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# Hemangiolympangioma of Testis: Case Report on Rare Entity

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## Abstract

Hemangiolympangioma (HLA) is a rare benign tumor involving both lymphatic system and blood vessels. It is also referred to as lymphatic-venous malformation. It can occur in any part of the body, most common location being head-and-neck followed by axilla. Most of these tumors are diagnosed in first 2 years of life. Clinically patients present with a slow growing painless mass. This tumor can recur locally and can invade adjacent organs resulting in serious complications. We present a very rare case of 63-year-old male with scrotal swelling with a radiological suspect of complex cyst or testicular neoplasm. Orchidectomy was performed, which showed features of HLA. By immunohistochemistry, the presence of lymphatic and vascular endothelial lining was confirmed. We document this case in view of the rare site of occurrence and its presentation in older age group.

**Key words:** Benign, Hemangiolympangioma, Male genital tract

## INTRODUCTION

Hemangiolympangiomas (HLA) is a rare lesion involving both lymphatics and blood vessels.<sup>[1]</sup> It is also referred to as lymphatic-venous malformation.<sup>[2]</sup> Although a benign condition, there is a possibility of invasion into adjacent tissues with high local recurrence rate. Common sites of involvement include axilla, abdominal cavity, and extremities.<sup>[3]</sup> Usually, it presents as a painless slow growing swelling.<sup>[4]</sup> In rare cases, it may be associated with acute onset testicular infarction or torsion with pain.<sup>[5]</sup> It is a benign vascular lesion with potential of growth by cellular proliferation and consists of abnormal development of the lymphovascular system in localized centers.<sup>[6]</sup> HLA in testis is rarely reported in the literature and hence we present this case.

## CASE HISTORY

A 63-year-old male presented with complaints of swelling in the right scrotum which was progressively increasing in size over the past 6 months. It was associated with pain on and off. Scrotal Doppler was done which showed a complex multiseptate cystic lesion in medial aspect of the right testis. The differential diagnosis of epididymal cyst or testicular neoplasm was given [Figure 1]. The right orchidectomy was performed.

On gross examination, testis was dilated with multiple cystic spaces of varying sizes filled with thick mucoid gelatinous material and extruded thin straw yellow color fluid on opening [Figure 2].

Microscopical examination showed testicular parenchyma with adjacent areas of multiple cystically dilated spaces of varying sizes lined by single layer of endothelial cells filled with lymphatic fluid [Figure 3a]. Adjacent areas also had capillary sized blood vessels lined by endothelial cells and filled with blood [Figure 3b]. Areas of infarction with adjacent dense acute on chronic inflammation were noted. Immunohistochemical stain CD34, CD31, and GLUT-

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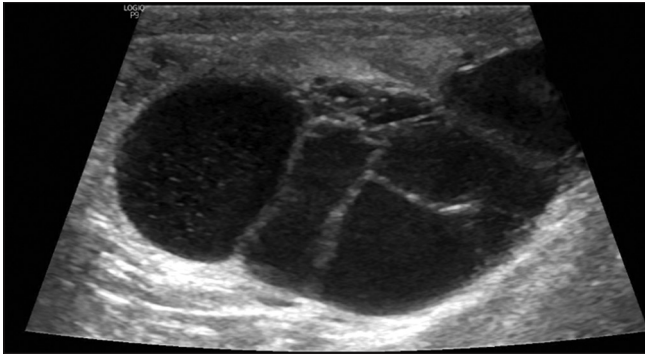
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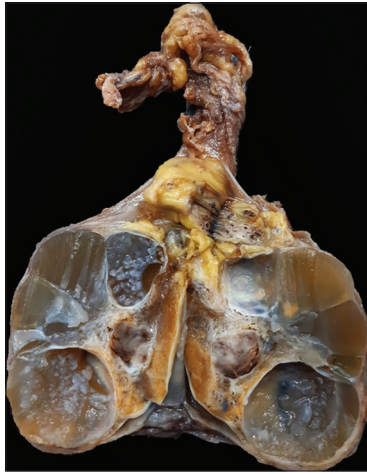
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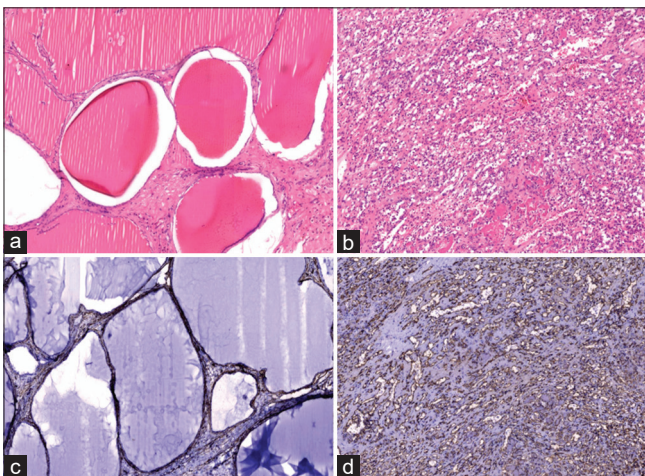
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**Figure 1: Scrotal Doppler showing complex multiseptated cystic lesion**



**Figure 2: Testis with multiple cystic spaces filled with thick gelatinous material**



**Figure 3: (a) Cystically dilated spaces filled with lymph. (b) Multiple capillary sized vessels. (c) IHC positivity for D2-40 in lymphatic and vascular endothelium. (d) IHC positivity for CD34 in vessel walls**

1 show positivity confirming the endothelial lining of blood vessels and D2-40 shows positivity in the lymphatic endothelium [Figure 3c and d]. On 2-month follow-up, the patient is stable.

## DISCUSSION

Vascular neoplasms are broadly classified into vascular tumors (hemangioma) and vascular malformations by Mulikan and Glowacki classification (1982). Lymphangiomas are further categorized into four – capillary, cavernous, cystic hygroma, and hemangiolymphangioma (HLA) by Landing and Faber.<sup>[7]</sup> HLA is a rare benign condition with involvement of both lymphatics and blood vessels. This can occur at any age and at any site of the body. Most of them are diagnosed in first 2 years of life. Frequency of occurrence decreases with age. Occurrence of HLA is more common in females than in males. The female to male ratio is 2.4:1.<sup>[3]</sup> Most common site of occurrence being head-and-neck, axilla, abdominal cavity, and extremities.<sup>[3,8]</sup> Rarely, it can occur in mediastinum, retroperitoneum, and groin. Usually, it is unifocal in origin but multifocality is not uncommon.<sup>[9]</sup>

Possible etiopathogenesis of this condition is related to embryogenesis. One theory suggests that obstruction of the venolymphatic communication between dysembryoplastic vascular tissue and systemic circulation may contribute to formation of HLA. This condition can coexist since both lymphatics and blood vessels are derived from mutual stem cells.<sup>[9]</sup> In case of lymphatic vessel, injury during trauma or surgery resulting in inadequate drainage of lymph is also considered as one of the causes for HLA.<sup>[9]</sup>

Patients usually present with swelling not associated with pain and with unknown etiology. This vascular malformations can present as a part of congenital cavernous syndrome, Klippel-Trenaunay-Weber syndrome, which includes the triad of multiple hemangiomas, asymmetric limb hypertrophy, and arteriovenous fistulas.<sup>[10]</sup> HLAs are benign vascular tumor, but propensity of invading underlying tissues is high with evidence of local recurrence. Complications depend on the affected organ, vascular compromise through obstruction, lymphedema, and even compartment syndrome.<sup>[3]</sup>

Diagnosis can be made by histopathological examination and radiology. Differential diagnosis can include hemangiopericytoma, angiosarcoma, pure hemangioma, or pure lymphatic malformations.<sup>[3]</sup> Cystic hemangioma of scrotum should also be considered as differential diagnosis if radiology reveals a cystic lesion.<sup>[11,12]</sup> Immunohistochemical markers such as D2-40 for lymphatics and CD31/CD34 for blood vessels can confirm the diagnosis. Studies mentioned that lymphatic endothelial cells also stain positive for CD34.<sup>[13]</sup>

This vascular malformations can be managed by laser therapy, embolization, sclerotherapy, electrocautery, radium implantation, cryotherapy, or complete surgical excision

which depends on anatomical site of involvement.<sup>[14]</sup> Even though this tumor has high local recurrence and a propensity for infiltration into adjacent organs, prognosis is favorable with complete resection of tumor. Recurrence is seen in 50–100% of cases if partial resection was done.<sup>[8]</sup>

## CONCLUSION

HLA is a rare benign vascular malformation which has a favorable prognosis after complete resection; however, it can have high rate of local recurrence. With the help of imaging and histopathological examination, diagnosis of this rare entity can be rendered.

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# Tuberculosis of Sternoclavicular Joint – A Case Report

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## Abstract

Tuberculosis is a prevalent disease in the Southeast Asian population. Extrapulmonary involvement is one of the major complications of tuberculosis. The involvement of the sternoclavicular joint is very rare. Here, we present a case report of a 50-year-old female with pulmonary tuberculosis and associated extrapulmonary involvement of sternoclavicular joint. We are highlighting the radiological appearance on CT and MRI which were further confirmed by histopathological examination.

**Key words:** CT, MRI, Sternoclavicular joint, Tuberculosis

## INTRODUCTION

Tuberculosis is a major health burden in Southeast Asia with an incidence as high as 60% of the global burden.<sup>[1]</sup> The commonly involved joints in tuberculosis are spine, hip joint, knee joint, foot, elbow, hand, and shoulders.<sup>[2]</sup> Sternum being resistant to infection is the least commonly affected one in tuberculosis. It is involved in <2% cases of tuberculosis.<sup>[3]</sup> Here, we present a case of pulmonary tuberculosis with sternoclavicular joint involvement.

## CASE REPORT

A 50-year-old female presented with the complaints of weight loss, fever, and evening rise of temperature for 6 months to the outpatient department. She complained of a painful swelling over the anterior part of chest on the right side for the past 3 months. On examination, the patient was afebrile. The chest swelling was tender. She was advised for routine blood tests, chest radiograph, Mantoux, and CT chest.

Her blood examination revealed erythrocyte sedimentation rate of 70 mm/h, Mantoux showed induration of 17 mm × 17 mm. Her Hb was 9 g/dl and total leukocyte count was within normal limits.

The chest radiograph (PA view) revealed ill-defined small radio-opacities diffusely scattered in bilateral lung fields after which CT chest was done.

The lung window showed multiple nodular opacities diffusely scattered in bilateral lung fields (Figure 1). A thick-walled cavity was noted in the upper lobe of the right lung. The mediastinal window revealed an ill-defined collection in the anterior chest wall adjacent to the sternoclavicular joint (Figure 2) along with multiple calcified mediastinal lymph nodes. The bone window showed mild erosion of the medial end of right clavicle and the sternum (Figure 3).

MRI chest wall was also done and showed a small collection near the right sternoclavicular joint in the intramuscular plane primarily involving the pectoralis major and extending up to the overlying subcutaneous plane. Bone edema was noted in the sternum and medial end of clavicle (Figure 4). Subsequently, she was advised FNAC from the lesion.

The histopathological examination revealed well-formed granulomas in a background of caseous necrosis confirming the diagnosis of tuberculosis. The patient was started on antitubercular treatment. On

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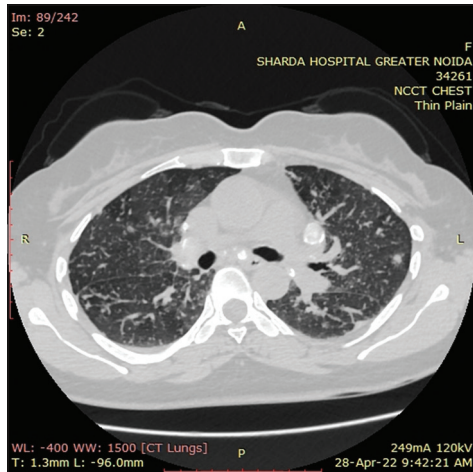


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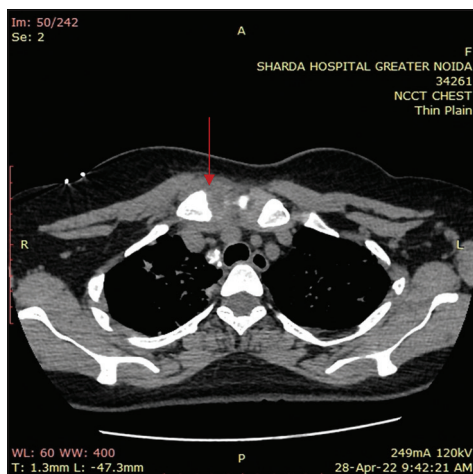
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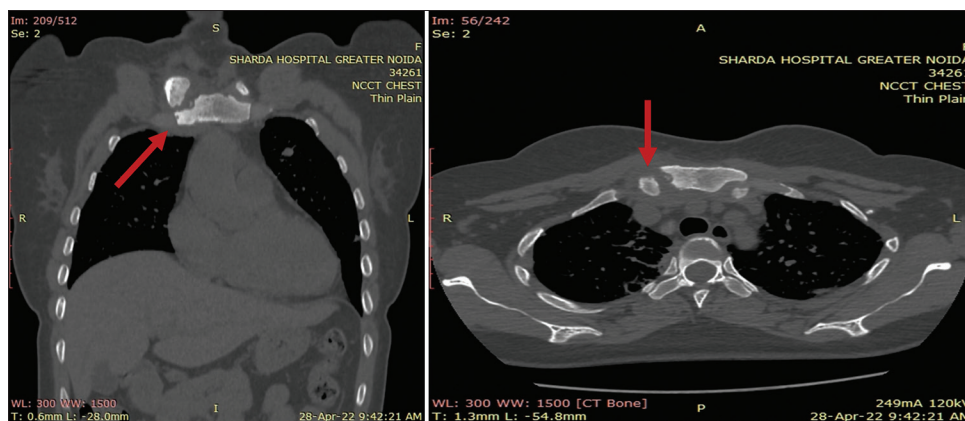
follow-up, the patient improved clinically over a period of 3 months.



**Figure 1: CT scan lung window (axial image) shows multiple nodular opacities in the upper and lower lobes on both the sides**



**Figure 2: CT scan mediastinal window (axial image) shows ill-defined soft tissue along the sternoclavicular joint on the right side (marked by red arrow). A small right paratracheal calcified lymph node is also seen**



**Figure 3: CT scan coronal and axial images (bone window) show bony erosion along the sternum and medial end of clavicle on the right side (marked by the red arrow)**

## DISCUSSION

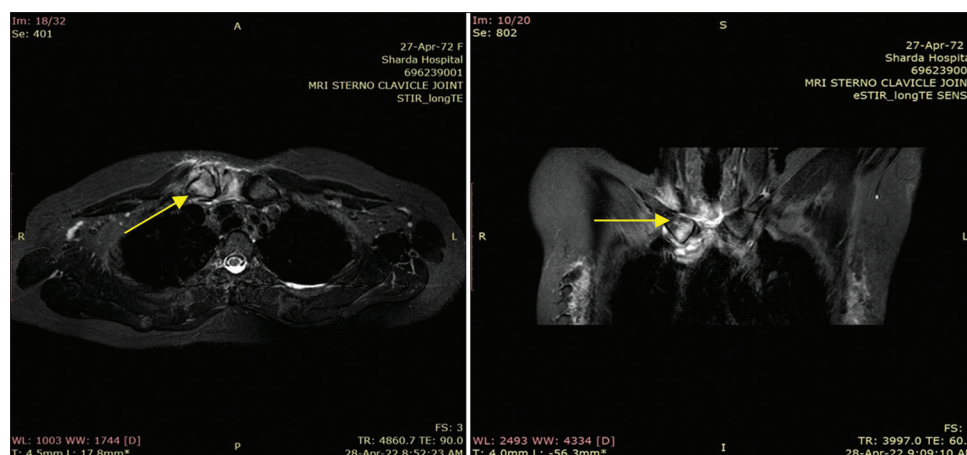
Tuberculosis can usually involve any body organ but pulmonary involvement is the most common form.<sup>[4]</sup> Osteoarticular involvement is seen in 1–3% of tuberculosis patients.<sup>[5]</sup> Sternal involvement in tuberculosis is usually due to a complication of pulmonary tuberculosis and most commonly affects middle-aged adults.<sup>[6]</sup> *Staphylococcus* has reported to be the most common pyogenic cause of sternal involvement.<sup>[4]</sup> It can be due to latent foci through hematogenous spread, lymphatic spread, or direct spread from hilar lymph nodes.<sup>[4]</sup> However, the hematogenous route is considered to be a more likely cause.<sup>[7]</sup> Tuberculosis involving the internal mammary lymph nodes can present as multiple cutaneous sinus tracts over the chest wall.<sup>[8]</sup>

Early diagnosis and treatment are essential because several complications can occur due to untreated sternal involvement including secondary infections, fistula formation, sternal fracture, tracheal compression, and possibility of its rupture into the mediastinum and pleura.<sup>[9]</sup>

CT scan is considered sensitive to detect bony destructions.<sup>[10]</sup> The common CT findings include bone loss and rarely sclerosis.<sup>[11]</sup> Soft-tissue masses and abscess with or without calcification can be the associated CT finding.<sup>[12,13]</sup> MRI is the modality of choice for delineation and soft-tissue involvement. The common findings in MRI examination are altered signal intensity in the sternum and clavicle (T1 hypointense and T2 hyperintense signal), soft-tissue changes, inflammatory signs like cellulitis, etc.<sup>[13]</sup>

Pyogenic osteomyelitis and malignancy are the common differentials for sternal tuberculosis.<sup>[1]</sup> Cartilage destruction is a feature of pyogenic osteomyelitis likely due to proteolytic enzymes while its sparing is seen in tuberculosis.<sup>[14]</sup>





**Figure 4: Magnetic resonance imaging axial and coronal STIR images show areas of hyperintense signal in the medial end clavicle along with an ill-defined collection in the soft tissue on the right side. The bone edema is marked by the yellow arrow**

The confirmation of diagnosis majorly depends on the histopathological examination. Needle aspiration is the least invasive and is the procedure of choice for the diagnosis.<sup>[4]</sup>

## CONCLUSION

Sternal involvement in tuberculosis is rare. However, when present early diagnosis using CT and MRI can be an essential tool to prevent further complications. Where CT serves as a tool for evaluation of bony destruction, MRI is essential for the assessment of soft-tissue involvement.

