Volume: 6 (Suppl)
Jul - Dec 2024

ISSN (Print): 2312-6531
ISSN (Online): 2958-5511

Foundation University Medical Journal

Recognized by:
Higher Education Commission, Pakistan (HEC)

Foundation University Islamabad,
Defence Avenue, DHA Phase-I,
Islamabad 44000, Pakistan.
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Foundation University Medical Journal

Vol. 6 (Suppl), Jul - Dec 2024
ISSN Print: 2312-6531
ISSN Online: 2958-5511

For electronic submission of articles (OJS)/ Online Issue:
fumj.fui.edu.pk

Email address for correspondence:
fumj@fui.edu.pk

Publication Office: Department of Pharmacology, Foundation University Medical College, DHA Phase - I, Islamabad, Pakistan 46000

FOUNDATION UNIVERSITY MEDICAL JOURNAL

Vol - 6 (Suppl), Jul - Dec 2024

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EDITORIAL

'ONE HEALTH' AND HEALTH PROFESSIONS EDUCATION: THE UPHILL PATH

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The whole cosmos is interconnected maintaining an intricate balance of creative – destruction. Similarly, here on the 'Pale Blue Dot', as Sagan called our planet Earth, every living and non-living thing is woven together. They all function according to the laws of nature including, cells and organs within our bodies.[1,2] The laws of nature demand respect. Disrespect has a price, at times very high.

The human trait to think, leads to curiosity. Its ability to seek, find, create and innovate is unstoppable. At times the brilliance of mind transgresses the laws of nature, inviting its wrath.

The burgeoning scientific progress, especially in the 20th century has led to extensive industrialization, massively increasing consumption of biofuels, disrupting the atmosphere due to greenhouse gas emissions, leading to global warming and ozone depletion, resulting in the climate change. Rise of temperature of more than 2^0 c would be detrimental.[3] The climate change has been further compounded by release of methane gas from extensive meat consumption, population growth and globalization. This has negatively affected the soil, threatening food security and food safety. Poor air quality adds to the plight.[3-5] Climate change is a human created self-destructive mode, now labelled as 'Anthropocene', a 'wicked problem' and a 'threat multiplier'.[3]

The changing climate has led to tremendous rise in the 'Emerging Infections Diseases (EIDs), since the middle of the 20th century. Many of the infections are due to 'Zoonosis' like, severe acute respiratory syndrome (SARS), Ebola, HIV, Avian influenza etc. [6]

The problem is a complex one. It is multifactorial, multifaceted, diabolic and gigantic which cannot be addressed by medical science alone. The way forward is connectedness, collaboration and coordination of the multiple disciplines. Apart from medical science, veterinary medicine, public health and ecology plays essential roles[6] alongside proficient governance policy making and advocacy.[4] This interdisciplinary and cross-sectoral way forward is labeled as 'One Health' approach.[3]

The 'One Health' approach is defined as, “An integrated, multidisciplinary approach that recognizes the interconnectedness between people, animals, plants and the shared environment at various levels, including local, regional, national and global”. Its goal is to ensure healthy humans, animals and ecosystems.[7]

Health professionals, doctors, nurses and pharmacists have a major role to play. They can educate the upcoming generations of health professionals, community and stakeholders, influence higher authorities on the significance of 'One Health', and decarbonize their facilities[8] which add around 5% to greenhouse gases emissions.[5]

The health professionals can play an active role in the 'one health' if they are educated and integrated in to cross-sectoral framework. The question is, what to teach and how much to teach specially, at the undergraduate and postgraduate level. Maxwell and Blashki suggest that apart from in-depth knowledge of zoonosis and climate change effects on the health, the curriculum content should focus on the breadth of education, that is, public health and eco health literacy with the skill to apply the knowledge.[4] Deciding how much to teach is challenging, given the high cognitive load and time constraints.[7]

How to teach is another area to ponder 'One Health' is collaborative approach, this requires collaborative learning of the multiple disciplines.

Several methods have been suggested to achieve this goal. One is the development of a common coursework with technology enhanced learning making it attainable. Other approaches include, “One Health Institute”

offering workshops as summer electives. It has been instituted by certain universities. The creation of "Centers of One Health Excellence (COHE)" is another method mentioned in the literature to create domestic and international network for interdisciplinary learning. The interaction to be enabled by communication through technology. The biennial conference of International Association of Ecology and Health (IAEH) is a useful platform for 'One Health' knowledge exchange.[6]

To further enhance the cross-sector collaboration, four global organizations including the World Health Organization (WHO) developed 'One Health' High-Level Expert Panel (OHHLEP) in May 2021. Moreover, important international events are happening to bolster climate change control since 1992 from Rio De Janero to the Paris agreement of 2015.[7]

Efforts towards 'One Health' approach have achieved some success stories. For e.g, rabies mitigation in Sri Lanka, Bhutan and Bangladesh and cost saving by Canadian Science Centre in Winnipeg through integrating laboratory facilities for human and animal contagious disease. However, these successes are sporadic and must be translated into worldwide action.[7]

The concept of 'One Health' is not new. It was highlighted by Virchow and Osler in the 19th century.[6] The deleterious efforts of the climate change demand effective application of 'One Health' approach to combat the rising number of emerging infectious diseases. In a 2006 article, WHO attributed 23% of global deaths to the environmental factors. While the 'One Health' approach is imperative, evidence of its effectiveness remains scarce.[5] Despite understanding the problem, there are multiple barriers impeding success including inadequate education, limited time, lack of funding and advocacy with inefficient governance.[8]

In my view, in any project where multiple stakeholders from diverse disciplines exist, integration of curriculum and collaborative quality learning is a very uphill task. Also, the success of 'One Health' depends on its standardized implementation, both at the local and global level - a Mount Everest to conquer. This challenge is compounded by resource constraints and varied governance at the global level which is not in sync.

Another critical issue, often overlooked due to economic interests, is the need to reduce greenhouse gases emissions to maintain the planetary health. While the 'one Health' approach is vital, breaking the link between the economic output and greenhouse emissions is even more crucial- But who is going to bell the cat? Money makes the mare go.[3]

The one health strategy is logical and appropriate to combat the rising menace of EIDs due to environmental change. But, its application is complex and arduous. Whatever the challenges may be the march to victory must go on. Definitely the path is uphill and long.

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RESEARCH ARTICLE

DIAGNOSTIC UTILITY OF THE GLASGOW-BLATCHFORD SCORE IN PREDICTING REBLEEDING IN UPPER GASTROINTESTINAL BLEEDING: A TERTIARY CARE STUDY

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ABSTRACT

Objective: *This study was conducted to ascertain the Glasgow-Blatchford bleeding score's diagnostic accuracy in upper GI bleeding patients as risk stratification tool for rebleeding.*

Study design: *Cross-sectional observational study.*

Place and duration of study: *The study was conducted at Medical unit DHQ Hospital, Rawalpindi from 7th August 2022 to 7th February 2023 after ethical approval.*

Patients and Methods: *A total of 165 patients of both genders, aged 20 to 50 years presenting with upper GI bleeding were included and written informed consent was taken. Patients having pre-existing bleeding disorder, anticoagulants or antiplatelets use, history of corrosive intake, traumatic GI bleed cases were excluded. The Glasgow Blatchford score (GBS) was calculated and cut off value >3 was taken as a risk factor for rebleed. Data were analyzed using SPSS-22, sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPPV) for GBS > 3 were calculated. Diagnostic accuracy of Blatchford score was calculated as risk stratification tool for rebleeding.*

Results: *Amongst 165 patients, mean age was 39.4 ± 5.8 years. There were 73(44.2%) females and 92(55.8%) males. There was upper GI rebleed in 32(24.2%) cases. Study found 80% sensitivity and 92% specificity of Glasgow Blatchford (GBS) score to predict the rebleed. The positive predictive value (PPV) was 76.2% and negative predictive value (NPPV) was 93.5%. GBS was 89.09% accurate in diagnosing the rebleed. Age group data stratification was substantial (p-value <0.001). There was a substantial gender-based data stratification (p-value <0.01). Significant data stratification was found for the duration of symptoms (p<0.001).*

Conclusion: *Glasgow Blatchford score is a sensitive and specific score for predicting risk of rebleeding in patients of upper GI bleed demonstrating high sensitivity, specificity and diagnostic accuracy. GBS score should be used to identify the emergency room patients at risk of rebleeding.*

Keywords: *Glasgow Blatchford score, gastrointestinal bleed, rebleeding*

INTRODUCTION

The emergency department is frequently visited due to upper GI bleed which affects approximately average 100 out of every 100,000 people annually. According to estimates, the death rate for these patients range from 2%-15% and in cases when there is rebleeding, it can reach 10% to 30%.[1] A Lahore based study by Butt N et al found mortality of 10.6% at one week and 14.8% at one month after GI bleed.[2] Attari SA et al in a study from Hyderabad concluded that variceal bleed and peptic ulcer disease are the most prevalent causes of GI bleed in their study population.[3] The prognosis of these individuals has been linked to a number of variables including age, hemodynamic state, history of blood transfusion, melena/ hematochezia/ hematemesis and history of chronic hepatic disorders.[4]

Stratification of patients is crucial to resource allocation and optimizing management (such as blood transfusions, endoscopic, radiological interventions or surgery).[5] One significant way towards lowering the

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Received: 30 Oct 2024; revision received: 19 Dec 2024; accepted: 23 Dec 2024

disease burden, its financial cost and its mortality rate is the screening of people who are at higher risk and the acceleration of diagnostic and therapeutic procedures.[6] Subsequently, several clinical prediction models have been suggested as a tool to identify individuals at risk for a poor outcome in order to optimize in-hospital care of upper GI bleeding. Montiero et al[7] published a review article regarding various scoring systems for upper GI bleed, including the Rockall score,[8] GBS score and T-score. These scores can be used by junior doctors, staff or the healthcare personnel in peripheral units where endoscopy isn't available, hence, filtering out the cases for urgent intervention.

The optimal risk score should be simple to compute at initial presentation and should accurately anticipate the results.[9] There are strengths and weaknesses in each of these models. Glasgow-Blatchford bleeding score (GBS) is one of these clinical rating systems. Although there isn't enough data to support it, this scoring system can be used to evaluate the severity of the illness and the chance of bleeding again.

This study was conducted to re-evaluate the diagnostic accuracy in our population; hence we can justify the use of Glasgow Blatchford score in all patients with upper GI bleed. In our resource limited setups we cannot closely follow up all the patients. This score may help the clinicians to sort high risk patients and keep a close follow-up.

PATIENTS AND METHODS

This cross-sectional observational study was conducted in medical unit DHQ Hospital Rawalpindi from 7th August 2020 till 27th February 2021, ex-post-facto approval from Ethical Review Committee (vide letter no. 149/19/RTH.Rwp dated: 14-09-2023) no ethical concerns were noted by the reviewers. Sample size of 165 was calculated by WHO calculator taking 20% prevalence of upper GI bleed, the GBS score sensitivity of 93.64% and specificity of 37.38%, keeping the confidence interval (CI) at 95% and absolute precision at 7%. The sampling technique was non-probability consecutive sampling.

Total 165 adult patients (age>18 years) of both the genders presenting with upper GI bleed were included. Patients presenting with hematemesis, coffee ground vomit, melena, hematochezia within past 24 hours were labelled as having “upper GI bleeding”. Episode of bleeding within 48 hours of first episode was labelled as having “re-occurrence of upper GI bleeding”. Patients having pre-existing bleeding disorder, history of anticoagulant and antiplatelet use, corrosive intake, traumatic GI bleed and those unable to give consent were excluded.

Written informed consent was taken followed by clinical evaluation. History of consuming anti-coagulation drugs or platelet aggregation inhibitors was documented. The Glasgow Blatchford score (GBS) was calculated[10] i.e., a tool for risk assessment to identify the urgency of upper GI endoscopy in upper GI hemorrhage cases. This score includes basic laboratory and clinical parameters (gender, pulse, blood pressure, hemoglobin, blood urea, history of melena, syncope, liver disease and heart failure). The cut off value of GBS score more than 3 was taken as a risk factor for rebleeding.

Demographic data regarding age, gender, duration of disease, baseline vitals including pulse rate, respiratory rate and blood pressure was noted. Laboratory tests including blood complete picture, renal functions, , and liver function tests were sent to hospital laboratory. Endoscopy was done in all patients by qualified consultant gastroenterologist. Patients were treated as per hospital protocols and observed for rebleeding till 48 hours of the first episode. Diagnostic accuracy of Blatchford score was calculated using rebleeding as a gold standard. Data were entered in proforma and confidentiality of data was ensured.

Data were analyzed using SPSS-22. Qualitative variables (gender and rebleeding) were presented as frequencies and percentages. Quantitative variables (age, duration of symptoms) were presented as mean and standard deviation. Data were stratified for age, gender and duration of symptoms. Chi-square test was applied to compare those with rebleed versus without rebleed with respect to various levels of GBS score. P-value <0.05 was taken as statistically significant. The description of true and false positives/negatives is given in table-I.

For upper GI bleed cases, sensitivity was calculated as the ability of GBS high score (>3) to detect rebleeding i.e., sensitivity=TP/(TP+FN). Specificity calculated as the ability of GBS high score to exclude those with no rebleeding i.e., specificity=TN/(TN+FP). Positive predictive value (PPV) calculated as proportion of positives that correspond to the high risk patients on rebleeding i.e, PPV=TP/(TP+FP). Negative predictive value (NPPV) calculated as proportion of negatives that correspond to low-risk patients on rebleeding i.e., NPPV=TN/(TN+FN). Diagnostic Accuracy was calculated as a proportion of correctly classified patients

at low and high risk by GBS score (TP+TN) among all the patients included in the study (TP+TN+FP+FN). The diagnostic accuracy, sensitivity, specificity, PPV and NPPV of GBS > 3 were calculated manually using 2x2 table and re-checked by MedCalc Diagnostic test evaluation calculator.

Table I: Table showing true positive, true negative, false positive and false negative results with respect to GBS score and episode of rebleeding.

		Rebleeding	
		Yes	**No**
Glasgow-Blatchford score > 3	**Yes**	True Positive(TP)	False Negative(FN)
	No	False Positive(FP)	True Negative(TN)

RESULTS

The study included a total of 165 patients of upper GI bleed. The mean age was 39.4±5.8 years. Amongst all, 73(44.2%) cases were females and 92(55.8%) were males. In 32(24.2%) of patients, there was upper gastrointestinal rebleeding. Study found 80% sensitivity and 92% specificity of Glasgow Blatchford's (GBS) score to predict rebleed in our patients. Positive predictive value was 76.2% while negative predictive value was 93.5% (Table-II). GBS was 89.09% accurate in diagnosing the rebleed in this study population. Age group data stratification was substantial (p-value <0.001). There was a substantial gender-based data stratification (p-value <0.01). Significant data stratification was found for the duration of symptoms as well (p-value <0.001; table-III).

DISCUSSION

A frequent reason for emergency department visits is bleeding in the upper GI tract, which carries a risk of bleeding again. Recurrent upper GI bleeding can be minimized by identifying the high-risk patients and

Table II: The diagnostic accuracy, sensitivity/specificity, positive & negative predictive value of Glasgow Blatchford score (n=165).

Glasgow Blatchford score (GBS)	Re-bleeding n (%)						Total
	Yes			No			
	n	% within re-bleed	% within GBS	n	% within re-bleed	% within GBS	
> 3	32	80%	76.2%	10	8%	23.8%	42(25.5%)
= 3	8	20%	6.5%	115	92%	93.5%	123(74.5%)
Sensitivity 80% (CI 64.35%-90.95%); Specificity 92% (CI 85.78%-96.1%); PPV 76.2% (CI 63.39%-85.54%); NPPV 93.5% (CI 88.53%-96.40%); Diagnostic accuracy 89.09% (CI 83.31%-93.41%)							

Table III: The diagnostic accuracy of Glasgow Blatchford score with respect to stratification for age, gender and duration of symptoms in upper gastrointestinal bleed cases (n=165).

Variable for stratification		Glasgow Blatchford score	Re-bleeding n (%)		Total	p-value	Diagnostic accuracy (95% CI)
			Yes	No			
			n(%)	n(%)			
Age	**41-50 years (n=75)**	> 3	16(21.3%)	2(2.7%)	18(24%)	<0.001	89.3% (80-95.3)
		= 3	6(8%)	51(68%)	57(76%)		
	30-40 years (n=90)	> 3	16(17.8%)	8(8.9%)	24(26.7%)	<0.001	88.8% (80.5-94.5)
		= 3	2(2.2%)	64(71.1%)	66(73.3%)		
Gender	**Female (n=73)**	> 3	18(24.7%)	2(2.7%)	20(27.4%)	<0.01	91.7% (82.9-96.9)
		= 3	4(5.5%)	49(67.1%)	53(72.6%)		
	Male (n=92)	> 3	14(15.2%)	8(8.7%)	22(23.9%)	<0.001	86.96% (78.32-93.1)
		= 3	4(4.3%)	66(71.7%)	70(76.1%)		
Symptom duration	**> 6 months (n=105)**	> 3	28(26.7%)	8(7.6%)	36(34.3%)	<0.001	86.67% (78.6-92.5)
		= 3	6(5.7%)	63(60%)	69(65.7%)		
	< 6 months (n=60)	> 3	4(6.7%)	2(3.3%)	6(10%)	<0.001	93.3% (83.8-98.2)
		= 3	2(3.3%)	52(86.7%)	54(90%)		

initiating therapy early. The current study compared the GBS score to upper gastrointestinal bleeding recurrence.

The results were compared with previous studies. The sensitivity, specificity, positive predictive value, negative predictive value, and accuracy rate of GBS for identifying patients with upper GI bleed in need of endoscopic intervention were calculated as 93.64%, 37.38%, 70.74%, 78.43%, and 72.00%, respectively, in a study by Samreen et al. on patients with upper GI bleeding.[6] Data stratification for age groups, gender and duration of symptoms was significant with p-value <0.001 in all cases.

Research on 174 individuals with upper GI bleeding was done by Srirajaskanthan et al.[11] Compared to the low-risk group (median 1, $p < 0.001$), the high-risk group (median = 10) had a considerably greater GBS. Receiver-operator characteristic (ROC) curves were produced to evaluate the GBS's validity in distinguishing between low and high-risk groups. The area under the ROC curve for the GBS was 0.96 (95% CI 0.95-1.00). The sensitivity and specificity of GBS for detecting high risk bleeding were 100% and 68%, respectively, whereas cut-off value of > or = 3 was applied. Thus, the GBS can be used to identify patients who have a low risk of upper GI bleeding at a cut-off value of < or = 2.

