ISSN 0971-8834 RNI-JK-ENG-1994-2673

JK-Practitioner

International Journal of Current Medical Science & Practice

October-December 2022 Volume 27: Number 4 www.jkpractitioner.com

CONTENTS

Review

Original Articles

Continued on inside front page…..

INDEXING AND ABSTRACTING:

THE JOURNAL IS INDEXED AND ABSTRACTED IN IndMED/EMBASE/EXCERPTA MEDICA, INDMED, SCOPUS, PUBMED (FOR MEDLINE) ULRICH'S PERIODICALS DIRECTORY USA, INDEX ACADEMICUS (IA), INDEX COPPERNICUS, EBSCO, GOOGLE SCHOLAR AND IS LISTED WORLD WIDE IN UNIVERSITY AND COLLEG DATABASES. Bibliographic details of the journal available in ICMR-NIC centre's IndMED database (http://indmed.nic.in)Full text of articles being made available in medIND database (http://medind.nic.in) (2002-2015 issues only) and at www.jkpractitioner.com (1994 till date)

Original Articles - Covid-19

Case Reports

DECLARATION UNDER SECTION 5 OF THE PRESS AND REGISTRATION BOOKS ACT OF ACT OF 1967 AS A AMENDED FROM (SEE RULE 1)

TITLE	JK-PRACTITIONER
PLACE OF PUBLICATION	SRINAGAR
PERIODICITY OF PUBLICATION	QUARTERLY
PUBLISHER'S NAME	DR. G. M. MALIK
WHETHER CITIZEN OF INDIA	YES
ADDRESS	JHELUM MARKET, BATMALOO
EDITOR'S NAME	DR. G.M. MALIK
WHETHER CITIZEN OF INDIA	YES
ADDRESS	JHELUM MARKET, BATMALOO SRINAGAR **190010,** KASHMIR INDIA
PARTICULARS OF OTHER INDIVIDUALS WHO ARE OWNERS/SHARE HOLDERS OF NEWSPAPER	

I Dr. G.M. Malik declare that the particulars given above are true to the best of my knowledge and belief.

www.jkpractitioner.com

Volume 27, Number (4)
October-December 2022

JK-Practitioner
ISSN 0971-8834

Volume 27, Number (4)
RNI-JK-ENG-1994-2673

AIMS AND SCOPE

JK-Practitioner is a multidisciplinary Medical Journal published quarterly from Srinagar. Emphasis is placed on matters related to medicine in the country in particular, while articles from anywhere in the world are given due importance. Besides original articles and case reports the journal includes clinical reviews, guest articles and special articles on current topics in medicine and therapeutics

INFORMATION FOR SUBSCRIBERS:-

The **JK-PRACTITIONER**- Frequency Quarterly, one volume per year beginning in January. Other issues in April, July and October. **Correspondence regarding Editorial matters** should be addressed to the Chief Editor, G M Malik, PO BOX No.884,GPO, Srinagar, Kashmir (INDIA).**Annual Subscription rates:-Personal** Rs.1500/- **Institutional** Rs.2000/-, **Reduced** Rs.1200/-**Institutional rate** applies to Libraries, Schools, Hospitals, Clinics,Commercial and Private institutions and organisations. **Reduced rate** is avaliable for medical students only.**Rates outside India** US $100/-Gulf countries SR 100/- .All other countries US $100 or equivalent. **Concessional Rate for personal subscription** is available for a three year term at Rs.4000/-. Outside India US $ 200/- Gulf Countries SR 250/-Postal Charges within the country are Rs.100/-extra for a oneycar subscription. **Single current issue** Rs.600/-. **Prices are subject to change**. **Change of Address**:- The publisher must be notified 60 days in advance. **Volume Index** appears in October issue. **Indexing /Abstracting Services**:- The journal is currently abstracted and indexed in in **EMBASE/Excerpta Medica** database, **IndMED, Pubmed (Medline)** and listed in **Ulrich's Periodicals Directory (USA), INSDOC (INDIA). And Index Academicus (IA) Scopus, SCI. Copyright information**:-When the manuscript is accepted for publication the authors agree to automatic transfer of the copyright to the publisher that the manuscript will not be published elsewhere inany language without the consent of the copyright holder. Old issues ofthe journal can be purchased at 15 % discount subject to availability. **INFORMATION FOR AUTHORS SUBMITTING MANUSCRIPTS:-**Manuscripts are to be submitted on a CD in **MS Word** with two hardcopies*.The articles undergo the standard review process. Please allow 9-12 weeks before information regarding acceptability, resubmission or rejection is conveyed to the authors. Once the articleis cleared for publication the authors will have to bear the publication cost.

WEBSITE : http:\\www. jkpractitioner.com

*To speed up the process of REVIEW, manuscripts could be submitted on **zaffar.abbas@gmail.com**

Design & Layout

Shaheed-e-Azam Press & Hospitality Pvt. Ltd.
SCO 3-4, Chowk Gurudwara Dukhniwaran Sahib,
Sirhind Road, Patiala-147001 (Punjab) India
0175-2357981, 98146-32807
email: shaheedeazampta@gmail.com

SUBMISSION CHECKLIST

Please make sure you have satisfied the points on the following checklist before submitting your manuscript.

1. Email addresses

Do you have a list of the email addresses for all the co-authors of the manuscript? You will need to provide these so that we can inform the co-authors when the manuscript has been received and when it is published.

2. Instructions for Authors , peer reviewers and editorial board selection

Have you read the detailed Instructions for Authors and are aware of the peer review and selection process.

3. Covering letter

Have you prepared a covering letter for your submission

4. Manuscript files

Do you have all the files for the manuscript in an acceptable format

5. Article-processing charges

An article processing charges are payable for articles accepted for publication in JK-Practitioner

6. Are you one of the authors of this article?

If not, you cannot submit the article on behalf of the authors. As part of the submission process you will assign a corresponding author for the article, and this can be yourself or a co-author Once the manuscript is submitted the contact author takes responsibility and receive correspondence sent throughout the peer review and production process.

7. Conditions of submission and JK-Practitioner Copyright and License Agreement

Do you confirm that all the authors of the manuscript have read and agreed to its content and are accountable for all aspects of the accuracy and integrity of the manuscript in accordance with ICMJE criteria? Do you confirm that you have ethical approval for any human or animal experimentation ? Do you confirm that the manuscript is original, has not already been published in a journal and is not currently under consideration by another journal? By submitting the manuscript , you are confirming these points and agreeing to these and all other terms of the JK-Practitioner Copyright and License Agreement

Yes, I am the submitting author of this article and I accept the conditions of submission and the JK-Practitioner Copyright and License Agreement.

Authorship Form

Each author should meet all criteria below (A, B, C, and D) and should indicate general and specific contributions by reading criteria A, B, C, and D and checking the appropriate boxes.

A. I certify t hat

• The manuscript represents original and valid work and that neither this manuscript nor one with substantially similar content under my authorship has been published or is being considered for publication elsewhere, except as described in the journal's submission form and cover letter submitted with the manuscript, and copies of closely related manuscripts have been provided; and I agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved; and If requested, I will provide the data or will cooperate fully in obtaining and providing the data on which the manuscript is based for examination by the editors or their assignees; and For papers with more than 1 author, I agree to allow the corresponding author to serve as the primary correspondent with the editorial office, to review the edited manuscript and proof, and to make decisions regarding release of information in the manuscript to the media, federal agencies, or both; or, if I am the only author, I will be the corresponding author and agree to serve in the roles described above.

B. I have given final approval of the submitted manuscript.

C. I have participated sufficiently in the work to take public responsibility for (check 1 of 2 below)

- part of the content
- the whole content.

D. To qualify for authorship, you must check at least 1 box for each of the 3 categories of contributions listed below.

I have made substantial contributions to the intellectual content of the paper as described below.

1. Check at least 1 of 2 below
- conception or design
- acquisition, analysis, or interpretation of data

2. Check at least 1 of 2 below
- drafting of the manuscript
- critical revision of the manuscript for important intellectual content

3. Check at least 1 below
- statistical analysis
- obtaining funding
- administrative, technical, or material support
- supervision
- no additional contributions
- other

Acknowledgement Statement.

Authors should obtain written permission from all individuals named in an Acknowledgment, since readers may infer their endorsement of data and conclusions. The corresponding author must check the following box:

A. I certify that all persons who have made substantial contributions to the work reported in this manuscript (eg, data collection, analysis, writing or editing assistance) but who do not fulfill the authorship criteria are named, along with their specific contributions in an Acknowledgment in the manuscript and all such persons have provided me with written permission to be named.

Confirmation of Reporting of Funding and Conflicts of Interest. Please check A and B. Also check C or D.

A. I certify that all funding, or other financial support, and material support for this work are clearly identified in the manuscript.

B. I have completed the ICMJE for Disclosure of Potential Conflicts of Interest (available at http://www.icmje.org) and will submit it to JK-Practitioner

C. I certify that all my potential conflicts of interest (as reported in the ICMJE), are disclosed in the Acknowledgment section of the manuscript.

OR

D. I have no potential conflicts of interest.

Review

Risk Assessment and Considerations for Dental Treatment of Medically Compromised Patients.

Anubhava Vardhan Sharma ,Meena Jain.

Author Affiliations
Anubhava Vardhan Sharma, PhD Scholar**, Meena Jain,** Professor & Head,
Department of Public Health Dentistry, Faculty of Dental Sciences, Manav Rachna International Institute of Research & Studies, Faridabad. Haryana. India.

Abstract

Periodontal diseases are associated with various pathogenic bacteria colonizing the subgingival & supragingival area. Initiation & progression of periodontal infections are altered by local & systemic conditions called risk factors. Systemic risk factors also have been identified as associated co-risk factors. Studies have shown various potentially important risk indicators. A sizeable percentage of patients in clinics have some form of periodontal disease which have to be clinically corelated with risk factors present so that treatment modalities can be altered. This paper discusses various risks for periodontal conditions and their role in regulating the management. It is important to recognize the aetiologic aspect and the pathogenesis of periodontal diseases to identify and appreciate the associated risk factors. As periodontal disease is multifactorial, effective disease management necessitates a clear k of all the associated risk factors.

JK-Practitioner2022;27(4):1-4

Correspondence
Dr. Anubhava Vardhan Sharma, PhD Scholar, Faculty of Dental Sciences, Manav Rachna International Institute of Research & Studies, Faridabad. Haryana. India.
Indexed:EMBASE,SCOPUS IndMED, ESBCO, Google Scholar besides other National and International Databases.
Cite this article as: Sharma AV, Jain M:Risk Assessment and Considerations for Dental Treatment of Medically Compromised Patients.JK Pract2022;27(4):1-4
KeyWords: Risk factors, Risk indicators , Periodontal diseases.

Introduction

According to American Academy of Periodontology (2008) risk assessment is a process by which assessments are made of likelihood of adverse effects as a result of exposure to specific health hazards or by the absence of beneficialinfluences[1]. Risk assessment is an acknowledged component of the American Academy of Periodontology guidelines for patient management and it has been concluded, risk assessment should be part of every comprehensive dental and periodontal evaluation. Risk assessment is more the just identification of disease, extending its spectrum to factors that influence the future disease progression. Thus, it improves clinical decision-making, reduces the need for complex periodontal therapy, improves treatment outcomes, and ultimately reduces the cost of oral health care [2].In a study by Martha E Nunn it was concluded that periodontal disease can no longer considered as a condition to which all members of the world are at equal risk if they do not follow good oral hygiene. It is well established that periodontal disease is associated with bacterial infection and host response. The rate, development, beginning and severity of the disease are often determined by systemic risk factors in the host like gender, smoking, alcohol, diabetes, stress and genetic factors [3]. Identification of various periodontal risk factors improved our understanding of pathogenesis of periodontal disease, there by building up new pathways for periodontal therapy as well as for periodontal disease prevention who are at risk [4].Axelsson [5-7] observed that stability of periodontal conditions reflects a dynamic equilibrium between bacterial challenge and an effective host response. When changes occur in either of these aspects, homeostasis is disturbed. It is also evident that diagnostic process must be based on a continuous monitoring of the multilevel risk profile. The time interval between diagnostic assessments should be calculated based on the over- all risk profile and the expected benefit for the patient. Use of specific risk profiles to determine the content and frequency of preventive services has been demonstrated to be very cost-effective. Bragger [8] stated that assessment of the risk level for disease progression in each individual patient would enable the practitioner to determine the frequency and extent of professional support necessary to maintain the attachment levels obtained following active therapy. The recognition of such risk levels would thus prevent both undertreatment, and excessive over- treatment, during supportive periodontal therapy (SPT).
A risk factor should satisfy two criteria:

i. It is biologically plausible as a causal agent for disease.
ii. It has been shown to precede the development of disease in prospective clinical studies.

Risk elements for periodontal diseases[9].

Risk factors	*Risk determinants*	*Risk indicators*	*Risk markers/predictors*
Tobacco smoking	Genetic factors	HIV/AIDS	Previous history of periodontal disease
Diabetes	Age	Osteoporosis	Bleeding on probing
Pathogenic bacteria	Gender	Infrequent dental visits	
Microbial tooth deposits	Socioeconomic status		
	Stress		

Risk factors are related biologically to occurrence of the disease , but they do not necessarily imply cause and effect, i.e. a patient with risk factor does not mean that they will develop the disease. Equally, absence of a risk factor does not mean that the disease will not develop [10].

Risk factors may be broadly categorized as:

I. Systemic risk factors – affecting the host response to the plaque biofilm, upsetting the host-microbial balance.
II. Local risk factors – factors local to the oral cavity, which may influence plaque accumulation or occlusal forces [11].

Age

As individual age, their risk for developing periodontal disease increases. Maximum adults population has gingivitis, a less severe form of periodontal disease surrounding three to four teeth and nearly 30% have significant periodontal disease. The study by Khalaf et al [12] showed that age accounted for a majority of tooth extractions in patients older than 35 years of age.

Use of tobacco [13].

It is established about the relationship between the amount and duration of smoking and the severity of periodontal pathology. Local and systemic mechanisms mediate the negative impact of tobacco on oral health. Heat produced during smoking may enhance attachment loss and the increased calculus deposits. Nicotine reduces collagen synthesis and protein secretion and inhibit bone formation. This results in impaired wound healing and increased susceptibility to periodontal diseases, which mat limit the success of treatment interventions. It also hinders immunological function and negatively affects immunoglobulin levels, which may increase susceptibility to microbial pathogens.

Diabetes mellitus

A link between type 1 and type 2 diabetes mellitus and periodontitis exists. Diabetes has been associated with a number of oral complications, including periodontal diseases , dental caries, salivary gland dysfunction and xerostomia, burning mouth syndrome and increased susceptibility to oral infections. Patients with diabetes are at increased risk of developing periodontitis as host response may be impaired, wound healing is delayed and collagenolytic activity is enhanced [14].

Stress

Hildebrand suggested relationship between stress and related body distress, according to him they are important risk indicators for periodontal disease and people under physical or psychological stress are likely to have higher biofilm plaque levels and increased gingivitis [15]. But according to Genco relationship remains unproven.

With advancement in genetic markers various studies have shown that Interleukin-1 genotype-positive patients show more advanced periodontal lesions [16]. Studies have suggested a theory that specific environmental factors can be strong risk factors and that they overwhelm any genetically determined susceptibility or resistance to disease [17].

Pregnancy

Periodontal diseases are associated with preterm delivery and low birth weight, which puts infants and mothers at risk of experiencing increased medical complications. Gingival crevicular fluid analysis has demonstrated significantly higher levels of the inflammatory mediators prostaglandin E2 in women who delivered pre-term birth weight infants [18].

Poor oral hygiene as a risk factor

Studies have shown significant reductions in probing depth, attachment gains with improvement in oral hygiene alone [19]. Poor oral hygiene boosts bacterial build up and biofilm plaque formation and increases certain species of pathogenic bacteria associated with more severe forms of periodontal diseases.

Risk indicators

Factors which are biologically plausible as a causative agent for a disease but has only been shown to the associated with diseases in cross sectional studies are risk indicators. Factors that have no current biological plausibility as causative agent but has been associated with disease on a cross sectional or longitudinal basis. Example the number of teeth missing in dentition is a risk predictor for disease but has no or little acceptability as a causative agent for periodontal disease [20].

Risk assessment

There are four levels to consider risk assessment, these specific methods allow clinician to distinct risk factors that may initiate periodontal disease from those responsible for its progression or for the failure of initial therapy [21].

a. Patient level – perform at initial examination

Hierarchy of evidence of risk factors[22]			
Study design	**Hypothesis generating**	**Hypothesis testing**	**Interpretation and health policy implementation**
• Anecdote • Case report • Case series	X		Suggest a relationship
Case control	X	X	Evidence for risk indicator
Cross sectional	X	X	Evidence for risk indicator
Longitudinal		X	Evidence for risk factor
Interventional		X	Strongest evidence for specific interaction to apply to population

b. Whole mouth level – perform at initial and post-initial examination
c. Tooth level – perform at post-initial/definitive therapy & maintenance
d. Site level –perform at post-definitive therapy & maintenance

Patient level risk assessment –
a. Family history for hereditary, inborn or genetic risk factors.
b. Medical history for systemic disease , e.g. diabetes mellitus, cardiovascular diseases, osteoporosis
c. Present dental history – assess motivation to oral hygiene
d. Social history includes smoking
e. Habits like bruxism

Mouth-level assessment –
a. Examination of attachment loss relative to age
b. Occlusal examination in static and dynamic relationship
c. Examination of levels of oral hygiene
d. Examination of plaque-retentive factors
e. Prescence of removable prosthesis
f. Levels of recession
g. Gingival inflammation and depth of pockets

Tooth level assessment –
a. Individual tooth mobility
b. Tooth movement or drifting
c. Residual bone support
d. Furcation lesion
e. Tooth anatomy
f. Prescence of ledges or deficiencies on restorations
g. Individual occlusal prematurities
h. Soft tissue contour
i. Sub gingival calculus

Study design for risk assessment

Several study designs for diseases with multi-factorial origin such as periodontitis can be used for risk assessment.

Medical risk categories of patient & dental considerations:

After complete evaluation of patient capturing and considering risk factors they can be classified to various categories. One of the most frequently used is given by the American Society of Anaesthesiologist commonly referred as ASA physical status classification system. Implementation of these modifications can be assigned in a temporal relationship to the provision of dental care [23].

ASA classification	Dental consideration
Physical status 1 A patient without systemic disease; A normal healthy patient	Routine dental therapy without modification
Physical status 2 A patient with mild systemic disease	Routine dental therapy with possible treatment limitations or special considerations
Physical status 3 A patient with severe systemic disease that limit activity but not incapacitating	Dental therapy with possible strict limitation or special considerations
Physical status 4 A patient with incapacitating systemic disease that is constant threat to life	Emergency dental therapy only with severe limitations or special considerations

Most dentists are not trained or experienced in risk assessment of periodontal diseases. Manually assessing the risk factors could be a complex process. A computer-generated risk assessment model can help in the identification of patients at elevated risk of developing periodontal diseases and may help the patients who require additional education or targeted interventions to prevent or minimize the impact of periodontal disease. Several models like Oral Health Information Suite (OHIS), Periodontal Risk Calculator (PRC), Functional diagram (Lang & Tonetti) and American Academy of Periodontology (AAP) self-assessment tool have been used to assess risk.

Conclusion

To overcome the barriers in risk assessment, dental fraternity should work towards educating health workers about risk-based care at all levels; promote use of risk assessment as standard of care for every patient; and build up simple easy to use risk assessment tools.

Practice of using risk assessment tool in routine practice would add only a small amount of time to patient visits but when compared to benefits it will achieve are manifold for entire health care system.

Conflicts of interest

The authors declare no conflict of interest.

References

1. American Academy of Periodontology Statement on Risk Assessment. Journal of Periodontology 2008;2:202
2. American Academy of Periodontology. Position paper. Diabetes and periodontal diseases. Journal of Periodontology 2000;71:664-678
3. Martha E Nunn. Understanding the etiology of periodontitis: an overview of periodontal risk factors. Periodontol. 2000. 2003;32:11-23.
4. Robert J, Genco and Wenche S. Borgnakke. Risk factor for periodontal disease. Periodontol. 2000. 2013;62:59-94.
5. Axelsson P, Lindhe J (1981a). Effect of controlled oral hygiene procedures on caries and periodontal disease in adults. Results after 6 years. J Clin Periodontol 1981;8:239-248.
6. Axelsson P, Lindhe J (1981b). The significance of maintenance care in the treatment of periodontal disease. J Clin Periodontol 1981;8:281-294.
7. Axelsson P, Lindhe J, Nyström B. On the prevention of caries and periodontal disease. Results of a 15-year longitudinal study in adults. J Clin Periodontol 1991;18:182-189
8. Brägger U, Håkanson D, Lang NP. Progression of periodontal disease in patients with mild to moderate adult periodontitis. J Clin Periodontol 1992;19:659-666.
9. Newman, Takei, Klokkevold, Carranza. Newman & Carranza's Clinical Periodontology.2019, Elsevier, Delhi 13th ed. 411.
10. Bruce L. Pihlstrom Periodontal risk assessment, diagnosis and treatment planning. Periodontol 2000 2001;25:37-58.
11. Timmerman MF, Van der Weijden. Risk factors for periodontitis. Int J Dent Hyg 2006;4:2-7.
12. Khalaf F, Al-Shammari, Areej K, et al. Risk indicators for tooth loss due to periodontal. J Periodontol 2005;76:1910-18.
13. Bergstrom J, Eliasson S. Jack Dock Exposure to tobacco smoking and periodontal health. J Clin Periodontol 2000;27:61-8.
14. Vernillo AT. Dental considerations for the treatment of patients with diabetes mellitus. J Am Dent Assoc 2003;134(supplement I): 245-335.
15. Hildebrand HC, Epstein J, Lorjova H. The influence of psychological stress on periodontal disease. J West Soc Periodontol Periodontal Abstr 2000;48:69-77.
16. Genco RJ, Ho AW, Grossi SG et al Relationship of stress, distress and inadequate coping behaviors to periodontal disease. J Periodontol 1999;707:711-23.
17. Kornman KS, Crane A, Wang HY, Newman MG, Pirk FW, Wilson TG Jr, *et al.* The interleukin –I genotype as a severity factor in adult periodontal disease. J Clin Periodontol 1997;24:72-7.
18. Offenbacher S, Katz V, Fertik G, Collins J, Boyd D, Maynor G, *et al.* Periodontal infection as a possible risk factor for preterm low birth weight. J Periodontol 1996;67:1103-13.
19. Axelsson P, Nystrom B, Lindhe J. The long-term effect of a plaque control program on tooth mortality, caries, and periodontal disease in adults. J Clin Periodontol 2004;31:749-57.
20. Bruce L. Pihlstrom Periodontal risk assessment, diagnosis and treatment planning. Periodontol 2000 2001;25:37-58.
21. Salvi GE, Lawrence HP, Offenbacher S, Beck JD. Influence of risk factors on the pathogenesis of periodontitits. Periodontol 2000 1997;14:173-201.
22. Ibrahim M. Epidemiology & health policy. Rockvile (MD). Aspen Sysyem corporation; 1985.
23. Jason H. Goodchild & Michael Glick. A different approach to medical risk assessment. Endodontic Topics 2003, 4, 1–8.

Original Article

Kidney Trauma – Grading and Management At a Tertiary Care Hospital.

Mohammad Talha, Suhail Masood Khan , Azhar Ajaz Khan ,Sanjay Kumar Bhasin

Abstract:

Aim and Objectives: To describe and establish the types and severity of various kidney injuries, as well as the strategies used to treat them, at Government Medical College Jammu.

Methodology: The study included 50 individuals over the age of 15 who had both blunt and penetrating kidney injuries. Injuries, grade management, and the final outcome were all documented. The data was analysed and descriptive statistics were calculated using SPSS version 27.

Results: Males had a greater frequency than females (82 percent). In 78 percent of instances, the mode of renal injury was blunt, but in 22 percent of cases, it was penetrating. Road traffic accidents caused the majority of blunt trauma (94.9%), whereas firearms caused the majority of penetrating injuries (63.6 percent). Haematuria was observed in 86% of the patients and missing in 14%. In 74 percent of the instances, minor renal damage was seen, whereas significant renal injury was observed in 26% of the cases. Seventy-two percent of the cases were handled conservatively. Nephrectomy was performed on all grade-V (14%) and one grade-IV (2%), respectively, patients. Renorrhaphy was performed in 6% of the patients. One incidence of urinary extravasation was observed (2 percent). Reno colic fistula occurred in one of the patients. There was no mortality in the non-surgical group; however, 4 percent of patients in the operational group died as a result of their injuries.

Conclusions: The majority of cases of kidney injury are caused by blunt trauma, and non-operative therapy is the best option for most blunt and penetrating renal trauma patients who are hemodynamically stable and do not have peritonitis.

JK-Practitioner2022;22(4):5-10

Introduction:

8-10% of all blunt and penetrating abdominal injuries result in renal damage [1]. In 80% to 90% of instances, the damage is blunt rather than penetrating [2].Renal injuries typically occur in conjunction with injury to other organs. Multiorgan involvement occurs in 80 percent of penetrating trauma patients and 75 percent of blunt trauma patients [3].Minor renal injuries account for 75% to 80% of all damage to the kidneys (Grade I-III). The American Association of Surgery in Trauma's organ injury survey committee categorization is used to classify renal injuries (AAST) [4].

Although there is widespread agreement on the cautious care of small renal injuries, there is still a divide of opinion on the management of serious renal trauma, with strong supporters for both conservative and aggressive surgical approaches [5].There has been a steady shift in the approach to penetrating renal injuries in selected instances due to the efficacy of non-operative therapy of blunt renal trauma. Because of advancements in imaging techniques, most patients with significant renal injuries may be monitored expectantly, with intervention only as needed [6].Urinalysis gives quick information in individuals who may have a renal laceration, but it must be examined in the context of the clinical situation [7].Patients with forceful abdominal injuries and probable renal damage may benefit from sonography. Prior to surgery, imaging in patients with multivisceral injuries needing emergency surgery is mainly restricted to excretory urography. CT scanning enables for reliable detection and staging of significant renal damage in stable individuals[8].

Author Affiliations
Mohammad Talha, Suhail , Sanjay Kumar Bhasin ,Department of Surgery ,Government Medical College, Jammu **;Masood Khan ,** Department of Urology ,GMC ,Jammu ;**Azhar Ajaz Khan** ,Department of Urology ,GMC ,Srinagar. J&K ,India

Correspondence
Dr. Suhail Masood Khan
Department of Urology,Government Medical College Jammu,
Old D-3, Faculty Quarters, Medical Enclave,
Bakshi Nagar Jammu.

Indexed
EMBASE ,SCOPUS, IndMED ,ESBCO ,Google Scholar besides other national and International Databases

Cite This Article as
Talha, M , Khan SM , Khan AA , Bhasin SK. Kidney Trauma – Grading and Management At a Tertiary Care Hospital.
JK Pract2022;27(4):5-10

Full length article available at **jkpractitioner.com** one month after publication

Keywords
Kidney trauma renal injuries

Avulsion of the renal pelvis, damage to the vascular pedicle, and life-threatening hemodynamic instability are all indications for surgery in renal trauma. Extravasations, devitalized segments, and co-existing bowel or pancreatic injuries, however, are still regarded relative reasons for renal examination [9].Angiographic treatments such as ultra-selective renal embolization can also be used to treat vascular damage [10].

Methodology

The goal of this study was to look at the pattern of various renal injuries, such as blunt or penetrating, the grade of injuries according to AAST, and the therapeutic approaches used in both forms of trauma, whether conservative or operational. This study was carried in the Department of General Surgery, Government Medical College Jammu, from January 2019 to December 2021. This study comprised 50 patients, both male and female, who presented with both blunt and penetrating renal trauma as a result of road traffic injuries, gunshot injuries, and falls. Those with other types of renal damage, such as iatrogenic injury, were not included in the research. In accordance with A.T.L.S. (Advanced Trauma and Life Support) norms, all patients conducted a primary and secondary survey. Patients who were hemodynamically unstable at the time of presentation were resuscitated and stabilised before being scanned. AAST was used to rate the renal injuries.Severity was assessed according to the depth of renal parenchymal damage and involvement of the Pelvicalyceal system and renal vessels.

Grade I

- subcapsular hematoma or contusion, without laceration

Grade II

- superficial laceration ≤1 cm depth not involving the collecting system (no evidence of urine extravasation)
- perirenal hematoma confined within the perirenal fascia

Grade III

- laceration >1 cm not involving the collecting system (no evidence of urine extravasation)
- vascular injury or active bleeding confined within the perirenal fascia

Grade IV

- laceration involving the collecting system with urinary extravasation laceration of the renal pelvis and/or complete ureteropelvic disruption
- vascular injury to segmental renal artery or vein
- segmental infarctions without associated active bleeding (i.e., due to vessel thrombosis)
- active bleeding extending beyond the perirenal fascia (i.e., into the retroperitoneum or peritoneum)

Grade V

- shattered kidney
- avulsion of renal hilum or laceration of the main renal artery or vein: devascularisation of a kidney due to hilar injury
- devascularised kidney with active bleeding

Except for those with shock that did not respond to resuscitation, persistent gross haematuria, concomitant abdominal visceral damage, and grade-V injuries, all instances of blunt renal trauma were treated conservatively at first. After resuscitation, operational therapy was considered in cases of penetrating damage caused by a weapon, stab injury from the front, and grade-V injury. Back stab injuries were first treated conservatively. The age, gender, mechanism of injury, degree of haematuria, treatment approach, operational findings (grade of damage and concomitant injuries), and early complications of the patient were all documented. Hemodynamic monitoring, parenteral fluid treatment with crystalloid, colloid, or blood transfusion, haematocrit measurement, prophylactic antibiotics, and bed rest were all used to treat the gross haematuria. All patients who were scheduled for surgery were examined through a midline incision. During the hospital stay and follow-up in the OPD, complications were examined. It was decided to use nonprobability sampling. SPSS (Statistical Package for Social Sciences) version 10 was used to examine the data, which was entered into a standardised proforma.

Results

There were 50 patients in the trial, including 41 (82%) men and 9 (18%) females. The average age was 26 years old, with a range of 16 to 54 years old. Thirty-nine patients (78%) had blunt trauma, whereas 11 patients (22%) had penetrating trauma. In 37 (94.9%) of the instances, blunt trauma was caused by a car collision, and in 2 (5.1%) of the cases, it was caused by a fall.

Penetrating injuries were caused by firearms in 7 (63.6%) instances and knife injuries in 4 (36.4%) cases. In all cases of penetrating damage caused by a gunshot, and only one case of stab injury, emergency surgery was performed. Three cases of back stab injuries were first treated conservatively.

Thirty-three cases of blunt renal trauma (84.6%) were treated conservatively. Six (15.4%) instances were originally investigated owing to

hemodynamic instability and acute abdomen as a result of related injuries.

In both forms of trauma, the spleen was injured 7 times (14%), the liver 3 times (6%), the mesentery 6 times (12%), the colon 4 times (8%), the small intestine 5 times (10%), the vertebral column 1 time (2%), the ribs 5 times (10%), and the skull was injured 4 times (8%).

Haematuria was present in 31 (62%) of the cases, was microscopic in 12 (24%) of the cases, and was missing in 7 (14%) of the cases.

Ten (20%) instances of grade I, fifteen (30%) cases of grade II, twelve (24%) cases of grade III, six (12%) cases of grade IV, and seven (14% cases of grade V) were identified. Four of the seven individuals with grade-V damage had a shattered kidney and three had a pedicle avulsion.

Table 1:Management of associated injuries.

Variable(s)			Total No(n)	Percentage (%)
Age (years)	Mean		26	
	Age range		16-54	
Sex	Male		41	82%
	Female		9	18%
Type of injury	Blunt	Road accidents	37	94.9%
	Penetrating	Falls	2	5.1%
		Firearm	7	63.6%
		Stab injury	4	36.4%
Degree of hematuria	Gross		31	62%
	Microscopic		12	24%
	Absent		7	14%
Grade of injury	I		10	20%
	II		15	30%
	III		12	24%
	IV		6	12%
	V		7	14%
Other organ injuries	Liver		3	6%
	Spleen		7	14%
	Mesentery		6	12%
	Colon		4	8%
	Small intestine		5	10%
	Vertebral column		1	2%
	Ribs		5	10%
	Head injury		4	8%

Nephrectomy was performed on all grade-V (14%) and one grade-IV (2%) patients. Renorrhaphy was performed in 3 (6%) of the cases. There were no early problems in the non-operative group, save for urinary extravasation in one instance (2%) that resolved after stenting [Table 2(A)]. Two of the three instances where a stab injury was treated conservatively resulted in no sequelae, while one patient developed a renocolic fistula. In the operating group, wound infection was found in 2 (4%) patients. There were no deaths in the non-surgical group; however, two patients (4%) died in the operational group due to related injuries [Table 2(B)].

Table 2(A): Kidney trauma – Type and management

Type of trauma	Method of management	Number	Percentage
Blunt Trauma	Conservative Operative	33	84.6%
	Operative	6	15.4%
PenetratingTrauma	Conservative	3	27.3%
	Operative	8	72.7%

Table 2(B) Complications associated with management

Management	Complications	Number	Percentage
Operative	Urinary Extravasation	1	2%
	Wound infection	2	4%
	Deaths	2	4%
Non-Operative	Reno colic fistula	1	2%

Discussion

The most prevalent cause of renal damage is blunt renal trauma, which accounts for over 85% of cases and is largely caused by car accidents [2]. The majority of penetrating and blunt kidney injuries, as well as certain high-grade renal injuries, may be treated conservatively [11]. Both therapy regimens aim to retain and optimise renal function while maintaining patient safety.

The average age of the participants in this research was 26, with a range of 16 to 61 years. According to Sabir et al., frequency was greater in young boys [12]. The ratio of females to males was 1:4.6. Penetrating renal trauma was detected in 11 (22%) instances while blunt renal trauma was seen in 39 (78%) cases.Gourgiotis et al.6 found that blunt and penetrating renal trauma occurred in 89 and 11 percent of patients, respectively. Except for one case of stab injury, all cases of grade IV and V injuries were caused by a motor vehicle accident or gunshot damage, implying that serious renal trauma requires a lot of force.

Haematuria was found to be gross in 62% of cases, microscopic in 24%, and non-existent in 14%. Over 95% of patients with renal trauma have red blood cells more than 5 per high-power field; nevertheless, the lack of haematuria does not rule out renal damage. It may be missing in as many as 24% of individuals with renal artery thrombosis and one-third of cases of ureteropelvic junction damage [13]. According to Khairy et al., the presence of gross haematuria is linked to a higher risk of non-renal intraabdominal damage [7].

In the examination of stable patients, intravenous urography is the first screening modality. In combination with results at laparotomy, intraoperative one-shot IVU can be utilised to rule out life-threatening renal damage and establish the presence of a contralateral working kidney [14]. Patients with suspected significant renal trauma or multivisceral damage had a CT scan. A CT scan is not recommended when a large haemorrhage necessitates an urgent laparotomy. In renal trauma, Salimi et al. discovered that CT scans have a better specificity (93.5%) and accuracy (91.6%) [15].

The researchers looked into seven cases of renal damage caused by gunshots and one example caused by a knife wound. Except for one instance of renocolic fistula, three cases of back stab injuries treated conservatively were devoid of sequelae. IVU was utilised to diagnose it, but a CT scan, as well as antegrade and retrograde pyelography, can also be employed. CT scan was determined to be the single most helpful diagnostic technique for renocolic fistulas by Gimenez et al [16]. Shefler et al. found in their analysis that nonoperative therapy is a viable option for the majority of mild penetrating renal injuries and many high-grade injuries [11]. In their study, Thall et al. discovered that type-III penetrating trauma may be handled conservatively, although surgical intervention may be required in individuals with concurrent intra-abdominal injuries or hemodynamic instability [17].

33 (84.6%) of patients with blunt renal trauma were treated conservatively. Surgical intervention was indicated in six patients (15.4 percent). Hemodynamic instability and acute abdomen were used as indicators for further investigation in this research. Avulsion of the renal pelvis, damage to the vascular pedicle, acute abdomen, and life-threatening hemodynamic instability are all acceptable reasons for surgery [18]. The best way to detect both renal and other visceral injuries is with a midline trans-peritoneal technique. Medial colon mobilisation allows for a better approach to the kidney. The rate of nephrectomy has decreased dramatically as a result of vascular management prior to renal investigations [19].

Renorrhaphy was performed in 6% of the patients. Urinary extravasations can be prevented by repairing the collecting system with a watertight seal. Absorbable sutures can be used to heal parenchyma using a capsule or gelatin sponge. Fibrin glue has recently been utilised to successfully close parenchymal flaws. A pedicled omentum flap can also be utilised to close a parenchymal defect. Renal capsules should be kept for future use in reconstruction.

All grade-V patients and one grade-IV patient had nephrectomy in this research. In the non-operative group, no deaths were observed. In their investigation, Kansas et al. discovered that exploring for related injuries does not improve the rate of nephrectomy [20]. After both blunt and penetrating trauma, the severity of the injury, the grade of renal impairment, hemodynamic instability, and the need for transfusions all predict nephrectomy [21]. After a penetrating injury, nephrectomy is more likely. According to Noor et al., the spleen was the most usually damaged related organ [22].

Three cases of renal damage of grade IV were managed conservatively. Isolated grade-IV renal injuries are often treated with caution. The most common reason for renal exploration and reconstruction is persistent bleeding [23]. Nephrectomy was performed on all grade-V injuries. Penetrating grade-V injuries require immediate surgical intervention; however, in some circumstances, blunt grade-V injuries can be treated. Sahai et al. investigated the viability of a nonoperative approach to blunt grade-V renal damage and discovered that in patients who are hemodynamically stable at the time of presentation, conservative therapy of blunt grade-V renal injury is achievable [24]. In one case, there was significant urine extravasation. It's still debatable if urine extravasation has a negative impact on patient outcomes. Percutaneous drainage, often with

ureteric stenting, gives full cure of chronic urine leakage when acute trauma is followed by considerable urinary extravasation [25]. According to Alsikafi et al., 3 (9%) of 34 patients with significant blunt injury with urine extravasation needed ureteric stenting for persistent extravasation, while 27 (91%) had spontaneous resolution [25]. In our study, there were no cases of delayed bleeding. Angiographic treatments such as super-selective renal embolization can also be used to treat it. Penetrating vascular renal injuries can also be efficiently treated with super-selective renal embolization [10].

CONCLUSION

The majority of cases of renal damage in this series were caused by blunt trauma, and non-operative therapy is the best option for most blunt and selected cases of penetrating renal trauma. It is effective in the majority of patients without peritonitis or hemodynamic instability and should be considered following thorough renal staging, regardless of the severity of renal impairment.

REFERENCES

1. Yao P, Gunasegaram A, Ladd LA, Morris DL. Novel surgical management of renal trauma: in line radiofrequency ablation coagulation. ANZ J Surg 2008; 78:601-4.
2. Dobrowolski Z, Kusionowicz J, Drewniak T, Habrat W, Lipczynski W, Jakubik P, et al. Renal and ureteric trauma: diagnosis and management in Poland. BJU Int 2002; 89:748-51.
3. Saidi A, Bocqueraz F, Descotes JL, Cadi P, Terrier N, Boillot B, et al. [Blunt kidney trauma: a ten-year experience]. Prog Urol 2004; 14:1125-31. French
4. Kuan JK, Wright JL, Nathens AB, Rivara FP, Wessells H. American association for the surgery of trauma organ injury scale for kidney injuries predicts nephrectomy, dialysis, and death in patients with blunt injury and nephrectomy for penetrating injuries. J Trauma 2006; 60:351-6.
5. Delgado Oliva FJ, Bonillo García MA, Gómez Pérez L, Oliver Amorós F, Gimeno Argente V, et al. Conservative approach in major renal trauma. Actas Urol Esp 2007; 31:132-9.
6. Gourgiotis S, Germanos S, Dimopoulos N, Vougas V, Anastasiou T, Baratsis S. Renal injury: 5-year experience and literature review. Urol Int 2006; 77:97-103.
7. Salem HK, Morsi HA, Zakaria A. Management of high-grade renal injuries in children after blunt abdominal trauma: experience of 40 cases. J Pediatr Urol 2007; 3:223-9. Epub 2006 Oct 16.
8. Goldman SM, Sandler CM. Urogenital trauma: imaging upper GU trauma. Eur J Radiol 2004; 50:84-95.
9. Rogers CG, Knight V, MacUra KJ, Ziegfeld S, Paidas CN, Mathews RI. High-grade renal injuries in children: is conservative management possible? Urology 2004; 64:574-9.
10. Poulakis V, Ferakis N, Becht E, Deliveliotis C, Duex M. Treatment of renal vascular injury by transcatheter embolization: immediate and long-term effects on renal function. J Endourol 2006; 20:405-9.
11. Shefler A, Gremitzky A, Vainrib M, Tykochinsky G, Shalev M, Richter S, et al. [The role of non-operative management of penetrating renal trauma]. Harefuah 2007; 146:345-8. Hebrew.
12. Sabir M, Babar AM. Epidemiology and management of renal Injuries. Pak J Surg 2002; 18:17-20.
13. Subramanian A, Rozycki GS, Master V. Ureteropelvic junction disruption after blunt abdominal trauma. J Trauma 2009; 66:287.
14. Rao AR, Cherian J, Arya N, Kapasi F, Shergill IS, Potluri B. Urological emergency: diagnosis and management of renal trauma. Br J Hosp Med 2005; 66:634-7.
15. Salimi J, Bakhtavar K, Solimani M, Khashayar P, Meysamie AP, Zargar M. Diagnostic accuracy of CT scan in abdominal blunt trauma. Chin J Traumatol 2009; 12:67-70.
16. Gimenez E, Raman JD, Lieberman M, Vaughan ED Jr. Cutaneous renocolic fistula associated with diverticulitis. Canadian J Urol 2008; 15:4191-3.
17. Thall EH, Stone NN, Cheng DL, Cohen EL, Fine EM, Leventhal I, et al. Conservative management of penetrating and blunt type- III renal injuries. Br J Urol 1996; 77:512-7.
18. Santucci RA, Fisher MB. The literature increasingly supports expectant (conservative) management of renal trauma: a systematic review. J Trauma 2005; 59:493-503.
19. Schmidlin F. [Renal trauma. Treatment strategies and indications for surgical exploration]. Urologe A 2005; 44:863-9. German.
20. Kansas BT, Eddy MJ, Mydlo JH, Uzzo RG. Incidence and management of penetrating renal trauma in patients with multiorgan injury: extended experience at an inner city trauma centre. J Urol 2004; 172:1355-60.
21. Davis KA, Reed RL 2nd, Santaniello J, Abodeely A, Esposito TJ, Poulakidas SJ, et al. Predictors of the need for nephrectomy after

renal trauma. J Trauma 2006; 60:164-9; discussion 169-70.
22. Noor A, Ather H. Difference in the outcome of patients managed with isolated renal injury and co-existent abdominal organ injury. J Ayub Med Coll (Abbottabad) 2003; 15:29-32.
23. Buckley JC, McAninch JW. Selective management of isolated and non-isolated grade-IV renal injuries. J Urol 2006; 176: 2498-502.
24. Sahai A, Cuthbert F, Niekrash R, Siddiqui M, Gulati MS. Endovascular management of grade-V blunt renal trauma with associated splenic injury. Nature Rev Urol 2009; 6:335-7.
25. Alsikafi NF, McAnincht JW, Elliott SP, Garcia M. Non-operative management outcomes of isolated urinary extravasation following renal lacerations due to external trauma. J Urol 2006; 176:2494-7. Comment in: p. 2349-50.

Original Article

Safety and Efficacy of Extracorporeal Shock Wave Lithotripsy and Percutaneous Nephrolithotomy for 1-2 cm Lower Calyceal Kidney Stones

Mujahid Ahmad Mir, Tajamul Hassan, Sajad Ahmad Malik, Mohammad Saleem Wani, Arif Hamid, Yaser Ahmed , Sajad Ahmad Para , Abdul Rouf Khawaja

Abstract

Background: Management of moderate sized (1-2 cm) lower calyceal kidney stone continues to be an unsettled question. We tried to study the safety and efficacy of extracorporeal shock wave lithotripsy (ESWL) and percutaneous nephrolithotomy (PCNL) for lower calyceal kidney stones 1-2 cm in size.

Materials and Methods: A prospective observational study which included patients with lower calyceal stones sized 1-2 cm, excluding, those with bilateral or radiolucent kidney stones, bleeding diathesis or pyonephrosis. Selected patients were grouped into Extracorporeal Shock Wave Lithotripsy (ESWL) as Group A and Percutaneous nephrolithotomy (PCNL) as Group B with due consideration of their calyceal anatomy. Patients were followed up by abdominal ultrasound and plain X-ray (NCCT if indicated) till stone clearance. Hospital stay, operative duration, outcomes and complications were recorded for each group.

Results: The patient characteristics of both groups were comparable except smoking history and median stone size. Among a total of 144 selected patients, 46.6% versus 25 % of the patients included in Group A were smokers or had a recent history of smoking. The median stone size differed significantly between the two groups (13 mm versus 18 mm). The stone free rate (SFR) was 71.7% and 85.7% for Groups A and B respectively ($P < 0.05$). Among the 43 patients with treatment success from Group A, 11(25.6%) patients needed second and 4(9.3%) patients the third session of ESWL. The complication rate was 10.7% (Clavian Dindo 2) for Group B patients. The mean fluoroscopy time, mean operative time and mean hospital duration were 210.01 seconds versus 133.6 seconds(p=0.011), 42.1 minutes versus 67.5 minutes (p=0.001) and 3.75 hours versus 92.3 hours (p=0.010) respectively in Group A and Group B patients.

Conclusion: Comparing with ESWL, PCNL is safe and has better stone free rate with a low retreatment rate for lower calyceal stones sized 10-20 mm. However, PCNL has more operative time, blood transfusion rate and requires longer hospital stay.

JK-Practitioner2022;27(4):11-15

Introduction

Achievement of maximum stone clearance while causing minimal morbidity to the patient is the primary goal of renal stone treatment. Widely accepted minimally invasive modalities described for this purpose are extracorporeal shockwave lithotripsy (ESWL), percutaneous nephrolithotomy (PCNL), and retrograde intrarenal surgery (RIRS).

Stone size is one of the main determinants of chosing treatment strategy in patients with nephrolithiasis. Kidney stones upto 1 cm are usually managed by ESWL whereas for stones >2 cm, PCNL is the preferred approach. However the literature on the management of 1-2 cm stones is still controversial[1]. ESWL though considered treatment of choice for most of the small sized renal stones, but for lower calyceal stones, the results are uncertain. Apart from stone size, the anatomical parameters like infundibulopelvic angle, the diameter, and length of infundibulum are most pivotal predictors of lower calyceal stone clearance.

Theoretically being less morbid with no need of anesthesia or hospitalization, ESWL was considered the best treatment modality for

Author Affiliations

Mujahid Ahmad Mir, Tajamul Hassan, Senior Residents; **Sajad Ahmad Malik, Yaser Ahmed ,Sajad Ahmad Para,** Assistant Professors; **Abdul Rouf Khawaja**,Associate Professor; **Mohammad Saleem Wani, Arif Hamid**, Professors; Department of Urology ,SKIMS ,Soura, Srinagar ,J&K ,India.

Correspondence

Dr.Mujahid Ahmad Mir
Department Of Urology , SKIMS, Soura, Srinagar- 190010
Phone: +91-9149776873 .
E-mail: drmamir1024@gmail.com

Indexed

EMBASE ,SCOPUS, IndMED ,ESBCO, Google Scholar besides other national and International Databases

Cite This Article as

Mir MA, Hassan T, Malik SA , Wani MS, Hamid A, Ahmed Y ,Para SA , Khawaja AR. Safety and Efficacy of Extracorporeal Shock Wave Lithotripsy and Percutaneous Nephrolithotomy for 1-2 cm Lower Calyceal Kidney Stones. JK Pract2022;27(4):11-15.

Full length article available at **jkpractitioner.com** one month after publication

Keywords

Extracorporeal Shock Wave Lithotripsy, Lower Calyx, Percutaneous Nephrolithotomy, Renal Stone.

lower calyceal stone of 1-2 cm size [2]. However, in view of better stone clearance and minimal morbidity, recent literature documents PCNL is being preferred by many urologists for lower calyceal stones sized more than 1 cm [3].

We undertook this study to analyse success rate and complication profile of PCNL and ESWL in management of lower calyceal stones of size 1-2 cm.

Patients and methods

It was a prospective observational study conducted between November 2018 and February 2021 at Department of Urology, SKIMS Soura Srinagar. Institutional ethical committee clearance was obtained under enrollment number IEC/SKIMS/RP75/2020 on 24.10.2020.

Patients aged 13 to 75 years, harboring lower pole stones of 10–20 mm size with well excreting kidney in absence of congenital abnormalities were selected for the study. Patients with bilateral or radiolucent kidney stones, bleeding diathesis or pyonephrosis were excluded from the study. Selected patients were divided into two groups of treatment methodology, following both surgeons' and patients' preference. Patients with radiologically documented infundibulo-pelvic angle < 45^0, infundibular diameter >3 cm or infundibular wideness < 5 mm were preferentially adviced for PCNL.

All participants signed an informed consent form before enrolment. All patients were subjected to clinical history along with physical examination and laboratory investigations. Laboratory workup included kidney and liver Function tests, complete blood count, fasting blood sugar level, bleeding profile, urine analysis and culture. Measurement of Hounsfield Unit of renal stone was done by CECT scan. Figure 1 shows the flow process of participants through our study. The treatment success was defined as the complete clearance of the lower calyceal calculi, or presence of clinically insignificant residual stones < 4 mm after 3 months of procedure.

Procedure

All the patients received a dose of third generation cephalosporin before the procedure.

Group -A (ESWL)

A total of 60 patients received ESWL treatment using Dornier Compact Delta –II (HM –III) equipment with an electromagnetic source having acoustic lens of focal length 15 cm. It has a voltage of 110kV, current 4 mA and power range of 0.1-9 Watt. Besides that, the equipment has both ultrasonography and fluoroscopic display to attain optimum focus. For ESWL treatment, the maximum number of shock waves was set to 3500 with energy level 4 for each session. Using water as a medium, shock waves are transmitted to the body and focused with the help of the acoustic lens system. This enables the reflection of released energy on the stone surface leading to stone disintegration. Imaging techniques (X-ray KUB and ultrasound –KUB) were used to determine the stone size.

Plain X-ray (KUB) was done to document fragmentation and clearance at the end of one and three months after the procedure. Post procedure, patients were adviced to maintain adequate hydration, pass urine in a container for collection of stone, antibiotics for seven days with on demand analgesics. Possible complications were explained to the patient. Follow up at 1 month after ESWL with an ultrasonography abdomen and plain X-ray KUB (NCCT if indicated) was adviced. A second session of ESWL was planned If there were fragments of significant size (>4mm). However minimum 30 days gap was maintained between two sessions. If there were only insignificant fragments the patients were re-evaluated after 1 month. The final results were considered after 3 months from the first session of ESWL. Failure was defined as residual stone fragments > 4 mm after three sessions of ESWL.

Group -B (PCNL)

Group B included 84 patients, who underwent PCNL.After cystoscopic ureteric catheterization, fluoroscopy-guided renal access was achieved under spinal or general anesthesia by a well versed endo-urological surgeon. The initial puncture was made using biplanar C-arm fluoroscopy. Subsequent to tract dilatation, adult size storznephroscope was used with 24 or 26 Fr sheath. Generally, the posterior calyx was selected for puncture, unless the stone was located directly on the anterior calyx for it will be difficult to approach via adjoining the posterior calyx Nephrostomy tube (18–20Fr) was placed in all patients at the end of PCNL procedure.. Fragmentation and removal of Stone were accomplished using pneumatic lithotripter. Ultrasound (KUB) and NCCT (KUB) were done on follow up after 2 weeks and 12 weeks respectively to affirm that the stone has been cleared completely. The complications were recorded and graded by ClavianDindo grading throughout the follow up process.