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# Association between Periodontitis and COVID-19 Infection: A Review Article

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## Abstract

COVID-19 is the largest epidemic of the 21<sup>st</sup> century. Virus SARS-CoV-2 causes the disease. SARS-CoV-2 (formerly nCov-19) is one of the severe acute respiratory-related coronavirus (SARS-CoV). The virus envelope is composed of a lipid bilayer, in which the membrane (M), the envelope (E), and the spike (S) structural proteins are concentrated. The molar ratio of E:S:M in the lipid bilayer is approximately 1:20:300. Periodontal dysbiosis leads to disruption of local homeostasis and immune mutations that increase microbial colonization, virulence, and disease resistance, and lead to the continuous recruitment of hyperfunctional PMN or hyperactive phenotypes. Similar to what happens in patients with COVID-19, these now inactive PMNs produce high levels of ROS and harmful enzymes as well as increasing levels of proinflammatory cytokines. Innovative methods may explain the strong interaction seen between periodontitis and COVID-19 intensity. Enthusiasm for periodontopathic viruses may exacerbate COVID-19 by inducing angiotensin-converting enzyme 2, a SARS-CoV-2 receptor, and inflammatory cytokines in the lower respiratory tract. Furthermore, it was suggested that periodontopathic viruses may increase the risk of SARS CoV-2 by cutting out its S glycoproteins and that the oral cavity, and especially the periodontal packs may act as a repository. Many studies currently appear to focus on confirming, whether the presence of periodontal disease affects COVID-19-related effects. It would be interesting, however, to see if there were any opportunities for communication between SARS-CoV-2 and the oral microbiome directly or in a phage-mediated manner.

**Key words:** COVID-19, Periodontitis, Periodontitis and COVID-19 association

## INTRODUCTION

COVID-19 is the largest epidemic of the 21<sup>st</sup> century. Virus SARS-CoV-2 causes the disease. SARS-CoV-2 (formerly nCov-19) is one of the severe acute respiratory-related coronavirus (SARS-CoV).<sup>[1]</sup> All coronaviruses are zoonotic, starting in animals, and then mutating recombination and adaptation, then passed on to humans. SARS-CoV causes acute respiratory syndrome (SARS), MERS-CoV causes Middle-East Respiratory Syndrome (MERS) and SARS-CoV-2 known as novel coronavirus causes coronavirus 2019, namely, COVID-19.

Periodontopathic bacteria stimulate the release of proinflammatory cytokines in the lower respiratory tract, and these cytokines may play a role in COVID-19.<sup>[2]</sup> It has also been suggested that periodontitis and periodontopathic bacteria can increase the oral colonization with SARS-CoV-2, and as a result, the oral cavity may act as a repository for the virus. The presence of bacteria in periodontal ulcers has been previously shown and it has been shown that periodontal pockets and plaque can carry germs, such as *Helicobacter Pylori* and *Chlamydia pneumonia*; and patients with periodontal disease are more likely to develop hospital-acquired pneumonia as a problem. Several approaches may explain the potential for oral diseases to increase lung infections, including the desire for oral diseases in the lower respiratory tract, especially in high-risk individuals.<sup>[3]</sup>

## STRUCTURE AND PROTEIN

Coronaviruses are large, almost circular particles with a distinct local view. Its magnitude varies widely between 80

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and 120 nm. Larger sizes are known from 50 to 200 nm in diameter. The total molecular weight is estimated at 40,000 kDa. They are enclosed in an envelope containing a number of protein molecules. The envelope of lipid bilayer, membrane proteins, and nucleocapsid protects the virus when it is outside the host cell.<sup>[4]</sup>

The virus envelope is made up of a lipid bilayer, in which the membrane (M), the envelope (E), and the spike (S) structural proteins are concentrated.<sup>[5]</sup> The molar ratio of E:S:M in the lipid bilayer is approximately 1:20:300. Protein E and M are structural proteins attached to the lipid bilayer to shape the virus envelope and maintain its size. S proteins are required for the interaction of host cells. However, the human coronavirus NL63 is unique in that its M-binding protein binds to the host cell, not its S protein. The diameter of the envelope is 85 nm. The virus envelope on electron micrographs looks like a separate pair of dense electric shells (shells that are almost visible in the electron beam are used to scan the virus particles) [Figure 1].

Spikes are a very distinctive feature of coronaviruses and have a look-like corona- or halo-like structure.<sup>[6]</sup> On average, a coronavirus cell has 74 surface spikes. Each spike is about 20 nm long and is composed of a S protein trimer. The S protein is made up of S1 and S2 subunits. The homotrimeric protein S is a Class I protein compound that mediates receptor binding and membrane bonding between the virus and the host cell. The S1 subunit forms the head of the spike and has a receptor-binding domain (RBD). The S2 subunit forms a stem that tightens the spike in the virus envelope and in protease activity allows for coagulation. These two subunits remain illegally connected as they are exposed to the virus site until they attach to the host cell membrane. In operation mode, three S1s are attached to

two S2 units. The subunit complex is broken down into individual units, where the virus binds and binds to the host cell under the action of protease compounds such as the cathepsin family and the transmembrane protease serine 2 (TMPRSS2) host cell.

## BIOMARKERS OF PERIODONTITIS

Periodontitis is associated with elevated serum levels of systemic inflammatory biomarkers, proteolytic and microbial biomarkers such as IL-1, IL-6, IL-10, TNF, CRP, Cystatin, ACP ALP, AST, ALT, Lactoferrin, Translactoferrin, MMP-8, MMP 9, MMP10, MMP13, Osteopontin, Fibronectin, Platelet derived factor, Vascular endothelial growth factors, IgG, and IgM. These can be found in saliva, GCF, and serum. They are all responsible for the destruction of soft and strong tissue and affect the health of the system.<sup>[7]</sup>

## BIOMARKERS FOR COVID-19

Systematic reviews and meta-analysis of Mahat *et al.* (2021)<sup>[8]</sup> have shown significant serum concentrations in CRP, ESR, PCT, IL-6, IL-10, IL-2R, ferritin, SAA, and NLR in COVID-19 difficult. Patients compared with those with weak COVID-19 patients. Similarly, they found increased levels of CRP, PCT, IL-6, ferritin, and NLR in non-survivors compared with survivors. These inflammatory parameters can help physicians quickly identify serious patients with COVID-19, which is why it is easier to start effective treatment. In addition, these inflammatory parameters can be used to predict the transition from mild to acute/critical changes in COVID-19 patients.

## PERIODONTITIS AND SYSTEMIC DISEASES

Gupta *et al.* suggested that a strong Th17 response to severe periodontitis could exacerbate the cytokine storm in COVID-19 (Gupta and Sahni, 2020).<sup>[10]</sup> Periodontitis is characterized by chronic unresolved inflammation in response to dysbiosis in subgingival biofilm (Curtis *et al.*, 2020).<sup>[11]</sup> Chronic inflammation often leads to low systemic levels and elevated levels of cytokines, such as Tumor Necrosis Factor- $\alpha$  (TNF- $\alpha$ ), Interleukin (IL) -1 $\beta$ , IL-4, IL-6 and -IL-10 (Chapple *et al.*, 2013; Acharya *et al.*, 2017),<sup>[12,13]</sup> as well as CRP and ferritin (Thounaojam, 2019).<sup>[14]</sup> Periodontitis may affect the systemic health. In fact, periodontitis has been independently associated with several NCDs, such as diabetes, heart disease, and even premature death (Sanz *et al.*, 2018; Genco and Sanz, 2020).<sup>[15,16]</sup> Periodontitis shares many risk factors with other NCDs, such as smoking, stress, unhealthy diets,

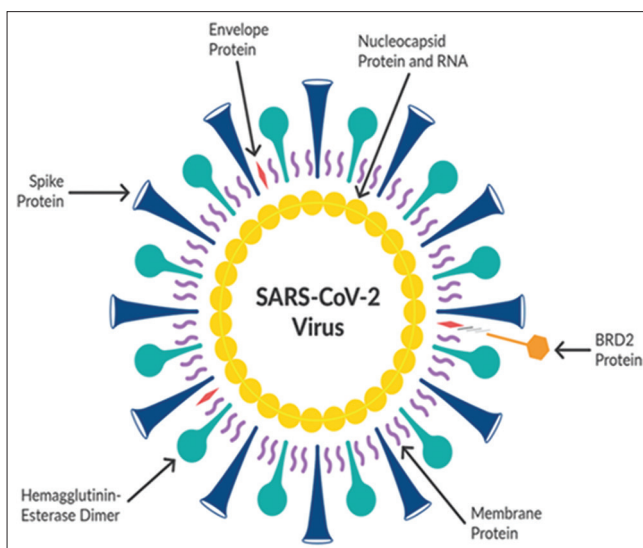


Figure 1: Structure of SARS-CoV-2 virus

glycemic control, or genetic and socioeconomic factors (Pihlstrom *et al.*, 2005; Petersen and Ogawa, 2012).<sup>[17,18]</sup> However, specific paths and pathological methods have been identified that link to specifically periodontitis these diseases, such as viral transmission (e.g., bacteremia), systemic inflammation, and autoimmune damage caused (Schenkein, Papapanou, Genco, and Sanz, 2020).<sup>[19]</sup> In addition, there is evidence that periodontal treatment leads to improved glycemic control in patients with type 2 diabetes (Teeuw *et al.*, 2010),<sup>[20]</sup> and metabolic syndrome (Montero *et al.*, 2020),<sup>[21]</sup> as well as improved kidney function associated with diabetes (Chambrone *et al.*, 2013).<sup>[22]</sup>

There are many studies that have investigated the link between periodontal disease and various diseases that have important areas of interest: Heart disease, diabetes, and the adverse pregnancy outcome. Interactions between periodontitis and many other diseases and conditions have also been reported, including respiratory illness; chronic kidney disease; arthritis; mental retardation; obesity; metabolic syndrome; and cancer. A person with a systemic disease or illness is more susceptible to COVID-19 and the complications may become lethal.

Serious cases of COVID-19 are often complicated by Acute Respiratory Distress Syndrome (ARDS), sepsis, and septic shock, leading to multiple organ damage (Yang, Yu, *et al.*, 2020).<sup>[23]</sup> Patients with severe COVID-19 and ARDS (Mehta *et al.*, 2020)<sup>[24]</sup> often exhibit improved immune responses, characterized by elevated levels of proinflammatory cytokines and widespread tissue damage; so-called cytokine storm syndrome (Yang, Shen, *et al.*, 2020).<sup>[25]</sup> COVID-19 mortality is associated with elevated serum levels of interleukin-6 (IL-6), C Reactive Protein (CRP), D-dimer, and ferritin (Ruan *et al.*, 2020),<sup>[26]</sup> suggesting clear interactions between the severity of the disease and the hyperinflammation driven by the unresolved virus. The severity of COVID-19 infection has been associated with patients suffering from comorbidities (e.g., high blood pressure, diabetes, and cardiovascular disease) (Wu *et al.*, 2020),<sup>[27]</sup> age and obesity. However, certain risk factors that lead to poor clinical outcomes have not yet been fully elucidated.

## ASSOCIATION BETWEEN PERIODONTITIS AND COVID-19 INFECTION [FIGURE 2]

Periodontal dysbiosis leads to disruption of local homeostasis and immune mutations that increase microbial colonization, virulence, and disease resistance, and result in the continuous recruitment of hyperfunctional PMN or hyperactive phenotypes. Similar to what happens in patients with COVID-19, these now inactive PMNs produce high

levels of ROS and harmful enzymes as well as increasing levels of proinflammatory cytokines. These actions lead to severe damage to the connective tissue in the affected teeth leading to pain, bleeding, and eventually loss of teeth.

Several studies have suggested the role of IL-6 in the pathogenetic pathways of COVID-19. When SARS-CoV-2 enters the respiratory tract, it triggers the release of proinflammatory cytokines, including interleukin (IL)-1 $\beta$  and IL-6. One of the mechanisms by which coronavirus kills can be the introduction of interstitial pneumonia, which is linked to excessive IL-6 production. Similarly, IL-17 has high levels in the serum of patients with COVID-19. In a recent study, an increase in IL-17, and 14 other cytokines, levels were positively associated with Murray's high rate of lung damage. Indeed, species of coronavirus have been shown to improve the adhesion of streptococcus to the epithelial cells of the respiratory tract, causing complications such as pneumonia and inflammatory lesions in the lungs and subsequent inhibition of bacterial expression. Finally, recent research has shown that intensive periodontal treatment reduces the risk of pneumonia in COVID-19 patients.<sup>[28]</sup>

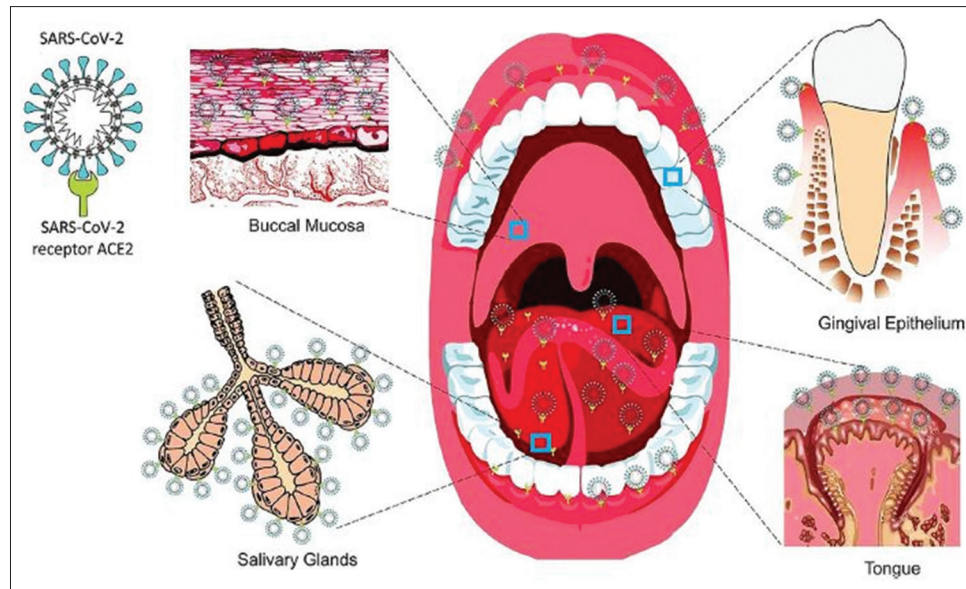
## PERIODONTITIS AND COVID-19 SEVERITY

Innovative methods may explain the strong interaction seen between periodontitis and COVID-19 intensity. Takahashi *et al.* suggested that periodontopathic viral cravings may exacerbate COVID-19 by inducing the expression of angiotensin converting enzyme 2, the SARS-CoV-2 receptor, and inflammatory cytokines in the lower respiratory tract (Takahashi *et al.*, 2020).<sup>[29]</sup> Furthermore, it was suggested that periodontopathic viruses may enhance the risk of SARS-CoV-2 by differentiating its S glycoproteins (Madapusi Balaji *et al.*, 2020; Takahashi *et al.*, 2020)<sup>[29,30]</sup> and that oral cavity, and especially periodontal pockets may act as a viral reservoir (Badran *et al.*, 2020; Bao *et al.*, 2020).<sup>[3,31]</sup> In patients with periodontitis, the expression of gingival epithelium CD-147 increases which may increase SARS-CoV-2 infiltration into cells. Similarly, microRNA-146a and 155 increase in the oral cavity during periodontitis, altering the antiviral host response. Gupta *et al.* have suggested that the production of Neutrophil Extracellular Trap is involved in the formation of both diseases (Gupta and Sahni, 2020).<sup>[10]</sup>

All of these approaches may also predict an increase in periodontal lesions, particularly necrotizing periodontal disease (NPD) during the epidemic (Patel and Woolley, 2020).<sup>[32]</sup>

Marouf *et al.* (2021)<sup>[33]</sup> found that the fatal effects of COVID-19 were significantly associated with higher





**Figure 2:** The interaction between angiotensin-converting enzyme 2 (ACE2) and SARS-CoV-2 spike protein (s) will allow viral entry, replication, and activation of innate antiviral response including proinflammatory cytokine production and infiltration of immune cells. This may result in manifestation of signs and symptoms in the oral cavity of COVID-19 patients. (b) Different sites of the oral cavity where virus and its receptors are reportedly detected including periodontal tissues, buccal mucosa, tongue, and salivary glands. COVID-19, coronavirus disease 2019; SARS-COV-2, severe acute respiratory syndrome-coronavirus-2<sup>[28]</sup>

**Table 1**

Time period	Biomarkers
<7 days	Total leucocyte count and lymphocyte count normal or slightly low ↑LDH, AST, ↑ALT, ↑CK, 1 CK-MB- may be early markers of severe disease and mortality.
7–14	Total leucocyte count and lymphocyte count progressively fall to reach nadir at 8–9 days. Thrombocytopenia may occur. ↑IL-6, IL-10, IL-1RA, and MCP-1
>14 days	Increasing total leucocyte count, lymphocyte, and platelet count predict recovery while reducing counts predict mortality.

ALT: Alanine transaminase, AST: Aspartate transaminase, CK: Creatine kinase, IL-6: Interleukin-6, LDH: Lactate dehydrogenase, MCP: Monocyte chemoattractant protein. (Samprathi *et al.* 2021).<sup>[9]</sup>

concentrations of D-dimer, WBC and CRP, and lower concentration of lymphocytes in the blood. Furthermore, patients admitted to the ICU and those in need of ventilation reported higher blood pressure levels of CRP and D-dimer. These results are consistent with the previous studies reporting high levels of inflammation in deceased patients with COVID-19 (Ruan *et al.*, 2020).<sup>[26]</sup> Interestingly, our COVID-19 cases with periodontitis also had higher levels of WBC and CRP in the serum than those without periodontitis, which may indicate a potential link through systemic inflammation. Effective treatment of periodontitis has been shown to improve the serum markers of systemic inflammation (CRP, IL-6) (D'Aiuto *et al.*, 2013),<sup>[34]</sup> as well as systemic metabolic control (Montero *et al.*, 2020) 21. If a causal link is established between the periodontal and the increased levels of

adverse effects in COVID-19 patients, then establishing and maintaining periodontal health may be an important part of the care of these patients.

## COVID-19 VACCINES

The purpose of these vaccines is to prevent infection with COVID-19. These are WHO, Moderna, Covishield, Pfizer/BioNTech, Janssen (Johnson and Oxford/Astra Zeneca, Johnson), Covaxin, BBIBP-Corv (Vero Cells), and Sinovac CoronaVac vaccines. There are also several vaccines that are under clinical evaluation. Although the current vaccines have proved to be very effective in combating (SARS-CoV-2) which has caused the epidemic, recent data have highlighted the emergence of a few mutant species. There has been uncertainty as to whether current vaccines will protect against this alternative [Table 1].

## CONCLUSION

There is a direct link between periodontal disease and the effects associated with COVID-19. However, as periodontal disease manifests and determines the systemic health, it may also play an indirect role in increasing the rate of illness directly related to the poor prognosis of COVID-19-related adverse effects. Maintaining oral hygiene continues to be important during the COVID-19 period, not only due to the direct link between periodontal inflammation and the COVID-19 but also due to the indirect system effects it may

have, to ultimately determine COVID-19-related prognosis and identification of the potential patients at risk.

Many studies currently appear to focus on confirming whether the presence of periodontal disease affects COVID-19-related effects. It would be interesting, however, to see if there were any communication between SARS-CoV-2 and the oral microbiome directly or in a phage-mediated manner.

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# Verification of Self-reporting Smoking Status by Urine Cotinine Levels in Patients of Chronic Obstructive Pulmonary Disease

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## Abstract

**Background:** Smoking is invariably one of the most common risk factors for chronic obstructive pulmonary disease (COPD). Self-reporting is the most common mode to ascertain the smoking status but it appears to be less dependable hence a need for a non-invasive marker like urine cotinine levels for determining the actual smoking status.