Similar outcomes were observed in Tatsuhiro Masaoka's study. Seventy-three (75.3%) of the ninety-three patients that were enrolled were categorized as high-risk. The high-risk group's Blatchford score was noticeably greater than the low-risk groups. The Blatchford scoring system of sensitivity and specificity found to be 100% and 13%, respectively, whereas cut-off value of 2 was applied.[12] Thus, it was determined that the Blatchford scoring system was helpful in differentiating between patients with GI hemorrhage admitted to the emergency department (ED) who were high-risk and those who were low-risk. Of the 354 patients, 326 (92%) had a Blatchford score that indicated a high chance of requiring clinical intervention (blood transfusions, endoscopic procedures, or surgical care to stop bleeding). Out of the 354 patients, 289 (81.6%) were divided clinical Rockall score as high-risk, and 248 (70.1%) by the total Rockall score. When using the Blatchford score instead of the clinical or full Rockall scores, the yield of detecting high-risk cases was much higher ($p<0.0001$).

A comparative study by Elif Yaka et al[13] concluded that GBS score has high sensitivity as compared to AIMS65 in identifying patients who were not likely to require interventions, including emergency endoscopy as per initial emergency room assessment. A recent meta-analysis included sixteen investigations: three compared the GBS, a modified version of the GBS, and cRockall; one compared the GBS and AIMS65; three examined the Glasgow Blatchford score (GBS); two examined AIMS65. Six studies compared the GBS and cRockall. While the cRockall and AIMS65 showed 0.93 and 0.24 and 0.79 and 0.61 overall sensitivity and specificity, respectively, the GBS showed 0.98 and 0.16. The 0.99 sensitivity and 0.08 specificity were displayed by the GBS with a 0-cutoff point. The GBS with a cutoff point of 0 was superior to other cutoff points and risk ratings for identifying patients who were low-risk, while having a somewhat low specificity.[12] We have used the cut-off value of GBS >3, certain international studies have used various cut-off values of GBS e.g. > 3 or > 4. While comparing and interpreting the results, we should consider the cut-off value used in the study that may be the reason for the variable results.[14]

Earlier in 2007 I-Chuan Chen et al[15] stated that Blatchford score may be a useful risk stratification tool to detect the need for intervention in acute non-variceal upper GI bleed cases. This was later verified by sequence of international studies.[16,17] Regional data form Pakistan shows that limited local data is available regarding GBS score in our population. A study by Samreen et al conducted at Holy Family Hospital Rawalpindi is worth mentioning which found a high diagnostic accuracy of GBS. The sensitivity, specificity, positive predictive value, negative predictive value, and accuracy rate of GBS for identifying patients with Upper GI bleed in need of endoscopic intervention were calculated as 93.64%, 37.38%, 70.74%, 78.43%, and 72.00%, respectively in patients with upper GI bleeding.[18] It was suggested by Samreen at al that this rating system's low specificity makes it unsuitable for regular routine use in every upper GI bleed patient.

Ebrahimi et al[19] conducted a meta-analysis on various score for upper GI bleed. He concluded that GBS score was highly sensitive for 30-days mortality and for rebleed risk assessment. The results of Khalil et al[20] in his study conducted at Fauji Foundation Hospital Rawalpindi also showed the significant accuracy of GBS score for risk assessment in upper GI bleed cases. At the cut-off value of ≥ 4, GBS score accurately identifies 97.7% of the high-risk upper GI bleed patients.

The data from our study will contribute to regional data and will also be helpful for international comparison.

This may help our emergency team at their initial encounter to filter out and prioritize the cases with high risk of re-bleed. Hence, intensifying the monitoring and improving the decision making regarding invasive intervention in upper GI bleed cases. All these measures ultimately lead to better outcome in terms of patient care and reduce the mortality in upper GI bleed cases. Also, GBS score can be calculated by physicians, emergency duty doctors and consultants who are in primary care centers or peripheries. This may alert about the severity of the condition followed by immediate referral. Similarly, GBS score may be used as an auxiliary tool by the gastroenterologists or endoscopists to decide for the urgency of the procedure in individual upper GI bleed cases.

Limitations of the study: It was a single center study with limited data. It was difficult to evaluate the GBS in emergency department (overburdened area).

CONCLUSION

The Glasgow-Blatchford Score is a valuable tool for predicting the risk of rebleeding in patients with upper GI bleeding, demonstrating high sensitivity, specificity, and diagnostic accuracy. This scoring system can guide risk stratification and resource allocation, particularly in resource-constrained emergency settings. .

Conflict of interest: The authors declare no conflict of interest.

Funding: Self-funded

Authors' Contributions:

Sidra Rehman: Conception of study / Designing / Planning, Experimentation / Study Conduction

Sadia Ahmed: Experimentation / Study Conduction, Analysis / Interpretation / Discussion

Abida Mateen: Experimentation / Study Conduction, Manuscript Writing

Usman Ali: Conception of study / Designing / Planning, Analysis / Interpretation / Discussion

Nadia Shams: Conception of study / Designing / Planning, Facilitated for Reagents / Material Analysis

Lubna Meraj: Critical Review, Facilitated for Reagents / Material Analysis

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RESEARCH ARTICLE

DIETARY TRANSITION AND ITS DETERMINANTS AMONG RESIDENTS OF SKARDU CITY

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ABSTRACT

Objective: *To assess the dietary transition among residents of Skardu city, its association with sociodemographic variables and the determinants of dietary transition.*

Study Design: *A cross-sectional study*

Place and duration of study: *Study was carried out on residents of Skardu city during a period of six months from March 2022-August 2022.*

Patients and Methods: *A total of 362 respondents, were randomly selected for the purpose of the study. Data on dietary transition was collected using Food Frequency questionnaire (FFQ) scale. Independent sample t-test and One Way ANOVA test were applied to check the association of dietary transition with sociodemographic factors.*

Results: *Majority were male (n=182, 50.3%) and were 18-25 years of age (n=168, 46.4%). There was significant association of dietary transition with some variables of sociodemographic characteristics (p value=<0.05). There was a significant association between modern food with sociodemographic characteristics of gender, age, marital status, other residency, education, job nature, family income, perceived health status and weight status (p value=<0.05). Association between traditional food with sociodemographic characteristics of age, gender, marital status, family structure, education, perceived health status and weight status (p value=<0.05). The mean score for modern food was 40.54±10.64 and traditional food was 37.24±8.43. The difference between two groups was significantly associated that p value is 0.0001.*

Conclusion: *The study concluded that majority of the respondents were undergoing food transition from modern to traditional and there was significant association with sociodemographic characteristics. Majority of the respondents started modern food before 10 years ago and come to know regarding modern food through community.*

Key words: *Dietary transition, Migration, Non-communicable diseases, Urbanization.*

INTRODUCTION

The increasing migration of individuals to cities and rapid demographic changes are transforming people's food environments and dietary habits. As a result of economic development, energy-dense processed foods have become more readily available in food markets.[1] This shift has contributed to the rising prevalence of nutrition-related non-communicable diseases, particularly obesity and overweight, alongside existing communicable diseases, creating a double burden of diseases due to dietary transition. For example, studies in Africa show that the prevalence of obesity and overweight in children was 8.5% in 2010 and increased to 12.7% in 2020.[2]

Over the past three to four decades, many countries and regions have rapidly entered a phase of nutrition transition, marked by an increased intake of ultra-processed foods (UPFs) and a significant decline in physical activity. This phase has been accompanied by a sharp rise in the prevalence of obesity, along with other nutrition-related health issues, non-communicable diseases (NCDs), including diabetes, hypertension, coronary heart disease, and major cancers.[3] Changes in

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Received: 09 Oct 2024; revision received: 23 Dec 2024; accepted: 24 Dec 2024

food consumption patterns, greater dietary diversity, and shifts in eating behaviors have significantly transformed traditional diets, which were primarily based on cereals and vegetables with limited animal-based foods. As these traditional diets evolved, cereals and low-fat mixed dishes were gradually replaced by a more Westernized diet. This shift led to a decline in cereal and vegetable intake, while consumption of animal products, processed foods, sweetened beverages, and ultra-processed foods high in energy, fat, sugar, and salt (HEFSS) increased. As a result, the macronutrient profile of the diet shifted from being carbohydrate-heavy to being higher in fats, contributing to adverse health outcomes, including both undernutrition and over nutrition, as well as diet-related non-communicable diseases. While undernutrition and nutrient deficiencies remain issues, the focus is increasingly shifting to diet-related non-communicable diseases, with obesity prevalence rising rapidly. [4]

To develop and implement effective policies for improved health outcomes, it is crucial to understand the key factors driving the nutrition transition in the country and assess the current stage of this transition. This involves examining the nutrition transition along with relevant policies that impact food supply, diet, and behavior. The present study was conducted to evaluate the factors associated with dietary transition among the residents of Skardu.

PATIENTS AND METHODS

A quantitative research approach using a cross-sectional study design was conducted to assess dietary transition and its determinants among the residents of Skardu city over a six-month period, from March 2022 to August 2022, following Institutional Review Board (letter no. MSPH-IRB/13-09 dated: 24-03-2022). The sample size was calculated using the WHO sample size calculator, with a required precision of 5% and a 95% confidence interval. [5]A total of 362 respondents (aged >18 years), who met the inclusion criteria, were randomly selected for the study. Respondents with mental or physical challenges were excluded. The study included individuals aged 18 and above, both male and female, who were permanent residents of Skardu city. Data were collected using an interview-based questionnaire, which was divided into three parts. The first part gathered sociodemographic information, the second part assessed modern food consumption using a Food Frequency Questionnaire (FFQ), and the third part evaluated traditional food using an adopted traditional tool.[5,6]

Data analysis was performed using SPSS version 26. Descriptive analysis was conducted using frequencies and percentages, while the independent t-test and one-way ANOVA were used to examine the association between modern and traditional food consumption and sociodemographic variables.

RESULTS

A total of 362 respondents participated in this study. The majority were male (50.3%) and belonged to the 18-25 age group. Most respondents were educated, with 48.6% holding a bachelor's degree or higher, 36.7% being intermediate-level students, and 8.3% having a primary education. Approximately 46% of respondents were from urban areas. In terms of employment, 58% were students, 25% were private employees, 11.3% were public servants, and 5.5% were business professionals.

Table I: Sociodemographic Characteristics

S. No.	Variable	Frequency (n)	Percentage (%)
1.	**Gender**		
	Male	182	50.3
	Female	180	49.7
2.	**Age**		
	18-25 years	168	46.4
	26-35 years	123	34.0
	36-45 years	38	10.5
	Above 45 years	33	9.1
3.	**Marital status**		
	Single	200	55.2
	Married	162	44.2
4.	**Family size**		
	Less than 5	52	14.4
	5-10	200	55.2
	Above 10	110	30.4
5.	**Place of residence**		
	Urban	166	45.9
	Rural	104	28.7
	Peri urban	92	25.4
6.	**Job nature**		
	Public	41	11.3
	Private	91	25.1
	Own business	20	5.5
	Student	210	58.0

Most respondents lived in joint families (53.3%), while 46.7% lived in nuclear families. Regarding perceived health status, the majority (76.8%) rated their health as good. The demographic characteristics of the respondents are shown in Table I.

Descriptive summary of Outcome Variables:

Out of the total 362 respondents, the majority frequently consumed modern foods such as milkshakes (28.2%), mineral water (16.3%), and juices (16.3%). Other

commonly consumed modern foods included cookies and cakes (14.9%), various fruits (24.0%), branded butter and margarine (24.3%), and cafeteria foods like samosas, pakoras, sandwiches, and rolls (27.3%). Most respondents had started eating modern foods within the past 10 years, and the majority learned about modern food through their community.

Among the 362 respondents, branded cooking oil was the most frequently used modern food (74.9%), followed by chapatti (72.9%), candy (35.1%), milkshakes (28.2%), cafeteria food (27.3%), fruits (24.0%), and bread (43.45%). Branded cooking oil was the most commonly used item in modern food preparations. Figure 1 illustrates the rarely used modern foods among the residents of Skardu city.

Descriptive Result for Respondents started to eat Modern Food:

Among the 362 respondents, 19.9% began eating modern food from birth, 46.1% started consuming modern food before the age of 10, 27% began at ages 10-20, and 7% started eating modern food after the age of 20. The descriptive results of how respondents learned about modern food are shown in Figure 2.

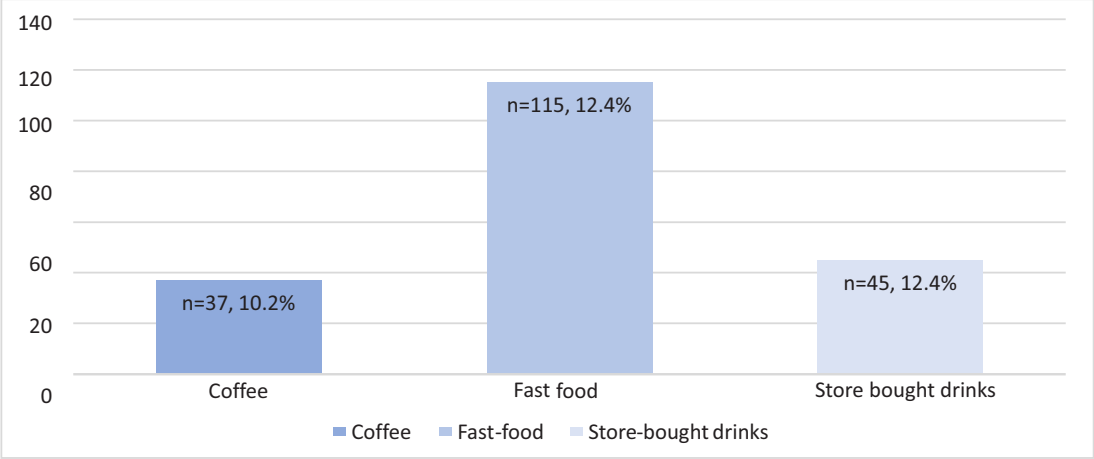

Figure 1: Rarely used Modern Food

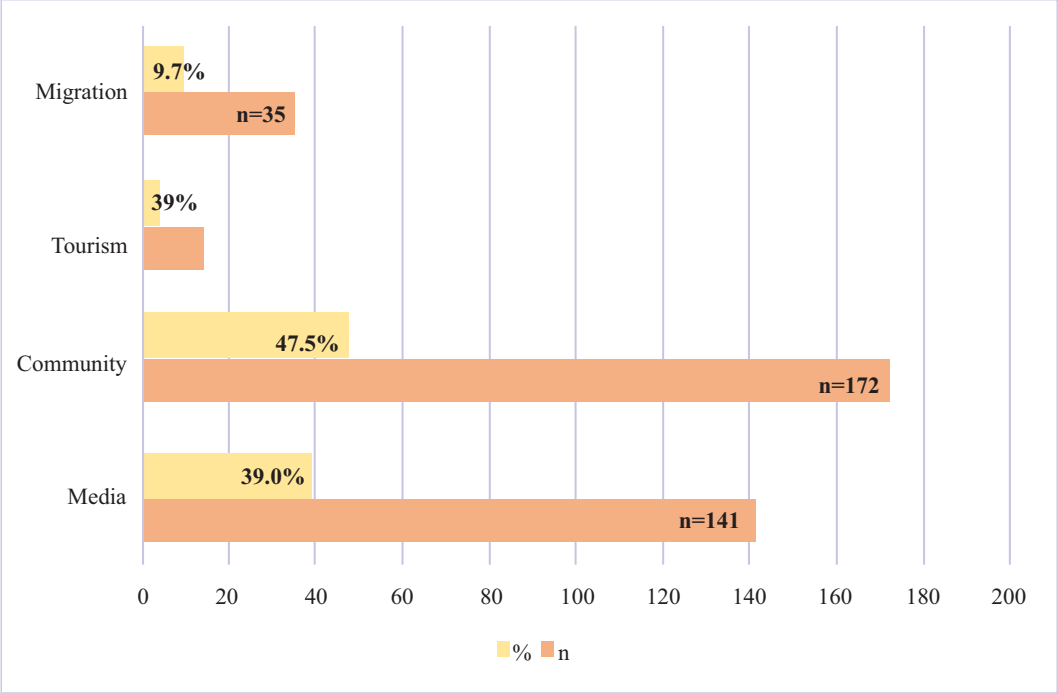

Figure 2: Respondent's source of knowledge regarding Modern Food

Table II. Descriptive Result for Traditional Food:

S. No.	Type of Traditional Food	Frequency (n)	Percentage (%)
1.	**Bro kiseer**		
	Never	191	52.8
	Monthly	105	29.0
	Weekly	48	13.3
	Daily	18	5.0
2.	**Prapo**		
	Never	73	20.2
	Monthly	214	59.1
	Weekly	70	19.3
	Daily	5	1.4
3.	**Marzan**		
	Never	129	35.6
	Monthly	182	50.3
	Weekly	46	12.7
	Daily	5	1.4
4.	**Tuskor**		
	Never	189	52.2
	Monthly	128	35.4
	Weekly	30	8.3
	Daily	15	4.1
5.	**Strabkhor**		
	Never	187	51.7
	Monthly	152	42.0
	Weekly	15	4.1
	Daily	5	2.2
6.	**Kulaq**		
	Never	107	29.6
	Monthly	94	26.0
	Weekly	123	34.0
	Daily	38	10.5
7.	**Soup**	40	11.0
	Never	105	29.0
	Monthly	186	51.4
	Weekly	31	8.6
	Daily		
8.	**Leafy vegetables**		
	Never	13	3.6
	Monthly	52	14.4
	Weekly	203	56.1
	Daily	94	26.0
9.	**Dried beans, Legume**		
	Never	96	26.5
	Monthly	129	35.6
	Weekly	127	35.1
	Daily	10	2.8
10.	**Chabato (Aloo salan+chah)**		
	Never	236	65.2
	Monthly	73	20.2
	Weekly	46	12.7
	Daily	7	1.9
11.	**Brozan**		
	Never	261	72.1
	Monthly	82	22.7
	Weekly	18	5.0
	Daily	1	0.3
12.	**Strub salan**		
	Never	225	62.2
	Monthly	101	27.9
	Weekly	34	9.4
	Daily	2	0.6
13.	**Phurfur**		
	Never	156	43.1
	Monthly	176	48.6
	Weekly	29	8.0
	Daily	1	0.3
14.	**Strub balay**		
	Never	197	54.5
	Monthly	133	36.7
	Weekly	31	8.6
	Daily	1	0.3
15.	**Chahbalay**		
	Never	208	57.5
	Monthly	128	35.5
	Weekly	24	6.6
	Daily	2	6
16.	**Trubalay**		
	Never	60	16.6
	Monthly	255	70.4
	Weekly	44	12.2
	Daily	3	8
17.	**Traspibalay**		
	Never	68	18.8
	Monthly	228	63.0
	Weekly	59	16.3
	Daily	7	1.9
18.	**Azok**		
	Never	22	6.1
	Monthly	145	40.1
	Weekly	149	41.2
	Daily	46	12.7