Statistical analysis

The statistical analysis was done with the aid of IBM SPSS Statistics (Version 16.0; IBM Corp., Armonk, New York, USA). Results obtained were denoted as mean (SD) value or rate (%) where appropriate. t-test approach was used to distinguish both groups. Considering the data obtained as a normal distribution, Chi- Square Test method was used to compare categorical data (numerical). P-value lesser than 0.05 indicates statistical significance.

Results

Over a period of two years and three months, 144 patients meeting the inclusion criteria were studied. Considering the calyceal anatomy, 60 patients were

selected for ESWL and PCNL was performed in 84 patients. There were 42 (67%) men and 18(33%) women in Group A while as 36 (42.86%) women and 48 (57.14%) men in Group B. An approximate male to female ratio was 1.2 in this study. Table 1 depicts the pre-operative clinical parameters of treatment groups. There was statistically significant difference only in stone size in addition to smoking history between the two groups in the study.

Table 1: Clinical parameters of patients

Variable	Group A ESWL (N=60)	Group B PCNL(N=84)	P-value
Gender N (%) **Male** **Female**	42(67) 18(33)	48(57.14) 36(42.86)	0.116
Age (years) **Mean (SD)**	34.1(13.42)	39.61(14.40)	0.814
BMI Median (Range)	22.30(20-27.5)	23.89(18-28.9)	0.808
SMOKERS N(%)	28(46.6)	21 (25)	0.007
Side N (%) **Right** **Left**	30 (50) 30(50)	54(64.3) 30(35.7)	0.086
Median Stone size mm (Range)	13 (10-20)	18(12-20)	0.003
Stone density (HU) Median (range)	1100(760-1760)	1300(1100-1800)	0.314

Group B had longer operative time compared to Group A, with p-value <0.001, as tabulated in Table 2. Significant difference was observed between the groups, in the context of stone free rate (SFR) (p<0.001).43 patients (71.67%) from Group A were stone free after 3 months while as the stone clearance rate in Group B was 85.71% .The mean fluoroscopy time was longer for Group A (210.01 seconds) compared to Group B (133.6 seconds). However, Group B had a longer Hospital stay (72-144 hours) compared to Group A (2-23 hours).

As far as complication profile was concerned, 56(93.33%) patients in Group A and all patients in Group B developed hematuria after the procedure. 9 (10.71%) patients in Group B needed blood transfusion. 3 patients (5%) of Group A and 5 patients (5.95%) in Group B developed sepsis and required hospitalization for treatment. 5 (8.33 %) patients in Group A developed ureteric colic and needed retrograde ureteroscopy. In Group B, none of the patients faced secondary organ injury.

Discussion

Being a less morbid procedure and performed with no anesthesia or hospitalization, ESWL is preferred treatment modality for renal stones. But in view of low clearance rate (25-85%) [4]. its use for lower pole calyceal stones (LPCSs) is contentious.

Table 2: operative parameters of the patients

Variable		Group A ESWL (N=60)	Group B PCNL(N=84)	P-value
Operative duration, (minutes) **Mean (SD)** **Range**		**42.11(5.55)** **20-48**	67.5(12.5) 55-100	0.001
Fluoroscopic time, (seconds) **Mean (SD)** **Range**		**210.01(103.01)** **65-459**	133.6(54.4) 34-251	0.011
Hospital stay, (hours) **Mean (SD)** **Range**		**3.75(5.85)** **2-23**	92.3(21.85) 72-144	0.010
Stone free rate, n (%) **Yes** **No**		**43(71.67)** **17(28.33)**	72(85.7) 12(14.3)	0.038
Complications ,N (%)	**Hematuria**	**56(93.3)**	84(100)	0.001
	Post operative sepsis	**3(5)**	5(5.95)	
	Blood transfusion	**0**	9(10.71)	
	Ureteric colic	**10(16.7)**	0	

The reason being that gravity hampers the migration of stone fragments from lower calyx into pelvis and hence affects stone clearance [5,6]. Moreover, the efficacy decreases with stone burden. These limitations along with its complications drive the wide use of other minimally invasive treatment modalities for nephrolithiasis such as PCNL especially for lower pole stones [7]. Literature is divided over the right choice between PCNL and ESWL for the management of renal stones 1-2 cm in size [8,9].

In our study the age of patient population ranged between 14 to 75 years with a mean of 37.3 ±28.4 years similar with the work by Fayad et al [10] which comprises patients in the age group of 20–60 years and an average of 46.3 years. The gender ratio in our study was 1.2 which is at par with a similar study conducted by Fayad et al in which the

male to female ratio was 1.5 [10]. The median BMI of patients in ESWL group and PCNL group was 22.3 and 23.89 respectively. The patient population was similar to that in studies conducted by Mohamed Gadelmoula et al [11]. The stone size and Hounsfield density was similar to that mentioned in the contemporary literature. In our study The maximum stone length ranged 10 -20 mm (median 13mm) and 12-20mm (median 18 mm) respectively for ESWL and PCNL groups, while it was 11.5-19.6 mm (median 15.5 mm) and 13-20.4mm (median 17.45 mm) in the work presented by Mohamed Gadelmoula et al [11]. A study by Gyan Prakash Singh et al [12] included stones 10 -20 mm in maximum dimension. The mean stone size selected by Montadhar H Nimaa et al [13] was15mm (10-20) and 17mm (12-20) respectively in ESWL and PCNL . The median Hounsfield density in our study population was 1100 and 1300 in ESWL and PCNL groups respectively while the corresponding values were 1262 and 1250 in the study done by Mohamed Gadelmoula et al [11].

In our study, Stone free rate (SFR) of 71.7% and 85.7 % were observed for ESWL and PCNL respectively after 3 months of procedure. The SFR after ESWL is governed by stone size, HU attenuation value, BMI in addition to stone location, infundibulopelvic angle and infundibular width. However, the efficacy of PCNL is not affected by these factors, as the intracorporeal lithotripsy devices can clear stone regardless of its type, size and BMI of patient [14]. Among the 43 patients with treatment success, 11(25.6%) patients needed second and 4(9.3%) patients the third session of ESWL**.** 17 (28.33%) patients needed PCNL on follow up for the stone could not be cleared even after three sessions of ESWL.SFR for ESWL in present study was similar when compared to previous studies by Kumar, et al [15]. (86.6%) and Singh et al [16] (85.7%).however in studies done by Yuruk et al. [17] and Albala et al. [18] SFR of 56.7% and 40% respectively were observed for EWSL. The discordance with the SFR may be explained in view of selection bias with regard to calyceal anatomy and Hounsfield density for ESWL in these studies. The SFR for PCNL in our study is at par with that observed in literature. As documented in recent studies, comparing the two treatment strategies, PCNL clearly has better SFR than that observed in ESWL. In our study, mean post procedure hospital stay in PCNL and ESWL group was 92.3±.43.70 and 3.75 ±11.70 hours respectively. The difference in mean hospital stay is statistically significant between ESWL group and PCNL group ($p<0.001$) similar to the findings observed by Saxby et al. [19].

The most common complication in our study population was hematuria reported respectively in 93.3% and 100% patients in ESWL and PCNL postoperatively (Clavian Grade 1).However 9 (10.7%) patients from PCNL group needed blood transfusion (Clavian Grade 2).No blood transfusion was required in ESWL patient population. Post-operative sepsis was observed in 3 (5%) and 5 (5.7%) patients in ESWL and PCNL groups respectively (Clavian Grade 1).These patients were readmitted for antibiotic treatment till they were afebrile and sepsis free. In a study by Gyan Prakash Singh [12] Grade II complications were seen in 1 patient(2.4%) and 5 patients (12.19%), Grade III complications seen in 0 and 2 patient(5%) of ESWL and PCNL respectively. In a study of Anup et al [15] Grade II complications in 1% and 2% in ESWL and PCNL respectively. There was no Grade 3 complication in this study. A study done by Okan Bas et al [14] revealed Grade II complications in 1.3 % and 4%, and Grade III complications in 1.3% and 4% of ESWL and PCNL respectively.

The limitations of our study include single center origin and small sample size in both the groups. Though intending to demonstrate the safety and efficacy of the two treatment modalities, the study involved definite selection criteria for each group and hence the conclusions can't be generalized. Moreover, we don't use flexible instruments and baskets to reduce stone fragments. Some patients also refused to do computerized tomography (CT) scan for its radiation dose and high cost which is more sensitive for this purpose.

Conclusion:

Comparing with ESWL, PCNL is safe and has better stone free rate with a low retreatment rate for lower calyceal stones sized 10-20 mm. However, PCNL has more operative time, blood transfusion rate and requires longer hospital stay. The newer innovations in PCNL like decreasing the sheath size and omission of nephrostomy tube may prove helpful in improvement of its complication profile too.

Author contribution and conflicts of interest:

All the authorshave made a substantial contribution to the information or material submitted for publication, and drafting of the manuscript. There are no conflicts of interest to disclose.

Ethical considerations:

The Institutional ethical committee approved the study (IEC/SKIMS protocol RP 75/2020) and all patients were Informed about the study and a signed written consent was obtained.

Financial support and sponsorship: Nil

References

1. Galvin DJ, Pearle MS.The contemporary management of renal and ureteric calculi. BJU Int 2006; 6: 1283-1288.
2. N etto NR Jr, Claro JF, Lemos GC, Cordato PL. Renal calculi in lower pole calices. What is the best method of treatment? J Urol 1991; 146: 721-723.

3. U nsal A, Resorlu B, Kara C, BayindirM.The role of percutaneous nephrolithotomy in the management of medium-sized (1-2 cm) lower-pole renal calculi. Acta ChirBelg 2011; 111: 308-311.
4. Türk C, Petřík A, Sarica K, Seitz C, Skolarikos A, Straub M, *et al.* EAU guidelines on interventional treatment for urolithiasis. Eur Urol2016; 69: 475-482.
5. Deem S, DeFade B, Modak A, Emmett M, Martinez F, et al. Percutaneous nephrolithotomy versus extracorporeal shock wave lithotripsy for moderate sized kidney stones. Urology 2011; 78: 739-743.
6. Cakiroglu B, Sinanoglu O, Tas T, Hazar IA, Balci MBC. The effect of inclined position on stone free rates in patients with lower calyceal stones during SWL session. ArchivioItaliano di Urologia e Andrologia 2015; 87: 38-40.
7. Coz F, Orvieto M, Bustos M, Lyng R, Stein C, Hinrichs A, *et al.* Extracorporeal shockwave lithotripsy of 2000 urinary calculi with the modulith SL-20: Success and failure according to size and location of stones. J Endourol 2000; 14:239-246.
8. McDougall E., Denstedt J., Brown R.D. Comparison of extracorporeal shock wave lithotripsy and percutaneous nephrolithotomy for the treatment of renal calculi in the lower pole calyces. J Endourol. 1989; 3: 265-266.
9. Cass AS. Extracorporeal shock-wave lithotripsy or percutaneous nephrolithotomy for lower pole nephrolithiasis? Endourol. 1996; 10: 17-20.
10. Fayad AS, Elsheikh MG, Ghoneima W. Tubeless mini-percutaneous nephrolithotomy versus retrograde intrarenal surgery for lower calyceal stones of ≤ 2 cm: A prospective randomised controlled study. Arab journal of urology 2017; 15: 36-41.
11. Mohamed Gadelmoula, Ahmad A. Elderwy, Islam F. Abdelkawi. Percutaneous nephrolithotomy versus shock wave lithotripsy for high-density moderate sized renal stones: A prospective randomized study: Urology Annals 2019 ; 4: 426-431.
12. Gyan Prakash Singh, Satyajit Samal,A prospective study of effectiveness of ESWL versus PCNL in patients with kidney stone size 1-2 cm: Annals of International Medical and Dental Research,2020; 4: 43-46.
13. Montadhar H Nimaaand Shahad A Ibraheem,Comparing the Efficacy and Safety of Percutaneous Nephrolithotomy vs. Extracorporeal Shock Wave Lithotripsy for Lower Calyceal Stones 1-2 cm: Med Sur Urol, an open access journal 2018; 4: 1-5.
14. Argyropoulos AN, Tolley DA. Evaluation of outcome following lithotripsy.CurrOpinUrol 2010; 20:154-158.
15. Kumar A, Kumar N, Vasudeva P, Kumar Jha S, Kumar R, et al. A prospective, randomized comparison of shock wave lithotripsy, retrograde intrarenal surgery and miniperc for treatment of 1 to 2 cm radiolucent lower calyceal renal calculi: A single center experience. J Urol 2015; 193: 160-164.
16. Singh BP, Prakash J, Sankhwar SN, Dhakad U, Sankhwar PL, et al. Retrograde intrarenal surgery vs extracorporeal shock wave lithotripsy for intermediate size inferior pole calculi: a prospective assessment of objective and subjective outcomes. Urology 2014; 83: 1016-1022.
17. Yuruk E, Binbay M, Sari E, Akman T, Altinyay E, et al. A prospective, randomized trial of management for asymptomatic lower pole calculi. The Journal of urology 2010; 183: 1424-1428.
18. Albala DM, Assimos DG, Clayman RV, Denstedt JD, Grasso, M, et al.Lower pole I: A prospective randomized trial of extracorporealshock wave lithotripsy and percutaneous nephrostolithotomy for lowerpole nephrolithiasis-initial results. The Journal of urology 2001; 166: 2072-2080
19. Saxby MF, Sorahan T Slaney P, Coppinger SWV ,A case-control study of percutaneous nephrolit-hotomy versus extracorporeal shock wave lithotripsy. Br J Urol 1997; 79: 317-323.

Original Article

Prevalence of Obstructive Sleep Apnea in Neurological Disorders.

Asma Rafi , Muzaffar Maqbool ,Samiullah Sami Malik Parvaiz Ahmad Shah ,Rakesh Kaul.

Abstract

Objective- Obstructive Sleep Apnea(OSA) is a sleep disorder that involves cessation or significant decrease in airflow in the presence of breathing effort. OSAS is still widely under recognized by many primary care physicians around the globe. Any neurological condition that results in impaired tone of the upper airway muscles can add to airway obstruction and result in OSA, increasing the morbidity and decreasing the Health Related Quality Of Life (HRQOL) in this subset of patients. Therefore, the objective of this study was to assess the prevalence of OSA in patients with neurological disorders.

Materials and Methods

A 12-month study was conducted on 123 patients visiting our department, having the following neurological disorders:
1) Stroke 2) Parkinson's Disease 3) Epilepsy 4) Myasthenia Gravis 5) Myotonic Dystrophy .They were screened for OSA based on history, clinical examination and questionnaires for severity of the same. Epworth Sleepiness Score ≥ 10 was considered as Excessive Daytime Sleepiness. The patients were then subjected to overnight Polysomnography (PSG) to study the actual prevalence of OSA in these patients

Results

Out of the studied 123 patients ,57 belonged to stroke group of which 35(61.4) has OSA. Out of 31 patients of Parkinsons Disease, 10 (32.3%) had OSA. Out of 25 patients of Epilepsy,=10 (40%) had OSA. Out of 7 patients of Myasthenia Gravis ,3 (42.9%) had OSA. And out of 3 studied patients of Myotonic Dystrophy, 1 (33.33%) had OSA. The overall prevalence of OSA in patients with neurological disorders was 47.96%.

Conclusion

Our study marks the importance of having a high clinical suspicion of OSA in patients having neurological disorders, its severity, its relationship with age, gender, anthropometric parameters, stage and duration of disease

JK-Practitioner 2022;27(4):16-23

Introduction

Obesity Hypoventilation Syndrome is the most severe form of disordered breathing, being associated with severe morbidity and a high mortality.[1] It is a potentially disabling condition characterized by disruptive snoring, repeated episodes of complete or partial pharyngeal obstruction during sleep, resulting in nocturnal hypoxemia, frequent arousals and excessive daytime sleepiness (EDS).[2] OSA is characterized by recurrent episodes of upper airway collapse during sleep, associated with recurrent oxyhemoglobin desaturations and arousals from sleep.[3] OSA associated with EDS is commonly called OSAS/OSAHS (Obstructive SleepApnea Syndrome/Obstructive Sleep Apnea-Hypopnea Syndrome).

Apnea is defined as the cessation of airflow for at least 10 seconds. Apnea may last for 30 seconds or even longer.[4]Hypopnea is defined if all these 4 conditions are met a) the peak signal excursions drop by 30% or greater of the pre-event baseline; b) the duration of this 30% excursion drop is 10 or more seconds, and c) there is 4% or greater oxygen desaturation frompre-event baseline[4].

Author Affiliations

Asma Rafi , Registrar ;**Muzaffar Maqbool ,**Associate Professor;
Parvaiz Ahmad Shah , Rakesh Kaul, Professors;Department of Medicine,Government Medical College,Srinagar,
Samiullah Sami Malik ,Senior Resident ,General Medicine HIMSAR &HAHC,New Delhi
INDIA

Correspondence

Dr. Asma Rafi
Registrar, Department of Medicine
Government Medical College Srinagar.
Phone number: +91 9596500012
E-mail address
drasmarafi@gmail.com

Indexed

EMBASE ,SCOPUS, IndMED ,ESBCO ,Google Scholar besides other national and International Databases

Cite This Article as

Rafi A ,Maqbool M ,Malik SS, Shah PA,,Kaul R.Prevalence of Obstructive Sleep Apnea in Neurological Disorders. JK Pract2022;27(4):16-23.

Full length article available at **jkpractitioner.com** one month after publication

Keywords

Polysomnography (PSG), Apnea Hypopnea Index (AHI), Continuous Positive Airway Pressure (CPAP), excessive daytime somnolence(EDS).

As per AASM guidelines, a patient is said to have OSA if any one of these conditions is met- a) Either symptoms of nocturnal breathing disturbances or daytime sleepiness or fatigue that occur despite sufficient opportunities to sleep b)Five or more episodes of apneas plus hypopneas per hour of sleep documented in a PSG c)PSG shows >15 scorable respiratory events per hour of sleep and/or evidence of respiratory effort during all or portion of each respiratory event and d) Another current sleep disorder, medical or neurologic, medication use, or substance use does not better account for the patient's condition.[4]

OSA is objectively diagnosed by an overnight sleep study called polysomnography (PSG), which measures parameters of sleep architecture and pathophysiological events during sleep.[5] A standard PSG monitors electrocardiography (ECG), pulse oximetry, respiratory effort, end tidal CO2(ETCO2), sound recordings for snoring, EMG (electromyography) recordings of surface limbs, continuous video monitoring.[6] 4 types of PSGs are available, out of which types II, III or IV (with at least 3 channels) are approved, if the patient is screened at clinical evaluation, provided the results are read by a trained sleep specialist.[7,8] AHI (Apnea Hypopnea Index) is measured by PSG for qualifying the severity of OSA the patient has.

Mild OSA- 5 to 15 events / hour Moderate , OSA- 16 to 30 events/ hour, Severe OSA- more than or equal to 30 events/hour [9]. Although PSG is considered as the gold standard for diagnosing OSA, following subjective scales have been used for identification of individuals at high risk of OSA.

1) Berlin Questionnaire [10]
2) Epworth Sleepiness Scale [11]
3) STOPBANG Questionnaire [12]

OSA remains a matter of huge concern in patients of neurological disorders, owing to impaired tone of the upper airway muscles. Obstruction can occur at the pharyngeal level because of primary bulbar weakness or the inability of the diaphragm and intercostal muscles to overcome changes in airway resistance, especially in REM sleep. Various neurological disorders are associated with higher incidence of OSA e.g. congenital myopathies, neuropathies, myotonic dystrophies, mitochondrial encephalomyopathies, stroke, epilepsy, myasthenia gravis, Parkinson's/Alzheimer's disease, spinal muscular atrophy, poliomyelitis etc.[13] OSA is frequently identified in stroke patients(being an independent risk factor for it),owing to nightly hypoxias and elevated sympathetic tone causing hypertension and increased platelet aggregation, endothelial dysfunction from the cytokine storm due to hypoxia, or a stroke occurring due to impaired upper airway musculature control.[14,15] Patients of myasthenia gravis have an above average number of apneas plus hypopneas during sleep, correlating directly with the duration of disease.[16]

So, the menace of OSA in patients with neurological disorders should be caught at an earliest with a keen eye for suspicion of the same, such that these patients are benefitted without having significant complications owing to delay in diagnosis. Several studies have been conducted where prevalence of OSA has been studied in individual neurological disorders with very scarce data present from our part of the world. This study is of importance as OSAS prevalence was studied together in commonly observed neurological disorders.

Methods

A prospective observational study was conducted on 123 adult patients over a period of 12 months. The patients were enrolled into the study after obtaining proper ethical approval from Ethical Committee of Government Medical College ,Srinagar , vide approval number 249/ETH/GMC/ICMR dated 4/3/2016. Written well informed consent was taken from the patients/ next of kin after explaining nature of study in a local simple language. Adult patients >18 years of age with mentioned neurological disorders (Stroke >4weeks prior to inclusion into the study, Parkinson's Disease, Epilepsy, Myasthenia Gravis and Myotonic Dystrophy) were enrolled in the study to look for prevalence of Obstructive Sleep Apnea (OSA) in these patients and also to study the relation of sleep related breathing disorders, if any, with gender, disease severity and duration of the disease. Both drug naïve and on-treatment patients were included in the study. Staging of PD was done using Modified Hoehn and Yahr Staging.[17] The appropriate disease severity scores and sleep related questionnaires were administered to the patients, including Epworth Sleepiness Scale, Berlin Questionnaire and STOPBANG Questionnaire to see the severity of OSA based on history. Excessive Daytime Sleepiness (EDS) was assessed using the Epworth Sleepiness Scale (ESS) with a score of more than or equal to 10 was taken as abnormal daytime sleepiness. All the patients were subjected to overnight polysomnography (PSG)-type III by Resmed (Sleepview) to see the actual prevalence of OSA with PSG reports certified by trained sleep specialist.

Statistical analysis:

When analyzing statistics, continuous variables were summarized as mean and standard deviation. Categorical variables were summarized as frequency and percentages. Chi-square test was used to test the independence between two categorical variables. Independent samples t-test was used to test the difference between two means. p-value of <0.05 was considered as statistically significant.

Results

Out of 57 enrolled Stroke patients, 33(57.9%)

patients were in age group of 60-79 years, 13 were above the age of 80 years and 11 were in age group of 40-59 years. 6 patients aged 40-59 years had OSA, 21 aged 60-79 years had OSA and 8 aged >80 years had OSA. p-value for age was 0.999. 25(62.5%) out of 40 studied males had OSA, and 10(58.8%) out of 17 studied females had OSA. This difference was statistically insignificant (p-value - 0.794). 31 patients had hemorrhagic stroke,16 had ischemic stroke,3 had SAH and 7 had TIA, out of which OSA was present in 19(61.5%) patients of hemorrhagic stroke,10(62.5%) of ischemic stroke, 2(66.7%) with SAH, and 4(57.1%) with TIA. There was no statistically significant difference between type of stroke and OSA prevalence (p-value - 0.999). Excessive daytime somnolence significantly correlated with OSA prevalence. 10 of these patients had mild daytime sleepiness,21 had moderate daytime sleepiness and 14 had excessive daytime sleepiness as per ESS (p-value-<0.001). 47 patients were high risk for OSA and 10 were low risk for OSA as per Berlin Questionnaire. When subjected to PSG, 35(61.4%) patients had OSA, 7 had mild, 19 had moderate and 9 had severe OSA based on AHI. Mean BMI of stroke patients with OSA (27.90±3.49) was significantly higher than stroke patients without OSA (24.37±1.79) with p- value of <0.001. Neck circumference was significantly higher in stroke patients with OSA (36.85±2.95) than in patients without OSA (32.80±5.45) with a p-value of 0.003. (Table 1)

We studied 31 patients having PD aged between 50 and 69 years. OSA prevalence was higher in advanced age groups but this difference didn't attain statistical significance (p-value-0.807). 9 out of 27 males and 1 out of 4 females in our study had OSA. This difference was statistically not significant. (p-value 0.946). 21 patients had predominant non-motor symptoms and 10 had motor ones. Excessive daytime somnolence significantly correlated with OSA prevalence. 6 of these patients had mild daytime sleepiness,4 had moderate daytime sleepiness and 5 had excessive daytime sleepiness as per ESS (p-value- <0.001). 17 patients were low risk and 14 were high risk for OSA as per BQ. OSA was present in 10(32.3%) studied patients of PD, out of whom 4 had mild and 6 had moderate OSA based on AHI. OSA prevalence increased with increase in H & Y stage of the disease but this difference wasn't statistically significant(p- value .655). Prevalence of OSA significantly increased with the duration of disease (p-value of .001). There was statistically no significant difference in BMI (p-value of .126) and neck circumference (p-value of .181) between Parkinson disease patients with and without OSA. (Table 2)

25 patients of Epilepsy were studied, aged 21-50 years, of whom 17 had GTCS while 8 had focal seizures. OSA was seen in 7(41.2%) out of 17 GTCS patients and 3(37.5%) out of 8 focal seizure patients and this difference was statistically insignificant(p-value of .984). 8 patients complained of mild daytime sleepiness,7 had moderate daytime sleepiness and 2 had excessive daytime sleepiness while the others didn't complain of it at all. 20 percent patients fared 0-4 points on the STOPBANG score and 4 percent patients scored 5,6 and 8 points respectively. As per BQ,16 patients were low risk for excessive daytime sleepiness while the rest were high risk. After PSG, as per AHI, OSA was found to be present in 10 patients i.e. 40% patients of the studied epileptic population. Of these, 6 (24%) had mild OSA, 3 (12%) had moderate OSA and 1(4%) had severe OSA. Mean BMI of epilepsy patients with OSA (24.67±1.09) was significantly higher than epilepsy patients without OSA(23.44±1.09) with p-value of .011. Neck circumference was significantly higher in study patients with OSA (36.97±0.86) than in patients without OSA (34.86±2.10) with a p-value of 0.007. (Table 3)

7 patients of MG were studied, aged 30-49 years. As per BQ, 4 patients were low risk, and 3 were high risk for excessive daytime sleepiness. According to ESS, 2 patients were having mild daytime sleepiness while 1 was having moderate daytime sleepiness. After PSG, OSA was found in 3(42.9%) out of these 7 studied patients, and in all of these, it was mild. Duration of disease significantly correlated with OSA prevalence (p-value of 0.049). Higher BMI (p-value 0.010) and increased neck circumference (p-value 0.040) significantly correlated with OSA prevalence. 3 patients of myotonic dystrophy were studied, aged 27-40 years,2 of whom were having type2 myotonic dystrophy. 1 of these 3 was high risk for excessive daytime somnolence as per BQ and had moderate daytime sleepiness as per ESS, which reflected in his PSG as well, revealing mild OSA. OSA was present in 1 (33.33%) of the 3 studied myotonic dystrophy patients. (Table 4)

Table 1: Baseline, clinical characteristics and anthropometry of studied stroke patients

Parameter	Frequency(%) N=57(100)	OSA N=35(61.4)	NO OSA N=22(38.6)	p-value
Age(Years)				
40-59	11(19.3)	6(54.5)	5(45.5)	
60-79	33(57.9)	21(63.6)	12(36.4)	.999
>80	13(22.7)	8(61.5)	5(38.5)	
Gender				
Male	40(70.2)	25(62.5)	15(37.5)	.794
Female	17(29.8)	10(58.8)	7(41.2)	
Type of Stroke				
Hemorrhagic	31(54.4)	19(61.3)	12(38.7)	
Ischemic	16(28.1)	10(62.5)	6(37.5)	.999
Subarachnoid hemorrhage	3(5.2)	2(66.7)	1(33.3)	
TIA	7(12.3)	4(57.1)	3(46.9)	
Epworth Sleepiness Score				
1-6	12(21.1)	0(0.0)	12(100.0)	<.001
7-9	10(17.5)	3(30.0)	7(70.0)	
10-15	21(36.8)	18(85.7)	3(14.3)	
>16	14(24.6)	14(100.0)	0(0.0)	
Anthropometry and OSA				
Parameter	**OSA**		**NO OSA**	
Body Mass Index Mean(SD)	27.90(3.49)		24.37(1.79)	<.001
Neck Circumference Mean(SD)	36.85(2.95)		32.80(5.45)	.003

Discussion

1) OSA and Stroke

We studied 57 patients of stroke, of whom 31 had hemorrhagic stroke,16 had ischemic stroke,3 had SAH and 3 had TIA. It was found that OSA was more prevalent in the elderly stroke patients than in younger ones, as also found out earlier by Johnson et.al in his study.[18] Overall prevalence of OSA in our studied subset of patients was 61.4%, similar to a study by Tosun et.al. [19] Literature worldwide suggests that OSA is more prevalent in ischemic strokes than in hemorrhagic strokes, but in our part of the world, the overall prevalence of hemorrhagic strokes is more than ischemic strokes with a male preponderance, as already concluded from a study by Shah et.al.[20] We also came across similar data in our study and prevalence of OSA thus was found to be almost comparable in both stroke subset groups. 2 of 3 patients of SAH(66.6%) had OSA, similar to a study by Schuilling et al.[21] p-value for BQ and ESS was <0.001, as also already seen in a study by Johns MW et al.[22] Mean BMI and neck circumference of stroke patients with OSA was significantly higher than stroke patients without OSA with p-value of <0.001 and 0.003 respectively. Similar results were obtained by Turkington et al in their study.[23] SDB after stroke presents either as OSA or CSA or both. Apneic/Hypopneic episodes of OSA initiate an inflammation cascade-IL1, IL6,TNF-alpha,IFN-gamma,SCD 40L and SP- selectin. These damage the vascular endothelium, cause platelet aggregation and more oxidative stress. All these factors in turn lead to cardiovascular disease and stroke.[24] These episodes also stimulate the sympathetic nervous system/inhibit the

parasympathetic nervous system, leading to the same cascade of endothelitis.[25] Also, when the oxyhemoglobin saturation becomes <90% and AHI is more or equal to 15 in stroke patients, oxygen desaturation leads to white matter hyperintensities in stroke and TIA patients.[26]

2) OSA and PD

31 patients of PD were studied in whom the prevalence of OSA was 32.3% and the patients were staged as per the modified H&Y stage, p-value for which was 0.015. Similar inference was previously drawn by Maria et al.[27] 40% prevalence of OSA was in the elderly age group 55-59 years. Non motor symptoms(67.7%) were more prevalent than motor ones(32.3%) in PD patients having OSA. This is in accordance with studies done by Antonia Maass,[28] and in another one by Neikrug et.al.[29] It was also found out that OSA prevalence in PD depended considerably on the duration of disease, p-value for which was 0.001 in our study. Several factors may predispose PD patients to develop OSA. First, PD patients are usually elderly, and ageing is a major risk factor for OSA. Secondly, PD patients have upper airway and pulmonary function abnormalities. They have upper airway obstruction due to hypokinesia and rigidity. In addition, restrictive lung disease, probably due to chest wall rigidity and postural abnormalities of the trunk can also occur in PD.[30] Autonomic dysfunction in PD might also contribute to OSA.[31]

Table 2: Baseline, clinical characteristics and anthropometry of studied Parkinson Diseasepatients

Parameter	Frequency (%) N=31(100)	OSA N=10(32.3)	NO OSA N=21(67.7)	p-value
Age(Years)				
50-54	4(12.9)	1(25.0)	3(75.0)	.807
55-59	5(16.1)	2(40.0)	3(60.0)	
60-64	12(38.7)	2(16.7)	10(83.3)	
65-69	10(32.3)	5(50.0)	5(50.0)	
Gender				
Male	27(87.1)	9(33.3)	18(66.7)	.946
Female	4(12.9)	1(25.0)	3(75.0)	
H&Y Stage				
1	10(32.3)	2(20.0)	8(80.0)	.655
2	10(32.3)	2(20.0)	8(80.0)	
3	8(25.7)	4(50.0)	4(50.0)	
4	3(9.7)	2(66.7)	1(33.3)	
Epworth Sleepiness Score				
1-6	16(51.6)	0(0.0)	16(100.0)	<.001
7-9	6(19.4)	2(33.3)	4(66.7)	
10-15	4(12.9)	3(75.0)	1(25.0)	
>16	5(16.1)	5(100.0)	0(0.0)	

Anthropometry and OSA			
Parameter	**OSA**	**NO OSA**	
Body Mass Index			
Mean(SD)	21.56(0.81)	22.02(0.92)	.181
Neck Circumference			
Mean(SD)	30.24(3.55)	31.64(1.46)	.126
Duration of Disease (inyears)			
Mean(SD)	4.90(2.02)	1.57(0.59)	.001

Table 3: Baseline, clinical characteristics and anthropometry of studied epilepsy patients

Parameter	Frequency(%) N=25(100)	OSA (%) N=10(40.0)	NO OSA (%) N=15(60.0)	p-value
Age(Years)				
21-30	14(56.0)	4(28.6)	10(71.4)	
31-40	8(32.0)	4(50.0)	4(50.0)	.738
41-50	3(12.0)	2(66.7)	1(33.3)	
Gender				
Male	21(84.0)	8(38.1)	13(61.9)	.905
Female	4(16.0)	2(50.0)	2(50.0)	
Type of Seizure Focal	8(32.0)	3(37.5)	5(62.5)	.984
GTCS	17(68.0)	7(41.2)	10(58.8)	
Epworth Sleepiness Score				
1-6	8(32.0)	0(0.0)	8(100.0)	<.001
7-9	8(32.0)	4(50.0)	4(50.0)	
10-15	7(28.0)	4(85.7)	3(14.3)	
>16	2(8.0)	2(100.0)	0(0.0)	
Anthropometry and OSA				
Parameter	**OSA**		**NO OSA**	
Body Mass Index Mean(SD)	24.67(1.09)		23.44(1.09)	.011
Neck Circumference Mean(SD)	36.97(0.86)		34.86(2.10)	.007

Table 4: OSA prevalence and severity in studied neurological disorders.

AHI*	Stroke	Parkinson Disease	Epilepsy	Myasthenia Gravis	Myotonic Dystrophy	Total N=123(%)
AHI<5 No OSA	22	21	15	4	2	64(52)
AHI 5-15 Mild OSA	7	4	6	3	1	21(17.1)
AHI 16-30 ModOSA	19	6	3	0	0	28(22.8)
AHI>30 SevereOSA	9	0	1	0	0	10(8.1)
%age OSA in group	61.4	47.6	40	42.8	33.33	
OSA was present in 47.96 % of the studied population						

*AHI- Apnea-Hypopnea Index.

3) OSA and Epilepsy

OSA and epilepsy, being a dangerous duo, have a reciprocal influence on each other. We studied 25 patients of epilepsy,21-50 years of age, and OSA prevalence wasn't significantly different in various age groups with p-value of 0.037, in contradiction to the study conducted by Chihorek et.al.[32] The reason for this could be our small sample size, of which majority were young, of the age group 21-30 years. Also considering epilepsy being a disease of the younger population and life expectancy being lesser in the Asian population, the difference vis-a-vis results in previous studies could hence be explained. 68% had GTCS, 32% had focal seizures. Majority of the patients having OSA had GTCS. This is also in accordance with the study by Bialasiewicz et.al.[33] 32% patients had mild daytime sleepiness,25% had moderate daytime sleepiness while8 had excessive daytime sleepiness as per ESS. Prevalence of OSA in our studied epileptic population was 40%. High likelihood of OSA in epileptics has been previously studied by Khatami et.al.[34] p-value for STOPBANG questionnaire was <0.001, in accordance with a study by Abrishami et.al.[35] Mean BMI and neck circumference of epilepsy patients with OSA was significantly higher than epilepsy patients without OSA with p-value of 0.011 and 0.007 respectively. Similar inference was drawn by Venturi et.al.[36] The pathogenic link between sleep apnea and seizures has been researched extensively and is thought to be due to increased neuronal excitability and synchronized discharge of neurons.[37,38]

4)

5) OSA and MG

MG is an autoimmune condition which can rarely be fatal but can be life threatening as it affects the muscles required for swallowing and ventilation. We studied 7 patients of MG in whom the prevalence of OSA was 42.9%, in conformity with a study by Rask et.al.[39] 42.8% patients complained of moderate as per BQ and ESS. Similar results were previously noted in a study by Oliviera et.al.[40] In our studied subset, apneas caused were mainly by peripheral mechanisms,as also corelated in a study by Gajdos et.al.[41] Mean BMI and neck circumference of myasthenia gravis patients with OSA was significantly higher than myasthenia gravis patients without OSA with p-value of 0.010 and 0.040 respectively. Results of similar nature have been previously noted by Nicolle et.al.[39] and Kang et al.[42] p-value for duration of disease was 0.049 similar to that in a study by Amino et.al in which they found that patients with a longerduration of MG tend to have more sleep apneas.[18]

6) OSA and Myotonic Dystrophy

Sleep Apnea is common in myotonic dystrophy and could be an important cause of respiratory failure in these patients. We studied 3 patients of myotonic dystrophy, 2 had type2 myotonic dystrophy while 1 had type1 myotonic dystrophy. The patient of type1 myotonic dystrophy complained of mild daytime somnolence and his PSG was also suggestive of mild OSA, while the other 2 neither had daytime somnolence nor OSA on PSG. The prevalence of OSA thus was 33.33% in these 3 patients of myotonic dystrophy. In a study by Bianchi et.al, prevalence of OSA was 69% in type 1 myotonic dystrophy and 43% in type2 myotonic dystrophy.[43] Our results could be due to a very small sample size. As underlined by Laberge et.al, the presence of SDB can affect daily life, general well being and social participation in myotonic dystrophy patients.[44]

Conclusion

There is a significant association between OSA and neurological disorders. BMI, neck circumference, staging and duration of disease corelated well with both the presence and severity of OSA, increased age being an independent risk factor for OSA except in young epileptics. In our study, the prevalence of OSA in Stroke was 61.4% with statistically no significant difference between hemorrhagic and ischemic strokes. In PD, it was 32.3%. In Epilepsy, it was 40%. In MG,it was 42.9%. In myotonic dystrophy, it was 33.3%. The overall prevalence of OSA as documented by PSG in these afore-mentioned neurological disorders was 47.96%. Early recognition of SDB by clinical assessment and documentation of OSA by PSG along with timely management with CPAP thus becomes imperative in improving HRQOL in patients with neurological disorders having SDB.

Limitations

The absence of healthy controls remains a limitation of this study along with a relatively small sample size especially for epilepsy, myasthenia gravis and myotonic dystrophy. Moreover, we have included both drug naive and on-treatment patients which might make it difficult to study the effect of drugs on sleep architecture. Studying excessive daytime sleepiness in epileptics could be even more challenging, owing to anti-epileptic drug effect, poor seizure control and/or inadequate sleep.

References

1. Anstead M, Phillips B. The spectrum of sleep-disordered breathing. Respir Care Clin N Am. 1999 Sep; 5(3): 363-77.
2. M. Casale et al. Obstructive sleep apnea syndrome: from phenotype to genetic basis. Curr Genomics.2009 Apr; 10(2): 119-126.
3. Guilleminault C et al. The sleep apnea syndromes. Annu Rev Med 1976; 27: 465-84.
4. American Academy of Sleep Medicine. International classification of sleep disorders, Diagnostic and coding manual. Second edition. Westchester, III: American Academy Of Sleep Medicine, 2005.
5. Downey R, Perkin RM. Upper airway resistance syndrome: sick, symptomatic but under recognized. Sleep 1993 Oct;16(7):620-23.
6. Ralph Downey, Zab Mosenifar. Obstructive Sleep Apnea. Updated:Jan 27,2017.
7. Campbell AJ, Neil AM. Home setup of polysomnography in the assessment of suspected obstructive sleep apnea, J Sleep Res.2011 Mar; (1 pt 2): 207-13.
8. Ayas NT, Fox J, Epstein L, Ryan CF, Fleetham JA. Initial use of Portable monitoring versus polysomnography to confirm obstructive sleep apnea in symptomatic patients: an economic decision model. Sleep Med. 2010 Mar; 11(3): 320-4.
9. Crummy F, Piper AJ, Naughton MT. Obesity and the lung: 2. Obesity and sleep-disordered breathing. Thorax. 2008; 63(8):738-46.
10. Adeline Tan, Jason D.C Yin et al. Using the Berlin questionnaire to predict obstructive sleep apnea in the general population. J Clin sleep Med.2017 Mar 15; 13(3) :427-432
11. Broaderick JE, Junghaenel DU et al. Pittsburgh and Epworth Sleep Scale items: accuracy of ratings across different reporting periods. Behav sleep Med, 2013; 173-188.
12. Mahesh Nagappa, Pu Liao et al. Validation of the STOPBANG questionnaire as a screening tool for obstructive sleep apnea among different populations: A systematic review and metaanalysis. PLoS one. 2015; 10(12): e0143697.

13. Seddon PC et al. Respiratory problems in children with neurological impairment. Arch Dis.Child 2003.
14. Lattimore J.D et al. Obstructive sleep apnea and cardiovascular disease. J Am Coll Cardiol. 2003 May; 41(9):1429-37.
15. Yaggi et al. Obstructive sleep apnea and stroke. Lancet Neurol. 2004 Jun; 3(6): 333-42.
16. Amino A et al. Sleep apnea in well controlled myasthenia gravis and the effect of thymectomy. J Neurol 1998 Feb; 245(2): 77-80.
17. Goetz CG, Poewe W, Rascol O, et al. Movement Disorder Society Task Force report on the Hoehn and Yahr staging scale: status and recommendations. Mov Disord. 2004 Sep. 19(9): 1020-8.
18. Johnson KG, Johnson DC. Frequency of Sleep Apnea in Stroke and TIA Patients: A Meta-analysis. Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine. 2010; 6(2):131-137.
19. Tosun A, Köktürk O, Karata GK, Ciftqi TUI Sepici V. Obstructive sleep apnea in ischemic stroke patients. Clinics (Sao Paulo). 2008 Oct; 63(5):625-30.
20. Parvaiz A Shah, G Hussain Bardi et al. Clinico-radiological profile of strokes in kashmir valley, North-West India : A study from a university hospital. Neurology Asia 2012 ; 17(1): 5-11
21. Schuiling WJ, Rinkel GJ, Watchenbach R, de Weerd AW. Disorders of sleep and wake in patients after subarachnoid haemorrhage. Stroke. 2005 Mar; 36(3):578-82.
22. Johns MW. A new method for measuring daytime sleepiness: the Epworth sleepiness scale. Sleep. 1991 Dec; 14(6): 540-5.
23. Turkington PM, Bamford J, Wanklyn P, Elliott MW. Prevalence and predictors of upper airway obstruction in the first 24 hours after acute stroke. Stroke. 2002 Aug;33(8):2037-42.
24. Shamsuzzaman AS, Gersh BJ, Somers VK. Obstructive sleep apnea: implications forcardiac and vascular disease. 2003, 290 (14): 1906-1914.
25. Bradlet TD, Floras JS. Obstructive sleep apnea and its cardiovascular consequences. Lancet.2009;373(9657):82-93.
26. Patel SK, Hanly PJ, Smith EE, et al. Nocturnal hypoxemia is associated with white matter hyperintensities in patients with a minor stroke or transient ischemic attack. J Clin Sleep Med. 2015;11(12): 1417-1424.
27. Maria B et al. Sleep breathing disorders in patients with idiopathic Parkinson's disease. Respir Med. 2003 Oct; 97(10): 1151-7.
28. Maass A, Reichmann H. Sleep and non-motor symptoms in Parkinson's disease, Journal of Neural Transmission. 2013; 120(4): 565-569.
29. Neikrug AB, Maglione JE, Liu L, et al. Effects of Sleep Disorders on the Non-Motor Symptoms of Parkinson Disease. Journal of Clinical Sleep Medicine. Official Publication of the American Academy of sleep Medicine. 2013; 9(11): 1119-1129.
30. Still H, Stacy M. Respiratory function in PD. Clin NeuroSci 1998;5: 131-135.
31. Jost WH. Autonomic dysfunctions in idiopathicPD. J.Neurol.2003;250(supple):128-30.
32. Chihorek AM et al. Sleep Apnea and Seizures in Older Adults. Neurology 2007 Nov 6;69: 1823.
33. Piotr Bialasiewicz, Dariusz. OSA and nocturnal epilepsy with tonic seizures. Epileptic Disord 2009; 11 (4): 320-3.
34. Khatami R, Zutter D, Siegel A, Mathis J, Donati F, Bassetti CL. Sleep-wake prospective study. Seizure. 2006 Jul; 15(5):299-306.
35. Abrishami A, Khajehdehi A, Chung F. A systematic review of screening questionnaires for obstructive sleep apnea. Can J Anaesth. 2010 May; 57(5): 423-38
36. Venturi M, Neves GS, Pontes I M, Valois A, Gomes Mda M. Risk and determinant factors for obstructive sleep apnea in patients with epilepsy. Arq Neuropsiquiatr. 2011 Dec; 69(6):924-7.
37. Devinsky O, Ehrenberg O et al. Epilepsy and Sleep Apnea Syndrome. Neurology 1994; 44: 2060.
38. Sivathamboo S, Perucca P et al. Sleep disordered breathing in epilepsy : Epidemiology, mechanisms and treatment. Sleep 2018: Jan 31-2018.
39. Nicolle MW, S Rask , WJ Koopman , CFP George J Adams and S Wiebe. Sleep apnea in patients with myasthenia gravis. Neurology 2006; July 11; 67(1):140-2.
40. Fernandes Oliveira E, Nacif SR, Alves Pereira N, et al. Sleep disorders in patients with myasthenia gravis: a systematic review. Journal of Physical Therapy Science. 2015;27(6):2013-2018.
41. Gajdos P, Quera Salva MA. Respiratory disorders during sleep and myasthenia. Rev Neurol (Paris).2001 Nov; 157(11 Pt 2): S145-7.
42. Kang HH, Kang JY, Ha JH, Lee J, Kim SK, Moon HS, Lee SH. The associations between anthropometric indices and obstructive sleep apnea in a Korean population. PLOS One. 2014 Dec 4;9(12):e114463
43. Bianchi ML, Losurdo A, Di Blasi C, Santoro M, Masciullo M, conte G, Valenza V, Damiani A, Della Marca G, Silvestri G. Prevalence and clinical correlates of sleep disordered breathing in myotonic dystrophy types 1 and 2. Sleep Breath. 2014 Sep;18(3):579-89.
44. Laberge L, Gagnon C, Dauvilliers Y. Daytime sleepiness and myotonic dystrophy. Curr Neurol Neurosci Rep. 2013 Apr; 13(4): 340.

Original Article

Assessing the Course and Outcome of Trauma Patients in Surgical Intensive Care Unit: A Hospital Based Prospective Observational Study.

Anjum Shamim, Tahleel Mohd Jeelani, Wasim Salman

Abstract

Background: Despite continued advances in intensive care unit technology and the availability of sophisticated interventions for the treatment of critically ill or severely injured patients, major trauma patients continue to die in the SICU. Identification of factors responsible for this state of affairs is of paramount in order to improve the outcome of these patients. Admission of patients with poor prognosis and/or prolonged use of the ICU facility results in other patients with a better prognosis being denied care; many of these die as a result. Understanding the magnitude of the problem and characterizing the patterns of injury in these patients is important in planning programmes targeted at preventing their occurrence and subsequently reduce ICU admissions. There is paucity of published data on SICU trauma admissions in our environment despite large number of trauma admissions to our ICU.

Aim

To assess the disease course of trauma patients admitted in Surgical Intensive Care Unit and study the various factors for improving the outcome of trauma patients in Surgical Intensive Care Unit.

Methods

The current research was an prospective observational study of 48 patients and has provided characterization of patients and their complications which develop after trauma in SICU. Valuable information gained will help identifying subjects at high risk for the future development of complications and be applied in clinical practice for preemptive strategies for better trauma SICU management and research.

Results

In this study It was seen that complications and mortality among ICU trauma patients are associated with different risk factors and course of management. This means that modifying factors influencing occurrence of complications can somewhat increase survival advantage to trauma patients admitted in our SICUs.

Conclusion

Before embarking on large expensive clinical trials targeting or manipulating specific variables, it is of paramount importance to conduct thorough studies adequately addressing the role and interactions of various risk factors in patients admitted with trauma to SICUs for better patient care and outcome. This study was conducted to describe the characteristics and treatment outcome of major trauma patients admitted into our ICU and to identify predictors of outcome.

JK-Practitioner2022;27(4):24-29

Introduction:

Despite continued advances in intensive care unit technology and the availability of sophisticated interventions for the treatment of critically ill or severely injured patients, major trauma patients continue to die in the ICU [1]. Identification of factors responsible for this state of affairs is of paramount in order to improve the outcome of these patients. Understanding the magnitude of the problem and characterizing the patterns of injury in these patients is important in planning programmes targeted at preventing their occurrence and subsequently reduce ICU admissions. There is paucity of published data on ICU trauma

Author Affiliations
Anjum Shamim, Wasim Salman ;Assistant Professors, Department of Anaesthesia, Government Medical College Anantnag,
Tahleel Mohd Jeelani, Senior Resident, Department of Anaesthesia, Government Medical College Baramulla,
Jammu & Kashmir
INDIA

Correspondence
Dr.Wasim Salman
Assistant Professor , Department of Anaesthesia, Government Medical College Anantnag.
Jammu & Kashmir,
India.
E mail
drwasimsalman@gmail.com
9419060400

Indexed
EMBASE ,SCOPUS, IndMED ,ESBCO, Google Scholar besides other national and International Databases

Cite This Article as
Shamim A, Jeelani TM, Salman W.Assessing the Course and Outcome of Trauma Patients in Surgical Intensive Care Unit: A Hospital Based Prospective Observational Study
JK Pract2022;27(4):24-29

Full length article available at **jkpractitioner.com** one month after publication

Keywords
SICU; Surgical Intensive Care Unit, ARDS: Acute Respiratory Distress Syndrome.MODS: Multiple Organ Dysfunction Syndrome

admissions to our ICU. This study was conducted to describe the characteristics and treatment outcome of major trauma patients admitted into our ICU and to identify predictors of outcome.

Care providers may have developed an intuitive impression that a prolonged SICU stay would probably have a terminal outcome. Thus the goal of this study is to investigate this impression in a defined SICU population. The goal is not to establish the guidelines to limit or withdraw therapy based on likelihood of death but rather to improve the prognosis. In our study we will be studying the course and outcome of trauma patients admitted in Surgical Intensive Care Unit.

Methods

This prospective observational study was conducted in Department of Anaesthesiology and Critical Care, of a Tertiary hospital after approval by institutional ethical committee.It was a prospective hospital based study of all trauma cases admitted in Surgical Intensive Care Unit SICU of the Hospital over a period of one and a half years. All the trauma patients admitted to SICU either directly from the emergency reception or from the operating room will be included in this study. The work up which included an informed consent of patients or their attendants, extensive history and physical examination of the patient was done.

Inclusion criteria

Age group 5 years and above

Trauma patients who are managed conservatively or operated upon but require SICU admission

Exclusion criteria

Trauma patients that do not require SICU admission

Patients who are in vegetative state like bedridden for a prolonged time, stroke patients or suffering from carcinoma

Statistical analysis

The recorded data was compiled and entered in a spreadsheet (Microsoft Excel, Office Excel Software Microsoft Microsoft Excel, Redmond, Washington: Microsoft 2003, Computer software).) and then exported to data editor of SPSS Version 20.0 (SPSS Inc.., Chicago, Ilinois, USA)Continuous variables were summarised in the form of means and standard deviations and categorical variables were expressed as frequencies and percentages.Graphically the data was presented by bars and line diagrams.Student's independent t-test was employed for comparing continuous variblesChi square test or Fisher's exact test , whichever appropriate was applied for comparing categorical variablesA P- value of less than 0.05 was considered statistically significant.