**Materials and Methods:** The cross-sectional study was conducted among 55 COPD patients  $\geq 40$  years attending the chest clinic and OPD in the Department of Medicine at UCMS & GTB Hospital, Delhi. Detailed history and clinical examination were done and CAT symptom score was calculated. Urine sample was collected to estimate the urine cotinine levels.

**Results:** The mean age was 61.22 years. About 89.1% (49) were male and 10.9% (6) were female. About 21.8% (12) of the participants had COPD Stage A, 29.1% (16) had Stage B, 1.8% (1) had Stage C, and 47.3% (26) had Stage D; mean urine cotinine was 48.25 ng/mL. About 65.5% (36) of cases biochemically verified to be smoking were non-smoker by self-reporting. Misreporting was 27.3% in the lower-middle class, 72.7% in upper-lower class, and 81.3% in the lower class. Disagreements between self-reported smoking status and urine cotinine-verified status were as follows – Stage A: 41.7%, Stage B: 56.2%, Stage C: 100%, and Stage D: 84.6%. Biochemically verified smoker's group had the larger proportion of participants with a history of hospital admission and was associated with higher GOLD COPD stage. The mean of CAT score was 12.95.

**Conclusion:** Urine cotinine level can be used as a reliable marker to verify the smoking status in the patients for proper management of COPD patients.

**Key words:** CAT score, Chronic obstructive pulmonary disease, Self-reported smoking, Urine cotinine

## INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is an underdiagnosed, progressive, and incurable lung disease characterized by persistent reduction in airflow. This is due to the abnormal inflammatory response of the lung to noxious particle and gases.<sup>[1]</sup> The substance in tobacco smoke, in particular, alkyl, alkenyl, peroxy, and organic free radicals, causes lipid peroxidation in plasma and

organelle membranes, leading to alteration in structure and membrane permeability and extensive membrane damage.<sup>[1,2]</sup>

Smoking cessation is a major and a cost-effective measure improving survival. Smoking cessation slows down the decline in the forced expiratory volume of air expelled in one second ( $FEV_1$ ). It restores the annual decline of breath capacity to a level approaching normal: The annual decrease of  $FEV_1$  is  $\sim 30$  ml/year for a non-smoker,  $\sim 31$  ml/year for an ex-smoker and  $\sim 62$  ml/year for a smoker.<sup>[3]</sup> In addition, smoking cessation reduces bronchial bacterial colonization and allows some recovery of the body's natural defenses, which, in turn, reduces the risk of aggravation. Finally, smoking cessation improves the effectiveness of medication, especially corticosteroids.<sup>[4]</sup>

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A major step in promoting smoking cessation is to first identify the true smoking status of the patients. Self-reporting of the true smoking status has been found to be grossly underreported so a biochemical marker needs to be used to validate the reporting, cotinine being the most preferred.<sup>[5,6]</sup> Cutoff values to biochemical verify smokers from non-smokers which vary between 31.5 and 550 ng/ml.<sup>[7,8]</sup>

COPD assessment test score (CAT) is a simple questionnaire to quantify the impact of COPD symptoms on the health status of the patients. It is positively correlated with severity of airflow limitation and is a good essay for evaluating the severity of disease, management of patient response to treatment, and prognosis.<sup>[9,10]</sup>

This study was conducted to validate the self-reported smoking status in COPD patients using urine cotinine levels and to correlate the urine cotinine levels with the CAT score.

## MATERIALS AND METHODS

### Study Setting

The study was conducted at the Department of Medicine and Department of Biochemistry at UCMS and Guru Teg Bahadur Hospital, Delhi.

### Duration of Study

The study was conducted from November 1, 2019, till October 31, 2021.

### Study Design

This was a cross-sectional study.

### Inclusion Criteria

Patients of COPD of age  $\geq 40$  years were included in the study.

### Exclusion Criteria

Subjects with the following conditions were excluded from the study:

1. Patients using other nicotine containing products (gutka, kani, etc.) or nicotine replacement therapy
2. Known case of any kidney disease or clinically having symptoms and signs suggestive of kidney disease
3. Patients not willing to participate.

### Sample Size

According to a published study, 47% of COPD patients had disagreement between the self-reported smoking status and that determined on the basis of the urinary cotinine concentration. According to the above estimate, taking into account, a relative error of 10% and confidence interval of 95%, sample size calculated was 433 COPD patients but

because of time and resource constraints, sample size was estimated to be 90. However, due to COVID pandemic and halting of regular OPD, enrolment of patients was not feasible for long duration. Hence, due to this situation, sample size was reduced to 55.

### Methodology

Fifty-five COPD patients  $\geq 40$  years of either sex in medicine department were enrolled for the study. Participants were evaluated with detailed history, examination to rule out the patients having kidney disease and to find the CAT symptom score. More than 50 ng/ml was taken as the cutoff of urine cotinine to identify current smokers.

### Consent and Ethics

Written and informed consent was taken and institutional ethical clearance was taken.

### Specimen Collection Transport and Processing

#### Urine specimen

Ten milliliters sample of urine sample was collected in sterile container and appropriately labeled. It was stored at biochemistry department laboratory where it was stored at  $-80^{\circ}\text{C}$ . After collecting the required samples, ELISA test was performed on the batch samples to estimate the urine cotinine levels.

### Statistical Analysis

Data were entered into Microsoft Excel spreadsheet and after cleaning will be analyzed using SPSS software v 20.0. Continuous variables such as cotinine levels, age, and others were presented as mean  $\pm$  standard deviation (SD); whereas, categorical variables such as accuracy of self-reported smoking status with respect to urine cotinine levels, severity status of COPD, etc., was presented as absolute and relative frequencies. The accuracy status of the self-reported smoking status among different sociodemographic groups, across various severity status of COPD was reported. The strength of correlation between urine cotinine levels and CAT score was assessed by Pearson's correlation coefficient. All tests were two tailed and  $P = 0.05$  was considered as statistically significant.

## RESULTS

The mean age was 61.22 years with SD of 8.11 among 55 patients enrolled in this study. About 89.1% (49) of the participants were male while 10.9% (6) of the participants were female. The mean smoking pack-year was 27.24. About 45.5% (25) of the participants had a history of  $\geq 1$  hospital admission while 54.5% (30) of the participants had no history of hospital admission. About 21.8% (12) of the participants had COPD Stage A. About 29.1% (16) had COPD Stage B. About 1.8% (1) had COPD Stage C.

About 47.3% (26) had COPD Stage D. The mean (SD) of CAT score was 12.95 [5.87]. Among different components of CAT score, breathlessness had maximum mean [SD] severity of 3.05 [1.06] while chest tightness had minimum mean severity of 0.53 [0.69].

The mean (SD) of urine cotinine (ng/mL) was 48.25 (22.06). The urine cotinine (ng/mL) ranged from 0.77 to 67.03.

About 3.6% (2) of the participants self-reported the smoking history while 96.4% (53) of the participants did not self-report.

As shown in Table 1, using 50 ng/ml as urine cotinine cutoff, 67.3% (37) of the participants were classified as smoker and 32.7% (18) of the participants were classified as non-smoker based on urine cotinine-verified results. About 3.6% (2) of the participants had self-reported to be currently smoking while 96.4% (53) of the participants had self-reported as not smoking.

The disagreements observed between the two methods were as follows: 65.5% (36) of cases classified to be smoker by urine cotinine were self-reported to be non-smoker. About 1.8% (1) cases classified as non-smoker by urine cotinine were reported as smoker by self-reporting. The two methods agreed in 32.7% of the cases and disagreed in 67.3% of the cases. There was poor disagreement between the two methods, and this agreement was not statistically significant (Cohen's kappa = -0.019,  $P = 0.596$ ).

In this study, disagreements between self-reported smoking status and urine cotinine-verified status within different stages of COPD were as follows – Stage A: 41.7% (5), Stage B: 56.2% (9), Stage C: 100% (1), and Stage D: 84.6% (22), as shown in Table 2. There was a statistically significant difference between the various groups in terms of distribution of misreporting ( $\chi^2 = 8.495$ ,  $P = 0.025$ ). Fisher's exact test was used to explore the association between “misreporting” and “COPD stage” as more than 20% of the total number of cells had an expected count of less than 5.

As shown in Table 3, misreporting of smoking status according to modified Kuppaswamy scale was as

follows: 27.3% (3) in the lower-middle class, 72.7% (16) in upper-lower class, and 81.8% (18) in the lower class. Chi-squared test was used to explore the association between “misreporting” and “Modified Kuppaswamy Scale.” There was a statistically significant difference between the various groups in terms of distribution of misreporting ( $\chi^2 = 10.405$ ,  $P = 0.006$ ).

In this study, biochemically verified smoker's group had 59.5% (22) of the participants with a history of hospital admission and 40.5% (15) did not have a history of hospital admission. Biochemically verified non-smoker's group had 16.7% (3) of the participants with a history of hospital admission and 83.3% (15) of the participants had no history of hospital admission, as shown in Table 4. There was a statistically significant difference between the various groups in terms of distribution of hospital admission ( $\chi^2 = 8.944$ ,  $P = 0.003$ ).

Biochemically verified smokers (patients with urine cotinine >50 ng/ml) were found to be distributed as follows: 10.8% (4) in COPD Stage A, 24.3% (9) of the participants in COPD Stage B, 2.7% (1) of the participants in COPD Stage C, and 62.2% (23) of the participants in COPD Stage D. Biochemically verified non-smokers (patients with urine cotinine ≤50 ng/ml) were found to be distributed as follows: 44.4% (8) in COPD Stage A, 38.9% (7) in COPD Stage B, 0% of the participants COPD Stage C, and 16.7% (3) of the participants in COPD Stage D. There was a statistically significant difference between the various groups in terms of distribution of COPD stage ( $\chi^2 = 12.950$ ,  $P = 0.002$ ). Biochemically verified smokers/those continuing to smoke were associated with higher GOLD COPD stage, as shown in Table 5.

**Table 2: Association between misreporting of smoking status and COPD stage**

COPD stage	Misreporting (%)			Fisher's exact test	
	Yes	No	Total	$\chi^2$	P-value
A	5 (41.7)	7 (58.3)	12 (100.0)	8.495	0.025
B	9 (56.2)	7 (43.8)	16 (100.0)		
C	1 (100.0)	0 (0.0)	1 (100.0)		
D	22 (84.6)	4 (15.4)	26 (100.0)		
Total	37 (67.3)	18 (32.7)	55 (100.0)		

**Table 1: Comparison of smoking status (self-report) with smoking status (urine cotinine)**

Smoking status	Smoking status (urine cotinine) (%)			Cohen's kappa	
	Yes	No	Total	k	P-value
Smoking status (self-report)					
Yes	1 (1.8)	1 (1.8)	2 (3.6)	-0.019	0.596
No	36 (65.5)	17 (30.9)	53 (96.4)		
Total	37 (67.3)	18 (32.7)	55 (100.0)		

**Table 3: Association between misreporting of smoking status and modified Kuppaswamy scale**

Modified Kuppaswamy scale	Misreporting (%)			Chi-squared test	
	Yes	No	Total	$\chi^2$	P-value
Lower-middle	3 (27.3)	8 (72.7)	11 (100.0)	10.405	0.006
Upper-lower	16 (72.7)	6 (27.3)	22 (100.0)		
Lower	18 (81.8)	4 (18.2)	22 (100.0)		
Total	37 (67.3)	18 (32.7)	55 (100.0)		

**Table 4: Study of association between urine cotinine-verified smoking status and history of hospital admission (n = 55)**

History of hospital admission	Urine cotinine-verified smoking status (%)			Chi-squared test	
	Yes	No	Total	$\chi^2$	P-value
Yes	22 (59.5)	3 (16.7)	25 (45.5)	8.944	0.003
No	15 (40.5)	15 (83.3)	30 (54.5)		
Total	37 (100.0)	18 (100.0)	55 (100.0)		

**Table 5: Study of association between urine cotinine-verified smoking status and COPD stage**

COPD stage	Urine cotinine-verified smoking status (%)			Fisher's exact test	
	Yes	No	Total	$\chi^2$	P-Value
A	4 (10.8)	8 (44.4)	12 (21.8)	12.950	0.002
B	9 (24.3)	7 (38.9)	16 (29.1)		
C	1 (2.7)	0 (0.0)	1 (1.8)		
D	23 (62.2)	3 (16.7)	26 (47.3)		
Total	37 (100.0)	18 (100.0)	55 (100.0)		

## DISCUSSION

This was a cross-sectional study conducted among COPD patients attending the chest clinic and OPD in the Department of Medicine at UCMS & GTB Hospital, Delhi, for a regular check-up and follow-up in which urine was taken as a sample to verify the self-reported smoking status which was obtained non-invasively and rapidly. The aim of this study was to verify self-reported smoking status in patients of COPD using urine cotinine levels and to correlate urine cotinine levels with CAT score. Although this study has been done abroad, similar study has not been done in COPD patients in India or Indian population.

In this study, the mean age (years) was  $61.22 \pm 8.11$ . The age ranged from 40 to 87 years. About 69% of the participants were above the age of  $\geq 60$  years. About 89.1% (49) of the participants were male and rest were female. The mean urine cotinine (ng/mL) was  $48.25 \pm 22.06$ .

About 3.6% (2) of the participants had reported smoking status as "Yes." About 96.4% (53) of the participants had declared their smoking status as "No."

The Calbiotech ELISA method for urine cotinine estimation recommends a cutoff value of  $>50$  ng/ml. A study done by Balhara *et al.* for verification of self-reports of the use of tobacco products also used a cutoff of  $>50$  ng/ml by ELISA method.<sup>[11]</sup> Therefore, in this study, the results were based on urine cotinine cutoff  $>50$  ng/ml to biochemically verify smoking status.

About 67.3% (37) of the participants had urine cotinine more than the cutoff and were categorized as smokers whereas 32.7% (18) of the participants had urine cotinine less than the cutoff and were categorized as non-smokers. The two methods agreed in 32.7% of the cases and disagreed in 67.3% of the cases.

The disagreements observed between the two methods using  $>50$  ng/ml urine cotinine as cutoff were as follows: 65.5% (36) of cases biochemically verified to be smoking were reported not to be smoking by self-reported smoking status. About 1.8% (1) of cases biochemically classified as non-smoker had reported to be smoking during self-reports.

The diagnostic performance of smoking status (self-report) in predicting actual smoking status (urine cotinine) was as follows: Sensitivity: 2.7%, specificity: 94.4%, positive predictive value: 50%, and negative predictive value: 32.08% with diagnostic accuracy: 32.73%.

Misreporting was maximum (81.3%) in the lower class according to modified Kuppuswamy scale. Participants in the lower class had the largest proportion of misreporting/disagreement between self-reported smoking status and urine cotinine-verified smoking status. Participants in the lower middle had the largest proportion of agreement between self-reported smoking status and urine cotinine-verified smoking status. It was observed that the higher socioeconomic class had lesser disagreement between self-reported and urine cotinine-verified smoking status in this study, statistically significant difference was observed between the various groups in terms of distribution of misreporting.

In the study by Kim *et al.* among Korean male adults, it was found that the ratio of cotinine-verified status to self-reported status tended to be greater in the groups with educational level and low household income although this correlation was not statistically significant.<sup>[12]</sup>

In this study, it was observed that patients with higher GOLD COPD stages such as C and D have more disagreement between self-reported and urine cotinine-verified smoking status as compared to GOLD COPD Stages A and B.

In the study done by Hilberink *et al.*, a cross-sectional smoking status validation study was conducted in 60 patients with COPD who initially reported that they had stopped smoking. In the analysis of urine samples, a cutoff point of 50 ng/mL of cotinine was used. About 72% (43) of patients out of 60 patients were classified by the urine cotinine test as non-smokers (median cotinine



level 13.0 ng/mL) while 28% (17) were classified as smokers (median cotinine level 134.0 ng/mL). During the time of the biochemical validation, 12 of the 17 patients, who were classified as smokers, reported that they did not and five said that they had smoked. Twelve patients (22%) out of 55 self-reported non-smokers were classified as smokers; thus, there was misreporting by 22% of patients.<sup>[13]</sup>

In a study done by Monninkhof *et al.* on COPD outpatients, it was found that patients were biochemically classified as smokers if their salivary cotinine level exceeded 20 ng/mL. At baseline out of total 188 patients, 118 self-reported as not smoking, 13.5% (16) of reported non-smokers had cotinine value more than cutoff. After 9 months of smoking cessation program, out of the 63 patients who took part and were followed, 23 patients reported abstinence but 52% (12) of these had cotinine value more than cutoff.<sup>[14]</sup>

In a cross-sectional study by Nuca *et al.* of 286 participants aged 35–44 years, the unstimulated salivary cotinine levels were measured using the NicAlert™ saliva test (Jant Pharmacal Corporation, Encino, CA, USA) with Level 0 interpreted as non-smokers, Levels 1–2 interpreted as occasional smoker, and 3–6 interpreted as active constant smokers. Of the self-reported 160 non-smokers, 113 participants had saliva cotinine in Levels 1–6, 10 self-reported occasional smokers, and 116 self-reported current constant smokers had saliva cotinine in Levels 1–6. There was a disagreement of 41% in self-reports and saliva cotinine results.<sup>[15]</sup>

In a study, Paci *et al.* done on 1075 inhabitants of Central Italy about the self-reported smoking status with urine cotinine cutoff of  $\geq 100$   $\mu\text{g/g}$  creatinine. According to the questionnaire, there were 275 smokers, but six of these present urinary cotinine levels lower than the cutoff, giving a 2.2% misclassification rating; 800 subjects declared to be non-smokers, but 26 of them present urinary cotinine levels higher than the cutoff (3.3%).<sup>[16]</sup>

In prevention of renal and vascular end-stage disease (PREVEND) a prospective cohort study by Kunutsor *et al.* on 4737 patients with mean age of 53 years. About 45.5% were men. The mean (SD) of urine cotinine was 370 (721) ng/mL. The cutoffs for urine cotinine were  $<100$  ng/mL, 100–500 ng/mL, and 500 ng/mL for the categories of never smokers, former smokers, and current smokers, respectively. Of the 1458 self-reported never smokers, 8 (0.5%) had urine cotinine concentrations consistent with active smoking; and of the 1997 self-reported former smokers, 53 (2.7%) had urine cotinine concentrations consistent with active smoking. Hence, the misclassification rate of active smokers (the number of misclassified active smokers divided by the number of

self-reported active smokers 40) was 4.8%. Furthermore, of the 3407 never smokers as assessed by urine cotinine concentrations, a majority (1887, 55.4%) were classified as former smokers by self-reports.<sup>[6]</sup>

This study suggests that patients with COPD commonly provide misinformation regarding their smoking status. In this study, there was a higher self-misreporting rate on verification by urine cotinine. The possible reasons are increased proportion of participants of age  $>60$  years, participants with low education level, low household income, and history of multiple previous visits. Analyses according to a study by Kim *et al.* showed that age older than 60 years, educational level of high school graduation or lower, multiple health check-ups, and urine cotinine levels  $<500$  ng/mL were associated with a higher discrepancy between self-reporting and cotinine-verified smoking status rates which can be explained due to face-to-face interviews which have been shown to be related to underreporting in smoking whereas paper surveys are deemed more accurate probably due to the sense of anonymity that it provides.<sup>[12]</sup>

About 1.8% of participants whose urine cotinine was lower than 50 ng/mL reported that they were currently smoking. Since the half-life of cotinine is about 18 h, it may not be detected in those who did not smoke 2 or more days before sample collection or in those attempting cessation of smoking. It was found in a study by Rebagliato that about half of the self-reported occasional smokers had cotinine values lower than cutoff.<sup>[17]</sup>

Similar discrepancy of self-reported status as smoker and urine cotinine less than the cutoff was seen in a study done in India on 131 psychiatric outpatients (male) with a mean age of 31.05 years by Balhara *et al.*, with a urine cotinine cutoff of  $>50$  ng/mL in which out of 107 self-reported non-smokers, 60 subjects have urine cotinine levels more than cutoff and 13 out of 24 self-reported smoker had urine cotinine levels less than cutoff. About 55.7% of the total self-reported smoking status was in disagreement with urine cotinine levels.<sup>[11]</sup>

In this study, the mean CAT score was  $12.95 \pm 5.87$ . There was a weak positive correlation between urine cotinine and CAT score and the correlation was not found to be statistically significant. The correlation coefficient ( $\rho$ ) between the two was 0.24 and  $p = 0.079$  was considered. According to a cross-sectional study by Karadogan *et al.* in 117 COPD patients in Turkey, it was found that current smokers are more likely to have a higher CAT score and higher CAT scores were associated with current smoking.<sup>[18]</sup> Our result of a weak positive but not statistically significant correlation could be due to less sample size.

