in various majors in different countries and has been validated in several studies and contexts.<sup>9,10</sup>

Assessing and reassessing students' self-perceived readiness for e-learning is essential to guide students more effectively and provide a more productive e-learning experience<sup>7</sup>. Therefore, this study aimed to assess dental students' self-perceived readiness for e-learning in multiple institutions in low-income and middle-income countries using the OLRS.

## METHODS

**Study design and sampling:** This cross-sectional survey, conducted between March and August 2023, included dental students from six countries: Egypt, India, Nigeria, Pakistan, Saudi Arabia, and Sudan. Convenience and snowball sampling techniques were used to recruit the participants and distribute the online survey links through the collaborators' contacts, including WhatsApp groups specific to dental students and institutional email lists. The selection of students with representatives from one public and one private institute within the same country ensures a diverse representation of different socioeconomic groups. The dental students who met the criteria of being registered in academic institutes, having studied some sessions online, having internet access, and being able to read and write in English.

### Questions and measures:

The data were collected using a structured questionnaire adapted from the ORLS Scale. The first part of the questionnaire included questions about socio-demographic information: age, gender, type of institution, and academic rank. Furthermore, the questionnaire contained additional aspects regarding online learning devices, kind of internet connection, educators' views on internet cost, and time spent online. The students were then divided by their study year into juniors (in years 1–3) and seniors (in years 4–5/6), as well as by their age (17–22 years = young, and >22 years = old), for a comprehensive analysis. The participants' responses were grouped based on their agreement or disagreement with the statements. This was done using a 5-point Likert scale. Specifically, responses of "strongly agree" and "agree" were combined to indicate agreement with the statement, while responses of "strongly disagree" and "disagree" were combined to indicate disagreement. The frequency of responses for each category was then divided into high and low using the mean as the cut-off point.

The second part of the questionnaire evaluated dental students' perceived readiness for e-learning using the 18-item (five domains) OLRS (7). Three questions measured 'computer/internet self-efficacy' (CIS): 'I feel confident in performing the basic functions of Microsoft Office programs (MS Word, MS Excel, and MS PowerPoint)'; 'I feel confident in my knowledge and skills of how to manage software (apps) for online learning'; 'I feel confident in using the internet (e.g. Google) to find or gather information for online learning.' A sum variable CIS had Cronbach's  $\alpha$  0.80. Five questions measured self-directed learning (SDL): 'I carry out my own study in the online learning setting'; 'I seek assistance when facing learning problems in the online learning setting'; 'I manage time well in the online learning setting'; 'I set up my learning goals in online learning'; 'I have higher expectations for my learning performance due to online learning'. A sum variable SDL with a Cronbach's  $\alpha$  0.73.

Three questions measured Learner's control (LC): 'I can direct my own online learning progress'; 'I am not distracted by other online activities when learning online (instant messages, internet browsing)'; 'I repeated the online instructional materials based on my needs'. A sum variable LC with a Cronbach's  $\alpha$  0.61.

Four questions measured 'motivation for learning' (MFL): 'I am open to new ideas in the online learning'; 'I have the motivation to learn in the online setting'; 'I improve from my mistake in the online setting'; 'I like to share my ideas with others in the online learning'. A sum variable MFL scored Cronbach's  $\alpha$  0.83.

Three questions measured online communication self-efficacy (OCS): 'I feel confident in using online tools (email, discussion) to communicate with others effectively'; 'I feel confident in expressing myself (emotions and humour) through text in the online learning'; 'I feel confident in posting questions in online discussions'. A sum variable OCS with Cronbach's  $\alpha$  0.81.

**Data analysis:** The data collected were organised, categorised, tabulated, and analysed using Statistical Package for Social Science (SPSS, 21). The data were presented as descriptive statistics, and the t-test and One-way analysis of variance (ANOVA) were used with a significance threshold of  $p \leq 0.05$  and a confidence interval of 95%.

## RESULTS

In this study, 665 dental students from six countries participated. Among them, 59.4% were female and 73.4% were younger students. Approximately 74% of the participants were from public institutes, and 54.4% were senior students. The highest percentage of participants came from Sudan (32.3%), followed by Nigeria (20%), while the fewest participants (9.9%) were from Egypt.

**Table No.1: Distribution of frequencies and percentages (%) of individual questions of the OLRS constructs.**

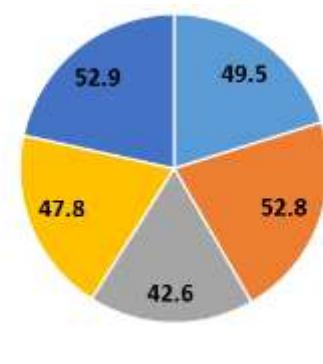
Questi on	Disagree	Neutral	Agree
<b>Computer/Internet Self-efficacy (CIS)</b>			
<b>CIS1</b>	86 (13)	217 (32.7)	360 (53.2)
<b>CIS1</b>	78 (11.8)	202 (30.5)	383 (57.8)
<b>CIS3</b>	35 (5.3)	113 (17.0)	516 (77.7)
<b>Self-Directed Learning (SDL)</b>			
<b>SDL1</b>	55 (8.4)	211 (32.0)	393 (59.7)
<b>SDL2</b>	102(15.5)	196 (29.8)	360 (75.7)
<b>SDL3</b>	244(36.9)	206 (31.2)	211 (32)
<b>SDL4</b>	202(30.4)	241 (36.5)	219 (33.1)
<b>SDL5</b>	259(39.4)	200 (30.4)	198 (30.2)
<b>Learners' control (LC)</b>			
<b>LC1</b>	162(24.6)	241 (36.6)	256 (38.9)
<b>LC2</b>	258(54.1)	164 (24.8)	140 (21.2)
<b>LC3</b>	69 (10.5)	234 (35.4)	358 (54.2)
<b>Motivation For Learning (MFL)</b>			
<b>MFL1</b>	110(16.6)	171 (25.9)	380 (57.4)
<b>MFL2</b>	182(27.6)	202 (30.6)	276 (41.8)
<b>MFL3</b>	111(16.9)	228 (34.5)	321 (48.7)
<b>MFL4</b>	169 (25)	225 (34.1)	270 (40.9)
<b>Online Communication Self-efficacy (OCS)</b>			
<b>OCS1</b>	137(20.8)	178 (26.9)	346 (52.4)
<b>OCS2</b>	197(29.9)	199 (30.2)	263 (39.9)
<b>OCS3</b>	170(25.7)	223 (33.7)	268 (40.5)

The OCS construct had the highest agreement level at 52.9%, closely followed by the SDL construct at 52.8%. In contrast, the LC construct had the lowest agreement level at 42.6% (Figure 1).

An analysis of the individual questions for each construct revealed that the highest percentage of student responses were in the 'agree' category, except for questions SDL3, SDL5, and LC2. (Table 1).

It was found that older male students scored significantly higher than their peers in all OLRS constructs. Additionally, public college students scored considerably higher than their counterparts in CIS, MFL, and OCS. Furthermore, senior students scored significantly higher than their peers in CIS and MFL (Tables 3).

In addition, pairwise comparison between the countries and the ORLS scores. Saudi Arabia scored higher than all countries in all constructs, followed by Nigeria and India, except CIS, where Pakistan scored higher than India. Sudan scored lower than all countries in all constructs (Table 2).



■ CIS ■ SDL ■ LC ■ MFL ■ OCS

**Figure No.1: Distribution of percentages of OLRS constructs.**

**Table No.2: The mean ( $\pm$ SD) of OLRS constructs by gender, age group, type of college, study level, and country.**

Variable	CIS	SDL	LC	MFL	OCS
<b>Gender</b>					
Male	11.48 $\pm$ 2.20	17.05 $\pm$ 3.20	9.80 $\pm$ 2.17	14.00 $\pm$ 3.10	10.52 $\pm$ 2.55
Female	10.78 $\pm$ 2.18	14.97 $\pm$ 3.35	8.71 $\pm$ 2.16	12.48 $\pm$ 3.22	8.92 $\pm$ 2.60
<b>Age group</b>					
Young	10.92 $\pm$ 2.20	15.45 $\pm$ 3.38	8.97 $\pm$ 2.18	12.82 $\pm$ 3.32	9.32 $\pm$ 2.69
Old	11.45 $\pm$ 2.21	16.81 $\pm$ 3.44	9.67 $\pm$ 2.27	13.88 $\pm$ 2.96	17.7 $\pm$ 2.59
<b>Type of college</b>					
Private	10.66 $\pm$ 2.06	15.47 $\pm$ 3.17	9.09 $\pm$ 2.03	12.58 $\pm$ 3.20	9.22 $\pm$ 2.44
Public	11.20 $\pm$ 2.25	15.93 $\pm$ 3.53	9.18 $\pm$ 2.29	13.28 $\pm$ 3.26	9.69 $\pm$ 2.77
<b>Study level</b>					
Junior	10.83 $\pm$ 2.18	15.62 $\pm$ 3.56	9.09 $\pm$ 2.20	12.70 $\pm$ 3.37	9.45 $\pm$ 2.71
Senior	11.25 $\pm$ 2.22	15.97 $\pm$ 3.33	9.21 $\pm$ 2.25	13.43 $\pm$ 3.13	9.67 $\pm$ 2.68
<b>Country</b>					
Egypt	10.56 $\pm$ 1.70	15.73 $\pm$ 3.07	9.15 $\pm$ 1.96	13.50 $\pm$ 2.51	9.44 $\pm$ 2.47
India	10.89 $\pm$ 1.68	16.41 $\pm$ 2.27	9.42 $\pm$ 1.69	13.54 $\pm$ 2.57	9.87 $\pm$ 1.84
Nigeria	11.83 $\pm$ 1.93	17.00 $\pm$ 3.40	9.24 $\pm$ 2.12	14.15 $\pm$ 2.73	11.00 $\pm$ 2.12
Pakistan	11.20 $\pm$ 2.25	15.71 $\pm$ 3.40	8.72 $\pm$ 2.27	12.63 $\pm$ 3.21	9.42 $\pm$ 2.46
Saudi Arabia	12.18 $\pm$ 2.21	17.89 $\pm$ 2.64	10.50 $\pm$ 2.04	14.96 $\pm$ 2.67	11.51 $\pm$ 2.13
Sudan	10.35 $\pm$ 2.38	14.17 $\pm$ 3.50	8.71 $\pm$ 2.41	11.68 $\pm$ 3.60	7.98 $\pm$ 2.70

Table No.3: Independent sample t test of the OLRS constructs by gender, age, type of college, and study level

Independent Variable	Construct	Mean Difference S. E.	95% C.I.
Gender	CIS	0.701 (0.173)	0.36 / 1.04**
	SDL	2.081 (0.260)	1.57 / 2.59**
	LC	1.090 (0.171)	0.75 / 1.43**
	MFL	1.519 (0.251)	1.03 / 2.01**
	OCS	1.597 (0.204)	1.19 / 1.99**
Age group	CIS	-0.532 (0.193)	-0.91 / -0.15**
	SDL	-1.357 (0.298)	-1.94 / -0.77**
	LC	-0.695 (0.194)	-1.08 / -0.315**
	MFL	-1.060 (0.283)	-1.62 / -0.50**
	OCS	-0.956 (0.234)	-1.41 / -0.49**
Type of college	CIS	-0.544 (0.195)	-0.09 / -0.16**
	SDL	-0.457 (0.304)	-1.05 / 0.14
	LC	-0.094 (0.197)	-0.48 / 0.29
	MFL	-0.0702 (0.287)	-1.27 / -0.14**
	OCS	-0.473 (0.238)	-0.94 / -0.01*
Study level	CIS	-0.422 (0.172)	-0.76 / -0.09**
	SDL	-0.352 (0.268)	-0.88 / 0.17
	LC	-0.118 (0.174)	-0.46 / 0.22
	MFL	-0.0731 (0.252)	-1.23 / -0.24**
	OCS	-0.222 (0.210)	-0.63 / 0.19

\* p≤0.05; \*\*p≤0.01

Table No.4: Spearman's correlation coefficient showing the correlation between the OLRS constructs.

Construct	SDL	LC	MFL	OCS
<b>CIS</b>	0.434**	0.354**	0.422**	0.441**
<b>SDL</b>		0.638**	0.646**	0.590**
<b>LC</b>			0.546**	0.441**
<b>MFL</b>				0.646**

\* p≤0.05; \*\*p≤0.01

Correlation analysis between the different constructs showed that the primary skills variables, CIS and OCS, significantly correlated with all four other constructs (p≤0.01). The strongest correlations were between MFL with SDL and OCS (p≤0.01), as well as SDL with LC (p≤0.01), followed by SDL with OCS and MFL with LC, while the weakest correlations were between SDL with CIS, MFL with CIS, and OCS with CIS, OCS with LC, and LC with CIS (Table 4).

## DISCUSSION

The self-perceived readiness of dental students for e-learning is a crucial aspect of the educational process, particularly given the widespread adoption of e-learning as a supplementary tool by academic institutions worldwide. However, it is essential to recognize that e-learning in clinical dental education poses significant challenges in developing practical skills<sup>11</sup>. This study assessed the self-perceived readiness of dental students for e-learning across multiple institutes.

Multiple previous studies<sup>3,12-14</sup> have shown a predominance of female students over male students in

dentistry. This contrasts with the study among Saudi students, which had an equal gender distribution<sup>15</sup>. This might be explained by the relatively recent introduction of female students in Saudi Arabia compared to the other countries included in the study.

According to the study's findings, more than half of the participants reported confidence in their OCS, which aligns with previous studies from Saudi Arabia, Pakistani, and South Africa<sup>12,13,15-17</sup>. This consistent alignment with existing research suggests that the majority of the students were already able to communicate well using online platforms, hence their perception of better readiness for e-learning regardless of the location of their institution. This might be because today's students are millennial learners who prefer the integration of innovative teaching modalities<sup>15</sup>.

Older male students, those attending public colleges, and senior students scored higher in OLRS constructs than their counterparts. This finding contrasts with a previous study that found no differences between these groups<sup>16</sup> but aligns with the results of Hattar's study<sup>3</sup>. Additionally, there were significant differences among Pakistani students, with senior students scoring higher than junior students<sup>12</sup>. Among Nigerian students, males and senior students had higher overall scores than their female and junior counterparts. In Vietnamese students, online communication skills were notably more vital in males<sup>14</sup>.

In this study, the countries' economic income levels were found to affect the students' self-perceived readiness for e-learning. For instance, with its

substantial institutional support, Saudi Arabia scored significantly higher in all constructs than other countries, except for Nigeria, where no statistical difference was observed in the MFL, CIS, and OCS constructs<sup>15</sup>.

Furthermore, the early implementation of e-learning in Nigerian higher educational institutes, even before the COVID-19 crisis, compared to other low and middle-income countries<sup>18</sup>, may explain the higher MFL, CIS, and OCS construct scores. Conversely, Sudan scored significantly lower in all the constructs than other countries involved in this study, except for Egypt and Pakistan<sup>12,19</sup>. This could be explained by the country's inability to implement e-learning in its higher educational institutes due to its lower financial support for higher educational institutes.

The study found a strong correlation between SDL as a primary outcome and the MFL, LC, CIS, and OCS; these results are similar to those reported by Nguyen and Tran<sup>14</sup>.

MFL is another important factor for e-learning, and this was derived from CIS, SDL, and LC, the latter being essential in strengthening these constructs. This was also found among Pakistani students<sup>12</sup>. Furthermore, some studies have confirmed that e-learning affects students' motivation<sup>20,21</sup>. This study's findings are limited to dental students' opinions in six countries. The limitation of the sample size, study design, and self-reporting questionnaire implies inevitable biases, including selection bias and information and social desirability, limiting the generalizability of reporting information.

Overall, the study provides information on dental students' e-readiness based on reliable and valid tools. It also gives better insight into dental students' e-readiness and helps us understand how best to support them in the transition to e-learning.

In general, dental students are positive about e-learning. In addition, this research can help dental educators create quality materials that improve e-learning. On the other hand, to tackle the constraints of e-learning and offer better methods to generate a suitable e-learning atmosphere.

## CONCLUSION

The findings highlight the significance of assessing dental students' perceived readiness for e-learning, a key determinant of educational success. While a general readiness was observed among students, notable differences emerged across various demographic factors. This variability in readiness underscores the need for targeted approaches to support e-learning, particularly in resource-constrained regions, to bridge the gap and ensure effective learning outcomes.

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# Assessment of Anatomical Landmarks in Dentulous Patients to Calculate Height of Occlusal Registration Blocks

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Height in Dentulous Patients by Assessing Anatomical Landmarks

## ABSTRACT

**Objective:** To determine the mean rim height in dentulous patients by assessing anatomical landmarks.

**Study Design:** Descriptive cross sectional study

**Place and Duration of Study:** This study was conducted at the Prosthodontics Department of Liaquat University of Medical & Health Sciences, Jamshoro, Sindh from Sep 2022 to March 2023.

**Methods:** Thirty patients were included in this study. Impressions were taken with alginate and models were poured. Measurement were taken using digital Vernier caliper for both arches on first permanent molars and canines from cusp tip to sulcus depth. Three readings were taken to identify a mean in case of any human or machine error.

**Results:** The patients' average age was  $28.10 \pm 5.97$  years. Mean height of 16.18 mm, 15.63 mm, 15.46 and 15.35 mm for First Molars teeth no. 16, 26, 36 and 46. Mean height was 19.5 mm, 19.07 mm, 18.09 mm and 18.06 mm for Canines teeth no. 13, 23, 33, and 43. The mean of mean height of all Molars teeth and all Canines teeth were  $15.65 \pm 1.16$  mm and  $18.68 \pm 1.47$  mm respectively.

**Conclusion:** In this population, for complete removable dental prosthesis fabrication, It is feasible to keep the maxillary anterior record rim's preset height of 19–20mm in male patients and 18-19mm in female patients. It could be help in fabricating denture which is functionally and aesthetically pleasing for edentulous patients.