Results

Table 1 showing arrival pH of patients admitted in SICU .Mean pH of 7.2042 and standard deviation of 0.0871**.** In our study data of on arrival pH of patients admitted in SICU showed that mean pH of 7.2042 and standard deviation of 0.08710. pH of patients ranged from 7.02-7.32 with maximum patients having pH of 7.09,7.29, 7.30 (all these having 8.3% frequency, 4 patients each); followed by 3 patients each (6.3%) having pH of 7.19, 7.23, 7.25, 7.27 followed by 4.2% patients (2 patients) having pH of 7.02, 7.05, 7.11, 7.15, 7.17, 7.20, 7.22, 7.24, 7.31, 7.32 each. While 1 patient each (2.1%) having pH of 7.10, 7.14, 7.16, 7.28.

ARRIVAL pH (Table 1)

pH	Frequency	Percent	Valid Percent	Cumulative Percentage
7.02	2	4.2	4.2	4.2
7.05	2	4.2	4.2	8.3
7.09	4	8.3	8.3	16.7
7.10	1	2.1	2.1	18.8
7.11	2	4.2	4.2	22.9
7.14	1	2.1	2.1	25.0
7.15	2	4.2	4.2	29.2
7.16	1	2.1	2.1	31.3
7.17	2	4.2	4.2	35.4
7.19	3	6.3	6.3	41.7
7.20	2	4.2	4.2	45.8
7.22	2	4.2	4.2	50.0
7.23	3	6.3	6.3	56.3
7.24	2	4.2	4.2	60.4
7.25	3	6.3	6.3	66.7
7.27	3	6.3	6.3	72.9
7.28	1	2.1	2.1	75.0
7.29	4	8.3	8.3	83.3
7.30	4	8.3	8.3	91.7
7.31	2	4.2	4.2	95.8
7.32	2	4.2	4.2	100.0
Total	48	100.0	100.0	

Table 2 showing the frequency data of days on ventilator of patients admitted in SICU .Mean of 18.83 days with standard deviation of 12.587. In our study data of frequency data of days on ventilator of patients admitted in SICU . Showed that mean of 18.83 days with standard deviation of 12.587.Range of days on ventilator were from 0 day-45 days with maximum patients remaining for 3 days (12.5%, 6 patients), followed by 29 days (8.3%, 4 patients). Rest patients in order of frequency showed following trends: 2 patients each (4.2%) remained on ventilator for 2 days, 7 days, 9 days, 12 days, 14 days, 18 days, 19 days, 23 days, 25 days, 28 days, 32 days, 34 days, 35 days respectively. While 1 patient each (2.1%) remained on ventilator for a period of 0 day, 1 day, 4 days, 5 days, 17 days, 24 days,26 days, 27 days, 30 days, 37 days, 38 days and 45 days respectively.

DAYS ON VENTILLATOR (Table 2)				
Days	Frequency	Percent	Valid Percent	Cumulative Percentage
0	1	2.1	2.1	2.1
1	1	2.1	2.1	4.2
2	2	4.2	4.2	8.3
3	6	12.5	12.5	20.8
4	1	2.1	2.1	22.9
5	1	2.1	2.1	25.0
7	2	4.2	4.2	29.2
9	2	4.2	4.2	33.3
12	2	4.2	4.2	37.5
14	2	4.2	4.2	41.7
17	1	2.1	2.1	43.8
18	2	4.2	4.2	47.9
19	2	4.2	4.2	52.1
23	2	4.2	4.2	56.3
24	1	2.1	2.1	58.3
25	2	4.2	4.2	62.5
26	1	2.1	2.1	64.6
27	1	2.1	2.1	66.7
28	2	4.2	4.2	70.8
29	4	8.3	8.3	79.2
30	1	2.1	2.1	81.3
32	2	4.2	4.2	85.4
34	2	4.2	4.2	89.6
35	2	4.2	4.2	93.8
37	1	2.1	2.1	95.8
38	1	2.1	2.1	97.9
45	1	2.1	2.1	100.0
Total	48	100.0	100.0	

Table 3 showing frequency of patients developing pneumonia during their stay in SICU .64.6% of trauma patients developed pneumonia .Data of frequency of patients developing complications during their stay in SICU showed that majority of patients developed respiratory complication especially, pneumonia. Out of the total patients we observed 64.6% (31 number) of trauma patients developed pneumonia.

Complications developed during SICU stay:

PNEUMONIA (Table 3)				
	Frequency	Percent	Valid Percent	Cumulative Percentage
NO	17	35.4	35.4	35.4
YES	31	64.6	64.6	100.0
Total	48	100.0	100.0	

Table 4 showing frequency of patients developing urinary tract infection during their stay in SICU .16.7% of patients developed UTI .Data on frequency of patients developing urinary tract infection during their stay in SICU showed that 16.7% of patients (8 out of total 48 patients) developed UTI while 83.3% patients didn't develop UTI.

URINARY TRACT INFECTION (Table 4)				
	Frequency	Percent	Valid Percent	Cumulative Percentage
NO	40	83.3	83.3	83.3
YES	8	16.7	16.7	100.0
Total	48	100.0	100.0	

Table 5 showing frequency of patients developing MODS during their stay in SICU .18.8% of patients developed MODS.Data of frequency of patients developing MODS during their stay in SICU showed that out of total 48 patients, 18.8% (9 patients) developed multiple organ dysfunction syndrome while 81.3% patients were not affected with MODS

Multiple Organ Dysfunction Syndrome (Table 5)				
	Frequency	Percent	Valid Percent	Cumulative Percentage
NO	39	81.3	81.3	81.3
YES	9	18.8	18.8	100.0
Total	48	100.0	100.0	

Table 6 showing frequency of patients developing ARDS during their stay in SICU .39.6% patients developed ARDS .Data of frequency of patients developing ARDS during their stay in SICU showed that 39.6% patients (19 patients out of 48) developed ARDS while 60.4% patients were not affected by ARDS during their stay in SICU.

Acute Respiratory Distress Syndrome (Table 6)				
	Frequency	Percent	Valid Percent	Cumulative Percent
NO	29	60.4	60.4	60.4
YES	19	39.6	39.6	100.0
Total	48	100.0	100.0	

Table 7 showing frequency of patients developing SEPSIS during their stay in SICU .60.4% patients developed sepsis .Data of frequency of patients developing SEPSIS during their stay in SICU .Sepsis was the 2nd most common complication after pneumonia that was developed in these patients under study. 60.4% (29 out of total 48) patients developed sepsis during their stay in SICU.

SEPSIS (Table 7)				
	Frequency	Percent	Valid Percent	Cumulative Percent
NO	19	39.6	39.6	39.6
YES	29	60.4	60.4	100.0
Total	48	100.0	100.0	

Table 8 showing the frequency survival of patients admitted in SICU .Out of 48 trauma patients admitted in SICU 62.5% patients were survivors while 37.5% patients died**.** In our study data of the frequency survival of patients admitted in SICU showed that out of 48 trauma patients admitted in SICU 62.5% (30 patients) were survivors while 37.5% patients (18 in number) died. So a survival rate of 62.5% was noted in our study on these patients.

SURVIVAL (Table 8)				
	Frequency	Percent	Valid Percent	Cumulative Percent
NONSURVIVOR	18	37.5	37.5	37.5
SURVIVOR	30	62.5	62.5	100.0
Total	48	100.0	100.0	

Table 9 showing AGE VS SURVIVAL RATE among patients admitted in SICU .Mortality is very high in elderly age group of 61 years and above (87.5%) and comparatively lesser in the younger age group.Chi-square analysis shows a (P value of 0.001) which is statistically significant and depicts that with increase in age there is increase in mortality of patients admitted in SICU .In our study data of age vs survival rate among patients admitted in SICU showed that maximum survival rate was in group upto 40 year age group, thereafter mortality rate increased significantly. Among various age group: age group ≤30 years had a survival rate of 84% (11 patients) while 15.4% patients (2 in number) had mortality. Age group 31-40 years showed the maximum survival among all the age groups. All the patients in this age group (100%, 10 patients) survived. In age group 41-50 years , the mortality rate increased than survival rate, while only 37.5% (5 patients) had the survival; a significant number of patients(62.5%, 4 in number) had the mortality. 51-60 year age group patients had the survival rate of 55%(5 patients) while the mortality rate was 44.4%(4 patients). Age group 61 year and above had the maximum mortality among all the age groups with only 1 patient surviving among the total of 8 patients in this group, thus the mortality rate of only 12.5% and mortality rate manifold higher i.e. 87.5%.

When all the data of different age groups was combined a total of total survival rate of 62.5% (30 patients) was observed in our study while the total mortality rate reached at 37.5% (18 patients). Depicts that with increase in age there is increase in mortality of patients admitted in SICU.

AGE VS SURVIVAL (Table 9)

			SURVIVAL		Total
			NO	YES	
AGE	≤30 years		2	11	13
		% among gp	15.4%	84.6%	100.0%
	31-40 years		0	10	10
		% among gp	0.0%	100.0%	100.0%
	41-50 years		5	3	8
		% among gp	62.5%	37.5%	100.0%
	51-60 years		4	5	9
		% among gp	44.4%	55.6%	100.0%
	61 & above		7	1	8
		% among gp	87.5%	12.5%	100.0%
Total			18	30	48
			37.5%	62.5%	100.0%

Table 10 showing COMPLICATIONS VS SURVIVAL RATES among patients admitted in SICU .Common complications seen in trauma patients admitted in SICU include Pneumonia, UTI(urinary tract infections), Sepsis, MODS (multiple organ dysfunction syndrome) ARDS (acute respiratory distress syndrome).This table shows that there is definite relationship between the no. of complications and the survival rates among trauma pts admitted in SICU .There is high mortality (57.9%) in pts who have more than 3 complications..Data showed that when the total numbers of complication were less (less than 3) the survival rate was quite higher i.e. 75.9%(22 patients survived out of total 29 patients having complications less than 3).Compared to it, survival rate decreasd significantly when the total number of complication were more than 3, where the survival rate decreased to 42.1% and mortality increased to 57.9% in these patients (only 8 patients survived out of total 19 patients in this group). Mortality increases with the increase in no. of complications

COMPLICATIONS VS SURVIVAL (Table 10)

		SURVIVAL		Total
		NO	YES	
Less than 3 Complications		7	22	29
	% among gps	24.1%	75.9%	100.0%
More than 3 complications		11	8	19
	% among gps	57.9%	42.1%	100.0%
Total		18	30	48
	% among gps	37.5%	62.5%	100.0%

Table 11 showing ARRIVAL GCS VS SURVIVAL RATES among trauma patients admitted in SICU .There is high mortality among patients (73.7%) with on arrival GCS of 8 or below.Data of arrival GCS vs survival rates among trauma patients admitted in SICU it was observed that survival rate were significantly different in patients with with GCS≥9 compared to those with GCS≤ 8.In patients whose on arrival GCS was ≥ 9 survival rate was quite high i.e. 86.2% (25 patients survived out of total 29 patients received with GCS≥ 9). In this group mortality rate was only 13.8% (4 patients out of 29).When compared it with group whose on arrival GCS was ≤ 8 in them survival rate was significantly low with 26.3% (only 5 out of 19 patients survived in this group). There was high mortality among patients (73.7%) with on arrival GCS of 8 or below.Chi-square analysis shows a (P value of 0.001) which is **statistically significant** and signifies that mortality is inversely related to the arrival GCS

GCS ON ARRIVAL VS SURVIVAL (Table 11)

		SURVIVAL		Total
		NO	YES	
GCS ≥ 9		4	25	29
	% among gps	13.8%	86.2%	100.0%
GCS ≤ 8		14	5	19
	% among gps	73.7%	26.3%	100.0%
Total		18	30	48
	% among gps	37.5%	62.5%	100.0%

58.1% of patients who developed pneumonia did not survive among 31 patients who developed pneumonia during their stay in SICU as in table 12.Data comparing pneumonia vs survival showed that among 31 patients who developed pneumonia during their stay in SICU 58.1% (18 patients) patients did not survive .While 100% of patients who didn't develop pneumonia survived.Chi-square analysis revealed a (P value of <0.005) which is statistically significant and signifies that mortality is directly related to presence or absence of pneumonia

Individual complications vs survival

PNEUMONIA VS SURVIVAL **(Table 12)**

	SURVIVAL		Total
	NO	YES	
NO PNEUMONIA	0	17	17
% among gps	0.0%	100.0%	100.0%
PNEUMONIA	18	13	31
% among gps	58.1%	41.9%	100.0%
Total Count	18	30	48
% within PNEUMONIA	37.5%	62.5%	100.0%

In table 13 ,37.5% of patients did not survive among 8 patients who developed UTI during their course of stay in SICU.Data comparing urinary tract infection vs survival revealed that survival rate was similar in both groups who had either uti or not with both groups having survival rate of 62.5%.Similarly mortality rate was similar in both groups who developed UTI or not with 37.5% in both groups. So out of total 18 patients in our study who had the mortality, 15 were not having UTI while 3 were having it. Chi-square analysis revealed a (P value of 0.647) which is not statistically significant and thus a definite association could not attributed to it

URINARY TRACT INFECTION VS SURVIVAL **(Table 13)**

	SURVIVAL		Total
	NO	YES	
NO UTI	15	25	40
% among gps	37.5%	62.5%	100.0%
UTI	3	5	8
% among gps	37.5%	62.5%	100.0%
Total	18	30	48
% Within UTI	37.5%	62.5%	

Table 14 shows 100% of trauma patients among 9 patients who developed MODS during their stay in SICU .Data showing MODS vs survival revealed that 100% (9 in number) of trauma patients who developed MODS during their stay in SICU didin't survive. While in those who didn't have MODS, the mortality rate was 23.1% and survival rate was 76.9%. Among the total mortality of 18 patients in our study 9 patients were having MODS while 9 patients didn't have.

Chi-square analysis revealed a (P value of < 0.005) which is **statistically significant** and shows a definite association between MODS & mortality

MODS VS SURVIVAL **(Table 14)**

	SURVIVAL		TOTAL
	NO	YES	
NO MODS	9	30	39
% among gps	23.1%	76.9%	100%
MODS	9	0	9
% among gps	100%	0%	100%
TOTAL COUNT	18	30	48
% within MODS	37.5%	62.5%	100%

Table 15 shows, 52.6% of patients died among 19 patients who developed ARDS during their stay in SICU **.** Data comparing ARDS vs survival revealed that 52.6% of patients (19 in number) developed ARDS during their stay in SICU . Among those who developed ARDS had survival rate of 47.4% (9 patients) and mortality rate of 52.6% (10 patients). Among those who didn't develop ARDS had survival rate of 27.6% (8 patients) and mortality rate of 72.4% (21 patients). Among total of 18 patients who didn't survive, 10 were having ARDS while 8 patients were not having ARDS. Chi-square analysis revealed a (P value of 0.074) which statistically insignificant

ARDS VS SURVIVAL **(Table 15)**

	SURVIVAL		Total
	NO	YES	
NO ARDS	8	21	29
% among gps	27.6%	72.4%	100.0%
ARDS	10	9	19
% among gps	52.6%	47.4%	100.0%
TOTAL	18	30	48
% within ARDS	37.5%	62.5%	100.0%

58.6% of patients died among 29 trauma patients who developed sepsis during their stay in SICU as in table 16.Data comparing sepsis vs survival revealed that only 1 patient without sepsis had mortality while 17 patients with sepsis had mortality. Among no sepsis group, out of 19 patients, 5.3% (1 in number) had mortality, while 94.7% patients (18 in number) survived. Among patients who developed sepsis, out of 29 patients, 58.6% (17 patients) was the mortality rate and 41.4% (12 patients) was the survival rate. Chi-square analysis revealed a (P value of 0.001) which is **statistically significant** and shows a definite relationship between the outcome.

SEPSIS VS SURVIVAL **(Table 16)**

	SURVIVAL		Total
	NO	YES	
NO SEPSIS	1	18	19
% among gps	5.3%	94.7%	100.0%
SEPSIS	17	12	29
% among gps	58.6%	41.4%	100.0%
TOTAL	18	30	48
% within SEPSIS	37.5%	62.5%	100.0%

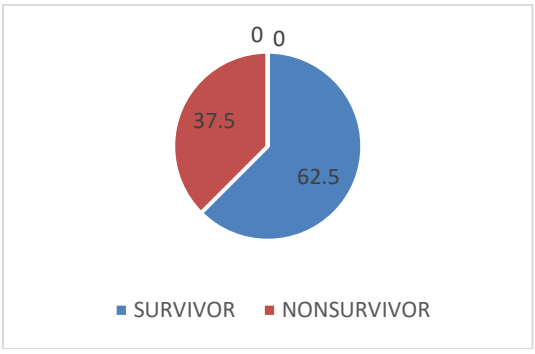


Figure 1 Percentage of Survivors and non-survivor in SICU

Pie chart 1 showing overall survivor and nonsurvivor percentage of patients admitted in SICU

Discussion:

Major trauma is often life threatening and usually presents as an emergency, requiring either immediate surgical intervention or intensive care or both.[3,4] Hospital complications are associated with significantly increased risk of mortality.The Intensive Care Unit is a specialized area where facilitiesfor the critically ill or severely injured patients are concentrated and where the level of care and supervision is considerably more sophisticated than in the ordinaryward.[5] Worldwide, intensive care unit requires avast use of up to date resources such as advanced monitors,organ support equipments and highly skilled staff.This however, often taxes the most buoyant health system seven of the developed nations. In most developingnations where there are several financial constraints resulting from poor funding of the healthcare generally and the ICU specifically, there is often alimit to the availability and specialization of this form ofcare. Besides allocation of resources, intensive carealso demands a tremendous amount of time and efforton behalf of the medical and nursing staff to treat andimprove survival of the critically ill patients. It thereforefollows that the role of the ICU must be justified whereverit exists. The allocation of ICU facilities when financial resources are limited is determined by cost/benefit and patient outcome.[6,7,8]Admission of patients with poor prognosis and/or prolonged use of the ICUfacility results in other patients with a better prognosisbeing denied care; many of these die as a result.Despite continued advances in intensive care unit technology and the availability of sophisticated interventionsfor the treatment of critically ill or severely injuredpatients, major trauma patients continue to die in the ICU. Identification of factors responsible for this state ofaffairs is of paramount in order to improve the outcomethese patients. Understanding the magnitude of the problemand characterizing the patterns of injury in thesepatients is important in planning programmes targeted at preventing their occurrence and subsequently reduce ICUadmissions. [9,10] There is paucity of published data on ICUtrauma admissions in our environment despite large numberof trauma admissions to our ICU.

Conflict of Interests: The authors declare that there is no conflict of interests regarding publication of this paper.

References:

1. Abubakar AS, Ojo EO, El-Nafaty AU, Edomwonyi NP: An audit of one-year intensive care practice in a developing country. The Internet Journal of Anesthesiology 2008, 18:2.
2. Mitchell VT, Scarlett MD, Amata AV: Trauma Admissions to the ICU of the University Hospital of the West Indies, Kingston, Jamaica. Trauma Care Fall/Winter 2001, 86-89.
3. Moini M, Rezaishiraz H, Zafarghandi MR: Characteristics and outcome of injured patients treated in urban trauma centers in Iran. J Trauma 2000, 48:503-7.
4. Duane TM, Rao RI, Aboutanous MB, Wolfe LG, Malhotra AK: Are trauma patients better off in a trauma ICU? J Emerg Trauma, Shock 2008, 1:74-7.
5. Abubakar AS, Ojo EO, El-Nafaty AU, Edomwonyi NP: An audit of one-year intensive care practice in a developing country. The Internet Journal of Anesthesiology 2008, 18:2
6. Mitchell VT, Scarlett MD, Amata AV: Trauma Admissions to the ICU of the University Hospital of the West Indies, Kingston, Jamaica. Trauma Care Fall/Winter 2001, 86-89.
7. World Health Organization. Global status report on road safety 2015. Geneva.
8. World Health Organization. Injuries and violence: the facts 2014. http://www.who.int. Accessed January 15, 2018.
9. Lozano R, Naghavi M, Foreman K, et al. Global and regional mortality from 235 causes of death for 20 age groups in 1990 and 2010: a systematic analysis for the Global Burden of Disease Study 2010. Lancet. 2012;380(9859):2095-2128.
10. Glance LG, Osler TM, Mukamel DB, Dick AW. Outcomes of adult trauma patients admitted to trauma centers in Pennsylvania, 2000-2009. Archives of surgery (Chicago, Ill : 1960). 2012;147(8):732-737.

Original Article

Ultrasonography Based Study of Endometrial Thickness as a Guideline for the Treatment of Dysfunctional Uterine Bleeding in Pre-Menopausal Kashmiri Women.

Zeenat Kausar, Ghulam Mohamad Bhat, Khalid Bashir

Abstract

Background: Dysfunctional uterine bleeding (DUB) is a common gynecological problem in women during reproductive life taking a substantial economic toll apart from intangible social and psychological brunt.

Objectives: 1 Estimate whether endometrial thickness (ET) can be used as a predictor of the type of treatment in the study population with symptoms of DUB.**2**. To determine the response of endometrial thickness to medical treatment and symptom regression on ultrasonography

Methods: This was a Prospective study on patients with diagnosed, dysfunctional uterine bleeding, in the Department of Obstetrics and Gynecology. ET of all DUB patients was measured at baseline and the outcome of different treatment modalities was observed and the effect on ET after 3 months of treatment was observed by doing repeat Ultrasonography.

Results: A total of 250 patients were included. There was a statistically significant relationship between the treatment modality and outcome over all levels of ET ($p<0.001$). DNC alone showed the lowest success rate for all levels of ET. DNC with Levonorgestrel(IUD) had 100% success rate. Medical treatment showed a very high success rate (97.5%) in the ET range 8mm to 9.9mm group but the success rate decreased at higher levels of ET (ET10 to11.9 group success rate =50%).

Conclusion: Medical treatment remains the treatment of choice in DUB patients with levels of endometrial thickness in the range of (8mm-9.9mm).The DNC with Levonorgestrel(IUD) provides highly efficacious option in the treatment of DUB patients which is reversible and spares fertility, unlike hysterectomies.

JK-Practitioner 2022;27(4):30-36

Introduction

Dysfunctional uterine bleeding (DUB) is a common gynecological problem in women during reproductive life taking a substantial economic toll apart from intangible social and psychological brunt. It is defined as unusual and excessive endometrial bleeding without structural pathology [1]. The 20% of gynecology outpatient department (OPD) visits accounts for DUB, and is a common enervating problem amongst women in all age groups [2]. About one-third of the hysterectomies are carried out for menstrual disturbances alone [3]. Up to 40 % of women with DUB will finally end up with some other diagnosis if intensively investigated [4]. Psychiatric morbidity is also related to DUB, females suffering from various psychiatric ailments have associated menstrual disturbances as well [5,6]. Patients under 40 years of age have a very low risk of developing endometrial carcinoma, [7] and so compulsory invasive pathological examination of the endometrium is not needed [8]. Measurement of ET with ultrasonography is commonly used nowadays. Its clinical importance and application extended throughout the phases of the reproductive lives of women. ET can vary with the menstrual cycle and with the use of hormone replacement therapy or selective estrogen receptor modulators. Ultrasonography is an excellent non-invasive tool to diagnose the anatomic cause of DUB.

Author Affiliations
Zeenat Kausar, MD, Senior Resident,
Ghulam Mohamad Bhat, MD ,Professor:Department of Anatomy ,
Khalid Bashir, M.D Senior Resident , Department of Community Medicine(SPM), Government Medical College, Srinagar. Jammu & Kashmir INDIA

Correspondence
Dr.Khalid Bashir
Senior Resident Department of Community Medicine(SPM), Government Medical College, Srinagar.
Email
drkhalidbashir.s@gmail.com

Indexed

EMBASE ,SCOPUS, IndMED ,ESBCO , Google Scholar besides other national and International Databases

Cite This Article as
Kausar Z, Bhat, GM ,Bashir K. Ultrasonography Based Study of Endometrial Thickness as a Guideline for the Treatment of Dysfunctional Uterine Bleeding in Pre-Menopausal Kashmiri Women.
JK Pract2022;27(4):30-36

Full length article available at **jkpractitioner.com** one month after publication

Keywords
Uterine bleeding, Endometrial thickness, Treatment

The ultrasonography procedure to evaluate dysfunctional uterine bleeding has several advantages over other diagnostic methods. We can perform serial ultrasonography on patients and assess their response to treatment. Ultrasonography is a potent, accessible, and reliable tool in the diagnosis and management of dysfunctional uterine bleeding (DUB) by determining measurements of an endometrial thickness (ET). The objective of the study was to investigate the utility of endometrial thickness (ET) measurement on USG in treating DUB patients, instead of solely relying on clinical conditions to observe and evaluate the response of various treatment modalities in dysfunctional uterine bleeding by taking endometrial thickness as a basic parameter.

Materials and Method:

The study was conducted by Department of Anatomy in collaboration with the Department of Radio-diagnosis and Imaging and the Department of Obstetrics and Gynecology at Lal Ded Hospital(associated hospital) of Government Medical College Srinagar. This was the first Prospective study conducted for a period of 18 months on patients with diagnosed, dysfunctional uterine bleeding, reporting to Department of Obstetrics and Gynecology. Proper informed and written consent was taken from all the patients included in the study (Annexure I) The subjects included in this study were of Kashmiri ethnicity. A complete history, physical examination, and investigations to rule out bleeding disorders or any uterine pathology were done. Parameters regarding the age of the patient, age at menarche, cycle regularity and frequency, number of days of bleeding, parity (in case of married), pregnancy / puerperal complication if any, significant medical, surgical/ past history were noted. A pre-structured proforma (Annexure-II) was used to collect relevant data.

The eligible subjects were chosen as per the following inclusion and exclusion criteria's of the study

Inclusion criteria

1. All patients in the reproductive age groups with diagnosed Dysfunctional uterine bleeding (DUB).

Exclusion criteria

1. Patient with demonstrable pelvic pathology like uterine polyps, sub-mucous myomas.

2. Neoplasm's (endometrial, cervical, vaginal, vulvar, and oviduct malignancies and granulosa theca cell ovarian tumors).

3.Patients with systemic diseases like thyroid dysfunction, hypertension, diabetes, bleeding tendencies, renal impairment, cirrhosis or collagen vascular diseases.

4. Polycystic ovarian disease diagnosed cases.

5. Past history of IUCD insertion.

6. Pregnancy.

7.Abortion(threatened, incomplete, or missed abortion), ectopic pregnancy, trophoblastic disease, placental polyp, and sub involution of the placental site),infection (endometritis, salpingitis).

8. Iatrogenic causes of abnormal uterine bleeding (use of sex steroids, hypothalamic depressants, digitalis, phenytoin, anticoagulants, and intrauterine contraceptive devices).

The ultrasonographic procedure(abdominal/vaginal) was explained to all subjects in detail and written consent was taken from each subject. A female attendant was always present while scanning the patient and all ultrasonography scans were performed by the same observer during the study. In ultrasonography transabdominal component was performed first and the transvaginal component was performed second, because of the higher resolution of the transvaginal probe, it usually was very helpful for a good evaluation of pelvic processes. After obtaining initial endometrial thickness, patients were referred back to Gynae OPD for further management and were advised a follow-up scan after three months to determine response to treatment by measurement of endometrial thickness on USG.

To determine the effect of various treatment modalities on endometrial thickness, we evaluated the response of medical treatment, surgical treatment, combined medical and surgical treatment based on endometrial thickness measurements on ultrasonography. Histopathology of all those DUB patients who underwent surgical treatment of DNC was sent after the procedure.

Results:

A total of 150 patients were observed for different treatment modalities for DUB during the study period. Endometrial thickness of all DUB patients was measured at baseline and the outcome of different treatment modalities was observed and the effect on Endometrial thickness after 3 months of treatment was seen by doing repeat Ultrasonography. Patients were divided into 3 groups based on endometrial thickness: Group 1; less than 8mm.Group 2; 8-11mm. Group 3; more than 11mm.

The age range of patients was 25 years to 46 years and above, with the maximum number of patients in the age range of 36-45years, n=65 patients. The lowest age at menarche was found to be 11 years in the study patients, with 14 years as the highest age, with the maximum number of patients having 12 years age at menarche, n=76.In menstrual history 82 patients had regular menstrual cycles Out of 150 patients 131 were married and just over half of the married patients(n=70) had undergone caesarean section for their last child mode of delivery, n=51 married patients were para 2.(Table I)

The history of abortion in the past was given by n=41. Married patients gave a history of use of different types of contraceptive methods with the maximum number of patients using barrier methods, n=79.(Table II)Patients who reported for DUB treatment during the study period did undergo USG at the baseline, the endometrial thickness of all these patients was measured which is shown in Table:-III, while as the maximum number of patients had endometrial thickness in the range of 8-9.9mm, n=99 patients .The initial treatment given to patients included Medical, DNC, and DNC with Levonorgestrel(IUD) insertion. Out of 150 patients, Medical treatment was received by 85 patients, DNC n=40, DNC with Levonorgestrel(IUD) n=25 patients, as shown in (Table IV).The relationship between treatment modality and treatment outcome for various levels of endometrial thickness is shown in (Table:V). There was a statistically significant relationship between the treatment modality and treatment outcome overall levels of endometrial thickness (All $p<0.001$). DNC alone showed the lowest success rate for all levels of endometrial thickness. DNC with Levonorgestrel(IUD) had a 100% overall success rate. Medical treatment showed a very high success rate(97.5%) in the endometrial thickness range 8mm-9.9mm group but the success rate decreased at higher levels of endometrial thickness (ET 10-11.9 group success rate =50%). Patients with very thick endometrium (ET>12mm) had received either DNC alone or DNC with Levonorgestrel(IUD) and none of them had received medical therapy during the study period .The overall success rate of medical therapy was 95.3% and of DNC with Levonorgestrel(IUD) was 100%. DNC alone showed the lowest overall success rate of 35%.

Discussion:

In the study effect of various treatment modalities on endometrial thickness was seen, instead of solely relying on clinical response to treatment. The response of medical treatment, surgical treatment, and combined medical and surgical treatment based on endometrial thickness measurements on ultrasonography was evaluated. In our study, we had one hundred fifty DUB patients with endometrial thickness at baseline presentation on Ultrasonography in the range of (8mm to >= 12mm). The maximum number of dysfunctional uterine bleeding (DUB) patients (44%)in the age range of 36 to 45 years, Shinde CD et al [9] observed in their study (38%) patients had more than 36 years of age, the bleeding disorders were more severe in them, their ET was > 8mm. G.L.Shobhitha et al [10] in their study found age group of patients ranged from 35-55 and the most common age group was 41-45(36.4%). Smita Pathak et al [11]found in their study most of the cases (36.77%) were seen in the age group of 41-50 years. Our study showed the maximum number of patients in the age range of 36- 45 years, which was slightly higher than these studies. In our study, 50% of patients had 12 years of age at menarche and 55% of patients in our study gave a history of regular menstrual cycles and 45% irregular menstrual cycles. Anjali Singh et al [12] found in their study, 50% patients were with normal (regular) menstrual cycles in the study, which shows regular menstrual cycles history was slightly lesser than our study. Bharat Talukdar et al [13] found majority of patients (54.37%), gave a history of the menstrual problems with irregular periods, which was higher than our study.

Our study found 88% patients were multiparous among which 39% patients were Para2, and 31% patients gave history of abortion. . L. Thulasi Devi et al [14] in their study had 54% DUB patients Para 2-Para 5. This shows multiparity has higher preponderance with DUB, which can be seen in our study as well.

Pallavi C. Dhamangaonkar et al [15] 81.4% were multipara in their study. Shinde CD et al [9] found in their study, 84% of patients were multiparous. G.L.Shobhitha et al [10] found majority of the women were multiparous (83.6%) in their studyIn our study 53.8% patients gave history of caesarean section in their last child mode of delivery. Pallavi C. Dhamangaonkar et al [15] found 10% of patients with previous lower segment caesarean section (LSCS), which is quite lower than our study. Barrier method was found in 60 % patients, 32% patients were Ligated, 8% did not use any contraceptive, 28.6% patients were not sterilized, while 71.4% patients had undergone tubal sterilization, which was higher than our study.

The endometrial thickness of all the study patients was measured at the baseline, maximum number of patients had endometrial thickness in the range of 8-9.9mm, (66% patients),10-11.9mm in 16% patients , 12mm and above in 18% patients. G.L.Shobhitha et al [10] found in their study maximum number of DUB patients having endometrial thickness in the range of 8-15 mm (45%), while as 34.5% patients had ET in the range of 4-8mm,16% patients had ET >15mm,3.6% patients had ET<4mm.Shinde CD et al [9] in their study had observed endometrial thickness of patients at baseline, ET (up to 8 mm) was seen in (61.6%), ET(8.1 to 11 mm) was seen in (23.4%)patients and ET (>than 11 mm) was seen in (15%) patients.

Our study observed that initial treatment given to patients included Medical, DNC and DNC with Levonorgestrel(IUD) insertion. Medical treatment was received by 56.7% patients, DNC 26.7% patients, DNC with Levonorgestrel(IUD) 16.7% patients. Shinde CD et al [9] in their study had seen response of various treatment modalities, in which 33% patients had received Medical treatment, 43% DNC and 7% patients advised hysterectomy.

Shinde CD et al [9] had not seen effect of DNC with Levonorgestrel(IUD) in their study. After thorough review of literature, no such study has been done, which has assessed the response of DUB patients to combined treatment modality (DNC with Levonorgestrel(IUD)).In our study we observed response to combined treatment modalities (DNC with Levonorgestrel(IUD)) as well.

In our study 80% patients showed symptom regression, 15% patients had recurrence to initial treatment with different treatment modalities and 5% patients showed no improvement. We observed the outcome of 30 patients who showed no improvement or recurrence to initial treatment. Repeat treatment of DNC with Levonorgestrel(IUD) insertion was given to 14 patients and 85.7% (n=12) patients showed improvement to this treatment modality, and 53% (n=16) patients underwent hysterectomy. This shows DNC with Levonorgestrel(IUD) is a very successful treatment modality. Orbo et al [16] found response to treatment was reported 100% with the LNG-IUS, and they concluded that the LNG-IUD treatment was significantly superior to oral medroxyprogesterone (10 mg daily) treatment. Vereide et al [17] reported that, after 3 months, all patients treated with LNG-IUS showed regression of hyperplasia, whereas only 55% of patients showed response to medical treatment in their study.

There was a statistically significant relationship between the treatment modality and treatment outcome over all levels of endometrial thickness (All $p<0.001$). DNC alone showed the lowest success rate for all levels of endometrial thickness. DNC with Levonorgestrel(IUD) had 100% overall success rate in the study. Medical treatment showed very high success rate (97.5%) in the endometrial thickness range 8mm-9.9mm group but the success rate decreased at higher levels of endometrial thickness (ET 10-11.9 group, success rate =50%). Patients with very thick endometrium (ET>12mm) had received either DNC alone or DNC with Levonorgestrel(IUD) and none of them had received medical therapy during the study period. The overall success rate of DNC alone was the lowest being of 35%, medical therapy showed a success rate of 95.3% while the success rate with DNC and Levonorgestrel(IUD) combination was 100% and this finding of ours is supported by a past study conducted by Orbo et al [16] which showed that the success rate of treatment with Levonorgestrel(IUD) alone was 100% in DUB patients and in our study effect of combined effect of DNC with Levonorgestrel(IUD) has shown an improved outcome of 100% as well. Shinde CD et al [9] In their study there was significant decrease in ET in DUB patients after medical line of treatment in different patterns of bleeding. In age group less than 25 year, 75% patient having normal ET responded to medical line of treatment while 25% was advised for surgical line of treatment. In 25-28 year of age group 100% responded well to medical line of treatment. In 3rd group of 29- 32 year, 82% patient having ET up to 8mm &100% patients with ET 8-11mm responded to medical treatment. In age group 41-44 year and greater than 44 year, 100% patients were advised for surgical line of treatment. Their average ET was 10.6mm. Here it shows that once there is increase in endometrial thickness with increase in age group, it is less likely to respond to medical therapy. The treatment modality DNC with Levonorgestrel(IUD) was not used by Shinde CD et al [9] which has shown highly successful results in our study, the medical only treatment is very much effective in their study, like in our study, especially in lower endometrial thickness and lower age group.

Pallavi C. Dhamangaonkar et al [15] found Levonorgestrel(IUD) caused a 80% decrease in MBL (Menstrual blood loss) at 4 months, 95% decrease in MBL by 1 year, and 100% decrease (amenorrhea) by 2 years. Hysterectomy was done in (5.7%) patients only. The efficacy of Levonorgestrel(IUD) was tested by subjective improvement and improvement in quality of life as told by patient as well as by Hb estimation after 4 months post insertion. Their study proved that Levonorgestrel(IUD) is an excellent alternative to hysterectomy, which is observed in our study as well. Shinde CD et al [9] had observed if endometrial thickness is <8mm preferred line of treatment would be medical treatment, while as ET >8mm, line of treatment depends upon age and type of bleeding. They observed that ET in younger age group is in the range of (<8mm).The preferred line of treatment will be either DNC or hysterectomy, when ET is >8 mm. They have not seen effect of DNC with LEVONORGESTREL(IUD) on endometrial thickness and outcome of treatment with same in DUB patients. Delate OM et al (2010) [18] conducted a study on management of DUB based on endometrial thickness. They found significant decrease in endometrial thickness after medical management patients. Their results supported effectiveness of treating DUB according to endometrial thickness. Machado LS et al (2005) [19]. They concluded that ultrasonography is a good initial screening tool in evaluation of women with DUB. An endometrial thickness of <5mm in post-menopausal bleeding means that curettage can be avoided, whereas there is no cut-off value for premenopausal women. Persadie RJ (2002) [20] reviewed the ultrasonographic assessment of endometrial thickness. ET can vary with menstrual cycle and use of hormone replacement therapy or SERM.

Llimitation:-We could not study the effect of Levonorgestrel(IUD) alone as no patient was observed to be on Levonorgestrel(IUD) alone in our study period.

Table I: Demographic and clinical characteristics of patients

Socio-demographic and clinical characteristics		Frequency	Percentage
Age (Years)	<=25	**20**	13.3
	26-30	**29**	19.3
	31-35	**31**	20.7
	36-45	**65**	43.3
	≥46	**5**	3.3
Age at menarche	11 years	**23**	15.3
	12 years	**76**	50.7
	13 years	**49**	32.7
	14 years	**2**	1.3
Menstrual Cycles	Regular	**82**	54.7
	Irregular	**68**	45.3
	Total	**150**	100.0
Marital status	Married	**131**	87.3
	Unmarried	**19**	12.7
Parity	0	**1**	0.8
	1	**29**	22.1
	2	**51**	38.9
	3	**29**	22.1
	4	**13**	9.9
	5	**7**	5.3
	6	**1**	0.8

Table II: Description of abortion, mode of delivery, time since last child birth of patients

		Frequency	Percentage
Abortion	Yes	41	31.3
	No	90	68.7
Last child mode of delivery	Caesarean	**70**	**53.8**
	Normal delivery	**60**	**46.2**
Time since birth of last child	≤3 years	**60**	**40.0**
	4-5 years	**40**	**26.7**
	6-10 years	**14**	**9.3**
	>10 years	**36**	**24.0**

Table III: Shows endometrial thickness of patients at baseline and after three months

		Frequency	Percentage
Endometrial Thickness Baseline (mm)	8-9.9	99	66.0
	10.0-11.9	24	16.0
	12.0 & above	27	18.0
Endometrial thickness at 3 months	Normal ET (<=7)	118	78.7
	Abnormal ET (>7)	32	21.3

Table IV: Shows frequency of patients to different treatment modalities

Treatment modalities	Frequency	Percentage
Medical	85	56.7
DNC	40	26.7
DNC with Levonorgestrel(IUD)	25	16.7
Treatment modalities	Frequency	Percentage
Medical	85	56.7
DNC	40	26.7
DNC with Levonorgestrel(IUD)	25	16.7

Table V: Shows response to different treatment modalities and on various ranges of endometrial thickness

Endometrial thickness (mm)	Treatment Modality	Successful N(%)	Not Successful N(%)	Total	p-value
ET 8-9.9 mm	**Medical**	**79(97.53)**	**2(2.4)**	**81**	**p=0.0001**
	DNC	**5(62.5)**	**3(37.5)**	**8**	
	DNC with Levonorgestrel(IUD)	**10(100)**	**0(0)**	**10**	
ET 10.0-11.9 mm	**Medical**	**2(50)**	**2(50)**	**4**	**p=0.0118**
	DNC	**4(36.36)**	**7(63.63)**	**11**	
	DNC with Levonorgestrel(IUD)	**9(100)**	**0(0)**	**9**	
ET ≥12 mm	**Medical**	**0(0)**	**0(0)**	**0**	**p=0.0008**
	DNC	**5(23.80)**	**16(76.19)**	**21**	
	DNC with Levonorgestrel(IUD)	**6(100)**	**0(0)**	**6**	
Total	**Medical**	**81(95.29)**	**4(4.70)**	**85**	**p<0.0001**
	DNC	**14(35)**	**26(65)**	**40**	
	DNC with Levonorgestrel(IUD)	**25(100)**	**0(0)**	**25**	

References:

1. Polaneczky MM, Slap GB. Menstrual disorders in the Adolescent: Dysmenorrheal and dysfunctional uterine bleeding. Pediaatr Rev1992; 13: 83- 87.
2. Awwad JT, Toth TL, Schiff I. Abnormal uterine bleeding in the perimenopause. Int J Fertil. 1993; 38:261.
3. Coulter A, Mc Pherson K, Vessey M. Do British Women Undergo too many or too few hysterectomies? Soc Sci Med1988; 27:987-94.
4. Beazley JM. Dysfunctional uterihaemorrhage. Br JHosp Med 1972; 7:573.
5. Ballinger CB. Psychiatric morbidity and menopause: screening of a general Population sample. Br Med J 1975; iii: 344-46.
6. Gath D, Osborn M, Bungay G et al. Psychiatric disorder and gynaecological Symptoms in middle-aged women: a community survey. Br Med J1987; 294:213-218.
7. Mackenzie JZ, Bibby JG. Critical assessment of Dilatation and curettage in 1029 women. Lancet 1978; ii: 566-69.
8. Grimes DA. Diagnostic dilatation and curettage: a Reappraisal Am J Obstet Gynecol1982; 142:1-6.
9. Shinde CD, Patil PG, Mane R. Endometrial thickness by USG as a guideline for the treatment of dysfunctional uterine bleeding in Premenopausal women. Int J Med Res Rev 2015; 3 (3):263-267.
10. G.L.Shobhitha1, V. Indira Kumari, P.Lakshmi Priya, B. Tripura Sundari. Endometrial Study by TVS and its correlation with histopathology in Abnormal Uterine Bleeding. IOSR Journal of Dental and Medical Sciences (IOSR-JDMS) Volume 14, Issue 4 Ver. II .2015 Apr; PP 21-32
11. Smita Pathak, Sneha Joshi, Dipak Kendre, Janice Jaison, Pooja Banwaskar. Study of organic lesions causing abnormal uterine bleeding (AUB). Indian Journal of Basic and Applied Medical Research. 2015 June; Vol.-4, Issue- 3, P. 171-178.
12. Anjali singh, Saroj singh, Veena mathur, Kalpana Singh. TVS in DUB and its correlation with histopathology. Journal of obstetrics and gynecology of India, 2001; 51(6): 116-121.

13. Bharat Talukdar and Sangita Mahela. Abnormal uterine bleeding in perimenopausal women. Correlation with sonographic findings and histopathological examination of hysterectomy specimens. J Midlife Health. 2016 Apr-Jun; 7(2): 73–77.
14. L. Thulasi Devi, Ravi Nimonkar. Ormeloxifene in the management of dysfunctional uterine bleeding. International Journal of Reproduction, Contraception, Obstetrics and Gynecology. Int J Reprod Contracept Obstet Gynecol. 2018 May;7(5):1885-1892.
15. Pallavi C. Dhamangaonkar, K. Anuradha, and Archana Saxena. Levonorgestrel intrauterine system (Levonorgestrel(IUD)): An emerging tool for conservative treatment of abnormal uterine bleeding. J Midlife Health. 2015 Jan-Mar; 6(1): 26–30.
16. Orbo A, Arnes M, Hancke C, Vereide AB, Pettersen I, Larsen K. Treatment results of endometrial hyperplasia after prospective D-score classification: A follow-up study comparing effect of LNG-IUD and oral progestins versus observation only. Gynecol Oncol. 2008; 111:68.
17. Vereide AB, Arnes M, Straume B, Maltau JM, Ørbo A. Nuclear morphometric changes and therapy monitoring in patients with endometrial hyperplasia: A study comparing effects of intrauterine levonorgestrel and systemic medroxyprogesterone. Gynecol Oncol. 2003; 91:526
18. Delate OM, Gupta A, Abraham C, Chandrareddy A, Bowers Jr CH, Cutlet JB. Management of Dysfunctional Uterine Bleeding based on Endometrial Thickness. International Journal of Women's Health. 2010; 2: 297-30292.
19. Machado LS, Mathew M, Al-Hassani A, Vaclavinkova V. Correlation of Endometrial thickness, cycle day and histopathology in women with abnormal uterine bleeding. Saudi Med J.2005; 26(2): 260-263.
20. Persadie RJ. Ultrasonographic assessment of endometrial thickness: a review. J Obstet Gynaecol Can. 2002 Feb; 24(2):131-6.

Original Article

Xanthogranulomatous Cholecystitis, Rare Variant of Chronic Cholecystitis - A Histopathological Study from Kashmir, India

Afiya Shafi, Jangbhadur Singh, Ashfaq- ul –Hassan, Haminder Kour

Abstract

Background

Xanthogranulomatous cholecystitis [XGC] is a rare inflammatory disease of gall bladder characterized by focal or diffuse destructive inflammatory process, with varying proportions of fibrous tissue, acute and chronic inflammatory cells and lipid laden foamy macrophages.

Material and Methods

The present study is 2 year retrospective study done in a medical college hospital. Forty-one (41) patients of XGC were diagnosed and various histomorphological changes were studied. The age, the sex, clinical features and Ultra sound details of patients were also reviewed and analyzed. It is a close differential diagnosis in most of cases of gall bladder carcinoma, and as such needs to be reported with care.

Results

The incidence of XGC in our study is 2.92 %.Cases included 25 females and 16 males, showing female dominance. Age ranged from 11 to 75 years, with fifth decade as the commonest age group. Most of the patients presented with pain abdomen followed by dyspepsia and vomiting. Three patients were suspected of mass lesion suggesting carcinoma but later proved to be XGC on histopathology. Ultrasonography revealed diffuse and local thickening of gall bladder wall in almost 35 patients with gall stones in 38 patients. Bile duct was free of any stone. Microscopy revealed mucosal ulceration, foamy macrophages, lymphocytes, plasma cells, eosinophils, giant cells - foreign body type and touton type, fibrosis, cholesterol clefts and bile pigment in varying proportions.

Conclusions

Although radiology is helpful in detecting various disorders of the gall bladder but many a times fails to differentiate between XGC and malignancy. It is very often misdiagnosed on clinical, radiological, pre operative and intra operative findings. Histopathological evaluation of XGC is the gold standard for diagnosing the lesion. Xanthogranulomatous cholecystitis should be reported carefully, as it mimics and is a close differential of carcinoma gall bladder.

JK-Practitioner2022;27(4):37-42

Introduction

Xanthogranulomatous cholecystitis is a benign uncommon variant of chronic cholecystitis characterized by focal or diffuse inflammation of gall bladder. XGC is traditionally a histopathological diagnosis. Its incidence is variable in different studies ranging from 1.2 % to 8.9 %. XGC was first described by Christensen and Ishak[1-3] as Fibro xanthogranulomatous inflammation in 1970. Later the condition was described as Ceroid – like histiocytic granuloma of gall bladder and biliary granulomatous cholecystitis [14]. Its primary characteristic is destructive inflammation that is focal or disseminated throughout the organ. Different amounts of fibrous tissue, acute and chronic inflammatory cells and lipid laiden macrophages are also present. Grossly, it shows yellow brown nodules with abnormal and asymmetrical thickening of the gall bladder wall [11]. Its pathogenesis is not clear. It is thought to start as a biliary obstruction with acute or chronic cholecystitis and increasing intra gall bladder pressure. This pressure causes rupture of Rokitansky- Asch off sinuses or mucosal ulcer with release of bile in interstitial tissue and a consequent Xanthogranulomatous inflammatory reaction [11]. Therefore this condition needs to be diagnosed carefully because of its resemblance to

Author Affiliations

Afiya Shafi , Jangbhadur Singh ,
Associate Professors,
Haminder Kour ,Senior Resident ;
Department of Pathology ,
Ashfaq- ul –Hassan
Associate Professor; Department of Anatomy
SKIMS Medical College, Srinagar ,India

Correspondence
Dr Jangbhadur Singh
Associate Professor, Pathology ,
SKIMS Medical College,
Srinagar India.

Indexed
EMBASE ,SCOPUS, IndMED, ESBCO ,Google Scholar besides other national and International Databases

Cite This Article as
Shafi A ,Singh J ,Hassan A , Kour H. Xanthogranulomatous Cholecystitis, Rare Variant of Chronic Cholecystitis - A Histopathological Study from Kashmir, India
JK Pract2022;27(4):37-42.

Full length article available at **jkpractitioner.com** one month after publication

Keywords
XGC-[Xanthogranulomatous cholecystitis], Carcinoma, Cholecystectomy

malignancy

Aims and Objectives:

- To study the histopathological spectrum of Xanthogranulomatous cholecystitis in gall bladder specimens reported at our institute.

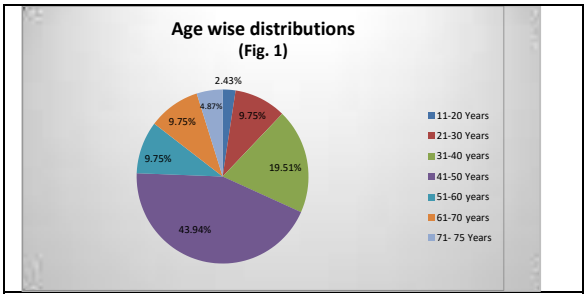


Figure 1. Age Wise Distributions

- To compare prevalence of XGC in our study with those reported from different parts of world.

Methods:

The study was done retrospectively for two years from January 2018 to December 2019 at SKIMS medical college Srinagar, Kashmir, by analyzing the clinical, radiological and histopathological features and results were compared with those in the literature. Data was retrieved from the archives of department of Pathology. A total of 1400 patients had undergone cholecystectomy during this period, out of which 41 patients (2.92 %) were diagnosed as XGC. Gross features like wall thickness, mucosal ulceration, fibrosis and color were mentioned in the histopathology forms.

Inclusion Criteria

All patients who had undergone cholecystectomy and the cases with clinical details like age, sex, clinical symptoms as retrieved from the archival files of the department were considered for study.

Exclusion criteria

The cases without clinical details like age, sex, clinical symptoms as retrieved from the archival files of the department were not included in the study.

Statistical Analysis

Data was analyzed statistically with the help of Statistics Software package SPSS-V:22.0.Continuous variables were represented by Descriptive statistics and the categorical variables in terms of Frequency and Percentage. All the comparisons were done by using the Chi-Square method,P value <0.05 was found statistically significant. Also appropriate statistical Charts were used to represent the data. Figure 3 & Table 1.

Results:

XGC was observed in 41 of 1400 patients who underwent cholecystectomy between January 2018 to December 2019, an incidence of 2.92 % [fig 1], out of which 25 [61 %] were females and 16 [39 %] were males [Fig 4], showing female dominance for the disease. Age in females ranged from 11-50 years and males from 30-75 years, and the commonest age group with the disease was in the fifth decade [Fig 1].The mean age of the patients diagnosed with xanthogranulomatou cholecystitis was 43 year. Most of the patients presented with pain abdomen were 32 [78.04 %], nausea and vomiting 16 [39.02 %], dyspepsia 28 [68.29 %] and fever 10 [24.39 %]. All patients underwent abdominal ultrasonography, which showed focal or diffuse wall thickening in the body and fundus. Three patients showed mass lesion suggestive of carcinoma and gall stones were seen in 38 patients [92.68 %]. No stone was seen in bile duct. There were no consistent biochemical or haematological findings in any of the patients. The erythrocyte sedimentation rate was also not determined in the patients.