It was also observed in our study that biochemically verified smoker's group had the statistically significant larger proportion of participants with a history of hospital admission. Biochemically verified non-smoker's group had the larger proportion of participants with no history of hospital admission. Hence, COPD patients who are continuing to smoke are more likely to be hospitalized than those who have stopped smoking.

Biochemically verified smokers/those continuing to smoke were statistically significantly associated with higher GOLD COPD stage and biochemically verified non-smokers were associated with lower GOLD COPD stage in this study. So, continued smoking likely to increase the severity of COPD.

## CONCLUSION

Urine cotinine levels are an important marker which can be used to denote and verify the actual smoking status in patients of COPD which can further help in proper diagnosis, staging the severity, proper assessment for the treatment and follow-up, and help in counseling and advising preventive therapy to reduce the hospital admissions and mortality.

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# Comparative Study of Histomorphological Features of Abruptio Placenta in Primigravida and Multigravida Mothers

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## Abstract

**Introduction:** Histopathological features give evidence about the etiopathological process of the disease. Abruptio being an important cause of perinatal mortality, histopathological features in abruptio in primi and multipara mothers were studied to know the etiopathological factors operating in them.

**Materials and Methods:** Thirty-three cases of multigravida and 17 cases of primigravida were included in the study. After obtaining consent, histomorphological features were studied from the sections of placenta, after routine hematoxylin and eosin staining. Histopathological features of acute abruptio and chronic abruptio were studied.

**Results:** Histopathological features of acute abruptio such as inter and intravillous hemorrhage, chorioamnionitis, chorioamnionitis with hemorrhage, acute deciduitis, decidual hemorrhage, and increased syncytiotrophoblastic knotting were present in all cases (100%) of primigravida. In multigravida, inter and intravillous hemorrhage and increased syncytiotrophoblastic knotting present all 33 (100%) cases. Chorioamnionitis presents in 26 (78%) cases, acute deciduitis presents only 3 (9%) cases, and decidual hemorrhage of 27 (82%) cases of multigravida. Histopathological features of chronic abruptio such as placental infarction, villitis, villous maldevelopment, maternal floor decidual necrosis, and decidual vasculopathy were present in 21(63.6%) cases of multigravida, villous infarction was seen in 15 (45.4) cases of multigravida whereas all these features of chronic abruptio were present only one case (5%) of primigravida.

**Conclusion:** This comparative study showed that the features of acute placental abruptio were seen in primigravida when compare to multigravida, the features of chronic placental abruptio were seen in multigravida.

**Key words:** Abruptio placenta, Histomorphology, Multipara, Primigravida

## INTRODUCTION

Abruptio placenta is an important cause of maternal mortality and perinatal mortality. The study of histomorphological features provide insight about the etiopathogenesis. Multigravida is a known risk for abruptio placenta<sup>[1]</sup> but abruptio occurs in primimothers also.

In abruptio, predominantly, two types of histopathological changes are seen in placenta. Chorioamnionitis, acute

deciduitis, and decidual hemorrhage suggest acute abruptio<sup>[2]</sup> and features such as placental infarction villous infarction and decidual vasculopathy, necrosis was seen in chronic abruptio.<sup>[3]</sup> In certain cases, both these features are seen suggesting acute on chronic injury.<sup>[4]</sup>

Studying the histomorphological features in primigravida and multigravida mothers with abruptio will provide the etiopathological factors operating in them and will identify the difference in etiopathogenesis if any.

## MATERIALS AND METHODS

The prospective study done in a tertiary care teaching hospital in India. Around 50 cases of abruptio placenta were included in the study. Thirty-three cases of them

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**Table 1: Histopathological features of acute abruption in primigravida and multigravida**

Histopathological features of acute abruption	Multigravida (33 cases) (%)	Primigravida (17 cases) (%)
Funisitis	12 (36.3)	8 (47)
Intervillous hemorrhage	33 (100)	17 (100)
Intravillous hemorrhage	33 (100)	17 (100%)
Chorioamnionitis	26 (78)	17 (100)
Chorioamnionitis with hemorrhage	18 (54.5)	17 (100)
Acute deciduitis	3 (9)	17 (100)
Decidual hemorrhage	27 (82)	17 (100)
Increased syncytiotrophoblastic knotting	33 (100)	17 (100)

**Table 2: Histopathological features of chronic abruption in primigravida and multigravida**

Histopathological features of chronic abruption	Multigravida (33 cases) (%)	Primigravida (17 cases) (%)
Placental infarction	21 (63.6)	1 (5)
Villitis	21 (63.6)	1 (5)
Villous infarction	15 (45.4)	1 (5)
Villous maldevelopment	21 (63.6)	1 (5)
Maternal floor decidual necrosis	21 (63.6)	1 (5)
Decidual vasculopathy	21 (63.6)	1 (5)

were multigravida and 17 cases of them were primigravida mothers.

After obtaining ethical clearance and consent, placental specimen were collected along with the clinical and demographical details of the mothers. Gross dissection done from the placental specimen followed by tissue processing and paraffin blocks were made. Histomorphological features were studied from the sections of these blocks after routine hematoxylin and eosin staining.

Histopathological features of acute abruption such as funisitis, inter and intervillous hemorrhage, chorioamnionitis, acute deciduitis, and histopathological features of chronic abruption such as placental infarction, villitis, villous infarction, villous malformation, and decidual vasculopathy were studied.

## RESULTS

In the present study, histopathological features of acute abruption such as funisitis present in 12 (36.3%) multigravida and 8 (47%) primigravida. Inter and intervillous hemorrhage, chorioamnionitis, chorioamnionitis with hemorrhage, acute deciduitis, decidual hemorrhage, and increased syncytiotrophoblastic knotting were present in all cases (100%) of primigravida. In multigravida, inter and intervillous hemorrhage and increased syncytiotrophoblastic knotting present all 33 (100%) cases. Chorioamnionitis presents in

26 (78%) cases, acute deciduitis presents only 3 (9%) cases, and decidual hemorrhage of 27 (82%) cases of multigravida.

Histopathological features of chronic abruption such as placental infarction, villitis, villous maldevelopment, maternal floor decidual necrosis, and decidual vasculopathy were present in 21 (63.6%) cases of multigravida, villous infarction was seen in 15 (45.4%) cases of multigravida whereas all these features of chronic abruption were present only one (5%) case of primigravida [Tables 1 and 2].

## DISCUSSION

Antepartum hemorrhage is an important cause of maternal mortality and adverse perinatal outcome.<sup>[5]</sup> Placenta previa and abruptio placenta are the major causes for antepartum hemorrhage.<sup>[6]</sup> Studying the histopathological features of placenta in abruptio placenta provides the major information about the etiopathogenesis of abruption.<sup>[7]</sup>

In Vaibhavi *et al.* study, the most common age of occurrence was 20–30 years, only 20% of cases were primigravida and, 80% were multigravida, denoting that the multiparity being a significant risk factor<sup>[8]</sup> In Minna Tikkanen study, placental abruption occurs most commonly in women more than 35 years, but this was attributed to multiparity ( $\geq 3$  deliveries) independent of age.<sup>[9,10]</sup> Chorioamnionitis with hemorrhage and acute deciduitis was significantly associated with placental abruption in primigravida.

Placental infarction, villitis, villous maldevelopment, and maternal floor decidual necrosis were significantly associated with placental abruption in multigravida. These were the features of acute abruption with chronic features.

Villous infarction was a significant feature of placental abruption in multigravida which was a feature associated with acute abruption with chronic features.

## CONCLUSION

This comparative study showed that the features of acute placental abruption were seen in primigravida when compare to multigravida, even though intervillous hemorrhage, intravillous hemorrhage, and increased syncytiotrophoblastic knotting are seen in both primi and multigravida. In addition to that, the features of chronic placental abruption were significantly seen in multigravida.

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# Outcomes of Tympanoplasty Among Patients of Chronic Otitis Media at Tertiary Medical College, Ajmer : An Observational Study

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## Abstract

**Introduction:** Among various autologous grafts, the following can be used: Temporalis fascia, fascia lata, periosteum, perichondrium, cartilage with and without perichondrium, veins, fatty tissue, and skin. The present study was conducted to evaluate the outcome of tympanoplasty using different types of graft.

**Materials and Methods:** A hospital-based prospective observational study was conducted in Department of ENT and Head and Neck Surgery at JLN Medical College and attached hospital, Ajmer from July 2017 to June 2019. Total 44 (88%) patients who were fulfilling inclusion criteria were included in the present study. All cases selected for the study were evaluated using preformed pro forma. Data were analyzed using Microsoft Excel.

**Results:** Ear discharge was the most common, followed by decreased hearing. Out of 44 patients, in 39 (88.6%) patients, temporalis fascia autograft was placed and in remaining 5 (11.4%) patients, tragal perichondrium was used. Most 35 (79.5%) had graft uptake and 9 (20.5%) patients rejected graft. Association of success rate with graft material was found to be statistically insignificant ( $P > 0.05$ ).

**Conclusion:** Overall graft taken up rate is around 80% in the present study. The results of graft taken up with temporalis fascia and tragal perichondrium were almost similar.

**Key words:** Graft material, Temporalis fascia, Tragal perichondrium, Tympanoplasty

## INTRODUCTION

Chronic otitis media (COM) is defined as the chronic inflammation of the mucoperiosteal lining of the middle ear cleft, that is, Eustachian tube, middle ear, aditus, and mastoid air cells which present with recurrent ear discharge through tympanic membrane perforation. It is the most common cause of hearing impairment in our country. Tympanic membrane perforation associated with COM has been considered as the major indication for tympanoplasty.<sup>[1]</sup>

Various graft materials have been used for tympanic membrane reconstruction such as temporalis fascia graft, perichondrium, vein, dura mater, cartilage, and periosteum.<sup>[2,3]</sup> Temporalis fascia is the most widely used and accepted graft as it is easy to harvest, can be harvested as much as possible in the same incision, adequately firm, and thickness, which is similar to tympanic membrane and is revision surgeries, has low basal metabolic rate so can survive for long time period, and is rich in collagen matrix.<sup>[3]</sup> In 1961, Heerman was the first to use temporalis fascia as the grafting material.<sup>[4]</sup> Tragal perichondrium was first used in tympanoplasty by Victor Goodhill in 1964.<sup>[5]</sup> It, such as a fascia, vein, and Periosteum, is a mesenchymal tissues and for that reason does not desquamate, it is thicker and stiffer than fascia or a vein.

The success rate of the most commonly used graft and fascia temporalis is between 93% and 97% in the primary tympanoplasty, especially in well-aerated middle ears.<sup>[6,7]</sup>

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In the last decade, however, there has been an increasing interest in using cartilage grafts as the primary alternative. The stiffness and strength of cartilage confer greater stability to the graft and have a key role in the resistance against shrinkage. However, there is some concern, that these same characteristics of stiffness and strength may have a negative effect on sound conduction.<sup>[7,8]</sup> The present study was conducted to evaluate the outcome of tympanoplasty using different types of graft.

## MATERIALS AND METHODS

This hospital-based and prospective observational study was conducted in the Department of ENT and Head and Neck Surgery at JLN Medical College and attached hospital, Ajmer from July 2017 to June 2019. Patients above 18 years of age of the patient who had chronic suppurative otitis media, mucosal or tubotympanic type of COM, dry ear for at least 3 weeks, and those having intact ossicular chain with conductive hearing loss were included in the study. The patient having cholesteatoma (Squamous type of COM) and those with sensory neural hearing loss were excluded from the study. Total 50 patients had the tympanoplasty during the study period, of which 44 (88%) patients who were fulfilling inclusion criteria were included in the present study. Six (12%) patients were excluded on the basis of intraoperative findings. A written and fully explained consent stating the voluntary participation of subjects in the study was taken before the enrolment of the subjects. All cases selected for the study were evaluated using preformed pro forma. A detailed history was taken including age, sex, socioeconomic status, occupation, nature, and duration of symptoms. All patients underwent thorough history and ENT examination. A battery of investigation including routine blood investigation, urine examination, X-ray mastoid B/L lateral oblique view, X-ray chest, ECG, pure-tone audiometry, Oto-telescopic examination, and examination under microscopic was performed in all patients. Tuning fork tests were performed. Quantitative hearing evaluation was performed by pure-tone audiometry. The patients were planned for surgery after proper investigations and pre-anesthetic check-up and clearance. Pre-anesthetic check-up and xylocaine sensitivity testing of all the patients were conducted. The procedure was undertaken under local anesthesia. All the surgeries were performed by retroauricular approach. Graft used was temporalis fascia and tragal perichondrium. Postoperatively, patients were given antibiotics and antihistaminic. Stitches were removed after 7 days. Clinical evaluation of subjective and objective hearing improvement following surgery with tuning fork test was done. Patients were evaluated for healing, graft uptake, and hearing. Microscopic examination was performed after 3 months to evaluate the condition

of the graft. Hearing evaluation was done by audiometry recording air conduction and bone conduction of all these patients for 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz preoperatively and after 3 months of procedure. Hearing results were reported using the guidelines recommended by the WHO and committee on hearing and equilibrium of the American Academy of Otolaryngology-Head and Neck Surgery for the evaluation of result of the treatment of conductive hearing loss. This includes reporting of the mean, standard deviation and range of the post-operative air-bone gap (AB gap), the number of decibels of change in the AB gap, and the change in high-tone bone-conduction level.<sup>[5,6]</sup> Successful outcome was defined as complete healing of the perforation.

## RESULTS

In the present study, most 35 (79.5%) patients were of 18–40 years age group and rest 9 (20.5%) were >41 years old. Around two-thirds 68.2% (30/44) patients were female and female-to-male ratio was 2.14:1. All patients had ear discharge, while second most common symptom was decreased hearing among 36 (81.8%) patients and 11 (25%) patients had earache. All patients had central perforation with more than half 26 (59.1%) had large size perforation, followed by moderate size in 13 (29.5%) and small size perforation was seen among 5 (16.4%) patients. More than half 61.4% (27/44) had hearing loss ranging from 41 to 60 dB, followed by 26–40 dB hearing loss in 29.5% (13/44) patients and least 4 (9.1%) had 61–80 dB hearing loss.

Table 1 depicts that hearing loss is proportionate to the size of perforation among patients and association of hearing loss with size of perforation was statistically significant ( $P < 0.05$ ). The grafting technique and use of grafting material were decided by the operating surgeon [Figure 1]. Among maximum 39 (88.6%) patients, temporal fascia was used as grafting material and rest 5 (11.4%) patients had tragal perichondrium as graft [Graph 1].

Table 2 among cases who had graft of temporal fascia, success rate was 79.5% and similar rate of success (80%) was seen among cases who had graft of tragal

**Table 1: Association of size of perforation with level of hearing loss**

Size	PTA			Total %	Test of Significance
	26–40 dB	41–60 dB	61–80 dB		
Small	4 (80)	1 (20)	–	5 (100)	$\chi^2=9.614$ , df=4, $P=0.047$
Medium	4 (30.8)	9 (69.2)	–	13 (100)	
Large	5 (19.2)	17 (65.4)	4 (15.4)	26 (100)	

PTA: Pure-tone audiometry



**Table 2: Association of status of graft with graft's material**

Status of graft	Type of material		Test of significance
	Temporal fascia	Tragal perichondrium	
Taken up	31 (79.5)	4 (80)	$\chi^2=0.316$ , Df=1, $P=0.574$
Rejected	8 (20.5)	1 (20)	
Total	39 (100)	5 (100)	

**Figure 1: Taken up temporalis fascia graft****Figure 2: Taken up tragal perichondrium graft**

perichondrium. Moreover, this difference in success rate was statistically not significant ( $P > 0.05$ ) [Figure 2].

Out of 44, most 79.5% (39/44) patients who had taken up graft successfully were evaluated for postoperative hearing gain. Out of 35 patients, maximum 22 (62.9%) had 11–20 dB post-operative hearing level, followed by 12 (34.3%) patients had 0–10 dB and only one (2.9%) patient had 21–30 dB post-operative hearing level. In the present study, graft rejection 9 (20.5%) and post auricular wound gaping 7 (15.90%) were main complications. Cases with

post-auricular wound gaping were treated conservatively with antibiotics and all cases did well following conservative management.

## DISCUSSION

From the beginning of ear surgery, various graft material for tympanic membrane reconstruction were tried. Graft material provides as a scaffold, on which remnant tympanic membrane grows. Temporalis fascia, tragal perichondrium, cartilage, and various other methods have been used. The present hospital-based and prospective observational study was conducted in the Department of ENT and Head and Neck Surgery at JLN Medical College and attached hospital, Ajmer from July 2017 to June 2019. The aim of the study was to study the, take up rate and hearing gain in type 1 tympanoplasty using different type of graft material.

The study consisted of 50 patients of CSOM (tubotympanic disease, dry for at least 3 weeks). Out of 50, six were excluded from the present study based on intraoperative findings. Maximum numbers of patients were seen in the age group 18–40 years in the present study (79.5%).