**Key Words:** Complete denture prosthodontics, occlusal plane height, Fabricating denture

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## INTRODUCTION

Complete denture prosthodontics is Skill. Since the rehabilitation of edentulous patients with conventional complete dentures, whether tissue or implant supported must focus in a variety of biological and mechanical factors in order to restore the functions and general health of the stomatognathic system.<sup>[1]</sup>

One of the most important aspects in determining the prognosis of patients who are entirely edentulous is the establishment of balanced occlusion that should be in line with the functional movements of the stomatognathic system<sup>[2]</sup>.

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One of the key factor that helps in establishing the optimal occlusion is the orientation of the occlusal plane. <sup>[3]</sup>. Which is defined as the average plane established by incisal and occlusal surfaces of teeth. It helps in attaining aesthetics, phonetics efficient mastication, stability and any alteration can lead to damage to surrounding of tissues and resorption of ridges.<sup>[4, 5]</sup>

Various studies have been carried out to determine height of occlusal plane in dentate patients amongst various population. According to a study, measured maxillary height at  $20.3 \pm 1.3$  mm and mandibular height  $15.0 \pm 1.3$  mm at first molar region whereas in other study, recommended the heights of 24 mm and 20 mm in maxilla and mandible. A study by More et al<sup>[6]</sup>. conducted in India reported mean height of 14.49 mm, 16.87 mm, 13.55 and 12.33 mm for permanent first molars teeth no. 16, 26, 36 and 46 and mean height of 18.91 mm, 19.37 mm, 13.79 mm and 14.19 mm for canine's teeth no. 13, 23, 33, and 43. It was also observed that the mean occlusal plane height in Asian population varies from western population.

The occlusal rim height serves the basis in achieving the parallelism of occlusal plane, recording the maxillomandibular relationship and arrangement of artificial teeth, that in turn helps in fabricating

denture which is functionally and aesthetically pleasing for edentulous patients. As the average height of the occlusal plane varies across different racial populations, as noted in the literature, the aim of this study is to determine the occlusal plane height in our local population considering the genetic and geographical variations as we in our vicinity rely on guidelines established as per international values.

## METHODS

This descriptive cross sectional study was conducted at Prosthodontics Department of Liaquat Medical University utilizing non-probability consecutive technique after approval from ethical review committee. A total number of 30 patients with age range 18-45 years, both genders having well aligned set of dentition, with intact permanent canines and molar devoid of any occlusal disharmony were included in this study after taking a written informed consent from each patient. Appropriate size of impression trays were selected and impression were made for both arches using alginate impression material (Cavex CA37 - Alginate) with manufacturer prescribed instructions. Impression were disinfected under tap water and using disinfectant by (SERPRO) for one minute. Within 12 minutes, impressions were poured with type III dental stone (Kopo-Hard CKH-52). Pouring was done using the powder/liquid ratios suggested by the manufacturer. After pouring for one to three hours, the casts were taken out, trimmed, cleaned, and left to dry on a bench. As reference teeth Permanent first molars (teeth no. 16 26 36 and 46) and canines (teeth no. 13 23 33 and 43) were chosen. The occlusal rim height was measured for each referenced tooth mentioned was recorded using vernier calliper from deepest portion of sulcus depth to tip of canines and mesio-palatal cusp of maxillary first molars and buccal cusps of mandibular molar respectively. This procedure was repeated three times on each side of both maxillary and mandibular arches on respected reference selected tooth in case of any human or machine error. The mean value was recorded in mm for each tooth i-e 16 26 36 46 and 13 23 33 43. All data was analyzed using SPSS version 20. For quantitative data like age and mean values of rim height, mean and standard deviation were measured; for qualitative variables include gender, frequency was calculated. Chi square test was applied and p value  $\leq 0.05$  was considered as significant.

## RESULTS

A total of 30 patient patients with sound well aligned dentition having completely erupted permanent canines and first molars were selected in this study. Figure 1 depicts the patients' age distribution. The patients' average age was  $28.10 \pm 5.97$  years. There were 16(53.33%) male and 14(46.67%) female as presented in figure 2. Mean occlusal plane height in permanent

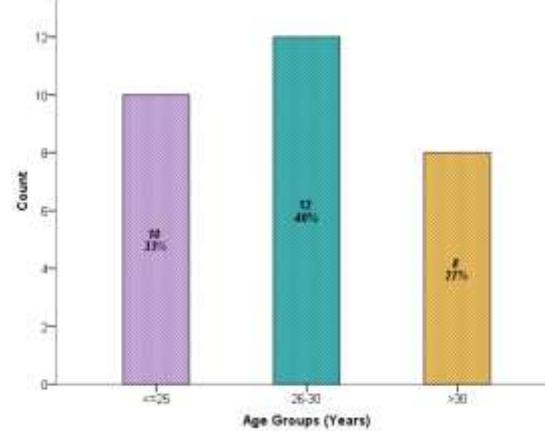
1st molars and canines in both the jaws in complete edentulous patients are depicted in figure 3 & 4. The mean of mean height of all molars teeth and all canine's teeth is showed in figure 5.

**Table No.1: Mean Height in Permanent 1st Molars and Canines in Both Jaws in Complete Edentulous Patients - By Age Groups - n=30**

Canines and Molar	Age Groups (Years)	n	Mean height	P-Value
Upper canines	$\leq 25$	10	$19.55 \pm 1.79$	0.304
	26-30	12	$19.41 \pm 0.48$	
	$>30$	8	$18.66 \pm 1.30$	
Lower canines	$\leq 25$	10	$18.23 \pm 1.64$	0.187
	26-30	12	$18.33 \pm 1.42$	
	$>30$	8	$17.48 \pm 1.14$	
Upper Molar	$\leq 25$	10	$16.12 \pm 1.18$	0.638
	26-30	12	$15.88 \pm 1.03$	
	$>30$	8	$15.65 \pm 0.82$	
Lower Molar	$\leq 25$	10	$15.78 \pm 1.42$	0.003
	26-30	12	$15.45 \pm 1.59$	
	$>30$	8	$14.86 \pm 1.34$	

**Table No.2: Mean Height in Permanent 1st Molars and Canines in Both Jaws in Complete Edentulous Patients - By Gender - n=30**

All canines and molar	Gender	n	Mean height	P-Value
Upper canines	Male	16	$19.95 \pm 1.21$	0.009
	Female	14	$18.52 \pm 1.56$	
Lower canines	Male	16	$18.66 \pm 1.31$	0.013
	Female	14	$17.39 \pm 1.29$	
Upper Molar	Male	16	$15.68 \pm 1.07$	0.210
	Female	14	$16.15 \pm 0.91$	
Lower Molar	Male	16	$15.05 \pm 1.73$	0.173
	Female	14	$15.80 \pm 1.01$	

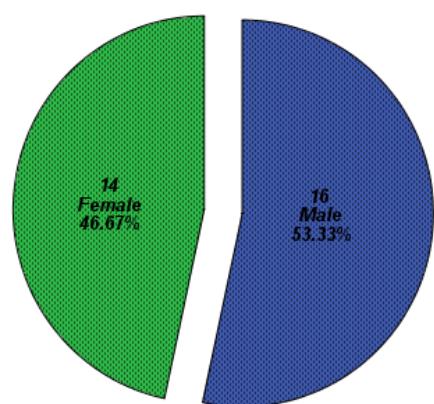


**Figure No.1: Patients Age Distribution - n=30**

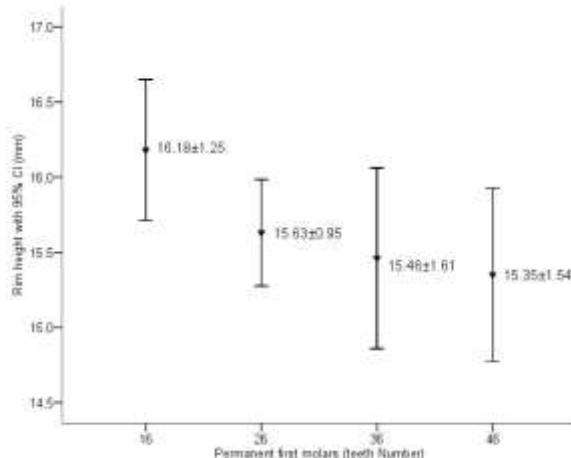
### Descriptive Statistics of Age

Age (Years):

Mean 28.10  
Standard deviation  $\pm 5.97$



**Figure No.2: Gender Distribution - n=30**

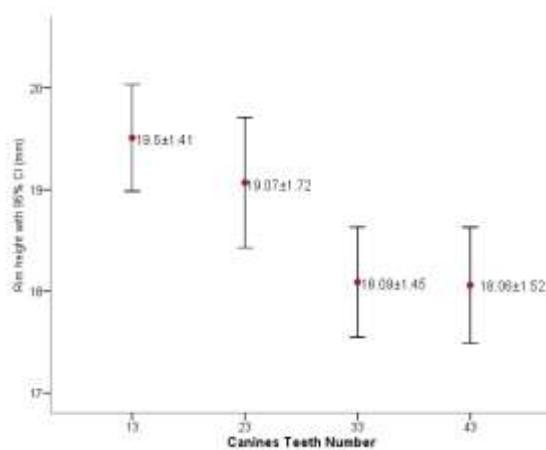


**Figure No.3: Occlusal Plane Height in Permanent 1<sup>st</sup> Molars in Both Jaws n=30**

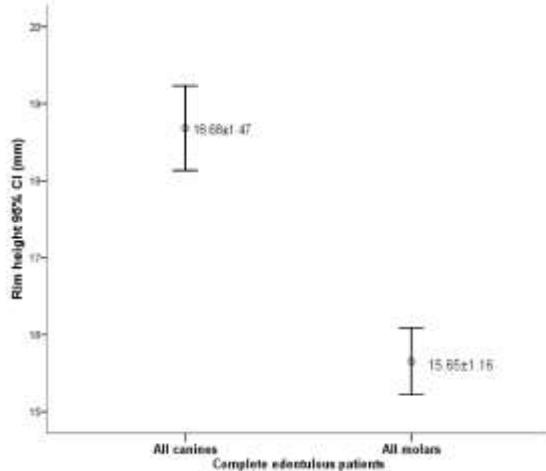
Stratification analysis was performed between age, gender and mean occlusal plane height for all molar and canines. There were not significant difference as reported in table 1 & 2.

## DISCUSSION

In current study average age of patients noted were  $28.10 \pm 5.97$  years, out of which 53% were males and 47% females. Jaw relation recording is very difficult step for fabrication of complete removable denture. Infinite relationships of mandible to the maxillae is called the Jaw relationship<sup>[7]</sup>. The recording procedure is comprising of orientation jaw relation, vertical jaw relation and horizontal relationship. Ensuring a quick and simple jaw relation procedure is essential. In order to do this, wax rims are made using average values per the recommendations of researchers.<sup>[8-10]</sup> Although many materials are used for making rims but it is usually made of modeling wax since it is easy to manipulate and convenient in use<sup>[10]</sup>.



**Figure No.4: Rim Height in Canines in Both Jaws - n=30**



**Figure No.5: Mean Occlusal Plane Height for Permanent 1<sup>st</sup> Molars and Canines in Both Jaws - n=30**

Various studies have been carried out to determine occlusal plane height but with diverse results. Another study measured maxillary height  $20.3 \pm 1.3$  mm and mandibular first molars height  $15.0 \pm 1.3$  mm where as Ellinger et al<sup>[7]</sup> suggested the heights of 24 mm and 20 mm in maxilla and mandible. Bishop<sup>[11]</sup> on the other hand suggested 20 and 18 mm. In our study, the occlusal plane height did not found to have significant difference in maxilla and mandible. The mean occlusal plane height for teeth no 16, 26, 36 and 46 was recorded 16.18 mm, 15.63 mm, 15.46 and 15.35 mm respectively. Our results are in nearby comparison with the results stated by Johnson and Winstanley<sup>[12]</sup> which reported the mean maxillary occlusal plane height 18 mm and mandibular 14.3. The results are in accordance to mentioned in Prosthodontic Treatment for Edentulous Patients<sup>[9]</sup>. The distance between mandibular incisal edge to labial mucosal fold was 18 mm using casts poured from mucostatic type impressions<sup>[13-14]</sup>. Distance in upper arch was 22 mm using the corresponding sites with a total of 40 mm

when mounted both together. In one of radiographic study done by Akinbami<sup>[14]</sup> found the average height in maxillary arch 20 mm and in mandible 16.3 mm. He suggested that the Occlusal Record Blocks height should be 24 mm and 20 mm for maxillary and mandibular jaws respectively.

The mean maxillary anterior occlusal plane height for females in our study is 18 mm and for males 19 mm where as in mandible it is 17mm and 18mm respectively for both genders. The mean maxillary posterior occlusal plane height for females in our study is 16 mm and for males 15 mm where as in mandible it is 15 mm respectively for both genders. Our results bear similarity with results of MORE et al<sup>[6]</sup> in maxilla but in mandible our values are slightly higher than the same study regardless of the study being conducted on similar Asian race. Rangarajan<sup>[15]</sup> and Nallaswamy<sup>[15]</sup> in contrast stated the maxillary height measurement as 22 mm in western population. The mean occlusal plane height anteriorly and posteriorly in both arches does not prove to have any significant relationship in comparison to age and also none of the literature have previously noted this relationship.

## CONCLUSION

Although the mean height of occlusal plane for fabrication of occlusal rim in construction of prosthesis has already been determined as per the guidelines but it was concluded that the set values vary for population as per geographic locations.

### Author's Contribution:

Concept & Design of Study: Sidra Soomro, Naseem Shaikh

Drafting: Naveed Memon, Aqsa Sajji

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Revisiting Critically: Sidra Soomro, Naseem Shaikh

Final Approval of version: By all above authors

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

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**Ethical Approval:** No. No.PR-057 dated 08.03.2021

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# An Audit of Infection Control Measures and their Relationship with Infection Rate among Burn Patients at Ayub Teaching Hospital, Abbottabad

Abdullah Mahmood, Firdous Khan and Muhammad Faizan Abbasi

Infection Control and Infection Rate among Burn Patients

## ABSTRACT

**Objective:** To assess the infection control protocols followed in our unit and see their impact on infection rate and patient outcome.

**Study Design:** Retrospective observational study

**Place and Duration of Study:** This study was conducted at the Department of Plastic Surgery and Burns Unit, Ayub Teaching Hospital, Abbottabad over a period of six months from January 1<sup>st</sup>, 2024 to June 30<sup>th</sup>, 2024.

**Methods:** A review of infection control protocols currently followed in our unit was made using a structured Performa. Data was collected only for those burn patients who developed signs of sepsis 48 hours after admission. Compliance to various protocols was determined and their relationship with infection rate was analyzed using Pearson Chi-square test with P value  $\leq 0.05$  taken as significant.

**Results:** Various lapses in infection control have been identified, including the lack of PPE and autoclave, inadequate use of hand sanitizer by staff and attendants, and non-compliance with proper cleaning and dressing practices. The overall infection rate was 68.8%. Appropriate cleaning of dressing room reduced infection rates to 30.9%, while reusing linen and inappropriate dressings increased rates to 87.3% (p value = 0.03 and 0.000 respectively). Attendants visiting multiple patients carried an infection rate of 89.1% (p value=0.000).

**Conclusion:** This audit underscores the critical role of rigorous infection control measures in determining outcomes for burn patients. Gaps in infection preventions were identified. Recommendations include ongoing education of staff, doctors and patient's attendants, adherence to protocols and repeated audits.

**Key Words:** Multi Drug Resistant Organisms, Infection Control Measures, Infection Rate

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## INTRODUCTION

Burn injuries are a major form of accidental trauma. They are considered to be the fourth most common cause of injury after accidental falls, physical assaults and road traffic accidents<sup>1</sup>. Approximately 265,000 people die from burn injuries each year. The majority of these injuries are reported from developing countries<sup>2</sup>. When burn injury occurs first organ to be damaged is skin, it acts as a protective barrier in humans. Loss of barrier leads to increased susceptibility to colonization by bacteria, which leads to increased infections<sup>3</sup>.

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It is important to treat burns adequately. If proper treatment is not given bacterial colonies overgrow and form biofilms on the wound surface. These biofilms hinder the process of re-epithelialization and also cause persistent inflammation in the burn wound<sup>4</sup>. If untreated, surface infections can progress to systemic infections, leading to sepsis. It has been seen that up to 75% of burn patients may die from sepsis within the first two weeks after burn<sup>5</sup>.

Nosocomial infections in burn patients pose significant treatment challenges for clinicians. Effective pre-hospital management, appropriate hospital treatment, choice of dressings, and wound care are crucial factors that influence the outcome in these infections<sup>6</sup>. Early in the course of burn injury wounds are mainly colonized by gram-positive organisms, which are later replaced by gram-negatives as the infection progresses<sup>7</sup>.

Infection control in burn units is one of the major challenges a physician faces. It requires strict measures to overcome this burden. Less physical contact, use of protective precautions, appropriate use of antibiotics, and careful monitoring to prevent the emergence of multidrug resistant strains is necessary<sup>8</sup>. Ideally, burn infections can be managed through patient isolation,

effective wound coverage by surgical and non-surgical methods, and frequent cultures to determine the specific flora associated with wound infections and adjust treatment accordingly<sup>9</sup>. Prolonged hospital stays and increased morbidity are often exacerbated by factors such as lack of resources, unavailability of appropriate dressings, and a lack of aseptic environment<sup>10</sup>.