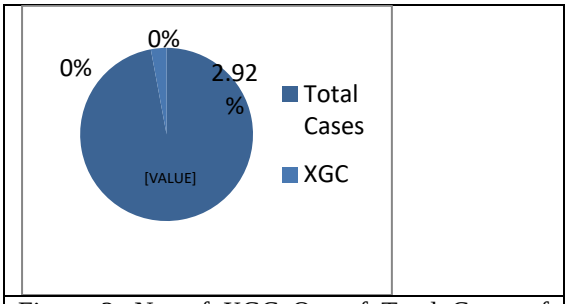


Figure 2. No. of XGC Out of Total Cases of Cholecystitis

Gross Features

Specimens were examined by the pathology department. In most of the cases mucosa was atrophied, other findings revealed gall bladder wall thickness ranging from 0.8 to 1.7 cm along with presence of small yellow brown nodules. Wall thickness was considered as an important finding in our study, as it has a strong correlation with carcinoma gall bladder. Gallstones were also seen in most of the cases. While studying the thickness of gallbladder wall, 95.1 % of gall bladders had wall thickness ranging from 0.8 -1.0 cm and 4.87 % had wall thickness of more than 1.0 cm.

While considering the age groups, fifth decade was the commonest age group (41-50 years) involved, constituting 43.94 % of total cases. We further observed that 94.4 % of patients in fifth decade, had wall thickness of 0.8-1.0 cm. Fig 3

In statistical analysis, the P value for all age groups, with wall thickness ranging from 0.8 - 1.0 cm and those with wall thickness of more than 1.0 cm is 0.938.

Microscopy

Histopathology revealed, the gall bladder wall was markedly thickened with severe inflammation and fibrosis(Fig. 4b) Mucosal ulceration was seen in 35 cases(Fig. 4c)) Foamy macrophages were seen

arranged in sheets and scattered singly along with chronic inflammatory cells composed of macrophages were large round to oval cells with abundant foamy to clear lipid containing cytoplasm with a single nucleus(Fig 4e). Bile pigment, cholesterol clefts and multi nucleated giant cells were also identified(Fig.4c & 4d). Lymphocytic infiltration was present in all the cases, forming lymphoid follicles in some, while as eosinophils were seen in only a few cases. Both foreign body and Touton type giant cells were seen in most of the cases.

Age (in Years)	GB Wall Thickness 0.8—1cm	GB Wall Thickness >1cm	Total	P Value
11-20	1	0	1	0.938 (NS)
21-30	4	0	4	
31-40	7	1	8	
41-50	17	1	18	
51-60	4	0	4	
61-70	4	0	4	
>70	2	0	2	
Total	**39**	**02**	**41**	

Table 1. Statistical Analysis Of Gallbladder wall Thickness with P Value Calculation

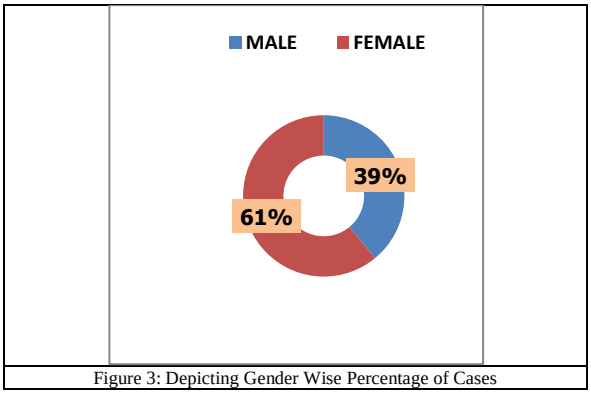


Figure 3: Depicting Gender Wise Percentage of Cases

DISCUSSION

XGC is a rare variant of cholecystitis. Incidence of XGC was 2.92 % in our study. Our study correlates with the study done by Gupta Kama et al [5] showing incidence of 2.0 % from UP, India and incidence of 3.2 % was shown by a study done by Khan Sabina et al [13] from Delhi, India. However there are studies which show higher incidence of 8 – 9 % as reported by Dixit in Varanasi [2], Data revealed as 25 females (61 %) and 16 males (39 %) in our study, showing a higher incidence of XGC in females. It correlates with the increased incidence of gall bladder disease in females. KM Roberts [1] and Zaheer et al [8] also reported the female preponderance of disease. Clinically, most of the patients in our study had pain abdomen and dyspepsia which correlate well with the findings of Robert et al(1)and Taskesen et al. [10] In our study, ultrasonography of the patients showed diffuse or local thickening of the gall bladder wall. Gall stones were seen in most of the cases and three cases were suspected of malignancy. Although radiology is helpful in detecting the abnormalities of gall bladder but in many occasions, it fails to differentiate between gall bladder malignancy and XGC. There are no specific characteristic radiological findings for XGC. Radiological changes seen in XGC are abnormal thickening of wall, fibrosis, formation of multiple brown intramural nodules and extensive involvement of adjacent organs. These changes may mimic malignancy[8]. Hale et al [7] displayed USG and CT features specific to XGC like presence of intramural echogenic nodules, a halo sign, intra hepatic duct dilatation and a loss of interface between gall bladder and liver. Although these features are also seen in gall bladder carcinoma, author stressed upon visualization of a continuous mucosal line and absence of pericholecystic fluid on CT suggesting a diagnosis of XGC rather than gall bladder carcinoma. However it is unclear till date how frequently these features are reported in routine practice. Lichtmen J B et al [15] reported moderate to marked thickening of gall bladder wall with hypoechoic nodules. Although, literature has indicated that MRI is most precise than CT and high resolution USG in the determination of XGC but presence of gall stones, diffuse thickening and collapsed lumen are autonomously connected with XGC on high resolution Ultra sound [6]. There is frequent association of gall stones with XGC. In our study, gall stones were seen in 80 % of patients. This is higher percentage when we compare with it to studies done by Zaheer et al [8](54 %) and Hideki Suzuki (54 %) (4)XGC can present with many complications, like gall bladder perforation, duodenal fistula, abscess formation and extension of inflammatory process to adjacent organs like liver, colon, etc. In a study done by Roberts et al,[7] three patients had fistulae from gall bladder, one to skin and two to duodenum, first report of this complication in XGC. In our study a few patients had developed adhesions with the adjacent organs. In our study, microscopic features included foamy macrophages in sheets as well as discrete, mixed inflammatory cells, cholesterol clefts, lipid droplets, hemosiderin deposits and giant cells of two types. Gall bladder wall was found thickened and fibrotic. The microscopic features are in corroboration with those reported by Zaheer et al, [8] Hale et al [7]and K M Roberts [1].Study done by KM Roberts [1] showed varied histomorphological changes in XGC. He described two types of Xanthoma cells, round cells and spindled cells. The spindle cells can raise the suspicion of malignancy. Hideki Suzuki (4)reported presence of hyperplasia in gall bladder mucosa with absence of atypia. We did not find any such change in our study. Rajab R [9] in their study described ducts of luschka and discussed features differentiating them from malignancy. Ducts of Luschka are developmental analomies and

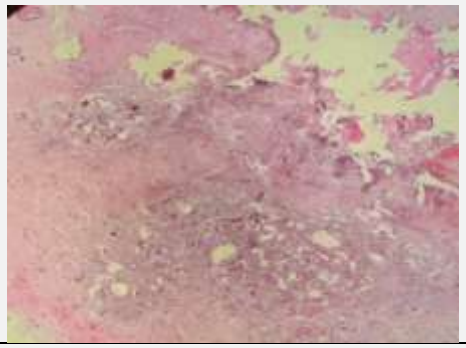
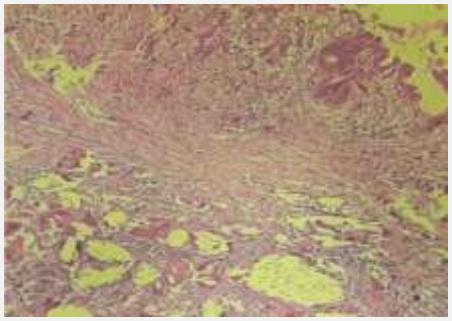
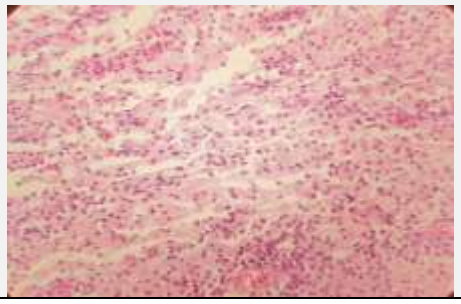
seen in 10 % of cholecystectomy specimens. When these ducts are numerous and in the background of the inflammatory infiltrate, show reactive atypia, these are mistaken for invasive adenocarcinoma. Ducts of luschka are located in adventitia only and their architecture is lobular or linear with concentric fibrosis, these ducts show only reactive features, while as malignancy of gall bladder shows nuclear variation, frequent mitosis, vascular and perineural invasion, where as in xanthogranulomatous cholecystitis, wall thickness is observed without any atypia in the glandular epithelium. The pathogenesis of XGC is unclear although role of cholesterol and bile is thought to be important. Takahasi et al [11] and Goodman Ishaq [3] have suggested the important event is the extravasation of bile in gall bladder wall, either from ruptured Rokitansky- Aschoff sinuses or focal mucosal ulceration. Fligel and Lewin [12] believe that in addition, a long standing or recurrent inflammatory process can be a reason. They also draw the analogy to Xanthogranulomatous pyelonephritis, where obstruction with stasis is important and suggested the possible role of gall stones in causing obstruction in XGC. In our study 80 % of cases had gall stones which can be compared with a study of Robert M et al [1] where all the cases had gall stones. Although XGC is benign change in gall bladder associated with a low mortality, duration of hospitalization is longer and post operative complications occur more often [10]. In our study we observed that all the age groups revealed increased thickness of the gall bladder wall, ranging from 0.8 - 1.7 cm, however as regards statistical analysis, P value 0.938 was calculated, which is not significant indicating that increased wall thickness is not a determining factor for diagnosis of Xantho granulomatous cholecystitis, as is seen in CT and Ultra sonographic evaluation of gall bladder diseases, where as XGC is totally a histopathological diagnosis, which correlates with the studies done by other authors at national and international levels.

A retrospective study concerns clinical, radiological, and surgical data as well as histopathological findings and postoperative results of 108 patients with XGC who were identified after evaluating 7916 cholecystectomy specimens between 2004 and 2014 in a single institute One hundred eight patients with XGC were evaluated (56 males and 52 females, mean age 62.3 years). Clinical findings at referral included acute and chronic cholecystitis, Mirizzi's syndrome, choledocholithiasis, cholangitis, and acute pancreatitis. Ultrasound was performed in all patients, CT in 25, contrast-enhanced MRI in 29, and magnetic resonance cholangiopancreatography (MRCP) in 25 patients. None of the patients were diagnosed preoperatively, but mild-moderate degrees of wall thickening were present in most. Fifty-four patients received open cholecystectomy, while 54 received laparoscopic intervention, among whom 23 were converted to open. Partial cholecystectomy was performed in 11 patients. Two patients with gallbladder adenocarcinoma were treated with radical cholecystectomy. XGC has nonspecific clinical and radiological findings; thus, preoperative diagnosis is generally absent. Open cholecystectomy is the recommended treatment modality. Conversion to open is frequently necessary after laparoscopy. Complete cholecystectomy is the ultimate goal; however, partial cholecystectomy may be preferred to protect the structures of the hepatic hilum [16]. Makimato S et al reviewed 31 patients of XGC.

Preoperative ultrasonography and computed tomography findings indicated acute cholecystitis, chronic cholecystitis, and suspicious XGC in 26 (83.9%) patients with thickening of the gallbladder wall and suspicious gallbladder cancer in 5 (16.1%) patients . Five patients with suspicious gall bladder carcinoma underwent open surgery, Intra operative frozen section analysis was useful in distinguishing XGC from gall bladder carcinoma in these patients and unnecessary extended surgeries were avoided[17].

Xanthogranulomatous cholecystitis (XGC) is an uncommon variant of chronic cholecystitis, characterized by focal or diffuse destructive inflammatory process. The importance of XGC is that it mimics gallbladder carcinoma (GBC) both preoperatively and intra-operatively, since it can present with peri cholecystic infiltration, hepatic involvement and lymphadenopathy. As a result of this misdiagnosis which is not infrequent, the patient may need to undergo an unnecessary radical cholecystectomy rather than only a cholecystectomy which is associated with greater morbidity and mortality [18].Conclusion:

Xanthogranulomatous cholecystitis deserves recognition as a distinct clinico -pathological entity. It is sometimes difficult to distinguish between Xanthogranulomatous cholecystitis and gall bladder carcinoma because it is clinically and radiologically overlapping. As Xanthogranulomatous cholecystitis is a difficult condition to diagnose pre or intra operatively and remains challenging in clinical practice. Definitive diagnosis relies exclusively on the histopathological examination. It is important to diagnose this disease correctly and carefully as it is frequently misdiagnosed as gall bladder carcinoma intra operatively and on clinico-radiological-presentation.

	***Figure 4(a).*** ***Xantho granulomatous cholecystitis with prominent lymphoid follicles and giant cells. 10X***
	***Figure 4(b).*** ***Xanthogranulomatous Cholecystitis with Fibromuscular Hyperplasia of Gall Bladder Wall. 4X***
	***Figure 4(c).*** ***Foreign Body Giant Cells around Cholesterol Clefts and Ulcerated Mucosal Lining. 10X***
	***Figure 4(d).*** ***Xanthogranulomatous Cholecystitis with Cholesterol Clefts and Bile Pigment. 20X***
	***Figure 4(e).*** ***Xanthogranulomatous Cholecystitis with Prominent Foamy Histiocytes (Xanthoma cells) in an Inflammatory Background. 40X***

References:

1. Roberts KM, Parsons MA (1987). Xanthogranulomatous cholecystitis: clinicopathological study of 13 cases – J Clin Pathol 40: 412 – 417.
2. Dixit VK, Prakash A, Gupta A, Pandey M et al (1998) Xanthogranulomatous cholecystitis. Dig Dis Sci 43: 940 – 942.
3. Christensen AH, Ishak KG (1970) Benign tumor and Pseudotumors of the gall bladder. Report of 180 Cases. Arch Pathol 90: 423 – 432.
4. Hideki Suzuki, Satoshiwada, Kenichiro Araki et al (2015) Xanthogranulomatous Cholecystitis:- Difficulty in differentiating from gall bladder cancer. World J Gastroenterol 21: 10166 – 10173.
5. Gupta Kamna, Faiz Amir et al (2019). The spectrum of Histopathological lesions in gall bladder in cholecystectomy specimens. International journal of clinical and Diagnostic pathology 2(1): 146 – 151.
6. Rahman Jawaria, Tahir Muhammad et al (2020). Xanthogranulomatous cholecystitis:- A Diagnostic challenge for Radiologists, Surgeons and pathologists. Cureus 12 (8): 10007.
7. Hale David Mathew, Roberts J Keith et al (2013). Xanthogranulomatous cholecystitis: a European and global perspective. HPB 2014, 16, 448 – 458.
8. Zaheer Sufian, Chouhan Minakashi et al (2020) clinicopathological correlation and varied histomorphological changes in Xanthogranulomatous cholecystitis (XGC). International Journal pathol Clin Res 6: 107.
9. Rajab R, Meara N, Chang F (2007) Florid ducts of Luschka mimicking well differentiated Adenocarcinoma of the gall bladder. International Journal Pathol 6: 1
10. Taskesen Fatih, Ari Kanoglu Zulfu et al (2014).A rare finding during a common procedure: Xanthogranulomatous Cholecytitis. Int surg; 99: 595 - 599.
11. Takahashi K, OkaK, Hakozaki H et al (1976) ceroid like histiocytic granuloma of gall bladder - a previously undescribed lesion. Acta pathol Jpn 26: 25 – 46.
12. Fligel S, Lewi KJ (1982). Xanthogranulomatous cholecystitis. Arch pathol lab Med 106: 302-4.
13. Khan Sabina, Abeer inara et al (2020). Xanthogranulomatous cholecystitis mimicking advanced gall bladder carcinoma – Analysis of 8 cases. Journal of cancer research and therapeutics 1180 – 19.
14. Amazon K, Rywlin AM (1980) Ceroid granulomas of the gall bladder. AmJ clin pathol 73: 123 – 127.
15. Lichtman JB, Varma VA (1987) ultrasound demonstration of Xanthogranulomatous Cholecystitis. J Clin ultrasound 15: 342 – 345.
16. YucelO,UzunMA,TilkiM,AlkanS,KilicogluZGGoret.XanthogranulomatousCholecystitis:Analysisof108Patients . Indian J Surg. 2017;79(6):510. Epub 2016 Jun 1. Indian J Surg. 2017;79(6):510. Epub 2016 Jun 1
17. Makimoto S,Takami T,Hatano K,et al . Xanthogranulomatous cholecystitis , a reuiew of 31 patients. Surg endosc 2021 ; 35;3874
18. Kishore R, Nundy S, Mehrotra S, et al. Strategies for Differentiating Gallbladder Carcinoma from Xanthogranulomatous Cholecystitis-a Tertiary Care Centre Experience. Indian J Surg Oncol 2017; 8:554.

Original Article

An Observational analytical Study to Determine the Effect of *Commiphora Mukul* on Thyroid Function in Hypothyroid Patients

Arsheed Iqbal, Zubair Ashai , Shiekh Zahoor Ahmad, Asma Afzal, Afrooza Jan

Abstract

Background: - Even though hormone replacement therapy with thyroxine has been proven effective in its management, but owing to adverse effects like angina, myocardial infarction, arrhythmias, anxiety, insomnia, immunoallergic hepatitis, decreased bone mineral density. *Commiphora mukul (Muqil)* activates the production of thyroid hormones Thyroxine (T_4),Triiodothyronine (T_3) , and improves hypothyroidism. Its lipid lowering effect is also related to its thyroid activity.2-Guggulestrone-a ketosteroid counteracts the thyroid suppressant activity of carbimazole. Its thermogenic effect helps in cold intolerance of hypothyroid patients.

Material and methods :The study was carried out at Regional Research Institute of Unani Medicine (RRIUM) Srinagar Jammu & Kashmir after approval by Institutional Ethical Committee. Hypothyroid patients fulfilling the inclusion and exclusion criteria were given *Commiphora mukul* 1 gm twice daily in the morning after breakfast and another dose in the evening to each patient with luke warm water. On enrolling and every follow up, patients were assessed for their symptoms and sampled for TSH ,T3, T4, and adverse drug reactions.

Conclusion:The drug causes subjective improvement on cold intolerance as well as objective improvement in TSH levels, indicating a thyroxine like effect rather than causing increase in T_3 and T_4, but it needs to be deciphered further.

JK-Practitioner2022;27(4):43-46

Introduction

Hypothyroidism prevalence in India is 11%, compared with only 2% in the UK and 4·6% in the USA.The thyroid gland secretes two significant hormones, thyroxine and triiodothyronine commonly called as T_4 and T_3 that has the profound effect of increasing the metabolic rate of the body [1-4]. Hypothyroidism can affect all organ systems ,and these manifestations are largely interdependant of the underlying disorder but are a function of the degree of hormone deficiency. The clinical features include somnolence, fatigue, weight gain, cold intolerance ,loss of appetite, constipation, hoarseness of voice, loss of libido,menorrhagia,polymenorrhea,dyslipidaemia,polyarthalgias,myalgias,decreased reflexes etc [5-8,9-17]. Even though hormone replacement therapy with thyroxine has been proven effective in its management, but owing to adverse effects like angina, myocardial infarction, arrhythmias, anxiety, insomnia, immunoallergic hepatitis, decreased bone mineral density [18-22].

A safe and effective drug needs to be researched for its management. *Commiphora mukul (Muqil)* was selected which has shown positive thyroid activity in experimental studies to correct hypothyroid state [23-25]. Research has demonstrated that *Commiphora mukul (Muqil)* activates the production of thyroid hormones Thyroxine (T_4),Triiodothyronine (T_3) , and improves hypothyroidism. Its lipid lowering effect is also related to its thyroid activity.2-Guggulestrone-a ketosteroid counteracts the thyroid suppressant activity of carbimazole. Its thermogenic effect helps in cold intolerance of hypothyroid patients [23-28].

Author Affiliations
Arsheed Iqbal, Shiekh Zahoor Ahmad, Asma Afzal, MD Scholars ,Department of Moalijat (Medicine) ,Regional Research Institute of Unani Medicine (Ministry of Ayush),Nassem Bagh campus ,University of Kashmir;**Zubair Ashai** ,Assistant Professor ,Department of Pharmacology ,GMC: Srinagar: **Afrooza Jan** Assistantn Professor, Department of Physiology. Govt Unani Medical College, Ganderbal : Jammu & Kashmir India.

Correspondence
Dr. Shiekh Zahoor Ahmad, MD Scholar, Deptt. of Moalajat (Medicine)
RRIUM, Srinagar. Jammu & Kashmir
Email:-
drshiekhzahoor@gmail.com

Indexed
EMBASE ,SCOPUS, IndMED, ESBCO, Google Scholar besides other national and International Databases

Cite This Article as
Iqbal A, Ashai Z ,Ahmad SZ, Afza A , Jan A.An Obsevational analytical Study to Determine the Effect of *Commiphora Mukul* on Thyroid Function in Hypothyroid Patients
JK Pract2022;27(4):43-46

Full length article available at **jkpractitioner.com** one month after publication

Keywords
Hypothyroidism, Incidence, Thyroid hormone, Thyroid stimulating Hormone(TSH), *Commiphora mukul (Muqil)*

Materials and Method

The study was carried out at Regional Research Institute of Unani Medicine (RRIUM) Srinagar Jammu & Kashmir after approval by Institutional Ethical Committee. Patients diagnosed as hypothyroid as per diagnostic criteria of American Thyroid Association were enrolled from the out-patient department of RRIUM Srinagar [28]. Diagnosed hypothyroid patients was provided with and explained Information Consent Form which included all the relevant information about the study, investigations, drug, method of treatment, adverse drug events and follow-up plan. Patients signing the ICF were included and study was conducted from 01 September and the enrolment of 30 patients was completed on 10 November 2018 as per the criteria. The duration of study was 60 days and Follow up was done on 15th day, 30th day, 45th day, 60th day in both the groups. On enrolling and every follow up, patients were assessed for their symptoms and sampled for CBC, ESR, sugar fasting LFT LFT ECG & Urine exam which were recorded in Case Record Form (CRF).

Inclusion Criteria:

Diagnosed patients of Hypothyroidism**.**

Patient in age group of 20 to 60 years.

Willingness to sign the informed consent, follow the protocol and participate in clinical trial voluntarily.

Exclusion Criteria:

Patients on other hypothyroidsm drugs severe hypothyroidism, myxedema coma acute myocardial infarction adrenal insufficiency myocarditis cardiac arrhythmias

The drug *Commiphora mukul* (*Muqil)* was purchased from market after inviting quotations from different suppliers by the Purchase Committee of Regional Research institute of Unani Medicine (RRIUM) Srinagar. The sample was duly identified by the expert for its originality. After proper cleaning ,the drug was grinded into a granular powder from the Pharmacy Deptt. Of Unani Medical College . Srinagar. The dosage of the test drug was 1 gm twice daily in the morning after breakfast and another dose in the evening to each patient with luke warm water.

Results

Table .1: Age Distribution (n=30)

Age(years)	Test group	
	No	%age
20-30	7	23.3
31-40	6	20.0
41-50	10	33.3
51-60	7	23.3
Total	30	100.0
Mean±SD	38.47±11.25	

Table.2 : Sex Distribution among (n=30)

SEX	Test group	
	No	%age
Male	7	23.3
Female	23	76.7
Total	30	100

The maximum number of patients were found in the age group 41-50 years (33.3%),followed by 20-30 years (23.3%),51-60 years(23.3%),20-30 years(6%). The Mean ± SD for age of patients was 38.4 ± 11.25. Out of 60 patients,76.7 % were females and 23.3% were males in Test group.

Table.3:- Triiodothyroxine among (n=30)

Triodothyroxine (T3)	Before Treatment		After Treatment		Percent change
	Mean	SD	Mean	SD	
Test group	114.90	23.56	118.90	23.78	3.48

The Mean ± SD for T_3 in was 114.90 ± 23.56 at baseline and 118.90 ±23.78 on 60th day was not statistically significant p>0.05.

Table.4:- Thyroxine (n=30)

T4	Before Treatment		After Treatment		Percent change
	Mean	SD	Mean	SD	
Test group	7.20	1.506	7.10	1.93	1.38

The Mean ± SD for T_4 in test was 7.20 ± 1.506 at baseline and 7.10 ± 1.93 on 60th day, was not statistically significant p>0.05.

The Mean ± SD for TSH in test group was 9.40 ±3.53 at baseline and 7.93 ± 4.37 on 60th day and was highly significant (p=.001)

Discussion

Our results of higher incidence of the disease in 3 and 4 decade of life as well as in females is consistent with known knowledge about the disease. The effects of drug on lowering the raised Serum TSH without statistically significant raise in T_3 and T_4 can be attributed to the thyroxine like activity of the drug . calorific (thermogenic) effect of the drug could be a reason for subjective relief of cold intolerance.. Studies have demonstrated that *Commiphora mukul* (***Muqil)*** activates the production of thyroid hormones Thyroxine (T_4), Triiodothyronine (T_3) , and improves the symptoms and signs of hypothyroidism.

There were no adverse drug effect reported for the dosage. The drug causes subjective improvement on cold intolerance as well as objective improvement in TSH levels, indicating a thyroxine like effect rather than causing increase in T_3 and T_4, but it needs to be deciphered further.

Refrences

1. Guyton C,MD.Effect of Thyroid hormone on specific bodily mechanism.Prism Books pvt Ltd.Banglore-India.8th ed.(1991):835-36
2. Jayakumar R V,Oomen Tittu,Thyroid hormone;Physiology and mechanism of action . *ITS Clinical Manual of Thyroid Disorders ,RV Jayakumar* , First ed. Elsevier Limited ;2012:11-14.
3. Benvenga S.Thyroid hormone transport proteins and the physiology of hormone binding.In :*The thyroid :Fundamental and Clinical* Text 9th ed,Braveman,LE,Utiger,RD,eds.Lippincott Williams and Wilkins :Philadelphia 2005:page 97.
4. Magner J A.Thyroid-stimulating hormone:biosynthesis,cell biology,and bioactivity.*Endocr Rev* 1990;11:354-85
5. Melmed,Polonsky,Larsen,Kronenberg . Williams Text Book of Endocrinology.13 th ed. RELX India.Pvt. Ltd ;2016 : 2-4,
6. Ralston,Penman,Strachan,Hobson.Davidson's Principles and Practice of Medicine.23rd ed.ELSEVIER;2018:632-43.
7. Jabbar P K,Danish E.Hypothyroidism: Introduction,etiology,and clinical features.ITS Clinical Manual of Thyroid Disorders ,RV Jayakumar , First ed. Elsevier Limited ;2012:129-30.
8. Liu Y Y,Brent G A.Thyroid hormone crosswalk with nuclear receptor signaling in metabolic regulation.*Trends Endocrinol Metab* 2010;21:166-73.
9. Smith T J,Bahn R S,Gorman CA.Connective tissue,glycosaminoglycans,and diseases of the thyroid.*Endocr Rev* 1989;10;366-91.
10. Baurer M,Goetz T,Glenn T,Whybrow PC.The thyroid brain interaction in thyroid disorders and mood disorders.*J Neuroendocrin* 2008;20:1101-14.
11. Bland J H,Frymoyer J W.Rheumatic syndromes of myxedema.*N Engl J Med* 1970;282:1171-4.
12. Klein I,Danzi S.Thyroid disease and the heart.*Circulation* 2007;116:1725-35.
13. Redmond G P.Thyroid dysfunction and women's reproductive health.*Thyroid* 2004;14 (Suppl 1) S5-15.
14. Krassas G E,Tziomalos K,Papadopoulou F,et al.Erectile dysfunction in patients with hyper-hypothyroidism:how common and should we treat? *J Clin Endocrinol Metab* 2008;93:1815-19.
15. Kamilaris T C,DeBold C R,Pavlou S N,et al.Effect of altered thyroid hormone levels on hypothalamic-pituitary-adrenal function. *J Clin Endocrinol Metab* 1987;65:994-9.
16. Kahaly G J,Dillmann W H.Thyroid hormone action in the heart. *Endocr Rev.2005;26:704-728.*
17. Combs C E,Nicholls J J,Duncan Bassett J H,Williams G R.Thyroid hormones and bone development.*Minerva Endocrinol*.2011;36:71-85.
18. Garber JR, Cobin RH, Gharib H, Hennessey JV, Klein I, Mechanick JI, Pessah-Pollack R, Singer PA, Woeber KA., American Association of Clinical Endocrinologists and American Thyroid Association Taskforce on Hypothyroidism in Adults. Clinical practice guidelines for hypothyroidism in adults: cosponsored by the American Association of Clinical Endocrinologists and the American Thyroid Association. Endocr Pract. 2012 Nov-Dec;18(6):988-1028)
19. Jonklaas J, Bianco AC, Bauer AJ, Burman KD, Cappola AR, Celi FS, Cooper DS, Kim BW, Peeters RP, Rosenthal MS, Sawka AM., American Thyroid Association Task Force on Thyroid Hormone Replacement. Guidelines for the treatment of hypothyroidism: prepared by the american thyroid association task force on thyroid hormone replacement. Thyroid. 2014 Dec;24(12):1670-751.
20. Mustafa C, Ozgül U, Zehra GC, Hülya C. Transient ST-segment elevation due to iatrogenic hyperthyroidism in a patient with normal coronary arteries. Intern Med. 2011;50(15):1595-7.
21. LiverTox: Clinical and Research Information on Drug-Induced Liver Injury [Internet]. National Institute of Diabetes and Digestive and Kidney Diseases; Bethesda (MD): Apr 15, 2019. Thyroid Hormone.
22. Gong IY, Atzema CL, Lega IC, Austin PC, Na Y, Rochon PA, Lipscombe LL. Levothyroxine dose and risk of atrial fibrillation: A nested case-control study. Am Heart J. 2021 Feb;232:47-56.

23. Tripathi YB,Tripathi Pratibha,et al.*Thyroid Stimulatory action of Guggulsterone:*Mechanism of action.Plant Medica 1988;9:271-277.
24. Panda S,Kar A.*Guggul (Commiphora mukul) induces triiodothyronine production:possible involvement of lipid peroxidation*.Life Sciences; 1999;12:137-
25. Shamala Pulugurtha.*The Effects of Guggul on Thyroid Function*.2017.LIVINGSTRONG.COM.
26. http://www.wilsonssyndrome.com/guggul-is-an-herb-that-supports-thyroid-health.
27. Roohi Azam,Shafia Mushtaq, Shubrin Nisar .*Muqil* –A Wonder Drug in Traditional Medicine.International Journal of Institutional Pharmacy and Life Sciences.May-June2015.
28. .American Thyroid Association ,*optimal thyroid health for all* at https://www.thyroid.org/hypothyroidism/

Original Article

Demographic Pattern and Management of Full Thickness Eyelid Defects

Altaf Rasool ,Hilal Ahmad Bhat ,Sheikh Adil Bashir ,Mir Yasir ,Umar Farooq Baba, Akram Hussain Bijli , Haroon Rashid Zargar ,Mir Mohsin , Adil Hafeez Wani.

Abstract

Background

The eyelids form an important aesthetic unit of the face. Their closure protects the globe and maintains the integrity of tear film. Defects of the eyelid are either congenital (coloboma) or acquired. Reconstruction of the eyelids should be done as early as possible to restore the anatomy and function of eyelids.

Objectives

To study the demographic pattern the full thickness eyelid defects in our state which is located in the high altitude Himalayan region. Various eyelid reconstruction methods, their complications, the functional and cosmetic outcome in these patients were also studied.

Methodology:

The research was carried from January 2012 to December 2018. Ninety patients with acquired eyelid defects were included in the study. Defects were classified as group A, B and C as per the size and reconstructed by various appropriate reconstructive eyelid procedures.

Results

With regard to the surgical technique we had the best results in direct closure and McGregor flap techniques both in terms of aesthesis and function. Overall functional and aesthetic outcome of these reconstructive procedures were found to be excellent in 76.66% and 66.66% patients respectively.

JK-Practitioner2022;27(4):47-51

Introduction

Eyelids are the fold of complex, delicate, mobile, thin structures present anterior to the globe and act as a shutter for the eyes. Their closure protects the globe and maintains the integrity of tear film while their opening creates a resultant palpebral fissure which is bounded by the upper and lower eyelid margins [1]. In addition, the eyelids form an important aesthetic unit of the face. Each eyelid has an anterior lamella formed by the skin, subcutaneous tissue and the orbicularis oculi muscle while the posterior lamella consists of the tarsal plate and conjunctiva [2]. Superior tarsus is broader and about 10 to 12 mm at its greatest vertical dimension and the inferior tarsus is 3 to 5 mm [3]. The orbital septum is a layer of dense connective tissue which is attached on one side to orbital margin and on the other side to tarsal plate and separates the superficial soft tissue of the eyelids from the orbital contents [4]. The medial and lateral canthal ligaments play significant role in supporting and shaping the eyelids [5]. The two arterial arcades namely, the superior marginal arcade (on the anterior tarsal surface, 2–3 mm from the lid margin) and the peripheral arcade (on the anterior surface of the Muller's muscle, just above the superior tarsal border) supplies the upper eyelid while only the marginal arcade (2 mm from the lid margin) is present in the lower eyelid [6].

Defects of the eyelid are either congenital or acquired. Congenital defect of the eyelids (coloboma) can be isolated or usually a part of the broader craniofacial clefts. However, the acquired defects are secondary to trauma, burns, post radiation or the excision of the neoplastic diseases of the eyelids. Reconstruction of the eyelids should be done as early as possible to restore the anatomy and function of eyelids. Various methods of reconstruction have been used depending upon the eyelid involved (upper /lower), size of defect, component loss and the status of surrounding tissue. The exact normalization of the eyelid position and movements should be the goal.Identical tissue should be ideally used for reconstruction of the eyelid.

Author Affiliations

Altaf Rasool MCh, Additional Professor, **Hilal Ahmad Bhat** MCh, Senior Resident ,**Sheikh Adil Bashir,** MCh, Professor **Mir Yasir** ,MCh**,** Assistant Professor ,**Umar Farooq Baba,** MCh **,**Associate Professor, **Akram Hussain Bijli** , Associate Professor , **Haroon Rashid Zargar** ,MCh Additional Professor **,Mir Mohsin ,** MCh ,Associate Professor **, Adil Hafeez Wani**, MCh ,Professor & Head: Department of Plastic Surgery, Sher-I-Kashmir Institute of Medical Sciences ,Srinagar ,J&K, India

Correspondence

Dr Mir Yasir
MCh Plastic surgery
Assistant Professor, Department of Plastic Surgery, Sher-i- Kashmir Institute of Medical Sciences, Srinagar, Jammu and Kashmir. 190011.
E mail : drmiryasir@yahoo.co.in
Cell no. : 9419107625

Indexed

EMBASE ,SCOPUS, IndMED ,ESBCO ,Google Scholar besides other national and International Databases

Cite This Article as

Rasool A ,Bhat HA ,Bashir SA ,Yasir Mir,,Baba, UF Bijli AH , Zargar HR ,Mohsin M , Wani AH. Demographic Pattern and Management of Full Thickness Eyelid Defects
K Pract2022;27(4):47-51

Full length article available at **jkpractitioner.com** one month after publication

Keywords

Eyelid defect, Eyelid reconstruction, Aesthetic outcome, Functional outcome.

Abundance of patients with full thickness eyelid defects and lack of any such study from our place urged us to add our experience to the literature and to see whether in any way it differs from the rest of the world.

Materials and Method

This study was conducted retrospectively from January 2012 to July 2015 and prospectively from August 2015 to December 2018 in the Department of Plastic, Reconstructive and Microvascular surgery in our tertiary care hospital. All the patients with acquired full thickness eyelid defects were included while the congenital colobomas and partial thickness eyelid defects were excluded from our study. Fifty one patients were included in the retrospective group. Retrospective medical records of the patients were retrieved from the Medical Record Department (MRD) of the hospital and patients were called telephonically and followed up in the outpatient department (OPD) for further evaluation and outcome.

Thirty nine patients were included in the prospective study group. These patients were thoroughly assessed and ophthalmology consultation sought as and when needed before any surgical intervention. Patients were operated under general anaesthesia. Eyelid defects resulted from the wide local excision of the neoplastic disease or after adequate debridement for the other etiologies and the final defect was measured with a measuring scale intra-operatively. Depending upon the size of the defects, the patients were categorized into three groups namely Group A with defect size <1/3rd, Group B with 1/3rd- 2/3rd and group C with >2/3rd of the total eyelid length. All the patients in group A were managed by direct closure with or without canthotomy or cantholysis. Group B patients were managed either by McGregor, lid switch technique or Mustarde cheek rotation technique and group C by either Tripier flap or by tissue outside lid namely Mustarde cheek rotation flap or median forehead flap. Inner lamella was reconstructed by nasal muco-perichondrial graft in case of Mustarde cheek rotation and median forehead flaps. Patients were assessed for any postoperative complications and usually discharged on 2 -4th postoperative day. Patients were then followed in the plastic surgery OPD weekly for the 1st month, then monthly up to 6 months and 3 monthly for 1 year and then six monthly afterwards. The final aesthetic and functional outcome was assessed at 6 month postoperatively.

The aesthetic outcome of the reconstructive procedures was classified into:

1. Excellent: The reconstructed lid was more or less similar to normal contralateral eyelid.

2. Satisfactory: The lid had noticeable scar but cosmetic result was satisfactory.

3. Acceptable: The lid had noticeable scar and change of colour of flap but final cosmetic result did not annoy the patient.

4. Poor: The reconstructed lid had unmatched colour of flap or flap necrosis and the final cosmetic appearance was bad.

The functional results of eyelid reconstruction were classified according to the ability of the reconstructed lid to perform three important functions i-e opening and closure of palpebral fissure, tear drainage and protection of globe. The functional results were classified into:

1. Excellent: The reconstructed lid performed all the above three mentioned functions.

2. Good: Two eyelid functions preserved (Globe protection plus one of the remaining two functions.)

3. Acceptable: Only globe protection preserved.

4. Poor: All the three functions lost.

Results

Out of ninety patients who were included in this study, fifty four were females. Seventy five patients were above the age of 50 years. Defects were secondary to neoplastic disease in seventy five patients while rest of the patients had post traumatic defects. Basal cell carcinoma (BCC) was seen in 66, Squamous cell carcinoma (SCC) in six and Sebaceous gland carcinoma (SGC) in three patients. Bear maul injury resulted in twelve and road traffic accident (RTA) in three patient. Lower eyelid was involved in fifty seven patients.

Twenty one patients were seen in group A and these patients were reconstructed by direct closure technique with or without canthotomy and cantholysis. (Fig I).

Highest number of patients were seen in group B (fifty one patients). thirty were reconstructed by McGregor flap (Fig II), six by lid switch flap(Fig III) and fifteen by Mustarde cheek rotation flap(Fig IV).

Group C consisted of eighteen patients. They were equally reconstructed by median forehead flap(Fig V), bipedicled tripier flap (Fig VI), and Mustarde cheek rotation with six patients in each group.

Ectropion was the only complication seen in group B and C defects. This was noticed in eight patients who were reconstructed either by forehead flap (2 patients) or by cheek rotation flap (6 patients). However the ectropion in all these patients was milder form and was managed conservatively.

Excellent functional results were seen in 69 patients and majority of these patients were seen

in direct closure and McGregor flap techniques (Fig VII).

Sixty patients had excellent cosmetic results and majority of these patients again belonged to the McGregor flap and direct closure techniques (Fig VIII).

Discussion

Eyelid is a delicate structure and replacement of like with like is a goal. However, there is hardly any tissue which matches the eyelid in all respects and thus results are not excellent when borrowing tissue from outside eyelid.

Our state is a valley lying within the high altitude Himalayan range and is bestowed with dense forests. This is a habitat for Himalyan black bears (Ursus thibetanus) and people here are exposed to high ultraviolet(UV) rays. High incidence of eyelid malignancies in our population is because of over exposure of people to UV rays. Further, Himalayan black bears are known to cause head and neck trauma with loss of tissue [7,8] and thus contribute to majority of trauma related eyelid defects in our series. Majority of the defects in our series were seen in elderly population and most of these were secondary to malignancy. This is because most of our rural population is working in their fields and are directly exposed to sunlight for years together before they develop malignancy. This prevalence of post tumor excisional eyelid defects were also reported by various other authors [9, 10]. However, posttraumatic defects were mostly seen in young age group in our series. These are the people who are the active workers in the family and who usually visit the nearby forests for the collection of fire wood and get entrapped in the bear encounters or get involved in RTA.

Basal cell carcinoma is the commonest eyelid tumor and mostly involve lower eyelid [11,12]. Lower eyelid is involved almost twice than upper eyelid in our series which is explained by the fact that both BCC and bear maul injury are more common in lower eyelid. However, delayed presentation of patients with eyelid malignancies in our patient resulted in more group B defects in contrast to group A defects seen by Ahmed et al [13].

Full thickness eyelid defects need reconstruction of both anterior and posterior lamellae of the eyelid. Eyelid defects in our patients were reconstructed by six different surgical techniques depending upon the location, size of the defect and the condition of the adjacent skin. Excellent outcome was seen in the Direct closure technique both in terms of function and cosmesis . This is because defects were small, all the structures of the eyelid were reconstructed from the same eyelid without change in orientation of the lid and reconstruction was tension free without any additional scar laterally. Comparable results with Direct closure technique were also seen by Ahmed et al [14].

McGregor flap technique was found to be good technique for all the group B patients with excellent functional and cosmetic results in eighty nine percent of patients in our series. Presence of Z plasty scar laterally and closure under some tension compromises the results compared to direct closure technique. Mukundan et al recommends that the McGregor flap is a useful option for the reconstruction of lower and upper eyelid defects as he found satisfactory functional and aesthetic results with the use of this flap for lower and upper lid defects in all cases [15].

Mustarde cheek rotation flap was done in twenty one patients in our series. Functional results were good in 71.42% and aesthetic outcome was satisfactory in majority (57.14%) of the patients. Mild ectropian in six patients and absence of eyelashes in the area of reconstruction compromised the aesthetic outcome in these patients. Good results were also reported by Oana et al in their study of eight patients of advanced basal cell carcinoma of the lower eyelid treated by Mustardee cheek rotation flap both functionally and aesthetically [14]. High cosmetic and functional acceptability by the patients was reported by Amit et al with this procedure [15].

Reconstruction with forehead flap resulted in acceptable cosmetic and functional outcome in our series. Mild ectopian, absence of eyelashes, bulky nature and visible scars were the reasons for relatively inferior results in this procedure. All the patients were satisfied with their functional and cosmetic outcomes in the series of eyelid and medial canthal reconstruction reported by Nourhan et al as there was adequate eyelid closure with well aligned and stable lower eyelid margin. However epiphora was seen in all the patients as lachrymal system reconstruction was not performed in any of the patients [16].

Good functional results were seen in fifty percent of the patients in both the switch flap and Tripier bipedicled flap but the aesthetic results of both the procedures were either satisfactory or acceptable. Presence of all the native structures of the eyelid used in the reconstruction makes the results better than the use of bulky structures, but staged nature and presence of trapdoor scars and dog ears within the confines of the small area of the eyelid makes cosmetic results a bit compromised.

Over all the functional as well as the cosmetic outcomes of all the procedures used in our series were found to be excellent because the bulk of the procedures done were those with excellent results.

Conclusion

Our state is located at higher altitude within the dense forests of the greater Himalayas. Being exposed to more sun exposure and to Himalayan

black bears, eyelid malignancy and post bear bite eyelid defects are more common. Proper planning of the eyelid reconstruction with various procedures has resulted in overall excellent cosmetic and functional outcome in our series especially with the direct closure and McGregor flap techniques.

Figure (I) Primary closure technique, (Ia)Preoperative Basal cell carcinoma upper eyelid, (Ib)Postexcision upper eyelid defect, (Ic) Immediate post op picture of primary closure technique, (Id) Follow-up results of same patient

Figure (II): McGregor flap technique for reconstruction of lower eyelid, (IIa) Basal cell carcinoma lower eyelid, (IIb) Marking for excision of the lesion and for reconstruction by McGregor flap, (IIc) Lower eyelid defect after excision of lesion, (IId) Postoperative picture of reconstruted lower eyelid by the McGregor flap.

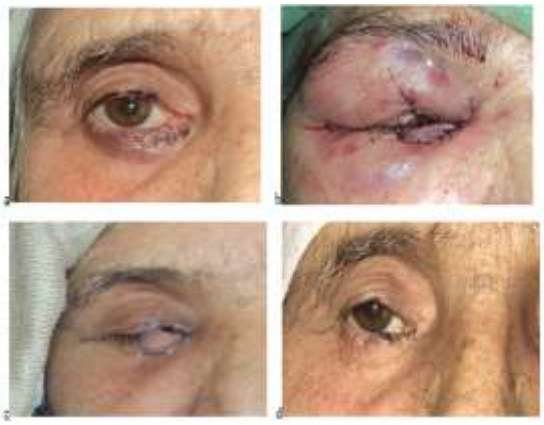


Figure (III) Eyelid reconstruction by switch procedure from upper lid, (IIIa) Basal cell carcinoma lower eyelid, (IIIb) Immediate postoperative picture after reconstruction of lower eyelid by switch procedure, (IIIc) Delayed postoperative picture, (IIId) Reconstructed lower eyelid after detachment and final insetting of flap.

Figure (IV) Reconstruction of the left lower eyelid with Mustarde cheek rotation flap, (IVa) Large lower eyelid lesion (SCC) involving more than 2/3rd of horizantal length of eyelid, IVb) Reconstructed lowereyelid by Mastardee cheek rotation flap, (IVc) Immediate postoperative pictures of the same patient, (IVd) Follow up picture of same patient showing excellent aesthetic results

Figure (V) Reconstruction of the left lower eyelid by the Median Forehead flap, (Va) Huge lower eyelid lesion, (Vb) Marking for excision and

reconstruction by forehead flap, (Vc) Postoperative picture of the same patient, (Vd) Delayed post operative picture

Figure (VI) Bipedicled tripier flap for reconstruction of lower eyelid from upper lid, (VIa) Preoperative picture of lower eyelid defect send for reconstruction,(VIb) Immediate postoperative pictures of reconstructed lower eyelid by bipedicled trepier flap, (VIc) Delayed postoperative picture of the same patient.

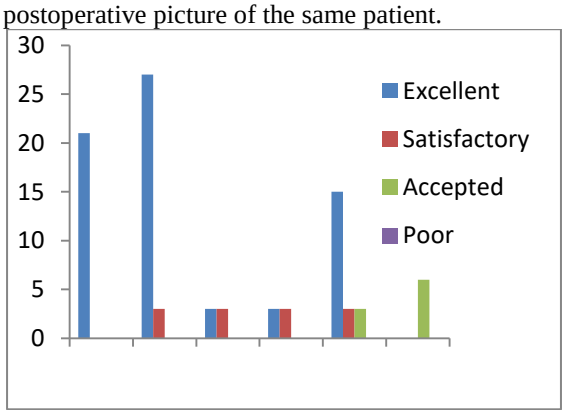


Figure VII (Funtional results in Eyelid Reconstruction)

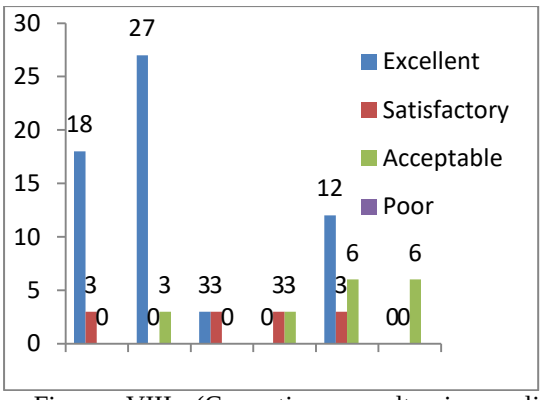


Figure VIII (Cosmetic results in eyelid reconstruction)

References

1. Rose JG, Lucarelli MJ, Cook BE, Lemke BN. Oculoplastic surgery atlas: eyelid disorders. In: Gladstone GJ, Black E, Myint S, Brazzo BG, Nesi FA, editors. Surgical anatomy of the eyelid. 2nd ed. New York, NY: Springer-Verl: 2002. p. 1–16.
2. Jones LT. An anatomical approach to the problems of the eyelids and lacrimal apparatus. *Arch Ophthalmol*. 1961;66:111–124.
3. Wesley RE, McCord CD, Jones NA. Height of the tarsus of the lower eyelid. *Am J Ophthalmol*.1980;90:102–05.
4. Anderson RL, Dixon RS. The role of Whitnall's ligament in ptosis surgery. *Arch Ophthalmol*.1979;97:705–07.
5. Muzaffar AR, Mendelson BC, Adams Jr WP. Surgical anatomy of the ligamentous attachments of the lower lid and lateral canthus . *Plast Reconst Surg*. *2002;110(3):873 – 84.*
6. DiFrancesco LM, Codner MA, McCord CD. Upper eyelid reconstruction. *Plast Reconstr Surg*.2004;114:98–107.
7. Rasool A, Wani AH, Darzi MA, Zaroo MI, Iqbal S, Bashir SA, Rashid S, Lone RA. Incidence and pattern of bear maul injuries in Kashmir. Injury. 2010 Jan;41(1):116-19.
8. Patil SB, Mody NB, Kale SM, Ingole SD. A review of 48 patients after bear attacks in Central India: Demographics, management and outcomes. Indian J Plast Surg 2015; 48(1):60-5.
9. Jean-Louis D, Iqal L, Raman M. Techniques and outcomes of total upper and lower eyelid reconstruction. Arch Opthalmol 2007;125(12):1601-09.
10. Ahmed N Kotb, Magdy F Hussein, Mohammad E Abdel Fattah. Lower eyelid reconstruction in full thickness defects. *Z.U.M.J.* March 2013;19:2.
11. Cook BE Jr, Bartley GB. Epidemiologic characteristics and clinical course of patients with malignant eyelid tumors in an incidence cohort in Olmsted County, Minnesota. *J American Academy Ophthal* 1999;106(4):764-50.
12. Abbas B, Mehdi T, Azadeh K, Reza BZ, Hamed E, Maryam A, and Hossein S. Eyelid Masses: A 10-year Survey from a Tertiary Eye Hospital in Tehran. *Middle East Afr J Ophthalmol*. 2013; 20(3): 187–92.
13. Mukundan PK, Ambookan PV, Dilliraj VK. Soft tissue defects of eyelid and malar region: an experience with the McGregor flap. *Plast Aesthet Res* 2015;2:69-72.
14. Oana RG, Sidonia PS, Nicolae G, Vlad P, Dragos P. Versatility of Mustarde cheek rotation prelaminated flap for reconstruction of the wide full thickness lower lid defects. *Timisoara medical journal* 2007;4:24-27.
15. Amit J, Nishtha S, Yamini, Gautam G. Mustarde's Flap for Post Basal Cell Carcinoma Excision Lower Eyelid Reconstruction: Our Experience. *Journal of Evidence based Medicine and Healthcare* 2015;2(26): 3924-28.
16. Nourhan AE, AlMaha AQ, Hind MA, Mohammad MA. The use of forehead flaps in the management of large basal cell carcinomas of the medial canthus/medial lower eyelid in Saudi patients. *Saudi J Ophthalmol*. 2013 Jul; 27(3): 223–25.