Table III: Association of Modern and Traditional Food with Sociodemographic characteristics

				Modern Food			Traditional Food		
S. No.	**Variables**		**n**	**Mean±SD**	**t test (df)**	***P*-value**	**Mean±SD**	**t test (df)**	**P-value**
1.	**Gender**	Male	182	39.40±10.38	2.069(360)	**0.039**	38.86±9.12	3.740(360)	**0.0001**
		Female	180	41.70±10.80			35.61±7.33		
2.	**Marital status**	Single	200	41.81±9.41	2.529(360)	**0.012**	39.17±8.40	4.989(360)	**0.0001**
		Married	162	38.98±11.83			34.86±7.85		
3.	**Age**	18-25 years	168	41.99±8.91			39.35±8.22		
		26-35 years	123	42.05±10.94	17.193(3)	**0.0001**	36.41±8.17	9.074	**0.0001**
		36-45 years	38	39.37±10.23			34.76±8.49		
		Above 45	33	28.91±11.16			32.48±7.34		
4.	**Education**	Illiterate	23	25.26±9.21			31.48±7.44		
		Primary	30	34.33±10.45	27.694(3)	**0.0001**	32.50±7.94	8.582	**0.0001**
		Intermediate	133	41.27±9.26			37.73±8.13		
		Bachelor & above	176	43.05±9.79			38.44±8.33		
5.	**Job nature**	Public	41	41.39±11.99			36.56±8.76		
		Private	91	44.87±7.76	7.915(3)	**0.0001**	37.88±8.32	0.490(3)	0.689
		Own business	20	37.95±11.35			38.55±10.44		
		Student	210	38.75±10.87			36.98±8.23		
6.	**Family income**	Less than 30000	158	37.41±10.41			37.65±8.96		
		30000-50000	109	40.88±10.22	18.288(2)	**0.0001**	37.27±7.79	0.518(2)	0.596
		Above 50000	95	45.37±9.66			36.54±8.25		
7.	**Perceived health**	Good	278	41.50±10.13			38.08±8.25		
	status	Fair	76	37.87±11.34	5.894(2)	**0.003**	34.79±8.40	6.742	**0.001**
		Poor	08	32.63±14.50			31.38±8.86		
8.	**Weight status**	Underweight	35	39.11±11.71			35.91±7.75		
		Normal	309	41.10±10.29	4.455(2)	**0.012**	37.77±8.41	6.630(2)	**0.001**
		Overweight	362	33.78±12.33			30.72±7.26		

DISCUSSION

The present study examined dietary transition and its determinants among residents of Skardu city. The results revealed that females (41.70±10.80) consumed modern food more frequently than males (39.40±10.38). A significant association was found between gender and both modern food ($p = 0.039$) and traditional food ($p = 0.0001$). A previous study indicated no significant gender-based differences ($p > 0.05$) in the frequency of snacking, with more males snacking frequently than females.[7] Another study conducted in China found that males had a higher intake of modern foods like rice, red meat, fat, and oils, which were positively associated with abdominal obesity compared to females.[8]

The study also found a significant association between marital status and food choices ($p < 0.05$). Single individuals (41.81±9.41) consumed modern food more frequently than married individuals (38.98±11.83). A 2016 study highlighted the connection between living arrangements and dietary behaviors, showing that non-married men had a lower intake of fruits and vegetables than non-married women.[9]

Additionally, the study revealed a significant association between age and food choices ($p = 0.0001$). Individuals under 45 years of age used modern food more frequently than traditional food, with the 26-35 age group (42.05±10.94) being the most frequent consumers of modern food. A previous study noted that adolescents in China between 1991 and 2000 consumed more meals and snacks outside the home.[10] Similarly, a study by the French Public Health Agency in 2006-2007 found a direct association between urban residence and an inverse relationship between age and consumption of ultra-processed food.[11]

The study also found that modern food consumption increased with lower educational levels. Illiterate individuals (25.26±9.21), those with primary education (34.33±10.45), intermediate education (41.27±9.26), and those with a bachelor's degree or higher (43.05±9.79) consumed modern food more frequently

than traditional food. A 2022 study showed a significant association between education and increased consumption of sugary beverages and unhealthy foods.[12]

Regarding place of residence, the study found no significant association between modern and traditional food consumption ($p > 0.05$). However, a previous study in Pakistan indicated that ultra-processed packaged foods and fast food were more readily available and convenient in urban areas than in peri-urban and rural areas.[13]

In terms of family income, individuals with incomes between Rs 30,000-50,000 and above Rs 50,000 consumed modern food more frequently than traditional food. A study in Mexico showed that family income influenced dietary transition, with higher income in developing countries associated with the consumption of healthier, more expensive food.[14]

Finally, the study found a significant association between food choices and weight status, with previous research also indicating the same and that males were at higher risk of obesity.[15]

CONCLUSION

This study revealed a significant association between modern and traditional food choices and sociodemographic characteristics. The majority of respondents were transitioning from modern to traditional foods and had started consuming modern food over 10 years ago. Most respondents learned about modern food through their community, including people, the market, family, friends, and health professionals.

Limitations:

Few limitations of the study are that it was a time bound research and was done in a specific area of Skardu City.

Future Recommendations:

Based on the current findings, it is recommended that awareness programs be implemented to help the local public understand the dynamics of food transition and address this public health issue. Prioritizing homemade modern food over commercially available modern food, increasing awareness among urban populations about the risks associated with modern food, encouraging gradual reductions in modern food intake and promoting physical activity to prevent long-term weight gain is of pivotal importance.

Conflict of interest: There is no conflict of interest.

Funding: none

Authors' Contributions:

Siddiqa Batoo1: Manuscript Writing, Analysis / Interpretation / Discussion, Experimentation / Study Conduction

Khizar Nabeel Ali: Conception of study / Designing / Planning, Critical Review

Sadaqat Hussain: Facilitated for Reagents / Material Analysis, Experimentation / Study Conduction

Suzzana Akbar Khan: Analysis / Interpretation / Discussion, Experimentation / Study Conduction

Sadaf Javed: Facilitated for Reagents / Material Analysis, Analysis / Interpretation / Discussion

Najam-us-Sabah: Experimentation / Study Conduction, Facilitated for Reagents / Material Analysis

Yusra Fatima Kiyani: Experimentation / Study Conduction, Analysis / Interpretation / Discussion

Muhammad Ibrahim: Facilitated for Reagents / Material Analysis, Analysis / Interpretation / Discussion

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RESEARCH ARTICLE

EFFECTS OF PSYCHOSOCIAL REHABILITATION IN PATIENTS WITH BREAST CANCER IN PRE-OPERATIVE PERIOD

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ABSTRACT

Objective: *To compare physical, clinical and psychosocial outcomes in patients having undergone a clinical program of prehabilitation planned for breast cancer surgery versus those having undergone conventional surgical treatment only.*

Study Design: *Quasi-experimental study.*

Place and Duration of Study: *Fauji Foundation Hospital, Rawalpindi from January to June 2024.*

Patients and Methods: *The patients were randomized into Group P (n=30) to receive pre-habilitation for four weeks prior to surgery and Group S (n=30) to receive conventional surgical resection without the pre-habilitation program. Prehabilitation parameters were assessed for pain, disability, anxiety, depression, physical and mental well-being using standard questionnaires. Primary variables studied were median scores for SF-12, HADS and SPADI scoring systems assessed between both groups before and 4 weeks after surgery.*

Results: *Median values for anxiety component of HADS scoring showed values of 3.00 (1.00) in Group P versus 8.00 (1.00) for Group S ($p<0.001$). Median values for depression component of the HADS scoring were 3.00 (1.00) versus 9.00 (1.00) between both groups ($p<0.001$). Median pain scores on the SPADI were 20.00 (6.00) versus 20.50 (8.00) between Group P and Group S ($p=0.982$). Median vales for the disability component showed values of 22.00 (4.00) in Group P versus 22.00 (3.00) for Group S ($p=0.514$).*

Conclusion: *We conclude that anxiety and depression levels were considerably improved with no clinical change in other parameters in the pre-habilitation program.*

Keywords: *Breast cancer, post-operative, prehabilitation, treatment, psychological outcomes*

INTRODUCTION

Breast cancer is the most common cancer diagnosed in women globally.[1] It is estimated that in 2022 alone, 2.3 million women were diagnosed with the condition worldwide.[2] This staggering number is projected to increase in the next decade due to increase in the diagnosis of the condition and prevalence of risk factors.[3] The treatment strategies involved include surgical and non-surgical options. Surgical option remains the gold standard option for definitive treatment of the disease in tumors which are deemed operable at the time of diagnosis.[4] Literature and studies have reported profound physical and psychosocial challenges faced by patients post-operatively. The cosmetics issues along with physical constraints hamper the quality of life and various program of rehabilitation have been developed to overcome these challenges.[5] This key aspect of cancer care has for a long time been focused on the post-operative aspect of patient care. Other programs such as peri-operative care according to the enhanced recovery after surgery (ERAS) protocol also cater mostly for post-operative improvement.[6]

There is now growing interest in developing programs which cater for the pre-operative aspect of patient preparation. Pilot and feasibility studies done in the UK for colorectal and urogenital surgeries have proven

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Received: 10 Oct 2024; revision received: 14 Dec 2024; accepted: 23 Dec 2024

beneficial in improving the overall physical and psychosocial profile of patients.[7,8] The concept of prehabilitation is now gaining traction as a routine, effective method to improve the anxiety, fear, depression and physical status associated with a cancer diagnosis in patients and proposed to improve patient outcomes of post-operative recovery, rehabilitation and discharge.[9] The program requires a multi-disciplinary approach and there is scant published data of prehabilitation programs both nationally and internationally. We aimed to incorporate physical, nutritional and psychosocial improvement parameters in a well-organized program in patients planned for a resectable breast cancer tumor. Our aim was to compare physical, clinical and psychosocial outcomes in patients having undergone a clinical program of prehabilitation planned for breast cancer surgery versus those having undergone conventional surgical treatment only to identify and design programs in helping patients to cope up with the physical and psychological distress of a major surgery that impacts them both cosmetically and mentally.

PATIENTS AND METHODS

This quasi-experimental study was carried out at the Fauji Foundation Hospital , Rawalpindi from Jan-Jun 2024 following Ethical Approval (vide letter no. 711/ERC/FFH/RWP dated 24/07/2023). Sample size was calculated keeping the confidence interval at 95%, power of test at 80% with anticipated proportion of patients expected to improve post-operative parameters after pre-habilitation therapy at 93% as compared to those without pre-habilitation at 64%.[10] Minimum sample size came out to be 28 patients in each group to see a significant change according to the WHO calculator. We made two groups of patients with 30 patients in each group making the total study sample of 60 patients.

All ASA-II and III female patients diagnosed with non-metastatic breast cancer planned for an elective modified radical mastectomy (MRM) in the next 4 weeks were included in the study.

Patients with metastatic disease, major cardiac or respiratory disease, low ejection fraction, post chemotherapy, failure to complete the pre-habilitation program and those unwilling to be included in the study were excluded.

The study method included all patients as per the inclusion criteria furnished. The patients were divided into Group P (n=30) to receive pre-habilitation for four weeks prior to surgery and Group S (n=30) to receive conventional surgical resection without under the pre-habilitation program. The program required a multi-disciplinary approach to patient assessment and standard assessment questionnaires were used to assess the patients and were translated into the language the understood for clarity and to remove any discrepancies with the results. The major interventions of the program included supervised exercise, nutritional directives, smoking cessation and psychosocial support. These parameters were assessed using the short form (SF-12) health survey to assess global health status, the hospital anxiety and depression scale (HADS) to assess mental wellness and shoulder pain and disability index (SPADI) to assess physical limitation of the affected side. The SF-12 scores the mental and physical component between scores of 0-100 with higher scores confirming to better quality of life (QOL).[11] The HADS score accounts for anxiety and depression and a score of 8 or more shows probability of anxiety and depression in the patient.[12] The SPADI score accounts for both pain and disability of the affected upper limb and higher values are associated with limitations in functional capacity.[13]

The program was started in conjunction with the anesthesia, nutritional, psychiatric, anesthesia and surgical departments. All consultants were requested to assess patients before and after the interventions and report their scoring systems accordingly unaware of the study protocol or its study outcomes. Patients added to the pre-habilitation groups were selected at random, but consent was taken from them to be included in the study. They were referred to the institute after being assessed by an anesthetist for surgical fitness and planned for surgery after 4 weeks for the condition. The supervised exercise portion consisted of resistance training (RT) thrice a week of all included patients undergoing two circuits of exercises to improve muscle strength, mobility and reduce fatigue of the upper body focusing on the upper limbs since these are the most affected after surgery and cause considerable morbidity. The first round consisted of chest press, calf raise, horizontal row and sit-stand) while the second round focused on (deadlift, shoulder press and extension exercises of the upper limbs). The initial repetition of the first week were between 8-12 and gradually increased to 28-36 at 4 weeks for all patients. Nutritional advice included an initial assessment of eating habits and removing high carbohydrate, low protein, processed foods and salt. Protein intake was encouraged since it promotes healthy wound healing and boosts immunity. All participants

were advised to consume 0.5–1g of protein per kg body weight daily, as assessed by a nutritionist. They were all advised to stop taking red meat since it is associated with an increased incidence of cancers. All diets were curated using ESPEN guidelines.[14] We did not find the incidence of smoking very high in the study population but those who did smoke were advised smoking cessation using nicotine patches, gums and counselling sessions thrice a week. The reason was to reduce the risk of respiratory complications and improve tissue healing and prevent wound infections. The psychosocial aspect was catered for by an expert psychiatrist and employe counselling sessions to improve distress and anxiety levels which are reported to be high among cancer patients. The sessions were designed to reduce fear of surgery by making the patients aware of the procedure and what to expect, to boost confidence by providing options for cosmetic improvement and quality of life through discussions and options available and patients were advised to undergo breathing exercises from videos to improve physiological symptoms and fatigue. These aspects have been reported to improve the overall mental status in cancer patients. After completion of four weeks, pre-operative scores were assessed and tabulated on forms and submitted in both groups. The patients were given the questionnaires before surgery in Group S and before pre-habilitation in Group P and this formed the baseline assessment. The scores were again assessed after 4 weeks and compared for differences.

Primary variables studied were median scores for SF-12, HADS and SPADI scoring systems assessed between both groups before and 4 weeks after surgery. Demographic data were statistically described in terms of mean and SD, frequencies, and percentages when

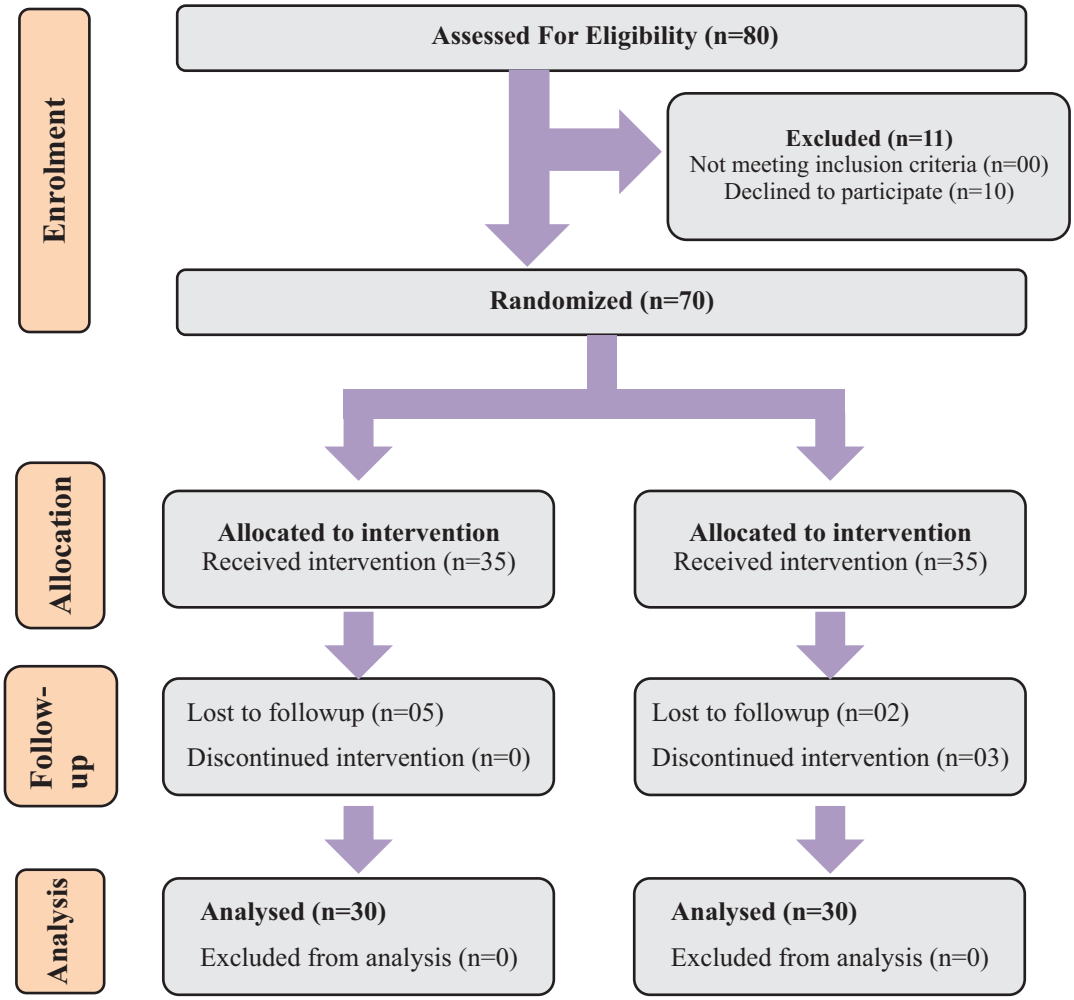

Figure 1 : Phases of the study

appropriate. T-test was used to compare statistically significant means between both groups. Chi-square test was used for frequency variables. Median values were compared using the Mann Whitney U test. The p value of <0.05 was considered statistically significant. All statistical calculations were performed using Statistical Package for Social Sciences 26.0

RESULTS

A total of 80 patients were assessed for eligibility to keep margin for lost to follow-up and patient reluctance or failure to complete the prehabilitation program. 10 patients declined to participate in the program and were excluded. 70 patients were randomized into the two groups. 05 were lost to follow-up in the conventional surgical group (Group S) while 02 were lost to follow-up and 03 discontinued program due to inability to continue course due to personal reasons. A total of 30 patients were analyzed in each of Group P and Group S for final analysis.