## METHODS

This was a retrospective study done at Department of Plastic Surgery & Burns, Ayub Teaching Hospital Abbottabad for duration of 6 months (1<sup>st</sup>January, 2024 to 30<sup>th</sup>June, 2024) following ethical approval. An Audit tool (Proforma) was made using infection control guidelines by World Health Organization (WHO), Center of Disease Control (CDC) and American Burn Association (ABA). The tool recorded variables such as hand hygiene, environmental cleaning, cross contamination and appropriate dressing changes. Infection control protocols were observed for only those burn patients who developed fever ( $>38^{\circ}\text{C}$ ) and other signs of sepsis (tachycardia, tachypnea, thrombocytopenia, unable to continue enteral feeding for more than 24 hours), 48 hours or more after being admitted to burn unit despite receiving prophylactic antibiotics. Wound and blood cultures were collected from these patients to identify infections, with positive cultures indicating infection or sepsis, and negative cultures ruling out infection. Patients who had fever or signs of sepsis at the time of admission, as well as plastic surgery patients with infections, were excluded from the study. Data was collected using patient charts,

hospital records, and daily progress reports and cleaning logs. Out of total 224 patients admitted during study period (102 plastic surgery, 122 burns patient), 80 met the inclusion criteria. Data was analyzed using SPSS v. 27. Compliance to various protocols is expressed in terms of percentages and relationship between various infection control measures and infection rate is determined using Pearson Chi-square test and P value  $\leq 0.05$  is taken as significant.

## RESULTS

Table 1 shows various infection control practices within the burn unit. **Hand sanitizer** was available all the time (100%) but its use while visiting the patients was observed in only 70% of the cases by staff, while attendants never used it before entering or after leaving patient's room.

**Personal Protective Equipment (PPE)** and autoclave were not available in the unit. Antimicrobial soaps were available in 80% of the cases, separate containers for soiled articles are largely lacking (92.5%). Non-compliance was observed in the proper cleaning of dressing rooms (62.5%) and changing linen after each dressing (85%). Additionally, inappropriate dressing materials were used in 67.5% of cases. It was observed that a high percentage of attendants (67.5%) visited other patients, further risking infection spread. Routine fumigation or decontamination of patient rooms and sterilization of dressing material containers is not performed at all. Overall infection rate was found to be 68.8% which is quite high.

**Table No.1: Percentages of compliance with various infection control protocols.**

Sr. No.	Variable	Response N=80	
		Yes (%)	No (%)
1	Is hand sanitizer available in the unit?	100%	0%
2	Is Personal Protective Equipment (PPE) available in the department?	0%	100%
3	Is there an autoclave in your unit?	0%	100%
4	Is your unit near the operation theater?	0%	100%
5	Are antimicrobial soaps available?	80%	20%
6	Are separate containers available for collecting soiled articles?	7.5%	92.5%
7	Is alcohol-based sanitizer used after entering/leaving a patient's room or after any procedure?	70%	30%
8	Is the dressing room cleaned properly after changing the dressing of each patient?	37.5%	62.5%
9	Were there two patients in the dressing room simultaneously during dressing change?	40%	60%
10	Was the linen changed after changing the dressing of each patient?	15%	85%
11	Was appropriate dressing according to wound type used?	32.5%	67.5%
12	Do attendants of one patient visit other patients?	67.5%	32.5%
13	Do patient attendants use sanitizer before touching or visiting the patient?	0%	100%
14	Is routine fumigation/decontamination of patient rooms carried out when a patient is discharged?	0%	100%
15	Is equipment used for changing the dressing of patients set up immediately prior to procedure?	2.5%	97.5%
16	Are containers containing dressing material (surgical gauzes, crape bandages etc.) frequently sterilized?	0%	100%
17	Cultures reported to be positive	N=55 (68.8%)	

Table No.2: Association between Infection Control Protocols and Infection Rate.

Infection Control Protocols		Percentage	Infection rate	P Value
Is the dressing room cleaned properly after changing the dressing of each patient?	Yes	37.5%	30.9%	0.07
	No	62.5%	69.1%	
Were there two patients in the dressing room simultaneously during dressing change?	Yes	40%	52.7%	0.001
	No	60%	47.3%	
Was the linen changed after changing the dressing of each patient?	Yes	15%	12.7%	0.39
	No	85%	87.3%	
Was appropriate dressing according to wound type used?	Yes	32.5%	12.7%	0.000
	No	67.5%	87.3%	
Do attendants of one patient visit other patients?	Yes	67.5%	89.1%	0.000
	No	32.5%	10.9%	
Is equipment used for changing the dressing of patients set up immediately prior to procedure?	Yes	2.5%	0.00%	0.03
	No	97.5%	100%	

Table 2 depicts the relationship of various infection control protocols and infection rate along with statistical significance. The data reveals that when the dressing room was cleaned after each patient's dressing, the infection rate was 30.9%. However, when cleaning was not performed, the infection rate increased significantly to 69.1%. Similarly, when more than one patient underwent dressing changes simultaneously in the same room, the infection rate was 52.7%, but this rate decreased to 47.3% when such practices were reduced (p value=0.001). The practice of changing contaminated linen with fresh linen after each dressing resulted in a lower infection rate of 12.7%. In contrast, reusing the same linen for multiple patients led to a much higher infection rate (87.3%). The use of appropriate dressings was associated with a much lower infection rate of 12.7%, whereas inappropriate dressing choices resulted in an infection rate of 87.3% (p value=0.000). Furthermore, the practice of attendants visiting multiple patients was linked to a high infection rate of 89.1% (p value=0.000). It is also observed when dressing materials were set up immediately before the dressing change, the infection rate was 0%. In contrast, when pre-set materials were used, the infection rate jumped to 100 % (p value=0.03). This data highlights the importance of adherence to infection control protocols in minimizing infection rates.

## DISCUSSION

This study highlights the compliance to various infection control measures being followed in Burn unit of Ayub Teaching Hospital and identifies differences from guidelines put forward by the WHO, CDC and ABA. Relationship of such practices with infection rates was also determined.

We observed that despite the availability of hand sanitizer in our unit, only 70% of the times it was used by staff while patient's attendants never used it. Educating both staff and attendants on maintaining 100% hand hygiene is essential for reducing infection rates, as supported by Boora et al<sup>11</sup>.

The lack of PPE and an autoclave indicates significant lapses in infection control. PPE is crucial to prevent microbial transmission, and an autoclave is necessary for eradicating multi-drug resistant organisms. Hospital administration must ensure these are provided. Instruments are currently washed with Povidone-iodine, which is insufficient for eliminating resistant organisms. Burn patients acquire infections from close environment for example bedrails, door handles, mattress, water tap, side tables<sup>12</sup>. These all are sources of infection as multiple people touch them and they are never sterilized. Limiting patient transport is also crucial, as excessive movement out of burn unit increases contamination risk. Ideally, the operating theater should be close to the burn unit to reduce environmental contamination, as suggested by Palmieri TL<sup>13</sup>.

We observed that appropriate cleaning of dressing room was done in only 40% cases and bed linen was changed after 24 hours. Each day multiple patients undergo dressing change on same bedsheet which increases cross contamination. We observed when fresh linen was used for each patient, infection rate reduced from 85% to 15%. Practically it is not possible to have that many linen changes in a day, we recommend use of disposable dignity sheets for each patient which can be easily disposed of. Due to the high patient load and the availability of only one dressing room, dressing changes for two or more patients simultaneously occurred 40% of the times, resulting in an infection rate of 52.7%. However, when dressing changes were conducted for only one patient at a time, the infection rate decreased to 47.3%. Inappropriate dressing materials were used in 67.5% of cases, leading to an infection rate of 87.3%, whereas appropriate dressings reduced the rate to 12.7%. We are still using liquid paraffin, surgical gauzes and Silver Sulphadiazine ointments covered by crape bandage on all types of burns. Shingleton S et al. recommends use of dressings that do not adhere to wound bed and not cause pain or bleeding upon removal<sup>14</sup>. Specialized dressings could

not be used because most patients have financial constraints and cannot bear the cost of such dressings. In this regard hospital should make efforts to provide such dressings through Sehat Sahulat Program (SSP), which is a social welfare reform introduced in health care system of Pakistan in 2015 for under privileged citizens to get access to appropriate health care without any financial burden<sup>15</sup>. In addition to using traditional dressings, we noted that materials such as surgical gauzes and crape bandages were pre-prepared and stored in containers within the dressing room for quick access, often remaining open and stocked for up to two to three days. Our observations revealed that using pre-prepared materials led to an infection rate of 100%, whereas using freshly opened materials resulted in a drop in infection rate to 0%. Furthermore, the containers containing these materials had never been sterilized. These practices must be urgently addressed, and frequent sterilization of all equipment should be implemented as a mandatory procedure. Various studies have shown the efficacy of newer dressings compared to traditional ones. Kumar et al. compared collagen dressing with Silver Sulphadiazine (SSD). Healing time was 15.91 days with collagen dressing as compared to 22.08 days with SSD<sup>16</sup>. Another study compared hydrogels with SSD. Hydrogels had 68.9% efficiency while SSD had 55.3%<sup>17</sup>. A large proportion of attendants visit other patients as a gesture of sympathy but this contributed to an infection rate of 89.1%. Limiting such visits would help in controlling infection transmission. Routine fumigation or decontamination is not performed, which can significantly increase the risk of infections in newly admitted patients. Gus et al. recommended use of Ultraviolet light, Hydrogen peroxide vapors and Narrow Spectrum Light Environmental Decontamination System. All of these are superior to traditional disinfectants<sup>18</sup>. Ladhani et al. recommends that nothing should go in or out of a room where Multidrug Resistant organisms are present without decontamination<sup>19</sup>.

## CONCLUSION

In conclusion our study highlights the key infection control measures and their compliance in our unit. Various flaws have been identified like lack of hand hygiene, Unavailability of PPE and autoclave. Improper decontamination of dressing room and patient rooms, use of non-specialized dressings and too many attendant visits. All these are contributing to a high infection rate (68.8%). It is important that strict compliance to protocols is ensured so that good standard care can be provided to the patients.

### Recommendations:

1. Regular education of staff and doctors regarding infection control measures should be done.

2. Separate rooms should be dedicated for burn and plastic surgery patients without using them interchangeably.
3. PPE and autoclave should be made available in the unit.
4. Dressing changes of patients with high exudate should be carried out in their own rooms instead of common dressing room.
5. Introduce a policy to provide specialized burn dressings in Sehat Sahulat Program.
6. Written guidelines regarding decontamination of instruments, floor and linen should be introduced and compliance should be monitored using daily logs/charts.
7. Use of dignity sheets should be mandatory during dressing changes.
8. One attendant per patient policy should be introduced.
9. We recommend strict adherence to the infection control measures for an extended period of time and then do re-audit to see improvements in patient outcome.

### Abbreviations:

Personal Protective Equipment (PPE), World Health Organization (WHO), Center of Disease Control (CDC), American Burn Association (ABA), Sehat Sahulat Program (SSP), Silver Sulphadiazine (SSD).

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Original Article

# Evaluation of Patients' Satisfaction with Nursing Care Quality in a Tertiary Care Hospital: A Cross-Sectional Study

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Nursing Care Quality in Tertiary Care Hospital

## ABSTRACT

**Objective:** Patients' satisfaction is highly affected by the quality of nursing care in a hospital. The aim of the study was to assess the level of patients' satisfaction with nursing care quality and the various factors which influence this satisfaction level in tertiary care hospitals of our population.

**Study Design:** Cross-sectional Observational study

**Place and Duration of Study:** This study was conducted at the across various Medical and Surgical Inpatient Wards at the M. Islam Teaching Hospital Gujranwala from January 2024 to May 2024.

**Methods:** A total of 138 patients of both genders, aged 18 years or older, conscious with 2 to 5 days of hospital stay and willing to participate were included in the study. Data was collected using PSNCQ Questionnaire with a 5-point Likert scale with responses recorded as Excellent=5, Very Good=4, Good=3, Fair=2, Poor=1. A comparison was made between the social and demographic characteristics and mean PSNCQQ score. Data analysis was conducted using SPSS version 25, with quantitative variables presented as Mean $\pm$ SD and qualitative variables as frequencies and percentages.

**Results:** The overall patient satisfaction with nursing care was moderate ( $M=3.12\pm0.29$ ). When analyzing items individually, the patients scored the "information provided" the lowest ( $2.14\pm0.84$ ) and "Restful Atmosphere Provided by Nurses" was graded the highest ( $4.13\pm1.08$ ). This study revealed significant difference between patient's age and gender and level of satisfaction with quality care provided by nurses ( $p>0.05$ ).

**Conclusion:** This study helps healthcare organizations understand patient opinions on nursing care and make targeted improvements by addressing areas of concern. It was concluded that the age and gender affect the patients' satisfaction with nursing care quality.

**Key Words:** Patients' care, Nursing care, Health care, Tertiary care hospital.

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## INTRODUCTION

The landscape of healthcare has been significantly transformed by several dynamic factors in recent years. Technological advancements have revolutionized medical practices and patient care, while the proliferation of online health information has empowered individuals to take a more active role in their healthcare decisions.

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Additionally, the evolving expectations and involvement of patients and their families in the decision-making process have placed a greater emphasis on the quality and service provided by healthcare institutions. These elements collectively serve as critical indicators of patient satisfaction, influence competition among healthcare facilities, and impact the overall cost of healthcare services.<sup>1</sup>

Patient satisfaction is the comparison between the care received and the care anticipated. There is a strong focus on delivering patient services in a structured manner to understand, assess, and fulfill the needs of patients.<sup>2</sup> Patient satisfaction is a multifaceted concept shaped by numerous elements. Among the key factors that intricately weave into the fabric of patient contentment are age, socioeconomic status, gender, marital status, communication, nursing care and hospital environment. Each of these aspects uniquely influences how patients perceive and experience healthcare, underscoring the complexity and individuality of their satisfaction.<sup>3</sup> Moreover, the nurse/patient ratio is also a crucial factor in assessing patient satisfaction, which reflects the patient's positive

and emotional response to their experiences and established criteria.<sup>4</sup>

Reviewed literature reveals that patient satisfaction level with nursing care and its influencing factors vary globally. This evidence presents a complex and diverse picture, emphasizing the importance of considering patient experiences within specific healthcare environments.<sup>5</sup>

In Pakistan's tertiary care hospitals, patient satisfaction with nursing care stands as a vital yet often neglected concern. This research set out with a pressing mission: to expose the precise areas where patient satisfaction is severely lacking, unveiling these critical shortcomings aims to drive impactful policy changes, address key issues, and ultimately revolutionize patient satisfaction with nursing care.<sup>1</sup>

## METHODS

### Research Framework, Location, and Participants:

We used a cross-sectional, descriptive approach to evaluate patients' satisfaction with the quality of nursing care in the Punjab Province of Pakistan. This study was conducted across various medical and surgical inpatient wards and units at the M. Islam Teaching Hospital, Gujranwala after taking ethical approval from the Ethical Review Committee. This study was conducted between January 2024 to May 2024. A total of 138 patients were included in this research, the inclusion criteria being: age 18 years or older, consciousness, hospital stay of at least 2 to 5 days, and willingness to participate. The co-operation rate was 100% and a written consent was taken from each participant.

**Table No.1: Questionnaire with regard to patients satisfaction**

Sr. No.	Questions	Excellent		Very Good		Good		Fair		Poor		Mean± SD	Min-Max
		n	%	n	%	n	%	n	%	n	%		
1	Information You Were Given	20	14.49%	70	50.72%	32	23.19%	5	3.62%	2	1.45%	2.14±0.84	1-5
2	Instructions	25	18.12%	71	51.45%	34	24.64%	4	2.90%	4	2.90%	2.21±0.88	1-5
3	Ease of Getting Information	16	11.59%	53	38.41%	19	13.77%	49	35.51%	1	0.72%	2.75±1.09	1-5
4	Information Given by Nurses	18	13.04%	59	42.75%	22	15.94%	38	27.54%	1	0.72%	2.60±1.05	1-5
5	Involving Family or Friends	10	7.25%	38	27.54%	50	36.23%	37	26.81%	3	2.17%	2.89±0.96	1-5
6	Involving Family/ Friends in Your Care	20	14.49%	25	18.12%	32	23.19%	53	38.41%	8	5.80%	3.03±1.18	1-5
7	Concern and Caring by Nurses	31	22.46%	23	16.67%	38	27.54%	27	19.57%	19	13.77%	2.86±1.34	1-5
8	Attention of Nurses to Your Condition	25	18.12%	19	13.77%	8	5.80%	40	28.99%	46	33.33%	3.46±1.51	1-5
9	Recognition of Your Opinions	21	15.22%	7	5.07%	21	15.22%	73	52.90%	16	11.59%	3.41±1.22	1-5
10	Consideration of Your Needs	4	2.90%	76	55.07%	0	0.00%	49	35.51%	9	6.52%	2.88±1.13	1-5
11	The Daily Routine of the Nurses	14	10.14%	45	32.61%	19	13.77%	42	30.43%	18	13.04%	3.04±1.25	1-5
12	Helpfulness	0	0.00%	30	21.74%	3	2.17%	69	50.00%	36	26.09%	3.80±1.06	2-5
13	Nursing Staff Response to Your Calls	20	14.49%	21	15.22%	13	9.42%	42	30.43%	42	30.43%	3.47±1.43	1-5
14	Skill and Competence of Nurses	15	10.87%	11	7.97%	16	11.59%	68	49.28%	28	20.29%	3.60±1.21	1-5
15	Coordination of Care	4	2.90%	58	42.03%	17	12.32%	40	28.99%	19	13.77%	3.09±1.17	1-5
16	Restful Atmosphere Provided by Nurses	0	0.00%	24	17.39%	0	0.00%	48	34.78%	66	47.83%	4.13±1.08	2-5
17	Privacy	38	27.54%	30	21.74%	30	21.74%	36	26.09%	14	10.14%	2.84±1.3	1-5

**Data collection and Questionnaire:** The questionnaire, adapted from the modified version of Laschinger Research Tool for Patient Satisfaction with Nursing Care Quality Questionnaire (PSNCQQ),<sup>6</sup> was translated into Urdu to facilitate patient comprehension. An interviewer-led approach was utilized to minimize bias and ensure accurate interpretation of the questions. The questionnaire employed a 5-point Likert scale: Poor=1, Fair=2, Good=3, Very Good=4, Excellent=5.