Original Article

Prevalence, Determinants and Feto Maternal Outcome of Severe Anemia in Pregnancy in a Teritiary Care Hospital

Beenish Jeelani , Shaheera Ajaz ,Rifat , Rabia Khursheed

Abstract

Background

Anemia is the most common preventable and correctable medical disorder occurring in pregnancy. Severe anemia (Hemoglobin <7gm%) is associated with poor fetomaternal outcome.Aims & Objectives : To study the prevalence, Determinants and fetomaternal outcome of pregnancies complicated by severe anemia attending our hospital. **Method**

A prospective study was conducted in SKIMS maternity hospital Srinagar, for a period of 1 year from January 2018 to January 2019.The study included all obstetric in patients with severe anemia (Hb<7gm%).

Results

Out of 2234 in patients, 190(8.5%) were with severe anemia. Out of these severely anemic patients 171 (90%) belonged to low socioeconomic status and 133(70%) were from rural areas. Severe anemia was more prevalent in age group of 20-24(25.2%).It was observed more in unbooked patients(74.2%) who reported to hospital with symptomatic severe anemia amongst whom 60% were multigravida.Thematernalcomplicationsincludedpretermlabor(37.8%),preeclampsia(15.2%),PPH(20%),IUGR(13.1%),IUFD(3.1%), Sepsis(6%), Abruptio placentae(2.6%),cardiac failure(1.05%). However, there was no maternal death in severe anemia in this study.

Conclusions

We found that severe anemia was more prevalent in patients who were unbooked and those with poor socio economical background . Severe Anemia is associated with severe maternal and fetal morbidity. Special attention should be given to this vulnerable population to reduce maternal and fetal complications associated with severe anemia.

JK-Practitioner2022;27(4):52-54

Introduction

Anemia in pregnancy may be defined by World Health Organization as hemoglobin of less than 11gms/dl and hematocrit of less than 30% [1]. Anemia is said be mild if hemoglobin is 10-10.9gm/dl, moderate for 7-9.9gm/dl and severe in less than 7.0gm/dl. According to the estimates of WHO, anemia has a prevalence of 23%in developed countries with almost double in developing countries [2].The average prevalence rate is 56% in developing counties with a great variation with respect to different regions of the world ranging from 35-100% [3]. There are many risk factors which contribute to anemia in pregnancy, the most common being iron deficiency which contributes to about 90% in India [4]. Other contributing factors are vitamin b12 deficiency and thalassemia trait, which are also common. Anemia is associated with severe adverse consequences in both mother and fetus. These adverse effects are not only bounded during pregnancy, neonatal and infant period but also increase the risk of non communicable diseases in adult life. Frequency of maternal complications is very high amongst severely anemic pregnant woman as compared to normal pregnant woman. The maternal complications include pregnancy induced hypertension, intercurrent infections, abruptio placentae, heart failure, preterm labor, intra uterine deaths and postpartum hemorrhage [5]. Fetal outcome of low birth weight, APGAR score of <7,perinatal deaths are also high in severe anemic pregnant patients [6]. Anemia is the disease of

Author Affiliations

Beenish Jeelani, Shaheera Ajaz ,Rifat , Senior Residents ,**Rabia Khursheed**,Additional Professor :

Department of Obstetrics & Gynecology ,Trust Hospital ,SKIMS ,Soura ,Srinagar, J&K, India.

Correspondence

DR.Shaheera Ajaz
Senior Resident , Department of Obg/Gynae Trust hospital SKIMS, Soura. Srinagar,J& K, India.
9419522226
Shaheeraajaz900@gmail.com

Indexed

EMBASE ,SCOPUS, IndMED ,ESBCO ,Google Scholar besides other national and International Databases

Cite This Article as

Jeelani B , Ajaz S ,Rifat ,Khursheed R.
Prevalence, Determinants and Feto Maternal Outcome of Severe Anemia in Pregnancy in a Teritiary Care Hospital
JK Pract2022;27(4):52-54

Full length article available at **jkpractitioner.com** one month after publication

Keywords

Anemia, Pregnancy, preterm labor, Hemoglobin (Hb), intra uterine growth retardation (IUGR), intra uterine fetal death (IUFD) and postpartum hemorrhage(PPH).

CHARACTERISTICS	NO. OF PATIENTS
AGE GROUP	
<20YEARS	19(10%)
20-24 YEARS	48(25.2%)
25-30 YEARS	82(43.1%)
>30 YEARS	41(21.5%)
GESTATIONAL AGE	
>37WEEKS	104(54.7%)
34-37WEEKS	62(32.6%)
<34WEEKS	24(12.6%)
SOCIOECONOMICAL STATUSLOWER	
UPPER	171(90%)
	19(10%)
BOOKED STATUS	49(25.7%)
BOOKED UNBOOKED	141(74.2%)
RESIDENCE	
RURAL	133(70%)
URBAN	57(30%)
PARITY	
PRIMIGRAVIDA	76(40%)
MULTIGRAVIDA	114(60%)

Table 1.Clinical and Demographic details

developing nations but can easily be diagnosed and treated by simple tools and techniques which are affordable and can be implemented even in primary health care settings. The aim of this work was to study the prevalence, Determinants and fetomaternal outcome of pregnancies complicated by severe anemia attending our hospital

Materials and Methods

The present study was a prospective observational study, conducted at Sher e Kashmir Institute of Medical sciences(SKIMS)in the Department of Gynaecology and obstetrics over a period of 1 year i.e. January 2018 to January 2019.

Inclusion criteria

The singleton pregnant women with severe anemia of Hb<7gm/dl were included in the study.

Exclusion Criteria

The pregnant patients withhb>7g/dl, anemia due to chronic diseases or blood disorders were excluded from the study

The pregnant patients with severe anemia (Hb <7g/dl) were selected from the inpatient pregnant women. Detailed clinical examination was done, history was taken .Pregnancy outcome and complications arising due to preexisting anemia were noted. Frequency and percentages were calculated to assess the distribution of the patient on the socio demographic variables such as age, living status, booked un booked status, residence, gestational age, parity ,past obstetric history was taken .The adverse outcome was seen in the form of preterm labor, postpartum hemorrhage, preeclampsia, IUGR, IUFD, abruption ,cardiac failure.

Statical Analysis:

Standard statistical procedures were used to analyze the data. Data were described as mean ± standard deviation and percentages. SPSS 20.0 (IBM SPSS Statistics for Windows, IBM Corp, Armonk, NY, USA) and Microsoft Excel software were used for data analysis

Results:

The number of deliveries during the study period was 2234. Out of 2234 patients 190(8.5%) were severely anemic. The demographic details are shown in Table 1. Severe anemia was more prevalent in age group of 20-24(25.2%).Maximum women belonged to low socioeconomic status (90%),living in rural areas(70%). Severe Anemia was more prevalent in unbooked patients(74.2%) and in multigravida(60%). The commonest complication was seen to be preterm labor in 72 cases(37.8%) followed by postpartum hemorrhage in 38 cases(20%), followed by preeclampsia in 30(15.7%), IUGR in 25 (13.1%), IUFD in 6 (3.1%), sepsis in 12 (6.3%), abruption placentae in 5 (2.6%) and cardiac failure in 2 2(1.05%).However no maternal death was noted due to severe anemia in our tertiary care cente

Discussion

The prevalence of anemia varies in different regions around the globe. It is 15% in western countries and ranges from 33%- 75% in developing countries [7 ,8 ,9].In the present study the prevalence of severe anemia(Hb<7) was found to be 8.5% whereas study by Riffat Jaleel reported 4.8% ,singal et al reported 5.54% as the prevalence of severe anemia [10 ,11].

The age group of 25-30 had the highest prevalence of severe anemia(43%) as found in Rajendratnam et al and others.[12, 13]Anemia was more common in low socioeconomic class (90%). Lack of essential nutrients and iron in poor class pregnant females leads to anemia in them .Studies from Allen et al,Bentley ME also reported the same observations [14, 15].Moreover, it was observed that in unbooked patients anemia was more common(74.2%) as compared to booked cases(25.7%) as the anemia went unregistered in patients not following to health care professionals whereas in booked patients,early identification, stratification of risk factors and treatment was prompt. Boniface et al also reported the same observation [16].

In our study it was observed that preterm labor was common with incidence of 37.8% in patients with Hb <7gm%.The results were comparable with Singhal et al were the incidence was 32.59%, 22% in Agarwal R study, 23.5% in Jaleel R study and 18.755 in Rohilla M et al [17-19]. Due to the impaired oxygen carrying capacity in anemia there is cellular and enzymatic dysfunction resulting in abnormal myometrial contractility which cases atonic uterus, moreover ,placental dysfunction leads to preterm labor. Pregnancy induced hypertension in present study was15.7% which was comparable with the study of Devi NB et al [20].In severe anemia there is deficiency of micronutrients and antioxidants such as calcium, magnesium, zinc which is attributed to development of pre eclampsia in anemic females.

Conclusion

We found that severe anemia was more prevalent in patients who were unbooked and those with poor socio economical background . Severe Anemia is associated with severe maternal and fetal morbidity. Special attention should be given to this vulnerable population to reduce maternal and fetal complications associated with severe anemia New and modern plans are to be implemented to improve general health and nutritional status of adolescent girls before they enter their

reproductive years.

Refrences

1. Irondeficiencyanemia: assessment, prevention, control. A guide of programme managers. Geneva,world health organization;2001(WHO/NHD/01.3)
2. Melku M,Addis Z,Alem M ,Enawgaw B,Prevalance and predictors of maternal anemia during pregnancy in Gondar,northwest Ethiopia: An institutional cross-sectional study.Anemia.2014;7:771.
3. Ghimire RH,Ghimire S.Maternal and Fetal outcome Following severe Anemia in pregnancy;result from Nobel Medical college Teaching hospital,Biratnagar,Nepal.J Nobel Med Coll.2013;2:22-6.
4. CDC criteria for anemia in children and childbearing-aged women.MMWR Morb Mortal Wkly Rep;1989;38:400-4.
5. Maternal outcome in cases of severe anemia in labour;Shalani Singh,khushpreet Kaur.
6. Rizwan F,Qamarunisa H,Memon A.Prevalence of anemia in pregnant women and its effects on maternal and fetal mortality.PakJMedsci,2010;26:92-5.
7. Dayal S Dayal A.Prevalence and consequences of anemia in pregnancy.Int J Med Res Review 2014:2:296-9.
8. Kalavani K Use of intravenous iron sucrose for treatment of anemia in pregnancy.The Indian J Med Res2013;138:16-7.
9. Ahmad MO ,Kalsoom U, Sughra U,Hadi U, Imran M .Effect of maternal anemia on fetal weight
.J Ayub Med Coll Abbottababad,2011;23;77-9.
10. Singhal SR, Nanda, S.Mandira. Sangwank. Sharma D. Maternal and Perinatal outcome in severe Anaemia. Indian Practitioner, 2007; No.60 (11):691-4.
11. Riffat Jaleel, Ayesha Khan. Severe anemia and Adverse pregnancy Outcome, Journal of surgery Pakistan (International) 13 (4) October-December 2008.
12. Rajeshwari K and Ashok Kumar Behera. The study of incidence of maternal anaemia in various age groups of women going to labour in Orissa. International Journal of Recent Trends in Science and Technology, Volume 12 (2) 2014: p 250-52
13. Rajaratanam J, Y,Rajaratanam,A., Ganesan, C. Jayaseelan S A. Maternal anaemia: persistent problem in rural Tamil Nadu. Natl Med J of India 2000: 242-45.
14. Allen LH. Biological mechanisms that might underlie iron's effects on fetal growth and preterm birth. J Nutr. 2001;131(2S–2):S581–9.
15. ME Bentley and PL Griffiths "The burden of anaemia among women in India" Eur J ClinNutr (2003) 57, 52-60.
16. Boniface Uji Ago, Sylvester Abeshi, Charles Njoku, Thomas UdagborAgan and John Ekabua. Obstetric outcomes of booked teenage pregnancies at University of Calabar Teaching Hospital, Nigeria. Adolescent Health Medicine and Therapeutics 2012:3 105–109.
17. Ranju Agarwal, Medical officer, Medical Hospital, Agra; A Multi centric study of anaemia. A step in conquering anaemia OBS &Gyae.Vol VIII No.11 2003
18. AwasthiA,ThakurR.,Dave A et al. Maternal and Perinatal outcome in case of Moderate and Severe Anaemia Complicating pregnancy .J ObsetGynaecol India 2001; 5-51.
19. Rohilla M, Ravindra A, Dhaliwal LK, Chopra S. Severe anaemia in pregnancy : A territory hospital from Northen India. J ObsetGynaecology 2010:30 (7):694-6.
20. Dr. B NirmalaDevi1,Dr. B Varalaxmi2Dr. T Jyothirmayi3,Dr.LahariN4 Maternal outcome in pregnancy with severe anaemia: Prospective study in a tertiary care hospital in Andhra Pradesh ,IOSR Journal of Dental and Medical Sciences (Apr. 2015)

Original Article

Correlation of Serum Phenytoin Levels With the Occurrence of Adverse Drug Reactions in Patients With Epilepsy in a Tertiary Care Hospital of Northern India

Mohd Adil, Muzaffar Ahmad Pukhta ,Samina Farhat , Tauseef Nazir

Abstract

Background

Phenytoin is the most commonly used anti-epileptic drug (AED) in our set up due to its cost-effectiveness and easy availability. Significant fluctuations in serum phenytoin levels leading to toxicities or treatment failures make it an ideal candidate for therapeutic drug monitoring (TDM).

Methods

Patients of age ≥18 years who were put on phenytoin were enrolled in Data was analysed using SPSS version 20.0. Chi square test, Kruskal Wallis test were used to analyse the data. Relationship of serum phenytoin levels versus ADRs was analysed using Mann-Whitney test.

Results

A total of 105 patients enrolled in the study, twenty patients (19%) had normal or therapeutic serum phenytoin levels. Thirty-nine patients (37.2%) had sub therapeutic serum phenytoin levels, while forty-six patients (43.8%) had toxic serum phenytoin levels. A total of 91 ADRs of 20 different types were reported by 48 patients of the study population. The most common organ system involved was neurological (49.4%) followed by gastrointestinal (26.4%), Skin/Connective Tissue (19.8%) and Haematological (4.4%). ADRs were present in 5.13% of the patients with sub therapeutic levels of phenytoin against the 82.60% of the patients with toxic levels of phenytoin. ADRs were present in 40% of the patients with serum phenytoin levels in normal or therapeutic range. There was a statistically significant relationship between serum phenytoin levels and the proportion of ADRs ($p<0.001$). ADRs were most common in the age group of 21-40 years (53.6%) and least common in the age group of 61-80 years (33.3%). There was, however, no statistically significant relationship between age and ADRs ($p=0.376$).

Conclusion

The TDM of phenytoin should adopt a multi-disciplinary approach with active involvement of neuro-physicians, pharmacologists, pharmacists and other technical staff for improving the overall management of epilepsy. TDM data will provide the clinicians with greater insight into the factors determining the patient's response to drug therapy.

JK-Practitioner2022;27(4):55-60

Introduction

Phenytoin is an anti-epileptic drug approved for monotherapy and adjunctive therapy of tonic-clonic seizures and focal seizures in patients across all age groups, besides, it is used for treating seizures that occur secondarily to a neurosurgical intervention or severe head injury. In addition, phenytoin is one of the AEDs used in the management of status epilepticus. Other uses include the treatment of trigeminal neuralgia as a monotherapy and for the treatment of cardiac arrhythmias [1]. Phenytoin is the most commonly prescribed AED in our set-up due to its cost effectiveness and easy availablilty [2].

Phenytoin has a narrow therapeutic range demanding a fine balance between therapeutic efficacy and dose related adverse reactions. Phenytoin exhibits a non-linear pharmacokinetic profile even within the therapeutic window, due to gradual saturation of the metabolising enzyme system, resulting in its decreased rate of elimination as dose increases. This means even a small change in the dose leads to wide fluctuations in the phenytoin levels in body fluids and hence variable clinical effect. The inter-individual variability can lead to 50-fold difference in plasma/serum phenytoin concentrations in patients taking the same dose. All these factors make phenytoin an ideal candidate for Therapeuti Drug Monitoring to ensure therapeutic efficacy [3]

Author Affiliations
Mohd Adil, Tauseef Nazir,Registrars,**Muzaffar Ahmad Puktha**, Associate Professor **Samina Farhat ,**Professor & Head;
Post-graduate Department of Pharmacology ,GMC: Srinagar: Jammu & Kashmir
India.

Correspondence
Dr.Tauseef Nazir,
Registrar/Demonstrator,
Post-graduate Department of Pharmacology, Government Medical College, Srinagar, J&K
9906156868
E mail tauseefnazir@yahoo.com

Indexed
EMBASE ,SCOPUS, IndMED ,ESBCO ,Google Scholar besides other national and International Databases

Cite This Article as
Adil M, Pukhta MA,Farhat S , Nazir T.
Correlation of Serum Phenytoin Levels With the Occurrence of Adverse Drug Reactions in Patients With Epilepsy in a Tertiary Care Hospital of Northern India JK Pract2022;27(4):55-60

Full length article available at **jkpractitioner.com** one month after publication

Keywords
Adverse drug reactions (ADRs), Epilepsy, HPLC, Phenytoin

Methods

The present study was conducted in the Department of Pharmacology, Government Medical College, Srinagar in collaboration with the Department of Medicine and department of Neurology SMHS Hospital, Government Medical College Srinagar after getting approval by Institutional Ethics Committee. Estimation of serum levels of Phenytoin was done using High Performance Liquid Chromatography and its correlation with the occurrence of adverse drug reactions was studied. The participants were provided with explicit explanation for their inclusion in the study by instituting written informed consent, duly translated in local vernacular. It was a cross-sectional, observational study for a period of one and a half year.

Inclusion criteria

All patients with seizures of either sex and age group ≥18 years of age who were prescribed phenytoin by the consulting physician were included in the study.

Exclusion criteria

- Patients who were unable to co-operate.
- Patients who were unable to give consent.
- Patients treated with traditional medicines alone.
- Patients with chronic illnesses like chronic liver or renal diseases.

Estimation of serum levels of phenytoin was done in the Department of Pharmacology, Government Medical College, Srinagar using Reverse phase high-performance liquid chromatography (RP-HPLC) from Agilent® technologies (1260 infinity series).

Following information was collected from the patients:

1) Age, sex, body weight (Kgs) and height (cm).

2) Clinical Characteristics: Duration of illness, number of previous episodes, any associated co morbidity.

3) Dose of Phenytoin at the time of the visit, duration of present treatment.

4) Any Adverse Drug Reaction/s – duration, severity.

The severity of ADRs was determined by using the modified Hart Wig and Siegel Scale (1992)[4]

Statistical Analysis

Data was entered in Microsoft Excel spreadsheet. Categorical variables were summarised as frequency and percentage. Continuous variables with a normal distribution were summarised as mean and standard deviation and the distribution was displayed as histogram. Relationship between two categorical variables was analysed using Chi-square test. Relationship of serum phenytoin levels versus ADRs was analysed using Mann-Whitney test. Two-sided p-values were reported and $p<0.05$ was considered statistically significant. Data was analysed using SPSS version 20.0

Results

Table 1Distribution of the study population according to Age

Age (years)	Frequency	Percent
< 20 years	10	9.5
21-40 years	56	53.3
41-60 years	24	22.9
61-80 years	15	14.3
Total	**105**	**100.0**

Table 1 shows the age distribution of the study population. The mean age of the patients was 38.9 years with a standard deviation of 16.08 years. Most of the patients were in the age group of 21-40 years (53.3%) followed by the age group of 41-60 years (22.9%), 61-80 years (14.3%) and 18-20years (9.5% each).

Table –2 Distribution of the study population according to sex

Sex	Frequency	Percent
Male	71	67.6
Female	34	32.4
Total	**105**	**100.0**

Table 2 shows the distribution of the study population according to sex. The study population comprised of 71 males (67.6%) and thirty four females (32.4%).

Table 3Distribution of study population according to serum levels of phenytoin

Serum level of phenytoin	Frequency	Percent
Sub therapeutic levels (< 10 µg/ml)	39	37.2
Normal (therapeutic) levels (10-20 µg/ml)	20	19.0
Toxic levels (>20 µg/ml)	46	43.8
Total	105	100

Table 3 shows the distribution of the study population according to their serum phenytoin levels (µg/ml). Out of a total of 105 patients enrolled for the study, only 20 patients (19%) had normal or therapeutic serum phenytoin levels. 39 patients (37.1%) had sub therapeutic levels, while 46 patients (43.8%) had toxic levels.

Table -4 Distribution of study population according to ADRs

ADR	Frequency	Percent
Present	48	45.7
Absent	57	54.3
Total	**105**	**100.0**

Table 4 shows the distribution of the study population according to ADRs. Out of a total of 105 patients enrolled for the study, 48 patients (45.7%) reported at least one or more ADRs and 57 patients (54.3%) showed no ADRs. The prevalence of ADRs in the study population was 45.7%.

Table 5 Adverse drug reactions in the study population

Type of ADR		Frequency (N=91)	Percent
Neurological	Ataxia	09	8.5
	Blurred vision	07	6.6
	Drowsiness	05	4.7
	Giddiness	03	2.8
	Headache	09	8.5
	Nystagmus	06	5.7
	Slurred speech	03	2.8
	Tremor	01	0.9
	Tingling and	02	1.9

	numbness		
Gastrointestinal	Decreased appetite	03	2.8
	Epigastric discomfort/Pain	06	5.7
	Nausea	09	8.5
	Vomiting	06	5.7
Skin/ Connective Tissue	Acne	05	4.7
	Gum hypertrophy	10	9.5
	Hirsuitism	01	0.9
	Skin rash	02	1.9
Haematological	Anemia	01	0.9
	Neutropenia	01	0.9
	Enlarged Lymph Nodes	02	1.9

Table 5 shows the different types of ADRs observed in the study population. A total of 20 different types of ADRs were reported by the study population. A total of 91 ADRs were reported by 48 patients. The most common ADR was gum hypertrophy (in 9.5% patients) followed by ataxia (in 8.5% patients), headache (in 8.5% patients), nausea (in 8.5% patients), blurred vision (in 6.6% patients), nystagmus (5.7% of patients) epigastric pain (in 5.7% patients), vomiting (in 5.7% patients), drowsiness (in 4.7% patients), acne (4.7% of patients), decreased appetite (2.8% of patients), giddiness(2.8% of patients), slurred speech (2.8% of patients), enlarged lymph nodes (1.9% of patients), skin rash (1.9% of patients), tingling and numbness (1.9% of patients), anaemia, hirsuitism, neutropenia and tremor were reported by 0.9% of patients each.

Table 6 Frequency of ADRs according to organ system involved

System involved	Frequency	Percentage
Neurological	45	49.4
Gastrointestinal	24	26.4
Skin/Connective Tissue	18	19.8
Haematological	4	4.4
Total	**91**	**100**

Table 6 shows the frequency of ADRs according to the organ system involved. The most common organ system involved was neurological (49.4%) followed by gastrointestinal (26.4%), Skin/Connective Tissue (19.8%) and Haematological (4.4%).

Table 7Distribution of study population according to Serum Phenytoin levels and ADRs

Serum phenytoin levels (µg/ml)		ADR		Total
		Present	Absent	
Sub therapeutic	Count	2	37	39
	%	5.13%	94.87%	100.0%
Therapeutic	Count	8	12	20
	%	40%	60%	100.0%
Toxic	Count	38	8	46
	%	82.60%	17.40%	100.0%
Total		**48**	**57**	**105**
		45.7	**54.3**	**100**
p <0.001, chi square test				

Table 7 and fig. 1 shows that ADRs were present in 5.13% of the patients with sub therapeutic levels of phenytoin against the 82.60% of the patients with toxic levels of phenytoin. ADRs were present in 40% of the patients with serum phenytoin levels in normal or therapeutic range. There was a statistically significant relationship between serum phenytoin levels and the proportion of ADR ($p<0.001$).

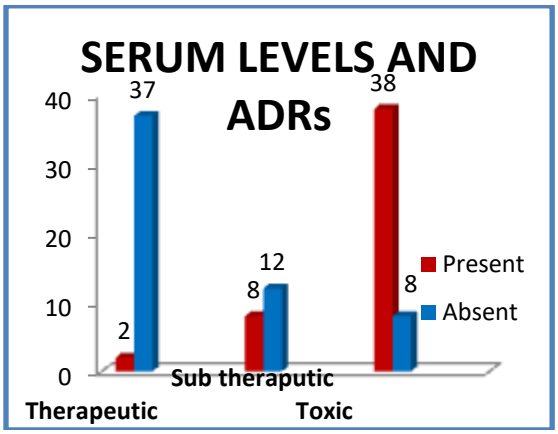


Fig.1

Table 8 Association of serum phenytoin levels with ADRs

Serum Phenytoin Levels	ADR	
	Present	Absent
Minimum	6.36	0.52
25th percentile	21.58	3.32
Median	37.98	7.90
75th percentile	54.46	14.61
Maximum	84.72	38.08
Mean	37.88	10.61
Standard deviation	19.40	9.60

p value <0.001

Table 8 and fig.2 shows that there was a statistically significant relationship between serum phenytoin levels and the proportion of ADR.

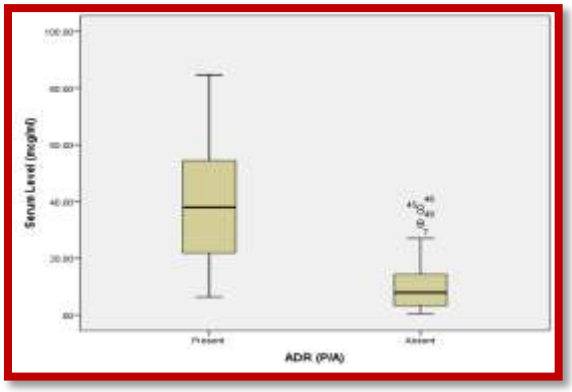


Fig. 2

Table 9 Distribution of study population according to Age and ADRs

Age (years)		ADR		Total
		Present	Absent	
<20 years	Count	4	6	10
	%	40%	60%	100.0%
21-40 years	Count	30	26	56
	%	53.6%	46.4%	100.0%
41-60 years	Count	9	15	24
	%	37.5%	62.5%	100.0%
61-80 years	Count	5	10	15
	%	33.3%	66.7%	100.0%
Total		**48**	**57**	**105**
		45.7	**54.3**	**100**
p= 0.376 , chi square test				

Table 9 and fig.3 shows that ADRs were most common in the age group of 21-40 years (53.6%) and least common in the age group of 61-80 years (33.3%). There was, however, no statistically significant relationship between age and ADRs (p=0.376).

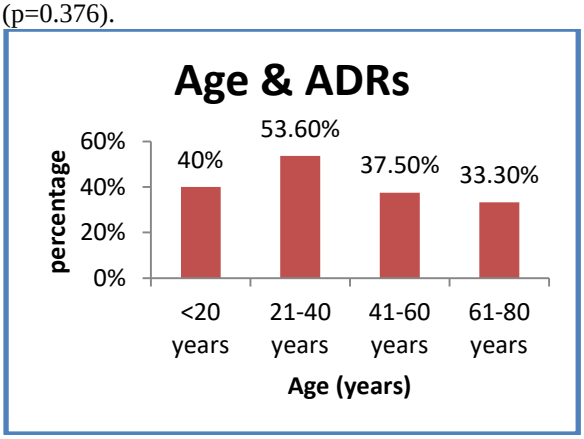


Fig.3

Table 10 Distribution of study population according to Sex and ADRs

SEX		ADR		Total
		Present	Absent	
Male	Count	32	39	71
	%	45.1%	54.9%	100.0%
Female	Count	16	18	34
	%	47.1%	52.9%	100.0%
Total	**Count**	**48**	**57**	**105**
	%	**45.7%**	**54.3%**	**100.0%**

p = 0.848, chi-square test

Table 10 and fig.4 shows that ADRs were reported in 47.1% of females as compared to 45.1% among males. There was no statistically significant relationship between sex and the proportion of ADRs (p=0.848).

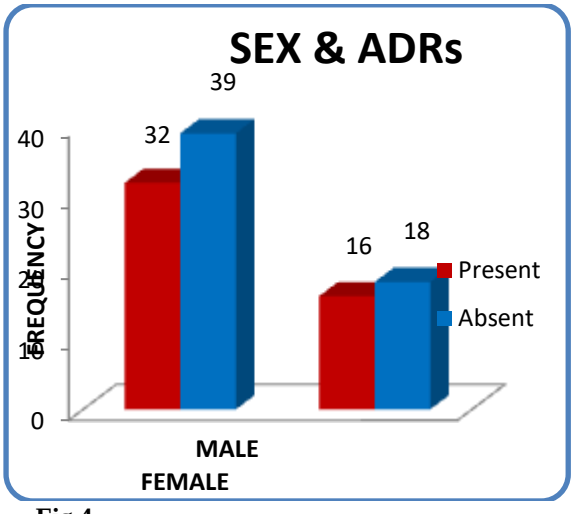


Fig.4

Discussion

Phenytoin is an anti-epileptic drug approved for monotherapy and adjunctive therapy of tonic-clonic seizures and focal seizures in patients across all age groups, besides, it is used for treating seizures that occur secondarily to a neurosurgical intervention or severe head injury. In addition, phenytoin is one of the AEDs used in the management of status epilepticus. Other uses include the treatment of trigeminal neuralgia as a monotherapy and for the treatment of cardiac arrhythmias [1]. Phenytoin is the most commonly prescribed AED in our set-up due to its cost-effectiveness and easy availablilty [2].

The present study was conducted in the Department of Pharmacology, Government Medical College, Srinagar in collaboration with the Department of Medicine, SMHS Hospital, Srinagar after getting approved by Institutional Ethics Committee, to study the estimation of drug levels of Phenytoin using High Performance Liquid Chromatography and its correlation with the occurrence of adverse drug reactions in patients with epilepsy.

Our study was a cross sectional observational study. The patients coming to the neurology out-patient department or patients admitted to neurology inpatient department were recruited for the study after being provided with explicit explanation for their inclusion in the Study by instituting Written Informed Consent, duly translated in local Vernacular.

Phenytoin has a narrow therapeutic range demanding a fine balance between therapeutic efficacy and dose related adverse reactions. Phenytoin exhibits a non-linear pharmacokinetic profile even within the therapeutic window, due to gradual saturation of the metabolising enzyme system, resulting in its decreased rate of elimination as dose increases. This means even a small change in the dose leads to wide fluctuations in the phenytoin levels in body fluids and hence variable clinical effect. The inter-individual variability can lead to 50-fold difference in plasma/serum phenytoin concentrations in patients taking the same dose. All these factors make phenytoin an ideal candidate for TDM to ensure therapeutic efficacy [3].

Estimation of serum levels of phenytoin was done in the Department of Pharmacology, Government Medical College, Srinagar using Reverse phase high-performance liquid chromatography (RP-HPLC) from Agilent® technologies (1260 infinity series).Selecting the most appropriate analytical methods is often not easy and the choice depends on the availability of staff, expertise and equipment, the nature of the service to be provided and the range of drugs to be assayed. The major advantage of chromatographic techniques is their flexibility and adaptability to a wide range of drugs.

Our study enrolled a total of 105 patients as study population. A study conducted by P.T. Lascelles et al [5] enrolled 111 patients in their study. Similarly G.W. Houghton and A.Richens [6] enrolled 170 patients in their study, S.K. Garget et al [7] enrolled

116 patients in phenytoin group in his study 'TDM of Antiepileptic drugs-A preliminary experience', while as a study conducted by Kiran Dahiya et al [2] enrolled 1255 patients on phenytoin monotherapy in their study.

Most of the participants in the study were in the young and middle age groups of 21-40 years (53.3%) and 41-60 years (22.9%), followed by 61-80 years(14.3%) and 18-20years (9.5% each), with a mean age of 38.9 years (SD 16.08 years). A study conducted by Sunee Lertsinudom et al [8] had a mean age of 38.21 years (SD 15.36). Another study conducted by Rasheva M et al [9] had a mean age of 42.2 years (SD 20.3). The study population comprised of 71 males (67.6%) and thirty four females (32.4%), with a male: female ratio of 2.08. Kiran Dahiya et al[2] had 63.8% males and 36.12% females enrolled in their study with a male: female ratio of 1.77.

Out of a total of 105 patients enrolled for the study, 48 patients (45.7%) reported at least one or more ADRs and 57 patients (54.3%) showed no ADRs. The prevalence of ADRs in the study population was 45.7%. In a study conducted by Abasher Hussain et al [10], the prevalence of ADRs due to phenytoin was 42.2%. Prudhivi Ramakrishna et al [11 found that Phenytoin resulted in a prevalence of 44.7% of ADRs when prescribed as monotherapy. A study conducted in a tertiary care hospital, Erode, Tamil Nadu by Keerthi Jayalekshmi et al [12] reported an ADR prevalence of 31.1%.

In our study, Sixty nine (75.8%) ADRs were mild in severity as per the modified Hartwig and Siegel scale. Only twenty two (24.2%) ADRs were moderate in severity. We did not observe any severe or 'lethal' ADRs in our study, while in contrast to the study by Prudhivi Ramakrishna et al [11] where 4 cases were found to be life threatening (severe category). This may be because majority of the patients enrolled in our study were on outpatient basis, besides the sample size of the study was relatively small. It has been reported by Prudhivi Ramakrishna et al [11] that majority of ADRs in outpatient settings were mild and self-limiting.

ADRs were most common in the age group of 21-40 years (53.6%) and least common in the age group of 61-80 years (33.3%). There was, however, no statistically significant relationship between age and ADRs (p=0.376).

ADRs were reported in 47.1% of females as compared to 45.1% among males. There was no statistically significant relationship between sex and the proportion of ADR (p=0.848).We recorded a total of twenty different types of ADRs in our study population. A total of 91 ADRs were reported by 48 patients. Gum hypertrophy reported in9.5% patients followed by ataxia (in 8.5% patients), headache (in 8.5% patients), nausea (in 8.5% patients), blurred vision (in 6.6% patients), nystagmus (5.7% of patients), epigastric pain (5.7%), vomiting (in 5.7% patients) were the most common ADRs observed in the study population in decreasing order of their of occurrence. When compared to other studies[13,14] conducted earlier, gum hypertrophy was reported as the commonest ADR by Prudhivi Ramakrishna et al [11] followed by nausea, vomiting and ataxia. In a study conducted by Abasher Hussain et al [10] nausea, vomiting, gum hypertrophy were reported as the most common ADRs to phenytoin monotherapy (8.9% each) followed by ataxia and nystagmus (6.67% each).

The most common organ system involved was neurological (49.4%) followed by gastrointestinal (26.4%). Other systems involved were Skin/Connective tissue (19.8%) and haematological (4.4%). Prudhivi Ramakrishna et al [11] in their study found that majority of the ADRs involved Central Nervous system followed by gastrointestinal system. Similarly Abasher Hussain et al [10] found the occurrence of ADRs in their study was most commonly involving Central Nervous system.

In our study, ADRs were present in 5.13% of the patients with sub therapeutic levels of phenytoin against the 82.60% of the patients with toxic levels of phenytoin. ADRs were present in 40% of the patients with serum phenytoin levels in normal or therapeutic range. There was a statistically significant relationship between serum phenytoin levels and the proportion of ADR ($p<0.001$). Henn Kutt et al [14] in their study reported a close and statistically significant correlation between blood drug levels of phenytoin and its toxic manifestations. Abasher Hussain et al [10] in their study concluded that there was no relationship between serum levels of AEDs and their side effects. The differences in results can possibly be explained as the study conducted by Abasher Hussain et al [10] had a very small sample size of 45 patients in phenytoin group with 84.45% patients having serum phenytoin levels within normal therapeutic range and only 15.55% patients outside normal limits. Since our study population had 19% of patients with serum phenytoin levels within normal therapeutic range, 43.8% had toxic levels and 37.1% had sub therapeutic levels. Otherwise the prevalence of ADRs and the ADR distribution was almost similar in the two studies.

Conclusion

The study is first of its genre in our set up. The concept of monitoring phenytoin levels in patients with epilepsy is primarily consequent to its narrow therapeutic range and significant pharmacokinetic variability. As a result, propensity of adverse drug reactions is higher in patients on long term therapy.

These factors make phenytoin an ideal candidate for therapeutic drug monitoring, which involves a multi-disciplinary approach involving clinicians, pharmacologists and other technical staff. The fundamental aim of this study was to analyse a relationship between serum levels and the occurrence of adverse drug reactions.

References

1. Therapeutic Drug Monitoring of Antiepileptic Drugs in Epilepsy: A 2018 Update Philip N.Patsalos, Edgar P. Spencer et al)
2. KiranDahiya, PiyushBansal, Veena Singh Ghalaut, RakeshDhankhar, PS Ghalaut. Therapeutic drug monitoring for antiepileptic drugs using HPLC: An experience at a tertiary care hospital in India. Neurology Asia 2010; 15(3): 233 – 237.
3. Melissa Faye Wu, WaiHing Lim: Phenytoin – A Guide to Therapeutic Drug Monitoring: Proceedings of Singapore Healthcare 2013;22(3).
4. Hartwig SC, Seigel J, Schneider PJ. Preventability and severity assessment in reporting adverse drug reactions. Am J Health Syst Pharm 1992; 49(9): 2229-32.
5. P. T. Lascelles, R. S. Kocen, AND E. H. Reynolds: The distribution of plasma phenytoin levels in epileptic patients; (J. Neurol. Neurosurg. Psychiat., 1970, 33, 501-505)
6. G.W. Houghton& A. Richens, Monica Leighton: Effect of age, height, weight and sex on serum phenytoin concentrations in epileptic patients; (Br. J. clin. Pharmac. (1975), 2, 251-256)
7. S.K. Garg, M.C. Gupta, S.S. Handu, V. K. Bhargava. Therapeutic drug monitoring of antiepileptic drugs – a preliminary experience. Indian Journal of Pharmacology 2000; 32: 28-30.
8. SuneeLertsinudom, AporaneeChaiyakum and et al: Therapeutic drug monitoring in epilepsy clinic – a multi-disciplinary approach; (Neurology International 2014; volume 6:5620)
9. Rasheva M, Staikov I and et al: Low serum levels of antiepileptic drugs in patients with epilepsy-Bad compliance or something else;**(** Austin J ClinNeurol - Volume 2 Issue 10 – 2015)
10. Abbashar Hussein, AmiraAbdulgalil, Faroug Omer, Hassan Eltoum, Ahmed Hamad, Omer El-Adil et al. Correlation between Serum Level of Antiepileptic Drugs and their Side Effects. OMJ. 2010; 25: 17-21.
11. Prudhivi Ramakrishna et al. Int. Res. J. Pharm. 2014, 5(8) Collection, detection, assessment, monitoring and prevention of adverse drug reactions of antiepileptic drugs.
12. Jayalekshmi et al. Journal of applied pharmaceutical science 6 (05); 2016: 119-123.
13. Philip N. Patsalos, David J. Berry, Blaise F. D. Bourgeois, James C. Cloyd, Tracy A. Glauser, Svein I. Johannessen et al. Antiepileptic drugs—best practice guidelines for therapeutic drug monitoring: A position paper by the subcommission on therapeutic drug monitoring, ILAE Commission on Therapeutic Strategies. Epilepsia 2008; 49(7): 1239–1276.
14. Kutt, H., Winters, W., Kokenge, R., and Mcdowell, F. (1964b). Diphenyhydantoin metabolism, blood levels and toxicity. *Arch. Neurol. (Chic.)*, 11, 642-648.

Original Article

A Descriptive Study Evaluating Perception and Utility of Teaching Personal Drug(P-Drug) Selection Among Undergraduate Medical Students.

M.Y. Bhat ,Samina Farhat , Z.S Bali.

Abstract

Background and Objectives

Learning how to evaluate and analyze information is becoming important skill so the present study on P-Drug selection was done with the objective of promoting practice of rational therapeutics among students as tremendous growth of pharmaceutical industry has led to the production of many drugs while most doctors use only 40-60 drugs routinely. In that context, incorporation of personal drug (P drug) selection exercise into medical curriculum was made recently for undergraduate students who are future practicing doctors, hence this study regarding P-drug concept was conducted for which few studies have been conducted.

Material and Methods

This observational cross sectional pre validated questionnaire based study was conducted among second professional medical students after introducing P-drug concept and its selection through problem based learning (PBL) during routine practical classes of two hours in three divided batches and analysing their perception and feedback. The results were expressed as counts and percentages.

Results

Of 185 enrolled students,150 attended and filled questionnaire containing items related to teaching, concept of P-drug, satisfaction value and practice of P-drug. Majority of the students responded in affirmative for all questions with 28(18.6%) opining for more exercise and 19(12.6%)desiring more time for better understanding of the concept. However 55(36.6%) students were still not confident in selecting P-drug.

Conclusion

For improving the quality of healthcare and practicing rational use of medicines, the P-drug concept is very helpful. Further feedback from students was positive and encouraging with scope for refinement of newly developed module based on student's perception.

JK-Practitioner2022;27(4):61-64

Introduction

Irrational use of medicines is a serious public health problem worldwide which can be due to use of too many medicines per patient, inappropriate use of antimicrobials often in inadequate dosage and insufficient duration, over use of injections when oral medications would be more appropriate, failure to prescribe in accordance with clinical guidelines or prescribing policy and inappropriate self-medication often of prescription only medicine [1]. It has been estimated by WHO that more than 50% of all medicines are prescribed, dispensed or sold inappropriately and about 50% of patients do not take them correctly [2]. This scenario underscores the need for educating the prescriber, the dispenser, the retailer and the public including the patient [3,4]. In spite of introducing various interventions namely educational, managerial and regulatory at prescriber level to promote rational prescribing, irrational prescribing is still a global problem [5]. One way to prevent the irrational prescribing by future doctors is by training the medical students on rational prescribing as prescribing is always a challenging task which requires knowledge of essential medicines, rational use of medicines and personal drugs (P-drug). Moreover young doctors are exposed to various factors that influence

Author Affiliations
MY Bhat,Assistant Professor **,Samina Farhat ,**Professor & Head **,ZS Bali** ,Lecturer
Department of Pharmacology ,Government Medical College ,Srinagar.
Jammu & Kashmir,
India.

Correspondence
Dr. Mohammad Younis Bhat
Assistant Professor
Department of Pharmacology
Govt Medical College Srinagar
190010
Email:
mohammad.younis50@yahoo.com
Ph: 9697948706

Indexed
EMBASE ,SCOPUS, IndMED ,ESBCO ,Google Scholar besides other national and International Databases

Cite This Article as
M.Y. Bhat ,Samina Farhat, Z.S Bali.A Descriptive Study Evaluating Perception and Utility of Teaching Personal Drug(P-Drug) Selection Among Undergraduate Medical Students. JK Pract2022;27(4):61-64

Full length article available at **jkpractitioner.com** one month after publication

Keywords
Undergraduate students, P-drug, medical curriculum, questionnaire, problem based learning, perception.

their prescribing behaviors like drug promotional materials, patient pressures, example of seniors and colleagues and in a study, majority of medical studies copy therapeutic drug choices from their teachers due to lack of experience [6]. With the renewal of the syllabus of pharmacology, many new topics have been included in practical curriculum and the concept of P-drug is one of them which has been included as traditional pharmacology teaching in medical schools concentrates on transferring knowledge about drugs rather than training students to treat patient in a most rational way [7]. In order to prevent serious health risks and socio economic burden to the patients, WHO has also given the Guide to Good Prescribing, which gives a guidance for structured problem solved six step process in choosing and prescribing a suitable drug for an individual patient that is P-drug concept .P-drug referred to as "Preferred" or "Particular" or "Personal" drug is the drug chosen by the physicians for a particular disease to treat it in a cost effective manner [8]. It is not just a name of the pharmacological substance but it also indicates dosage schedule, dosage forms and duration of treatment [9]. P-drug concept varies differently from one country to another and doctors to doctors due to availability, cost, essential drug list, medical culture, different national formularies and interpretation of every individual about a drug information [8, 10] and by developing and compiling one's own set of P-drugs, one can learn to handle pharmacological concepts and drug related data in an effective and confident manner and prescribing alternatives when the same P-drug can't be used [11]. Since the P-drug concept has been newly included in curriculum, we planned and conducted this study to investigate students perception and utility regarding P-drug selection, teaching assessments, feedback and suggestions regarding the new educational interventions for the sake of further improvement.

Materials and Methods

This prospective cross sectional pre-validated questionnaire based study was carried out in the Department of Pharmacology, Government Medical College, Srinagar (J&K),a teaching post graduate institute among second professional undergraduate medical students of strength 185 who happen to be first batch of new competency based medical curriculum at end of their session during routine practical classes within stipulated time of two hours in their corresponding groups. A revalidated questionnaire was developed on P-drug concept having items related to teaching concept of P-drug, satisfaction, value and practice of P-drug. After giving informed consent and being anonymous in response, the feedback forms containing questions on different aspects and an open ended question on P-drug as depicted under were collected. Teaching module was developed with objective that at the end of 2nd year of MBBS course so that students should be able to select their own P-drug for the given disease using their pharmacological knowledge of drugs and discussing disease conditions like acute attack of angina pectoris, uncomplicated cystitis, hypertension with co morbidity like diabetes, glaucoma in a 70 year old male and acute watery diarrhea with mild dehydration in the form of problem based learning (PBL) as a practical tool for the training of students on "how to prescribe" rather than "what to prescribe"were chosen.P-drug selection for a given case scenario was taught after dividing into five steps including defining the diagnosis, specify the therapeutic objective, making an inventory of effective group of drugs, choose an effective group following the method described by Joshi and Jayawickramaharaj [12] involving criteria of efficacy (pharmacodynamic and kinetic profile of a drug must allow the drug to reach a minimum plasma concentration and with easy dosing schedule),safety(priority being given to drugs of proven efficacy and safety),suitability(involving contraindications, interactions and any change in physiology of patient which are otherwise effective and safe like pregnancy, lactation, hepatic and renal failure history of allergy, children, elderly and dosage form which are easy to handle),**cost**(being important criterion in both developed and developing countries and looking for at the total cost of treatment rather than cost per treatment) and finally choosing a P-drug. Data was analyzed using simple descriptive statistics like percentage.

Results

Out of enrolled 185 second professional undergraduate students, 150 were present and responded in the questionnaire. The questionnaire and percentage response of the students regarding different closed ended questions evaluating teaching, concept of P-drug, satisfaction value and practice of P-drug is shown below. Along with closed ended questions, students were directed to put their comments about different aspects of P-drug selection and teaching involving application, judgement, introduction from beginning of second year, more exercise, more explanations, compare and contrasting concepts and any other positive and negative aspects of P-drug selection discussed, learnt and imbibed during teaching learning activity.

Discussion

In this study P-drug selection was taught to second professional medical students through various case scenarios as problem based learning (PBL) which holds a distinct advantage over the traditional didactic lecture where students learn passively through rote method [13] with the aim of developing habit of rational use of drugs which includes the right drug, right patient, in the right

Questionnaire and Students feedback regarding P-Drug Selection

Teaching	Allocated time was adequate (2 hr)	Yes 131	No 19
	Explanation was clear	Yes 149	No 1
	Understood the steps very well	Yes 149	No 1
	More exercises are required to understand the process better	Yes 122	No 28
	Taught us how to prescribe for a given clinical condition	Yes 148	No 2
Concept of P-drug	Was the P-drug concept interesting to you?	Yes 150	No 0
	Is P-drug concept significant?	Yes 146	No 4
	Is P-drug list same everywhere?	Yes 0	No 150
	Does P-drug concept improve understanding of various pharmacological aspects of the drug?	Yes 150	No 0
Satisfaction, value and practice of P-drug	Should be taught to all medical students	Yes 148	No 2
	Imparted skills required to select safe and effective drugs	Yes 144	No 6
	A welcome change in the routine curriculum	Yes 146	No 4
	Are you now confident in selecting a P-drug for the case scenario taught	Yes 95	No 55
	Relevant to future practice	Yes 149	No 1

dosage and at the right cost thereby contributing to high quality healthcare and reducing irrational use which leads to health hazards and wastage of resources that are already insufficient in a majority of healthcare system [14] particularly in the present era of "drug explosion "where availability of numerous drugs has converted global drug scenario into a "therapeutic jungle". The concept of P-drug is a new addition to the competency based medical curriculum as most of the senior clinicians and even among junior residents taught about the concept, percentage of practicing P-drug is less though they were exposed to this in their pharmacology curriculum during MBBS non formally [15]. This indicates that P-drug concept has remained confined to pharmacology and has not become popular among clinicians which can be considered as major cause of error in prescribing with its adverse consequences subsequently [16-18].

Selection of P-drugs is one's own affair without involvement of others, but medical teachers having gained expertise from long standing practice of teaching may provide vital information to the students about the use of existing drugs thereby helping them a lot in selecting their own P-drug [19], hence this study was planned and executed so that undergraduate students who are future doctors can be motivated towards the concept of P-drug through effective lectures in practical hours and evaluate them through a questionnaire for further improvements as required. In present study students were guided for selecting a P-drug for a given case scenario as per knowledge and judgement,however in literature various methods like multi attributive utility analysis (MAUA) [20], modified MAUA [21] and awarding positive and negative points or pluses and minuses to the various criteria for each drug [20] were used for selecting a group/drug. Majority of the students responded with affirmative in most of questions like 148(98.6%) students opined that exercise taught them how to prescribe for a given clinical condition, all students found the concept interesting,146(97.3%) found it significant,149(99.33%) expressed their opinion that P-drug concept improves understanding of various pharmacological aspects of the drug used and majority of them opined that exercise imparted skills required to select safe and effective drug welcome change in the routine curriculum and the concept being relevant to future practice. However 19(12.6%) students opined that allocated time that is two hours was not adequate, 28(18.6%)pressed for more exercise in selecting P-drug and 55(36.6%) students viewed that they were still not confident in selecting a P-drug which calls for developing more modules and use of Task based learning (TBL) which in continuation of problem based learning as one of their educational tool [22]. Lastly, in individual comments made by students worth mentioning were that the session made us realize what to know about drugs while reading from book, concept of P-drug makes subject of pharmacology interesting and should have been taught earlier, the concept integrates basic and clinical pharmacology, should be taught to every practitioner and faculty and selection of P-drug should be made in groups of 5 to 6 students so that they can learn to work in team and share knowledge in selecting right drug for given scenario.

Conclusion

The concept of P-drug for the undergraduate practical curriculum is a good instrument to promote the practice of rational therapeutics with the objective to promote use of cost effective, safe and suitable medicines as traditional teaching in pharmacology is characterized by passive transfer and memorizing of information about drug classes and individual compounds. However, the concept needs to be utilized in its right perspective so that it does not leave enough to question its utility. The inclusion of P-drug concept with clinical cases makes the topic more interesting, more understanding and valuable and also makes the future of upcoming physicians more responsible for a rational prescription which could be the reason that majority of students vouched strongly in teaching concept of P-drug and last but not least, institutional teaching review board should conduct regular teaching programs on P-drug among interns, resident and practicing doctors if the P-drug concept is to succeed.

Limitations

Study was based on student's perception which were taken just after few P-drug selection exercises as mentioned. Students feedback taken after many such exercises over whole of second year of the course might have given clearer picture of this method of teaching and assessment. Moreover introduction and use of task based learning (TBL) in groups was not done in current study.

Acknowledgement

Authors greatly acknowledge students of batch 2020 of GMC Srinagar who responded in the questionnaire.

Funding and Sponsorship

No funding sources.

Conflict of Interest

None declared.

Ethical Approval

Not needed as P-drug concept being part of practical curriculum and a core competency.