Mean age of patients in Group P was 57.70±2.89 years versus 57.67±2.39 years in Group S (p=0.961). Mean weight was 74.83±3.63 kg in Group P versus 74.43±3.57 in Group S (p=0.669). 05 (16.7%) patients were smoker and 25 (83.3%) were non-smoker in Group P versus 06 (20%) smokers and 24 (80%) non-smokers in Group S (p=0.739). 17 (56.7%) patients belonged to urban areas and 13 (43.3%) were from rural areas in Group P versus 20 (66.7%) in urban versus 10 (33.3%) patients were from rural areas (p=0.426) (Table-I).

Comparison between primary variables showed that on SF-12 questionnaire assessing physical and mental health, median scores for the physical component were 45.00 (5.00) in Group P versus 46.00 (10.00) in Group S (p=0.204). Mental wellness scores on the same questionnaire for Group P were 43.00 (4.00) versus 46.00 (10.00) for Group S (p=0.028). Median values for anxiety component of HADS scoring showed values of 3.00 (1.00) in Group P versus 8.00 (1.00) for Group S (p<0.001). Median values for depression component of the HADS scoring were 3.00 (1.00) versus 9.00 (1.00) between both groups (p<0.001). Median pain scores on the SPADI were 20.00 (6.00) versus 20.50 (8.00) between Group P and Group S (p=0.982). Median vales for the disability component showed values of 22.00 (4.00) in Group P versus 22.00 (3.00) for Group S (p=0.514) (Table-II) (Figure-II).

Table-I: Demographic and operative character-istics between both groups (n=60)

Variable	Group P (n=30)	Group S (n=30)	*p* Value
Mean Age (Years)	57.70±2.89	57.67±2.39	0.961
Mean Weight (Kg)	74.83±3.63	74.43±3.57	0.669
Smoker			
• **Yes**	05 (16.7%)	06 (20%)	0.739
• **No**	25 (83.3%)	24 (80%)	
Residence			
• **Urban**	17 (56.7%)	20 (66.7%)	0.426
• **Rural**	13 (43.3%)	10 (33.3%)	

Table-II: Comparison of questionnaire scores between both groups (n=60)

Variable	Group P (n=30)	Group S (n=30)	*p* Value
Median SF-12 questionnaire values			
• **Physical component**	45.00 (5.00)	46.00 (10.00)	**0.204**
• **Mental component**	43.00 (4.00)	46.00 (10.00)	**0.028**
Median HADS scoring questionnaire values			
• **Anxiety component**	3.00 (1.00)	8.00 (1.00)	**<0.001**
• **Depression component**	3.00 (1.00)	9.00 (1.00)	**<0.001**
Median SPADI scoring values			
• **Pain component**	20.00 (6.00)	20.50 (8.00)	**0.982**
• **Disability component**	22.00 (4.00)	22.00 (3.00)	**0.514**

DISCUSSION

The study was carried out with two aims in mind. The team at the institute intended to introduce pre-habilitation programs which have now been widely applied to various surgical setups globally. The type of surgeries and their assessment protocols have shown diversity in the results for a pre-habilitation program and that is why we wanted to see whether breast cancer patients can benefit from this or not. The second aim was to assess whether these programs can be successfully carried out in our setups or not considering patient

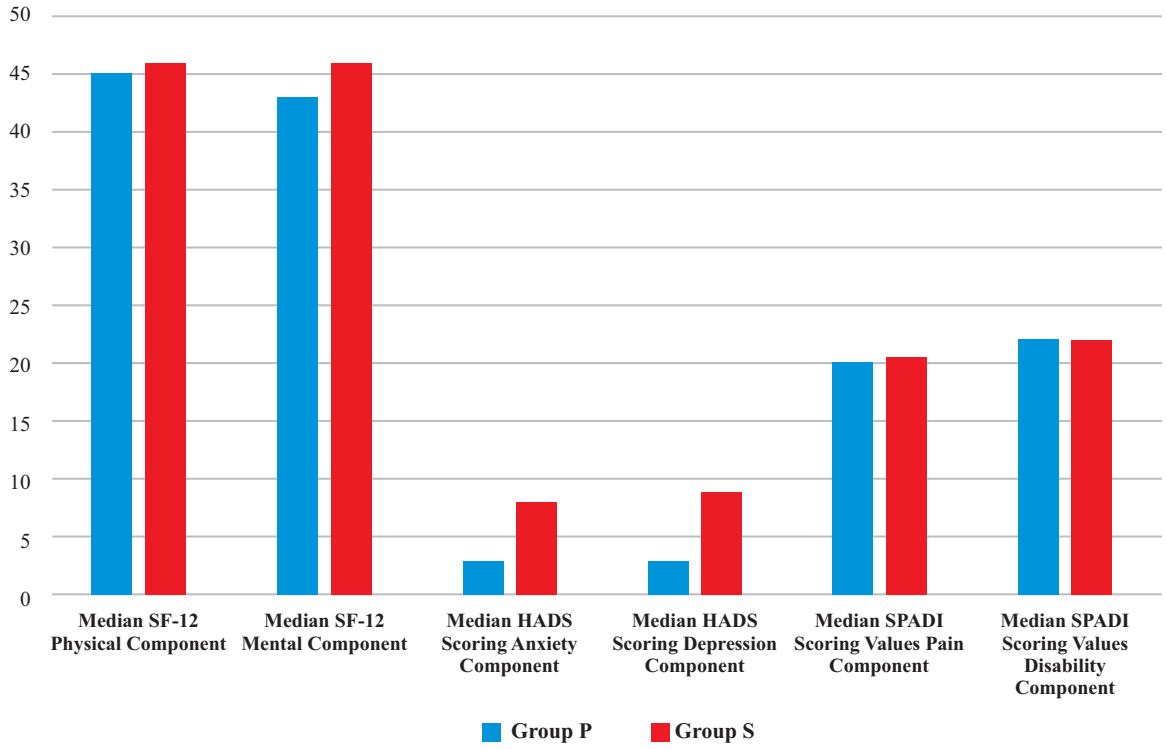

Figure - 2: Median questionnaire scores between both groups

compliance owing to monetary constraints in our country and long distances to centers of excellence for these sessions and programs. We were successful in achieving complete compliance in the pre-habilitation group except for very few patients who left mid-program citing family obligations and resource constraints.

Our study results provided considerable insights that multi-disciplinary approach although beneficial did not yield very promising results in all areas of patient assessment and improvement.[15] The main profound effect seen was in the improvement in all forms of mental status improvement be it anxiety, depression or psychosocial improvement. The results of the questionnaire were statistically significant for the HADS scoring, both the anxiety and depression components and also the mental status improvement in the SF-12 health survey questionnaire.[16] Our study did find that compared to studies carried out by Wu et al and Toohey et al, which concluded that only anxiety was improved, and no improvement was seen in other parameters[10,17], we saw a marked improvement in all assessment protocols of mental health showing improvement in anxiety, depression as well as psychosocial mental health. But other studies carried out in developing countries by Brahambhatt et al showed results confirming to our study[18] A careful assessment by our team inferred that the social demographic and educational status in our country especially for females does not provides enough chances for education on breast cancer and its awareness and the mental part of the assessment had improved profoundly for these patients because compared to the developed world, these patients were counselled and became comfortable with respect to what to expect surgically, cosmetically and became aware that they have options and a good chance of survival post-surgery. This resulted in better mental status, decreased anxiety and depression.

We, do, however, propose that since psychosocial aspect remains the major issue addressed, a multi-modal prehabilitation program may be designed excluding the nutritional, physical and pain focused programs and instead focus on improving the stress, anxiety and depression level in these patients.

RECOMMEDATIONS

The study recommends a focused multi-modal pre-habilitation program for improvement of stress, anxiety and depression in patients with breast cancer undergoing

surgical resection.

CONCLUSION

We conclude anxiety and depression levels were considerably improved with no clinical change in other parameters in the pre-habilitation program

Limitations

The limitations are that the study is single center only. A multi-center study would result in a wider demographic area with more confirmative results.

Conflict of interest: none

Funding: none

Authors' Contribution

Bisma Nauman: Conception, Analysis, Conduction

Sarah Haque: Analysis, Critical Review

Taib Khurshid: Conduction, Analysis

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RESEARCH ARTICLE

BACK PAIN AMONG MEDICAL STUDENTS AND ITS ASSOCIATED RISK FACTORS

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ABSTRACT

Objective: *The aim of the study was to identify the frequency and risk factors associated with low back pain among medical and dental students.*

Study Design: *Cross-sectional study.*

Place and Duration of Study: *The study was conducted at Hitec Medical Institute, Taxila from May to October 2024.*

Patients and Methods: *A validated questionnaire was used to collect data from 207 students. Data was analyzed to assess the prevalence of low back pain and its contributing factors. The chi-square test was applied to determine the association between exercise and back pain. The mean age and BMI of participants were 21.36 ±0.501 and 19.2 ±0.613 respectively.*

Results: *A higher prevalence of pain was observed among female students (63.3%). Third-year students reported more back pain compared to first- and second-year students. Key contributing factors included prolonged sitting (25%), uncomfortable seating, exam-related stress (18.4%), and improper posture (17.4%). A significant association was found between regular exercise and reduced back pain (P = 0.005).*

Conclusion: *Back and neck pain are common among medical and dental students with significant contributing factors such as prolonged sitting and poor posture. Implementing strategies like posture correction, ergonomic interventions, and promoting regular physical activity may help alleviate pain and improve musculoskeletal health in this population.*

Keywords: *Back Pain, Neck Pain, Medical students*

INTRODUCTION

Low back and neck pain affects a significant proportion of the population. An increased prevalence of back pain and neck pain are reported among Medical students.[1,2] During the period of medical training, students are exposed to stress, long study and training hours in hospital wards and clinics.[3] The nature of medical student's daily work increases the risk of musculoskeletal pain (MSP) among medical students.[3] The Global Burden of Disease (GBD) 2021 low back pain study claims that more than 800 million people will have low back pain by 2050. According to studies, it was found that lower back pain had the sixth highest burden out of the 291 conditions which were studied previously.[4] Certain factors such as age, gender, body mass index as well as behavioral and psycho-social factors like physical exercise, stress, sleeping hours, long sitting hours, seats, duration of reading and posture increase the risk of back pain.[5] A study of student groups found that the mean hours spent by medical students in recumbent or sitting postures was 9.5 (±5.34) hours per day.[6] According to a study in China, the prevalence of musculoskeletal disorders was 67.6% occurring

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Received: 13 Nov 2024; revision received: 26 Dec 2024; accepted: 27 Dec 2024

frequently in lower back, neck and shoulder regions. A study conducted in Karachi, Pakistan concluded that medical students have an increased prevalence of low back pain associated with factors such as long sitting hours.[7] Posture related back pain was the primary contributor to back pain.[8]

Back pain is an increasingly prevalent issue among medical students due to the rigorous demands of their training which often involves prolonged periods of study and high levels of computer usage. In a student-centered learning curriculum as in our private medical college, students are primarily responsible for preparing and engaging with course materials through extensive computer work. This reliance on digital learning and sedentary study habits has the potential to exacerbate back pain, impacting both academic performance and long-term health. Understanding the prevalence and contributing factors of back pain in this context is essential for implementing early interventional strategies. Addressing modifiable risk factors can help to prevent or reduce the burden of back pain, fostering better physical well-being and quality of life for future healthcare providers.

The main aim of this study is to determine the frequency of neck and back pain and the factors associated with it. Our study aimed to promote awareness among medical students regarding back pain management and prevention strategies. This study would carve-out a way to curb the rising cases of low back and neck pain.

PATIENTS AND METHODS

A cross-sectional study was conducted at Hitec Medical Institute from May to October 2024 following Ethical Approval (vide letter no. HITEC-IRB-38-2024 dated: 06-06-2024) on a sample of 207 students of 1st, 2nd and 3rd year MBBS and BDS students. The sample size was calculated using the WHO sample size calculator. The margin of error was taken as 5% with the confidence level of 95% & the anticipated frequency was 50% while the total population was 450. The calculated sample size was 207. Non-probability convenience sampling technique was adopted for sample selection. Diagnosed cases of structural deformity and Spondylosis were excluded from the sample. Self-designed Proforma based on a validated Oswestry low back pain disability questionnaire was used for data collection. Questionnaires were distributed among 1st, 2nd, and 3rd year MBBS and BDS students studying at Hitec medical and dental institute. The years above these were excluded because they were considered clinical years and had lesser hours spent sitting in the classroom. Response by students were noted regarding their back and neck pain. Data were analyzed by using SPSS-28. Mean and standard deviation were calculated for numerical variables. Numerical variables include age, height, and weight. Categorical variables include gender, class, and questions related to back pain. Frequency and percentages were calculated for categorical variables. The chi-square test was applied to find out the association between back pain and physical activities like exercise and sports.

RESULTS

The mean age for the medical students was found to be 21.36 ± 0.501 and the mean BMI was 19.2 ± 0.613. Out of 207 students, 76 (7%) were males and 131(63%) were females. Approximately 125 (60.3%) students were suffering from neck and back pain. More females 96(63.3%) were comparatively suffering from neck and back pain than males 29 (36.7%) as shown in the bar chart below.

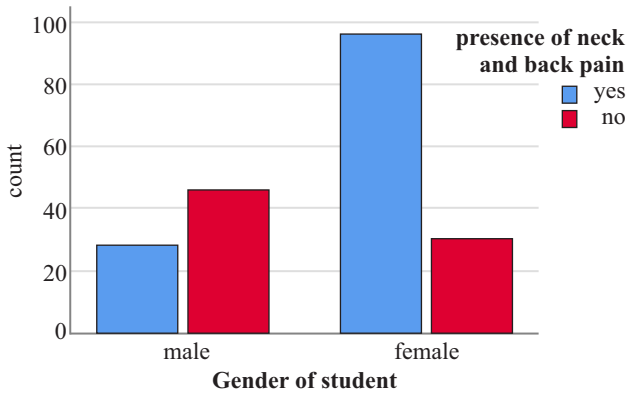

Fig 1: Bar chart showing the frequency of neck and back pain among male and female student

Out of 125 students suffering from back pain, 73(35.7%) reported back pain during medical school and 52(25.5%) had back pain before coming to medical school. About 83 (40%) of the total students had localized pain, 25% reported it in the neck region,18.8% in the upper back and 16.9% in the lower back.

The regions in which pain was localized are shown in the Table I:

The presence of back pain was higher among the Students of 3rd year as compared to 1st and 2nd year and those who had back pain spend almost 8 to 12 hours sitting per day.

The time duration during which back pain developed in

the life of medical students is shown in the Table I.

Table I: Data on back and neck pain regarding site and trigger of pain

Category	Subcategory	Frequency	Percent
Frequency of Pain in Localized Region	Neck	52	25.1
	Upper Back	38	18.8
	Lower Back	35	16.9
	Total	**126**	**60.9**
Cross Tabulation: Neck and Back Pain	MS1 (1st Year) - Yes	21	-
	MS2 (2nd Year) - Yes	41	-
	MS3 (3rd Year) - Yes	63	-
	MS1 (1st Year) - No	45	-
	MS2 (2nd Year) - No	27	-
	MS3 (3rd Year) - No	5	-
	Total Students	**202**	-
When Neck and Back Pain Started	During Medical School	53	25.6
	Before Medical School	72	35.7
	Total	**125**	**61.4**
Subjective Triggers of Back Pain	Exam-Related Stress	36	18.4
	Sitting/Uncomfortable Benches	53	25.6
	Improper Body Postures	36	17.4
	Total Triggers	**125**	**61.4**

Long sitting hours or uncomfortable benches were the most triggering (25%) factor for back pain, whereas stress during the exam period and improper body postures turned out to be 18.4% and 17.4% respectively as shown in Table I.

In comparison of hours during the day, in working (college) hours moderate pain is reported the most and mild pain is seen during rest hours at night as shown below.

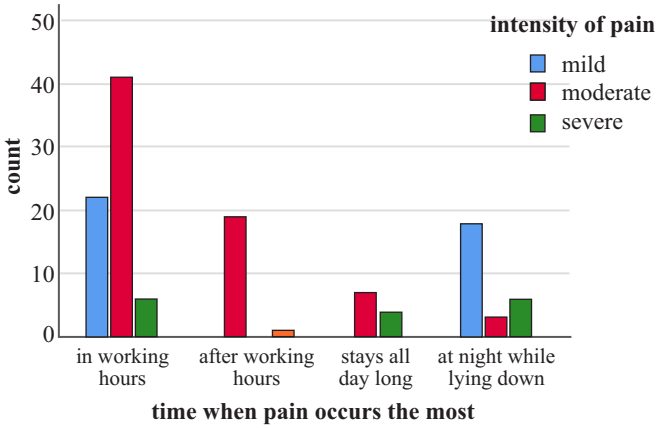

Fig 2: Frequency of pain Intensity in different hours of the day

During working hours at school, level of comfort of benches/chairs was also analysed and results were as follows.