**Data Analysis:** We categorized the PSNCQQ scores based on the average item score out of five: a score below 2.5 represented low satisfaction, scores between 2.5 and 3.75 indicated moderate satisfaction, and scores above 3.75 reflected high satisfaction. This scoring approach aligns with previous studies utilizing the PSNCQQ.<sup>7</sup> Data analysis was done using SPSS version 25, with quantitative variables expressed as mean ± standard deviation (SD) and qualitative variables reported as frequencies and percentages.

## RESULTS

**Sample description:** In this study 138 admitted patients of M. Islam Teaching Hospital were included. Among study participants 85 (61.6%) were male and 53 (38.4%) were female. Mean age of study participants was  $39.52\pm13.76$  years. Age of study participants ranges between 18-76 years. Marital status of participants showed that 25 (18.1%) participants were single and 113 (81.9%) were married. Mean length of hospital stay of study participants was  $4.92\pm1.53$  days. Hospital stay of participants ranges between 2 to 5 days.

18	Discharge Instructions	0	0.00%	23	16.67%	0	0.00%	69	50.00%	46	33.33%	4.00±1	2-5
19	Coordination of Care After Discharge	9	6.52%	26	18.84%	57	41.30%	27	19.57%	19	13.77%	3.15±.09	1-5
		Total	PSNCQQ Score									3.12±0.29	2.53-3.84

**Table No.2: Comparison of PSNCQQ Score in relation to patients characteristics**

		PSNCQQ Score				p-value
		Mean	SD	Min	Max	
Age (Years)	12-24	3.16	0.26	2.68	3.68	0.032*, (a)
	25-36	3.12	0.30	2.53	3.74	
	37-48	3.02	0.29	2.58	3.63	
	49-60	3.16	0.28	2.63	3.63	
	>60	3.32	0.29	2.84	3.84	
Hospital Stay (Days)	2-3	3.16	0.32	2.58	3.84	0.161 <sup>(a)</sup>
	4-5	3.07	0.28	2.53	3.68	
	>5	3.17	0.29	2.63	3.74	
Gender	Male	3.17	0.30	2.63	3.84	0.018*, (b)
	Female	3.05	0.26	2.53	3.68	
Marital Status	Single	3.06	0.29	2.58	3.63	0.227 <sup>(b)</sup>
	Married	3.14	0.29	2.53	3.84	

**Note:** As the PSNCQQ score fulfill the assumption of normality so parametric tests were applied

(a): One Way ANOVA

(b): Independent sample t-test

(\*): p-value <0.05

**Patients' Satisfaction:** Generally, patients reported a moderate level of satisfaction with the care they received from nurses with the mean of  $3.12\pm0.29$  as shown in Table-1. When analyzing items individually, the patients scored the "information provided" the lowest, mean being  $2.14\pm0.84$ . On the other hand, "Restful Atmosphere Provided by Nurses" was graded the highest with the mean of  $4.13\pm1.08$ .

**Patient satisfaction and influencing factors:** A statistically significant variation in mean PSNCQQ scores was detected across different age categories with  $p=0.032$ . The older adults (60+ years) reported higher levels of satisfaction with nursing care quality with mean of  $3.32\pm0.29$ . Gender was found to be a significant factor affecting participant satisfaction with males being more satisfied as compared to females showing statistically significant p value of 0.018. PSNCQQ score showed no significant difference for marital status and hospital stay of patients.

## DISCUSSION

We evaluated patient satisfaction regarding nursing care in a private teaching hospital in Gujranwala, Pakistan. The survey targeted hospitalized patients across various departments. Our research aimed to explore the critical factors influencing patient satisfaction with nursing care, as identified by the PSNCQQ. The primary focus was on patients' satisfaction with nursing care, while the secondary focus was on identifying factors that influenced this satisfaction. The results of this study agree with some previous findings, but also show some differences.

Our primary findings align with a study by Elayan<sup>7</sup> that assessed the satisfaction of patients or caregivers with nursing care reported moderate satisfaction levels. In contrast, research conducted in Ethiopia<sup>8</sup> reported that less than half of the patients were satisfied with the nursing care. Our findings may be attributed to the nurses' readiness to manage patient care, which is likely influenced by the nurses' educational background and practical experience. This results in boosted confidence and improved rapport with patients and colleagues alike.<sup>9</sup>

Our study found that sociodemographic variables affected patients' satisfaction levels, with older patients generally being more satisfied than their younger counterparts. This pattern is in line with findings from a recent study of COVID-19 patients in Saudi Arabia<sup>9</sup> and another study conducted in India.<sup>10</sup> However, this finding contrasts with another study which found no significant age-related differences in patient satisfaction.<sup>9</sup> Similarly, research from Turkey painted a different picture, revealing that older patients were less happy with the nursing care they received.<sup>11</sup> This discrepancy highlights the complexity of patient satisfaction and suggests that regional and environmental factors may play a significant part. In general, age seems to play a role in shaping patients' satisfaction, with older individuals often reporting higher satisfaction levels.<sup>12,13</sup> One reason for this trend could be that older adults tend to be more social and accepting compared to their younger counterparts. This broader social acceptance may contribute to their more positive experiences and higher satisfaction with care. Our study found that male patients reported higher satisfaction levels compared to female patients, aligning with findings from research conducted in Saudi Arabia<sup>14</sup> and India.<sup>10</sup> However, studies from Saudi Arabia,<sup>15</sup> Oman,<sup>16</sup> Jordan,<sup>7</sup> and Turkey,<sup>11</sup> showed different trends. These variations underscore the complexity of satisfaction patterns and suggest that gender-related factors may affect patient satisfaction in diverse ways across different regions.

This study echoes the findings of and Alhowaymel,<sup>9</sup> where no significant difference in satisfaction was linked to patients' marital status. However, this narrative contrasts with research from Turkey,<sup>11</sup> and in Ethiopia,<sup>2</sup> showed that patients who were unmarried were less likely to express satisfaction with their care. This divergence in results highlights how marital status may impact patient satisfaction differently across various contexts.

A study conducted in Pakistan at Civil hospital Karachi<sup>4</sup> revealed that patients were highly satisfied in the adequate workload areas of nurses and moderately satisfied in the units where the nurses had more

workload. However, gender and patient age did not affect the patient satisfaction and the p-value as not significant. Another study conducted in Multan<sup>1</sup> showed no difference in satisfaction between age groups and genders, but patients in Obs / Gynae wards were more satisfied than those in other wards.

This study's limitations include a small sample size and lack of inter-ward comparisons. Future research should consider a multi-center approach, encompassing both private and public hospitals, to enhance generalizability. Additionally, assessing patient satisfaction post-discharge may yield different results, as patients may respond more candidly when not concerned about impacting their care.

## CONCLUSION

This study helps healthcare organizations understand patient opinions on nursing care. By analyzing patient feedback, such organizations can make targeted improvements, enhancing care quality and addressing areas of concern. This not only boosts patient satisfaction but also strengthens the organization's reputation and trustworthiness in the healthcare community.

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# Significance of Accurate Defect Size Estimation and Overlapping of Mesh in Open Inguinal Hernia Repair

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Estimation and Overlapping of Mesh in Open Inguinal Hernia Repair

## ABSTRACT

**Objective:** Importance of accurate defect size estimation and its relevance in open inguinal hernia repair.

**Study Design:** Descriptive prospective cohort study

**Place and Duration of Study:** This study was conducted at the Department of Surgery Abbasi Shaheed Hospital with one year duration February 2023 to February 2024.

**Methods:** 194 participants selected through consecutive sampling divided into two groups F1 and F2. 97 participants in each group. Ethical review board approved study. For defect size estimation European hernia society (EHS) classification is used in F1 and ultrasound and EHS classification in F2. Lichtenstein repair with mesh size 6x11cm opted. Overlapping of mesh, defect sizes, fixation of mesh, recurrence, seroma, wound dehiscence, transient testicular swelling, testicular atrophy & urinary retention are taken as variables analyzed through mean, median mode, relative risk, P-value, graph and charts. Statistical Package for social sciences (SPSS) used. Patients followed up on 10<sup>th</sup> day<sup>3rd</sup> month and 6<sup>th</sup> month postoperatively.

**Results:** Mean age in F1 and F2 44 years, median 45 years and mode 50 years, standard deviation 15.868. In F1 defect sizes measured through EHS classification: no patients <1.5cm (01 finger breadth), 49.48% patients 1.5-3 cm (02 finger breadth), 50.5% patients >3cm (>2 finger breadth). In F2 group: 3% patients <1.5cm (01 finger breadth), 59.7% patients 1.5-3cm (2 finger breadth), 37.11% patients >3cm (>2 finger breadth). In Group F1: recurrence 2%, seroma 13%, wound dehiscence 11%, transient testicular swelling 3%, spinal headache 10%, testicular atrophy 1% and 3% patients had urinary retention. In Group F2: recurrence 1%, seroma 4%, wound dehiscence 3%, transient testicular swelling 1%, spinal headache 5%, no testicular atrophy, and urinary retention found in 1% patients.

**Conclusion:** Accurate defect size estimation has significant impact on outcome in open inguinal hernia repair furthermore, proper mesh implantation reduce postoperative complications.

**Key Words:** Lichtenstein repair, Inguinal hernia repair

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## INTRODUCTION

In 20<sup>th</sup> century Lichtenstein introduce Tension free Mesh Repair of inguinal hernia. Lichtenstein repair is the most popular surgical technique of open inguinal hernia repair nowadays. After performing Lichtenstein repair 20-40% shrinkage of mesh occurs therefore importance of accurate estimation of defect sizes gain importance in open inguinal hernia repair.

The normal criteria of overlapping of mesh is 2cm beyond pubic tubercle 3-4 cm medial to hernia defect and 5-6 cm lateral to hernia defect. Mesh should be well enough extend 3-4 cm beyond Hasselbach's triangle. The ideal size of mesh uses in Lichtenstein repair is 7.5x15cm.<sup>1-4</sup> The ideal mesh should be of light weight, less dense and of large pores.<sup>5</sup> In one study 9x15cm size mesh is considered suitable for Lichtenstein repair.<sup>6,7</sup>

## METHODS

It is prospective cohort study. Ethical review board Abbasi Shaheed Hospital approved study. Sample size derived from formula & it has 194 participants. Consecutive sampling method used. All patients divided equally into two groups F1 and F2 with 97 participants in each group. In F1 we used European Hernia society (EHS) classification for estimation of defect size and in F2 we used ultrasound and EHS classification. Inclusion criteria is direct and indirect inguinal hernia, male gender, age 20-85. Exclusion

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criteria: Recurrent, strangulated or obstructed inguinal hernia, female, age<20 years and > 85 years. Variables are age, number of patients having lateral inguinal hernia, medial inguinal hernia, defect sizes measured through ultrasound and European hernia Society(EHS) classification<sup>8</sup>, fixation of mesh, postoperative complications like recurrence, seroma, wound dehiscence, transient testicular swelling, spinal headache, testicular atrophy and urinary retention. Variables analysed through Mean, median, mode, Relative risk, P-value, graphs and charts. Statistical package for social sciences (SPSS) used.

## RESULTS

Age range of both groups F1 and F2 is 20-85 years. Mean age of both groups 44.42 years, Median 45 years and mode 50 years. The standard deviation(STD) is 15.80866.(Table 1) Majority of patients have age 20-40 years=45.9%, then 41--60years=38.1%, 61-80 years = 15.5%, and >80years:0.5%.

In F1 group 45 patients of age range 20-40 years,39 patients of age range 41-60 years,13 patients of age range 61-80 years (Figure 1).In F2 group 44 patients of age range 20-40years,35 patients of age range 41-60 years.17 patients of age range 61-80 years and 01 patient is of greater than 80 years. (Figure 1)

In group F1 42 patients had lateral inguinal hernia in which 25 patients had right lateral inguinal hernia and 17 patients had left lateral inguinal hernia. In F2 43 patients had lateral inguinal hernia in which 34 patients had right lateral inguinal hernia and 09 patients had left

lateral inguinal hernia .In Group F1 50 patients had medial inguinal hernia in which 30 patients had right medial inguinal hernia and 20 patients had left medial inguinal hernia. In Group F2 49 patients had medial inguinal hernia in which 25 had right medial inguinal hernia and 24 patients had left medial inguinal hernia. (Table-1)

In F1 01 patient had combine (Medial+Lateral) inguinal hernia and 04 patients had bilateral (Right+Left) inguinal hernia. In F2 02 patients had combine (Medial+Lateral) inguinal hernia and 03 patients had bilateral(Right+Left) inguinal hernia.

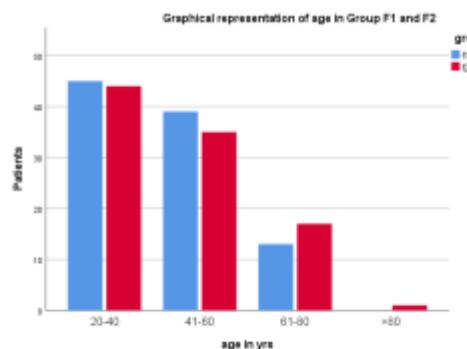
In Group F1 EHS classification is used to determine defect sizes, In Group F2 ultrasound used for defect size estimation showed 02 patients had defect sizes 1-1.5cm,63 patients had 1.5-3cm,32 patients had >3cm defect size.

In Group F1 according to EHS classification used no patients of inguinal hernia had <1.5cm(01finger breadth) defect size,48 patients of inguinal hernia had 1.5-3cm(02 finger breadth) defect size,49 patients of inguinal hernia had defect size >3cm(>2 finger breadth).In Group F2,03 patients of inguinal hernia had <1.5cm(01 finger breadth) defect size,58 patients of inguinal hernia had 1.5-3cm(02 finger breadth)defect size,36 patients of inguinal hernia had >3cm(>2 finger breadth). EHS defect sizes of both groups have P-value: 0.001, mean of defect size through EHS classification is 2.39 cm, median is 2cm, mode is 2cm.Standard deviation recorded in defect sizes is 0.519 with variance 0.26.

**Table No.1: Statistical analysis of Group F1 and F2**

	Group F1	Group F2	Statistical Analysis
Patients no	97	97	
Age (Years)			
20-40	45 (46.39%)	44 (46.2%)	Mean:44 ,median:45
41-60	39 (40.2%)	35 (36%)	Mode:50,STD:15.868
61-80	13 (13.4%)	17 (17.5%)	
>80	0	01	
Lateral Inguinal Hernia	42 (43.2%) Right:25,Left:17	43(44.3%) Right:34,Left:09	
Medial Inguinal Hernia	50 (51.5%) Right:30,Left:20	49 (50.5%) Right:25,Left:24	
Bilateral inguinal hernia	04	03	
Combine inguinal hernia	01	02	
Defect Size in cm Ultrasound	Not done		P:0.001
1-1.5cm	-	02	
1.5-3cm	-	63	
>3cm	-	32	
EHS Defect size in cm			P;0.001,skewness:0.139
01 Finger Breadth<1.5cm	00	03 (3%)	STD:0.519,Mean:2.39
02 Finger Breadth1.5-3cm	48 (49.48%)	58 (59.7%)	Variance:0.26,
>02 Finger Breadth>3cm	49 (50.5%)	36 (37.11%)	Median:2,Mode:2
Overlapping of mesh	97	97	

2cm over pubic tubercle,3-4cm medial to hernia defect and 5-6 cm lateral to hernia defect			
Fixation of Mesh			
Over edge	06	03	
0.5cm away from edge	91	94	
Postoperative Complication			
Recurrence	02	01	
Seroma	13	04	P=0.02,RR:1.61
Wound Dehiscence	11	03	P=0.02,RR:1.64
Transient testicular swelling	03	01	
Spinal headache	10	05	-
Testicular Atrophy	01	00	-
Urinary Retention	03	01	-



**Figure No.1: Age distribution in group F1 and F2**

When compared age with per-operative defect size estimation with help of EHS(European hernia society) classification system in groups F1 and F2 we found age group 20-40 years: no patient had defect size <1.5cm(01 finger breadth),64 patients had defect size 1.5-3cm(02 finger breadth),25 patients had defect sizes >3cm(>02 finger breadth).In age group 41-60 years: 02 patients had defect size <1.5cm(01 finger breadth),37 patients were defect size 1.5-3cm(02 finger breadth),35 patients were defect size >3cm(>02 finger breadth).In age group 61-80 years :01 patient had defect size <1.5cm(01 finger breadth),11 patients had defect size 1.5-3cm(02 finger breadth) and 18 patients had defect size >3cm(>02 finger breadth).In age group >80 years: 01 patient had defect size 1.5-3cm(02 finger breadth) (p=0.002).

We compared lateral and medial inguinal hernia with per-operative EHS classification dependant defect sizes in group F1 and F2. In patients with lateral inguinal hernia 02 patients had defect sizes less than 1.5cm(01 finger breadth),57 patients had defect size1.5-3 cm (02 finger breadth), 26 patients had defect size >3cm(>02 finger breadth). P-value is 0.001 which shows significant relationship between Per-operative EHS defect sizes and lateral inguinal hernia .In medial

inguinal hernia with respect to EHS defect size we found 01 patient had defect size<1.5cm (01 finger breadth), 49 patients had defect size 1.5-03cm (02 finger breadth), 59 patients had defect size >3cm (>02 finger breadth).P-value=0.001 which signifies positive association between two variables.

Total three patients had recurrence after the repair of inguinal hernia. In Group F1 02 and in F2 01 participant had recurrence of large defect size (>3.5cm) direct inguinal hernia.