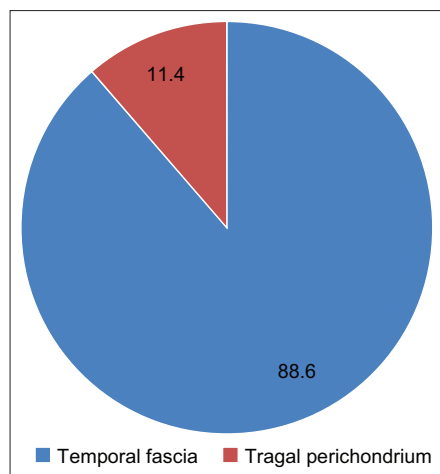
Younger patients were more in the present study; reasons may as be onset of COM early in life and patients having active life seeking early advice for deafness. In the present study, the ratio of female: male population was 2.14:1 which was comparable to the study by Thakur *et al.*<sup>[8]</sup> and Mahmud *et al.*<sup>[9]</sup>

The most common chief complaint was ear discharge (100%) which was similar to Parida.<sup>[10]</sup>

Majority of the patients operated had large perforation (59.1%) which was almost similar to the studies by Thakur *et al.*<sup>[8]</sup> and Jaiswani<sup>[11]</sup> constituting 47% and 40%, respectively.

Table 1 shows that hearing loss was proportionate to the size of perforation in majority of the patients similar to Mehta *et al.*<sup>[12]</sup> In the present study, success rate using temporalis fascia autograft and tragal perichondrium was 79.5% and 80%, respectively, though numbers of cases are small to make any conclusion [Table 2]. Singh *et al.*<sup>[13]</sup> also state that use of the different graft materials has similar results in graft up take. It can be concluded the type of graft does not alter the outcome of the surgery.

Out of 44, most 79.5% (39/44) patients who had successful graft take up were evaluated for postoperative hearing gain. In the present study, 22 (62.9%) cases had post-operative hearing levels between 11 and 20 dB, followed by 12 (34.3%) cases had post-operative hearing level between 0 and 10 dB, whereas in a study by Sergi



**Graph 1: Distribution of type of graft material**

*et al.*,<sup>[1]</sup> 46.15% cases had post-operative hearing level between 0 and 10 dB and 32.69% had hearing level ranging between 11 and 20 dB.

In the present study, post-auricular wound gapping and graft rejection were main complications which were 15.90% and 20.5%, respectively. In a study by Fukuchi *et al.*,<sup>[14]</sup> post-auricular wound gapping and graft rejection were seen in 22% and 46% of the cases.

## CONCLUSION

The present study depicted that results of graft taken up with temporalis fascia and tragal perichondrium were almost similar. Thus, it can be concluded that the success rate of graft does not depend on the type of graft.

## Limitations

The number of cases taken for study purpose is less. Further study on large population needs to be done.

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# Role of Magnetic Resonance Imaging in Differentiating the Features of Rheumatoid and Tubercular Arthritis

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## Abstract

**Introduction:** Rheumatoid arthritis (RA) is a chronic autoimmune inflammatory arthritic disease affecting about 1% of global population while tuberculosis (TB) is a disease that is being most frequently reported in the literature and musculoskeletal TB occurs in 1–3%. Differentiation between rheumatoid and tubercular arthritis is difficult as the both arthritis may not only have same clinical course but also same radiological features. The role of magnetic resonance imaging (MRI) has been advocated in characterization of both rheumatoid and tubercular arthritis and differentiation between the two.

**Materials and Methods:** The study is retrospective in nature which is conducted in the Department of Radiodiagnosis, GSVM Medical College, Kanpur, with the help of orthopedics department in a duration period from January 2020 to October 2021. The study subjects are selected based on inclusion and exclusion criteria.

**Results:** Uneven synovial thickening is visualized more in rheumatoid (88.5%) than in tubercular arthritis (32.4%) and patients with RA present with higher grade of degree of synovial thickening. Patients with tubercular arthritis have higher grade of bony erosion size as compared to RA. In tubercular arthritis (67.6%), patients show rim enhancement while in RA (15.4%), patients show rim enhancement.

**Conclusion:** In the present study, we conclude that MRI becomes unparalleled imaging in differentiating diagnosis of rheumatoid and TB arthritis when clinical and plain radiographic features are inconclusive, especially at early stage or with atypical presentation because of the excellent soft-tissue detail and the ability of contrast-enhanced T1-weighted imaging to differentiate between joint effusion and synovial thickening.

**Key words:** Musculoskeletal and oligoarticular, Rheumatoid arthritis, Spondylitis, Tubercular arthritis

## INTRODUCTION

Rheumatoid arthritis (RA) is a chronic autoimmune inflammatory arthritic disease affecting about 1% of global population.<sup>[1]</sup> It often presents with symmetrical polyarthritis commonly involving peripheral joint. It may also manifest as monoarticular disease. Early diagnosis is often difficult as serological and conventional radiological features are often absent. Tuberculosis (TB) is a disease

that is being most frequently reported in the literature. Extrapulmonary TB occurs in approximately 20% of the patients with TB. Of that, musculoskeletal TB occurs in 1–3%.<sup>[2]</sup> Spondylitis constitutes 50% of the cases followed by peripheral arthritis in 30%.<sup>[3]</sup> Peripheral tubercular arthritis is generally a monoarticular disease that typically involves large or medium sized joints such as hip or knee.

Delay in the diagnosis of the both arthritis may lead to severe joint destruction and joint deformity. Differentiation between rheumatoid and tubercular arthritis is difficult as the both arthritis may not only have same clinical course but also same radiological features such as bone erosion, joint effusion, and periarticular osteoporosis.<sup>[4]</sup> The distinction by the number of joints involved does not always hold true because early asymmetric oligoarticular involvement of RA is not rare,<sup>[5]</sup> and polyarticular involvement in tuberculous

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**Table 1: Distribution among joints**

Joint	Result		
	Rheumatoid (%)	Tubercular (%)	Total (%)
Bilateral hip	0 (0.0)	1 (2.9)	1 (1.7)
Left ankle	8 (30.8)	6 (17.6)	14 (23.3)
Left elbow	1 (3.8)	1 (2.9)	2 (3.3)
Left hip	0 (0.0)	13 (38.2)	13 (21.7)
Left knee	4 (15.4)	1 (2.9)	5 (8.3)
Left shoulder	1 (3.8)	0 (0.0)	1 (1.7)
Left wrist	3 (11.5)	0 (0.0)	3 (5.0)
Right ankle	2 (7.7)	2 (5.9)	4 (6.7)
Right elbow	1 (3.8)	1 (2.9)	2 (3.3)
Right hip	0 (0)	8 (23.5)	8 (13.3)
Right knee	2 (7.7)	1 (2.9)	3 (5.0)
Right shoulder	2 (7.7)	0 (0.0)	2 (3.3)
Right wrist	2 (7.7)	0 (0.0)	2 (3.3)
Total	26	34	60

**Table 2: Distribution of all parameters**

Grade	RA (%)	TB (%)	Total (%)
Uneven synovial thickening			
No	3 (11.5)	23 (67.6)	26 (43.3)
Yes	23 (88.5)	11 (32.4)	34 (56.7)
Degree of synovial thickening			
0	0 (0)	0 (0)	0 (0)
1	2 (7.7)	19 (55.9)	21 (35)
2	12 (46.2)	15 (44.1)	27 (45)
3	12 (46.2)	0 (0.0)	12 (20)
Size of bony erosion			
0	11 (42.3)	3 (8.8)	14 (23.3)
1	4 (15.3)	4 (11.7)	8 (13.3)
2	9 (34.6)	6 (17.6)	15 (25)
3	2 (7.6)	7 (20.5)	9 (15)
4	0 (0)	14 (41.1)	14 (23.3)
Rim enhancement of erosion			
No	22 (84.6)	11 (32.4)	33 (55)
Yes	4 (15.4)	23 (67.6)	27 (45)
Bone marrow edema			
No	7 (26.9)	10 (29.4)	17 (28.3)
Yes	19 (73.1)	24 (70.6)	43 (71.7)
Soft-tissue edema			
0	9 (34.6)	10 (29.4)	19 (31.7)
1	13 (50)	18 (52.9)	31 (51.7)
2	4 (15.4)	6 (17.6)	10 (16.7)
Extra-articular cystic lesion			
No	21 (80.8)	20 (58.8)	41 (68.3)
Yes	5 (19.2)	14 (41.2)	19 (31.7)

RA: Rheumatoid arthritis, TB: Tuberculosis

arthritis has been reported.<sup>[2]</sup> There have been many reports where tubercular arthritis was misdiagnosed as RA.<sup>[4,6,7]</sup>

The role of magnetic resonance imaging (MRI) has been advocated in characterization of both rheumatoid and tubercular arthritis and differentiation between the two. Excellent soft-tissue detail and multiplanar capability make MRI an unparalleled imaging technique for the evaluation of joint diseases. MRI may help by demonstrating early changes, which are not visible on radiographs, such as synovitis, bone marrow edema, and

central erosions. MRI can also demonstrate joint fluid, synovial hypertrophy, pannus, bone erosions, cartilage destruction, associated osteomyelitis, and intra-articular and extra-articular abscesses.<sup>[8]</sup> Conventional spin-echo T1-weighted (T1W) and T2-weighted (T2W) images are sufficient to demonstrate anatomy, as well as pathology; proton-density sequences better demonstrate articular cartilage abnormality; post-contrast medium enhanced T1W images differentiate effusion from synovitis and acute synovitis from chronic synovitis; fat-suppressed, post-contrast medium enhanced T1W images are used for better delineation of inflamed tissues.

There is a scanty literature available on MRI features of rheumatoid and tubercular arthritis. The purpose of this study was to determine the MRI features of rheumatoid and tubercular arthritis, especially on differentiating features.

## MATERIALS AND METHODS

The study is conducted in the Department of Radiodiagnosis, GSVM Medical College, Kanpur, with the help of orthopedics department in a duration period from January 2020 to October 2021. The study design is retrospective.

The inclusion criteria of study are the patients that were clinically and pathologically diagnosed either rheumatoid or tubercular arthritis and having joint manifestations for the 1<sup>st</sup> time with clinical symptoms duration of 2–36 months. Patients with the age group of more than 80 years and history of trauma are excluded from the study.

MRI was performed on various MR scanners including 1.5 T and 3 T machine. In all patients, T1-weighted spin-echo and fast T2-weighted spin-echo images with fat suppression, proton-density sequence, and gadolinium-enhanced spin-echo T1-weighted images were acquired with the help of various coils including wrist, shoulder, knee, head, and body surface coils.

MR images were analyzed retrospectively for the following:

- Uniformity of synovial thickening
- Degree of synovial thickening,
- Size of bone erosion
- Enhancement around bone erosion
- Degree of marrow edema
- Degree of soft-tissue edema, and
- The presence of extra-articular cystic masses.

Analysis of the features on MRI on the basis of the classification suggested by Choi *et al.*<sup>[9]</sup> The degree of



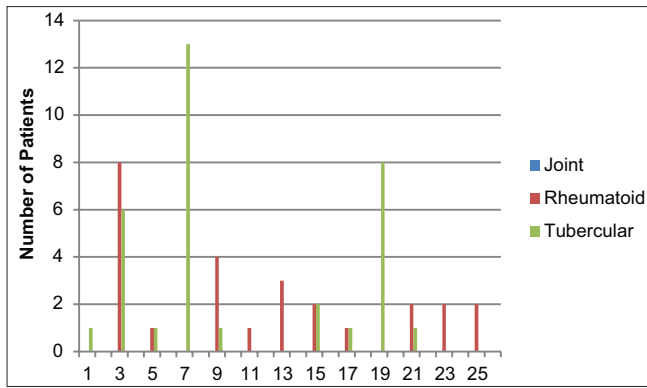


Figure 1: Distribution among joints

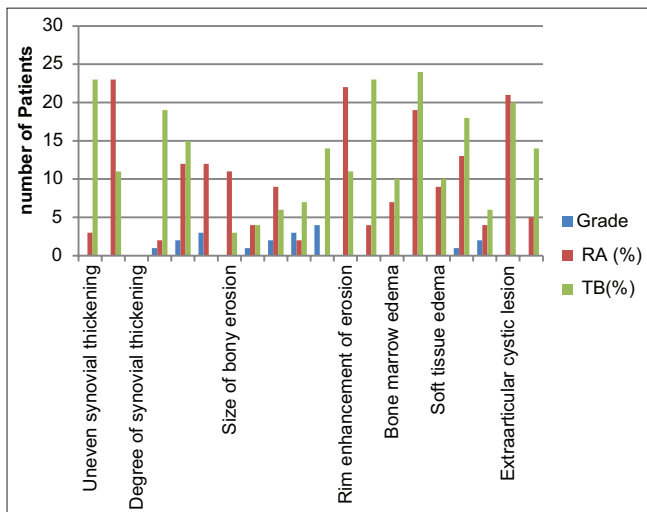
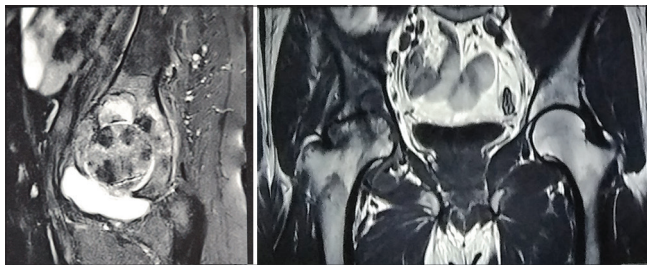


Figure 2: Distribution of all parameters



**Figure 3: Sagittal T2-weighted fat-saturated and coronal T1-weighted magnetic resonance imaging sequences of a 45-year-old male with tubercular arthritis sequence show even thin synovial thickening of hip joint with marrow edema acetabulum and femoral head region and multiple subchondral lytic lesions with joint effusion visualized**

synovial thickening after IV gadolinium administration was classified into four grades according to the maximal thickness of enhancing synovium: Grade 0, 0–3 mm; Grade 1, 3.1–6 mm; Grade 2, 6.1–9 mm; and Grade 3, >9 mm. Size of the largest bone erosion in longest diameter was reported. The size of the bone erosions was classified into five grades: Grade 0, no erosion; Grade 1, <6 mm; Grade 2, 6–10 mm; Grade 3, 11–15 mm; and Grade 4,

>15 mm on T1-weighted images. Enhancement around bone erosion was determined on gadolinium-enhanced images as either present or absent. The number of erosions was not counted. Bone marrow edema was classified into four grades after calculation of the extent of marrow edema for the joint as ([maximal distance from articular margin to outer margin of signal change of bone marrow on sagittal or coronal image/maximal diameter of articular surface on axial image] × 100[%]) into the following four grades: Grade 0, no edema; Grade 1, 1–25%; Grade 2, 26–50%; and Grade 3, >50%. Soft-tissue edema was classified into three grades after measuring the maximal vertical distance from the outer margin of joint capsule to the outer margin of periarticular soft-tissue edema on coronal or sagittal image as follows: Grade 0, no edema; Grade 1, 0.1–1 cm; and Grade 2, >1 cm.

### Statistical Analysis

For statistical analysis, data were entered into a Microsoft Excel spreadsheet and then analyzed by SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and Graph Pad Prism version 5. Two-sample *t*-tests for a difference in mean involved independent samples or unpaired samples. Paired *t*-tests were a form of blocking and had greater power than unpaired tests. One-way analysis of variance was a technique used to compare means of three or more samples for numerical data (using the F distribution). Unpaired proportions were compared by Chi-square test or Fisher's exact test, as appropriate.

Once a *t*-value is determined, *P*-value can be found using a table of values from Student's *t*-distribution.  $P \leq 0.05$  was considered for statistically significant.

### RESULTS

In the present study, 41–50 years are the most common age group with RA while 1–20 years are the most common age group in tubercular arthritis. In rheumatoid, 73.1% of patients were female while in tubercular, 70.6% of patients were male. In rheumatoid, 23 (88.5%) patients had uneven synovial thickening while in tubercular, 11 (32.4%) patients had uneven synovial thickening, that is, uneven synovial thickening is visualized more in rheumatoid than in tubercular arthritis.

In rheumatoid arthritis, 46.2% of patients were degree of synovial thickening with Grade 2 and 46.2% of patients were with Grade 3 while in tubercular arthritis, 55.9% of patients were degree of synovial thickening with Grade 1 and 44.1% of patients were Grade 2, that is, patients with RA present with higher grade of degree of synovial thickening.

In rheumatoid arthritis, 21 (80.8%) patients were bony erosion size of Grade 1 and 4 (15.4%) patients were bony erosion size of Grade 2. In tubercular arthritis, 9 (26.5%) patients were bony erosion size of Grade 1 and 23 (67.6%) patients were bony erosion size of Grade 2, that is, patients with tubercular arthritis have higher grade of bony erosion size as compared to RA.

In tubercular arthritis, 23 (67.6%) patients were rim enhancement while in RA, 4 (15.4%) patients were rim enhancement, that is, patients with tubercular arthritis rim enhancement are more common as compared to RA. Bone marrow edema and soft-tissue edema are present in both rheumatoid and tubercular arthritis, the difference between them is not statistically significant [Tables 1, 2 and Figures 1-3].

## DISCUSSION

RA usually presents as polyarthritis typically involving peripheral joints such as wrist and hand joints while tubercular arthritis presents as monoarthritis involving large or medium joints such as hip and knee. However, vice versa can also happen. Synovial tissue is the predominantly involved in both tubercular and RA.

In RA, the initial abnormalities include acute synovitis, joint effusion, periarticular edema, and juxta-articular hyperemia. As the disease progress synovial proliferation starts forming pannus and marginal bone erosions are found at the anatomic bare area. Intrusion of the pannus into the marrow spaces leads to the formation of subchondral bone cyst. Eventually, the whole joint cavity is filled with proliferating pannus, precipitating fibrous and bony ankylosis.

Tubercular arthritis begins granuloma formation in synovium which may caseate with or without cystic necrosis which may result in central as well as peripheral erosions and progress to cartilage destruction. If the disease is not timely treated lead to severe joint destruction and ankylosis. However on microscopic examination, RA shows infiltration by plasma cells and lymphocytes while in tubercular arthritis contains necrotic fibrin such as material, caseous areas, leukocytes, and mononuclear phagocytes.

In the available literature, the hypointensity of synovium on T2-weighted images has been found to be typical of tubercular arthritis. Sawlani *et al.*<sup>[10]</sup> and Sanghvi *et al.*<sup>[11]</sup> found hypointense synovium on T2-weighted imaging in 40% and 75% of cases in their study. Choi *et al.*<sup>[9]</sup> evaluated 63 joints with clinically or pathologically proven RA involving 36 joints and tuberculous arthritis involving 27 joints. Non-uniform synovial thickening was noted

in 72–86% of rheumatoid cases and 45–55% cases of tubercular arthritis while in the present study, 23 (88.5%) patients with RA have uneven synovial thickening, and in tubercular arthritis, 11 (32.4%) patients had uneven synovial thickening.

Bone change of RA occurs after proliferative pannus extension over the cartilage with cartilaginous and destruction secretion of degrading enzymes, mainly metalloproteinases. TNF- $\alpha$  and IL-1 also play a prominent role in bone destruction. However, in tuberculous arthritis, cartilaginous destruction is associated with phagocytic and vascular processes without involvement of proteolytic enzymes. Bone erosion is seen after cartilaginous erosion, due to insinuation of granulation tissue between cartilage and subchondral bone. Agarwal *et al.*<sup>[12]</sup> large erosions with rim enhancement are visualized in tubercular arthritis. Subchondral bone erosion was more frequent in tuberculous arthritis in the present study, which may have occurred because of this subchondral extension of pannus. In the present study, bone erosions are more common in patients with tubercular arthritis with higher grade.