References

1. World Health Organization. The Role of Education in the Rational Use of Medicines. SEARO Technical Publication Series No. 45. October, 2006. WHO-SEARO; 2006. [Last accessed on 2015 Jul 09]. Available from: http://www.apps.who.int/medicinedocs/documents/s16792e/s16792e.pdf . [Google Scholar]
2. World Health Organization. The Rational Use of Drugs, Report on the Conference of Experts. Nairobi: WHO; 1985. [Google Scholar]
3. World Health Organization. Medicines: Rational use of medicines. Fact Sheet No. 338. WHO Media Centre: World Health Organization; 2010. [Google Scholar]
4. le Grand A, Hogerzeil HV, Haaijer-Ruskamp FM. Intervention research in rational use of drugs: A review. Health Policy Plan. 1999;14:89–102. [PubMed] [Google Scholar]
5. Soumerai S, Quick J, Avorn J, Tawfik Y. Changing the unchangeable: principles and experiences in improving prescribing accuracy. World Paediatrics and Child Care 1987;3:287-91.
6. Tichelaar J, Richir MC, Avis HJ, Scholten HJ, Antonini NF, De Vries Th PGM. Do medical students copy the drug treatment choices of their teachers or do they think for themselves? Eur J Clin Pharmacol 2010;66:407–12.
7. Hogerzeil HV. Promoting rational prescribing: an international perspective. Br J Clin Pharmac 1995; 39:1-6.
8. World Health Organization.Guide to Good Prescribing.Ganeva:WHO;1994.
9. Medhi B, Prakash A. Advance Pharmacology. 1st ed.Hyderabad: BS Publication;2014. p. 222-5.
10. Goodman LS, Gilman A. Goodman and Gilman. The Pharmacological Basis of Therapeutics. New York: McMillan Publications Co.; 1992. p. 8.
11. Parmar DM, Jadav SP. The concept of personal drugs in the undergraduate pharmacology practical curriculum. Indian J Pharmacol. 2007;39(3):165-167.
12. Joshi MP,Jayawickramarajah PJ.A problem oriented pharmacotheraphy package for undergraduate medical students.Med Teach.1996;18:75-76.
13. Nii LJ, Chin A. Comparative trial of problem-based learning versus didactic lectures on clerkship performance. Am. J. Pharm. Educ.1996;60:162-164.
14. Shivhare SC,Kunjwani HK,Manikrao AM,Bondre AV.Drug Hazards and Rational Use of Drugs:A Review.J.Chem.Pharma.Res .2010;2(1):106-12.
15. Patricio KP,Alves NA,Arenales NG,Queluz TT.Teaching the Rational Use of Medicines to medical students:A qualitative research.BMC Med Educ.2012;12:56.
16. World Health Organization. Factsheet: WHO Policy Perspectives on Medicines-Promoting rational use of medicines: Core components Geneva: WHO; 2002. Available from: htpp://www.who.int/entity/medicines/publications/policyperspectives/ppm05en.pdf. [Last cited on 2013 Dec 20].
17. World Health Organization: Selection and rational use of medicines. Fact sheet: N338, 2010. Available from: http://www.who.int/mediacentre/factsheets/fs338/en/. [Last cited on 2013 Dec 20].
18. Maxwell S, Walley T, Ferner RE. Using drugs safely. BMJ. 2002;324:930-1.
19. Khilani G. The concept of personal drugs in the undergraduate pharmacology practical Curriculum. Indian J Pharmacol 2008;40:131-32.
20. Hogerzeil HV, Barnes KI, Henning RH, Kocabasoglu YE, Moller H, Smith AJ, Summers RS, de Vries TPGM. Teachers' guide to good prescribing. Geneva:World Health Organization; 2001.
21. Shankar PR, Palaian S, Gyawali S, Mishra P, Mohan L. Personal Drug Selection: Problem-Based Learning in Pharmacology: Experience from a Medical School in Nepal. PLoS ONE [Internet] 2007 [cited 2010 Nov 7];2(6): e524: [about 5 p.]. Available from: doi:10.1371/journal.pone.0000524.
22. SharifahSulaiha SA, Nurjahan MI, Nagarajah Lee. Task-Based Learning: Student‟s perception of their skill in participating in small group discussions. IeJSME.2009;3(1):8-12.

Original Article

To study the doctor patient communication and patient satisfaction in postoperative patients: a questionnaire based study.

Sajad Hussain , Nowsheen , Aadil Majeed , Farooq A. Jan

Abstract

Background

Effective interpersonal communication between health care provider and patient is an important element for improving patient satisfaction, treatment compliance and health outcome.

Materials and methods

It was a descriptive type of cross sectional study The sample consisted of postoperative patients in the surgical wards of the hospital. A self structured questionnaire was prepared and administered to patients. Emergency care unit patients, patients undergoing surgery, debilitated patients, non-cooperative patients were excluded. Verbal consent from participants was also taken.

Results

A total of 150 patients participated in the study. The patients had already undergone surgery. The patients were taken from different surgical wards viz general surgery, CVTS, and plastic surgery. In the present study it was observed that 84.7% of patients were satisfied with way history was taken from them. However only 61.3% of patients said that that examination was done properly and privacy was maintained at that time. Informed consent was taken in 90.7% patients and diagnosis was explained completely in 96% cases.

Conclusion

Though satisfaction level in our study was good it can still be increased by improving doctor patient communication.

JK-Practitioner2022;27(4):65-67

Introduction

The goal for health care from the traditional hospital treatment to the modern emergency treatment primarily is to provide quality care. But the quality care is ascertained in many ways from different perspectives. Doctors may count it on the number of remissions or successful treatment. And for the patients, it may be probably, efficiency, promptness, equitable care, and positive interpersonal relationship with doctors. Often, satisfied patients felt that they have been listened to, treated kindly, and had positive interpersonal dynamics.

Effective interpersonal communication between health care provider and patient is an important element for improving patient satisfaction, treatment compliance and health outcome. Patients who understand the nature of their illness and its treatment and faith on the provider show greater satisfaction with the care received and more likely to comply with treatment regimens. Several studies conducted in developed countries show strong positive health outcomes and improved quality of care associated with effective communication [1].

Maintaining good technical as well as interpersonal skills is essential for the doctors to satisfy their patients [2]. In addition, the demonstration of professionalism and ethical practice are also required to meet the expectations of patients. [3]. Moreover, the success of technical procedures, treatment and medication depends upon favorable communication with patients.

There has been a shift in recent years in how doctors collect information about underlying disease processes [4]. The ultimate objective of any doctor-patient communication is to improve the patient's health and medical care; sometime doctors tend to overestimate their abilities in communication. Good communication means it should be patient-centered; satisfied patients are more likely to comply with treatment, keep follow up appointment and the utilize health services effectively. Approaches to measuring patient satisfaction can be direct or indirect. In the

Author Affiliations

Sajad Hussain , Resident Medical Officer,**Nowsheen ,** Senior Resident , **Farooq A. Jan** Professor ;
Department of Hospital Administration ,**Aadil Majeeds** Senior Resident b,Internal Medicine:
SKIMS ,Soura ,Srinagar ,Kashmir, J&K ,India.,

Correspondence

Dr Sajad Hussain
Resident Medical Officer
,Hospital Administration, SKIMS , Soura, Srinagar
E mail
drdrbhatsajad31@gmail.com

Indexed

EMBASE ,SCOPUS, IndMED ,ESBCO ,Google Scholar besides other national and International Databases

Cite This Article as

Hussain S , Nowsheen , Majeed A , Jan FA.To study the doctor patient communication and patient satisfaction in postoperative patients: a questionnaire based study. K Pract2022;27(4):65-67

Full length article available at **jkpractitioner.com** one month after publication

Keywords

patient satisfaction

field surveys sample the general population and patients from alternative health care delivery systems. The indirect method is cumbersome, but provides information for total quality management [5]. The direct approach is to ask the patients to evaluate their satisfaction with encounters in a particular health care facility or with specific providers in the form of interviews.

Materials & Methods

It was a descriptive type of cross sectional study carried out from jan 2020- feb 2020 in tertiary care teaching hospital, SKIMS Soura Srinagar. The sample consisted of postoperative patients in the surgical wards of the hospital. A total sample size of 150 patients was calculated using the formula n= Z2 (1-α/2) P(1-P) / d2 [6] where P was taken as 0.86 from previous studies [7]. The sampling method used was Systematic Random Sampling. Daily record of IPD admissions was obtained from the medical record department and every 11th patient from the list was included in the study after taking consent. Emergency care unit patients, patients undergoing surgery, debilitated patients, non-cooperative patients were excluded. Verbal consent from participants was also taken. A self structured questionnaire was prepared and administered to patients. The questionnaire was validated with a pilot study. Questionnaires were checked for completeness and data was entered in Microsoft excel. Descriptive statistics were used for analysis.

Results

A total of 150 patients participated in the study. The patients had already undergone surgery. The patients were taken from different surgical wards viz general surgery, CVTS, and plastic surgery. In our study 56.7% were males (table 1). As per residence 62% patients were from rural background(table 2). In our study 74.7% respondents were married and 64% were educated.(table 3 and 4)

Table 1. Gender distribution

Gender	Number
Male	85(56.7%)
Female	65(42.3%)

Table 2: Residence

Gender	Number
Rural	93(62%)
Urban	57(48%)

Table 3:Marital status

Gender	Number
Married	112(74.7%)
Unmarried	38(25.3%)

Table 4:Educational status

Gender	Number
Educated	96(64%)
Uneducated	54(36%)

In the present study it was observed that 84.7% of patients were satisfied with way history was taken from them. However only 61.3% of patients said that that examination was done properly and privacy was maintained at that time. Informed consent was taken in 90.7% patients and diagnosis was explained completely in 96% cases. Informed consent implies an understanding by the patient the nature of his condition, the nature of the proposed treatment or procedure, alternative procedures, risks and benefits involved in both the proposed and alternative procedure, potential risks of not receiving treatment, relative chances of success and failure of both procedures and all these disclosures must be in a language the patient (guardian in case of a minor or insane patient) can understand. Table 5 provides the study patients recorded responses.

Table 5: Responses of the study participants

S no	Response	Yes	No
1	Detailed history of the problem asked	127(84.7%)	23(12.3%)
2	Enough time for examination taken maintaining privacy	92(61.3%)	58(47.7)
3	Queries answered satisfactorily	108(72%)	42(28%)
4	Informed consent taken	136(90.7%)	14(9.3%)
5	Do's & don'ts of medications explained	89(59.3%)	61(40.7)
6	Investigations done & reports explained	132(88%)	18(12%)
7	Diagnosis explained completely	144(96%)	6(4%)s
8	Paramedical staff behavior was good	121(80.7%)	29(19.3%)
9	Availability of medicine in hospital	102(68%)	42(32%)

Discussion

Doctor-patient communication is of utmost importance, for the patient as well as for the doctor. The population of this area depends mainly on this hospital for health care needs. About 85% patients said that the doctor asked detailed history of their problem. However, 61.3% responded that the doctors did examination properly and maintained privacy during this. 72% responded that doctors explained the causes of their complaints satisfactorily. Informed consent was not taken in about 10% patients, whereas in a study conducted at the St. Joseph General Hospital, Canada it was just 14% [7]. In our study the satisfaction level was good around 80 to 90% A study conducted in the Kano Hospital by Iliyasu Z et al [8] showed that 86.9% patients were satisfied with the services provided at that hospital. Similar findings were also seen with the St. Joseph Hospital, Canada where 92.5% patients were satisfied.

Conclusion

Though satisfaction level in our study was good it can still be increased by improving doctor patient communication. Doctor patient communication appears to be the most important component of patient satisfaction.

References

1. Sharma Sushil Kumar. 2012. Communication Skills for Social and Health Care. Manglam Publishers. Pp.29
2. Abioye Kuteyi EA, Bello IS, Olaleye TM, Ayeni IO, Amedi MI. Determinants of patient satisfaction with physician interaction: a cross-sectional survey at the Obafemi Awolowo University Health Center, Ille-lfe, Nigeria. SA Fam Pract. 2010;52(6):557–62.
3. Chen JY, Tao ML, Tisnado D, Malin J, Ko C, Timmer M, Adams JL, Ganz PA, Kahn KL. Impact of physician- patient discussions on patient satisfaction. Med Care. 2008;46:1157–62.
4. Feinstein AR. Science, Clinical Medicine, and the spectrum of disease. In: Besson PB, McDermott W, editors. Textbook of Medicine. Philadelphia: Saunders; 1975. pp. 4–6.
5. Banerjee A, Sanyal D. Doctor–patient relationship: A cross-sectional study on concordance, trust, and patient enablement. J Family Community Med. 2012 Jan-Apr; 19(1): 12–19.
6. Lawanga SK, Lemeshow S. Sample size determination in health studies: A practical manual. Geneva: WHO; 1991
7. Iliyasu Z, Abubakar IS, Lawan UM, Gajida AU. Patients satisfaction with services obtain from Aminu Kano teaching hospital, Kano, Northern Nigeria. Nigerian Journal of Clinical Practice. Dec. 2010 Vol. 13(4):371-78
8. Hukezalie M, Ekomiak T. A study on patient satisfaction: St. Joseph g

Original Article

Awareness of bio-medical waste management among different cadres of dental healthcare workers: An Institution Based Study

Faisal Arshad ,Parveen Akhtar Lone ,Mohan Singh

Abstract

Introduction

Waste generated from hospitals is bio hazardous, highly infectious & toxic. Indiscriminate disposal of hospital waste possesses health risk to human & animal population because of the high potential of disease transmission through unregulated waste pose a dangerous threat not only to human health safety but also to environment for current & future generations, so it is of utmost importance to handle biomedical waste in environmentally sound manner. The aim of this study was to assess the knowledge, practices & attitude of biomedical waste management in dental health care workers so that regular training programs may be provided for proper handling of biomedical waste generated in dental health Institution.

Material &Methods

This cross-sectional study was conducted amongst dental health care workers (DHCWs) on volunteer basis. Study was conducted in 70 volunteers including doctors, paramedical /nursing staff, junior residents, post graduate and undergraduate students. Survey was conducted using a predesigned questionnaire about the basic knowledge, segregation of waste at source, color coding & injury reporting. The hard copy of the questionnaires were collected and the correct answers were tabulated on the excel sheet and sent for statistical analysis.

Results

ANOVA and unpaired t-test were done. Percentage wise data was derived. Doctors had highest knowledge about the biomedical waste management followed by paramedical staff/nurses, junior residents, post graduate and undergraduate students. The knowledge about needle stick injury was found to be less in all the cadres.

Conclusion

The knowledge about the biomedical waste management was found more in faculty/Doctors followed by paramedics/nursing staff and post graduate and undergraduate students.The importance of biomedical waste management training needs to be imparted at all levels amongst dental care providers, because lack of knowledge impacts the practices of appropriate waste disposal.

JK-Practitioner2022;27(4):68-73

Introduction

Biomedical waste is any solid, liquid & fluid including its containers, sharps & laboratory waste generated during diagnosis, treatment & research on humans or animals, or testing of biologic waste or immunization [1,2] of the hospital waste 75-80% is general waste,15% pathologic & infective waste 3% chemical & pharmaceutical waste & 1% radioactive & cytotoxic waste[3]. Segregation of biomedical waste rules were given by Government of India,[4] Ministry of Environment, Forest and Climate Change in 2016 which prescribed simple categories (color coded) for segregation of different BMWs, an amendment in 2018 also came into force with the aim to improve the compliance to the rules [2].

The World Health Organization describes the healthcare waste as discarded, untreated materials from healthcare activities, which have the potential of transmitting infectious agents to humans [1] .Biomedical waste management (BMWM) is an integral part of infection control program and if mismanaged medical waste can contaminate entire environment of hospital & all individuals exposed to

Author Affiliations

Faisal Arshad

Registrar,Department of Orthodontics;**Parveen Akhtar Lone ,** Professor and Head ,Department of Oral & Maxillofacial Surgery**;Mohan Singh ,**Ex.Medical Superintendent:

Indira Gandhi Government Dental College and Hospital, Jammu. J&K ,India.

Correspondence

Dr.Parveen Akhtar Lone

Prof & HOD, Department Of Oral & Maxillofacial Surgery, Indira Gandhi Government Dental College and Hospital, Jammu.

Corresponding author:parveen.lone@yahoo.com

Indexed

EMBASE ,SCOPUS, IndMED ,ESBCO ,Google Scholar besides other national and International Databases

Cite This Article as

Arshad F, Lone PA, Singh M. Awareness of bio-medical waste management among different cadres of dental healthcare workers: an institution based study

JK Pract2022;27(4):68-73

Full length article available at **jkpractitioner.com** one month after publication

Keywords

Biomedical waste management (BMWM), Dental Health Care workers (DHCWs),

BMW are potentially at risk of being injured or infected [5].

Dentistry like other medical field contributes large amount of environmentally unfriendly waste which have significant environmental impact. Dentistry deals with diagnosis prevention & treatment (surgical,non-surgical & other procedures) of diseases ,disorders/conditions of oral cavity ,maxillofacial areas & adjacent & associated structures [6]. Dental treatment require a variety of materials & equipment, thereby generating large amount of waste like dental amalgam, lead, silver, waxes, gypsum, gloves, syringes, sharps like wires, blades, reamers files infectious waste like extracted teeth, cotton & gauge soaked with blood & saliva etc that has detrimental effect on environment & may be hazardous to human life [7].

This questionnaire study used three determinants to assess the effective management of bio medical waste which were Knowledge, practices & attitude. knowledge is defined as awareness regarding biomedical waste management. Attitude is defined as their feelings & practice is defined as the identification, segregation &packaging of biomedical waste [8] Right attitude, proper knowledge practice of safety measures can ensure safe disposal of these wastes. However, in developing countries BMW management has not received sufficient attention, hence BMW management is still a challenge to the hospitals [9].

Material & Methods

This cross-sectional study was conducted amongst dental health care providers working at Indira Gandhi Government dental college and hospital, Jammu. Permissions were obtained to conduct the study. The sample size was calculated to be (n=70) for a power of 90%. The sample included faculty/doctors, Post graduate students, paramedics/nursing staff/ Junior residents/ Undergraduate students of Indira Gandhi Government Dental College and Hospital, Jammu.. Sample from all the strata was taken to know the awareness about the biomedical waste management.

A pre designed questionnaire (Fig 1) from National Pollution Board containing 32 questions was distributed among faculty/ doctors, paramedics, junior resident, post graduate and undergraduate students. Each question was having options. Each correct answer was carrying one mark. The questionnaires were distributed among all the above mentioned strata working in a dental institution. The questions were pertaining to the basic knowledge, level of awareness on biomedical waste management practice, attitude and behaviour assessment towards biomedical waste, level of knowledge about the needle stick injury.

The questionnaires were distributed as hard copies among all the participants and 10 minutes was the designated time to fill the questionnaire which were then collected back. All the filled up -questionnaires were collected and evaluated. The data for correct answer of each question was tabulated in the excel sheets and sent for statistical analysis.

Results

The data was subjected to various statistical tests which include ANOVA, unpaired t-test. Table 1 reveals the Percentage wise results were derived for the correct response of each question and p- value was considered significant at p= .005.

The results revealed the percentages of correct responses given by the Faculty/doctors, paramedic/ nursing staff, post graduate students, Junior residents, Undergraduate students.

1.**The level of Basic knowledge** regarding the biomedical waste was seen in descending order as follows: Faculty/ Doctors> paramedics/nursing staff> Junior Residents > Post graduate students> Under graduate students.

2.**The level of awareness** regarding the biomedical waste was seen in descending order as follows: Faculty/ doctors> paramedics>Junior residents>post graduate students> Under graduate students.

3.**Attitude/ Behavior assessment towards biomedical waste** in descending order as follows: Faculty /doctor>paramedics> Junior residents>post graduates>Under graduates

4.**Knowledge about needle stick injury** in descending order as follows: Faculty /Doctors> Paramedics> Junior residents> Post graduates> Undergraduate student

The overall statistical significance was found in the following order: Basic Knowledge > Level of awareness> Behavior/attitude assessment towards biomedical waste management>knowledge about needle stick injury

Most of the correct responses regarding the level of basic knowledge, awareness, attitude/Behaviour, knowledge about needle stick injury was given by the faculty/ doctors followed by paramedics, junior residents and then post graduate and undergraduate students.

The overall basic knowledge, level of awareness was more among all the participants as compared to the behavior, practice and knowledge about needle stick injury.

Discussion

The health threat for public life has been reported worldwide due to improper biomedical waste management, not only this, it is also a grave threat to environment for current as well as future generation [9-10]. At global level 18-54% of HCFs have un satisfactory BMWM facilities; predictors include lack of awareness, insufficient resources &

A QUESTIONARE STUDY ON AWARENESS OF BIOMEDICAL WASTE MANAGEMENT AMONG DIFFERENT CADERS OF DENTAL HEALTHCARE WORKERS-AN INSTITUTION BASED STUDY

Name : **Age :** **Sex:** **Designation :**

(Tick any one response according to your knowledge & understanding of Biomedical Waste Management for each Question)

1. Who regulates the safe transport of medical waste ?

a) J&K State Pollution Control Board

b) Transport Corporation of India (c) Collage Administration

2. Do you need a spate permit to transport biomedical waste?

(a) Yes (b) No (c) Cannot say

Section 2 : Level of awareness on biomedical waste management practice .

3. Do you know about color coding segregation of BM waste ? *(a) Yes (b) No (c) Not Sure*

4. Do you follow color coding segregation of BM waste ?

(a) Yes (b) No (c) Sometimes

5. Is waste disposal practice correct in your hospital ?

(a) Yes (b) No (c) Cannot Comment

6 . Objects that may be capable of causing or cuts , that may have been exposed to blood or body fluids including scalpels , needles , are considered biomedical waste. How should these objects be disposed of ?

a) Black Bags (b) Yellow Bags (c) Clear Bags (d) White Bags

7. Objects like glass , ampoules , test tubes and slides are BM waste . How should these objects be disposed ?

(a) Cardboard Box with blue marking (b) Black (c) White (Translucent) (d) do not know

8. Cytotoxic waste is placed in which container/ Bag

(a) Yellow (b) Black (c)Red (d) do not know

9. The approximate proportion of infectious waste among total waste generated from health care facility is :

(a) 10 –20 % (b) 30 – 40 % (c) 50 – 60 %(d) 60 – 90 %

10. The color code for disposal of normal waste from the hospital is ?

(a) Yellow (b) Black (c) Red (d) Blue

11. All the following steps should be followed after an exposure with infected blood/ body fluid and contaminated sharps EXPERT : ( )

(a) Exposed parts to be washed with soap and water
(b) Pricked fingers should be kept in antiseptic lotion
(c) Splashes to eyes should be irrigated with sterile irritants
(d) Splashes to skin to be flushed with H2o

12 . All the following statements about hazardous waste containers are true, except for :

(a) Containers must be closed except when removing or adding waste
(b) Containers must be clean from outside
(c) contents must be compatible with the type of waste containers
(d) Any type of container, including food containers, can be used to contain the hazardous waste

Section 3 : Attitude / Behavior assessment towards biomedical waste.

13. Safe management of health care waste is not an issue at all.

(a) Agree (b) Disagree (c) Cannot Comment

14. Waste management of health care is not an issue at all.

(a) Agree (b) Disagree (c) Cannot Comment

15. Safe management efforts by the hospital increase the financial burden on management.

(a) Agree (b) Disagree (c) Cannot Comment

16. Safe management of health care waste is an extra burden on work :

(a) Agree (b) Disagree (c) Cannot Comment

17. Do you think that separate classes or a continuing education programme to upgrade existing knowledge about biomedical waste management is necessary ?

(a) Yes (b) No (c)Cannot Comment

18 . Will you like to attend voluntarily programmes that enhance and upgrade your knowledge about biomedical waste management ?

(a) Agree (b) Disagree (c) Cannot Comment

19 . Waste to be incinerated should be treated & chlorinated disinfectant .

(a) Agree (b) Disagree (c) Cannot Comment

20. Do you think an effluent treatment plant for disinfection of infected water should be set up in hospital?

(a) Agree (b) Disagree (c) Cannot Comment

21. Do you think it is important to report to the pollution Control Board about particular institution , If it is not complying with the guidelines for biomedical waste management ?

(a) Agree (b) Disagree (c) Cannot Comment

22. Do you think that labeling the container before filling it with waste is any clinical significance ?

(a) Yes (b) No (c) Cannot Comment

Section 4 : Level of knowledge among nurses , doctor's attendants , lab technician on needle – stick injuries ?

23 . Is needle stick injury a concern ?

(a) Yes (b) No (c)Do not know

24 . Do you re – cap the used needles ?

(a) Yes (b) No (c) Do not bother

25 . Do you discard the used needle immediately ?

(a) Yes (b) No (c) Have not noticed

26 . Are you aware of consequences of needle–stick injury ?

(a) Yes (b) No (c)Not connected

27 . Have you sustained a needle – stick injury during the last 12 months ?

(a) Yes (b) No (c)Do not remember

28. If Yes , how many injuries ( )

29 . How did the most recent incident happen ?

(a) Poor , disposal of needle
(b) Individual carelessness / accident (c) Cannot remember

30 . To whom did you report the injury ?

a) Line manager (b) Occupational health
c) Infection control (d) Nobody / other

31 . Did you fill in an incident report ?

(a) Yes (b) No (c) Cannot Remember

32 .Have you been fully inoculated against hepatitis B ?

(a) Yes (b) No (c) Not Sure

Fig 1:Pre designed questionnaire

Table 1: correct response of the participants regarding the biomedical waste management : basic knowledge, level of awareness, attitude / behavior assessment towards biomedical waste, knowledge about needle stick injury.

CORRECT RESPONSE	POST GRADUATE STUDENTS (n=10)	JUNIOR RESIDENTS (n=10)	PARAMEDICS/NURSING STAFF (n=20)	UG STUDENTS (n=15)	FACULTY / DOCTORS (n=15)	p-Value
BASIC KNOWLEDGE						
QUESTION 1	5(50%)	7(70%)	18(90%)	7(46.7%)	14(93.3%)	0.007**
QUESTION 2	6(60%)	6(60%)	14(70%)	6(40%)	12(80%)	0.218
LEVEL OF AWARENESS						
QUESTION 3	5(50%)	7(70%)	18(90%)	6(40%)	10(66.7%)	0.028*
QUESTION 4	3(30%)	7(70%)	19(95%)	7(46.7%)	13(86.7%)	<0.001**
QUESTION 5	3(30%)	4(40%)	13(65%)	4(26.7%)	11(73.3%)	0.036*
QUESTION 6	2(20%)	6(60%)	12(60%)	3(20%)	13(86.7%)	<0.001**
QUESTION 7	4(40%)	6(60%)	16(80%)	4(26.7%)	9(60%)	0.023*
QUESTION 8	2(20%)	4(40%)	9(45%)	3(20%)	8(53.3%)	0.257
QUESTION 9	4(40%)	3(30%)	8(40%)	1(6.7%)	10(66.7%)	0.013*
QUESTION 10	2(20%)	6(60%)	13(65%)	4(26.7%)	13(86.7%)	<0.001**
QUESTION 11	0(0%)	2(20%)	3(15%)	2(13.3%)	12(80%)	<0.001**
QUESTION 12	1(10%)	1(10%)	16(80%)	9(60%)	13(86.7%)	<0.001**
ATTITUDE/BEHAVIOR ASSESSMENT TOWARDS BIOMEDICAL WASTE						
QUESTION 13	1(10%)	6(60%)	14(70%)	6(40%)	11(73.3%)	0.008**
QUESTION 14	2(20%)	7(70%)	13(65%)	7(46.7%)	13(86.7%)	0.011*
QUESTION 15	1(10%)	4(40%)	7(35%)	4(26.7%)	14(93.3%)	<0.001**
QUESTION 16	4(40%)	5(50%)	12(60%)	3(20%)	13(86.7%)	0.004**
QUESTION 17	5(50%)	7(70%)	17(85%)	7(46.7%)	11(73.3%)	0.120
QUESTION 18	5(50%)	7(70%)	18(90%)	6(40%)	12(80%)	0.012*
QUESTION 19	4(40%)	6(60%)	12(60%)	6(40%)	11(73.3%)	0.352
QUESTION 20	5(50%)	7(70%)	17(85%)	7(46.7%)	14(93.3%)	0.013*
QUESTION 21	5(50%)	7(70%)	17(85%)	7(46.7%)	9(60%)	0.126
QUESTION 22	5(50%)	7(70%)	16(80%)	6(40%)	10(66.7%)	0.139

KNOWLEDGE ABOUT NEEDLE STICK INJURY						
QUESTION 23	5(50%)	7(70%)	16(80%)	7(46.7%)	10(66.7%)	0.265
QUESTION 24	5(50%)	7(70%)	15(75%)	7(46.7%)	11(73.3%)	0.353
QUESTION 25	5(50%)	6(60%)	16(80%)	6(40%)	12(80%)	0.072*
QUESTION 26	5(50%)	7(70%)	18(90%)	6(40%)	10(66.7%)	0.022*
QUESTION 27	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	1.000
QUESTION 28	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	1.000
QUESTION 29	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	1.000
QUESTION 30	1(10%)	3(30%)	8(40%)	1(6.7%)	14(93.3%)	<0.001**
QUESTION 31	1(10%)	2(20%)	8(40%)	3(20%)	9(60%)	0.055*
QUESTION 32	6(60%)	2(20%)	2(10%)	3(20%)	12(80%)	<0.001**

poor disposal mechanisms. In south Asian countries 56% of facilities lack adequate waste disposal treatment [11].

In the present study, the biomedical waste management rules among doctors, paramedical and nursing staff was comparatively good and similar to findings from other studies [12,13] in contrast to the study done by Ismail et al. that proved, knowledge and understanding regarding BMWM was insufficient among all the groups and 90% doctors were unapprised about the rules of BMWM [14].

Although Knowledge about waste segregation & colour coding of containers was found very low but slightly better among doctors than paramedic and nursing staff as well as students suggestive of need for training among both technically & non technically qualified staff is critical for proper management of bio medical waste

Bhagawati G et al [15] in their studies reported only 37% staff suffered by needle stick injuries & low reporting was attributed to the fact that most of technical & non-technical staff was unaware about reporting injuries. similarly, the practice of reporting injuries from improperly managed biomedical waste was found almost nil amongst technical, non-technical & sanitary staff

In the present study, overall awareness regarding the biomedical waste management practices was high among dental health care workers (DHCWs) but faculty/doctors depicted better results. These results are in accordance with Nirupama et al. and Soyam et al., who concluded that more than half of the HCWs knew correctly about BMWM rule [16,17].

The present study reported majority of participants had unsatisfactory knowledge, attitude & practice about proper biomedical waste management reason may be due to change in colour coding bins from time to time which is similar to studies by Arora et al. [18].

Sanitary staff, doctors, students, paramedical staff including nurses are groups involved in BMWM & play a major role in ensuring a safe hospital environment & should be involved in CMEs & Training programmes

The limitation of the above study was a very long and exhaustive questionnaire. Several short studies on various aspects like segregation of the biomedical waste management should be carried out on regular intervals.

Conclusion

This study concluded that training programmes, workshops on biomedical waste management with full participation of all cadres of health workers and awareness about the management and risks associated with biomedical waste management through distribution of pamphlets ,booklets, putting posters at critical places where bins are kept should be done more frequently. This study recommends the strict implementation of biomedical waste management rules and keeping all the caders updated with the latest biomedical waste management.

References

1. National guidelines on hospital waste management based up on the bio-medical waste management and handling rules, 1998. Government of India, Ministry of Health and Family Welfare. New Delhi.
2. Rahman S, Acık Y, Gülbayrak C, Erhan D,

Nazlıer K, Deveci E: Methods of collecting, storing and disposal of medical wastes in healthcare institutions. (Sağlık Kuruluşlarının Tıbbi Atıkları Toplama, Depolama ve Bertaraf Etme Yöntemleri). Firat Saglik Hizmetleri Dergisi 2009, 4(11):3–14.
3. Ege H: Management of medical wastes in province of Adana; Problems and solution offers.(Adana İli Tıbbi Atık Yönetimi; Sorunlar ve Çözüm Önerileri), Master Thesis. Adana, Turkey: University of Cukurova, Institute of Science, Department of Environmental Engineering publication; 2009.
4. Radha R. Assessment of existing KAP regarding biomedical waste management among health care workers in tertiary care rural hospital. Int J Health Sci Res 2012;2:14-9.
5. Available from American Dental Associations. http://www.ada.org/prof/ed/specialities/definitions.asp.
6. B.T. Nandish, Kamalakanth Shenoy, Ravi Shankar K.S. Recycling of Materials used in Dentistry with Reference to its Economical and Environmental Aspects. International Journal of Health and Rehabilitation Sciences, 2013, Vol. 2, No. 3, P140–145.
7. Park K. Hospital waste management. In Park's textbook of preventive and social medicine. 22nd ed. Jabalpur: M/S Banarasid as Bhanot publishers;2009.p.694-9.
8. Silva CE, Hoppe AE. Ravanello MM, Mello N. Medical waste management in the south of Brazil.Waste Manag 2005;25:600-5.
9. Chartier Y, Emmanuel J, Pieper U, Prüss A, Rushbrook P, Stringer R, et al., editors. Safe Management of Wastes from Health-Care Activities. 2nd ed. Geneva, Switzerland: WHO Blue Book; 2014
10. World Health Organization (WHO). Wastes from Health-Care Activities. Factsheet No. 253; November, 2011. Available from: http://www.who. int/mediacentre/factsheets/fs253/en.
11. WHO. Review of health impacts from microbiological hazards in health-care wastes.Geneva: World Health Organization; 2004.
12. Saini S, Nagarajan SS, Sarma RK. Knowledge; Attitude and Practices of Bio-Medical Waste Management Amongst Staff of a Tertiary Level Hospital in India. J Acad Hosp Adm 2005;17:2
13. Rao PH. Report: Hospital waste management--awareness and practices: A study of three states in India. Waste Manage Res 2008;26:297-30
14. Ismail IM, Kulkarni AG, Kamble SV, et al. Knowledge, attitude and practice about bio-medical waste management among personnel of a tertiary healthcare institute in Dakshina Kannada, Karnataka. Al Ameen J Med Sci 2013;6(4):376–380
15. Bhagawati G, Nandwani S, Singhal S. Awareness and practices regarding bio-medical waste management among health care workers in a tertiary care hospital in Delhi. Indian J Med Microbiol 2015;33:580-2
16. Nirupama N, Shafee M, Jogdand GS, et al. Knowledge, attitude & practices regarding biomedical waste management. Indian J Community Med 2010;35(2):369–370. DOI: 10.4103/0970-0218.66871
17. Soyam GC, Hiwarkar PA, Kawalkar UG, et al. KAP study of bio-medical waste management among healthcare workers in Delhi. Int J Community Med Public Health 2017;4(9):3332–3337.
18. Arora L, Agarwal S. Knowledge, attitude and practice regarding waste management in selected hospital students of university of Rajasthan, Jaipur. Int J Chem Environ Pharm Res 2011; 2:40-3

Original Article

Changing Trends in Covid-19 Positivity in Kolkata: A Study Based on Rapid Antigen Testing in a Teaching Hospital.

Raj HJ, Paul D , Hazra A , Ray R

Abstract:

Background

Real time polymerase chain reaction (RT-PCR) is considered as the gold standard investigation for diagnosing Covid-19. However, it is resource intensive and time consuming. Rapid antigen test (RAT) done on similarly collected swab samples has emerged as an alternative testing strategy with the advantages of requiring less resources and offering quick results. We have analysed the trends of RAT results in our centre which is a nodal centre for Covid-19 diagnosis in our state.

Methods

Symptomatic and asymptomatic individuals attending the fever clinic of our teaching hospital from July 2020 to February 2022 were subjected to RAT following the guidelines recommended by the Indian Council of Medical Research (ICMR). Nasopharyngeal swab samples were collected by trained operators and ICMR approved immune-chromatography based rapid test kits were used.

Results

Total 45018 samples were collected and tested from July 2020 to February 2022; consisting of 25178 samples (55.93%) from male and 19840 (44.07%) from female subjects. Of them, 1802 (4.0%) were RAT positive for Covid-19. Positivity in males was higher than in females (4.03% versus 3.97%, $p = 0.752$). Proportion of positive results among people of age ≥ 60 years was lower than in those < 60 years (4.98 % versus 3.82%, $p < 0.001$). Highest number of positive cases was noted in April, 2021 followed by October, July and August of 2020. February, 2021 recorded the lowest number of positive cases. Again, a shooting rise of positivity was noted in January 2022 followed by steep fall. Three waves can be distinguished with a statistically significant difference in peak positivity.

Conclusion

The study has revealed the trend of infection in mild to moderate and suspected but asymptomatic cases. RAT has been established as a convenient strategy for tracking the trend of infection. Results based on RAT testing can help in planning for local containment strategies and in preparation for any potential resurgence of infection.

JK-Practitioner2022;27(4):74-79

Introduction

The Asian continent started experiencing a new epidemic of respiratory tract infection (RTI) from the dying moments of 2019 that has been linked to a novel corona virus (CoV) originating from Wuhan, Hubei province, China, christened as Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). Within a couple of months, the disease started spreading across countries and continents, forcing the World Health Organization (WHO) to declare this infectious disease, Coronavirus disease 2019 (Covid-19), as a global pandemic on March 11, 2020.[1,2] As of date, none of us have experienced a pandemic on such a scale since the 'Spanish flu' that ravaged the world a century ago.

According to phylogenetic analysis, this novel virus belongs to genus beta-coronavirus, in subfamily Coronavirinae and family Coronaviridae,.[3] The different Coronaviruses (CoV) exhibit 54% sequence identity of the whole RNA, 58% identity for the non-structural proteins coding region and 43% identity for the structural

Author Affiliations

Raj HJ,Associate Professor , **Paul D,**Assistant Professor, **Ray R ,** Professor and Head :
Department of Microbiology**,**
Hazra A' Professor ,Department of Pharmacology:
Institute of Post Graduate Medical Education and Research ,Kolkata,West Bengal ,India.

Correspondence

Dr.Raja Ray
Professor and Head ,
Department of Microbiology,
Institute of Post Graduate Medical Education and Research ,Kolkata,West Bengal ,India.
E mail rjrm175@gmail.com
9433323454

Indexed

EMBASE ,SCOPUS, IndMED ,ESBCO ,Google Scholar besides other national and International Databases

Cite This Article as

Raj HJ, Paul D , Hazra A , Ray R
..
Changing Trends in Covid-19 Positivity in Kolkata: JK Pract2022;27(4):74-79

Full length article available at **jkpractitioner.com** one month after publication

Keywords

Covid-19, rapid antigen test, polymerase chain reaction

protein coding region.[3] Sequence analysis shows that the new CoV incorporates the typical genome structure of CoV and belongs to the cluster of beta-CoV that includes bat-SARS-like (SL)-ZC45, bat-SL ZXC21, SARS-CoV and Middle East respiratory syndrome coronavirus (MERS-CoV)[3].The virus spreads rapidly owing to its predominantly respiratory mode of transmission (droplet borne and possibly airborne too in some settings) and susceptible naïve population[4]. For diagnosis, SARS-CoV-2 genomic RNA is detected from upper and lower respiratory tract samples (e.g. nasopharyngeal swab, throat swab, nasal swab, bronchoalveolar lavage (BAL) fluid, endotracheal aspirate (ETA) etc.) by Real Time Reverse Transcriptase Polymerase Chain Reaction (rRT-PCR) method analysis[5].

The rapidity with which the pandemic has spread has led to a global crisis in laboratory organization, trained manpower and flow of logistics. This is more perceivable in developing countries like ours with the established health infrastructure and resources proving to be inadequate to manage a crisis on this scale. India has nearly reached the grim milestone of 20 million confirmed cases of Covid-19[6].Between May to Oct, 2020, India experienced the first wave of Covid-19. The active caseload waned from Nov, 2020, onwards reaching a nadir in Feb, 2021. However, from Mar, 2021, a more intense second wave hit the country, rising sharply to overwhelm our health infrastructure and leading to a crisis in trained heath manpower, hospital beds, life-saving drugs, medical oxygen, intensive care unit (ICU) facilities, ventilators and so forth. Unlike in the first wave, the disease spread to smaller cities and towns and even to remote villages in the second wave and the majority of districts in the country attained Covid-19 test positivity rates in excess of 10%. Fortunately, from early Jun, 2021, the second wave seems to be ebbing.

The rRT-PCR test is currently regarded as the gold standard for diagnosis of Covid-19. It is a sophisticated molecular test requiring biosafety level 2 (BSL-2) scale laboratory infrastructures, trained molecular technologists and microbiologists for processing of samples and interpretation of results of qualitative molecular detection of COVID-19. The test takes minimum 8-12 hours' time – from collection of swab samples and generation of test report – considering sample transit time. Higher sample load invariably increases the turnaround time of reporting. This inherent delay in reporting has a negative impact on rapid decision making regarding isolation of patients, quarantine of contacts and admission to health facilities when the clinical condition of the patient starts deteriorating. This is all the more true for areas that have suboptimal resources, logistics and transport facilities. All these can lead to further transmission of infection in the vicinity that could potentially have been prevented. Therefore, the need of the hour is wider screening and rapid detection of infection. Positive cases can be quickly isolated at home or in safe homes, asymptomatic contacts can be screened rapidly, quick triage undertaken for patients with severe acute respiratory illness (SARI) presenting to emergency departments, and deserving patients admitted to ward or ICU set-ups. Many developers and manufacturers have developed rapid antigen testing (RAT) kits and devices making wider rapid screening and point-of-care testing for Covid-19 feasible. These kits are based on SARS-CoV-2 antigens from respiratory samples. Shortly after their arrival, competent central and state government authorities have approved the use of pre-standardized immunochromatographic rapid testing kits in India. The present study is based on the rapid testing of symptomatic and asymptomatic visitors of fever clinics.

Material and methods

We conducted a record based study in a tertiary care referral and teaching hospital in Kolkata city, West Bengal, which has served as one of the nodal centers for Covid-19 testing in the state. Institutional ethics committee approval was obtained beforehand. The approval granted waiver of the written informed consent requirement considering the study's record based nature.

The study was conducted between July, 2020 to February 2022 with patients visiting the outpatient department (OPD) fever clinic of the hospital whose samples were sent to the Department of Microbiology for testing. All adult (> 18 years age) patients, with suspicion of COVID-19, attending the fever clinic of the hospital, were included in the study, following the Indian Council of Medical Research (ICMR) strategy for COVID-19 testing[7].Two types of patients were included; firstly, those having respiratory and extra-respiratory symptoms of COVID-19 with or without fever; secondly, those who were asymptomatic but in contact with laboratory confirmed cases of COVID-19 were tested between 5 to 10 days following exposure. A sample referral form was duly filled up by the referring clinician, declaring the chief symptomatology and/or the rationale of testing for the patient concerned and salient relevant history (travel, exposure, household cases) of the patient. Following the ICMR strategy[18] RAT positive cases were declared positive, and details uploaded in the ICMR portal. Symptomatic cases showing negative results on RAT were further tested by rRT-PCR in the microbiology department. The ICMR strategy is outlined in Figure 1.

Test kits

Following kits approved by ICMR were used for RAT[9].Kits were supplied by state health authority:

- The Standard Q rapid antigen detection test (SD Biosensor, Inc., Gurugram)
- ANGCARD Covid-19 Antigen Test kit (Angstrom Biotech Pvt. Ltd., Alwar, Rajasthan)

- OSKIT RAT kit (Oscar Medicare Pvt. Ltd., New Delhi)

All three kits are based on the principle of immune-chromatography with lateral flow assay. The method uses monoclonal antibodies conjugated to colloidal gold and another monoclonal antibody immobilized on a nitrocellulose membrane. As the test sample flows through the nitrocellulose membrane it mixes with gold conjugated antibodies. If the sample contains corona virus antigen, the colloidal gold-antibody conjugate binds to the antigen, forming an antigen-antibody-colloidal gold complex. The whole complex then migrates through the nitrocellulose strip by capillary action. When the complex meets the immobilized antibody at Test or 'T' line the complex is trapped forming an antibody-antigen-antibody-colloidal gold complex that takes a pink/purple hue. This colored band indicates positivity of the sample for coronavirus antigen. To serve as a procedural control, an additional line of anti-rabbit IgG antibody has been immobilized on the strip at Control or 'C' line. If the test is valid or the test is performed correctly, it should give a pink/purple band on contact with the conjugate at the 'C' line region also.

Test procedure:

The test was conducted on nasopharyngeal swabs collected by trained sample collectors. Samples were taken from both sides of the nasopharynx using a swab provided with the manufactures' kit to maximize the viral load. Before collection of samples, the patients were instructed to clean the nose to remove excessive secretion. The sterile swab was then inserted into the nasal cavity at an angle of 90° in a 50-70° extended neck position to swab the surface of the posterior nasopharynx. The swab was kept in the nasopharynx for 5-10 seconds to properly absorb secretions and then gently removed in a rotatory motion. The swab was then placed into the small tube containing the extraction buffer provided with the kit and either stirred into the buffer for 4-5 times (SD Biosensor, Inc., Gurugram) or stirred while squeezing the buffer tube, more than ten times swiftly (OSKIT RAT kit) or stirred into the buffer for more than 4-5 times as per instructions provided by the manufacturer. Lastly the swab was squeezed against the tube wall, withdrawn and discarded in the appropriate bin or box following biomedical waste disposal rules. A nozzle was placed tightly onto this extraction buffer tube. While testing, three or four drops of the extracted specimen were put onto the specimen well of the test card or cassette and was set aside.

Interpretation of test results

The test results were interpreted after 15-30 minutes (for OSKIT and SD Biosensor) or after 20-25 minutes (for ANGCARD test kit). If the test card developed pink/purple bands at both 'T' (Test) and 'C' (Control) sites, the result was taken as positive. Line against only 'C' was considered as negative. A line at 'T' without a line at 'C' region was deemed invalid test.

Statistical considerations

Statistical analysis has been done by GraphPad prism version 5.0 (GraphPad software, Inc., 2007) software. Independent proportions have been compared by Fisher's exact test or Chi-square test as appropriate. Odds ratios (OR) and 95% confidence intervals (CI) have been presented where deemed relevant.

Result

Total 45,018 samples were collected and tested between July, 2020 to February 2022; that consisted of 25178 samples (55.93%) from male and 19840 (44.07%) from female patients. Age wise, 7171 (15.93%) samples were from geriatric population (age ≥ 60 years) and rest 37847 (84.07%) were from < 60 years age group.

Overall, among the samples tested 1802 (4 %) were RAT positive for Covid-19. Positivity in male subjects (1015; 4.03%) was higher than that of females (787; 3.97%) as shown in Table 1 . However, this difference was statistically not significant (p = 0.752). The odds ratio for risk of positivity in males, as compared to females, was 1.017 (95% CI 0.925 to 1.118).

As shown in Table 2, positivity proportion among the geriatric population was 4.98% (n= 357), and that for < 60 years age group was 3.82% (n= 1445). This difference was statistically significant (p < 0.001). The odds ratio for risk of positivity in older age group, as compared to their younger counterparts, was 1.320 (95% CI 1.172 to 1.486).

Table 3 depict the month wise testing of samples for RAT and the positivity rate thereof. They clearly indicate the changing pattern with time and season, with the first peak being in Oct, 2020 and a second sharper peak in April, 2021; whereas the third peak came on January 2022.

Positivity rate during the peak period of the first wave (August to October 2020) was 9.53% (95% CI 8.86 to 10.25) while that during the peak of second wave (April and May) was 12.67% (95% CI 11.81 to 13.58%). This fluctuation was statistically highly significant (p < 0.001). Again the rate was raised in December 2021 till January 2022 marking the third wave. The fluctuation was again significant statistically (Table .3).

Table 1: Gender wise distribution of samples and rapid antigen test positive cases

Gender	Number of samples	Number of positives (%)	95% CI (%)
Male	25178	1015(4.03)	3.79 – 4.28
Female	19840	787(3.97)	3.71 – 4.25
Total	45018	1802 (4.00)	3.82 – 4.18

* Figure in the parentheses indicate percentage

† Chi-square test p = 0.752 for comparison between males and females.

Table 2: Age-group wise distribution of samples and rapid antigen test positive cases

Age Group	Number of samples	Number positive (%)	95% CI (%)
≥ 60 years	7171	357 (4.98)	4.49 - 5.52
< 60 years	37847	1445 (3.82)	3.63 - 4.02
Total	45018	1802 (4.00)	3.82 - 4.18

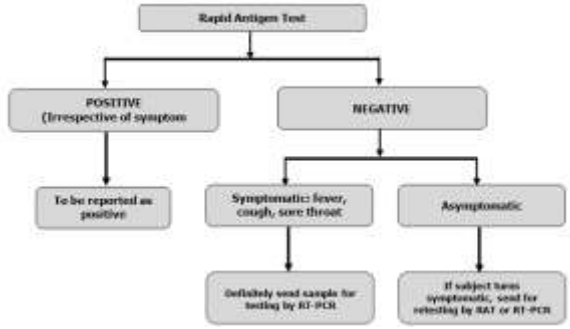
***** Figure in the parentheses indicate percentage

† Chi-square test $p < 0.001$ for comparison between age groups.

Table 3: Month wise trend of rapid antigen test positivity in nasopharyngeal swab samples from Covid-19 suspects.

Month	Number of samples	Number positive (%)	95% CI
2020 July	360	44 (12.22)	9.23 -16.01
2020 August	1652	179 (10.84)	9.43 - 12.43
2020 September	2756	195 (7.08)	6.18 – 8.10
2020 October	2489	283 (11.37)	10.18 – 12.68
2020 November	2695	124 (4.60)	3.87 – 5.46
2020 December	1686	34 (2.02)	1.45 – 2.81
2021 January	2197	03 (0.14)	0.05 – 0.41
2021 February	2200	02 (0.09)	0.02 – 0.33
2021 March	2479	07 (0.28)	0.14 – 0.58
2021 April	2274	484 (21.28)	19.65 – 23.01
2021 May	3139	202 (6.44)	5.63 – 7.35
2021 June	2254	11 (0.49)	0.27 – 0.97
2021 July	2489	7 (0.28)	0.14 – 0.58
2021 August	2552	5 (0.20)	0.09 – 0.46
2021 September	2400	17 (0.71)	0.44 – 1.13
2021 October	2063	21 (1.02)	0.67 – 1.55
2021 November	2387	21 (0.88)	0.58 – 1.34
2021 December	2314	27 (1.17)	0.81 – 1.72
2022 January	3105	132 (4.25)	3.58 – 5.02
2022 February	1527	4 (0.26)	0.08 – 0.72
Total	**45018**	**1802 (4.00)**	**3.82 – 4.18**

Discussion



SARS-CoV-2 is one of the most virulent pathogens causing severe acute respiratory illness. Unlike the earlier two coronavirus epidemics of Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS), it also appears to progress to a multisystem disorder with autoimmune inflammation. Tracking it trends in a country and region are vitally important from the perspective of disease control and prevention. RAT has been widely employed in epidemiological surveillance because of the ease of its use in the field and at the point of care and the rapidity with which test results are available compared to the more definitive but resource intensive rRT-PCR testing.

The advantages of RAT such as rapid results, reasonable price and being safe due to viral inactivation and the fact that this does not require sophisticated laboratory or technical expertise make it an ideal test to be rolled out in high-prevalence community settings. Rapid RAT results will imply quick detection, isolation, and admission of infected persons. Further, while suspected patients are kept in a holding area until the RT-PCR reports arrive, there is high likelihood of COVID-19-negative SARI patients contracting COVID-19 due to cross-transmission. A rapid test can avert this possibility. Based on these features, this test has been adopted in the diagnostic algorithms for Indian hospitals and an advisory has been issued by the ICMR in this regard[10]. Following this advisory negative RAT in symptomatic cases was followed up by rRT-PCR test.