In Group F1 13 patients and in F2 04 patients had inguinoscrotal seroma. The P value is 0.02 and Relative Risk is 1.61 which shows positive association and risk in exposed group .When compared inguinoscrotal seroma with EHS defect size it showed that inguinoscrotal seroma occurred in 17 patients in both groups out of which 15 patients had larger defect sizes according to EHS classification >3cm and 02 patients had inguinoscrotal seroma formation with hernia defect sizes1.5-3cm. The p-value is 0.001 which is significant and proves positive association between two variables.

In Group F1 11 patients had wound dehiscence and in F2 03 patient had wound dehiscence. P-value is 0.02 and Relative Risk is 1.64.which is positive association and explained risk in exposed group .When we compared wound dehiscence with EHS classification we found 14 patients had developed wound dehiscence in both groups in which 12 patients had defect size of >3cm and 02 patients had defect size of 1.5-3 cm. P-value is 0.001 which is significant and reflected association of large defect size and occurrence of wound dehiscence.

In Groups, F1 had 03 patients of transient testicular swelling and 01 patient of transient testicular swelling in F2.The reason for transient testicular swelling after Lichtenstein repair was hyper vascularity Postoperative colour doppler ultrasound proved hyper vascularity with no testicular damage and obstruction. Swelling

resolved conservatively by applying scrotal plaster and using tight underwears.

In Groups, F1 had 10 patients of spinal headache and in F2 05 patients had spinal headache. Spinal headache depends upon spinal anesthesia technique quality and proper dose of anesthetic given. All patients recovered by conservative treatment included bed rest, stimulants like coffee, tea, analgesic and gabapentin.

In group F1 01 patient reported testicular atrophy who had large indirect inguinal hernia with hernia defect size  $>3\text{cm}$ . Patient developed hematoma postoperatively which subsided within 01 month but reported testicular atrophy after 9 months. In F2 no patient had testicular atrophy. In this study 03 patients developed urinary retention in group F1 and 01 patient had urinary retention in group F2.

## DISCUSSION

Lichtenstein repair procedure of choice in this study. Many studies advocated open mesh technique as procedure of choice for inguinal hernias.

Sensitivity of ultrasound 100% and 80% for diagnosis of indirect and direct inguinal hernia, respectively.<sup>9-10</sup>

This study correlated different defect sizes identified on ultrasound with the surgical findings and found it significant. Another study showed preoperative ultrasound had positive predictive value of 90.9% for identifying inguinal hernia in need of surgery. Positive predictive value for patients without visible swelling is 84.6%. Body Mass Index (BMI) was identified as most likely potential predictor of false positive ultrasound.

When compare age with lateral inguinal hernia in Group F1 and F2 we found significant relation between age and decreasing number of lateral inguinal hernia with the age  $>50$  years.

When we compare age with medial inguinal hernia patients in Group F1 and F2 there is significant relation between age and medial inguinal hernia patients. Slightly increase number of medial inguinal hernia in age 40-85 years shows association of risk factors in development of medial inguinal hernia in patients.

We compared age with per-operative defect size measured through EHS (European hernia society) classification system we found  $p$  value=0.002 which shows significant relation between defect sizes of various patients and age. There is increase in defect sizes at increasing age which shows age related changes, chronic cough, constipation, Benign prostatic hyperplasia (BPH), decreasing in immunity level, collagen deficiencies, autoimmune disorders have an impact on defect sizes in inguinal hernia patients.

When we compare lateral and medial inguinal hernia with per-operative EHS classification  $P$ -value=0.001 showed significant relationship between Per-operative EHS defect sizes and lateral inguinal hernia.

In medial inguinal hernia with respect to EHS defect size we found  $P$ -value=0.001 which signifies positive association between two variables.

Fixation of mesh is very important, proper fixation reduces postoperative complications. Kirks et al advocated suture placement 0.5cm distance away from the edge of mesh. Overlapping of mesh is mandatory in Lichtenstein repair. Proper overlapping needs proper mesh size and in Lichtenstein repair we use 6x11cm prolene mesh for overlap.<sup>11</sup> Ideal mesh should be less dense, light weight and large pore size. In one study rate of recurrence is 1.95%. Improper fixation and inadequate repair are the causes<sup>12</sup>. In our study rate of recurrence is 1.5%.<sup>13</sup> Patient's risk factors, large defect size $>3.5\text{cm}$  and weak abdominal wall are the causes.<sup>14</sup> One study showed increased rate of seroma formation 5.7%-8.5% in Lichtenstein repair due to mesh effect on surrounding tissue and known effect of Prolene on tissue. In another study 10% is the rate of seroma formation.<sup>15</sup> In our study the rate of seroma formation is 8.5%. The cause of seroma formation is mesh effect and closure technique. The rate of wound dehiscence in open inguinal hernia mesh repair is 6.2% in one study.<sup>16</sup> In our study the rate of wound dehiscence is 7%. Many factors contributing to wound dehiscence including mesh infection, wound infection, foreign body retention, improper closure technique, systemic diseases like diabetes mellitus, hypertension, smoking and malnutrition. According to one study rate of transient testicular swelling is 7%.<sup>16-17</sup> In our study rate of transient testicular swelling is 2%. The cause of transient testicular swelling was hypervascularity on Doppler ultrasound with no testicular damage and obstruction and swelling subsided after wearing scrotal support in all cases.<sup>18</sup> Postoperative headaches are common in patients undergoing Lichtenstein repair under spinal anesthesia.<sup>19</sup> In our study 15 patients developed spinal headache. Main reasons are quality of anesthetic, spinal anesthesia technique, positioning of patient and hydration. All patients relieved by taking coffee, tea or analgesics and by taking gabapentin. Rate of testicular atrophy in our study is 0.6. It is an uncommon complication. Main causes found to be injury to pampiniform venous plexuses and collateral arterial plexuses. Rate of testicular atrophy is 0.3-0.5% in some studies.<sup>20</sup> In this study rate of urinary retention is 2% in which all four patients relieved after passing folley's catheter. In a study rate of urinary retention is 10%.<sup>21</sup> The cause of urinary retention in our study is spinal anesthesia effect which is relieved by conservative measures.

## CONCLUSION

Through our study it is evident that European Hernia society classification and ultrasound are key modalities in inguinal hernia defect size estimation. Measurement of defect size and use of large mesh 7.5x15cm in large

inguinal hernia with defect >3.5 cm may reduce recurrence.

**Author's Contribution:**

Concept & Design of Study: Muhammad Fahad  
 Drafting: Muhammad Fahad  
 Data Analysis: Muhammad Fahad  
 Revisiting Critically: Azfaruddin Qureshi,  
 Fareeda Islam  
 Final Approval of version: By all above authors

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

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# Complementary Feeding Practices and Nutritional Status of 06-24 Months Old Child

Jahanzeb Khan Afridi, Shahrukh Yar, Asif Nawaz Afridi, Mian Abdur Rehman, Mustafa Kamal and Muhammad Kashif Hussain

## ABSTRACT

**Objective:** In order to have a baseline knowledge of the prevalence and effects of CFPs on the nutritional status of the target group, it was necessary to measure complementary feeding indicators among children aged 6-24 months in the study population.

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

**Place and Duration of Study:** This study was conducted at the Department of Paeds, HMC, Peshawar from Jan 2023 to Jan 2024.

**Methods:** The study was a descriptive cross-sectional one on 150 children at a probation age of 6-24 months. Questionnaires are structured, instruction includes feeding practices and frequency, choice of food inclusive of snacks. Necessary anthropometric indices were collected to determine the nutritional condition of the students. The null hypothesis was addressed using descriptive statistics which incorporated inferential which required use of mean standard deviation and P values.

**Results:** The age of the children was calculated mean, SD, and Pf, for this purpose: The mean age of the 150 children was  $14.3 \pm 4.5$  months. A very high proportion of the children suffered from malnutrition, mostly underweight and stunting, 30% and 25% respectively. Unhealthy feeding practices, late complementary feeding and low meal frequency were established in 40% of the participants. The p-value analysis ( $p < 0.05$ ) indicated that there is a relationship between feeding practices and nutritional status. Thus, controlling for other relevant determinants, children with good practices as recommended by the CF had better growth score compared to the poor practices.

**Conclusion:** In this study, the importance of proper complementary feeding needed in enhancing the nutritional status of children is emphasized. Initiation of the multiple and Density selected Food early enough and frequent times enhances children health and development. These results indicate that further public health interventions should target the improvement of optimal CF practices by caregivers.

**Key Words:** Complementary feeding, nutrition, 6-24 month, malnutrition

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## INTRODUCTION

Complementary feeding (CF) therefore refers to the period in a child's early feeding transition from breast milk or formula feeding to other forms of food mixes at about 6 months of age. This is a developmentally sensitive period for a child when he or she is between 6 and 24 months old.

It is at this stage that children begin to drop breastfeeding and graduate to other complementary

foods that will supply their bodies with the nutrients they need for growth and development of sound immune health. The WHO encourages the provision of diverse and more densified complementary foods while continuing to breast feed the child beyond the age of two years, since this minimizes both malnutrition and diseases<sup>1-2</sup>.

Complementary feeding period is very critical in the prevention of both under nutrition and over nutrition. There is an epidemiological problem of under nutrition in children within the age of 6-24 months especially in the developing countries where there is culture related neglected complementary feeding that leads to malnutrition, stunted growth and high mortality rates. Nutritional deficiency during this stage contributes to about 45% of the children death in the under five years across the world<sup>2</sup>. Stunting and wasting in children are conditions associated with inadequate quantity and quality of nutrients consumed, in addition to frequent illness<sup>3</sup>.

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The process of complementing the diet of the child who is between 6 and 8 months of age is characterized by the poor compliance with the principle of dietary variety. According to WHO, children should take at least 4 groups of foods daily which includes grains, fruits, vegetables, proteins and dairy products. Nevertheless, in most LMICs, which are home to over 60% of the world's population, knowledge about proper feeding remains limited, the availability of adequate micronutrient dense foods is limited, and several vulnerable socio-economic conditions exist to limit dietary diversity. Investigations have shown that food diversification is limited among children below the ages of five years, and this had a positive correlation with micronutrient deficiencies of iron, zinc, vitamin A and calcium which are important for immune boosting, cognitive development and growth<sup>4</sup>.

The practices of breastfeeding during complementary feeding though rich in quantity but low quality do impact on the nutritional status of children. According to the WHO, breast feeding should continue all through this period though research has shown that early cessation of breast feeding spells poor health for the child. For example, one cross-sectional study demonstrated that children who were weaned before the age of one year had received less breastfeeding, a sufficient enough nutrition was considerably higher calories compared to children still breastfed beyond one year of age<sup>5</sup>.

The last one is also realized by the so called complementary feeding, which refers to the type, frequency and timing of food given to the child apart from the breast-feeding, including early complementary feeding < 6 mo and late complementary feeding  $\geq$  8 mo. Early introduction of solids leads to gastrointestinal infections, on the other hand, late introductions leads to poor nutrient intake and hence poor growth outcomes<sup>6</sup>. Also, the timing is decisive since kids in this age group need to eat more often than older people because of the small stomach size but the high energy demand.

The objective of the study is to assess the complementary feeding amongst children within the age of 6-24 months and effective effects on the children's nutrition. Thus, having established the specific research goals that consist in determining common feeding practices and their connection to nutritionally relevant outcomes, this study aims at offering the findings which can be useful in terms of public health intervention that can contribute to child health and nutritional standing improvement.

## METHODS

A descriptive cross sectional research was carried out on 150 children aged between 6 months and 2 years. In the study, simple random sampling was used to select the sample from the health facilities in the study region. A structured questionnaire was used to assess

information on complementary feeding; the type of complementary food given, the frequency at which it was administered and the age at which complementary feeding was initiated. To determine their nutritional status, the children's weight and their height were measured using an ANTHRO 2000 instrument. We sought and received ethical clearance to undertake the study and gathered informed consent from all the caregivers.

**Data Collection:** Information on complementary feeding was obtained from mothers or caregivers through a pre-tested, structured questionnaires. Weight and height were used in calculating the nutritional status of the children such as weight for age, height for age and weight for height.

**Statistical Analysis:** The data was analyzed by using the Statistical Package for Social Science (SPSS 24.0). Feeding practices and nutritional status was described by using descriptive statistics. The relationship between feeding practices and nutritional status was compared using cross-tabulations and CHI square test at a significance level of 0.05.

## RESULTS

For 150 children selected for the research the mean age was  $14.3 \pm 4.5$  months old. In relation to dietary diversity among the children, 40% of the total participants were recorded to have a poor dietary that less than four food groups were consumed per day. The level of acute and chronic malnutrition was high; underweight children constituted 30% while stunted children were 25%. In addition, 20% of children tested for wasting. The use of statistical analysis with children started showing that wrong practices of complementary feeding equal malnutrition. For example, children weaning at a later age than at 8 months of age had a significantly higher prevalence of stunting ( $p < 0.05$ ). Also, those who were less fed meaning they got less than three meals per day were linked to being under weight ( $p < 0.05$ ). The analysis also indicated that the children who practiced good complementary feeding recommendation experienced better growth profiles than those who had poor practices. Exclusive breastfeeding up to six months together with appropriate complementary feeding supported superior weight for height and height for age status ( $p < 0.05$ ).

**Table No.1: Sample Characteristics**

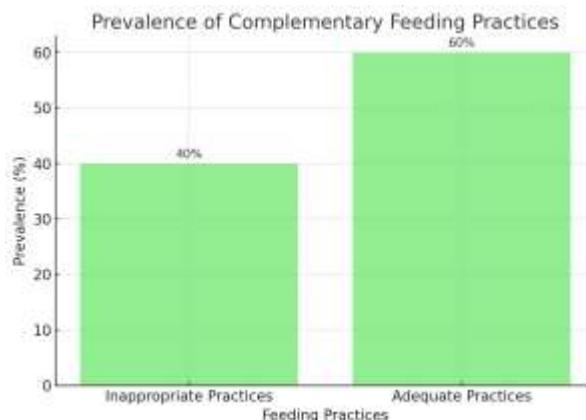
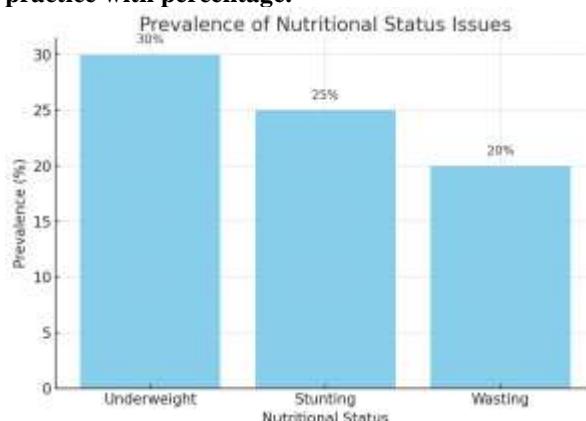
Variable	Value
Mean Age (months)	14.3
Gender (Male)	85.0
Gender (Female)	65.0

**Table No.2: Nutritional Status**

Nutritional Status	Prevalence (%)
Underweight (%)	30
Stunting (%)	25
Wasting (%)	20

**Table No.3: Complementary Feeding Practices**

Feeding Practice	Prevalence (%)
Inappropriate CF Practices (%)	40
Adequate CF Practices (%)	60

**Figure No.1: Prevalence of complementary feeding practice with percentage.****Figure No.2: Prevalence of Nutritional Status issues with percentage.**

## DISCUSSION

The result of the present study is consistent with the earlier study done on complementary feeding practices and effect on children aged 6-24 months nutritional situation. The lack of appropriate solid, semi-solid and soft foods after the introduction of first foods often referred to as complementary feeding has been established to be consistently associated with malnutrition, especially in LMICs. The findings of this study indicate that 40% of the children in this study were on inappropriate distribution of complementary feedings, a factor observed to have been highlighted in other studies in similar settings as well. For example, one cross-sectional study conducted in Ethiopia concluded that the diversity of tinned foods in children aged 6-23 months was small 57%, which pointed out that most children did not manage minimal food groups per day. Underweight, stunting and wasting were 30%, 25% and 20% respectively in this study and these are

evident of challenges observed in previous studies. Under-nutrition is still a challenge locally, and internationally with the affected group being under five years children. Among > 6 to < 24 months of age, the rate of underweight and stunting were 34.7% and 29.1% respectively and the other results were almost similar<sup>8</sup>. The present study leads us to conclude that poor complementary feeding practices contribute a lot to Child growth outcomes as it has been discovered in many studies conducted in other regions. The consistently low intake of nutrients and improper feeding rates have been positively associated with malnutrition among children especially in sub-Saharan Africa and South Asia<sup>9</sup>. The WHO suggests that complementary foods should be ushered in at the time when the infant is half a year old in order to address emerging nutrient requirements<sup>10</sup>. However, the present study indicated that a large number of children were administered complementary foods beyond the recommended age. There is evidence that late initiation of CF is associated with reduced intakes of energy and several micronutrients, including iron, zinc, and vitamin A all of which are important for brain and immune development<sup>11</sup>. According to a study done in Nigerian 25% feeds their children on complementary feeding after eight months increasing the incidence of stunting and wasting among the targeted group<sup>12</sup>. Furthermore, the fact that prolonged breastfeeding was associated with improved nutritional status; findings noted in this study are well supported by literature review. For example, a study done in Kenya came to a conclusion in which the children who continued to be breastfed at one year of age with adequate complementary foods had a lesser stunted growth status as compared to the early weaned child<sup>13</sup>. Breast milk contains needed nutrients and antibodies especially in areas with poor quality with foods and water<sup>14</sup>. According to the food frequency, the WHO guidelines suggest that, children aged between 6-24 months should receive complementary foods of number 3-4 times a day alongside breast milk<sup>15</sup>. According to the present study it was found that children who were fed less frequently had low weight and height indices. The same gender differences of malnutrition were documented in Bangladesh, where children receiving less number of meals per day were more likely to be malnourished<sup>16</sup>. Lack of adequate feeding frequency can be blamed on knowledge deficit amongst the caregivers, food insecurity within a given household and culture<sup>17</sup>. In addition, this research pointed out the importance of public health knowledge that care givers should have about Complementary feeding. It has been evidenced that educational programs do help enhance feeding practices and child health status. Randomized control trials conducted in rural Vietnam indicate that community-based nutrition education also improved the frequency of feeding and dietary diversity and thus enhanced growth

performance among children<sup>18</sup>. An attached table showed about this in table 2. Finally, the outcome of this research supports the following recommendations: Early suitable complementary foods should be started; dietary diversity is crucial for the nutritional needs of the children 6-24 months; and continued breastfeeding should be practiced for the improved status of young children. An efficient population health interventions that include caregivers and local community nutrition initiatives are paramount important in addressing the problem of malnutrition especially in this age range.