Extra-articular cystic lesion is seen as cold abscess in tubercular arthritic patients. On MRI, it is visualized as a cystic mass with even, thin rim enhancement usually not surrounded by prominent surrounding edema. Hence, it is difficult to differentiate it from bursal fluid collection and other extra-articular cystic lesion in RA. In the present study, extra-articular cystic mass was more frequently seen in tuberculous arthritis. This study has many limitations. Many and different joints are compared for two different diseases, for example, like many hip joints are imaged in tubercular arthritis. The study is retrospective in nature, the sensitivity, specificity, and positive and negative predicted value of findings could not be determined.

## CONCLUSION

In the present study, we conclude that MRI becomes unparalleled imaging in differentiating diagnosis of rheumatoid and TB arthritis when clinical and plain radiographic features are inconclusive specially at early stage or with atypical presentation because of the excellent soft-tissue detail and the ability of contrast-enhanced T1-weighted imaging to differentiate between joint effusion and synovial thickening.

Uneven and thick synovial proliferation was more frequently seen in RA, whereas, even and thin synovium, large bone erosions, rim enhancement around bone erosion, and extra-articular cystic masses were more frequently seen in tuberculous arthritis. Bone marrow and soft-tissue

edema is present in both arthritis; however, they could not differentiate with each other significantly. Evaluation with MRI is significantly helpful in differentiation between RA and tuberculous arthritis.

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# Comparative Observational Analysis of Outcome of Conventional Septoplasty and Endoscopic Septoplasty at Tertiary Care Facility, Jaipur

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## Abstract

**Introduction:** Septoplasty, that is, surgical correction of the deviated nasal septum, is the most common ear, nose, and throat operation.

**Aim:** The aim of the study was to compare the objective and subjective outcome of traditional septoplasty and endoscopic septoplasty (ES).

**Materials and Methods:** This hospital-based, observational, and prospective study was conducted at tertiary care facility from June 2017 to September 2020. A total of 325 patients were included in the study and out of them, 168 (51.7%) underwent conventional septoplasty and 157 (48.3%) underwent ES. Pre- and post-operative assessments included nasal endoscopy, rhinomanometry, and nasal obstruction and septoplasty effectiveness scale questionnaire. The post-operative evaluation was performed at 3 months after surgery. Pain was assessed using a visual analog scale during recovery (4 h after the removal of nasal packaging). All patients underwent an endoscopic follow-up at 7, 15, 30, and 90 days after surgery. Data were analyzed using Microsoft Excel 2019.

**Results:** There was no difference in effectiveness of both techniques in decreasing nasal obstruction and discharge ( $P > 0.05$ ). Post-operative complications such as pain, synechiae, early post-operative bleeding, septal tears, and incomplete correction are less frequent in the endoscopic group ( $P < 0.05$ ). The rhinomanometric analysis reveals improvement in both groups ( $p < 0.05$ ), however the difference between the two groups was not significant ( $p > 0.05$ ). Subjective questionnaires show a good symptoms relief with an improved quality of life.

**Conclusions:** The present study shows that both the techniques are effective in reducing nasal obstruction and related symptoms with fewer overall complications in the endoscopic approach. Thus, endoscopic approach can be a valuable teaching tool.

**Key words:** Conventional septoplasty, Deviated nasal septum, Endoscopic septoplasty, Outcome

## INTRODUCTION

The term DNS refers to the deviated nasal septum, which is one of the leading causes of the nasal obstruction. The nasal septal deviation is detected in 19% of newborns, 37% of children, and 89% of adults.<sup>[1-3]</sup> It can lead to recurrent

infections of the paranasal sinuses and, for some patients, it may be associated with contact point headaches.<sup>[4]</sup>

Surgical correction of the deviated nasal septum is known as septoplasty. It is the most common ear, nose, and throat (ENT) operation in adults.<sup>[5]</sup> It aims to straighten the deviated nasal septum. There are two approaches of septoplasty: Conventional septoplasty (CS) by means of an external light source and endoscopic septoplasty (ES) which is done using endoscope.

The main advantage of ES over CS is the better visualization of septal deformities, allowing more conservative and less

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invasive surgery, even in revision cases. The endoscopic view provides an excellent teaching tool.<sup>[6]</sup> A recent meta-analysis by Hong *et al.*<sup>[7]</sup> underlined the ongoing debate regarding which approach had better outcomes and fewer complications and concluded that endoscopic view has better outcomes compare to conventional, though the findings seem to be inconclusive due to low quality inclusion cases.

The aim of the present study was to compare post-operative outcomes and the rate of complications in patients who underwent either endoscopic or CS without coprocedures. Post-operative outcomes were assessed by means of objective (active anterior rhinomanometry [RMM] and subjective measures (visual analog scale [VAS] for pain and nasal obstruction and septoplasty effectiveness scale [NOSE])<sup>[4]</sup> at 3 months after surgery.

## MATERIALS AND METHODS

This hospital-based, observational, and prospective study was conducted in the Department of Otorhinolaryngology and Head Neck Surgery at S.M.S. Medical College and Attached Group of Hospitals, Jaipur from June 2017 to September 2020 after clearance from the Ethical Committee.

All the patients above 18 years of age presented with only complaint of nasal obstruction and gross deviated nasal septum were included in the study. Patients with associated complaints of vasomotor or allergic rhinitis, acute or chronic rhinosinusitis, having a history of previous nasal surgery, and for rhinoplasty, and/or turbinate surgery and/or sinus surgery were excluded from the study. Total 500 patients attended ENT outpatient department with complaint of nasal obstruction and gross deviated nasal deviation. Out of these, 125 had associated complaint of sinusitis and gross external nasal deformity and 50 patients were below 18 years of age. Hence, 175 patients were excluded from the study. A total of 325 patients were included in the study and out of them, 168 (51.7%) underwent CS and 157 (48.3%) underwent ES. Pre- and post-operative assessments included nasal endoscopy, RMM, and NOSE questionnaire. The post-operative evaluation was performed at 3 months after surgery. Pain was assessed using a VAS during recovery (4 h after the removal of nasal packaging). CS was performed with headlight illumination, nasal speculum, and Freer elevator. After decongestion with adrenaline and submucosal injection of local anesthesia (xylocaine 2% with epinephrine), a mucosal hemi transfixion incision was performed with a 15-blade scalpel. Then, an elevator was used to elevate a

mucoperichondrial flap and the quadrangular cartilage was incised anteriorly. A contralateral mucoperichondrial flap was then raised. The bony septal deviation was incised carefully with a dovetail scalpel and hammer instrument. The incised cartilage and bone were then removed *en bloc* using Weil forceps. Elevated flaps were laid back down. Mucosal incision was sometimes fixed with reabsorbable stitches and nasal cavities were packed with finger glove coated Merocel for 24 h. ES was carried under general anesthesia, using a zero-degree 4 mm endoscope. After the infiltration on both sides of the septum with xylocaine 2% with pinephrine, a hemitransfixion incision was made with elevation of the mucoperichondrial flap using the suction elevator under direct endoscopic visualization. Flap raising continued bilaterally to completely dissect the septal deformity. Cartilage or bone was excised with punches, endoscopic scissors, or forceps. The flaps were repositioned back after suction clearance, without sutures, and the nasal cavities were packed with a finger glove coated Merocel that was removed after 24 h. All patients underwent an endoscopic follow-up at 7, 15, 30, and 90 days after surgery.

## RESULTS

[Table 1] shows that total 325 patients underwent septoplasty. Out of these, 168 (51.7%) underwent CS and 157 (48.3%) underwent ES. Mean age of participants of conventional group and endoscopic group was  $42.5 \pm 11.4$  and  $44.6 \pm 12.3$  years, respectively. Male to female ratio was 93:75 in conventional group and 95:62 in endoscopic group. Preoperatively and postoperatively, there was no statistically significant difference in mean NOSE score, RMM score, and VAS score in between patients of both study groups ( $P > 0.05$ ).

There was a statistically significant reduction in NOSE score in both the groups CS (pre  $12.3 \pm 2.1$  vs. post  $4.5 \pm$

**Table 1: Comparison of variables between patients of both study groups**

Variable	CS (n=168)	ES (n=157)	P-value
Age (Years)	42.5±11.4	44.6±12.3	>0.05
Male: Female	93:75	95:62	>0.05
NOSE score			
Pre-operative	12.3±2.1	13.1±2.3	>0.05
Post-operative	4.5±1.1	3.8±1.2	
RMM score			
Pre-operative	0.91±0.08	0.87±0.08	>0.05
Post-operative	0.26±0.06	0.25±0.07	
VAS score			
Pre-operative	2.4±0.8	2.6±0.9	>0.05
Post-operative	8.1±0.9	8.3±0.8	

CS: Conventional septoplasty, ES: Endoscopic septoplasty, VAS: Visual analog scale, RMM: Rhinomanometry, NOSE: Nasal obstruction and septoplasty effectiveness scale

1.1;  $P < 0.05$ ) and in ES group (pre  $13.1 \pm 2.3$  vs. post  $3.8 \pm 1.2$ ;  $P < 0.05$ ). Similarly, there was a significant reduction in RMM score from pre-operative to post-operative in both study groups ( $P < 0.05$ ). There was a statistically significant increase in mean VAS score of patients in both study groups (CS – pre  $2.4 \pm 0.8$  vs. post  $8.1 \pm 0.9$  and ES – pre  $2.6 \pm 0.9$  vs. post  $8.3 \pm 0.8$ ).

[Table 2] shows that the number of patients who had hemorrhage after CS was 25 (14.9%) which was significantly ( $P < 0.05$ ) higher than patients of ES group 11 (7%). Similarly, the number of patients who had post-operative complications such as adhesion, persistent nasal deviation, and septal tear in CS group was significantly higher than patients who had same complications in ES group ( $P < 0.05$ ).

## DISCUSSION

DNS may lead to remarkable decrease in quality of life. The present study depicted that both endoscopic and traditional septoplasty approaches are effective in improving post-operative nasal function as well as subjective nasal functionality measured by patient self-assessment at 3 months after surgery, in agreement with the recent literature.<sup>[4,8-15]</sup> Brennan *et al.*<sup>[16]</sup> stated that ideal septoplasty procedure should correct the deviation without any complication. The present study included conventional and ES without associated nasal surgery. Thus, it remained to be a more objective test of evaluating the two techniques. Paradis and Rotenberg<sup>[17]</sup> found that both CS and ES showed significant improvement in the NOSE score after septoplasty and there was no superiority between both techniques according to the NOSE scale. In the present study, similar outcomes were obtained, NOSE and global quality of life scores (VAS scores) significantly improved postoperatively. In the present study, both septoplasty techniques were not superior to each other according to the NOSE and VAS. In the present study and literature, there was no difference between two techniques in terms of improvement in quality of life. This situation may be related with the absence of serious or major complications such as persistent deviation, synechia, or septal perforation that influenced the patient's quality of life in long-term.

The incidence of some complications in the ES group in the present study was significantly lower in accordance with the literature. Intra- and post-operative hemorrhage rates were noted statistically more frequent in CS group. Similarly, Sathyaki *et al.*<sup>[13]</sup> reported that hemorrhage was more common in cases who underwent CS. The probable cause of this is that more brutal manipulations such as excision of inferior bone deviation in CS. In the present study, intra-operative mucosal flap laceration incidence was statistically less common in ES group compared to CS group. In a systematic review by Hong *et al.*,<sup>[7]</sup> the risk developing flap laceration in CS patients was 1.8 times (RR: 1.84 [95% CI, 1.27–2.68],  $P = 0.001$ ) greater than the patients who underwent ES.

ES was also associated with a significantly less persistent septum deviation rates 5.7% in comparison to CS (20.2%), that is,  $P < 0.001$ . On the other hand, the persistent deviation was not different between the two groups in a few literatures.<sup>[12,13]</sup>

The present study highlighted some remarkable advantages in support of ES technique. ES approach seemed to be least invasive, with minor tissue handling, leading to less post-operative complications. Functional objective and subjective results were good over CS. Finally, in ES, the video assistance allows the junior surgeons to better understand the procedure, acquiring the technique and being supervised by a senior when operating alone and thus should be considered as an excellent and effective teaching tool.

## CONCLUSIONS

The present study shows that following endoscopic and CS, there was a significant improvement in RMM score, NOSE, and VAS score; however, the difference between the two groups was not significant ( $P < 0.05$ ).

Post-operative complications such as hemorrhage, nasal adhesions, persistent septal deviation, and septal tear were significantly lower among patients who undergone ES compared to patients who had conventional approach. Thus, among both techniques, ES could be a better approach in management of septoplasty.

## Limitations

The main limitation of the present study is the absence of randomization. Further studies need to be done to determine which is better, whether endoscopic or CS.

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**Table 2: Distribution of post-operative complications in both study groups**

Complications	CS (n=168)	ES (n=157)	P-value
Hemorrhage	25 (14.9)	11 (7)	0.037
Adhesions/Synechiae	10 (6)	2 (1.3)	0.04
Persistent deviation	34 (20.2)	9 (5.7)	<0.001
Septal tear	29 (17.3)	12 (7.6)	0.015

CS: Conventional septoplasty, ES: Endoscopic septoplasty, VAS: Visual analog scale, RMM: Rhinomanometry, NOSE: Nasal obstruction and septoplasty effectiveness scale

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# Prevalence of Overweight and Obesity among Medical Students

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## Abstract

**Introduction:** Obesity is an upcoming emergency lifestyle disease in our country, especially among young adults. In India, morbidity and mortality occurs even with low body mass index (BMI). There has been steady increase in obesity among adolescents and young adults. The prevalence of generalized obesity and central obesity among young adults range from 11.8% to 31.3% and 16.9% to 36.3%, respectively. There is increase in number of young adults suffering with depression mainly due to body shaming and bullying by the peer group due to obesity. Hence, the study of psychosocial impact is also included in our study.

**Materials and Methods:** A cross-sectional study was conducted among undergraduate medical students aged 17–24 years in a private medical college in Chennai. After getting informed consent, the pre-designed questionnaire was sent to subjects. To measure weight, standardized weighing scales used. To measure height, portable anthropometry rod was used. BMI is calculated with QUETELTS index.

**Results:** Among 436 students enrolled in study, 43.3% ( $n = 186$ ) were male and 56.7% ( $n = 247$ ) were female. Among the total boys, 57.6% ( $n = 109$ ) were overweight. Among girls, 49.7% ( $n = 123$ ) were overweight and obese. Overall prevalence of overweight and obesity is 53.2% ( $n = 232$ ). Among these, around 22.9% ( $n = 100$ ) belong to overweight category and 30.3% ( $n = 132$ ) were obese. In our study, about 51% ( $n = 35$ ) of late adolescence belong to overweight and obese category. Among study participants, around 30 (6.8%) had positive family history of obesity. Considering psychosocial impact, 26.8% were disappointed with their appearance, 26% bullied for their weight. About 61% taking steps to reduce their weight. Around 60% of the smokers and alcoholic were obese.

**Conclusion:** Our study concluded that the prevalence of overweight and obesity among medical students is more than 50% which is very high compared to general population.

**Key words:** Medical students, Obesity, Overweight, Prevalence

## INTRODUCTION

Obesity is an upcoming emergency lifestyle disease in our country especially among young adults. Overweight and obesity are defined as abnormal accumulation of fat in the body. According to the WHO, body mass index (BMI) more than 30 is considered as obesity.<sup>[1]</sup> In Asian population, BMI values have been modified as more than or equal to 23 as

overweight and BMI more than or equal to 25 as obesity.<sup>[2]</sup> In India, morbidity and mortality occurs even with low BMI. This is mainly because cardiovascular death occurs with elevated body fat percentage which is seen at low BMI levels among Asian people, including Indians as documented in many studies.<sup>[3]</sup> The prevalence of obesity in India lies between 10% and 50%.<sup>[4]</sup> The main cause for obesity in Indians is nutritional shift from typical carbohydrate diet to high calorie fast food which is more common among college students.<sup>[5]</sup> Obesity can be multi factorial which includes genetic predisposition, lack of physical activity [Figure 1]<sup>[6]</sup> and diet. There has been steady increase in obesity among adolescents and young adults in the recent past. According to recent ICMR STUDY 2015, the prevalence of generalized obesity and central obesity among young adults range from 11.8% to 31.3% and 16.9% to 36.3%, respectively.

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Our medical students are future health-care providers. They are by themselves more prone for obesity due to their sedentary lifestyle, stress, and disordered eating habits and spending more time with their books and gadgets. The obese young adults are later prone for many complications such as hypertension, dyslipidemia due, obesity, diabetes mellitus, coronary artery disease, infertility, stroke, and arthritis.<sup>[7-9]</sup> In spite of these issues, it still remains a neglected problem. Many studies have proved high prevalence of obesity among medical students in India.<sup>[10-12]</sup> Psychosocial impact of obesity among young adults is being least bothered. There is increase in number of young adults suffering with depression and the most common cause being body shaping and bullying by the peer group due to obesity. Hence, this is also included in the present study. The main objective of the present study is to determine the prevalence of overweight and obesity among college going young adults.

### Aims and Objectives

#### Primary objective

The objective of this study was to estimate the prevalence of overweight and obesity among medical students aged 17–24 years in a private medical college at Chennai.

#### Secondary objective

The objectives of this study were as follows:

1. To assess the risk of comorbidities among obese young adults
2. To assess psychological impact of obesity on them.

## MATERIALS AND METHODS

### Methodology

A cross-sectional study was conducted among undergraduate medical students aged 17–24 years in a private medical college in Chennai, Tamil Nadu during the year 2021.

### Exclusion Criteria

The following criteria were excluded from the study:

1. Students on chronic medications
2. Students with history of past or present pregnancy
3. Students not willing to participate in the study
4. Physically challenged students.

### Ethical Clearance

Ethical clearance has been obtained from Institutional Ethics Committee. The permission taken from Head of Institution, Dean and Head of the Department. Informed written consent was obtained from each student before filling the questionnaire.

### Data Collection

Students who participated in the study received verbal and written explanation of the procedure involved and the

expected benefits from the study. After getting informed consent, the pre-designed questionnaire was sent to subjects and explained that results would only be expressed as a group data and confidentiality would be maintained throughout and after the study.