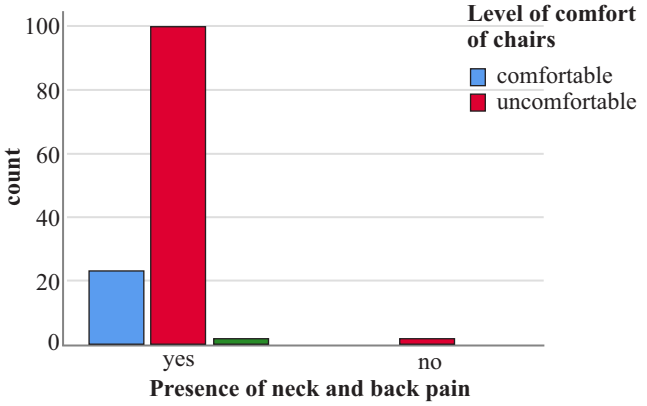

Fig 3: Frequency of pain associated with level of comfort of the chair

The most common method used by the students to minimize the pain was changing posture

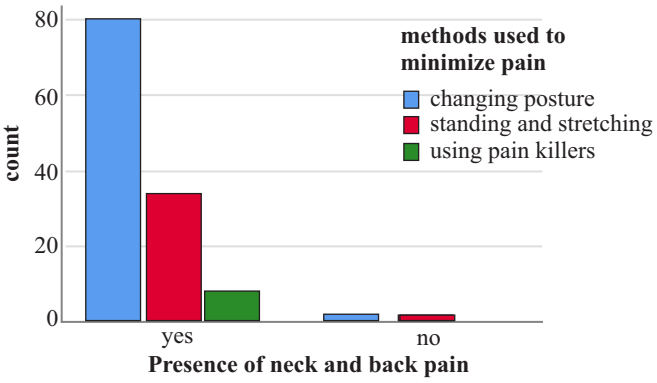

Fig 4: Methods used to reduce back/neck pain and association with walk and sports

Chi square test showed significant association of back pain with exercise (P=0.005). Students doing exercise were less experiencing the pain as compared to the students not doing the exercise.

Table II: Chi-Square Test

	Value	df	*p* value
Pearson Chi-Square	7.886	1	.005

DISCUSSION

This study was conducted on medical and dental students to determine the prevalence and factors associated with neck and back pain. The majority of the students (61.9%) were found to be suffering from neck pain and back pain which is rather alarming. The proportion of the students suffering from back pain (35.7%) was greater than the students suffering from neck pain (25.1%). Upper back pain was reported among 18.8% students whereas 16.9% students reported lower back pain. More females 96(63.3%) were suffering from neck and back pain than males 29 (36.7%). This situation is indicative of a serious health threat to the younger generation. The results are comparable to another study conducted among the medical students of Malaysia which also showed similar alarming results. The prevalence of musculoskeletal pain (at least one body site) was reported among 45.7% students in the past week and 65.1% students in the previous year. The prevalence of low back pain was the highest in the past week and in the previous year (27.2%, and 46.1% respectively), followed by neck pain (24.1% and 41.8% respectively).[9] The study conducted in Serbia, 75.8% medical students reported low back pain at some point in their lives, 59.5% in the last 12 months, and 17.2% suffered at the moment of survey. Chronic low back pain was reported by 12.4% of the students. Occurrence of low back pain was higher in the females as compared to males.[1] Another study conducted by Aymeric Amelot et al in France also showed an increased prevalence of low-back pain which was reported among 835/1243 (72.1%) students. Frequency of low back pain was variable, 523 (42.1%) of students suffered several times a month, 232 (18.7%) several times a week, and 80 (6.4%) several times a day.[10] In our study, 25% of students reported the pain to be in their neck region which shows that the increased neck pain must be due to long hours of bending of neck for study purposes among medical students. Medical students have more sitting hours in a day because lectures and study time engage them almost twice as much. In other words, medical students have a considerably more sedentary lifestyle. A similar study also showed a 12-month low back pain prevalence of 63% among physiotherapy students.[11] Another study [12] did not support the opinion of "sitting" to be associated with low back pain. It further stated that low back pain is uncommon in the first decade of life, but prevalence increases steeply during the teenage years. It was noted that mostly 3rd year medical students reported back pain while there was a lower ratio of students suffering from back pain in 2nd and 1st years subsequently which shows that the incidence of back pain has something to do with the increase in age and increase in study stress. The results are also comparable with another study conducted in KSA which showed that one of the factors significantly associated with musculoskeletal pain in at least one body site at any time was being in the clinical year rather than the basic sciences years ($P = 0.032$.)[13]

In our study 35% of the students reported that they had back pain before coming to medical school and only 25% started having it during medical school which shows that despite long sitting hours, a sedentary lifestyle might be the cause of developing back pain among students. Our study showed that the most triggering factor for back pain was not the stress of exams but it was long uncomfortable hours sitting on benches that mostly triggered back pain. The study conducted among medical students in Bangladesh also supported that Ergonomic features of chairs i.e. back support, adjustable back support and adjustable sitting surface significantly ($p < 0.05$) influenced the outcomes.[14] Although the lack of exercise was reported as a risk factor for low back pain in the study done in Ethiopia which is in accordance with our research as our data also showed that most of the students who had back pain were never involved in healthy sports or exercise while on the other hand those students who were not suffering from back pain reported that they were involved either in sports or twenty to thirty minutes of walking per day which proved to be beneficial for them.

These findings offer insight into the significant impact of back and neck pain on medical students, which needs to be addressed. Universities should take preventive measures in order to provide their students with a decent environment for a successful academic life. In addition, developing and implementing corrective measures to improve the quality of life of medical students are warranted. Variables which were not assessed in this study but should be investigated in further studies are smoking and psychological distress.

CONCLUSION

The study revealed the association of several factors with the occurrence of back and neck pain among medical students at the medical institute such as inadequate physical activity, prolonged study sessions, and poor neck posture. However, regular physical exercise demonstrated a protective effect, reducing the risk of back and neck pain among medical and dental students.

Conflict of interest: none

Funding: none

Authors Contribution

Anwar Bibi: Conception of study / Designing / Planning, Analysis / Interpretation / Discussion

Raima Siddiqui: Manuscript Writing

Nadia Nisar: Critical Review, Facilitated for Reagents / Material Analysis

Aashi Ahmed: Critical Review, Facilitated for Reagents / Material Analysis

Mohsin Raza: Experimentation / Study Conduction

Momina Butt: Experimentation / Study Conduction

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RESEARCH ARTICLE

THE EVALUATION OF PATIENT SATISFACTION AND PERCEIVED QUALITY OF CARE IN OPD SETTINGS IN MIRPUR AJK: A CROSS-SECTIONAL STUDY

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ABSTRACT

Objective: *Patient satisfaction is a reliable indicator of healthcare quality and an outcome measure for physicians. This study sought to assess patient satisfaction at Ahsan's Medical Complex, Mirpur Azad Jammu and Kashmir, Pakistan.*

Study Design: *Cross-sectional study.*

Place and Duration of Study: *Ahsan's Medical Complex, Mirpur Azad Jammu and Kashmir, Pakistan from August to October 2024*

Patients and Methods: *One hundred and seventy patients participating in face-to-face interviews using convenience sampling method. The Patient Satisfaction Questionnaire Short Form (PSQ-18) was used to rate patient satisfaction across seven dimensions. The responses were summarized using descriptive statistics and the data was analyzed using SPSS.*

Results: *One hundred and seventy participants had a variety of demographic features, with the largest age groups being 27-36 years (28%) and 37-46 years (23%), majority were female (71%) and married (91%). The PSQ-18 results showed high overall patient satisfaction, with a 90% rating in the high satisfaction category. Patients expressed high levels of satisfaction with interpersonal manner, communication, time spent with clinicians and accessibility. However, 10% patients reported moderate or low satisfaction levels, citing worries regarding technical quality and economical elements of care.*

Conclusions: *In general, patients were satisfied with the medical care they received, particularly with the interpersonal and communication skills of the staff.*

Keywords: *Patient satisfaction, healthcare quality, PSQ-18, Technical quality*

INTRODUCTION

The World Health Organization emphasizes the necessity of providing high-quality medical services in the healthcare system. Healthcare systems should prioritize meeting the population's needs while treating individuals with dignity and respect.[1] The healthcare system has transformed from a noble profession to a customer-oriented service sector, impacted by internet access, patient expectations, health insurance and medical technological advancements.[2] Patient perception and satisfaction are essential for enhancing healthcare quality, performance and clinical efficacy. It evaluates the perceived quality of care and serves as a feedback instrument for medical professionals, providing noteworthy information about various

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Received: 14 Nov 2024; revision received: 23 Dec 2024; accepted: 27 Dec 2024

healthcare subjects, including their treatment efficacy and level of understanding. Adopting a client-centered approach, modifying attitudes, and creating a pleasant environment can all help providers improve their services.[3,4]

A mixed-method cross-sectional research of 410 outpatient service participants in Fiji's Suva Subdivision revealed that most patients (69.3%) were satisfied with their consultations. Patient satisfaction was substantially related to age, gender, education level, waiting time, doctor's communication behavior, and patient trust.[2] A cross-sectional observational study was conducted at Ayub Teaching Hospital in Abbottabad, Pakistan, which involved 240 patients; 78.69% were satisfied with the registration process, 82.62% were satisfied with staff courtesy and 51.80% were confident with hospital hygiene. The overall satisfaction score was 58.03%, with 32.79% satisfied with the staff's technical and professional expertise and 9.18% satisfied with medical treatment affordability.[3] A study of 66,348 hospital patients and 2963 inpatient nurses in England revealed that patients' views of care were considerably harmed by a lack of trust in nurses and doctors and an increase in missed nursing care. The study discovered that missed care was negatively related to six out of eight outcomes, correlated favorably with larger patient-to-nurse ratios, and negatively associated with better work environments.[4] The study assessed patient satisfaction with inpatient care at the Black Lion Specialized Hospital in Addis Abeba, Ethiopia. Out of 398 participants, 46.2% were pleased. Patient and healthcare professional interactions and facility amenities accounted for 96.4% of the variability in satisfaction levels.[5] The study at the University Polyclinic in Messina, Italy, evaluates patient satisfaction in healthcare departments. A survey yielded over 350 observations, which were used to generate a logistic model. Patient satisfaction is influenced by care quality, parking lot availability, structure cleanliness and physician judgment.[6]

A cross-sectional study was conducted in Ebonyi State, Nigeria, to assess patients' satisfaction with the quality of care in general hospitals. Out of 396 patients, 39.4% were men and 60.6% were women. Most patients were between 18 and 39 years, had a secondary education, were married, made less than $18,000 yearly and traded. Patients expressed satisfaction with tangibility, dependability, responsiveness, assurance, and empathy.[7] Patient satisfaction surveys are essential for detecting gaps and executing quality improvements in the healthcare industry. They help reduce costs, meet patient expectations, develop effective management strategies, evaluate plan implementation and compare healthcare institutions. Patient satisfaction encompasses necessary medical care, therapies and healthcare provider actions and behaviors. Doctors must have strong technical and interpersonal abilities to ensure patient satisfaction.[8-13]

Doctors must maintain professionalism and ethical practices to meet patient expectations. Their technical expertise includes experience, diagnosis, clinical procedure performance, prescription and knowledge of medical developments.[14,15] Patient satisfaction is a multidimensional construct influenced by health care's technical, infrastructural, functional, environmental and interpersonal aspects. A satisfied patient chooses health services and comply with treatment and follow-up recommendations.[16,17] Dissatisfied patients may stop seeking healthcare from a physician they believe to be inept, resulting in delays and self-medication. Patient contentment is imperative to accelerating the transition to high-quality health systems in low- and middle-income nations.[18,19]

The current literature on patient satisfaction in healthcare settings is extensive, covering various factors such as doctor-patient communication, technical quality and overall satisfaction. However, there remains a gap in understanding how satisfaction varies across different aspects of healthcare services in private hospitals in regions like Azad Jammu and Kashmir (AJK), Pakistan, particularly in relation to accessibility, time spent with doctors and financial hardships. Existing studies often focus on broader regional or public healthcare settings and there is limited research addressing these specific domains within private healthcare institutions in this region. A questionnaire-based cross-sectional study was undertaken at Ahsan's Medical Complex in Mirpur, Azad Jammu, Pakistan. Our study aimed to evaluate patient satisfaction, providing valuable data for doctors and hospital administration to identify and address issues.

PATIENTS AND METHODS

This cross-sectional study was conducted at Ahsan's Medical Complex, a major private hospital in Azad Jammu and Kashmir (AJK), Pakistan from August to October 2024 following Ethical Approval (vide letter No. 609 dated 01-08-2024), to assess patient satisfaction. The hospital was selected due to its comprehensive medical services and high patient traffic, making it an ideal setting for this investigation. A

convenience sampling technique was used to select 170 participants for the study.[9] While the sample size was considered sufficient for a representative assessment of patient satisfaction, the absence of a formal justification such as a power analysis to support this claim is a limitation. A probability sampling method may have enhanced the robustness of the sample.

Data was collected using the Patient Satisfaction Questionnaire Short Form (PSQ-18), a validated tool designed to assess various aspects of patient satisfaction.[10] The PSQ-18 evaluates seven key areas: overall satisfaction, technical quality, interpersonal style, communication, financial hardships, time spent with doctors and accessibility. The scoring system involves a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree), with higher scores indicating greater satisfaction. Items are reverse-scored to maintain consistency and the total score, ranging from 18 to 90, reflects overall satisfaction across the domains assessed. The data were processed using SPSS version 23, with descriptive statistics such as frequencies, means and standard deviations used to summarize the results.

RESULTS

The study included 170 participants with a diverse range of ages. The largest age group was 27-36 years, which made up 28% of the sample, followed by the 37-46 years age group at 23%, the 47-56-year age group at 19% and the 57-76-year age group at 17%. Smaller proportions were represented in the 7-16-year (3%), 17-26-year (3%), 67-76-year (4%) and 77-86-year (3%) age ranges. The majority of participants were females, accounting for 71% of the study population and 29% were males. The vast majority of the participants, 91%, reported being married, providing significant insight into the participants' personal lives while only 9% were unmarried. Looking at educational attainment, the largest group was with no formal education, comprising 31% of the sample, followed by those with only primary level education, consisted of 30% participants. Smaller population had completed secondary school (14%), higher secondary school (9%), undergraduate degrees (11%) and postgraduate degrees (5%). Regarding employment status, over half of the study sample, 64%, were unemployed. Another 29% were employed, while 7% were retired. The demographic details of the participants have been shown in table I.

Table I: Demographic characteristics of the participants

Demographic Characteristics	N (170)	Percentage
Age		
7-16 years	5	3 %
17-26 years	5	3 %
27-36 years	47	28 %
37-46 years	39	23 %
47-56 years	33	19 %
57-66 years	29	17%
67-76 years	7	4 %
77-86 years	5	3%
Gender		
Male	49	29 %
Female	121	71 %
Marital Status		
Unmarried	16	9 %
Married	154	91 %
Education		
Uneducated	52	31 %
Primary	51	30 %
Secondary	24	14 %
Higher secondary	16	9 %
Graduation	19	11 %
Masters	8	5 %
Employment		
Employed	49	29%
Unemployed	109	64%
Retired	12	7 %

The sample was collected from different OPDs is mentioned in Table II.

Table II : Distribution of OPDs of the participants

OPDs	Frequency (n=170) %
Orthopedic Surgery	51 (30%)
General Medicine	30 (18%)
ENT	14 (8%)
Neurosurgery	27 (16%)
Urology	24 (14%)
Gynecology and Obstetrics	10 (6%)
General Surgery	14 (8%)

The general satisfaction subscale consists of questions 3 and 17. For item 3, 50% strongly agreed, while 48% agreed that their medical care was nearly excellent,

indicating a high degree of overall satisfaction. For item 17, the majority strongly agreed that they are dissatisfied with some parts of their medical care despite the high overall satisfaction. Items 2, 4, 6, and 14 are in the technical quality subscale. 36% strongly agreed with item 2, whereas 58% agreed that the doctor's office has everything needed to provide comprehensive medical care. However, for item 4, 59% participants strongly agreed that they sometimes wonder if the doctor's diagnosis is correct. Similarly, for item 14, 5% participants agreed and 1% were uncertain about their doctor's ability. These mixed responses suggested some concerns about the technical quality of care. The interpersonal manner subscale consists of items 10 and 11. For item 10, most participants (39% disagreed, 56% strongly disagreed) indicating that doctors do not

Table III: Responses of the participants to PSQ-18 items.