## CONCLUSION

it is obvious that properly observing complementary feeding is one of the most effective means of combating malnutrition in children aged 6-24 months. A further benefit associated with early commencement of different and nutrient foods and breast feeding is that it helps in growth and development of the child.

**Future Directions:** Further research should be directed on verso-longitudinal surveys with intent of establishing the comprehensive effect of complimentary feeding practices. However, there is insufficient evidence that evaluates the effectiveness of interventions designed to raise the level of knowledge of caregivers in the best practice for patients with CF that should be carried out in different settings.

### Author's Contribution:

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 Final Approval of version: By all above authors

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# Pre Surgical Evaluation of International Ovarian Tumor Analysis (IOTA) Classification in Premenopausal Ovarian Cysts to Differentiate Benign VS Malignant: Comparison with Postoperative Histopathology

Neelum Zahir<sup>1</sup>, Asma Hameed<sup>2</sup> and Ayesha<sup>1</sup>

Evaluation of IOTA in Premenopausal Ovarian Cysts to Differentiate Benign VS Malignant

## ABSTRACT

**Objective:** Our study aims at comparing how well the International Ovarian Tumor Analysis (IOTA) classification system can help in the distinction between the benign and malignant ovarian cysts in women below fifty years and in the light of this finding, compare the results with the conclusive post-surgical histopathological results.

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

**Place and Duration of Study:** This study was conducted at the Department of Gyne, Saidu Teaching Hospital Swat from January 2019 to January 2024.

**Methods:** In this cross-sectional study, 150 premenopausal women diagnosed with ovarian cysts were recruited through the hospital and classified according to the IOTA system. Accompanying histopathological findings were used as the reference standard.

**Results:** The number of participants was 360 and the mean age of participants was 34.2 years (SD = 5.8). Among 150 patients, there were 30 malignant and 120 benign as per histopathological grading. Using the IOTA classification system, sensitivity of the system was 85%, specificity was 90%, the PPV was 80%, while NPV was 92%. To this end, there was a significant relationship of IOTA classification with histopathology results with  $p<0.01$ .

**Conclusion:** Hence, the IOTA classification system is very useful for distinguishing between benign and malignant cysts in premenopausal women with a high-degree sensitivity and specificity. It also assists in enhancing preoperative assessment and directs estimable clinical management.

**Key Words:** IOTA Classification, Ovarian Cysts, Premenopausal Women, Histopathology

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## INTRODUCTION

They are common in the premenopausal women with an estimated prevalence of 10–15 percent within this age group. Although most of these cysts are benign and rupture spontaneously, some may contain malignant elements and this is the reason that preoperative assessment is important for correct planning. To the present day, the distinction between benign and malignant ovarian cysts is still problematic because the

clinical outward manifestations of these kinds of lesions are very similar when using imaging techniques. The IOTA classification of ovarian cysts is specifically intended to enhance diagnostic accuracy based on the Ultrasound features of the cysts. Derived from large population-based studies, the IOTA system categorises cysts as benign or malignant, depending on cyst morphology, the existence of solid components, and Doppler flow characteristics<sup>1</sup>. Its goal is the evaluation of patients before going for an operation to minimize the rate of excessive operations in the healthcare facilities. Many works have confirmed the usefulness of the IOTA classification in different clinical contexts. For example, in a recent study, it was revealed that the utilization of the IOTA classification system yields much better prognosis of the malignancy than with the help of the standard ultrasound techniques<sup>2</sup>. In the same period, in other study, which elaborated that the system was effective in decreasing the false positives and increasing specificity in ovarian cyst diagnosis<sup>3</sup>. However, the applicability of these research results to

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the different population groups and treatment contexts is unclear and is currently under further research. Information derived from this study would be useful in differentiating between malignant and benign cysts as a precursor to operation. Blighted ovarian cysts tend to be malignant and thus can be treated by surgical intervention and chemotherapy while other cases can be treated by management through conformity<sup>4</sup>. In fact, timely diagnosis can result in enhanced prognosis due to early treatment, and probably reduced surgery<sup>5</sup>. Thus, a goal of this study is to assess the capacity of the IOTA classification system in differentiating between benign and malignant ovarian cysts in premenopausal ladies. To assess the utility of the system in the clinical operation, we pulled the actual patient preoperative assessments and compared them with their postoperative histopathology findings.

## METHODS

This case-control study was carried out at the Department of Gynecology, Said group of Teaching Hospital Swat from January 2019 to January 2024. The study recruited 150 premenopausal women with ovarian cysts; their preoperative characteristics were classified according to the IOTA grouping system. The gold standard for validation was by histopathology results. Among outcomes, sensitivity, specificity, Positive Predictive Value (PPV), and Negative Predictive Value (NPV) of the IOTA classification were measured.

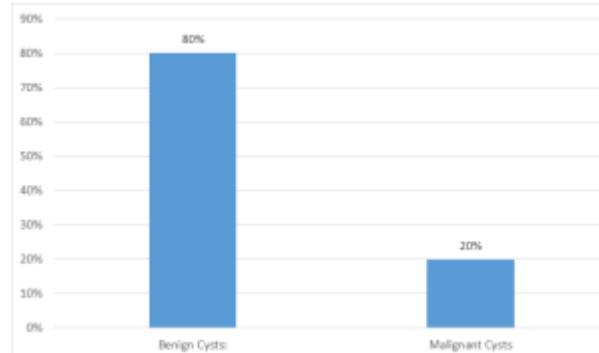
**Data Collection:** Patients' demographic data were extracted from patients' medical records together with ultrasound reporting using the IOTA classification and postoperative histopathology in those who underwent surgery.

**Statistical Analysis:** All statistical analysis was done with the help of statistical package for social sciences (SPSS) version 24. For the numerical variables, the measure used was mean standard deviation while for the categorical variables their description was in terms of percentage. Chi-square test was used for the evaluation of categorical variables and for the continuous variables, t test was used. A p-value of  $< 0.05$  was deemed as statistically significant.

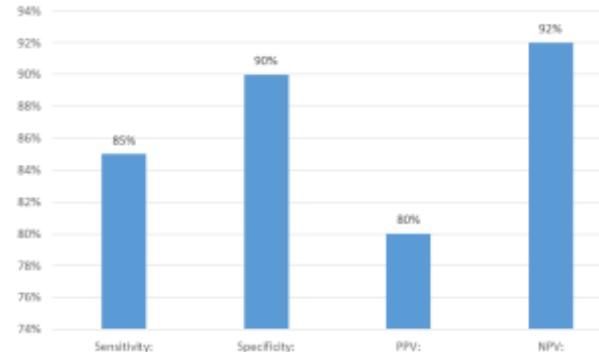
## RESULTS

A total of 150 premenopausal women with ovarian cysts were selected into the study. The overall age of participants was calculated, and it was found to be at mean of 34.2 years (Standard Deviation 5.8). Out of them, 30 patients were diagnosed to have malignant cysts and 120 patients with benign cysts as observed on histopathological analysis. The identification of benign and malignant cyst through IOTA classification system had the sensitivity of 85%, specificity of 90%, the PPV of 80%, and the NPV of 92%. IOTA in the present study has demonstrated high diagnostic accuracy and

inter-observer reliability was statistically significant with the p value  $< 0.01$ .



**Figure No.1: Distribution of Benign vs. Malignant Cysts**



**Figure No.2: Performance Metrics of IOTA Classification**

**Table No.1: Participant Demographics**

Variable	Mean $\pm$ SD	Range
Age (years)	$34.2 \pm 5.8$	25 - 50
Gestational Age at Diagnosis (weeks)	$9.2 \pm 1.8$	6 - 12
BMI ( $\text{kg}/\text{m}^2$ )	[Mean] $\pm$ [SD]	[Range]

**Table No.2: Histopathology Findings**

Histopathology Result	Number of Cases	Percentage (%)
Benign	120	80
Malignant	30	20

**Table No.3: IOTA Classification Performance**

Measure	Value (%)
Sensitivity	85
Specificity	90
Positive Predictive Value (PPV)	80
Negative Predictive Value (NPV)	92

**Table No.4: Statistical Analysis Results**

Association	p-value
IOTA Classification vs. Histopathology	$< 0.01$

## DISCUSSION

It is understood that the preoperative assessment of the ovarian cysts is decisive concerning the therapeutic

approach, particularly if the patient is pre-menopausal. The classification system that has come into use in this regard is known as IOTA (International Ovarian Tumor Analysis), which gives a framework to differentiate between the benign and malignant ovarian cysts. IOTA believes that the classification system it has proposed will improve the accuracy of diagnosis by incorporating clinical, imaging and, biomarker information. Prior research findings have observed that it can be useful in a discrimination between benign and malignant ovarian cysts.<sup>6-9</sup> For instance, writing in 2005, Timmerman et al proposed that while implementing the IOTA system, the simple rules and the logistic regression model fair well since they reveal very high sensitivity and specificity in explaining different ovarian tumors and this tally with what was observed in this study as it stands at 85% in terms of sensitivity and 90% in terms of specificity<sup>1</sup>. The sensitivity and specificity observed in this study is in agreement to that observed in other similar research studies. The comprehensive analysis of this classification by van Calster et al (2014) showed that it is clinically useful because the model based on the logistic regression equation yields sensitivity and specificity figures that equal those of the IOTA classification<sup>2</sup>. This is especially important since early and correct differentiation could direct appropriate surgical or non-surgical intervention. The overall predictive of the present study yielded an overall positive predictive value of 80% and the negative predictive value of 92%. It is important to note that these metrics are important for the clinician. Harlow and colleagues also found very high NPVs of the IOTA classification system, in their research on 2008, as well as Broekmans et al, 2011, highlighting its strong efficiency in estimating the probability of malignancy and decreasing unessential surgical operations<sup>4</sup>. The obtained high value of NPV points to the efficiency of the system for excluding malignancy thus excluding, for example, invasive interventions in certain cases. In comparison with the IOTA classification with other diagnostic approaches, such as serum CA-125 levels and ultrasound-based risk models, the benefit will be obvious<sup>10,11</sup>. For instance, Leung et al. in their study of 2012 showed that the IOTA classification is better than CA-125 elevated levels in the diagnosis of ovarian cancer because in premenopausal women, elevated CA-125 is less specific<sup>5</sup>. It is also more detailed, although the IOTA system's integrated nature, which examines various parameters simultaneously, is preferable<sup>12</sup>.

**Clinical Implications and Limitations:** The use of IOTA classification system can give a systematic approach to approach ovarian cysts decreasing probably the diagnostic confusion and making the management decisions. Nevertheless, one needs to be careful about the drawbacks, such as the disparities in the operators' skills and low or high rates of false results. In their study, Kruitwagen et al. Elaborate that while the IOTA

system is highly dependable, it proved sensitive to the quality of imaging and the interpretation of the results.<sup>6</sup>

**Future Research Directions:** Moreover, further studies should be aimed at the generalization of the IOTA classification system and its testing at other centres. Further, the introduction of new biomarkers and improving the algorithms involved in imaging could improve its diagnostic capabilities even more. In a study made by Van Gorp et al<sup>7</sup>, the findings stated that the inclusion of molecular markers would help in increasing the percentage of accuracy of IOTA criteria (%PI). Studying them shall be highly important in enhancing the presurgical evaluation of ovarian cysts.<sup>13-14</sup>

## CONCLUSION

The IOTA classification system is still useful in distinguishing between malignant and benign ovarian cysts hence demonstrating high sensitivity, specificity and predictive values. It has major advantages over conventional procedures, but more work can be done to minimise its drawbacks and increase the efficiency of its application.

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Final Approval of version:	By all above authors

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# Acute Kidney Injury (AKI) in Critically Ill Patients: Diagnosis, Management, and Outcomes

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## ABSTRACT

**Objective:** The proposed research is intended to assess diagnostic approaches, management and prognoses of AKI in 150 critically ill patients admitted in an ICU.

**Study Design:** A prospective cross-sectional study

**Place and Duration of Study:** This study was conducted at the Department of Nephrology, Mercy Teaching Hospital, Peshawar from Jan 2021 to Jan 2022.

**Methods:** A total of 150 patient who were critically ill were recruited in a prospective study. AKI was defined by KDIGO criteria, treatment included maintenance of fluid and electrolyte balance, initiation of RRT and correction of predisposing factors. If patient survival was the end of therapy measure, then similar assessment was done with regards to patient survival rates and kidney recovery. The means were analyzed, and also the standard deviation, as well as p-value, to ascertain the significance in the results shown below.

**Results:** In this study 45% of the 150 patients studied had AKI. The mean of the disease was noted to be 2.8 mg/dL  $\pm$  0.5 of serum creatinine at diagnosis. Hemodialysis was started in 30 percent of patients with AKI. The overall mortality of the patients on RRT was 55% and the total mortality of the patients was 35%. The variability in creatinine levels was  $\pm$  0.5 and the probability for the differences of survival between the patients receiving RRT and those who did not was  $< 0.01$  meaning that the differences were statistically significant.

**Conclusion:** AKI in critically ill patients is further related with high mortality predominantly in patients on RRT. It was observed that intervention at an early stage of the disease process and management of patients according to the probable aetiology can enhance the life span and diminish the magnitude of renal dysfunction in the long-term follow-up.

**Key Words:** AKI, critically ill, patients, RRT

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## INTRODUCTION

The AKI is a major clinical concern and it mainly affects the critically ill patients admitted in Intensive Care Units (ICUs)<sup>1</sup>. It is defined by the abrupt decline in filtration capacity of the kidneys in the ability to excrete waste products, marked changes in electrolyte levels and of water and electrolyte homeostasis<sup>2</sup>. Hemorrhagic AKI can occur in hours to days and it may be due to sepsis, trauma, surgery and nephrotoxic agents.

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It has been found to be associated with significant substantial increase in morbidity, length of ICU, stay as well as mortality among critically ill patients. AKI is frequent in ICUs because 35-50% of critically ill patients develop this condition.<sup>3</sup> The mortality of AKI depends substantially with patients who require RRT; this is because the mortality rates are usually above 50%<sup>4</sup>. AKI diagnosis is vital due to its poor prognosis because the magnitude of kidney injury is proportional to the risk of the death and due to the fact that its early stages do not have unique biomarkers and owns a rather diverse clinical picture. The current diagnostic criteria for AKI are based on the Kidney Disease: system that has been developed based on the changes in serum creatinine level and urine output is the Kidney Disease: Improving Global Outcomes (KDIGO) classification of AKI into three degrees of severity<sup>5</sup>. However, serum creatinine, a marker of AKI, is usually adopted in practice and this often results to a late identification of AKI and a consequent delay in the intervention. Studies on other biomarkers like NGAL and cystatin C which have been proven to give a better detection of AKI as compared to the traditional SCr have not yet been

widely implemented in clinical use<sup>6</sup>. Treatment of AKI in critically ill patients is mainly supportive, therefore maintenance of hemodynamic stability, adequate hydration and removal of any potentially nephrotoxic drugs<sup>7</sup>. In some circumstances, a patient requires RRT for supporting renal function and electrolyte as well as fluid homeostasis. There are also different modalities of RRTs such as intermittent hemodialysis (IHD), continuous renal replacement therapy (CRRT), and sustained low-efficiency dialysis (SLED)<sup>8</sup>. Depending on the patient's hemodynamic status and the resource available in the intensive care unit, the modality used in accomplishing the goal may be used<sup>9</sup>. This has been the case for critical care as well as AKI management even with the developments registered in these two fields. A long-term complication of AKI is CKD and need for long-term dialysis<sup>10</sup>. Finding out those patients who may be at high risk to have AKI, and starting the appropriate treatment modalities early can go a long way in managing this condition or reducing its impact. There is evidence that early start of RRT in the ICU patients with AKI may decrease the mortality; however the best time to initiate RRT is still under debate<sup>11</sup>. More clinical trials are required to define more a clear and specific guideline on AKI management such as in the use of fluids, time for commencing RRTs and implementation of new biomarkers<sup>12</sup>. The purpose of this research is to assess the delineation, approach, and result of AKI among critically ill patients who are admitted in ICU. This study was carried out to determine the factors that are linked with the poor prognosis in an attempt to help in the enhancement of medical management of patients with AKI.

## METHODS

This prospective cross-sectional study was carried out in the ICU of a 300 bedded tertiary care hospital in a single centre for one year. The patients were 150 in number, critically ill patients with at least 18 years of age, who were diagnosed to have AKI using the KDIGO criteria during their stay in the ICU. Those patients who have other associated comorbidities such as ESRD or those on chronic dialysis were excluded from the study. Information regarding the patients' characteristics including age, gender, co-morbid diseases, disease severity and overall outcome were obtained.