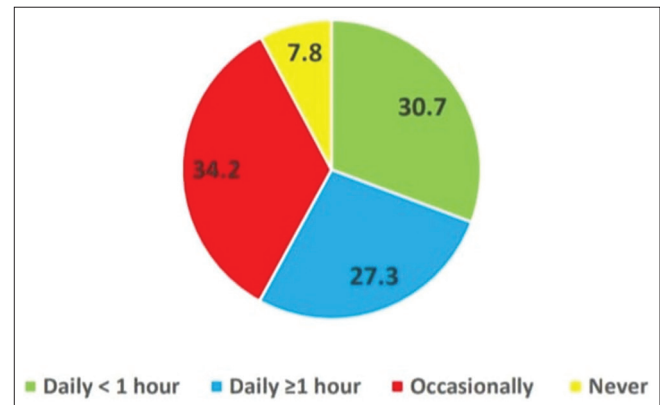


Figure 1: Frequency percentage of physical activity duration

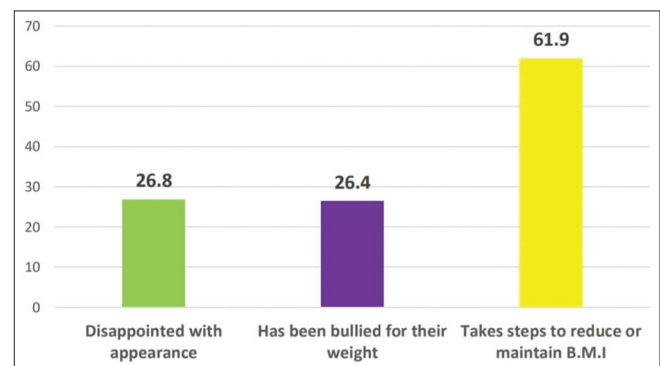


Figure 2: Psychosocial impact of obesity

Table 1: Sociodemographic profile of the study subjects

Variable (Classification of Variable)	Number (Out of 436)	Percentage (%)	95% C. I
<b>Age</b>			
< 20 years	68	15.6	12.3 – 19.4
≥ 20 years	368	84.4	80.6 – 87.7
<b>Gender</b>			
Male	189	43.3	38.6 – 48.1
Female	247	56.7	51.9 – 61.4
<b>Place of permanent residence</b>			
Rural	90	20.6	16.9 – 24.8
Urban	346	79.4	75.2 – 83.1
<b>Family H/O Obesity</b>			
Present	127	29.1	24.9 – 33.6
Absent	309	70.9	66.4 – 75.1

Table 2: BMI of the study subjects

BMI	Number	Percentage
Underweight (<18.5)	36	8.3
Lean BMI (18.5–22.9)	168	38.5
Overweight (23–24.9)	100	22.9
Obese (≥24.9)	132	30.3

BMI: Body mass index

**Table 3: Profile of comorbidities and other illness among study subjects**

Variable (Classification of Variable)	No of Males (Out of 189)	No of Females (Out of 247)	P – Value	Total No (Out of 436) (%)
<b>History of knee joint pains</b>				
Present	11	15	0.46	26 (6 %)
Absent	178	232		410 (94 %)
<b>History of Gastroesophageal reflux disease</b>				
Present	12	18	0.36	30 (6.9%)
Absent	177	229		406 (95.1%)
<b>History of Asthma</b>				
Present	9	3	0.026*	12 (2.8%)
Absent	180	244		424 (97.2 %)
<b>History of Hypothyroidism</b>				
Present	1	6	0.12	7 (1.6%)
Absent	188	241		429 (98.4%)
<b>History of snoring</b>				
Present	18	12	0.04*	30 (6.9%)
Absent	171	235		406 (95.1%)
<b>History of Alcohol intake</b>				
Present	11	5	0.03*	16 (3.7%)
Absent	178	242		420 (96.3%)
<b>History of smoking</b>				
Present	11	0	0.0002*	11 (2.5%)
Absent	178	247		425 (97.5%)

(\* - Statistically significant)

**Table 4: Association between obesity and various factors**

Variable	Grouping of Variable (Number)	Number of Subjects with overweight and obesity (out of 232)	Number of Subjects without overweight and obesity (out of 204)	Odds ratio (95% C.I of odds ratio)	Chi square value	p-value
Age	≥ 20 years (368)	197	171	1.05 (0.65 – 1.82)	0.10	0.75
	< 20 Years (68)	35	33	1.00		
Gender	Males (189)	109	80	1.37 (0.94 – 2.01)	2.67	0.051
	Females (247)	123	124	1.00		
Smoking	Yes (11)	7	4	1.56 (0.45 – 5.39)	0.16	0.35
	No (425)	225	200	1.00		
Alcohol consumption	Yes (16)	10	6	1.49 (0.53 – 4.16)	0.57	0.22
	No (420)	222	198	1.00		
Knee pains	Yes (26)	14	12	1.03 (0.46 – 2.28)	0.004	0.47
	No (410)	218	192	1.00		
H/O Snoring	Yes (30)	20	10	1.83 (0.84 – 4.01)	2.33	0.06
	No (406)	212	194	1.00		
H/O GERD	Yes (30)	20	10	1.83 (0.84 – 4.01)	2.33	0.06
	No (406)	212	194	1.00		
Disappointment with appearance	Yes (117)	88	29	3.69 (2.30 – 5.92)	31.02	<0.0000001*
	No (319)	144	175	1.00		
Bullied for appearance	Yes (115)	82	33	2.83 (1.79 – 4.49)	20.49	0.000003*
	No (321)	150	171	1.00		
Takes steps to maintain weight	Yes (270)	174	96	3.38 (2.25 – 5.06)	35.86	<0.0000001*
	No (166)	58	108	1.00		

### Study Instruments

1. Pre-designed, Pre-tested, and semi-structured questionnaire
2. Physical measurements, such as height and weight, were assessed and BMI was calculated by QUETLETS index.<sup>[13,14]</sup>

### Questionnaire

It contains participants demographic and socioeconomic characteristics such as age, sex, income, smoking, alcohol, family history, diet pattern, and physical activity, comorbidities of obesity such as GERD, arthritis and OSAS, history of being bullied for obesity, and history of any efforts taken for weight reduction.

To measure weight, standardized weighing scales used. To measure height, portable anthropometry rod was used. Participants were asked to stand with back against rod, look straight, and heels touching the rod without any footwear. Sliding horizontal bar gently touches head compressing hair.

BMI is calculated with QUETELTS index (weight in kilograms/height in meter<sup>2</sup>).

### Statistical Analysis

It was done with super version two software. Tests of significance were done using Chi-square test with statistical significance level set at  $P < 0.05$ .

## RESULTS

Among 436 students enrolled in study, 43.3% ( $n = 186$ ) were male and 56.7% ( $n = 247$ ) were female [Table 1]. Among the total boys, 57.6% ( $n = 109$ ) were overweight and obese. Among girls, 49.7% ( $n = 123$ ) were overweight and obese. Overall prevalence of overweight and obesity is 53.2% ( $n = 232$ ). Among these, around 22.9% ( $n = 100$ ) belong to overweight category and 30.3% ( $n = 132$ ) were obese [Table 2].

In the present study, about 68 students belong to late adolescent category (17–19 years). Among them, 51% ( $n = 35$ ) belong to overweight and obese category. The percentage of boys with overweight and obesity was more compared to girls through not statistically significant. Among study participants, around 30 (6.8%) had positive family history of obesity. Around 57 (13%) students were engaged in daily physical activity such as exercise, walking, and jogging. To our surprise, 8% were not involved in any activity. Considering psychosocial impact, 26.8% were disappointed with their appearance, 26% were bullied for their weight. About 61% of students were taking steps to reduce their weight. Considering various associated factors such as smoking and alcohol consumption, around 11 (2.52%) students were smokers and 16 (3.6%) were alcoholics. Around 60% of these smokers and alcoholic were obese, though not statistically significant. Considering co morbidities, among 26 students who had knee pain 14 were obese (42%). Among 30 students who had snoring

(OSAS), 20 (66%) and among 30 students who had gastro esophageal reflux disease, 20 were obese (66%) though not statistically significant [Table 3].

## DISCUSSION

In the present study, the overall prevalence of overweight and obesity was 53.2% among which 30.3% were obese exclusively. There is increased prevalence of obesity in males than females though not statistically significant. This is in concordance with Keshab Parajuli study done in Karnataka,<sup>[15]</sup> where there was 28.7% overweight among male students and 18.6% among female students.

In the present study, 30% of obese study participants had positive family history of obesity. About 26.8% students were disappointed about their appearance among which 26% were bullied for their weight [Figure 2]. Hence, this could be considered as an important factor for causing depression among these young adults. Around 10% of our students are taking efforts to reduce and maintain their weight. Among the obese study participants, about 75.2% ( $n = 88$ ) were highly disappointed about their appearance, and around 71.3% ( $n = 82$ ) were bullied for their appearance since childhood. The prevalence of obesity among smokers and alcoholics range around 60% in our study. There is 42% obese study participants with recurrent knee pain and 66% with snoring episodes [Table 4].

## CONCLUSION

Obesity being a very important risk factor for several comorbidities,<sup>[16]</sup> it is very important to take necessary precautions to prevent and control it. The present study concluded that prevalence of overweight and obesity among medical students is very high compared to general population, mainly due to their erratic eating habits<sup>[17]</sup> and stress. More than 50% of students were overweight or obese. This study could create awareness among medical students to adopt a healthy lifestyle. There is also an increased psychosocial impact on these students due to obesity.

## LIMITATIONS OF THE STUDY

Due to ongoing pandemic, we could not evaluate further comorbidities such as prevalence of fatty liver among them.

## FURTHER RECOMMENDATIONS

In future, further evaluation such as lipid profile, glucose intolerance, hypertension, and fatty liver can also be studied.

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# Add on Effect of Oral Antioxidants in Melasma Patients at Tertiary Care Center: An Observational Study

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## Abstract

**Background:** Melasma is common, complex acquired pigmentary disorder having tremendous psychological and social impact. Our aim was to know clinical profile of melasma and to evaluate the efficacy and safety of oral antioxidants, along with standard treatment.

**Materials and Methods:** An observational study performed after clearance from the Institutional Ethics Committee. Total 152 patients having melasma were enrolled in study by simple random sampling. Complete history, clinical examination, and relevant investigations were done. Both groups were given topical sunscreen and modified Kligman regimen for 3 months. Group B in addition was given oral antioxidants for 6 weeks. Data were analyzed by application of descriptive analysis, Mean, SD, and Z test.

**Results:** There was female predominance (84.2%), exacerbation by sun exposure in 52.6%. Most common type was centrofacial (50.7%), most common pattern according to wood's lamp examination and dermoscopic examination was epidermal (47.7%). Excellent and very good response noted in 47.4% and 31.6% patients, respectively, in Group B which was more than Group A patients. Group B (56%) patients had more reduction of Mean Modified MASI score compared to Group A (48.6%) at 12<sup>th</sup> week. About 34.2% of patients had some side effects, which were more in Group A (21%). Erythema (28.8%) was the most common followed by telangiectasia (25%) and burning.

**Conclusion:** Melasma is distressing condition having chronic progressive relapsing course. Although topical modified Kligman regimen is gold standard treatment, oral antioxidants reduce oxidative stress and delay the onset of UVB-induced erythema. Beta-carotene helps by giving additional sun protection apart from topical sunscreen and Modified Kligman Regimen.

**Key words:** Antioxidants, Beta-carotene, Melasma

## INTRODUCTION

Melasma is a common acquired, complex, and pigmentary disorder of sun exposed skin which presents as symmetrical, light to dark brown colored patches with irregular, serrated, and geographic borders. It is a common cosmetic problem causing tremendous psychological and social impact. Females are more prone to develop melasma especially in

the 3<sup>rd</sup> and 4<sup>th</sup> decades. It is more common in those who lives in area, where ultraviolet exposure is more, resulting in more amount of melanin production. It is more common in Fitzpatrick skin types IV, V, and VI and Hispanic, Caribbean, and Asian races.<sup>[1]</sup> In India, most common disorder of hyperpigmentation is melasma having incidence of approximately 10%.<sup>[2]</sup> Although it has multifactorial pathogenesis, exact mechanism is not known. Dysfunctional melanogenesis plays an important pivotal role. Two groups of factors seem to be implicated in pathogenesis of melasma: One is "endogenous factors" which include genetic predisposition and cutaneous vasculature; another is "exogenous factors" which include sun exposure, pregnancy, use of oral contraceptives and steroids, and use of cosmetics and photosensitizing medications.<sup>[3]</sup>

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- Based on the site of involvement, three types of melasma are seen
  - Centrofacial melasma – involves bilateral cheeks, forehead, upper lip, nose, and chin. (contributing 66% of cases)
  - Malar melasma – involves cheeks and nose (20% of cases)
  - Mandibular melasma – involves the rami of mandible (15% of cases)
- On histopathological examination, melasma is divided into three patterns
  - Epidermal melasma – excess of melanin is deposited into basal, suprabasal, and stratum corneum layers
  - Dermal – melanophages are seen in superficial and deep dermis
  - Mixed – combination of epidermal and dermal component.

Melasma has chronic progressive course and relapse is invariable. Management of melasma is challenging and requires long-term treatment plan, but still there is no complete cure. Different therapeutic modalities have been used in the treatment of melasma. This study was conducted to know about clinical profile of melasma and efficacy and safety of oral antioxidants in melasma patients.

## MATERIALS AND METHODS

After obtaining Institutional Ethical Committee approval, observational analytic study of 152 clinically diagnosed melasma patients fulfilling inclusion criteria was included in the study after informed consent. Patients with age <18 years, non-willing for participation in the study, and pregnant females were excluded from the study. Patients were divided into two groups (A and B) of 76 patients in each. In Group A (Regimen-1), patients were advised to apply topical sunscreen at daytime and modified Kligman regimen [4% HQ, 0.05% tretinoin and fluocinolone acetonide (0.01%)] at night for 3 months. In Group B (Regimen-2), in addition to regimen 1, patients were given oral antioxidants in once daily dose for 6 weeks. Detailed history and clinical examination were carried out in each patient. Skin type of the patients was classified according to Fitzpatrick's classification (Type I-VI). Wood's lamp and dermoscopic examinations were performed in all patients. Subjective and objective assessment were done. MASI score was calculated and data was analyzed using STATA 14.2. Categorical variables were expressed in frequency and percentages and were compared by performing Pearson's Chi square-test. Continuous variables were presented as Mean  $\pm$  SD. Wilcoxon signed rank test was used to

compare the mean of Topical sunscreen + Modified Kligman regimen group and Topical sunscreen + Modified Kligman regimen + Oral Antioxidants group.  $P < 0.05$  was considered as statistically significant.

## RESULTS

Out of 152 clinically diagnosed melasma patients, majority (72.3%) were in 4<sup>th</sup>–5<sup>th</sup> decades. Most common age group having melasma in study was 30–39 years (comprising 46% of Group A patients and 43.4% of Group B patients). Mean age was found to be 35.5 years. Youngest patient was of 19 years and eldest patient was of 56 years old. Female predominance (84.2%) was noted with female: male ratio of 5.3:1. Majority of patients (69%) were having melasma of duration of 1–5 years, followed by 5–10 years (26.4%) and  $\leq 1$  year (24.3%). Only 4.6% had  $\geq 10$  years of duration. Mean duration of all 152 melasma patients was 4.5 years. Out of 128 female patients of our study, only 47 (36.7%) have onset of melasma during pregnancy. Only 26.3% of patients had family history of melasma, rest 73.7% had no family history of melasma in one or other family member. History of exacerbation by sun exposure was noted in 52.6% of patients. About 85% patients denied history of any topical application. About 77% patients did not have history of oral contraceptive pills. All patients were having Fitzpatrick skin type IV (24.3%) or V (75.7%).

Centrofacial pattern was most common in females with 34 (53.9%) in Group A and 38 (58.5%) in Group B, second was malar pattern, seen in 23 (36.5%) females in Group A and 18 (27.7%) in Group B. Mandibular pattern was observed in 6 (9.6%) females in Group A and 9 (13.8%) in Group B. These findings are elaborated in Table 1. Malar pattern was the most common in males seen in 19/25 (79.2%) males, followed by centrofacial pattern with 5/25 (20.8%) males. Mandibular type was not noticed in our study [Graph 1].

On Wood's lamp examination, in both the groups, most common pattern was epidermal which was seen in 35 (46%) and 37 (48.8%) numbers of patients in Groups A and B, respectively [Figure 1]. In Group A, mixed and dermal type of melasma was seen in 31 (40.7%) and 10 (13.1%) patients [Figure 2]. While in Group B, mixed and dermal type of

**Table 1: Type of melasma in females**

Type of melasma	Group A	Percent	Group B	Percent	Both Groups	Percent
Centrofacial	34	53.9	38	58.5	72	56.3
Malar	23	36.5	18	27.7	41	32
Mandibular	6	9.6	9	13.8	15	11.7
Total	63	100	65	100	128	100

melasma was seen in 31 (40.7%) and 8 (10.5%) patients, respectively [Graph 2].

Out of 152 patients, 23 (15.2%) patients were having some kind of thyroid abnormality. Among them in Group A, 9 (5.9%) patients were having hypothyroidism, while in Group B, 14 (9.3%) patients were having thyroid abnormality, in which 13 (8.6%) patients were having hypothyroidism and 1 (0.7%) patient was having hyperthyroidism. Subjective assessment was done by asking patients at the end of follow-up about the percentage of improvement in melasma lesions and was graded as: poor response (<25% improvement), good (25–50% improvement), very good (50–75% improvement), and excellent response (>75% improvement).

More numbers of patients with excellent (47.4%) and very good (31.6%) subjective improvement were seen in Group B patients [Figures 3 and 4], while Group A patients showed very good (25.1%) and good (28.9%) response in more number of patients [Figures 5 and 6]. Good and poor response were seen more in Group A patients with 22 (28.9%) and 13 (17.1%) in number. Eleven (14.5%) and 5 (6.5%) patients in Group B showed good and poor response. Hence, more numbers of patients with excellent and very good subjective improvement were seen in Group B (Topical sunscreen + Modified Kligman regimen + Oral Antioxidants) compared to Group A (Topical sunscreen + Modified Kligman regimen). These findings are mentioned in Graph 3.

As elaborated in Graph 4 and Table 2, Group A patients had reduction of mean MASI score from 7.11 to 3.66

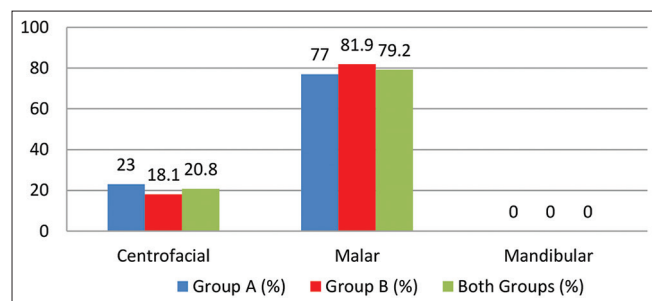
showing 48.6% reduction from baseline. While in Group B, reduction of mean MASI score was from 7.10 to 2.10, with 56% reduction from baseline. Hence, 7.4% more reduction was achieved in Group B patients, in which oral antioxidants capsules were given additionally.

At baseline, *P*-value between Group A and Group B was 0.9797, that is, >0.05 suggesting that difference was statistically non-significant. *P*-value at the end of study, at 12<sup>th</sup> week, was 0.0000, <0.05 which suggests that mean MASI score between Group A and Group B, there was statistically significant difference [Table 3].