The analytical performance of RAT depends on various factors, including the duration of illness, technique of sample collection, mixing of nasopharyngeal swab fluid with buffer and the viral load in the sample. In asymptomatic cases the sensitivity is modest as it is difficult to judge the pre-test probability. In the present study overall 4% of the total samples tested were RAT positive. The positivity was modestly higher in males than in females (4.03% versus 3.97%) though the difference is not statistically significant (p=0.752). A systematic review and meta-analysis by Abate BB et al have found higher prevalence of symptomatic Covid-19 infection among males in comparison to females[11]. Though the exact reasons are obscure they concluded that smoking and alcoholism may have contributed to the higher prevalence. They have also opined higher outdoor activities among males as a contributing factor. Studies have hypothesized that angiotensin-converting enzyme-2 (ACE-2) encoded by ACE-2 gene has been found to be the receptor for SARS-CoV-2,[12] and interestingly Asian males have been reported to have higher expression of ACE-2 receptors than females while studying the expression level and pattern of human ACE-2 using single-cell RNA-sequencing.[13]However, any genetic predisposition for males calls for in-depth study. Thirdly, the biological differences in immune system of male and female owing to various sex hormones might contribute to the reduced susceptibility of females to SARS CoV-2 and other viral infection[14]. Fourthly, the increased susceptibility might also be driven by behavior and lifestyle, such as far higher levels of smoking and drinking among men compared to women in India, and higher resistance among males to conform to protective behavior like mask usage and frequent hand washing. This as a contributing factor is also supported by a few contemporary studies from other countries too[15,16]. And it is noteworthy to mention that the outcome and clinical severity of Covid 19 infection is more adverse and higher for male than female as found by

studies[17]. However, we have found secular trend for male and female positivity in all three waves suggesting no less risk for women and necessitating equal vigilant attitude and life style for them in the face of infection threat.

Our study has created a database on the seasonal pattern of cases in last 19 months in the defined geographical area. This information can alert the local civic authority for containment measures to be adopted in the face of surge severity. No study based on RAT data has been published yet from this part of the country. Thus this study offers a pioneering baseline to evaluate the usefulness of RAT in corona pandemic.

Positivity among the elderly (≥ 60 years age group) population was more than that of 18 to 60 years age group (4.98% versus 3.82%) in this study. Lockdown and continuous awareness programs from government agencies, municipalities and social organizations have generated concern among the senior citizens and curtailed their free movement unlike anything witnessed before. In spite of restricted outdoor movement of ≥ 60 years people in the
pandemic situation they show higher susceptibility. Co-morbidities like hypertension, diabetes mellitus and other age related changes may have increased the susceptibility.

The pattern of month-wise sample testing and RAT positivity depicts the changing trend of the pandemic. As seen from Table 3 and Figure 4, there was gradual rise in RAT positivity from July, 2020 to October, 2020 followed by a steady fall from November, 2020 to March 2021. If this is considered the first wave, then, August to October, 2020 was its peak period. During the end of this period, it was hoped and felt that probably the pandemic was getting controlled; but from the very next month the positivity started climbing with great vigor. April, 2021 has shown highest monthly positivity (21.28%) till now. Epidemiologists have blamed indiscriminate gathering, violation of Covid appropriate behavior and extremely poor adherence to personal protective behavior. April and May might be considered the peak of the second wave. The surges in two waves show a statistically significant difference. Positivity dramatically took a steep rise from end of December 2021 (1.17%) and reached another peak in January 2022 (4.25%) marking the third wave (caused by Omicron variant of SARS-CoV-2) which flattened by February 2022, denoting the end of this wave. Despite apprehensions, the third wave had far lesser vigor than its previous counterpart. However, owing to reluctance of the common people to undergo tests, as the clinical severity was far less, a good many number of cases might had gone untraced in the third wave.

As the waves commenced and the sample load started increasing; the study group was instructed to gear up RAT facilities and facilitate its dissemination in rural and semiurban settings like primary health centers and also plan for doorstep testing for quick capturing of cases. Though the latter is not being done at present, doorstep testing based on RAT can eventually reduce apathy in common people to go to hospital (due to various personal, social and other inconveniences) for testing.

The present study has its share of limitations. Firstly, as the study was conducted in the setting of on OPD based fever clinic, only samples from mild to moderate or asymptomatic individuals were tested. Severely symptomatic cases like SARI cases tested by RAT were not included. We did not compare RAT performance against the gold standard method (r-RT PCR) in this study. In reality, negative RAT, if solely relied upon, could miss 25-30% cases[18]. However, another study to compare RAT with RT-PCR, to evaluate the sensitivity and specificity in this geographical area and study population, is in the pipeline, and will be done by the same study group. Thirdly, a positive RAT is not cent percent suggestive of Covid-19[19]. The current RAT kits can show cross reactivity with other SARS corona viruses and such false positivity has not been evaluated in this study.

Despite these limitations, in conclusion we can reiterate that RAT is useful for quick detection and decision making in field and resource limited conditions. Cases were at surge in September and October of last year. Then there was rapid decline. Rebound surge took place only recently. The study has revealed the trend of infection in mild to moderate and suspected but asymptomatic cases. RAT has been established as a convenient strategy for tracking the trend of infection. Results based on RAT testing can help in planning for local containment strategies and preparing for any potential resurgence of infection.

References:

1. Cucinotta D, Vanelli M. WHO declares COVID-19 a pandemic. Acta Biomed 2020; 91: 157-60.
2. Coronavirus disease 2019: Events as they happen. [Internet] World Health Organization. [cited 2021 Jun 29] Available from:https://www.who.int/emergencies/diseases/novel-coronavirus-2019/events-asthey-happen.
3. Chen Y, Liu Q, Guo D. Emerging coronaviruses: Genome structure, replication, and pathogenesis. J MedVirol 2020; 92:418-23.
4. Zheng J. SARS-CoV-2: An emerging coronavirus that causes a global threat. Int J Biol Sci 2020; 16: 1678-85.
5. Wang W, Xu Y, Gao R, Lu R, Han K, Wu G, et al. Detection of SARS-CoV-2 in different types of clinical specimens. J Am Med Assoc 2020; 323: 1843-4. Available from

6. https://www.worldometers.info/coronavirus/country /india/ accessed on May 21, 2021.
7. Strategy for COVID-19 testing in India (Version 5,dated 2020 May 18). [Internet] Indian Council of Medical Research. [Cited 2021 Jun 29]. Availablefrom:https://www.icmr.gov.in/pdf/covid/strategy/Testing_Strategy_v5_18052020.pdf.
8. Advisory on strategy for COVID-19 testing in India (Version 6, dated 2020 Sep 4). [Internet] Indian Council of Medical Research [cited 2021 Jun 29].Available from:https://www.icmr.gov.in/pdf/covid/strategy/Testing_Strategy_v6_04092020.pdf.
9. Portal for upload of COVID Tests [Data upload portal on the Internet]. Indian Council of Medical Research [cited 2021 Jun 29]. Available from: https://cvstatus.icmr.gov.in/add_record.php.
10. Advisory on use of rapid antigen detection test for COVID-19 [Internet]. Indian Council of Medical Research [cited 2021 Jun 29]. Available from:https://www.icmr.gov.in/pdf/covid/strategy/Advisory_for_rapid_antigen_test14062020.pdf.
11. Abate BB, Kassie AM, Kassaw MW, et al. Sex difference in coronavirus disease (COVID-19): asystematic review and meta-analysis. BMJ Open 2020;10:e040129. doi:10.1136/ bmjopen-2020-040129
12. Cao Y, Li L, Feng Z, Wan S, Huang P, Sun X, et al. Comparative genetic analysis of the novel coronavirus (2019-nCoV/SARS-CoV-2) receptor ACE2 in different populations. Cell Discov 2020; 6: 4-7. doi: 10.1038/s41421-020-0147-1.
13. Zhao Y, Zhao Z, Wang Y, Zhou Y, Ma Y, Zuo W. Single-cell RNA expression profiling of ACE2, the receptor of SARS-CoV-2. Am J Respir Crit Care Med 2020; 202: 756-759. Erratum in: Am J Respir Crit Care Med 2021; 203: 782.
14. Ghazeeri G, Abdullah L, Abbas O. Immunological differences in women compared with men: overview and contributing factors. Am J Reprod Immunol 2011; 66: 163-9.
15. Jiang X, Rayner S, Luo M-H, Luo Min-Hua. Does SARS-CoV-2 has a longer incubation period than SARS and MERS? J Med Virol 2020;92:476–8.
16. Li R, Pei S, Chen B, et al. Substantial undocumented infection facilitates the rapid dissemination of novel coronavirus (SARSCoV-2). Science 2020; 368:489–93.
17. Falahi S, Kenarkoohi A. Sex and Gender Differences in the Outcome of Patients With COVID-19. J Med Virol (2021) 93(1):151–2. doi: 10.1002/jmv.26243
18. Kim H, Hong H, Yoon SH. Diagnostic performance of CT and reverse transcriptase polymerase chain reaction for coronavirus disease 2019: A meta-analysis. Radiology 2020; 296: E145-55.
19. Standard Q COVID-19 Ag kit package insert. [Internet] Suwon-si, Gyeonggi-do, Republic of Korea: SD Biosensor, Inc. [cited 2021 Jun 29] Available from: https://www.who.int/diagnostics_laboratory/eual/eul_0563_117_00_standard_q_covid19_ag_ifu.pdf.

Original Article

Age and Gender Differentials in Susceptibility, Severity and Outcome of Covid-19 Cases In Northern India.

Aishiya Ishrat, Devraj , Saba Choudhary

Abstract:

Background

Sex and age is increasingly associated with epidemiology and outcome of many diseases. This also appears to hold true for COVID-19 infection. Early reports on COVID-19 case fatalities in India suggest that males are at higher risk than females. It is uncertain whether males experience a greater risk of mortality throughout the age band or there are sex differentials in survival risk. In order to present disaggregated interpretation of age-sex specific COVID-19 infection and mortality risk in India we adopt a gender and age lens.

Aim

The present study was conducted to determine biological attributes of variation in age and gender on Covid-19 status (deceased/recovered).

Method

In this retrospective study, the data was collected from the hospital in Kargil. A total of 3132 COVID-19 positive patient's record was included. The records were evaluated to scrutinize age and gender relationship with COVID-19 status (recovered/deceased) of the study subjects.

Results

The male COVID-19 cases (75.79%) were more than females (24.20%) and mean age of diseased and recuperated patients was 32.52 and 32.3589 respectively. The overall case fatality rate (CFR) among males and females is 0.59 (95% C.I. = 0.35-0.99) and 0.26 (95% C.I. = 0.07-0.96) respectively.

Conclusions

Early evidence shows that both genders have the same prevalence; men with COVID-19 are at higher risk for worse outcomes and deaths. The odds for recovery among females were suggestively higher than males. With increasing age the odds of recovery decline.

JK-Practitioner2022;27(4):80-83

Introduction

The COVID-19 pandemic has tested the global health systems and medical sciences. The SARS-CoV-2 (Severe Acute Respiratory system Coronavirus-2) virus has infected about 10% of the global population and since the end of May 2020; India has been ranked as 2nd most affected country in the world[1]. Also, as of May 21,2020, with over 112,000 cases [2],India accounts for 11th utmost share of 2.24% in global burden of COVID-19.

Various postulations were made for the differential impact of COVID-19 on age and gender. The environmental and socio-economic factors were also utilized for depicting the vulnerability to COVID-19[I][3,4]. The susceptibility to external pathogen also differs due to biological differences at various age[5] and between the genders (male and female [6]. Advanced age and pre-existing comorbid conditions and metabolic conditions have now been widely reported to be associated with poor outcome[7,8].

Case fatality rate (CFR) has considerable relevance and can provide much needed conclusions regarding survival patterns. CFR is best portrayed as a dynamic rate and is defined as the percentage of confirmed deaths in total confirmed cases. For instance, based on the cases observed till April 20,2020, a recent study estimates an overall COVID-19 CFR of 3.2% for India[9].

Since, there were so many COVID-19 positive cases in India, but little information is available that highlighting the age and gender perspectives of COVID-19. Therefore, the current study was an attempt to study the association amid age, gender and patients status (recovered/deceased) among positive COVID-19 cases.

Author Affiliations
Aishiya Ishrat, Devraj ;Lecturers Government Medical College ,Jammu
Saba Choudhary; Medical Officer Hospital,Ladakh.

Correspondence
Dr.Saba Choudhary
Medical Officer ,
Hospital Kadakh

Indexed
EMBASE ,SCOPUS, IndMED ,ESBCO , Google Scholar besides other national and International Databases

Cite This Article as
Ishrat A, Devraj , Choudhary S. Age and gender differentials in susceptibility, severity and outcome of covid-19 cases in northern India.
JK Pract2022;27(4):80-83

Full length article available at **jkpractitioner.com** one month after publication

Keywords

COVID-19, Gender, Age, CFR and Severity.

Method:
In this retrospective study, the data was collected from the hospital in
Kargil (March 21 to May 22). A total of 3132 COVID-19 positive patient's record was included in this study. The records were evaluated to scrutinize age and gender relationship with COVID-19 status (recovered/deceased) of the study subjects. We analyze the encumbrance of recovered cases and deaths for age-sex groups. CFR is assessed as ratio of confirmed deaths in total confirmed cases.

Result

Between March 2021 and May 2022, a total of 3132 individuals were tested for the presence of SARS CoV-2 infection. The present study included a total of 3132 cases in which males were 2374 and females were 758. Most COVID-19 cases were in the age group 20-29 years. Gender wise males were affected more than females. Also, more deaths were observed in male patients than females. Though females of lower age categories (20-29) have greater chances of getting COVID-19 infection than males (Table 1).
Case fatality rate was more in males 0.59(95% C.I. = 0.35 – 0.99) as compared to females 0.26(95% C.I = 0.07 – 0.96). With increase in age there was an upward rise of CFR. Likewise, gender in which CFR was higher was that of males. 30-39 years of age group people exhibited increase in CFR, which was than observed to surge with escalation of age of the COVID-19 affected cases. Highest CFR was observed in age group 80-95 years 26.66(95% C.I. = 10.9 – 51.95) (Table 2)
The odds of being infected with COVID-19 was higher in age group 80-95 years (O.R = 830.18, 95% C.I. = 85.78-8034) followed by 70-79 years (O.R. = 167.05, 95% C.I. = 17.02 – 1640), 50-59 years (O.R. = 25.37, 95% C.I. = 2.63 – 244.7), 40-49 years (O.R. = 11.36, 95% C.I. = 1.03-125.5), showing higher risk of COVID-19 infection with advancing age (Table 3). (p value = <0.0001) shows a good significance thus explaining age and COVID-19 outcome is significantly related (Table 3). In existing study men's cases inclined to be more serious than women's. Also, the number of men who died from Covid-19 is more than women. Males are at increased risk for developing COVID-19 then females with 2.24 (955 C.I. = 0.51-9.88) times more risk. Correspondingly, midst the total number of deceased and recovered patients, the proportion of deceased patients increases with age while the proportion of recovered patients is more in age group 0-39 years. The association of gender with COVID-19 outcome isn't statistically significant (p value = 0.42) (Table3). Another set of longitudinal scrutiny was done on COVID-19 patient's status record that is recovered or deceased. Among the total number of deceased and recovered COVID-19 cases, mean age of deceased was 63.3750 ± 17.08 while mean age of recovered cases was 32.3589 ± 13.900 and the difference between them is statistically highly significant (p value = 0.0001) (Table 4)

Table 1 : Age and Gender based Number of Cases and Deaths

Age Group	CASES			DEATHS		
	Male	Female	TOTAL	MALE	FEMALE	TOTAL
0 to 4 years	7	2	9	-	-	-
5 to 19 years	313	176	489	-	-	-
20 to 29 years	793	220	1013	-	-	-
30 to 39 years	623	150	773	1	-	1
40 to 49 years	323	81	404	2	-	2
50 to 59 years	201	72	273	3	-	3
60 to 69 years	73	39	112	2	1	3
70 to 79 years	29	15	44	3	-	3
80 to 95 years	12	3	15	3	1	4
TOTAL	2374	758	3132	14	2	16

Table 2 : Age and gender- wise CFRs

Age Group	Male CFR(95% C.I)	Female CFR(95% C.I)	TOTAL CFR(95% C.I)
0-4	0(0-35.43)	0(0-65.76)	0(0-2.09)
5-19	0(0-1.21)	0(0-2.14)	0(0-0.05)
20-29	0(0-0.48)	0(0-1.72)	0(0-0.03)
30-39	0.16(0.03-0.9)	0(0-2.49)	0.13(0.02-0.73)
40-49	0.62(0.17-2.23)	0(0-4.53)	0.50(0.14-1.79)
50-59	1.49(0.51-4.3)	0(0-5.06)	1.10(0.37-3.18)
60-69	2.74(0.75-9.45)	2.56(0.45-13.18)	2.69(0.92-7.58)
70-79	10.34(3.58-26.38)	0(0-20.39)	6.82(2.35-18.22)
80-95	25(8.9-53.23)	33.33(6.15-79.23)	26.66(10.9-51.95)
TOTAL	0.59(0.35-0.99)	0.26(0.07-0.96)	0.51(0.31-0.83)

Table 3 : Association of Age and gender with Covid-19 Outcome

Age Group	**Covid-19 Outcome**		Total	**Odds Ratios (95% CI)**	M.H chi-square for linear trend	P - value
	Died	Recovered				
0 to 39 years	1	2283	2284	1(Reference)	114.89	<0.0001
40 to 49 years	2	402	404	11.36(1.03-125.5)		
50 to 59 years	3	270	273	25.37(2.63 – 244.7)		
60 to 69 years	3	109	112	62.83(6.48 – 608.9)		
70 to 79 years	3	41	44	167.05(17.02 – 1640)		
80 to 95 years	4	11	15	830.18(85.78-8034)		
Gender						
Males	14	2360	2374	2.24(0.51-9.88)	0.644	0.42
Females	2	756	758			
Total	16		3132			

Table 4: Comparison age between cases died and cases recovered.

Cases	N	Mean age	Std. Deviation	Significance	
				t-value	p-value
Died	16	63.3750	17.08752	8.89	<0.0001
Recovered	3116	32.3589	13.90086		

Discussion

Coronavirus is a family of viruses that cause illnesses ranging from common cold to severe pneumonia, such as SARS [10]. The SARS CoV-2 virus being a novel virus can infect human race irrespective of age categories and gender [11]. However, there exist individual variations in biological and genetic variation, physiological functions, immune responses and other risk factors across age categories and gender. As a result, the odds of getting COVID-19 infection might vary among gender and diverse age categories.

The current study aims to explore the chances of getting COVID-19 infection based on gender and different age categories with predicted chances of getting recovered or deaths. In this study the data from March 2021 to May 2022 was collected from Kargil, 3132 COVID-19 infected patients records were obtained and analyzed to determine the role of age and gender in predicting the status of patients. Several studies across the world show that older males were more prone (>50%) in getting SARS CoV-2 infection[12][12-14]. In present study male COVID-19 patients were higher (75.79%) than females COVID-19 patients (24.20%), which is in accordance to study[15].

Preliminary evidence from various countries suggests that men are at a greater risk of both infections and deaths, but these inferences should be carefully interpreted[16].The early reports of COVID-19 cases and deaths in India suggest that males are at a greater disadvantage than females with CFR of 3.3% and 2.9% respectively[9].

The odds ratio shows that possibility for getting recovered from COVID-19 infection was high in females than males. Gender is a risk factor for higher severity and mortality in COVID-19 patients. This could be attributed to higher rates of smoking, genetic and biological differences, prior respiratory conditions, lower hand washing rates resulting in higher mortality and morbidity among males[17].

Conclusion:

The chances of getting COVID-19 infection vary with age and gender. The likelihood of getting recovered declines with increasing age and plunges among males as compared to females. The disparity in infection rates and stakes of recovery and deaths across age and gender might be explained on the basis of biological, genetic variations and other factors separately. These results can be instrumental in evaluating the predictable burden of possible future outbreaks, understanding the impacts, new treatment strategies, new treatment strategies and designing policy responses to such crisis.

Conflict of Interest: No conflict of interest.

Financial support: None.

References

1. WHO coronavirus disease (COVID-19) dashboard.https://covid19.who.int/?gclid=Cj0KCQjww_f2BRC-ARIsAP3zarH9e-pD1WIUN8gqV1mMbbv8UtsUDSv0CdxxhklRSF1u7XZNzJsVg4YaAsUyEALw_wcB; 2020.
2. COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU) [Internet]. https://coronavirus.jhu.edu/map.html. Updated 2020. Accessed May 21, 2020.
3. Sarkar A, Chouhan P. COVID-19: district level vulnerability assessment in India. *Clin. Epidemiol. Glob.Health.*2020. https://doi.org/10.1016/j.cegh.2020.08.017.
4. Lulbadda KT, Kobbekaduwa D, Guruge ML. The impact of temperature, population size and median age on COVID-19 (SARS-CoV-2) outbreak.*Clin.Epidemiol.Glob.Health*.2020. https://doi.org/10.1016/j.cegh.2020.09.004.
5. Lee BW, Yap HK, Chew FT, et al. Age- and Sex-Related changes in lymphocyte subpopulations of healthy Asian subjects: from birth to adulthood. *Commun.Clin.Cytom.*1996;26:8–15. https://doi.org/10.1002/(SICI)1097-0320(19960315)26:1<8. AID-CYTO2>3.0.CO;2-E. PubMed PMID: 8809475.
6. FurmanD, Hejblum BP, SimonN, etal. Systems analysis of sex differences reveals an immunosuppressive role for testosterone in the response to in uenza vaccination. *Proc. Natl. Acad.Sci.U.S.A*.2014;111:869–874. https://doi.org/10.1073/pnas.1321060111. PubMed PMID: 24367114.
7. Boehmer TK, DeVies J, Caruso E, van Santen KL, Tang S, Black CL, et al. Changing Age Distribution of the COVID-19 Pandemic—United States, May–August 2020. MMWR Morb Mortal WklyRep2020;69:1404–9. https://doi.org/10.15585/mmwr.mm6939e1 PMID: 33001872
8. Razzaghi H, Wang Y, Lu H, Marshall KE, Dowling NF, Paz-Bailey G, et al. Estimated County-Level Prevalence of Selected Underlying Medical Conditions Associated with Increased Risk for Severe COVID-19 Illness—United States, 2018. MMWR Morb Mortal Wkly Rep 2020;69:945–50. https://doi. org/10.15585/mmwr.mm6929a1PMID: 32701937
9. Dhillon P, Sampurna Kundu CS, Ram U, Dwivedi LK, Yadav S, Unisa S. *IIPS Analytical Series on COVID-19: Paper 4. Case-Fatality Ratio and Recovery Rate of COVID-19: Scenario of Most A ected Countries and Indian States*. Mumbai: International Institute for Population Sciences; 2020.
10. Drosten C, Gunther S, Preiser W, van der Werf S, Brodt HR, Becker S, et al. Identification of a novel coronavirus in patients with severe acute respiratory syndrome. *N Engl J Med.* (2003) 348:1967–76. doi: 10.1056/NEJMoa 030747

11. Yanping Zhang. Analysis of epidemiological characteristics of new coronavirus pneumonia. 2nd 41. Chinese Journal of Epidemiology; 2020:145–151. https://doi. org/10.3760/cma.j.issn.0254-6450.2020.02.003.
12. JinJMM,BaiP,HeW,etal.Gender differences inpatientswithCOVID-19:focuson severity and mortality. Front. Publ. Health. 2020;8:152. https://doi.org/10.3389/ fpubh.2020.00152.
13. Mallapaty S. The coronavirus is most deadly if you are older and male - new data reveal the risks. Nature. 2020;585:16–17. https://doi.org/10.1038/d41586-020- 02483-2. PubMed PMID: 32860026.
14. Munayco C, Chowell G, Tariq A, Undurraga EA, Mizumoto K. Risk of death by age and gender from CoVID-19 in Peru, March-May, 2020. Aging. 2020;12:13869–13881. https://doi.org/10.18632/aging.103687. PubMed PMID: 32692724.
15. K Savitesh, Khanna P, Rajagopal V et al. Biological attributes of age and gender variations in Indian COVID-19 cases: A retrospective data analysis. Clinical Epidemiology and Global Health 11 (2021) 100788. https://doi.org/10.1016/j.cegh.2021.100788
16. Wenham C, Smith J, Morgan R; Gender and COVID-19 Working Group. COVID-19: the gendered impacts of the outbreak. Lancet 2020;395(10227):846-8.
17. Betron M, Gottert A, Pulerwitz J, Shattuck D, Stevanovic-Fenn N. Men and COVID- 19: adding a gender lens. Global Publ Health. 2020;15:1090–1092. https://doi.org/ 10.1080/17441692.2020.1769702. PubMed PMID: 32436422.

Original Article

Perceived Stress Among School Students Caused by Virtual Classrooms Amid Covid-19 Pandemic

Gurmeet Kaur, Retash Shan, Dev Raj

Abstract

Background

COVID-19 pandemic has been a unique global experience in the history of pandemics – impacting every individual's mental health and well being. School students were, however, affected the most with the sudden transition from real physical class-rooms to 'virtual-classrooms' which entailed along with it new challenges of technical learning, network failures, chaotic time-schedules and prolonged screen-time.

Purpose The aim of this study was to estimate the prevalence of perceived stress by the school students (senior secondary and secondary class students).

Materials and Methods

This was a cross-sectional study in which the level of perceived stress was measured in 277 school students with the help of an online questionnaire "The Perceived Stress Scale -10", a globally used, validated and reliable stress assessment tool.

Results

58.12% showed moderate level of perceived stress whereas 35.38% showed high and 6.50% low stress respectively. No statistically significant association was found between perceived stress and age, gender and education level.

Conclusion

The present study suggests that online mode of learning does put school students under stress, a fact which the education policy makers should keep in mind and accordingly take measures to alleviate the same.

JK-Practitioner2022;27(4):84-89

Introduction

The COVID-19 pandemic has been a global phenomenon for the past two years and has disrupted the lives of people from all walks of life, putting people under huge psychological pressure. The students class is specifically affected because of the advent of new mode of learning/teaching methods i.e. online learning and its associated challenges, such as technical incapabilities, frequent network failure and separation from school[1].High stress and anxiety levels were observed in students before the pandemic as well[2,3]. . Recent studies have reported a significant increase in perceived stress among students during the COVID-19 pandemic in many countries such as Saudi Arabia[[4],China[5], India[6],Germany[7], France[8] and Uganda[9].

At the time of research, the schools were still closed as a measure to contain the spread of pandemic. This step, though justified, however did have a significant impact on the psychological health of school students[10]

Perceived stress is the assessment of the degree to which the situation in one's life is seen as stressful[11],it refers to how unpredictable, uncontrollable and overloaded individuals find their lives[12].

Perceived stress is strongly related to both anxiety and depression symptoms[13].Recent studies have reported that stress during the COVID-19 pandemic increased school burnout in students[14-17]-which is referred to as the students' sense of tiredness towards the school or the academic process[18,19]. This may cause more psychological problems to students[20].

Also, many studies show that recent outbreaks such as Ebola, SARS impacted mental health and well being [21]. During a SARS outbreak, a population based survey showed post-crisis mental distress[22].

Author Affiliations
Gurmeet Kaur, Associate Professor, **Retash Shan,** Senior Resident,
Department of Physiology **;Dev Raj** Lecturer,Department of Community Medicine**:**
Government Medical College Jammu ,J&K, India

Correspondence
Dr. Gurmeet Kaur
Associate Professor ,Department of Physiology ,GMC, Jammu
9419231346
E-mail address:
drgurmeetksabar@rediffmail.com

Indexed
EMBASE ,SCOPUS, IndMED ,ESBCO ,Google Scholar besides other national and International Databases

Cite This Article as
Kaur G, Shan R, Raj D. Perceived stress among school students caused by virtual classrooms amid covid-19 pandemic
JK Pract2022;27(4):84-89

Full length article available at **jkpractitioner.com** one month after publication

Keywords
Perceived Stress, School-students, COVID-19, mental health.

As damaging as the physical effect of the global pandemic are, there is strong speculation about the second wave of mental health crisis, particularly for school aged children[23].

The aim of this study was to assess levels of perceived stress among secondary school students (14-18 years) and apprise the education policy makers accordingly so that they can take appropriate steps to reduce the stress.

Material and methods

The current study was conducted during the period of home isolation on the closure of universities and schools due to COVID-19 pandemic from 15th March 2022 to 7th April 2022. The data for this study was obtained using a cross-sectional survey. Because of the restricted movement period due to existing COVID-19 pandemic, data collection was done via the internet using digital platform.

This study included both male and female students, studying in secondary and senior secondary classes (IX – XII) of different schools (Age group 14-18 years) in Jammu and nearby regions.

In this study, convenience sampling was utilized to collect data. The sample size was calculated to be 265 based on marginal error 15%, α – 5% and β – 0.2% (Software Open Epi version 3). However, the study was done on 277 students. Consent was taken from the respective heads of the institutions before the start of the survey. A brief introduction about the study's background, protocol, objectives, voluntary nature of participation, declaration of anonymity and confidentiality were explained in detail to the heads of institutions. Google forms were used to create a link for the survey, which was posted by school authorities on their school educational platform.

The following were the study's inclusion criteria:

1. The students of secondary and higher secondary classes, well conversant with English language, enrolled in private schools.
2. Students who regularly attended online classes during the closure of their schools during COVID-19 outbreak.

Study Instrument: The online survey comprised of three sections. The first section involved demographic questions that included age, gender, level (class) of education and place of residence.

The Perceived Stress Scale (PSS-10): This scale developed by Cohen et al consists of the questions that are used to measure the perception of stress experienced by the participants over the past month. The PSS is a very commonly used stress assessment tool with acceptable psychometric properties. All questions of PSS-10 are reliable in predicting the level of stress. Though the PSS is temporal and its predictive validity may decrease over time, yet it can be used to determine daily activities, events and changes in a situation; it has been documented for its reliability and validity by several studies. The PSS comprises of ten questions that ask about your feelings and thoughts during the last month. It includes the five point Likert scale that captures responses ranging from never (0) to very often (4). The total score of the PSS-10 ranges from 0-40; total mean scores of 0-13 indicate low stress, 14-26 indicate moderate stress and 27-40 indicate high stress[12] . But only employing PSS to measure the level of perceived stress does not clarify whether cause of stress is COVID-19 or some other reason unless separate and specific information is sought regarding attitude towards pandemic. Therefore, in the third section was included yet another questionnaire, validated and used by a previous study[1] to understand student's attitude / concerns towards COVID-19 and fears associated with it. The questionnaire elicited information on attitude towards COVID-19, e-learning and major challenges faced during lockdown period. These responses were correlated with the PSS factors statistically.

Perceived Stress Score – [PSS-10]

For each question choose from the following alternatives:

[0 - never, 1 – almost never, 2 – sometimes, 3 – fairly often, 4 – very often].

1) In the last month, how often have you been upset because of something that happened unexpectedly?
2) In the last month, how often have you felt that you were unable to control the important things in your life?
3) In the last month, how often have you felt nervous and stressed?
4) In the last month, how often have you felt confident about your ability to handle your personal problems?
5) In the last month, how often have you felt that things were going your way?
6) In the last month, how often have you found that you could not cope with all the things that you had to do?
7) In the last month, how often have you been able to control irritations in your life?
8) In the last month, how often have you felt that you were on top of things?
9) In the last month, how often have you been angered because of things that happened that were outside of your control?
10) In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?

Self-Reported Questionnaire To Assess Student's Attitude Towards The Pandemic

Kindly answer Q1 & Q2 on the scale of 0 to 4 as per the reference given with each question. [0 - never, 1 – almost never, 2 – sometimes, 3 – fairly often, 4 – very often]

1. Were you scared/ stressed by the Covid-19 pandemic?

2. Were you worried about your studies during the lockdown period?
3. What was the major challenge/ problem during the Covid-19 pandemic period?

o attending online classes
o availability of food/ essential utilities
o self/ time management

Ethical Clearance

An IEC clearance was obtained from the Institutional Ethical Committee of Govt. Medical College, Jammu before the commencement of the study.

Statistical Analysis

All the collected data was entered in the Microsoft excel sheet and then analyzed using computer software Microsoft excel SPSS version 22 for window. The qualitative data and quantitative data were reported as (frequency and percentage) and (mean and standard deviation) respectively. X2 -test was used for the qualitative variables to test the association and unpaired student t-test was used to test the significance between quantitative variables. A p-value less than 0.05 was considered as significant. All p-values were two tailed.

Results

Table 1 represents the demographic details of participating students. Total 277 students responded, of which 261 (94.2%) were females. The mean and standard deviation of their age is 15.16 ± 1.060 years. The participants belonged to Jammu district of J & K (UT) and were students of private schools who attended online academic activities.

The mean perceived stress was 24.10 with Standard Deviation 6.693. Table 3 shows the prevalence of perceived stress among the secondary and senior secondary students. The prevalence of moderate stress (score 14-26) was 58.12% ; whereas prevalence of high stress (score 27-40) was 35.38 and low stress (score 0-13) was 6.50.

The results of this study showed that there was no significant association between the level of stress and demographic variables: gender, age and educational level (Table 4).

Self-Reported Questionnaire To Assess Student's Attitude Towards The Pandemic Kindly answer Q1 & Q2 on the scale of 0 to 4 as per the reference given with each question. [0 - never, 1 al

Table 1: Distribution of subjects studied.

Parameters			Frequency(n)	Percent(%)
Gender	Female		261	94.2
	Male		16	5.8
	Total		277	100.0
Age (in years)	14.00		91	32.9
	15.00		93	33.6
	16.00		57	20.6
	17.00		31	11.2
	18.00		5	1.8
	Total		277	100.0
	Mean ± SD		15.16±1.060	
Education Level	Secondary	IX-Class	69	24.9
		X -Class	137	49.5
	Sr. Secondary	XI-Class	36	13.0
		XII-Class	35	12.6
	Total		277	100.0

Discussion

Many studies have been conducted to explore the level of perceived stress among students from competitive specialties such as medicine, dentistry and nursing during the COVID-19 outbreak in many parts of the country. This study, however was carried out in the less explored section of students – the school students (secondary school students) who are at the threshold of their careers and were left confused by the sudden transition to a new mode of learning i.e. e-learning during COVID-19 lockdown which involved 'virtual classrooms' with no face-to-face contact with their teachers, peers and friends. This new

paradigm of learning became a 'stressor' in student's life. This study showed no significant association of demographic variables - gender, age and education level with the stress.

Table 2: Responses of participants to the Perceived Stress Scale and other questions (n =277)

Question number	Stress									
	0		1		2		3		4	
	N	%	N	%	N	%	N	%	n	%
1	21	7.6	18	6.5	110	39.7	70	25.3	58	20.9
2	20	7.2	29	10.5	71	25.6	92	33.2	65	23.5
3	10	3.6	17	6.1	57	20.6	59	21.3	134	48.4
4	29	10.5	86	31.0	111	40.1	39	14.1	12	4.3
5	14	5.1	33	11.9	127	45.8	57	20.6	46	16.6
6	17	6.1	31	11.2	82	29.6	73	26.4	74	26.7
7	24	8.7	64	23.1	96	34.7	61	22.0	32	11.6
8	12	4.3	36	13.0	120	43.3	68	24.5	41	14.8
9	15	5.4	31	11.2	76	27.4	84	30.3	71	25.6
10	14	5.1	37	13.4	90	32.5	70	25.3	66	23.8
Other Questions										
Q1	27	9.7	36	13.0	108	39.0	52	18.8	54	19.5
Q2	11	4.0	11	4.0	52	18.8	77	27.8	126	45.5
Q3	What was the major challenge/ problem during the Covid-19 pandemic period?									
Options			Frequency				Percent			
Attending online classes			82				29.6			
Availability of food/ essential utilities			10				3.6			
Self/ time management			185				66.8			
Total			277				100.0			

Table 3: Prevalence of perceived Stress among the Secondary and Senior Secondary Students and its Comparison between Gender and Education level.

(a) Prevalence of perceived Stress among the Secondary and Senior Secondary Students			
Perceived stress scale	Frequency(n)	prevalence	(95% C I for prevalence)
Low stress (0 – 13)	18	6.50	(4.15 – 10.40)
Moderate stress (14 – 26)	161	58.12	(52.24 – 63.78)
High stress (27 – 40)	98	35.38	(29.98 – 41.17)
Total	277	100.0	-

(b) Comparison of level of Stress between Gender and Education level.						
Parameters		N	Mean	Std. Deviation	Significance	
					t-value	p-value
Gender	Female	261	24.2107	6.69254	1.065	0.288
	Males	16	22.3750	6.67208		
Education Level	SEC	206	24.1602	6.78870	0.235	0.815
	SR. SEC	71	23.9437	6.45177		

Table 3(a) shows that the prevalence of stress level among the students. Table 3(b) shows no statistically significant difference of mean stress score between males and females ($p = 0.288$) and between students of secondary and senior secondary classes ($p = 0.815$).

Table 4: Association of Stress with Gender, Age & Education level and Correlation of Q1 and Q2 with PSS.

(a) Association of Stress with Gender, Age and Education level

Parameters		Stress									
		Low		Moderate		Severe		Total		χ^2-value	p-value
		n	%	N	%	n	%	n	%		
Gender	Female	17	94.4	151	93.79	93	94.9	261	94.2	0.139	0.933
	Male	1	5.56	10	6.21	5	5.1	16	5.78		
	Total	18	100	161	100	98	100	277	100		
Age	<16	13	72.22	112	69.57	59	60.2	184	66.4	2.684	0.261
	≥16	5	27.78	49	30.43	39	39.8	93	33.6		
	Total	18	100	161	100	98	100	277	100		
Education Level	SEC.	15	83.33	119	73.91	72	73.47	206	74.4	0.818	0.664
	SR. SEC.	3	16.67	42	26.09	26	26.53	71	25.6		
	Total	18	100	161	100	98	100	277	100		

(b) Correlation of Q1 and Q2 with PSS.

Variable	(n)	Correlation (r)	p-value
Q1	277	0.160	0.008
Q2	277	0.188	0.002

Table 4 (a) shows no statistically significant association of gender, age and education level with the stress (p-value = 0.933, 0.261 and 0.664 respectively).

Table 4 (b) shows positive and significant correlation of Q1 & Q2 with stress (p-value 0.008 & 0.002 respectively).

This is in contrast to some studies [10 ,25],which reported high levels of stress among females as compared to males; this was attributed to hormonal changes and with higher risk perception among females [10,24].On the other hand, our results are in sync with the study of Rehman et al [26],which also reported no statistically significant difference in stress levels of females and males.

The present study also did not show any statistical significant difference in perceived stress level among different educational levels and age. This could be because there is not much age difference in the two educational levels taken in this study – senior secondary (17-18 years) and secondary students (15-16 years).

Limitation

Although this study gives a fair idea of how the senior school students have been coping with stress induced by COVID-19 lockdown, it has some limitations. The study sample was small, hence the results cannot be generalized. Also, there could be reporting bias as the answers were reported by the participants themselves. Finally, the design of the study was cross-sectional which has a limitation in determining a causal relationship between factors of interest and perceived stress.

Conclusion

This study revealed moderate level of perceived stress among secondary school students during school closure due to the COVID-19 pandemic. The sudden transition to online mode of learning from class-room learning entailed along with it difficulties in learning new technology, procurement of e-learning gadgets, adaptation to chaotic working hours, prolonged screen time, lack of socialization and sedentary lifestyles. All of this had a negative impact on young students' well being. Given the uncertain future and unknown status of pandemic vis-à-vis students, there is need for constant involvement of counselors and psychologists to take care of mental health and well being of the students. A UNICEF report shows that online courses should take place according to a well organized plan; otherwise they represent an additional stress for students with negative consequences linked to their mental health and well being.

Acknowledgement: We thank the participants of the study and the head of the institutions for their co-operation in the research.

Financial Support and Sponsorship: Nil

Conflicts of Interest: here are no conflicts of interest.

References:

1. Chhetri B, Goyal ML, Mittal M, Batlineni G. Estimating the prevalence of stress among Indian students during the COVID-19 pandemic: A cross-sectional study from India. Journal of Taibah University Medical Sciences 2021;16(2):260-267.
2. Aslen I, Ochnik D, Ciner O. Exploring Perceived stress among students in Turkey

during the COVID-19 Pandemic. Int. J Environ Res Public Health 2020;17(23):8961.
3. Robotham D, Julian C. Stress and the higher education student: A critical review of the literature. J Furth High Educ 2006;30:107-117.
4. Abdulghani HM, Saltar K, Ahmed T, Akram A. Association of COVID-19 pandemic with undergraduate medical students' perceived stress and coping. Psychol Res Behav Manag 2020;13:871-881.
5. Liu Z, Liu R, Zhang Y, Zhang R, Liang L, Wang y *et al*. Association between perceived stress and depression among medical students during the outbreak of Covid-19: the mediating role of insomnia. J Affect Disord 2021;292:89-94.
6. Agrawal N, Sharma H, Dabas A, Mishra A. Perceived stress among medical students and doctors in India during COVID-19 pandemic. MAMC J Med Sci 2021;7(1):14.
7. Goppert SA, Pfost M. Undergraduate students' perceived stress levels in summer term 2020 – A comparison to preceding academic terms. Front Psychol 2021;12:2055.
8. Bourion-Bedes, Tarquinio C, Batt H, Tarquinio P, Lebreuilly R, Sorsana C, *et al*. Stress and associated factors among French university students under the Covid-19 lockdown: the results of the PIMS-COVID-19 study. J Affect Disord 283:108-114.
9. Olum R, Nakwagala FN, Odokonyero R. Prevalence and factors associated with depression among medical students at Makerere University, Uganda. Adv. Med Edu Pract 2020;11:853-860.
10. Radwan E, Radwan A, Radwan W *et al*. Perceived stress among school students in Distance LeariningDuring the COVID-19 Pandemic in the Gaza strip, Palestine. Augmented Hum Res 2021;6(12).
11. Lazarus RS, Folkman S. Stress, Appraisal and Coping. In: Encyclopedia of behavioral Medicine. New York. Springer Publishing Company 1984 p1913-1915.
12. Cohen S, Kamarck T, Mermelstein R. A Global Measure of Perceived Stress. J Health Soc Beh 1983;24:385.
13. Salleh M. R. Life event, stress and illness. Maleys J Med Sci 2008;15:9-18.
14. Gundogan, S. The relationship of COVID-19 Student Stress with School Burnout, Depression and Subjective Well-Being: Adaptation of COVID-19 Student Stress Scale into Turkish. Asia-Pacific Edu Res 2022. Available from: https://doi.org/10.1007/s-40299-021-00641-2.
15. Castillo FA. State-anxiety and academic burnout regarding university access selective examination in Spain during and after the COVID-19 lockdown. Frontiers in Psychology 2021;12:17.
16. Jiang Y. Mobile social media usage and anxiety among university students during the COVID-19 pandemic: The Mediating role of psychological capital and the moderating role of academic burnout. Frontiers in Psychology 2021;12:76.
17. Vu BT, Bosmans G. Psychological impact of COVID-19 anxiety on learning burnout in Vietnamese students. School Psychology International 2021. Available from: https://doi.org/10.1177/01430343211013875.
18. Wang J, Bu L, Li Y, Song J, I Li. The mediating effect of academic engagement between psychological capital and academic burnout among nursing students during the COVID-19 pandemic: A cross-sectional study. Nurse education Today. 2021. Available from: https://doi.org/10.1016/j.nedt.2021.104938.
19. Salmela-A, K Kiuru, N, Leskinen E and Nurmi JE. School burnout inventory (SBI) reliability and validity. European Journal of Psychological Assessment 2009;25(1):48-57.
20. Tang, X, Upadyaya K, Salmela AK. School burnout and psychosocial problems among adolescents: Grit as a resilience factor. Journal of Adolescence 2021;86:77-89.
21. Taylor MR, Agho KE, Stevens GJ, Raphael B. Factors influencing psychological distress during a disease epidemic: data from Australia's first outbreak of equine influenza. BMC Publ Health 2008;13;1-13.
22. Peng EY, Lee M, Tsai S, Yang C, Morisky DE, Tsai L *et al*. Population-based post-crisis psychological distress: an example from the SARS outbreak in Taiwan. J Formos Med Assos 2010;109(7):524-532.
23. Schwartz KD, Cortns DE, McMorris CA, Makarenko E, Arnold P, Bavel MV et al. COVID-19 and Student Well-Being: Stress and Mental Health during Return-to-School. Canadian Journal of School Psychology 2021;36(2):166-185.
24. ALAteeq DA, Aljhani S, ALEesa D. Perceived stress among students in virtual classrooms during the COVID-19 outbreak in KSA. J. Taibah Univ Med Sci 2020;15(5):398-403.
25. Ganjoo M, Farhadi A, Baghbani R et al. Association between Health locus of control and perceived stress in college students during the COVID-19 outbreak: a cross-sectional study in Iran. BMC Psychiatry 2021; 21:529.
26. Rehman U, Shahnawaz MG, Khan NH, Kharshiing KD, Khursheed M, Gupta K, Kashyap D, Uniyal R. Depression, anxiety and stress among Indians in times of COVID-19 lockdown. Community Ment. Health J 2021;57(1):42-48.

Original Article

Pattern of Occupational Dermatosis in Health Care Workers Due to Personal Protective Equipments Use In Covid -19

Shazia Jeelani , Subreen Kour Bali , Iffat Hassan ,Yaqzata Bashir

Abstract

Background

The pandemic of the 21st century Coronavirus disease 19 (COVID 19) caused by severe acute respiratory syndrome came with a very high infectivity. Personal protective equipment (PPE) prevent the health care workers from droplet and contact transmission of virus while they are treating COVID 19 patients. Due to the frequent use of protective devices and frequent hand hygiene among healthcare workers during this pandemic came a second mini pandemic- Pandemic of occupational dermatitis.

Materials and Methods

A cross-sectional type of observational study was conducted. A google questionnaire was circulated on social media to the healthcare workers. The responses were recorded in Google Sheets and transferred to Microsoft Excel. The statistical analysis was done using data editor,S PSS Version 20.

Results

The study included 124 doctors, 54 nurses, 20 wardboys , 10 technicians and 10 in other health care workers.13.9% had the allergic predisposition The most common type of dermatoses seen in HCW was hand dermatitis (56.9%, 124/218) followed by facial acne(39.4%.86/218) and sweat dermatitis (38.5%, 84/218).The most common cause of hand dermatis was use of gloves (latex and non latex) in 82.2 % (102/124) and sanitizers in 63.7% (79/124) , soap in 21.7% (27/124).

Conclusion

There is need to make the health care workers aware about the proper and correct use of PPE in order to prevent and decrease the occupational dermatosis in due to personal protective equiments use in COVID -19

JK-Practitioner2022;27(4):90-93

Introduction

The pandemic of the 21st century Coronavirus disease 19 (COVID 19) caused by severe acute respiratory syndrome came with a very high infectivity [1].The cause of rapid spread of virus is human to human transmission, high infectivity, uppers respiratory mode of transmission [2].Health care workers are the frontline workers participating actively to fight against COVID 19 pandemic. Personal protective equipment (PPE) prevent the health care workers from droplet and contact transmission of virus while they are treating COVID 19 patients [3].

Health care workers are at increased risk of skin damage. Skin damage can be due to hand hygiene practices (frequent sanitizer use, frequent handwashing) and due to prolonged use of personal protective equipments, such as latex gloves, N95 masks, goggles, and protective clothing to escape from this virus. Skin damage due to PPE could be due to the increase frequency and duration of use, wearing of tightly fit equipments and allery to the material [4].

Due to the frequent use of protective devices and frequent hand hygiene among healthcare workers during this pandemic came a second mini pandemic- Pandemic of occupational dermatitis. In this study we aimed to evaluate the clinical features and pattern of occupation dermatosis in health care workers due to the personal protective equipment use in covid 19

Author Affiliations

Shazia Jeelani , Associate Professor , **Subreen Kour Bali ,** Senior Resident , **,Iffat Hassan ,**Professor & Head **, ,Yaqzata Bashir,** Senior Resident: Department of Dermatology ,Venereology and Leprosy, Government Medical College, Srinagar ,J&K, India

Correspondence

Shazia Jeelani ,Associate Professor, Department of Dermatology ,Venereology and Leprosy,Government Medical College ,Srinager.

E mail shazia46@gmail.com

Indexed

EMBASE ,SCOPUS, IndMED ,ESBCO ,Google Scholar besides other national and International Databases

Cite This Article as

Bali SK ,Jeelani S ,Hassan I,Bashir Y.
Pattern of Occupational Dermatosis in Health Care Workers Due to Personal Protective Equipments Use In Covid -19.JK Pract2022;27(4):90-93

Full length article available at **jkpractitioner.com** one month after publication

Keywords

Covid-19 ,Dermatosis,Health Care Worker

Materials and Methods:

This is a cross-sectional type of observational study conducted in September 2020 after approval from the Institutional Ethics Committee.

A specific questionnaire was formulated to collect relevant data. Questionnaire was made accessible online through the link created using Google Forms. Link was circulated among healthcare workers that included, using social media platforms (WhatsApp). The HCW were categorized as : doctors, nursing staff, laboratory technicians, ward boys and other(nursing orderlies, cleaners, etc) . Question answered by the participants helped us to collect information regarding the demographic data, healthcare role, type of PPE worn, duration and frequency of protective device worn, frequency of handwashing, dermatological symptoms and signs and quality of life impairment. They also had option to send their photographs online if they needed some treatment. The responses were recorded in Google Sheets and transferred to Microsoft Excel. The statistical analysis was done using data editor,SPSS Version 20.

Results

A total of 218 responses from google questionnaire were obtained from health care workers.. There were 126 (57.8%) males and 92(42.2%) females in this study. The mean age of the health care workers was 31.3 ± 6.5 years. Most of the HCW (60.6%) belonged to age group of 21to 30 years . The study included 124 doctors, 54 nurses, 20 wardboys , 10 technicians and 10 in other health care workers.13.9% had the allergic predisposition . Out of 218 health care workers, 118 (54.1%) were working exclusive in COVID facility. The components of PPE used by the health care workers is shown in Table 1.The most common type of dermatoses seen in HCW was hand dermatitis (124/218) followed by facial acne and sweat dermatitis. (Table 2). The cause of hand dermatis was use of gloves (latex and non latex) in 82.2 % (102/124) and sanitizers in 63.7% (79/124) , soap in 21.7% (27/124).The common symptom observed in our study was various redness of skin (66.5 %) , followed by itching (58.7%) , dryness of skin(55.9%), burning (14.6%) and pain (3.6%) (Table 3) . Table 4shows commonly observed signs in HCW in our study. The commonly affected site was nasal bridge(58.7%) followed by hands (50 %), chin and cheeks (42.2%)

Table 1: Components of PPE

PPE worn	No. of Patients	Percentage
Full	54	24.8
Surgical hand Mask	31	14.2
N 95 mask	187	85.7
Gloves	166	76
Faceshield	90	41.2
Protective googles	86	39.4
Surgical cap	**152**	**69.7**

Table 2: Type of dermatoses

Type of dermatoses	No. of Patients	Percentage
Irritant contact dermatitis	56	25.7
Allergic contact dermatitis	28	12.8
Sweat dermatitis	84	38.5
Facial acne	86	39.4
Lip lick dermatitis	9	4.2
Retroauricular dermatitis	14	6.4
Hand dermatitis	124	56.9

Table 3 Skin-related symptoms

Symtpoms	No. of Patients	Percentage
Itching	128	58.7
Redness of skin	145	66.5
Burning	32	14.6
Pain	8	3.6
Skin tightness/ dryness	122	55.9

Table 4 Skin-related signs

Signs	No. of Patients	Percentage
Erythema	94	43.1
Erosions	40	18.3
Vesicles	37	16.9
Scaring	36	16.5
Urticaria	48	22.0
Papules	54	24.8
Pressure Indentations	64	29.4
Redness eyes	18	8.3
Lacrimation	14	6.4
Rhinorrhea	19	8.7

Figure 1: Hand dermatitis due to gloves.