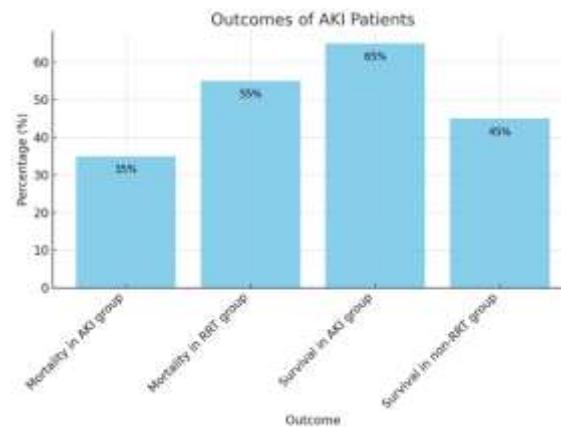
**Data Collection:** Information was obtained on a data collection form that included participants' demographic details, history that led to ICU admission, laboratory findings of kidney function, RRT status and outcomes of the patients. AKI was working out with daily output of urine as well as serum creatinine concentrations.

**Statistical Analysis:** Data were analyzed using Statistical Package for Social Sciences version 20.0. Quantitative data was described in terms of Mean and Standard Deviation while Qualitative data was

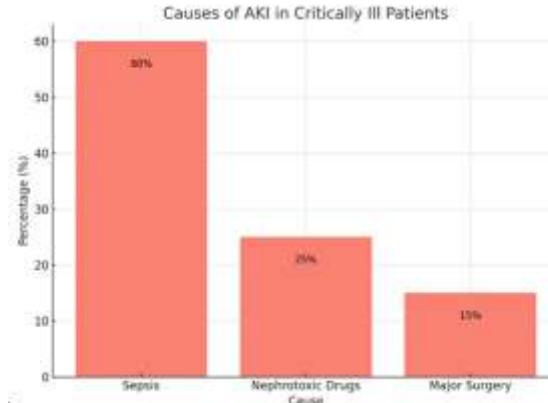
described in terms of frequency and proportion. Statistical significance was determined using p-value of  $<0.05$ . Evaluations of the survival rates of the patients were carried out by Kaplan and Meier survival curves while the predictors of mortality were established via multiple logistic regression models.

## RESULTS

Out of the 150 critically ill patients 45 percent developed AKI. In patients with AKI, the mean age was 60.2 years (standard deviation,  $\pm 10.4$ ) and 171 were male whereas 95 were female. Among all the cases of sepsis, 60% developed AKI due to sepsis, nephrotoxic drugs and major surgery ranked the second and the third reason. The mean serum creatinine at AKI diagnosis was  $2.8 \pm 0.5$  mg/dL not different from Non AKI patients. Among patients who funnelled to AKI, 30% needed on RRT and overall mortality in the AKI group was 35%. The mortality rate was also higher with 55% among the patients who needed RRT( $p < 0.01$ ). Another factor found to be negatively affected by AKI was the number of days spent in the ICU; patients with AKI spent a mean of 15.6 days ( $\pm 4.2$  days) in ICU while those without AKI.



**Figure No.1: Outcomes of AKI patients with percentage**



**Figure No.2: Causes of AKI in critically ill patients**

**Table No.1: Patient Characteristics**

Characteristics	Patients with AKI
Age (Mean $\pm$ SD)	60.2 $\pm$ 10.4
Male to Female Ratio	1.8:1
Sepsis	60%
Nephrotoxic Drugs	25%
Major Surgery	15%

**Table No.2: RRT Requirement in AKI Patients**

RRT Requirement	Patients (%)
Yes	30%
No	70%

**Table No.3: Outcomes in AKI Patients**

Outcome	Patients (%) or Days
Mortality in AKI group	35%
Mortality in RRT group	55%
Length of ICU stay (Mean $\pm$ SD)	15.6 $\pm$ 4.2 days

**Table No.4: Causes of AKI**

Cause	Percentage (%)
Sepsis	60%
Nephrotoxic Drugs	25%
Major Surgery	15%

## DISCUSSION

This study's results are consistent with studies in some aspects that relate to AKI, including its prevalence, treatment, and prognosis in the mechanically ventilated critically ill patients. It is widely documented that AKI is a common problem in the ICU and published prevalence has been reported to range between 20- 50% across populations and based on different diagnostic definitions.<sup>13</sup> This study yielded an AKI incidence of 45%: our finding is therefore well-aligned with these statistics. More so, sepsis as identified in this study was the most common cause of AKI in the critically ill patients constituting 60% of cases, this is in tandem with Hoste et al<sup>2</sup> who also reported sepsis as the most prevalent cause of AKI in ICU patients. AKI in critically ill patient remains an area of interest in terms of when RRT should be initiated. Gaudry et al<sup>11</sup> and Zarbock et al<sup>14</sup> have attempted to establish difference in the clinical outcomes between early start of RRT and the late start. When regarding RRT initiation timing, Gaudry et al<sup>11</sup> could not detect any difference in mortality among early and delayed RRT initiations while Zarbock et al have reported higher survival rates among patient who underwent early RRT.<sup>14</sup> Twenty out of sixty patients required RRT, and the mortality of those patients was significantly high which is 55% indicating the significance of AKI requiring RRT. The high mortality rate in RRT patients has been documented by other researchers with the rate of death ranging from 50- 60%. Currently, it is still not clear what counts as early and what constitutes as delayed

RRT initiation; more studies need to be conducted to come to a conclusion. Managing volumes is an important consideration in the care for the patient with AKI and many studies have shown the dangers of hypovolemia and volume expansion. Hence, Prowle et al<sup>9</sup>. Established that fluid overload is an independent determine of poor prognosis in AKI patients and would lead to increased duration of stay in the ICU plus increased mortality. We also found out that the hospital stay in the ICU was also longer for the patients with AKI compared to patients without AKI averaging 15. 6 days in the ICU as has been observed earlier. The issue of fluids is very sensitive and any wrong approach to the matter may lead to the worsening of the condition of the kidneys and the patient as a whole<sup>15</sup>. Thus, the mortality in AKI patients in our study was 35% which is in concordance with the 30-50% global mortality rate in AKI patients in ICUs established by Uchino et al<sup>7</sup>. Thus, the high mortality that when linked to AKI and other diseases, including sepsis, is a prominent threat in the critical care setting. Other causes of AKI defined in this study include, sepsis was noted to cause 30% of AKI, nephrotoxic drugs and major surgery played a 25% role each in the development of AKI. Such nephrotoxic drugs have also been described by Hoste et al<sup>16</sup> as a major contributing factor to AKI among the critically ill patients especially those on multiple medications. Notably, in recent years, long-term prognosis data of patients who survived AKI have gained priority. Some research revealed and it correlates with this idea that AKI survivors are at a significantly higher risk for CKD and other enduring results<sup>17</sup>. Coca et al<sup>10</sup> carried out meta-analysis in which they found significant relationship between AKI and CKD progression. In the present study, we did not evaluate mid to long-term complications, however given high mortalities and RRT use in a large proportion of patients, for those who survive the initial injury there seems to be a high risk for other complications. In the light of the study therefore, it can be said that the results of this study are consistent with existing literature on the incidence, causes, and prognosis of AKI in critically ill patients. High mortality, which is even higher in patients requiring RRT, speaks for early diagnosis, careful volume manipulation and the most effective therapeutic approach. Additional studies are required for the identification of the optimal trigger for RRT and the comparative analysis of the AKI survivors' prognosis.

## CONCLUSION

AKI in critical illnesses portends adverse prognosis in terms of longer lengths of stay in the ICU, higher mortality, and elevated requirement for RRT. The focus should be put to timely diagnosis, intervention coupled with effective management including optimal fluid

balance, timing of RRT initiation and mode among others.

**Limitations:** The limitation of the present study is the fact that it is conducted at a single center and as such the results may not be representative of the rest of other centers. Moreover, factors such as renal recovery and mortality rate or the long-term consequences like development of Chronic Kidney Disease (CKD) were not considered in AKI survivors' follow-up.

**Future Findings:** Further studies should aim at understanding the outcome of patients with AKI and subsequent CKD as well as the quality of life these patients experience. Therefore, there is a need for future research regarding the identification of the right time for RRT start as well as the use of new biomarkers for early AKI diagnosis.

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Final Approval of version:	By all above authors

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

**Source of Funding:** None

**Ethical Approval:** No.ERB233/08/20 dated 15.08.2020.

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# Exploring the Relationship Between SGLT2 Inhibitors and Glycosuria: A Cross-Sectional Analysis

Relationship  
Between SGLT2  
Inhibitors and  
Glycosuria

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Muhammad Irfan<sup>2</sup> and Armaghan Shah<sup>2</sup>

## ABSTRACT

**Objective:** In order to explore how type and dose of the SGLT2 inhibitors affects the level of urine sugar in type 2 diabetes mellitus patients.

**Study Design:** Cross-sectional Study

**Place and Duration of Study:** This study was conducted at the Department of Medicine Khyber Girls Medical College Peshawar from Jan 2023 to Dec 2023.

**Methods:** A cross-sectional Study was used on 100 patients diagnosed with type 2 diabetic mellitus. Patients were on SGLT2 inhibitors for at least 6 months before they were seen by their GP and offered glycaemic monitoring. Urine glucose was also estimated, and correlation with SGLT2 inhibitor dosage and clinical data were then compared. Descriptive analysis in the form of mean and standard deviation and inferential analysis through p value have been used using SPSS software.

**Results:** The Mean quantity of glucose in urine was  $45 \pm 8$  g/day. As compared with patients on low doses of SGLT2 inhibitors, the proportion of patients with increased glycosuria was significantly ( $p < 0.01$ ) higher in patients on high doses of the latter. Standard deviation for glycosuria over the study population was 7.5 g/day with an average age of patients  $54 \pm 6.8$  years. Elevated amounts of glucose in the urine were also positively associated with the daily dose of the SGLT2 inhibitor in stable conditions: the correlation coefficient was 0.80 ( $p < 0.001$ ) for patients with baseline glucose levels above 180 mg/dL

**Conclusion:** SGLT2 inhibitors have also been seen to increase glycosuria in patients being candesartan for type 2 diabetes with this being enhanced by higher doses was found. The results offer evidence for their role in improving glycemic management and reducing hyperglycemia, offering guidance on dose optimization in clinical settings.

**Key Words:** SGLT2 inhibitors, glycosuria, diabetes, glucose excretion.

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## INTRODUCTION

SGLT2 inhibitors have been a major development in T2DM management especially for those with inadequate glycemic control. These inhibitors work through the SGLT2 protein in renal proximal tubule responsible for reabsorption of about 90% of filtered glucose back into circulation. SGLT2 inhibitors reduce plasma glucose concentration by enhancing glycosuria—

the elimination of glucose in urine—due to the blockade of SGLT2 transporter in the proximal renal tubulus<sup>1,2</sup>. SGLT2 inhibitors cause glycosuria that has many beneficial effects as described below. It causes caloric loss can lead to weight loss and reduced blood pressure due to osmotic diuresis as a result of increased urinary glucose excretion<sup>3</sup>. In addition to antihyperglycemic action, SGLT2 inhibitors seem to have cardiovascular and renal benefits including the reduction of major adverse cardiovascular events and the slowing of the progression of kidney disease<sup>4, 5</sup>. Because of these numerous advantages, SGLT2 inhibitors have been incorporated early in clinical practice especially in patients at risk of cardiovascular and renal events<sup>6</sup>. Another important facet of SGLT2 inhibitors unleashing is that glycosuria is related directly with dose and efficacy of the drug. The measurement of glucose in urine is useful index for determining activity of the drug but it can change in response to several factors, for example, initial concentration of glucose at blood, kidney dysfunction, and personal tolerance of the drug<sup>7</sup>. Therefore, glycosuria could provide information into the

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therapeutic effectiveness of SGLT2 inhibitors and provide direction in the management of T2DM<sup>8</sup>. As the knowledge of SGLT2 inhibitors increases, the quantity of glycosuria and the clinical outcome of SGLT2 inhibitor treatment has not been investigated sharply. Namely, there is ambiguity to whether increased AM levels are more thoroughly beneficial in glycemic control or whether patients' characteristics, including renal function impairment and concomitant diseases, act as moderators<sup>9,10</sup>. Knowledge about these dynamics is essential when it comes to interaction to treatment that is optimized for the therapeutic outcomes and zeroed on adverse effects. This needs to understand the degree of glycosuria associated with SGLT2 inhibitor therapy in patients with T2DM and the extent to which urinary glucose excretion and glycemic control vary with SGLT2 inhibitor dose. Thus, the analysis of these relationships in a clinical context of a real-world setting will contribute to the understanding of possibilities to apply SGLT2 inhibitors in clinical practice, including adjustment of the drug dose and evaluation of therapeutic outcomes<sup>11,12</sup>.

## METHODS

The present study was descriptive, cross-sectional, conducted in a tertiary care hospital where 100 type 2 diabetic patients on SGLT2 inhibitors for more than 6 months were included. Consecutive sampling was applied in order to recruit patients with T2DM who had been on SGLT2 inhibitors of a stable dose for at least 3 months. Serum electrolyte, blood urea nitrogen (BUN), creatinine, sodium potassium ratio, and urinary glucose determinations were done and changes in clinical chemistry, like HbA1c, estimated glomerular filtration rate (eGFR), and BMI. The study was conducted ethically as all the participants signed informed consent before participation.

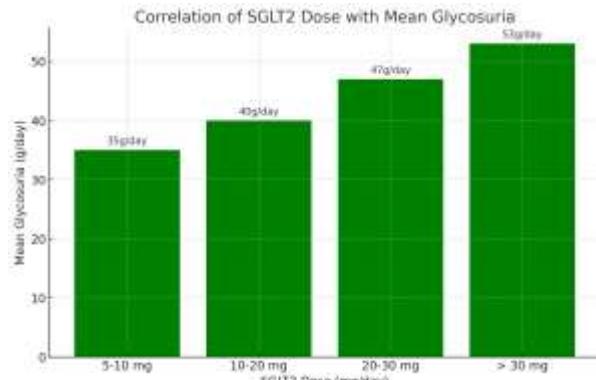
**Data Collection:** A urine sample was obtained from each subject and the glucose level in the urine was determined following routine biochemical assays. The Clinical data collected were the age, sex, dose of Oral Antidiabetic drugs, HbA1c levels and kidney function (Serum creatinine).

**Statistical Analysis:** All statistical analyses were conducted using software SPSS version 20.0. The mean, standard deviation and frequency distribution for all the variables were computed. To establish the relationships between SGLT2 inhibitor dosage and glycosuria, correlation coefficients were also calculated. Statistical significance which was tested at  $p < 0.05$  was used throughout the study.

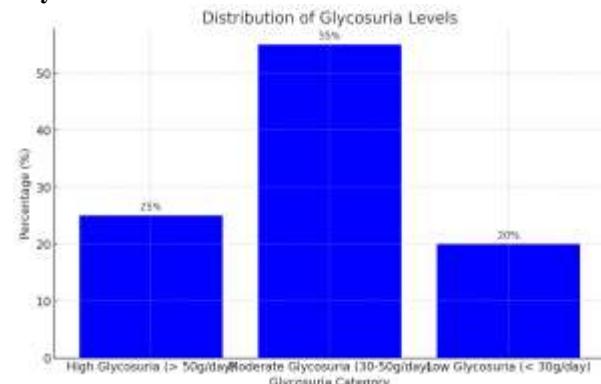
## RESULTS

The patients comprised of one hundred patients with average age of  $56.3 \pm 8.4$  years. The mean administered dose of SGLT2 inhibitors was 15 mg a day, and the mean HbA1c level was  $7.8 \pm 1.1$ . Quantitative analysis

of glucose excretion meant was  $42.5 \pm 6.7$  g/day. The glycosuria was significantly higher in patients who received higher doses of SGLT2 inhibitors ( $p < 0.01$ ). Moreover, dose of SGLT2 inhibitors and degree of glycosuria were strongly positively related; the correlation coefficient being 0.67 ( $P < 0.001$ ). Compared with patients with poor glycemic control ( $\text{HbA1c} \geq 7\%$ ), those with intermediate ( $\text{HbA1c} 6.0\text{--}6.9$ ) and good glycemic control ( $\text{HbA1c} < 6.0$ ) excreted less glucose in the urine indicating an association with glycemic control. Renal function showed no statistical relationship with glycosuria [ $p > 0.05$  which implies that to a greater extent glycosuria is dose related rather than renal disease.