PSQ 18 Items	Response	N (170)	Mean	Standard Deviation
1.Doctors are good about explaining the reason for medical tests. (Communication)	Strongly agree Agree	126 (74%) 44 (26%)	0.26	0.439
2. I think my doctor's office has everything needed to provide complete medical care. (Technical Quality)	Strongly agree Agree Uncertain	61 (36%) 99 (58%) 10 (6%)	0.70	0.574
3. The medical care I have been receiving is just about perfect. (General Satisfaction)	Strongly agree Agree Uncertain	86 (50%) 81 (48%) 3 (2%)	0.51	0.536
4. Sometimes doctors make me wonder if their diagnosis is correct. (Technical Quality)	Strongly agree Agree Uncertain	101 (59%) 59 (35%) 10 (6%)	0.46	0.607
5. I feel confident that I can get the medical care I need without being set back financially. (Financial Aspects)	Strongly agree Agree Uncertain	26 (15%) 100 (59%) 44 (26%)	1.11	0.635
6. When I go for medical care, they are careful to check everything when treating and examining me. (Technical Quality)	Strongly agree Agree	91 (54%) 79 (46%)	0.46	0.500
7. I have to pay for more of my medical care than I can afford. (Financial Aspects)	Agree Uncertain Disagree	52 (30%) 109 (64%) 9 (6%)	1.75	0.545
8. I have easy access to the medical specialists I need. (Accessibility and Convenience)	Strongly agree Agree Uncertain Disagree Strongly Disagree	51 (30%) 93 (54%) 12 (7%) 9 (6%) 5 (3%)	0.96	0.922
9. Where I get medical care, people have to wait too long for emergency treatment. (Accessibility and Convenience)	Agree Uncertain Disagree Strongly Disagree	14 (8%) 27 (16%) 89 (52%) 40 (24%)	2.91	0.849
10. Doctors act too businesslike and impersonal toward me. (Interpersonal Manner)	Agree Uncertain Disagree Strongly Disagree	6 (3%) 4 (2%) 67 (39%) 95 (56%)	3.48	0.681

11. My doctors treat me in a very friendly and courteous manner. (Interpersonal Manner)	Strongly agree Agree Uncertain Disagree Strongly Disagree	40 (24%) 92 (54%) 29 (17%) 5 (3%) 4 (2%)	1.06	0.858
12. Those who provide my medical care sometimes hurry too much when they treat me. (Time Spent with Doctor)	Uncertain Disagree Strongly Disagree	2 (1%) 126 (74%) 42 (25%)	3.24	0.452
13. Doctors sometimes ignore what I tell them. (Communication)	Uncertain Disagree Strongly Disagree	2 (1%) 51 (30%) 117 (69%)	3.68	0.494
14. I have some doubts about the ability of the doctors who treat me. (Technical Quality)	Agree Uncertain Disagree Strongly Disagree	9 (5%) 2 (1%) 95 (56%) 64 (38%)	3.26	0.718
15. Doctors usually spend plenty of time with me. (Time Spent with Doctor)	Strongly agree Agree Uncertain Disagree Strongly Disagree	6 (3%) 89 (52%) 37 (23%) 31 (18%) 7 (4%)	1.67	0.953
16. I find it hard to get an appointment for medical care right away. (Accessibility and Convenience)	Agree Uncertain Disagree Strongly Disagree	9 (5%) 19 (11%) 122 (72%) 20 (12%)	2.92	0.647
17. I am dissatisfied with some things about the medical care I receive. (General Satisfaction)	Strongly agree Agree Uncertain Disagree Strongly Disagree	6 (3%) 2 (1%) 4 (2%) 32 (19%) 126 (75%)	3.59	0.867
18. I am able to get medical care whenever I need it. (Accessibility and Convenience)	Strongly agree Agree Uncertain Disagree Strongly Disagree	56 (33%) 95 (56%) 7 (4%) 5 (3%) 7 (4%)	0.89	0.907

act too businesslike and impersonal. For item 11, 24% strongly agreed, while 54% agreed that their doctor treated them courteously and kindly. These results show high satisfaction with the providers' interpersonal skills. Items 1 and 13 are part of the communication subscale. On item 1, 26% of participants agreed and 74% strongly agreed that doctors are adept at describing the purpose of medical tests. However, regarding item 13, 69% of participants strongly disagreed and 30% argued that doctors occasionally disregard what they tell them. These findings suggest generally effective communication between patients and providers. Items 5 and 7 make up the subscale for financial aspects. For item 5, 15% strongly agreed and 59% agreed that they were confident they could receive the medical treatment they required without incurring financial

hardship. However, for item 7, 30% of respondents agreed that they must pay for more medical treatment than they can afford. These comments demonstrated some concern about the financial aspects of treatment. Items 12 and 15 are included in the subscale of time spent with the doctor. For item 12, 74% of participants disagreed, with 25% strongly disagreeing that individuals delivering medical care are sometimes excessively rushed. Regarding item 15, 3% strongly agreed and 52% agreed that the doctor typically spends much time with them. The accessibility and convenience subscale consist of items, 8, 9, 16 and 18. For item 8, 30% participants strongly agreed and 54% agreed they had easy access to the needed medical specialist. For item 9, 52% participants disagreed and 24% strongly disagreed that people must wait too long for emergency treatment. For item 16. 72% participants disagreed and 12% strongly disagreed that getting a medical appointment right away is hard. For item 18, 33% strongly agreed, while 56% agreed they could access medical care anytime needed. These data showed that patients were quite satisfied with the accessibility and ease of medical care. Table III shows the participants' detailed responses.

The total possible score on the PSQ-18 ranges from 18 (lowest satisfaction) to 90 (most satisfaction), depending on the scoring method utilized. In this study, the average total PSQ-18 score was 90, indicating a high degree of patient satisfaction. The distribution of total scores among the 170 participants was as follows (Table IV).

Table IV: Distribution of PSQ-18 Score Range among Participants

Total Score Range	Number of Participants
81-90	112 (66%)
71-80	40 (24%)
61-70	10 (6%)
51-60	6 (4%)
41-50	2 (1%)
31-40	0
21-30	0
=20	0

The PSQ-18 score distribution reveals three degrees of satisfaction: high (90%), moderate (10%), and low (1%). High satisfaction suggests that 90% of patients were highly satisfied with their healthcare services, showing that the hospital performed exceptionally well in fulfilling patient expectations and providing quality care. Moderate satisfaction indicates opportunities for development, such as technical quality or financial aspects. Low satisfaction means that only 1% of patients reported significant unpleasant experiences or low overall satisfaction, indicating an opportunity for the hospital to address unmet needs or concerns in this group.

DISCUSSION

Patient satisfaction with health care is an essential and frequently used quality indicator. Assessing patient satisfaction evaluates treatment quality and identifies opportunities for improvement for future services.[11] The study, conducted in the Suva Subdivision health centers in Fiji, assessed patient satisfaction and its determinants in 2018. The findings revealed that the majority of patients (69.3%) were generally satisfied with their consultations. Factors such as age, gender, education level, waiting time, doctors' communication behavior and patient trust were significantly associated with satisfaction. The study highlighted that patients who trusted their doctors and were seen within one hour were significantly more likely to report high satisfaction with their consultation. Additionally, the doctors' communication style was a key factor in enhancing patient satisfaction, with many patients expressing that the quality of consultation made the wait worthwhile. These results align with similar findings at Ahsan's Medical Complex in Azad Jammu and Kashmir, Pakistan, where patients were highly satisfied with their medical care, particularly in terms of overall satisfaction, communication and the perceived quality of care. Both studies emphasize the importance of trust, communication and timely care in shaping patient satisfaction, as seen in earlier research using the PSQ-18.[2] Regarding the interpersonal approach, participants overwhelmingly claimed that their doctors do not act businesslike or impersonally but rather treat them with amiability and courteousness. This aligns with earlier research conducted by Akin LH et al. in 2021 which surveyed 66,348 hospital patients and 2,963 inpatient nurses across 161 NHS trusts in England, provides valuable insights into how hospital care is perceived by patients. It found that patient satisfaction is strongly linked to confidence in nurses and doctors, staffing levels and the overall hospital work environment. Specifically, patients' perceptions of care were significantly impacted by a lack of confidence in

healthcare providers and increased missed nursing care. The study showed that higher patient-to-nurse ratios and poorer work environments were associated with lower patient satisfaction. Conversely, improved nurse staffing levels were positively linked to better patient satisfaction.[4]

The study in Ebonyi State, Nigeria, aimed to assess patient satisfaction with the quality of care in general hospitals using the SERVQUAL model. A sample of 400 patients was surveyed and 396 responses were retrieved. The results indicated that patients were particularly satisfied with the responsiveness, assurance and empathy dimensions, with average scores of 3.06, 3.07 and 3.12, respectively. Satisfaction with tangibility and reliability was lower, with scores of 2.57 and 2.84. The majority of participants were females (60.6%) and aged between 18-39 years (58.8%). These findings align with earlier research that highlights the importance of effective communication in enhancing patient satisfaction. Similar to the study in Ebonyi, patients at Ahsan's Medical Complex expressed high satisfaction, particularly with doctor-patient communication. Patients believed that their doctors were skilled in explaining procedures and medical tests, contributing to the overall satisfaction with their care. This supports the view that strong communication is a key factor in improving patient satisfaction across various healthcare settings.[7]

The study examined the relationship between patient characteristics, postoperative outcomes and nonresponse to the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey after total knee arthroplasty (TKA). Among 4,804 TKA patients, 1,498 (31.22%) returned the survey. Multivariate analysis revealed that patients who did not return the survey were more likely to have higher American Society of Anesthesia (ASA) scores, be partially or totally dependent, experience readmission, be discharged to a location other than home or have longer hospital stays. These findings emphasize that certain patient factors, including higher postoperative risks, may influence survey participation. Similarly, this aligns with findings from studies at Ahsan's Medical Complex, where patients expressed high satisfaction with the time spent with their doctors. The majority reported that doctors did not rush through appointments and dedicated adequate time to consultations. This highlights the importance of doctor-patient interaction and the significant role it plays in patient satisfaction, further reinforcing the need for quality time spent with healthcare providers.[8]

The retrospective survey review evaluated patient satisfaction in neurosurgical spine versus non-spine clinics at Stanford Medical Center using the Press Ganey survey. A total of 578 spine clinic patients and 1,048 non-spine clinic patients were analyzed, with the survey covering 40 questions related to physician and nursing care, personal concerns, room conditions, treatment, discharge and overall clinic assessment. Results showed that spine clinic patients reported lower satisfaction scores in several categories, including physician care (89.5 vs. 92.6), nurse care (91.3 vs. 93.4), room conditions (81.0 vs. 83.1) and overall clinic assessment (92.9 vs. 95.5). These findings align with our research highlighting the importance of accessibility and convenience in patient satisfaction. In this study, patients valued quick access to medical professionals, low wait times and the ability to schedule visits, which are consistent with prior studies emphasizing these factors. However, similar to the concerns raised in this study regarding physician competence and diagnosis accuracy, patients at Stanford's spine clinic expressed lower satisfaction in aspects related to physician care and room conditions.[12]

This cross-sectional study assessed patient satisfaction at a tertiary care hospital in Haryana by conducting exit interviews with patients from the outpatient department (OPD) and inpatient department (IPD) between January and March 2019. Satisfaction was evaluated across four domains: registration process, interaction with the doctor, hospital infrastructure, and medicine availability. The results revealed that 84% of patients were satisfied with OPD services, while 77% were satisfied with IPD services. Factors such as being male, literate and certain social groups were associated with higher satisfaction levels. Specifically, students, retired and unemployed individuals, as well as those from reserved social castes, showed higher satisfaction with IPD services. These findings align with similar results observed at Ahsan's Medical Complex in Azad Jammu and Kashmir, where patients generally reported high satisfaction with their medical care, particularly in areas like communication and overall care quality. However, both studies also highlighted areas for improvement, such as addressing financial concerns in healthcare, which may affect patient satisfaction. This emphasizes the need for continued efforts to improve healthcare services and ensure 100% patient satisfaction in both settings, while also focusing on addressing areas of concern, particularly related to the affordability and accessibility of care.[13]

A significant gap in the existing literature is the need for

additional studies on patient satisfaction in Pakistan's private healthcare industry. Most studies are focused on public-sector facilities, indicating a need for more information from the expanding commercial hospital scene. This study contributes to closing this gap by offering insights into patient perceptions of care quality at a significant regional private hospital.[17,18] Future research could use more rigorous selection procedures, such as random sampling, to ensure a more representative sample of patients receiving care at Ahsan's Medical Complex and other regional private hospitals. Additionally, incorporating qualitative data-gathering methods, such as in-depth interviews or focus group discussions, could provide a more nuanced understanding of the elements influencing patient satisfaction.[20] A notable limitation of this study was the absence of a formal ethical review committee. While efforts were made to obtain approval from local authorities, this does not fully substitute for the independent oversight provided by an ethics committee. Such oversight is essential to ensure the protection of participant rights and the confidentiality of collected data.

Overall, the PSQ-18 results suggest that this study population was generally satisfied with the medical care they receive, particularly high levels of satisfaction in interpersonal manner, communication, time spent with the doctor and accessibility or convenience. Some areas of potential concern include technical quality and financial aspect of care.

Conclusion:

In conclusion, this study shows that patients at Ahsan's Medical Complex are generally satisfied with their care, particularly in areas such as interpersonal communication, time with doctors and accessibility. These findings contribute to the growing body of research on patient satisfaction and can guide healthcare providers and administrators in delivering high-quality, patient-centered care.

Conflict of interest: none

Funding: none

Authors' contributions:

Fatima Khurshid: Conception of study, Manuscript Writing

Ayesha Khurshid: Study Conduction

Ahsan Ul Haq: Critical Review

Khawar Hussain Awan: Analysis / Interpretation

Sidra Qureshi: Analysis / Interpretation

Sana Tariq: Discussion

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REVIEW ARTICLE

BIOSAFETY IN THE AGE OF BIOTECHNOLOGY: CHALLENGES AND OPPORTUNITIES WITH GENETICALLY MODIFIED ORGANISMS

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ABSTRACT

Genetically modified organisms (GMOs) have emerged as a product of biotechnological advancements, raising concerns about biosafety and regulatory frameworks. This review explores the intersection of GMO technology and biosafety, covering its evolution, applications as well as regulatory measures. Scientists have used recombinant DNA technology, a mechanism for genetic manipulation to alter organisms. This has significant implications for organismal phenotypes and protein production. GMOs hold significant promise for agriculture, medicine, and industry offering potential benefits for food security and national development. However, concerns remain regarding their environmental impact and human health risks. These concerns include transgene transfer, biodiversity loss, and potential health implications, alongside regulatory frameworks, and risk management strategies. Several international agreements, like the Convention on Biological Diversity and the Cartagena Protocol on Biosafety, aim to regulate GMOs and safeguard biodiversity. Pakistan has implemented Biosafety Rules of 2005 and has established the regulatory bodies like the National Biosafety Committee (NBC). Bacillus thuringiensis (Bt) cotton, a genetically modified crop, is grown in Pakistan. Several studies on food safety and environmental safety have been carried out about BT Cotton's biosafety concerns. This review provides a comprehensive overview of the evolution, applications, risks, and regulatory landscape of GMOs, offering insights into their role in sustainable development and biosafety governance.

Keywords: *Genetically modified organisms (GMOs), Biosafety, Cartagena Protocol, National Biosafety Committee (NBC), risk assessment, containment measures*

INTRODUCTION

Genetically modified organisms are created through the application of biotechnology enabling scientists to transfer genes from one organism to another through genetic alteration. As a result, the organism develops differently, giving rise to new kinds of plants and animals. Biosafety is the system created through policies and procedures to ensure this application is done in an environmentally safe manner.[1] Through the use of genetic engineering, it is now likely to modify the genetic makeup of distinct animals, leading to the discovery of novel gene combinations.[2]

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Received: 26 Apr 2024; revision received: 24 Dec 2024; accepted: 26 Dec 2024

By the use of recombinant DNA technology, a genetically modified organism has had its genetic makeup changed.[3] Recombinant DNA technology is the process of linking DNA molecules from numerous sources into one molecule in a test tube. Consequently, changing the genes of an organism permits the altering of the protein production and/or phenotype. The term "test tube" in the context of genetically modified organisms (GMOs) describes the carefully monitored lab settings used to carry out genetic alterations. For gene editing procedures like CRISPR-Cas9 or recombinant DNA approaches, it entails employing test tubes or comparable equipment to ensure accurate alterations and reduce contamination. These techniques make it easier to produce organisms with desired

characteristics for use in medicine, agriculture, and research.[4]

Genes can be transferred through the manipulation of DNA via genetic engineering. Khan and Ramay in 2013 stated that genetically modified products encompass pharmaceuticals and vaccines, food items and their component parts, feeds and fibers.[5]

Plant breeders in the past have crossed different plant types for altering the genetic composition and introducing the desired features. 'Selective breeding' is the term for this technique.[6] These days, advancements in research and development have improved our knowledge of the science underlying genes. It is indeed possible for scientists to transfer a single gene from one organism's DNA to another resulting in the desired characteristics. For instance, a plant that can withstand a certain pest or illness, the transfer is also feasible to occur between unrelated species.[7] GMOs examples include genetically modified agricultural crops that are more productive and resistant to pests or diseases.[8] Most common GMO crops include soybeans, cotton and maize.[2] Genetic engineering and modern biotechnology have many uses in industry, agriculture, and medicine. In medical industry the genetically altered Escherichia coli produce recombinant insulin. By introducing the human insulin gene into E. coli, researchers can make the bacteria produce insulin that is exactly like what is produced in the human body. This method transformed the treatment of diabetes by offering a more scalable and safer substitute for insulin derived from animals.[9] It's no secret that contemporary biotechnology has great promise for boosting food security, agricultural production, and overall national development especially in developing nations where agriculture plays a major role.[2] Genetically modified organisms (GMOs) are created when new qualities are incorporated into plants, animals, and microorganisms through the application of genetic engineering in agriculture. These GMOs are subsequently used to cultivate, produce, and manufacture genetically modified foods.

Worldwide in 2019, genetically modified crops were cultivated on 190.4 million hectares land. The main purpose of the added features i.e. genetic modification in the agriculture industry was to keep the crops safe from pests and illnesses. GMOs are anticipated to become widely used as a result of growing acceptance towards GMOs and the development of more varied products. Modern biotechnology has a lot of potential benefits, but there was also a lot of concerns around the world that its products could be harmful to the environment or human health.[7]

People who were more considerate of the environment began to worry that the subsequent GMOs will spread quickly, effecting on-target and endangered species, reduce biodiversity, and other negative effects.[10-12] Some people thought that genetically modified foods (GM foods) made with contemporary biotechnology were completely unique and separate from traditional foods in terms of human health. They should thus be avoided as they had the potential to be hazardous (i.e. poisonous). Concerns about GMOs going beyond safety concerns include the possibility of a seed monopoly, harm to farmers' rights to save seeds and unethical behavior (such as "playing God"), etc.[13]

Animals benefiting from GMOs have higher resistance, productivity, and feed efficiency; they also provide superior meat, egg, and milk yields and have better diagnostic tools and animal health.[14] Better yields, flavor, and quality, shorter maturity times, higher resistance to pests, diseases, and herbicides as well as new products and growing methods are all benefits for crops. Bioprocessing for agricultural products has made natural waste management more effective. This includes 'friendly' bioherbicides and bioinsecticides, initiatives for conserving soil, water, and energy, as well as enhanced food security for expanding populations in society.[15]

Concerns about the use of genetically modified organisms were raised by Consulting and Audit Canada for Emergency Preparedness Canada (CACEPC) in 1995. The first category pertains to issues of access and intellectual property. This includes foreign exploitation of natural resources for biopiracy, the dominance of a small number of firms in the world's food supply, and the growing reliance of developing nations on industrialized nations. The second category involves etymological concerns. These include the transgression of inherent values of natural organisms, the manipulation of nature through gene-swapping across species, opposition to eating plant DNA and vice versa, and the stress imposed on animals. In certain nations (like the United States), labeling is not required for certain foods by U.S. Department of Agriculture (USDA) in July 2018, mixing genetically modified and non-GM crops might lead to confusing labeling.

Antibiotic resistance markers, allergies and unknown consequences are some potential health impacts that concerns the use of GMOs. Possible implications on the environment include loss of biodiversity of flora and fauna, unintentional transgene transfer through cross-pollination, and unknown effects on other creatures

(such as soil microorganisms).[16] Recent advancements in GMOs related to society could be biased towards the needs of wealthy nations.