Figure 2: Maskne due to mask

Figure 3: The scar on the bridge of the nose due to

Discussion

The pattern of skin changes due to COVID 19 pandemic in healthcare workers (HCW) can be classified under two broad groups: Skin changes due to hand hygiene practices (frequent sanitizer use, frequent handwashing) and skin changes due to prolonged use of personal protective equipment. In our study hand dermatitis was the commonest dermatoses observed in HCW during COVID 19 pandemic. Similar observation was noted in the study by Deoghare S et al[4},Hand hygiene practices of HCW included frequent use of alcohol based sanitizer and frequent handwashing with soaps. Soaps and sanitizers are the cheapest, effective and simplest form of defence against COVID 19. However, their excessive and non- judicious use causes depletion of normal commensal and disruption of skin barrier which predisposes to irritant and allergic contact dermatitis.. Common allergens present in soaps and antiseptic solutions are fragrances, polyethylene glycol,chloroxylenol, chlorhexidine and benzalkonium chloride. Common Irritants: (sodium lauryl sulphate) SLS, cetrimide, chloroxylenol, sodium hydroxide {5-7}. HCW use gloves which are made of different polymers including latex, nitrile, rubber, polyvinyl chloride. Preferred gloves during COVID 19 pandemic were nitrile and latex gloves due to better protection and durability[8]. HCW are susceptible to develop allergic reaction to natural rubber, thiuram, carbamix or other rubber accelerators[9]. When gloves are used for prolonged period of time they lead to increased sweating, maceration which predispose to allergic and irritant dermatitis [10]Gloves also cause worsening of the pre-existing hand dermatitis due to occlusion and maceration. The most common site involved were knuckles and web spaces because at these sites allergens and irritants tend to accumulate. One of the predisposing factor for the development of hand eczema can be presence of atopic diathesis . In our study 13.9% had the allergic predisposition.

Second common dermatosis present in health care workers was facial acne. Masks provide adequate protection from virus. Mask frequently used by health care workers were surgical mask and N95 mask. Both these mask can induce maskne (a type of acne mechanica) or can worsen pre-existing acne. Masks induce change in skin microenvironment which include dehydration, increase transepidermal water loss, sebum dysregulation and increased PH[11]. These changes are pro-comedogenic and are capable to promote *Cutibacterium acnes* multiplication, and thus induce innate immune response leading to inflammatory lesions (papules and pustules) [12]. Thus, the prolonged and continuous use of masks created a new intertrigenous area.

The most common symptom reported in our study was redness of skin (66.5%) , itching(58.7%) and dryness of skin(55.9%) . The most common sign was erythema (43.1%), pressure indentations (29.4%) and papules (24.8%). In the study conducted by Lan J et dryness and desquamation were the most common symptom (70.3%) and sign (62.2%), respectively[13].The common skin eruptions reported by Lin et al in their study were dryness or scales

(68.6%), papules or erythema (60.4%), and maceration (52.9%) [14]. In our study the most common site involved was nasal bridge(58.7%) followed by hands (50 %), chin and cheeks (42.2%). In the study of Lan the commonly affected sites were nasal bridge (83.1%) cheek (78.7%) , hands (74.5%) and forehead (57.2%) [13]. Snuggly fitted masks and goggles lead to increased pressure on anatomical points, such as nasal bridge and the zygoma leading to friction-related damage leading skin maceration and damage. Other factors which leads to skin damage are prolonged use of PPE, lack of proper cleaning. Increase occlusion and sweating also predispose to various bacterial and fungal infection [15].

Thus due to increase hand hygiene practices and PPE the prevalence of adverse skin
reactions increased in HCW and exacerbation of underlying skin conditions was has resulted from greater utilization of PPE.

Limitation

The major limitation of this study was that the results may reflect a small portion of HCW as the questionnaire was circulated via social media , HCW with skin complaints responded more and also young HCW responded more compared to senior HCW. This may had led to potentially biased reflection of the true opinions of all HCW.

Conclusion

As the pandemic has not ended yet and HCW are at higher risk. They have to wear PPE and maintain hand hygiene methods. In order to prevent skin dermatoses due to PPE certain measures can be taken .N95 mask straps should be worn on the crown of the head, so should not be sitting on top of the ears. Prophylactic dressings can be used under surgical masks (thin hydrocolloid dressing or thin foam dressing. Facial PPE should be worn correctly and also ensure the size is also correct. Face mask should be be moderately tight and gently pinch the metal clip at the bridge of the nose. Surgical mask can be worn inside o N95 mask. Line the inside of gloves with fragrance fee emollient.Use non- latex gloves, nitrile gloves. Wear layer of plastic gloves inside the latex gloves. Reverse the gloves to inside out. PPEs can be modified by using the bio friendly textiles for masks, gloves and full, PPE dresses.

References

1. Shereen MA, Khan S, Kazmi A, Bashir N, Siddique R. COVID-19 infection: Origin, transmission, and characteristics of human coronaviruses. J Adv Res 2020;24:91-8.
2. Wang C, Wang Z, Wang G, Lau JY, Zhang K, Li W. COVID-19 in early 2021: current status and looking forward. Signal Transduct Target Ther. 2021 Mar 8;6(1):114.
3. Lan J, Song Z, Miao X, Li H, Li Y, Dong L, Yang J, An X, Zhang Y, Yang L, Zhou N, Yang L, Li J, Cao J, Wang J, Tao J. Skin damage among health care workers managing coronavirus disease-2019. J Am Acad Dermatol. 2020 May;82(5):1215-1216.
4. Deoghare S, Pol D, Kothari R, Kumar A, Deora MS. Dermatological manifestations among doctors using personal protective equipment in coronavirus disease 19 pandemic: A study based on self-reported questionnaire and telephonic consultation. Clin Dermatol Rev 2022;6:42-6.
5. 6.Lachapelle JM. A comparison of the irritant and allergenic properties of antiseptics. Eur J Dermatol. 2014 Jan-Feb;24(1):3-9.
6. 7..Abdallah C. Perioperative chlorhexidine allergy: Is it serious? J Anaesthesiol Clin Pharmacol. 2015 Apr-Jun;31(2):152-4.
7. Rodriguez-Homs LG, Atwater AR. Allergens in Medical Hand Skin Cleansers. Dermatitis. 2019 Nov/Dec;30(6):336-341.
8. Kwon KT, Ko JH, Shin H, Sung M, Kim JY. Drive-through screening center for COVID-19: a safe and efficient screening system against massive community outbreak. J Korean Med Sci 2020;35(11):123
9. Bolognia JL, Schaffer JV, Cerroni L. Dermatology, 4th ed. London: Elsevier Health Sciences; 2018.
10. Tabary M, Araghi F, Nasiri S, Dadkhahfar S. Dealing with skin reactions to gloves during the COVID-19 pandemic.
11. Hua W, Zuo Y, Wan R, et al. Short-term skin reactions following use of N95 respirators and medical masks. Contact Dermatitis. 2020;83(2):115-121.
12. Jusuf NK, Putra IB, Sari L. Differences of microbiomes found in non-inflammatory and inflammatory lesions of acne vulgaris. Clin Cosmet Investig Dermatol. 2020;13:773-780.
13. Lan J, Song Z, Miao X, Li H, Li Y, Dong L, Yang J, An X, Zhang Y, Yang L, Zhou N, Yang L, Li J, Cao J, Wang J, Tao J. Skin damage among health care workers managing coronavirus disease-2019. J Am Acad Dermatol. 2020 May;82(5):1215-1216.
14. Lin P, Zhu S, Huang Y, Li L, Tao J, Lei T, *et al.* Adverse skin reactions among healthcare workers during the coronavirus disease 2019 outbreak: A survey in Wuhan and its surrounding regions. Br J Dermatol 2020;183:190-2.
15. Thatiparthi A, Liu J, Martin A, Wu JJ. Adverse Effects of COVID-19 and Face Masks: A Systematic Review. *J Clin Aesthet Dermatol*. 2021;14(9 Suppl 1):S39-S45.

Original Article

Assessment of Burden in Caregivers of Corona Positive Patients Admitted in Guru Nanak Dev Hospital Under Government Medical College Amritsar

Rajiv Arora , Khushbinder Singh, , Manmeet Kaur , Raminder Sidhu, Amarbirpal Singh

Abstract

Background & Objectives

COVID-19 was declared a pandemic on 12 March 2020 by the World Health Organization. COVID-19 pandemic causes an economic burden and affects the mental well-being of individuals. The study aimed to assess the socio-demographic profile and level of burden in caregivers of COVID-19 inpatients.

Materials & Methods

The key caregivers were interviewed using Zarit Burden Interview (ZBI) to investigate the caregiving burden in a sample of 100 caregivers of corona-positive patients admitted to Guru Nanak Dev Hospital under Govt. Medical College.

Statistical Analysis

One-way Analysis of Variance (ANOVA) was used to find the association of mean scores of Zarit Burden Interview scores with socio-demographic variables.

Results

In our study, the majority of the family caregivers of corona-positive patients in the hospital setting were males (76%), belonged to the 21-40 years age group (58%), married (64%), Sikh by religion (69%), employed (58%) and from the rural region (56%). The mean ZBI score was 59.80+/-12.29 (moderate to severe burden). The mean objective burden score was 8.81+/-2.034. The mean subjective burden score was 8.68+/-2.155. The mean score for subjective objective burden was 2.92+/-1.107. Participants in the age group <20 years and >60 years showed higher levels of objective burden ($p<0.05$) but no significant association was seen with total burden, subjective burden, and subjective objective burden ($p>0.05$). A significant association was found between subjective objective burden and type of religion, education status, and area of caregivers ($p<0.05$). No significant association was seen between gender, employment status, marital status, family type, and type of oxygen support with mean scores of zarit burden interview, objective burden, subjective burden, and subjective objective burden ($p>0.05$).

Conclusion

The results showed that caregiver burden was moderate to severe in family caregivers of COVID-19 inpatients. The mental health policymakers should consider measures to reduce the burden on family caregivers of COVID-19 patients

JK-Practitioner2022;27(4):94-98

Introduction

Corona viruses were discovered in 1965 and have continued to be studied until the mid-1980s.Coronaviruses exist naturally in mammals and birds and belongs to the Coronaviridae family. So far seven human-transmitted corona viruses have been identified. It includes many viruses from common cold virus to more serious diseases such as severe acute respiratory syndrome (SARS), Middle East respiratory syndrome (MERS), and COVID-19[1].

The COVID-19 species became widespread in Wuhan, China in December 2019.The disease has been declared as a pandemic on 12 March 2020 by the World Health Organization. The first case of COVID-19 infection in India was reported from Kerala on January 30, 2020 in a 20 years old female who returned from Wuhan city, China to India [2].

Author Affiliations

Rajiv Arora ,Associate Professor, **Khushbinder Singh,** Assistant Professor **, Manmeet Kaur , Amarbirpal Singh ,**Senior Residents, **Raminder Sidhu,** Psychiatric Social Worker: Psychiatry Department , Govt. Medical College, Amritsar.

Correspondence

Dr. Khushbinder Singh, Assistant Professor, Psychiatry Department ,Govt. Medical College, Amritsar.
Email ID: dhotindia@gmail.com
Mobile no.: 98786-78860

Indexed

EMBASE ,SCOPUS, IndMED ,ESBCO ,Google Scholar besides other national and International Databases

Cite This Article as

Arora R , Singh K , Kaur M , Sidhu, R , Singh A.Assessment of Burden in Caregivers of Corona Positive Patients Admitted in Guru Nanak Dev Hospital Under Government Medical College Amritsar
JK Pract2022;27(4):94-98

Full length article available at **jkpractitioner.com** one month after publication

Keywords

Burden, COVID-19, caregivers, pandemic

Various public health measures like quarantine, social distancing and community containment were taken to further prevent the spread of pandemic. All these new measures have changed the dynamics of social relationships [3].

The pandemic has caused substantial impact on the mental health of all groups of people besides direct health impact including mortality related to the disease [4-5] . COVID-19 pandemic causes economic burden and affects the mental well-being of individuals. The disease not only affects the patients but also the caregivers and can disrupt the social and familial relationships[6].

Family caregivers are involved in patient's care and disease control during the course of an illness and its treatment. The major psychosocial stresses during COVID-19 pandemic are fear of the disease and its impact, feelings of helplessness, ambiguity about the future, anxiety, sadness, anger, grieving reactions, economic worries, psychological stress in interpersonal relationships and fear of death [7].

Care giving Intensity (CI), which is defined as the amount and type of care provided by caregivers, is also affected when a person is infected with COVID-19.[8] Caregiver Burden, defined as impact on physical and mental health, is an important concept in research. It is also affected during COVID-19 pandemic and it impacts multiple aspects of health and quality of life among informal caregivers [9,10].

A descriptive cross-sectional study was conducted by Abasat Mirzaei et al in 2020 in Iran with 210 family caregivers of COVID-19 inpatients and outpatients selected via simple randomization. Data were collected using the Zarit caregiver burden scale and a demographics form. The care burden scores were 83.2% and 80.9% in the family caregivers of inpatients and outpatients, respectively, indicating the severity of care burden for COVID-19 patients. The results showed that the mean score of care burden in the family caregivers did not differ significantly in terms of gender, age, level of education, and occupation [p> 0.05]. However, the mean score of objective, subjective, and subjective-objective caregiver burden in male family caregivers was significantly higher than those of female counterparts [p <0.01]. The mean score of total caregiver burden and its components did not differ significantly in the studied family caregivers regarding age, education level, and occupation [p> 0.05]. The mean scores of objective, subjective, and objective-subjective caregiver burden in family caregivers of inpatients were significantly higher than those of outpatient family caregivers [p <0.001] [11].

Therefore, the objectives of this exploratory study were to explore changes in burden in family caregivers of COVID-19 inpatients and to identify socio-demographic factors associated with changes in caregiver burden.

Aims and objectives

1. To find out the socio-demographic profile of key caregivers of COVID-19 patients.
2. To study the level of care giving burden in caregivers of COVID-19 patients.

Materials and methods

Type of study: The present study was cross sectional study, descriptive in nature.

Sample: After taking permission from institutional ethical committee, a total of 100 key caregivers of COVID-19 patients admitted in various COVID wards of Govt. Medical College, Amritsar were selected and studied. Precise aim of interview, nature of study was explained to the enrolled key caregivers and they were reassured about the confidentiality of the information given. All the selected key caregivers were administered the proforma containing socio-demographic profile. The key caregivers were interviewed using Zarit Burden Interview (ZBI) to investigate the care giving burden among the key caregivers. SPSS version 23.0 was used to analyze the results. One way Analysis of Variance (ANOVA) was used to find the association of mean scores of Zarit Burden Interview scores with socio-demographic variables.

Selection Criteria for Caregivers

INCLUSION CRITERIA

1. Identified as current key caregivers of COVID-19 patients admitted in corona wards.
2. Aged more than 18 years
3. Having no chronic illness since last 1 year
4. Providing written informed consent

EXCLUSION CRITERIA

1. Caregivers who had a cognitive impairment or an intellectual disability
2. Children and young people <18 years
3. Caregivers not giving consent

Instruments

Zarit Burden Interview

The Zarit Burden Interview (ZBI) is a 22-item instrument for measuring the caregiver's perceived burden of providing family care. The 22 items are assessed on a 5-point Likert scale, ranging from 0 = 'never' to 4 = 'nearly always'. Item scores are added up to give a total score ranging from 0 to 88, with higher scores indicating greater burden. The questions focus on major areas such as caregiver's health, psychological well-being, finances, social life and the relationship between the caregiver and the patient [12].

Results

The participant's socio-demographic characteristics are presented in Table 1. The caregivers of COVID-19 patients were distributed over a range of demographic subgroups. Majority of caregivers were males (76%) (Figure 1A). The majority of caregivers belong to 21-40years age group followed by 41-60 years age group. 56% of caregivers belong to rural region. Majority of caregivers were married (64%). 33% caregivers were studied up to middle class followed by illiterate group (21%). Majority of patients were employed (58%). 51% caregivers belonged to nuclear families while 48% caregivers belonged to joint families. 81% of patients who were admitted in hospital, were without oxygen mask while 10% were on Non Rebreather Mask (NRB), 4% patients were on ventilator support while 3% patients were on Non Invasive Ventilation (NIV), 2% patients were on high flow oxygen mask (Figure 1B).

Other Observations

Association between age of caregivers, religion, education status, locality of caregivers and mean scores of zarit burden interview, objective burden, subjective burden and subjective objective burden**.**

Participants in age group <20 years and >60 years showed higher levels of objective burden ($p<0.05$) but no significant association was seen with total burden, subjective burden and subjective objective burden ($p>0.05$). No significant association was found between mean scores of zarit burden interview, objective burden and subjective burden with religion, education status and area of caregivers ($p>0.05$).

Table 1:Distribution of caregivers on socio- demographic variables

CATEGORY	VARIABLES	FREQUENCY	PERCENTAGE (%)
Gender	Male	76	76
	Female	24	24
Age	0 – 20 yrs	5	5.0
	21 – 40 yrs	58	58.0
	41 – 60 yrs	34	34.0
	>60 yrs	3	3.0
Religion	Sikh	69	69.0
	Hindu	30	30.0
	Muslim	0	0.0
	Christian	1	1.0
Area	Rural	56	56.0
	Urban	44	44.0
Marital Status	Never Married	33	33.0
	Married	64	64.0
	Divorced	0	0.0
	Widow/Widower	2	2.0
	Separated	1	1.0
Education	Illiterate	21	21.0
	Literate	10	10.0
	Primary	15	15.0
	Middle	33	33.0
	10^{th} - 12^{th}	17	17.0
	Graduation	4	4.0
	PG	0	0.0
Employment	Employed	58	58.0
	Unemployed	39	39.0
	Student	3	3.0
Family Type	Joint	48	48.0
	Nuclear	51	51.0
	With Friends	0	0.0
	Any other	1	1.0
	Alone	0	0.0
Type of Oxygen Support	Without Oxygen Mask	81	81.0
	Non Rebreather Mask (NRB)	10	10.0
	High Flow Oxygen mask	2	2.0
	Non Invasive Ventilation (NIV)	3	3.0
	Ventilator	4	4.0

Table2.Assessment of mean scores of Zarit Burden Interview (N=100).

Variable	Mean	SD
Zarit Burden Interview	59.80	12.291
Objective Burden	8.81	2.034
Subjective Burden	8.68	2.155
Subjective objective Burden	2.92	1.107

The mean scores for each component of zarit burden interview (ZBI) are presented in table 2. The mean ZBI score was 59.80+/-12.29. The mean objective burden score was 8.81+/-2.034. The mean subjective burden score was 8.68+/-2.155. The mean score for subjective objective burden was 2.92+/-1.107.

Fig 1 Percentage Severity of Burden

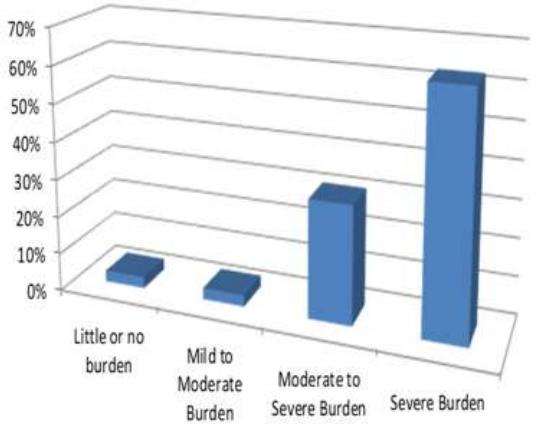


Figure 1 shows the percentage of caregivers on different severity of Zarit Burden Interview scores. Little or no burden was shown by 3%. Mild to moderate burden was shown by 3%. 31% of caregivers showed moderate to severe burden and 63% of caregivers showed severe burden.However, a significant association was found between type of religion, education status, area of caregivers and subjective objective burden ($p<0.05$).

Association between gender, employment status, marital status, family type, type of oxygen support and means scores of Zarit burden interview, objective burden, subjective burden and subjective objective burden.

No significant association was seen between gender, employment status, marital status, family type, type of oxygen support and mean scores of Zarit burden interview, objective burden, subjective burden and subjective objective burden ($p>0.05$).

Discussion

Apart from person infected with COVID-19, mental health and psychological well-being of family members, friends and relatives is also affected. Family caregivers, who are involved in a patient care during the course and treatment of an illness, sometimes feel burdened. COVID- 19 infection imposes both objective and subjective burden in family caregivers [7].

A search through available databases reveals only one study examining the care burden in family caregivers of COVID-19 patients, although there were studies on the care burden of caregivers in other chronic diseases.

In our study, 76% of the family caregivers of corona positive patients in the hospital setting were males, 58% belonged to 21-40 years age group, 64% were married, 69% were Sikh by religion, 58% were employed and 56% belonged to rural region. A descriptive cross-sectional study was conducted in in Iran in 2020 by Abasat Mirzaei et al with 210 family caregivers of COVID-19 inpatients and outpatients. In this study, 60% family caregivers of inpatients

Outcome variable	Independent variable	Frequency	Mean	Standard Deviation	Fisher value	P value
Zarit Burden Interview	0 – 20 yrs	5	52.80	11.476	2.039	0.114
	21 – 40 yrs	58	58.10	14.361		
	41 – 60 yrs	34	63.32	7.048		
	>60 yrs	3	64.33	8.327		
Objective Burden	0 – 20 yrs	5	10.20	1.483	3.283	0.024
	21 – 40 yrs	58	8.33	2.227		
	41 – 60 yrs	34	9.29	1.548		
	>60 yrs	3	10.33	.577		
Subjective Burden	0 – 20 yrs	5	9.40	1.517	.362	0.781
	21 – 40 yrs	58	8.52	2.226		
	41 – 60 yrs	34	8.82	2.181		
	>60 yrs	3	9.00	1.732		
Subjective objective Burden	0 – 20 yrs	5	2.40	1.517	1.451	0.233
	21 – 40 yrs	58	2.86	1.161		
	41 – 60 yrs	34	3.00	.953		
	>60 years	3	4.00	.000		
Zarit Burden Interview	Sikh	69	60.62	12.221	.550	0.579
	Hindu	30	57.83	12.638		
	Christian	1	62.00	.		
Objective Burden	Sikh	69	9.03	2.014	1.525	0.223
	Hindu	30	8.37	2.042		
	Christian	1	7.00	.		
Subjective Burden	Sikh	69	8.70	2.303	.303	0.740
	Hindu	30	8.70	1.822		
	Christian	1	7.00	.		
Subjective objective Burden	Sikh	69	3.12	.948	3.801	0.026
	Hindu	30	2.47	1.332		
	Christian	1	3.00	.		
Zarit Burden Interview	Illiterate	21	63.95	7.324	1.497	0.198
	Literate	10	65.20	4.962		
	Primary	15	58.93	10.046		
	Middle	33	57.27	13.307		
	10^{th} - 12^{th}	17	58.88	15.740		
	Graduation	4	52.50	22.472		
Objective Burden	Illiterate	21	9.81	1.365	1.603	0.167
	Literate	10	9.20	1.229		
	Primary	15	8.33	1.759		
	Middle	33	8.55	2.251		
	10^{th} - 12^{th}	17	8.41	2.647		
	Graduation	4	8.25	1.708		
Subjective Burden	Illiterate	21	9.19	1.990	1.176	0.327
	Literate	10	9.40	1.174		
	Primary	15	8.27	2.314		
	Middle	33	8.82	2.023		
	10^{th} - 12^{th}	17	7.82	2.811		
	Graduation	4	8.25	1.708		
Subjective objective Burden	Illiterate	21	3.38	.740	2.948	0.016
	Literate	10	3.40	.843		
	Primary	15	2.60	1.242		
	Middle	33	2.97	.918		
	10^{th} - 12^{th}	17	2.53	1.281		
	Graduation	4	1.75	2.062		
Zarit Burden Interview	Rural	56	60.23	12.513	.156	0.694
	Urban	44	59.25	12.124		
Objective Burden	Rural	56	8.89	2.077	.210	0.648
	Urban	44	8.70	1.995		
Subjective Burden	Rural	56	8.64	2.292	.037	0.847
	Urban	56	8.73	1.993		
Subjective objective Burden	Rural	56	3.18	.876	7.390	0.008

Table 3:One Way ANOVA for ← sociodemographic variables regarding ZBI

were males, 46.3% belonged to 31-40 years age group [11]. In another study which was done in Spain to assess the psychological impact of COVID-19 pandemic in 3055 adults, most participants were of young adults age (mean age 32.15 years), married (38%), employed or self-employed (53.2%) and well educated (72%) [13]. It was a community based study in general population while our study included participants who were family caregivers in hospital based corona positive inpatients, which may be the reason for different demographic characteristics of participants.

In our study, the mean ZBI score was 59.80+/-12.29. This means family caregivers feel moderate to severe burden, while caring for the patients infected with COVID-19. The mean objective burden score was 8.81+/-2.034. The mean subjective burden score was 8.68+/-2.155. The mean score for subjective objective burden was 2.92+/-1.107. According to the results of the study done by Abasat Mirzaei et al., the caregiver burden was severe in family caregivers, both of inpatients [83.2%] and outpatients [80.9%], with no significant difference between the groups. The mean scores of objective, subjective, and objective-subjective caregiver burden were significantly higher in family caregivers of inpatients than those of outpatients[11].

In our study, although males has higher scores in total caregiver burden and its components but no significant association was seen between gender of caregivers and mean scores of zarit burden interview, objective burden, subjective burden and subjective objective burden ($p>0.05$).In a study done by Abasat Mirzaei et al to evaluate burden in 210 family caregivers of COVID-19 patients, the results showed that the mean score of care burden in the family caregivers did not differ significantly in terms of gender. However, the mean scores of objective, subjective, and subjective-objective caregiver burden in male family caregivers were significantly higher than those of female counterparts [$p <0.01$][11].

No significant association was seen between age of caregivers and total burden, subjective burden and subjective objective burden scores ($p>0.05$). No significant association was found between mean scores of zarit burden interview, objective burden, subjective burden and subjective objective burden with employment status ($p>0.05$). No significant association was found between mean scores of zarit burden interview, objective burden and subjective burden with education status ($p>0.05$). The results of the study done by Abasat Mirzaei et al also showed that the mean score of total caregiver burden and its components did not differ significantly in the studied family caregivers regarding age, education level, and occupation [$p> 0.05$][11].

This study has several limitations. First limitation is that it was a cross sectional study. Cross sectional study design is an inferior study design as compared to longitudinal study which limitates the implications of the study. Secondly, in our study, nature of participation was voluntary which results in selection bias because it is possible that caregivers of corona positive patients, who were more stressed, may have not participated in the study, thus affecting generalizability of findings. Third, in our study we did not compare the levels of caregiver burden of corona positive patients to caregivers of patients with other medical and surgical illnesses. Further, future follow-up of the same population will enable us to identify risk
and protective factors for the persistent and evolution of mental health consequences in patients with COVID-19 and their relatives.

Conclusion

The results showed that caregiver burden was moderate to severe in family caregivers of COVID-19 inpatients. Due to emergence of COVID-19 pandemic, its novelty and limited information about the disease and the high incidence of the disease, mental health policy makers should consider measures to reduce burden in family caregivers of COVID-19 patients.

Acknowledgments

Financial Support Received: None

Conflict of Interest: None declared

References

1. Weiss SR, Navas-Martin S. Coronavirus pathogenesis and the emerging pathogen severe acute respiratory syndrome coronavirus. Microbiol Mol Biol Rev 2005;69(4):635-664
2. Andrews MA, Areekal B, Rajesh KR, Krishnan J, Suryakala R, Krishnan B, et al. First confirmed case of COVID-19 infection in India: A case report. Indian J Med Res 2020;151:490-492
3. De Luca R, Calabrò RS. How the COVID-19 pandemic is changing mental health disease management: the growing need of telecounseling in Italy. Innov Clin Neurosci 2020;17(4-6):16
4. Pfefferbaum B, North CS. Mental health and the Covid-19 pandemic. N Engl J Med 2020;383(6):510-512
5. Sharma A. Estimating older adult mortality from COVID-19. J Gerontol B Psychol Sci Soc Sci 2021;76(3):e68-74
6. Arnout BA, Al-Dabbagh ZS, Al Eid NA, Al Eid MA, Al-Musaibeh SS, Al-Miqtiq MN, et al. The effects of corona virus (COVID-19) outbreak on the individuals' mental health and on the decision makers: A comparative epidemiological study. Int J Res Med Sci 2020;9(3):26-47
7. World Health Organization. Home care for patients with suspected novel coronavirus (nCoV) infection presenting with mild symptoms and management of contacts. Interim guidance. 2020. Available at: https://apps.who.int/iris/handle/10665/33067
8. Jacobs JC, Laporte A, Van Houtven CH, Coyte PC. Caregiving intensity and retirement status in Canada. Soc Sci Med 2014;102:74-82
9. Lightfoot E, Moone RP. Caregiving in times of uncertainty: Helping adult children of aging parents find support during the COVID-19 outbreak. J Gerontol Soc Work 2020;63(6-7):542-552
10. Pucciarelli G, Vellone E, Savini S, Simeone S, Ausili D, Alvaro R, et al. Roles of changing physical function and caregiver burden on quality of life in stroke: A longitudinal dyadic analysis. Stroke 2017;48(3):733-739
11. Mirzaei A, Raesi R, Saghari S, Raei M. Evaluation of Family Caregiver Burden among COVID-19 Patients. The Open Public Health J 2020;13:808-814
12. Philip Yap B. Validity and Reliability of the Zarit Burden Interview in Assessing Caregiving Burden. Ann Acad Med Singap 2010;39(10):758-763
13. Rodríguez-Rey R, Garrido-Hernansaiz H, Collado S. Psychological Impact and Associated Factors During the Initial Stage of the Coronavirus (COVID-19) Pandemic Among the General Population in Spain. Front. Psychol 2020;11:1540

Case Report

Opening the Pandora Box of a Drug Addict Through Fundus Examination

Navni Garg, Mohd Saif, Shagil Khan,Abdul Waris

Abstract

We present a case of an intravenous drug abuser who got multiple system involvement including retinopathy along with acquiring HIV and HCV infection.

JK-Practitioner2022;27(4):99-101

Intravenous drug abuse (IVDA) in youth can involve all systems. Talc retinopathy is a well-established ocular finding in longterm intravenous drug users [1].The retinal deposits usually pose only a minimal threat to vision [2]. IDA-associated infective endocarditis (IE) represents a considerable proportion of overall cases of IE, mainly affecting young people [3]. HIV-positive IVDAs have a higher ratio of right-sided IE and *Staphylococcus aureus* IE than HIV-negative IVDAs [4]. Intravenous drug use increases infective endocarditis risk through a variety of mechanisms. Drug may contain particulate matter (e.g. talc) that damage cardiac valves if injected intravenously. In addition, poor injection hygiene and injecting contaminated drug solutions can introduce high circulating bacterial loads [5]. In intravenous drug users (IDUs), the incidence of IE is 2%–5% and it is responsible for 5%–10% of deaths [6]. It can cause a characteristic crystalline maculopathy [2].Talc is a filler in oral medications such as methylphenidate as well as narcotics such as heroin, and is commonly described as an embolic phenomenon affecting the retinal arteries and capillaries [1].Talc particles first embolize the pulmonary vasculature. After months to years of repeated injections, collateral vasculature develops, allowing particles to enter the systemic circulation and embolize to other organs such as the eye. In addition to ocular complications, intravenous drug abusers are at high risk for contracting various infections and the development of pulmonary and cardiovascular diseases[7]. Both HIV and HCV can be spread through body fluids. Certain behaviours like sharing injecttion equipment can lead to transmission of such pathogens [8].

To the best of our knowledge we could not find a plethora of such findings in any drug addict among available literature. Here it is a rare report with vital message for medical fraternity. In this report, we describe an intravenous drug abuser who got multiple system involvement including retinopathy along with acquiring HIV and HCV infection.

Case report

A 20 years young male presented to the Emergency department with fever for 2 months and altered sensorium for 3 days. Considering the provisional diagnosis of meningoencephalitis, patient was started on empirical treatment and was referred to our Institute of Ophthalmology for fundus evaluation to look for signs of raised intracranial tension.

Fundus examination of each eye revealed normal disc and vessels with small, glistening white particles that were scattered throughout posterior poles suggestive of talc retinopathy(figure 1) along with multiple roth spots (figure 2) and multifocal active choroiditis.

Physical examination revealed neck rigidity, left hemiplegia and early mid systolic murmur at mitral valve. He also started developing irregular, non-tender, erythematous, hemorrhagic macules on the palm and soles bilaterally, suggestive of janeway lesions (figure 3). Few days later, he gave a history of intravenous drug abuse for 3.5 years.

Author Affiliations
Navni Garg, Mohd Saif, Shagil Khan,Abdul Waris:
Institute of Ophthalmology, JNMCH, AMU, Aligarh , India

Correspondence
Dr. Abdul Waris, FICO (UK), FICS (USA), FRCS (Edin), FRCS (Glasgow), VR Faculty, Institute of Ophthalmology, JNMCH, AMU, Aligarh:
waris_eye@yahoo.co.in , *a.waris@amu.ac.in*

Indexed
EMBASE ,SCOPUS,IndMED, ESBCO, Google Scholar besides other national and International Databases

Cite This Article as
Garg N, Saif M , Khan S,Waris A.Opening the Pandora Box of a Drug Addict Through Fundus Examination
JK Pract2022;27(4):99-101

Full length article available at **jkpractitioner.com** one month after publication

Keywords
Intravenous drug abuse (IVDA), HIV and HCV

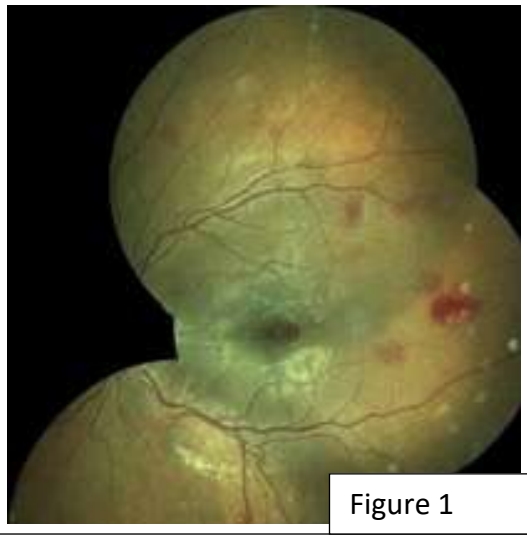


Figure 1

Lab parameters came out to be positive for Human Immunodeficiency virus (HIV) and Hepatitis C virus (HCV). Echocardiography revealed infective endocarditis with large vegetation on mitral valve. Contrast enhanced MRI brain was suggestive of meningitis with ring enhancing Lesion (Figure 4) and ultrasonagraphy of the abdomen showed multiple splenic abscess. Blood parameters showed lymphocytosis, hypochromic anemia with thrombocytopenia, renal and liver function test were also deranged along with increased fibrin degradation products and d-dimer values. Blood culture was positive for methicillin resistant Staphylococcus aureus. Chest X-ray was normal and sputum examination for acid fast bacilli was negative. Gram staining of sputum suggested gram positive cocci. Patient was diagnosed as people living with

HIV/AIDS with Hepatitis C with intravenous drug abuse with native mitral valve infective endocarditis with multiple septic emboli with septic acute kidney injury with disseminated intravascular coagulation with disseminated tuberculosis with bilateral talc retinopathy. He was kept nil per oral during his admission in the hospital and was treated with injectable vancomycin, paracetamol, pantoprazole, ondansetron, dexamethasone, dextrose, vitamin K etc. Anti-tubercular treatment (ATT) was started and anti-retroviral treatment was commenced two weeks after ATT. Two units packed red blood cells and three units fresh frozen plasma were also transfused. After 15 days of hospital stay, patient was discharged in improved and satisfactory clinical conditions with allowance of oral intake.

Figure 2

Figure 3

Discussion

There has always been a strong association in intravenous drug abusers and infective endocarditis. The tricuspid valve is the most frequently affected (60% to 70%), followed by the mitral and aortic valves (20% to 30%); pulmonic valve infection is rare (< 1%). More than one valve is infected in 5% to 10% of cases.5

But in this case, mitral valve involvement was found to be evident on physical examination and echocardiography. Another striking feature in this case was the fundus examination which provided a gateway

to the diagnosis of infective endocarditis because of the presence of roth spots along with long term history of intravenous drug abuse and janeway lesions. Also, presence of multifocal choroiditis in the fundus examination and ring enhancing lesion on contrast enhanced MRI led to the additional diagnosis of disseminated tuberculosis which led to the commencement of anti tubercular treatment. Fundus examination also revealed small, glistening white particles that were scattered throughout both posterior poles suggestive of talc retinopathy. Talc

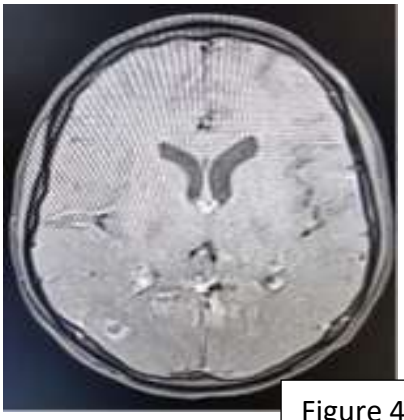


Figure 4

particles first embolize the pulmonary vasculature. After months to years of repeated injections, collateral vasculature develops, allowing particles to enter the systemic circulation and embolize to other organs [9]. Various deranged blood parameters were suggestive of multiple system involvement as septic acute kidney injury and disseminated intravascular coagulation.

Proper diagnosis was made possible due to collaborative approach of physicians and ophthalmologists which led to appropriate management of the patient to which he responded both physically and clinically.

Conclusion

Intravenous drug abusers put themselves at risk for contracting or transmitting viral infections such as human immunodeficiency virus (HIV), acquired immune deficiency syndrome (AIDS) or hepatitis mainly because of injecting drugs by sharing needles. Infective endocarditis is a common complication among injecting drug users. The retinal deposits found in talc retinopathy usually pose only a minimal threat to vision. However, these can cause retinal ischemia both in the macular region and in the peripheral retina. Fundus examination in any drug addict should be mandatory. It helped in opening a pandora's box with multiple diagnosis which led to proper management of patient. Proper photographs and records are essential to be kept for follow up. Also, before examining any drug addict, ophthalmologist must take proper universal precautions. Direct ophthalmoscopy should be avoided in such patients.

Declaration of patient consent:

The author certify that they have obtained all appropriate patient consent. The patient has given consent for his images and other clinical information to be reported in the journal. They understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Financial support and sponsorship Nil.

Conflicts of interest

There are no conflicts of interest.

References

1. Zoumalan CI, Marmor MF. Revisiting Talc Retinopathy. Arch Ophthalmol. 2007;125(7):988.
2. Ruys, Joke; de Smet, Marc D.; Van de Sompel, Wivine . Bilateral talc maculopathy and fibrovascular proliferation in a drug abuser. Retinal Cases and Brief Reports. 2010; 4(2), 123-124.
3. Scheggi V, Del Pace S, Ceschia N, Vanni F, Merilli I, Sottili E, et al. Infective endocarditis in intravenous drug abusers: clinical challenges emerging from a single-centre experience. BMC Infect Dis. 2021 Sep 27;21(1):1010.
4. Miró JM, del Río A, Mestres CA. Infective endocarditis in intravenous drug abusers and HIV-1 infected patients. Infect Dis Clin North Am. 2002 Jun;16(2):273-95, vii-viii.
5. H. Cooper, J. Brady, D. Ciccarone, et al. Nationwide increase in the number of hospitalizations for illicit injection drug use-related infective endocarditis. Clin Infect Dis, 45 (2007), pp. 1200-1203.
6. A. Weymann, T. Borst, A.F. Popov, et al. Surgical treatment of infective endocarditis in active intravenous drug users: a justified procedure? J Cardiothorac Surg, 9 (2014), pp. 58
7. Tran KH, Ilsen PF. Peripheral retinal neovascularization in talc retinopathy. Optometry. 2007 Aug;78(8):409-14.
8. Bostan N, Mahmood T. An overview about hepatitis C: a devastating virus. Crit Rev Microbiol. 2010;36(2):91–133.
9. Sharma MC, Ho AC. Macular fibrosis associated with talc retinopathy. Am J Ophthalmol 1999;128:517–519.

Case Report

Cesarean Scar Pregnancy: A case report

Nighat Firdous,Rabiya Nisar ,Muhammad Arslan Mughal,Samia Iqbal

Abstract

Cesarean scar pregnancy (CSP) is one of the rarest forms of pregnancy in which the gestational sac is implanted in a previous scar site and surrounded by myometrium and fibrous tissue[1]. The rising rate of cesarean deliveries alongside with short inter-pregnancy intervals forms one of the important risk factors associated with rising incidence of scar pregnancy. The widespread availability and use of ultrasound in diagnosis of pregnancy remains the cornerstone in the diagnosis of scar pregnancies. Cesarean scar pregnancy is a life-threatening condition which can result in scar dehiscence, uterine rupture, massive internal hemorrhage and subsequent maternal death. This article discusses the clinical presentation, risk factors, complications and treatment modalities for CSP.

The patient presented with typical symptoms of lower abdominal pain, nausea, dizziness and mild per-vaginal spotting. Her ultrasound along with doppler study revealed an 8-week gestational sac with live embryo and active trophoblastic activity in relation to scar site.

JK-Practitioner2022;27(4):102-104

Cesarean scar pregnancy is one of the rarest forms of pregnancy in which gestational sac is implanted in a previous scar site and surrounded by myometrium and fibrous tissue [1]. The various risk factors associated with CSP include multiple cesarean deliveries, short interpregnancy interval, hysterotomy, dilatation and curettage, manual removal of placenta[2]. The first case of CSP was reported in 1978 in English medical literature. The incidence of CSP varies from 1:1800 to 2216 pregnancies with rate of 0.15% in women with previous cesarean section and 6.1% of all ectopic pregnancies [2].Scar pregnancy differs from intrauterine pregnancy with placenta accreta since in placenta accreta there is absence of decidua basalis which leads to varying degree of myometrial invasion by the active trophoblastic tissue while the embryo primarily is implanted within the intrauterine cavity, however, in scar pregnancy, the gestational sac is surrounded by myometrium along with the fibrous tissue, separated from endometrial cavity.

Two types of scar pregnancies have been identified:

1. Type I: implantation in previous scar progressing towards cervicoisthmic space or uterine cavity.
2. Type II: deep implantation in scar defect followed by infiltrating growth in myometrium and serosa, which may result in uterine rupture and massive internal hemorrhage.

Case Report

A 34-year-old G3P2 female, previous 2 scars, presented at 7 weeks 3 days amenorrhea with history of self-induced abortion (by taking oral abortifacients) and per-vaginal spotting and scar line pain from 5 days along with associated history of severe nausea, vomiting and crampy abdominal pain. Patient has had previous 2 cesarean sections with short inter-pregnancy interval as 18 months and 13 months respectively. She has had scar hematoma in her second pregnancy which was explored during the intraoperative period. She has a history of abscess formation in her left breast which was incised and drained. Her menstrual cycle is regular and she has no significant history of prolonged OCP use. Her family history is significant for hypertension. Patient is non-smoker, non-addict and has no known drug allergies. On examination, patient was well oriented in time, place and person. Her vitals on presentation were was follows: BP= 100/70, pulse= 86/min,

Author Affiliations

Nighat Firdous,Department of Obstetrics & Gynaecology,LD Hospital ,Srinagar ;**Rabiya Nisar , Samia Iqbal ,**Modern Hospital ,Rajbagh

Muhammad Arslan Mughal, Rawal Institute of Health Sciences,Islamabad: J&K ,India

Correspondence

Dr.Rabiya Nisar
Modern Hospital ,Rajbagh ,Srinagar.
E mail rabiabhat123@gmail.com
6005872446

Indexed

EMBASE ,SCOPUS, IndMED ,ESBCO ,Google Scholar besides other national and International Databases

Cite This Article as

Firdous N,Nisar R ,Mughal, MA, Iqbal S.Cesarean Scar Pregnancy: A case report.JK Pract2022;27(4):102-104

Full length article available at **jkpractitioner.com** one month after publication

Keywords

Scar pregnancy, cesarean section, uterine rupture, maternal mortality

spO2= 97%, temperature= 98. 6°F.On general examination, patient was apprehensive and visibly pale. Abdominal examination revealed SFH of about 8 weeks and tenderness of scar line. Her per-vaginal examination revealed around 1 cm dilated cervical os with mild pv spotting. Her baseline investigations were as follows:

Hb= 10.2 g/dl, TLC= 10200/cumm, platelets= 122000/cumm

Hepatitis B & C = negative

HIV = negative

Blood group = A positive

Serum β-Hcg = positive

Her TVS revealed a single viable intrauterine fetal pole in lower uterine segment in relation to previous LSCS scar site with definite cardiac pulsations. Her myometrial scar site thickness= 4.5mm

No evidence of serosal or mucosal invasion.

GA as per CRL = 7 weeks 3 days.

After the patient was admitted, double IV line was secured and empiric antibiotic cover and fluid therapy was initiated along with arrangement of blood donors. All the complications and possible outcomes such as need for hysterectomy, hypovolemic shock, sepsis, DIC and death were

explained to patient and husband. Patient developed increased severity in pain along with active per vaginal bleed and associated symptoms of nausea, headache and dizziness following which patient was immediately shifted to operating room for laparotomy. On exploration, uterus was fixed to anterior abdominal wall and lateral wall. There were multiple adhesions with omentum which were cut and ligated. The bladder was high up which was carefully drawn down. Uterus was visualized which revealed an impending rupture at the scar site. The area was explored, scar freshened and re-sutured after completed removal of products of conception. Bilateral tubal ligation was done after taking consent from both patient and her husband. A drain was left in pelvis and balloon tamponade through cervix done to reduce risk of post-op bleed. Post operative period remained uneventful. Drain was removed upon minimal drainage and tamponade was removed 24 hours post-surgery. Post operative Hb= 7g/dl following which iron infusion and supplementation was advised.

Upon weekly follows, patient is doing fine and has symptomatically improved till date with steady decline in β-HCG levels.

Discussion

Cesarean scar pregnancy is one of the rarest forms of pregnancy in which gestational sac is implanted in a previous scar site and surrounded by myometrium and fibrous tissue [1]. The various risk factors associated with CSP include multiple cesarean deliveries, short interpregnancy interval, hysterotomy, dilatation and curettage, manual removal of placenta [2]. The first case of CSP was reported in 1978 in English medical literature. The incidence of CSP varies from 1:1800 to 2216 pregnancies with rate of 0.15% in women with previous cesarean section and 6.1% of all ectopic pregnancies2. Scar pregnancy differs from intrauterine pregnancy with placenta accreta since in placenta accreta there is absence of decidua basalis which leads to varying degree of myometrial invasion by the active trophoblastic tissue while the embryo primarily is implanted within the intrauterine cavity, however, in scar pregnancy, the gestational sac is surrounded by myometrium along with the fibrous tissue, separated from endometrial cavity.

Two types of scar pregnancies have been identified:

1. Type I: implantation in previous scar progressing towards cervicoisthmic space or uterine cavity.
2. Type II: deep implantation in scar defect followed by infiltrating growth in myometrium and serosa, which may result in uterine rupture and massive internal hemorrhage.
3. Presentation and diagnosis:

Patients typically present in their first trimester of pregnancy with PV bleeding and varying degree of lower abdominal pain and tenderness. There may be associated symptoms of nausea, vomiting, dehydration and in severe cases patient may present in an unconscious state and in shock, usually, hypovolemic shock secondary to massive internal blood loss.

With increasing availability and awareness of various ultrasound modalities, the diagnosis of scar pregnancy has become early and accurate. Transvaginal ultrasound imaging remains the

investigation of choice for diagnosis of CSP. The diagnosis is confirmed by typically finding and gestational sac primarily implanted in relation to scar site with no evidence of implantation/ products of conception in either the uterine cavity or the cervical canal, to differentiate it from missed or active miscarriage.

Primarily diagnosis depends on history, presenting symptoms, serum β-HCG levels and TVS.

TVS diagnosis includes following criteria [2].

I. An empty uterine cavity and cervical canal
II. A gestational sac located at the anterior wall of the isthmic portion, separated from endometrial cavity of fallopian tube in previous cesarean scar
III. A gestational sac embedded within the myometrium and fibrous tissue of cesarean section scar at the lower uterine segment with an absence of defect in the myometrium between the bladder and the sac
IV. A high-velocity low-impedance vascular flow surrounding the gestational sac

High resolution and color ultrasound, however remains very vital to differentiate scar pregnancy from anterior cervical pregnancy, inevitable abortion or a cervicoisthmic pregnancy.

In cervical pregnancy, endometrial cavity is empty and gestational sac is seen in cervix, giving a typical hour-glass shape to uterus with ballooned cervical canal.

In case of inevitable abortion, gestational sac is found in cervical canal and is typically avascular on doppler along with associated gradual fall in serum β-HCG levels.

In cervicoisthmic pregnancy, a layer of healthy myometrium can be visualized between bladder and gestational sac.

Management modalities

The main goal of management is to prevent life-threatening hemorrhage and salvage the reproductive capability of the patient along with assurance of quality health and life.

The choice of treatment varies in each case and primarily depends on patient history, gestational age at presentation, hemodynamic stability of patient, imaging results and availability of technical expertise.

The various modalities include:

A. Conservative medical management:

This method includes administration of systemic methotrexate, local embryocides such as KCL, hyperosmolar glucose or both.

Methotrexate only regimen is reserved for pregnancies of gestational age less than 8 weeks with no fetal cardiac activity. The success rate is higher when β-HCG levels are less than 5000 mIU/ml and myometrial thickness is less than 2mm.

Administration of local embryocides followed by TVS-guided aspiration of sac is also one of the effective modalities in hemodynamically stable patients. However, both these methods require close monitoring of patient due to the possibilities of side effects related to therapy such as, palpitations, nausea, pyrexia, generalized body rash. In addition to close monitoring during therapy, long term follow up is required as it may take up to 16 weeks for β-HCG levels to drop to non-pregnant levels and if high peak systolic velocity persists on doppler, these women are at higher risk of internal bleed and uterine rupture, warranting emergency management.

B. Hysteroscopic evacuation and Laparoscopic management:

This modality of management offers a vision guided evacuation of products of conception which is relatively safe. This intervention can prevent open interventions whenever suitable in terms of hemodynamic stability and availability. This method provides wide range of interventions which could be done to salvage reproductive health of patient such as, laparoscopic bilateral uterine artery ligation, wound repair and hence preservation of uterus.

C. Open surgical intervention:

This remains the method of choice for hemodynamically unstable patients as well as for patients in which other methods of intervention have failed. This method involves scar repair along with reconstruction and reinforcement of scar site to prevent further such pregnancy. However, in certain cases of uncontrolled hemorrhage, hysterectomy may be warranted to save the life of the patient.

Conclusion

Scar pregnancy is one of the rarest forms of pregnancies wherein the gestational sac gets implanted at the previous scar site. Various risk factors include, previous scars, previous check curettages or evacuations, short interpregnancy interval and myomectomy.

USG remains a very important investigation for early diagnosis and management of such condition. It can be treated conservatively, laparoscopically or by open surgical intervention depending upon the hemodynamic stability, gestational age and availability of expertise and resources.

References

1. Julio Elio jr, non-tubal ectopic pregnancy, federal university of Sao Paulo, march 25, 2020
2. Maduri Arvind Patel, scar ectopic pregnancy, J obstet gynaecol India. 2015 Dec ; 65(6): 372-375.

In Conversation With Dr. Sharad Kumar Agarwal, National President, Indian Medical Association (IMA)

Welcome: At the airport **At IMA House**

The National President, addressing the gathering

Those Who Spoke on the Occasion

Prof. GH Hajini **Prof.GM Malik**

Prof. Masood Tanvir Principal GMC, Srinagar

Prof. Saleem Khan **Prof. Ismail Quadri**

Prof.Mohd Lateef Chisti

IMA State Branch Executive Members

The National President , IMA, Dr. Sharad Kumar Agrawal on a visit to the valley, had deliberations with the members of the Kashmir Branch of IMA at the IMA House Kashmir , On 21st January, 2023.