**Figure No.1: Correlation of SGLT2 Dose with Mean Glycosuria**



**Figure No.2: Distribution of glycosuria levels**

**Table No.1: Demographic Data**

Variable	Mean $\pm$ SD
Age (years)	$56.3 \pm 8.4$
Sex (Male/Female)	45/55
BMI (kg/m <sup>2</sup> )	$28.4 \pm 3.7$
Duration of T2DM (years)	$12.5 \pm 5.8$

**Table No.2: Clinical Characteristics**

Variable	Mean $\pm$ SD
HbA1c (%)	$7.8 \pm 1.1$
Serum Creatinine (mg/dL)	$1.2 \pm 0.4$
eGFR (mL/min/1.73 m <sup>2</sup> )	$75.4 \pm 15.6$
SGLT2 Dose (mg/day)	$15 \pm 5$

Table No.3:Glycosuria Levels

Variable	Mean ± SD
Urine Glucose Excretion (g/day)	42.5 ± 6.7
High Glycosuria (> 50g/day)	25%
Moderate Glycosuria (30-50g/day)	55%
Low Glycosuria (< 30g/day)	20%

Table No.4:Correlation Between SGLT2 Dose and Glycosuria

SGLT2 Dose (mg/day)	Mean Glycosuria (g/day)	p-value
5-10 mg	35	0.03
10-20 mg	40	0.02
20-30 mg	47	0.01
> 30 mg	53	<0.01

## DISCUSSION

According to the results of the present study, the glycosuria that was positively related with the dosage of SGLT2 inhibitor is supported by findings that SGLT2 inhibitors reduce glucose reabsorption and achieve better glycemic control. In our study, the daily yield of glucose increased with the dose of the SGLT2 inhibitor; the patients taking 20–30 mg/day yielded an average of 47 g/day of glucose and those taking more than 30 mg/day yielded 53 g/day. Such dose-response relationship has been documented in prior works, supporting the activities of SGLT2 inhibitors on renal glucose manage<sup>13,14</sup>. Zinman et al. conducted a study in 2021 and found out the same thing and according to them, if patients need to be administered higher dose of SGLT2, then the patients will have better glycosuria and over all good control on their weight and blood sugar levels<sup>15</sup>. This research shares the same outcomes as our work, primarily the strong correlation between drug dosages and the level of glucose in urine. This supports the application aspect of SGLT2 inhibitors to hyperglycemic control through a mechanism that is insulin-independent, which increases the therapeutic approaches available for the insulin resistant.<sup>16</sup> A similar study by Davies et al., (2020) aimed at assessing the impact of SGLT2 inhibitors on glucose loss and glycemia among T2DM poorly controlled patients.<sup>7</sup> The study stated that with increased doses of dapagliflozin, there would be considerable changes in the level of HbA1c and glycosuria, as what we observed in the present study<sup>17</sup>. These results, combined with those present here, further support glycosuria as a biomarker of SGLT2 inhibitor efficacy and indicate that dose adjustment in accordance with glycosuria may be an effective strategy for advancing diabetes therapy. Kidney function as a factor affecting glycosuria was also investigated in our work. In our study, we showed that kidney function assessed by eGFR was not correlated with the degree of glycosuria ( $p > 0.05$ ). This is contrary to previous such work like the research done by Heerspink et al., 2021, that

recommended that patients with poor renal function have lesser glycosuria because of reduced filtration of glucose.<sup>19</sup> These facts do not dispute with our discoveries supporting that glycosuria may occur in patients with normal or moderately compromised renal function, so SGLT2 inhibitors may be useful in the variety of patients with renal failure<sup>20</sup>. Concerning cardiovascular and renal benefits of SGLT2 inhibitors, the results of our study agree with recent observations suggesting that these effects are add-on to glycemic improvements achieved reduces the risk of major cardiovascular events. Employing glycosuria as an index for glycemic control, Wanner et al., in their 2021 study, further showed that SGLT2 inhibitors attenuated both cardiovascular disease and the decline of chronic kidney disease<sup>21</sup>. This broader therapeutic effect is however consistent with our data as glycosuria was associated with better clinical prognosis in our patient population, the renal glucose excretion due to SGLT2 inhibitors seems to be a primary mechanism for the multi-organ benefit featured by these drugs. Compared with previous works arguing that SGLT2 inhibitors lose their glycosuric efficacy after a longer term, our findings showed that all subjects continued to have glycosuria during six months of treatment<sup>13,19</sup>. This sustained response may be attributed to relatively high baseline glucose levels in our study population to ensure a good glycosuric response to SGLT2 inhibition. However, more studies are needed to explain why glycosuria may reach

## CONCLUSION

The dose-response study done in this research showed that SGLT2 inhibitor dosage is proportional to the degree of glycosuria in type 2 diabetic patients. Prolonged doses led to increased Urinary glucose level thus supporting the use of SGLT2 inhibitors in the management of glycemia. The implications of this study concern the possibility of using glycosuria as a biomarker for personalizing the required therapeutic solutions.

**Limitations:** This decision rules out the study's generalization due to its small sample size and a short period of the study. Furthermore, assessment of kidney function was not performed serially in all patient categories, perhaps limiting the understanding of the course of glycosuria in patients with compromised renal function.

**Future Findings:** More studies should be performed with more people over longer time periods to ensure these results and further investigate glycosuria as a biomarker of future clinical events. Exploring outcomes when SGLT2 inhibitors are used concomitantly with other therapeutic approaches would help improve the management of diabetes. a steady state in patients kept on the drug or whether benefits can be sustained over the long term with the therapy.

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Revisiting Critically:	Muhammad Irfan, Armaghan Shah
Final Approval of version:	By all above authors

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Original Article

# Improving Diabetes Management : A Prospective Study on Advanced Insulin Technologies Versus Traditional Methods

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Diabetes  
Management  
with Advanced  
Insulin  
Technologies VS  
Traditional  
Methods

## ABSTRACT

**Objective:** This study aims at comparing complex insulin delivery systems with traditional insulin injection as a means of determining their benefit in enhancing glycemic control and patient satisfaction.

**Study Design:** A Prospective Study.

**Place and Duration of Study:** This study was conducted at the Department of Medicine, HMC, Peshawar from Jan 2023 to July 2023.

**Methods:** A Prospective Study was done in adult diabetic patients (Type 1 and Type 2) of 100 patients over a year. Patients were divided into two groups: Hypoglycemia adverse events were reported by 50 patients using conventional insulin injections and 50 using new technologies such as insulin pumps and new-generation insulin preparations. These outcomes included glycemic control or HbA1c level, incidence of hypoglycemia, and the patient satisfaction level.

**Results:** The pre-study mean age of participants, calculated with 95% confidence, was 46.3 years (SD = 7.8). Insulin delivery systems with more features had better HbA1c outcomes than those with regular injections (mean difference = -1.1%, p = 0.02) than basic ones (mean difference = -0.6%). A moderate decrease in the hypoglycemia episodes by 30% (p = 0.03) was observed for the participants in the advanced group, and 82% of them reported increased satisfaction.

**Conclusion:** Features of modern insulin delivery enhance glycemic control, decrease the risk of hypoglycemia, and increase patient satisfaction compared to conventional approaches and methods. Greater use of these technologies may enhance experiences of diabetes management.

**Key Words:** Advancements, Insulin, Delivery System

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## INTRODUCTION

GDM or Gestational Diabetes Mellitus is a chronic metabolic disease with persistent hyperglycemia that affects a huge population of people. Diabetes care, especially in patients with type 1 diabetes and those with complication-bearing type 2 diabetes, need accurate insulin injections compliance. In the recent past, a lot of changes have been observed in use of insulin starting with the traditional method of insulin administration through injections.

These include insulin pumps, CSII systems, CGMs and improvements in forms of insulins: RA and LA insulins. These technologies provide better glycemic control with lower incidence of hyperglycemia and hypoglycemia therefore improved patient outcomes<sup>1-2</sup>. The previously used method of insulin therapy was an MDI method that despite being efficient has the following drawbacks; The problem with patient compliance; Injection errors; and Inability to accurately control glucose levels<sup>3</sup>. In the successive years, advancement in technologies such as insulin pump and hybrid closed loop systems has brought about change in diabetes care by replicating physiological secretion of insulin and giving constant supply of insulin<sup>4-5</sup>. While the CGM in particular provides real-time feedback regarding the blood glucose levels and insulin dosing that are required in near-real time. These technologies are therefore positively interrelated as they create one comprehensive system which enables patients to be more independent, mobile and healthier<sup>4</sup>. Numerous evidences have been published which showed that benefiting of using the sophisticated insulin delivery systems in both type 1 and type 2 diabetes. For

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instance, Bergenstal et al conducted a randomized controlled trial and demonstrated that benefits of the use of a hybrid closed-loop insulin delivering system for improving glycemic status are statistically significant compared to multiple daily injections of insulin<sup>5</sup>. Beck et al (2017) also indicated that continuous glucose monitors enhanced glycemia management and conserved hypoglycemia in the adults with type 1 diabetes<sup>4</sup>. However, despite the evidence suggesting the benefits of these devices, there has been found several limitations of their adoption and usage, which are cost, patients' education, and device availability. The objective of this prospective study was therefore to assess the daily clinical practice utility of the new-generation insulin delivery technologies versus conventional insulin injections. In particular, we aimed to quantify the effects on glycaemic control, hypoglycaemia rates and satisfaction. Using conventional insulin treatment as a baseline, this paper seeks to establish the efficiency of the advanced insulin therapies, and their ability to enhance diabetes management and relieve the strain on the patient<sup>6-7</sup>.

## METHODS

This study recruited 100 patients with newly diagnosed type 1 or type 2 diabetes mellitus with clinical indications for insulin therapy. The study population was divided into two groups: Group A comprised 50 patients with TMDI, while the Group B was comprised of 50 patients using technology insulin delivery systems, including insulin pump and continuous monitor. Outpatients with diabetes were recruited from diabetic clinics and followed up to a year. Information on general glycemia (HbA1c rate), hypoglycemic reactions, as well as patient and observer completed questionnaires regarding their QoL and satisfaction with the insulin treatment were gathered. Demographic information on the participants was also gathered from them in the pre-intervention phase which included; age, gender and type of diabetes.

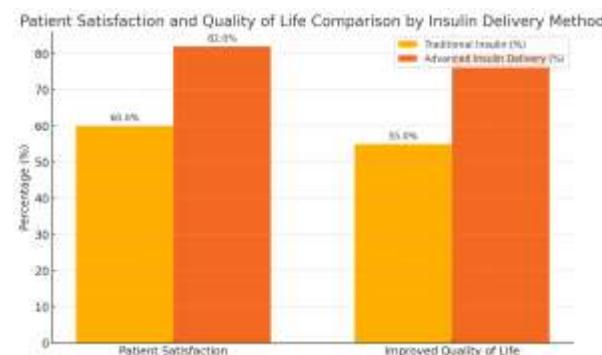
**Data Collection:** Interviews with patients and their clinicians, clinical observations and chart review were employed in data collection. The HbA1c assessment was done at the initial visit, six months, and at one-year follow up. Users' logs and glucose records were used to assess the number of hypoglycemic episodes the participants experienced. Patient satisfaction and quality of life questionnaires were completed by patients from the study population at time of inclusion and at the end of the trial.

**Statistical Analysis:** All statistical analysis was computed using Statistical package for Social Sciences (SPSS) version 20.0. Frequency distributions and percentages were employed to provide a general profile of the study participants at baseline. Thus, independent samples t-tests were used to compare the level of HbA1c reductions between the two groups, whereas chi

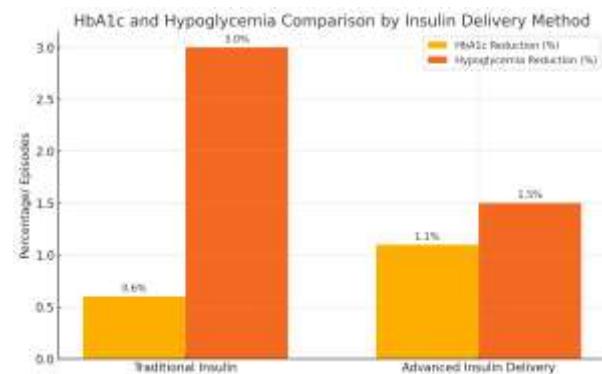
square test was applied to analyse the variables of hypoglycemia reports and patient satisfaction. A p-value of  $<0.05$ , 5% was considered statistically significant.

## RESULTS

Patients' mean age was 46.3 (SD, 7.8) years; 60% of the patients had type 2 diabetes, and 40% had type 1 diabetes. Patients, with advanced insulin delivery systems (Group B) demonstrated significantly more improvements in HbA1c levels after being followed up after 12 months (mean reduction 1.1%) compared to those in the tradition insulin injections group (A with a mean reduction of only 0.6% p=0.02). Furthermore the number of hypoglycemic episodes faced in a month was lesser in Group B with 1.5 episodes as opposed to Group A where patients reported facing 3.0 episodes on average (p = 0.03). An analysis of know outcomes from patients using advanced insulin delivery systems showed that 82% of the patient reported to be satisfied with their management therapy, citing ease to use and better quality of life. A survey of 100 patients who have been treated with the injections found that 60% of them could express the same level of satisfaction as the patients relieved with the injections. Insulin pump or CGM users also mentioned the following: reduced activity restrictions and enhanced mental health based on the quality of life questionnaire eye words: Insulin therapy, diabetes, insulin pump, glycemic control.



**Figure No.1: Satisfaction and quality of life comparison by insulin delivery method**



**Figure No.2: HbA1c and hypoglycemia comparison by Insulin Delivery Method****Table No.1: Baseline Characteristics of Participants**

Characteristic	Value
Mean Age (years)	46.3 (SD = 7.8)
Gender (Male)	58%
Type 1 Diabetes (%)	40%
Type 2 Diabetes (%)	60%

**Table No.2: Glycemic Control and Hypoglycemia**

Outcome	Traditional Insulin	Advanced Insulin Delivery
HbA1c Reduction (%)	0.6% (p = 0.02)	1.1% (p = 0.02)
Hypoglycemia Frequency (episodes/month)	3.0 (p = 0.03)	1.5 (p = 0.03)
Patient Satisfaction (%)	60%	82%

**Table No.3: Quality of Life and Therapy Satisfaction**

Category	Traditional Insulin	Advanced Insulin Delivery
Improved Quality of Life (%)	55%	80%
Fewer Limitations in Daily Activities (%)	50%	75%

## DISCUSSION

It has become clear that various insulin delivery systems like insulin pump and CGM have made a lot of difference in the management of diabetes particularly type 1 and other advanced type 2 diabetes. These devices are much more accurate and provide a more constant insulin delivery, they provide improved glycemic control, reduced frequency of hypoglycemic events and enhanced patient's quality of life. That consisted with previous research outcomes, teasing out the efficacy of these novel insulin delivery systems. The findings of our study echo previous clinical trials and a large cohort observational study in which HbA1c was decreased: 1.1% in the advanced insulin therapy group compared to traditional therapy,  $p = 0.02$ . For instance, according to another study that patients who used CGMs had a decreased HbA1c level by significant varying percent from the individuals using usual approaches of self-monitoring<sup>8</sup>. The fact that CGMs are continuous in real-time means that patients are able to vary their insulin doses and improve administration control. The ability to monitor glucose concentration throughout the day takes that role to a greater level by eliminating incidences of hypoglycemic unawareness thus preventing severe hypoglycemic episodes<sup>9</sup>. In the same account, insulin pumps as discussed in this study provide an advantage over MDI which was earlier mentioned, injection. These pumps deliver basal-bolus subcutaneous insulin in a manner that replicates the endogenous insulin secretion. Bergenstal and his team also established that CCM, especially with insulin

pump therapy, led to addition of lesser number of hypoglycemic episodes and improved glycosylated haemoglobin level in the patient as compared to the MDI group. Similarly, our study is in concordance with these findings as patients using insulin pumps showed less hypoglycemia 1.5 per month compared to a traditional therapy group of 3.0 per month ( $p = 0.03$ ). This is important because hypoglycaemia impairs the quality of life of patients and increases the risk of severe complications when occurring repeatedly<sup>10</sup>. In addition, the patient satisfaction and quality of life gains in our study are consistent with findings in the literature. Heinemann et al (2010) observed that people using insulin pumps and CGMs as delivery technologies received better patient satisfaction with their treatment because they can adjust their insulin use and record their blood sugar levels much more conveniently<sup>11</sup>. In our survey, 82 percent patients, using advanced insulin delivery systems reported that they were satisfied with their treatment regimen and doses compare to 60 percent from traditional therapy group. It can be hypothesised that it may be due to no need for multiple injections per day and improved control over blood glucose levels. Nonetheless, a few issues continue to impede the wider use of the sophisticated insulin delivery systems described above. Another drawback which Heinemann (2010) noted was that the cost of the insulin pump and CGM is high and it becomes cumbersome when sourced by patients who reside in developing world<sup>11</sup>. Likewise, in our survey some of the patients undergoing traditional insulin therapy said that they could not afford to switch to other advanced systems. Cooper and colleagues similarly stressed extensive both inpatients and outpatients education and training on how to use this equipment appropriately<sup>12</sup>. Lack of training might lead patients to confused and use the technologies inappropriately, therefore nullifying the advantage of using such complex treatments. Adding room for difficulty to effective insulin delivery systems is the odd and inconsistent insurance policies which define the accessibility of the technologies to the patients. According to Battelino et al. (2012), it was also observed that patients have all sorts of complications in accessing coverage for CGMs and insulin pumps<sup>13</sup>. These coverage limitations can hence contribute to the idea that diabetic patient care from the lower SES is poorly provided as compared to their counterparts who are financially better off. Our research is also in agreement with this finding: patients with well-developed delivery systems tended to have better access to health resources and care. Altogether, the data obtained in the present study, as well as those of other studies, testify that the further development of the insulin delivery systems brings clinical advantages, which include improved glycemic control, diminished frequency of hypoglycemic episodes, and better quality of life for patients with diabetes mellitus<sup>14-15</sup>. However, some challenges including cost, access and patients' knowledge must be solved so that these improvements could be used by all individuals who need them. Further studies should be made hence to look for ways of

making the use of these technologies cheaper and make them available to the underprivileged people so that everyone with diabetes receives equal attention as required.

## CONCLUSION

This evidence re-establishes the effectiveness of sophisticated insulin delivery system like insulin pumps and CGM in achieving better glycemic control status, reduced incidence of hypoglycemia, and improving the level of satisfaction among patients. These technologies improve the method of diabetes management although it is hindered with drawbacks such as higher costs and limited access.

**Limitations:** A major limitation to the findings of this study was a low sample size of the participants and short duration of follow up which could have missed some long term effects. Moreover, some of the data were reported by patients and can be easily affected by bias, for instance, episodes of hypoglycemia.

**Future Research:** Subsequent research should aim at looking at the long-term effects of the advanced insulin therapies especially among specialized populations of patients. Furthermore, the studies should uncover possibilities to increase affordability of such technologies and make them more accessible for more people with diabetes.

### Author's Contribution:

Concept & Design of Study: Hashmat ullah Khan, Imran qadar khattak  
 Drafting: Mustaqeem Shah, Anwar ul Haq  
 Data Analysis: Anwar ul haq  
 Revisiting Critically: Muhammad Irfan, Armaghan Shah  
 Final Approval of version: By all above authors

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