Convention on Biological Diversity (CBD) and Cartagena Protocol on Biosafety

An addition to the Convention on Biological Diversity is an international accord on biosafety called as the Cartagena Protocol on Biosafety. The goal of the Biosafety Protocol is to safeguard biological variety against the possible threats posed by genetically modified organisms. An international agreement known as the Convention on Biological Diversity (CBD) was made at Rio de Janeiro Earth Summit in year 1992. Preserving biological variety, making sustainable use of its constituents and distributing benefits from genetic resources fairly and equally are the three fundamental objectives of the Convention. It became operative on December 29, 1993 after being available for signature on June 5, 1992. Pakistan ratified the Convention on June 5, 1992, and was accepted as a party on July 26, 1994.

The conservation of biological diversity was acknowledged as "a common concern of humankind" and an essential component of the development process for the first time in international law by the agreement. Genetic resources, animals, and ecosystems are all covered under the pact. It connects the financial objective of using biological resources responsibly with conventional conservation initiatives. It establishes guidelines for the just and equal division of gains from the use of genetic resources, particularly those intended for commercial application. Through its Cartagena Protocol on Biosafety, it addresses technological development and transfer, benefit-sharing, and biosafety issues. It also covers the quickly developing sector of biotechnology. A significant feature of the Convention is that its terms are obligatory on the countries who ratify it.[17]

A Cartagena Protocol on Biosafety to the Convention on Biodiversity was adopted on January 29, 2000, and it went into effect on September 11, 2003, to adopt adequate measures on trans boundary movements of (live GMOs) LMOs. The Protocol addresses the safe handling, transmission, and application of living modified organisms (LMOs) including transnationally transmissible microorganisms, plants and animals. The goal of the Cartagena Protocol is to prevent negative consequences on biodiversity conservation and sustainable usage while avoiding needless disruptions to the global food trade. As of 2018, 198 nations, including those in our region like Bangladesh, India, and Iran, had deposited instruments of ratification or accession to the Cartagena Protocol with the UN. Pakistan signed this protocol on June 4th, 2001.[18]

Risk Communication, Management and Assessment posed to/by GMOs:

It is generally acknowledged that each nation must set up a regulatory framework expressly to evaluate the safety of modern biotechnology products due to the possible threats that genetically modified organisms may pose to humans and the environment whether actual or perceived.[17] Each nation can select from several choices to investigate the advantages of contemporary biotechnology while also addressing worries about the possible negative impacts of the introduction of genetically modified organisms on the environment and human health. The options pertain to the goals and design of the regulatory system, the means of implementation and regulatory structures, as well as other factors like public involvement, the ability to stand alone or integrate into other national goals, and the ability to be in line with other regional and international commitments. [19]

Regardless of the approach chosen by the nation, a biosafety framework usually consists of four key components: a guiding framework, a system for compliance & monitoring, a national biosafety policy tool (such as a decree, act & law) and procedures for guaranteeing accountability, transparency, and public participation.[20]

GMOs Fate in Pakistan and Role of the Ministry of Environment

In order to fully utilize this cutting-edge technology and ensure the safety of both humans and the environment, Pakistan Biosafety Rules were notified on April 21, 2005. These rules regulate the production, importation, and storage of genetically modified organisms and gene technological products for research purposes, regardless of whether the research is carried out in public or private research and development laboratories or teaching laboratories. The effort covered the development of genetically modified organisms for use in plants, animals, and microorganisms, as well as their commercial release into the field and their import, export, sale and purchase.

Following the publication of the Biosafety Rules in 2005, the National Biosafety Guidelines in 2005 were created. These guidelines specify the appropriate

protocol and documentation needed to conduct the aforementioned GMO-related activities within the safety parameters. Legal protection for the National Biosafety Guidelines and their execution in the nation is provided by the Pakistan Biosafety Rules 2005.

Three tiers, National Biosafety Committee (NBC), Technical Advisory Committee (TAC), and Institutional Biosafety Committee (IBC), are the foundation of the framework for overseeing and putting the National Biosafety Guidelines into practice, as outlined in the Biosafety Rules, 2005. Overseeing all laboratory work, field trials, commercial release, import, export, sale, and procurement of genetically modified organisms and their products, NBC is led by the Secretary of the Ministry of the Environment. According to the National Biosafety Guidelines 2005, all applications and requests for any kind of GMO-related activity must be presented to the appropriate IBC, which serves as the baseline regulatory, implementing and monitoring body. These must then be given to TAC for evaluation, and NBC will take any additional required action based on its recommendations.[21]

Guideline for work with genetically modified microorganisms

When working with genetically modified microorganisms, initial evaluation of the nature of the biological system is required for microorganisms that have previously been used safely in the field. Microorganisms from a strain proven to perform the same functions as those used in previous documented field studies are considered suitable. These microorganisms must be limited to locations and environments similar to the earlier studies and have a proven history of safe use.[22]

As stated in the Regulations and Containment Section, the study may continue with appropriate containment levels for experimental microorganisms that do not meet the previously indicated requirements. Microbes are contained appropriately biologically, meaning that before being field tested, they are rendered non-reproducible; alternatively, modifications are made to restrict the amount of time that microorganisms can survive outside and confine them within target areas; recombinant DNA techniques are applied to microorganisms only within designated areas; and physical measures are taken to prevent microorganism dispersal within the target areas or trial site.[23]

For microorganisms that have not previously been used safely in the field, a preliminary risk assessment may be performed to evaluate the complete spectrum of potential environmental consequences. Biological control of plant pests can overpower target species and produce harmful toxins or pathogens. It may leave toxic residues with secondary negative effects or spread diseases in wild populations. Excess nutrient supply from controlled plants can disrupt the chemistry of nearby plants which should be monitored.[24]

Guideline for work with genetically modified plants

When working with genetically modified plants in the field, it is important to first analyze the biological systems' nature. Work may continue in compliance with the fundamental guidelines suitable for the specific plant in question if experimental plants are thought to have a history of safe field use. The organism must be modified through standard breeding techniques, showing unique traits that distinguish it from traditionally bred plants. The introduced genetic material should also be safe and not harmful to the environment. [25]

If experimental plants don't fit the above requirements, work can still be done as long as the right containment level and standards are followed. There must be no cross-hybridization, plans in place to restrict the spread of plants and plant materials, and introduced gene expression that is stable and does not change in response to environmental changes, among other requirements, for the aforementioned containment measures to be effective.[9]

For the plants that have not previously been used safely in the field, work may begin with a preliminary risk assessment to determine the effects on the experiment site's ecology: enhanced resilience to diseases and pests, proclivity for weeding, and effects on other targets and non-target organisms. Effects on open-air ecology, possibility for cross-hybridization, weed promotion and stimulation, invasion of natural populations beyond the trial site, and effects on other factors in the environment may also be addressed.[24]

Guideline for work with genetically modified animals

The following guidelines should be followed while breeding genetically engineered animals: Identifiable containers should be used to breed non-engineered animals, and genetically modified animals should be kept separate from other animals. Animals modified through genetic engineering should be housed and identified individually. After sterilization and burning if required, wastes associated with genetically modified animals should be disposed of. GMO animals should be

transported outside of the work area in containers that are strong and well-constructed to keep them from escaping. Genetically engineered animal containers need to be handled carefully, and this needs to be mentioned. Performance testing should be conducted on the facilities, equipment, and management systems used in these investigations.[26]

At every work area, a sign identifying genetically modified animals should be displayed. Additionally, the area must be kept clean, personnel should only wear work clothes there, and the person in charge must inform receiving personnel of all pertinent information when transferring genetically modified animals to other facilities.[24,27]

Regulation and containment for experimental genetically modified microorganism

Having Past Field Experience: To conduct field testing on microorganisms that have previously undergone fieldwork, a project proposal must be submitted to the IBC. This proposal will assess the adequacy of biosafety protocols. Regulatory compliance and the specific microorganisms being studied must be taken into consideration while designing containment and control measures for fieldwork. Only after gaining an IBC endorsement can the work start. All assessments and recommendations must be sent by the IBC to the NBC via the TAC to obtain documentation and information.[28]

Without Past Field Work Experience: Field testing experimental microorganisms without previous fieldwork experience should be carried out with guidance and approval from the IBC and NBC. Approvals in these situations will be determined by the biosafety risks that may be discovered from the submitted written proposals. Before receiving approval from the NBC, the project supervisor is not allowed to start any work.

Since untested experimental microorganisms carry dangers, the following needs to be considered when designing procedures for field trial control and containment: The NBC has approved the levels of regulation and containment for the testing medium, which includes soil, water and air used for microorganism analysis. A clear demarcation and posting of the boundaries are required for testing zones. "No Entry" placards. Testing locations are used under tight regulations. An NBC-approved method of close observation and efficacy is used to track the spread of experimental microorganisms. At the end of the project, plans are established to eliminate or deactivate the experimental microbes. Additional actions that the IBC or NBC judge appropriate.[24]

Regulation and containment for experimental genetically modified Plants

Despite previous field work experience, experimental plant field testing still involves submitting a proposal to the IBC that will assess the effectiveness of the biosafety measures. This proposal can be submitted at home or abroad. The applicable regulations should be followed while implementing measures to contain and manage field work. In certain cases, work may commence only after gaining an IBC endorsement. The IBC must transmit all suggestions and the committees' assessments, to the National Biosafety Committee through concerned ministries for records and information.[28]

IBC and the relevant ministry should provide advice, counsel and direction before field testing experimental plants that have never been subjected to previous field operations. Permissions in these situations will be granted based on any biosafety information gleaned from the submitted written proposals. It is forbidden for the project manager to start working until the NBC gives their approval.[25]

The scale and duration of contained cultivation is appropriate to both the nature of the investigation and the particular plant, and measures for the control and containment of field trials must account for the following, given the risks associated with using untested experimental plants: contained tests may be carried out in plant glass houses. For the specific plant being studied, the selected location is appropriate. Isolated from feral populations, test plots are fenced in. Along the perimeter, there are "No Entry" signs posted regularly. When work is over, plans are made to gather, burn, and destroy experimental plants and plant materials.[9]

The IBC regularly surveys and directs plant cultivation in accordance with the growth or developmental trends of each individual plant.[28,29]

Regulation and containment for experimental genetically modified animals

After gaining IBC approval, genetically modified animals with a history of previous field experience, whether domestically or overseas, may undertake field trials. For records and information, the IBC is required to forward all recommendations and the committee's evaluation to the National Biosafety Committee (NBC) via the relevant ministry. Under the supervision, advice,

and guidance of IBC and the relevant ministry, field testing of experimental animals that have never been utilized for field research should start. The project manager is not allowed to start working before the NBC gives its approval. Field trials must be controlled and contained at all times, considering potential dangers related to the use of genetically modified animals.[26,28,30]

Implementation of Project "National Biosafety Centre"

The Secretariat of the National Biosafety Committee is the National Biosafety Centre. The necessary infrastructure for putting the 2005 Biosafety Guidelines and Rules into effect is provided by the National Biosafety Centre. Protecting people against the unfavorable effects of genetically modified organisms is the center's main goal. Public notifications, notices, workshops, and seminars may be organized nationwide on the federal and provincial levels to increase awareness about GMOs and the risks they pose to human health and the environment.[31,32]

A Case study

Patent GMO, Bt Cotton, which has a toxin gene from a Bacillus species added to it, is genetically engineered in Pakistan. Several studies on food safety and environmental safety have been carried out about Bt Cotton's biosafety concerns.[33,34] Research on the security of the environment pollen escape revealed that the pollen travel is restricted because of precautionary measures; there is no possibility of transfer from cultured diploid species to tetraploid Bt hybrids, now the wild species of Bt cotton are nonexistent. The study found no significant variations in germination and vigor between Bt and non-Bt cotton. Therefore, there is no discernible difference between the two types of cotton in terms of weediness and aggression potential.

Impact of Bt on non-target organisms

On non-target species like sucking pests (aphids, whiteflies, and mites), cotton hybrids had no toxic effects. Both Bt and non-Bt cotton hybrids showed the continued activity of beneficial insects such as ladybirds, beetles, honeybees, and spiders. Bt protein found in soil, indicate that the Cry1Ac protein was broken down quickly in the soil, protein was not found in soil samples. According to calculations, the half-life of the Cry1Ac protein in plant tissues is 41 days, which is similar to the rates of degradation observed for Bt microbial formulations. The impact of Bt protein on soil microflora was determined by comparing the populations of microorganisms and soil invertebrates, such as earthworms, in Bt and non-Bt samples. The results indicated no discernible differences in these populations. Bt protein impact on soil microflora between Bt and non-Bt samples revealed no appreciable variation in the population of microorganisms and soil invertebrates, such as earthworms.[9,35]

Conference

In conclusion, a strong regulatory framework and extensive biosafety procedures are needed for the production and use of genetically modified organisms to mitigate any potential dangers. While there are advantages to GMOs, such as increased food security and agricultural production, concerns over their effects on the environment and public health are legitimate. Nations like Pakistan have regulated the manufacture, import, and use of genetically modified organisms by establishing rules and supervision systems such as the National Biosafety Guidelines (2005) and the Pakistan Biosafety Rules (2005) to achieve a balance. In conjunction with the National Biosafety Centre, this multi-tiered system of committees seeks to safeguard the environment and human health while promoting the appropriate use of genetically modified organisms. Ultimately, a comprehensive approach that considers both the potential benefits and the legitimate concerns surrounding GMOs is essential for their safe and sustainable deployment.

Future Recommendations

In future, ongoing assessments of the long-term effects of genetically modified organisms on the environment and human health to inform regulatory actions, should be made. Expanding the global collaboration and standardize biosafety frameworks to promote information exchange and standardized risk assessment. Developing public involvement and awareness campaigns to help people better grasp the advantages and disadvantages of genetically modified organisms. Encouraging the study of substitute sustainable agriculture methods to expand the range of options available to replace GMOs.

Conflict of interest: none

Funding: none

Authors' contributions:

Ayesha Saeed: Conception of study/Designing/ Planning/ Manuscript Writing

Sidra Abbas: Manuscript Writing

Shaghufta Perveen: Manuscript Writing

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REVIEW ARTICLE

ADDRESSING RESEARCH ETHICAL DILEMMAS ON COGNITIVELY IMPAIRED MENTALLY ILL PATIENTS (CIMI): INSIGHTS FROM A PRISMA-GUIDED REVIEW

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ABSTRACT

Participants reserve the right to privacy and confidentiality like other patients to maintain their dignity. This research aims to identify the problems encountered by the researchers and the solutions they proposed while researching cognitively impaired mentally ill patients, to encourage the involvement of this neglected population in terms of research and hence management. The objective of this review was to identify the ethical solutions while researching cognitively impaired mentally ill patients. 21 studies, fulfilling the inclusion criteria from 2003-2024 were selected. This review follows the Cochrane Book of Systematic Review and PRISMA guidelines 2020. Informed consent remained the most inevitable challenge for researchers. There should be the revision of policies for researching such vulnerable populations to find ways to minimize the ailment while keeping in mind the privacy and safety concerns of research participants. Ethical recommendations for research involving cognitively impaired, mentally ill patients include adaptive consent processes using simplified language, involvement of legal guardians, and continuous consent reassessments. Privacy protections and strict data handling protocols are essential, along with minimizing risks and maximizing benefits. Researchers should receive specialized training, and studies should be regularly reviewed by ethics committees to ensure adherence to high ethical standards.

Key words: *Ethics, Cognitive Impairment, Informed Consent, Cognitively Impaired Mentally Ill, Ethical Dilemmas*

INTRODUCTION

The ability of individuals to make a meaningful decision becomes questionable when they are cognitively impaired or mentally ill, so, often neglected as research participants or consent givers.[1] This violates their right to decision-making alongside the potential risk of undertreatment. But why this is happening, remains a question, so we conducted a review that involves challenges faced by researchers while conducting research on such patients and their recommendations. Cognitively impaired mentally ill (CIMI) patients have a mental disability that considerably impairs cognition, or capacity to recall and process information. This includes Alzheimer's disease, schizophrenia, and severe depression.[2,3,4] The prevalence of cognitively impaired mentally ill patients is difficult to estimate, as there is no agreed-upon definition of what constitutes "cognitive impairment." However, multiple studies revealed that 1.7-40% of individuals suffering from common infections report cognitive impairment.[5] The unknown incidence of CIMI patients is due to the underdiagnosed cases or if diagnosed, do not opt for medical treatment.[6] Still, estimates reveal up to 10% of the population may suffer cognitive impairment at some point in their lives.[7,8]

CIMI presents a unique challenge when it comes to conducting research. The nature of their impairment indicates an inability to give appropriate consent or an inability to understand the information given to them. This can make it difficult to obtain reliable data for research patients.[9] A study involving cognitively

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Received: 02 Oct 2024; revision received: 26 Nov 2024; accepted: 27 Dec 2024

impaired patients needs a special consideration of the benefits-to-risk ratio while proceeding with research. Such types of research can be beneficial for the patients and may enhance evidence-based patient care,[10] but the patient's safety and ability to process or understand the provided information must also be considered as risk factors to avoid any physical, emotional, or mental harm.[11,12]

Studying CIMI patients is tricky, so it's better to work as a team of professionals who are already a part of that community for the selection of an appropriate research design.[9] Choosing an appropriate research design is crucial so as to provide an answer to the research question. For example, if someone wants to determine the efficacy of some treatment, they may select a randomized control trial but as these patients might be unable to give informed consent, it is important to obtain special consent from ethical review boards or policymakers to ensure patient autonomy.[13]

Adhering to ethical principles protects the rights and welfare of the participants along with increasing the researcher's value.[14] Furthermore, researchers must ensure that confidentiality is maintained and that collected data is used in a way that is respectful of participants' rights and dignity.[15,16] The goal of research is to improve the understanding of mental illness and develop new treatments but it is also important to remember that patients may be vulnerable and risks should be minimized as much as possible.[14,9,15]

The aim of this review is to find the difficulties encountered and recommendations while conducting research on cognitively impaired mentally ill patients. This may enhance the recruitment of both healthy volunteers and people with mental illness as they express identical viewpoints.

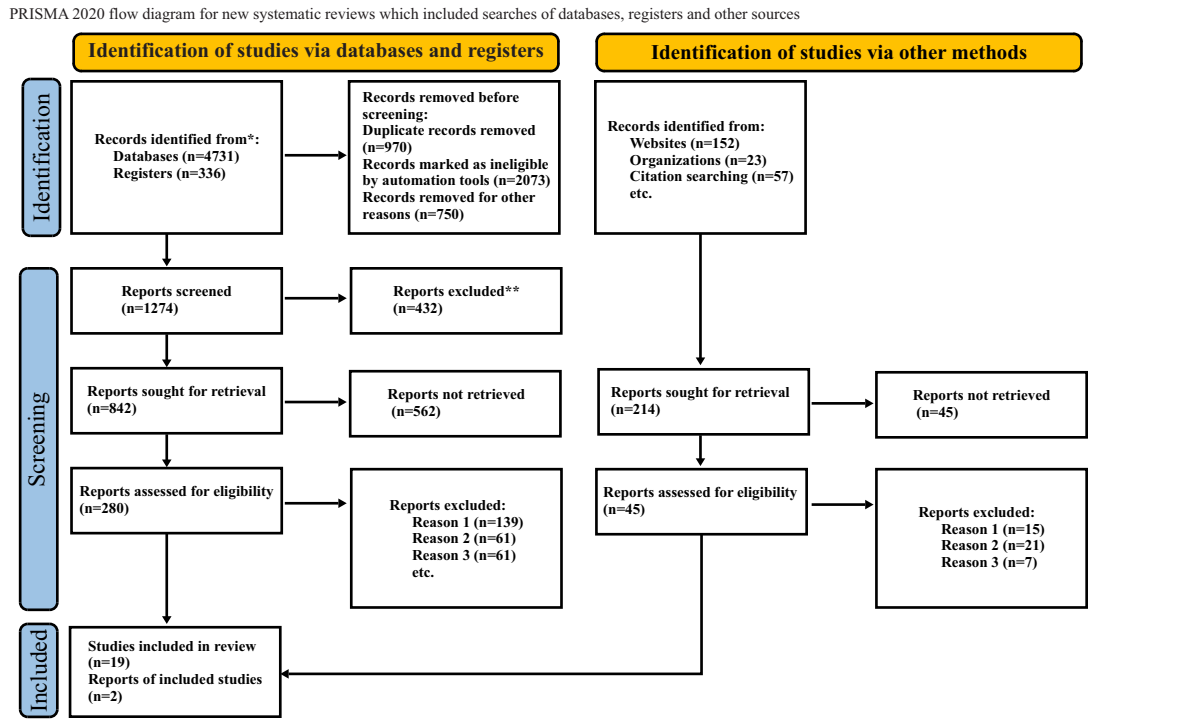
The rationale of this systematic review is to understand the difficulties encountered during conducting research on cognitively impaired patients and find ethical considerations to counter such challenges while keeping in mind the safety and wellness of research participants.

METHODOLOGY

The duration of this systematic review was November 2023- March 2024. The data was extracted from November 2005 to January 2024, and out of 5299 matching articles, only 22 discussed the ethical challenges and considerations while researching cognitively impaired patients (Fig 1&2). Keywords used were ethics and research, Informed Consent, Cognitive impairment and ethics, challenges, and cognitive impairment. (Table I)

Data Selection:

Various databases like WOS, PubMed, ScienceDirect,



*Consider, if feasible to do so, reporting the number of records identified from each database or register searched (rather than the total number across all databases/registers)
**If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools.

Figure 1: Prisma flow diagram showing a selection of studies for current systematic review.

Willey's, Google Scholar, and registries were searched for the acquisition of data via different automation tools like Segment, Protocols, and Zapier. The last data was searched on January 2024, all authors worked independently for data search and self-reviewed the data after the use of automation tools. Data extraction involved a standardized form where relevant information on ethical challenges was systematically identified. Quality assessment was conducted using a modified risk of bias tool to evaluate the robustness of each study. Automation tools such as Segment, Protocols, and Zapier played a crucial role in retrieving data from diverse databases by filtering relevant studies based on predefined keywords and automating the removal of duplicates. These tools ensured consistency and reduced the risk of bias in study selection. All data was reviewed independently by authors to validate the findings, with counter-reviews conducted to further ensure accuracy. To limit the bias, the received data was counter-reviewed. Quantitative or qualitative studies, particularly clinical trials and epidemiological studies describing ethics and informed consent while conducting research on cognitively impaired patients were included.

Inclusion criteria:

1. Studies on ethical challenges and considerations while researching cognitively impaired patients.

Exclusion criteria:

1. Studies involving patients without significant cognitive impairment.
2. Studies focusing on clinical challenges in mentally ill patients, rather than ethical challenges while conducting research.

Study Protocol

Guidelines from the Cochrane handbook of Systematic Reviews was followed while conducting this systematic review and is reported based on PRISMA 2020 guidelines. The initial draught was produced after careful consideration of these papers. The contributors' levels of clinical and research experience were integrated into the second edition. On a virtual platform, a thorough conversation about the paper's numerous features was done with each author. A position on ethical matters was developed by combining the contributions of all authors.

RESULTS

The final selection of 22 studies was carefully reviewed to address the existing challenges and ethical recommendations associated with conducting research involving vulnerable populations, particularly those with cognitive impairments or severe illnesses. These studies, originating from diverse research backgrounds, emphasize global perspectives on ethical considerations, reflecting various legal, cultural, and institutional challenges in research involving consent and patient autonomy.

While assessing the results of each study we found some important challenges which were common in most of the studies and created significant impact. These included informed consent, patient patient-centric environment, social stigma, and obtaining ethical approval from concerned departments. Table I, Figure 2

The current study also proposed certain ethical recommendations based on the results. These include developing simplified and accessible consent materials alongside cognitive assessment tools tailored to capacity levels that may ensure that even individuals with limited cognitive function can participate meaningfully. It also

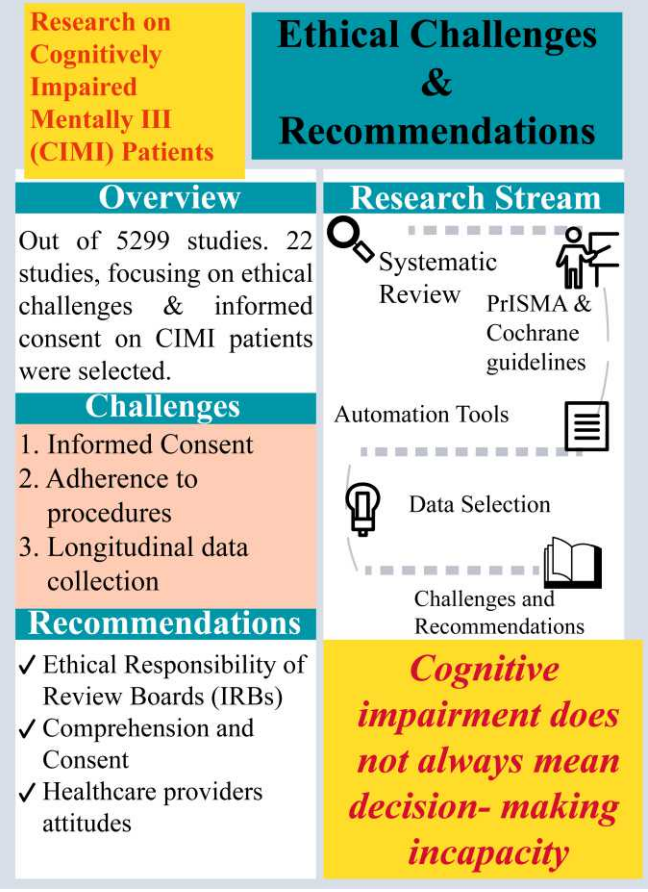


Figure 2: An overview for visualization of the main crux of the study.

suggests supportive decision-making while respecting participants' right to assent or dissent, even with cognitive limitations. Researchers should strive to

maintain autonomy and safeguard human rights throughout the study. The current study also presented solutions for following national and international ethical guidelines, including principles like autonomy, beneficence, and justice, that may protect against coercion and ensure participants' well-being. We also propose employing validated, easy-to-use assessment tools tailored to older or cognitively impaired participants to improve the feasibility of assessing consent capacity without imposing significant time constraints.

Table I: Ethical challenges faced by the researchers and the best-proposed solutions for research on Cognitively Impaired Mentally Ill patients.

Sr. No.	Author	Challenges	Ethical recommendations
1.	Laing (2024)[17]	Consent and lack of emotional and social support to the consent givers.	Attention should be paid to the laws and policies involving consent from mentally ill patients or their assigned relatives.
2.	Lange MM (2013)[18]	Informed Consent.	The importance of autonomy also requires that, even if a surrogate is chosen, participants should be told about the potential research before agreeing or disagreeing to participate.
3.	Witham G (2015)[19]	Lack of Patient patient-friendly environment.	Health practitioners can start to develop more flexible ways to care through interaction with the larger environment by allowing the circumstances to develop where different choices are acceptable.
4.	Warner J (2008)[20]	The Mini-Mental State Examination alone was insufficient to predict the ability of informed consent after controlling for confounding factors.	To determine the eligibility of giving consent, cognitive testing alone is insufficient. Researchers and practitioners should be aware of the difficult procedures involved in assessing capacity.
5.	Monroe(2012)[21]	Social stigma and barriers	When studying people with cognitive impairment, researchers must be careful to take several precautions to protect all participants. Researchers should not be discouraged from adding people with dementia to their studies by the need to take the time to implement additional protections.
6.	Duke(2010)[22]	Numerous issues are raised by the literature on palliative care while conducting research on such patients.	Concerning the morality of studying patients with life - threatening illnesses, specifically if such is morally acceptable, the researcher must conduct the study.
7.	Casarett (2003)[23]	Unawareness/lack of following the guidelines for taking informed consent.	Guidelines for the prudent application of processes for evaluating decision-making competence must be followed.
8.	Williams et al (2006) [24]	Bias	Patients in healthcare as well as the people who are caring for them want to take part in studies. Younger hospice patients had a higher likelihood of being enthusiastic about taking part. The desire to participate was the same for older patients in the hospital and older non -hospital patients. So, such patients should be included, and the researcher should not be biased.

9.	M.Ruiz(2014)[25]	Informed consent and Ethical committee barriers.	The study demonstrates that subjects with dementia can still contribute significantly to the treatment or handling of fellow patients.
10.	*Doyle, C* (2013)[26]	Informed consent	The review's findings were analyzed considering national guidelines, and it was determined how capacity should be assessed, what constitutes best interests, how to ascertain and respect the assent and dissent of a person with dementia, and whether such individuals should be involved in high-risk research.
11.	*I.Hellstrom*[27](2012)	Informed consent. Ethical review barriers.	Institutional policies vary widely, researchers must collaborate closely with individual review boards to guarantee safety and scientific rigor.
12.	G.Hougham (2003)[28]	Lack of IRB approval and informed consent.	Policies must be made to protect the human rights of giving informed consent or not and must be followed.
13.	U.Oruche (2009)[15]	Informed consent.	Additional ethical issues arise when using subjects with cognitive impairment in research because they may be more susceptible to coercion. Because of this, nurse researchers not only need to comprehend the common rule's additional precautions for protecti ng participants with cognitive impairments in research but also the principles of informed consent (autonomy, beneficence, nonmaleficence, and justice). These protections include acquiescence, legal representation, and prior informed consent.
14.	N.Ries (2020)[29]	Informed consent by the subjects.	Researchers revealed inconsistent methods for determining whether potential volunteers could give informed consent to their experiments. For this, a variety of instruments are utilized, ranging from more broad cognitive function screens to research -specific tests (such as the MacArthur Competence Assessment Tool for Clinical Research) (e.g., Mini Mental State Exam).
15.	L.Dunn (2015)[30]	Noncollaboration of research results to research participants.	Researchers have different ethical responsibilities when "returning results" to study participants than clinicians, who must follow the beneficence and non-maleficence principles and return results as part of the entire therapy strategy.
16.	T.Gilbert (2017)[13]	Time constraints and informed consent. Subjects' lack of interest.	The best-validated questionnaire now is the MacCAT -CR. But it seems time-consuming and tough to use. Because of its simplicity, relevance, and applicability to older patients, a more modern test called the University of California Brief Assessment must be used.
17.	M.Chandra (2021) [11]	Informed consent	The logistics of including senior citizens in research, improving caregiver assistance, and promoting supportive decision-making must be considered by research policies. Along with enhanced care planning that will guarantee the well-being of study participants, it will also need to address the development of capacity assessment tools.
18.	L.Fields (2015)[31]	Informed consent.	Patients' comprehension of treatment alternatives may be hampered by cognitive limitations. Best practices should be followed when assessing a patient's ability to comprehend treatment alternatives if they have cognitive impairment.

19.	O.Silva (2020)[32]	Participants autonomy.	It is essential to design and carry out ethical studies to protect participants' rights, autonomy, and general well-being. An ethics board evaluation does not signal the start or end of ethical research. In a broader examination of morality, the "person -oriented research ethics" paradigm (American Anthropological Association 2012; Cascio and Racine 2018) offers benchmarks for comprehending the relational and experiential facets of research ethics.
20.	Van Rookhuijzen (2014) [33]	nil	These older subjects were able to develop supported justifications for taking part in a clinical trial despite their (moderate) cognitive impairment. Therefore, it is conceivable that they were able to decide this for themselves, as confirmed by their family. Future clinical research on older adults with minor cognitive impairment must consider the desire to give selflessly to projects that may help others.
21.	H. Taylor (2015) [34]	Patient access for consent	In addition to the substituted informed consent by authorized individuals, vulnerable research participants should be given the ability to at least consent to the research procedure.
22.	L. Roberts (2014) [35]	Ethical concerns for vulnerable participants	Studies involving sick persons are viewed as morally acceptable by clinical research volunteers and healthy clinical research "nave" subjects, but their replies reveal concern about research involving vulnerable subpopulations and research that imposes significant burdens and dangers. Research participants who are physically ill may be more eager to undergo difficult and dangerous research.

DISCUSSION

The current review included 22 research studies from 5299 studies selected from different databases, registrars, and websites from the period 2005-2024. The present study suggests exclusion of individuals with cognitive impairment from trials due to their inability to consent, follow procedure, and give longitudinal data is a significant barrier to this type of research. However, depending on the risk-benefit profile, numerous studies among older persons show a strong willingness to participate in research if they become disabled and unable to give consent. Instead of excluding people with dementia from studies, one institutional review board (IRB) recommended that researchers screen for decisional capacity, conduct more thorough and detailed capacity assessments for studies involving higher levels of risk, and ask for an IRB-appointed proxy for those who are unable to consent.

Most patients with a serious mental disease may make logical decisions about their medical care and can participate in decisions about treatments despite temporal deficits, according to authors of several research. As a result, the degree of impairment that may be a component of the mental disease rarely equates to decision-making incapacity. The results also show that, in routine clinical practice, people with psychotic disorders or other serious mental illnesses can make sophisticated risk-reward judgments. Small variations from ideal performance may be caused by limitations in the capacity to completely comprehend the worth of various possibilities for responses and choices. [33-35]

The current study emphasizes the responsibility of ethical review boards to particularly focus on studies in CIMI patients and maintain follow-up till completion of such studies. This highlights the role of the Ethical Committee in previous studies, which oversees not only approving the start of studies but also continuously ensuring that the approved study complies with the ethical standards.[36] According to a study, certain individuals may be more susceptible to engaging in misconduct, highlighting an essential consideration for all involved in research ethics. Ethical guidelines in

research recognize that vulnerability is an intrinsic aspect of the human experience. This analysis centers on developing a typology of vulnerability sources and demonstrating how these different sources create specific obligations for researchers. A key principle is that researchers must avoid actions that increase the vulnerability of study participants. To illustrate this approach, we examine two cases: an international research study involving a vulnerable population and a domestic study of individuals with impairments.[18]

The current study highlighted challenges in gatekeeping individuals with intellectual disabilities and mental health issues. Beyond the oversight of ethics committees and governance, identifying and recruiting vulnerable participants often proves difficult due to healthcare providers' perceptions and judgments on whether to "permit" access to certain patient groups. These perceptions and conclusions appear to be closely tied to ingrained attitudes toward mental illness. Similarly, William's clinical trial encouraged the inclusion of this demographic in research since they have shown that many in-patients were interested in participating in research and could explain the benefits and barriers.[24,22,23,26]

The study emphasizes that researchers must recognize and mitigate vulnerabilities in participants, ensuring their responsibilities do not exacerbate these vulnerabilities, particularly in marginalized populations. In contrast, few authors declared that patients' comprehension of treatment alternatives may be hampered by cognitive limitations. Similarly, others report that when assessing a patient's ability to comprehend treatment alternatives if they have cognitive impairment. This is necessary for proper informed consent. Therefore, it is crucial to correctly identify patients whose capacity is in doubt, assess their capacity, determine their competence, and rely on suitable alternative consent procedures.[31,32,30]

CONCLUSION

The significance of the inclusion of cognitively impaired individuals as research participants is beyond doubt. Neglecting such a population may lead to greater suffering in already vulnerable populations owing to a lack of appropriate data to support best clinical practices.

CIMI patients are unable to decide consent and hence are at risk of being exploited, so it is a huge responsibility for a researcher and team to be ethically imperative and take necessary steps while conducting research on this vulnerable population. Ethical considerations that need to be addressed include obtaining informed consent from the research participant or the nearest of kin/guardian if the participant doesn't hold the capability to understand the information provided. Researchers should maintain confidentiality and not let the integrity of participants hurt. If proper precautions are followed, then research may include such vulnerable populations in their study. Researchers may include such individuals by offering alternative exclusion until a fundamental shift in the viewpoint of funders of ethical boards takes place. Additionally, a transdisciplinary approach may provide a deeper comprehension of how this issue impacts individual disciplines and might aid in working as a unit to mishandle such a population.

List of Abbreviations:

Cognitively Impaired Mentally Ill (CIMI)

Institutional Review Board (IRB)

Limitations of study

Non-availability of open-access articles is the major limitation of this study.

Conflict of Interest: None

Acknowledgment: None

Funding: none

Authors' contributions:

Aqsa Saleem, Iqra Saleem, Duaa Younus, Nimra Khalid, Seher Naeem, Sampana Fatima: Conception of study / Designing / Planning, Analysis / Interpretation / Discussion, Critical Review, Manuscript Writing

Delima Maria: Analysis / Interpretation / Discussion, Critical Review, Manuscript Writing

Rafia Yasmin Khan: Analysis / Interpretation / Discussion, Manuscript Writing

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