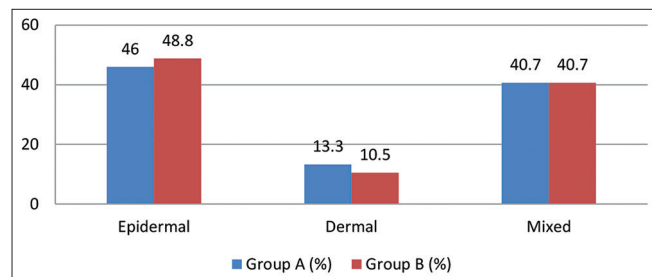
About 34.2% of patients had some side effects with more number of it in Group A (21%) than the Group B (13.2%). Erythema (28.8%) was the most common, followed by telangiectasia (25%) and burning (23.1%). Others were acne form eruption, hypertrichosis, exogenous ochronosis, and hypopigmentation in few patients.

## DISCUSSION

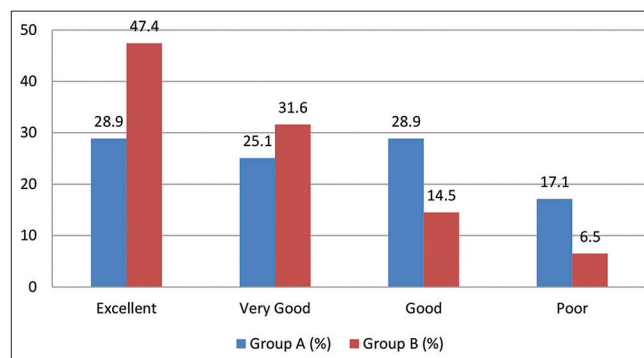
This condition causing melanogenesis is significant due to the fact that melasma usually relapses frequently, is difficult to treat and cure, and severely affects social and emotional well-being of patients. In the present study, majority of the patients were seen in 4<sup>th</sup>–5<sup>th</sup> decades (72.3%). This finding was comparable to the study done by Khurana *et al.*, which has shown most common age



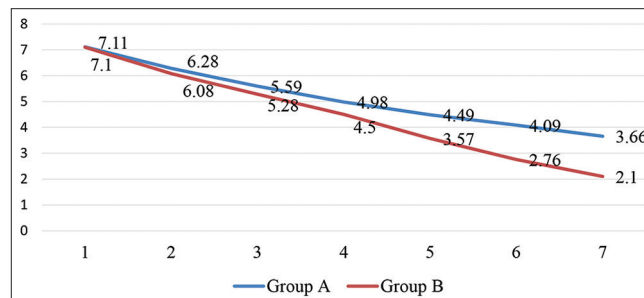
Graph 1: Type of melasma in males



Graph 2: Pattern of melasma (%) in both groups on Wood's lamp examination



Graph 3: Subjective assessment in Group A and B



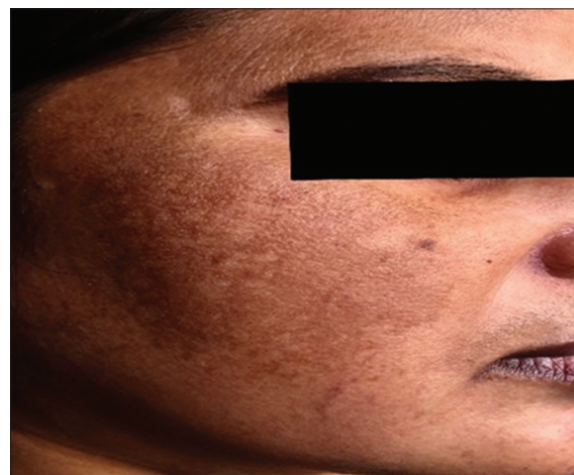
Graph 4: Objective assessment in form of MASI score

**Table 2: Reduction of percentage (%) in both groups at 2, 4, 6, 8, 10, and 12<sup>th</sup> week**

Time	Group A	Percentage Reduction of MASI score (%)	Group B	Percentage Reduction of MASI score (%)
	Mean MASI score		Mean MASI score <sup>2</sup>	
0 week	7.11		7.1	
2 <sup>nd</sup> week	6.28	11.7	6.08	14.4
4 <sup>th</sup> week	5.59	21.4	5.28	11.2
6 <sup>th</sup> week	4.98	30	4.5	22.2
8 <sup>th</sup> week	4.49	36.8	3.57	35.3
10 <sup>th</sup> week	4.09	42.5	2.76	46.7
12 <sup>th</sup> week	3.66	48.6	2.1	56

**Table 3: Mean±SD of both groups and P-value**

Time	Mean±SD (GroupA)	Mean±SD (Group B)	P-value
0 week	7.11±3.32	7.1±3.05	0.9797
2 <sup>nd</sup> week	6.28±2.87	6.08±2.84	0.6765
4 <sup>th</sup> week	5.59±2.64	5.28±2.72	0.4794
6 <sup>th</sup> week	4.98±2.39	4.5±2.36	0.2105
8 <sup>th</sup> week	4.49±2.27	3.57±1.95	0.0086
10 <sup>th</sup> week	4.09±2.12	2.76±1.60	0.0000
12 <sup>th</sup> week	3.66±2.00	2.1±1.25	0.0000

**Figure 1: Epidermal pattern****Figure 2: Dermal pattern****Figure 3: Group B patient at 2<sup>nd</sup> week****Figure 4: Group B patient at 12<sup>th</sup> week**

group of 30–50 years (65.27%).<sup>[4]</sup> Female predominance (84.2%) was seen in our study with female-to-male ratio of 5.3:1. It was comparable to a study done by Satish *et al.*, which showed female preponderance with 80.8% and female-to-male ratio of 4.2:1.<sup>[5]</sup> The study done by Sarkar *et al.* also showed similar findings with 86% females in their study.<sup>[6]</sup> In the present study, most of patients had Fitzpatrick skin type V (75.7%) and 24.3% had Fitzpatrick skin type IV which was comparable to a study of Wali and





**Figure 5: Group A patient at 2<sup>nd</sup> week**



**Figure 6: Group A patient at 12<sup>th</sup> week**

Parwani which had shown that all 20 patients in their study had shown Fitzpatrick skin Type IV and V.<sup>[7]</sup> In our study, 44.7% of patients had duration of melasma in 1–5 years followed by 26.4% in 5–10 years, 24.3% in  $\leq 1$  year, and 4.6% in  $>10$  years duration. This finding was comparable to the study done by Lima *et al.*, in which 5–10 years duration was seen in 45% of patients, followed by 36% with 10–20 years and 18% with  $< 5$  years duration.<sup>[8]</sup> About 52.6% of patients had exacerbation after sun exposure in our study which was similar to a study done by Achar *et al.*, in which 55.1% had exacerbation.<sup>[9]</sup> Most common type of melasma seen in our study was centrofacial (50.7%) followed by Malar (39.5%) and least common was Mandibular (9.8%). This finding was similar to study done by Sarkar *et al.*<sup>[10]</sup> In the present study, epidermal melasma was common which was seen in 47.4% of patients, followed by mixed melasma in 40.8% and dermal pattern in 11.8% of patients, which was comparable to a study done by Dharni *et al.* who had shown the 48.75% patients with epidermal melasma, 45% patients with dermal melasma, and five patients with the mixed type of melasma under Wood's lamp examination.<sup>[11]</sup> Excellent

and very good response were noted by more patients in Group B (47.4% and 31.6%, respectively). Group A patients were having excellent and very good response in 28.9% and 25.1%, respectively. In Group A, Mean Modified MASI score was reduced from 7.11 at baseline to 3.66 at 12<sup>th</sup> week. While in study done by Sarkar *et al.*, mean MASI score was reduced from 10.96 to 2.65 at 12<sup>th</sup> week.<sup>[10]</sup> Group B had 56% reduction in Mean Modified MASI score (from 7.1 to 2). The study done by Wanick *et al.* had shown 19.5% reduction of Mean MASI score from baseline at 12 week.<sup>[12]</sup> Another study by Khuraiya *et al.* used topical application of Modified Kligman Regimen on split face area, showed that at baseline Mean Modified MASI score was 3.7 which reduced to 2.81, 1.79, and 1.2 on 4<sup>th</sup>, 8<sup>th</sup>, and 12<sup>th</sup> week, respectively.<sup>[13]</sup> A comparative study of oral tranexamic acid capsules and topical modified Kligman regimen, in which Mean Modified MASI score was 2.614 at 0 week which reduced to 0.450 at 4<sup>th</sup> week which is also comparable to our study.<sup>[14]</sup> Handog *et al.* demonstrated that when oral antioxidants were used as adjuvants, in comparison to placebo, significant improvement of melasma was noticed.<sup>[15]</sup> In our study, side effects such as erythema and burning were less common in Group B patients compared to Group A due to beneficial effects of oral antioxidants. Oral formulation of carotenoids allows for their systemic effect to reach the dermis and epidermis, resulting in reduced pigment migration from epidermis to dermis.<sup>[16]</sup>

## CONCLUSION

Melasma is a common acquired pigmentary disorder that often motivates the search for dermatological care. It is cosmetically distressing condition with variable response to treatment and recurrence. Oral antioxidants reduce oxidative stress and delay the onset of UVB-induced erythema. Oral antioxidants containing beta-carotene give additional sun protection in addition to topical sunscreen and Modified Kligman Regimen, help in reducing pigmentation and preventing further. They also help in reducing adverse effects which occur due to Modified Kligman Regimen application. Although topical Modified Kligman Regimen remains the gold standard treatment for melasma, addition of oral antioxidants achieve more satisfactory results in melasma patients.

## ACKNOWLEDGMENT

Nil.

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# Risk Assessment and Quality of Life Management in Emergency Health-care System in a Rural Set Up: A Simulating Model in 2020 in IIMSAR and BCRHH, Haldia, West Bengal

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## Abstract

**Introduction:** Every aspect in the management of quality of life is dictated by the risk assessment. The mode of management is ill defined and not yet assessed with optimum satisfaction of the service provider as well as those of the beneficiaries. The art in science is a stretchable factor by which discord generation in the management of a patient in the form of emergency care is partially explained mimicking the tip of an iceberg.

**Materials and Methods:** The study is a preliminary observation in the College of Medicine and Jawaharlal Nehru Memorial Hospital (COM and JNMH), Kalyani. This was performed for a 24 h [from 8 am to 8 am]. All the patients attended the hospital emergency on the November 4, 2017, from 8 am to the next morning till 8 am were included and the patients of obstetrical emergencies were excluded from the study.

**Results:** There are arguably only two indications for medical management-improvement of symptoms (quality of life) and improvement of prognosis (quantity of life). The likelihood of achieving a meaningful improvement in symptoms or prognosis (the benefit) must be balanced against the risk of death or an outcome that results in a reduced quality of life (the cost). Sequential organ failure assessment score, Oxygen lack-alteration of mental state (Glasgow Coma Scale <14), volume decrease in systolic blood pressure <100 mmHg, respiration rate >22/min, urine output 0.5 ml/kg/h, and WBC count >[10 × 10<sup>12</sup>] goes high and lactic acidosis. Life-threatening organ dysfunction caused by a deregulated host response to infection integrated Human Blood Banking System.

**Conclusions:** Again it is said that success is not always a sign of good judgment, equally failure may result from factors you could not have anticipated. Observations in our ER [COM and JNMH] with a simulation in of rural set up in COMJNMH with discharged [D] and admission [A] of a random control [irrespective of time, disease and major assessment for risk].

**Key words:** Cost and benefit, Quality of life, Quantity of life, Risk and benefit

## INTRODUCTION

Every aspect in the management of quality of life is dictated by the risk assessment. The mode of management is ill defined and not yet assessed with optimum satisfaction of the service provider as well as those of the beneficiaries.

The art in science is a stretchable factor by which discord generation in the management of a patient in the form of emergency care is partially explained mimicking the tip of an iceberg. The whole act is a multidirectional approach which is not available in our model. Many decisions can be made purely on the basis of collective learning and personal experience while others require evidences in the process of risk management.

Emergency departments (EDs) are particularly stressful work environments. This can be explained by difficult work conditions including significant workload and psychological demands, lack of resources, and poor support.<sup>[1]</sup> In

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consequence, ED nurses and physicians showed moderate to high levels of burnout.<sup>[2]</sup> However, the majority of research on stress in EDs is conducted in urban settings.

Even so, in comparison to their urban counterparts, nurses, and physicians in rural settings face more challenging working conditions. In addition to the difficult working conditions common to urban settings, specific challenges to rural areas include limited access to specialized care, geographical distance from specialized centers, poor emergency transport capabilities,<sup>[3]</sup> and limited training.<sup>[4]</sup> Rural health-care facilities also face chronic problems with staff recruitment and retention.<sup>[4]</sup> In fact, almost every country reports shortages of health professionals in rural areas.<sup>[5]</sup> This shortage could increase the workload of regular staff, negatively affecting morale and making healthy lifestyles difficult to achieve. Working in such conditions is likely to contribute to burnout and to poor quality of work life (QWL) in rural ED nurses and physicians. Policy-makers need evidence that would allow them to identify which factors could increase the recruitment and retention of nurses and physicians practicing in rural areas.<sup>[5]</sup> It is important to assess their particular difficulties, as rural EDs constitute a safety net of sorts for the 20% of Canadians who live in rural areas. However, to the best of our knowledge, no studies to date have explored factors favoring recruitment and retention, QWL in rural ED nurses and physicians and the associations between these factors.

### Aims and Objectives

*Primarily to assess risks of mortality and morbidity in ER in patients*

Patients are attended in the emergency and are managed and assessed as quick as possible following the model<sup>[6]</sup> [art in science] and modified sepsis-3 model of Sequential organ failure assessment [SOFA]<sup>[7,8]</sup> altered mental state, fast respiration rate, and low blood pressure (BP) (science in art).

### Secondary

- To minimize the indoor admission by keeping close assessment in the observation room with the compact team<sup>[9]</sup> formed on that day schedule
- This is a preliminary assessment on the “cost versus benefit” in quality of life management.

## MATERIALS AND METHODS

There is no cost assessed for the management of a costly human life particularly in the management of an emergency health-care system but still we are there to assess it in terms of a business. There are ways to think that what percentage of an infrastructure is really needed to keep a man in a safe zone, the art of science that dictate the life management akin to achieving a comfortable profit in a fare business.

A checklist for the safety measurement in life care system. The study is a preliminary observation in the College of Medicine and Jawaharlal Nehru Memorial Hospital [COM and JNMH], Kalyani. This was performed for a 24 h [from 8 am to 8 am].

### Inclusion Criteria

All the patients attended the hospital emergency on the November 4, 2017, from 8 am to the next morning till 8 am.

### Exclusion Criteria

The patients of obstetrical emergencies were excluded from the study.

The study design was based on the four steps as dictated by the well accepted mnemonics SWOT

- Strength of the study is by the immediate and late state of quality of life improvement through an organized approach
- Weakness of the study: Long-term follow-up is essential but our study is too short to be free from biasness
- Opportunity: The initial management in emergency is more suitable so that delay in the process of management may deteriorate the condition. So prognosis is altered
- Threats: In emergency is another event which hinders the scientific decision in the process of management. Human, bacterial, viral, fungal, and chemical threats are immediate and poorly assessed in the short time of management.

### Methodology

Patient	Age, Sex, BMI, Functional status
Disease	Severity, previous investigations, complications
co morbidity	Cardiac, respiratory, renal, hepatic, neurological, endocrine, metabolic, hematological, pregnancies, preterm birth
Surgery	Open versus Laparoscopy, elective or emergency, one stage versus multiple,
Physiology	Temperature, blood gases, hematocrit, leukocyte count, urine output, conscious level, blood pressure, coagulation status

[B] The design of the study model has been modified to a form as below: Asking questions and assessing simultaneously the following parameters.

Patient	Age, Sex, BMI, Functional status
Disease	Severity, previous investigations, complications
comorbidity	Cardiac, respiratory, renal, hepatic, neurological, endocrine, metabolic, hematological, pregnancies, preterm birth
Surgery	Open versus Laparoscopy, elective or emergency, one stage versus multiple
Physiology	Pulse, Temperature, respiration, urine output, conscious level, blood pressure
Modalities	USG, CT, X-ray, MRI, random glucose, ECG [done according to the need]

The infrastructure means man, money, and materials when man is the corner stone for the sustainable act. They are the total team worked in this emergency room. This air-conditioned emergency has eight observation beds. The team members were primarily discussed within themselves about the strategic plan to work in a common group with a predefined home work to follow from the beginning to end. The team members are as below.<sup>[9]</sup>

Medical officer	1
House staff	1
Internee	1+(1)
Paramedical trainees (BSF and health assistants)	4
Group -D	2
Nursing staff	1
Medical student (final year)	1

The steps of management we followed with basic control in observation/ER room as below:

1. Attended the patient without delay and allowed to sit or rest on bed
2. Asked about the condition [in short]
3. Pulse, BP, in need pulse oximeter is applied for assessment
4. We took the help of electrocardiogram, X ray
5. We excluded computed tomography, magnetic resonance imaging in this emergency because they are rarely available in rural set up and mostly avoided in emergency life care procedure.

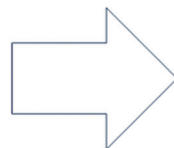
We followed the management procedure in the format:

Resuscitation

Restitution

Restoration 4R

Rehabilitation



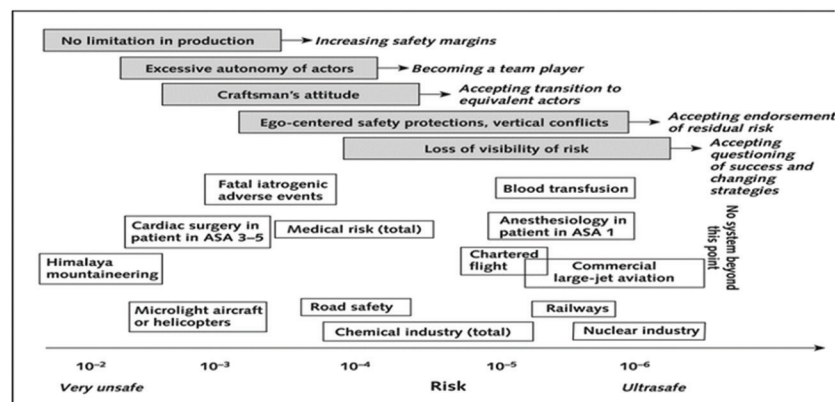
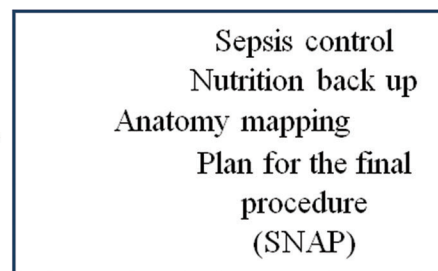
## RESULTS AND DISCUSSION

There are arguably only two indications for medical management-improvement of symptoms (quality of life) and improvement of prognosis (quantity of life). The likelihood of achieving a meaningful improvement in symptoms or prognosis (the benefit) must be balanced against the risk of death or an outcome that results in a reduced quality of life (the cost).<sup>[7]</sup> SOFA score, oxygen lack-alteration of mental state (Glasgow Coma Scale <14), volume decrease in systolic BP <100 mmHg, respiration rate >22/min, and urine output 0.5 ml/kg/h, WBC count >[10 × 10<sup>12</sup>] goes high and lactic acidosis. Life-threatening organ dysfunction caused by a deregulated host response to infection Integrated Human Blood Banking System (IHBBS).

### IHBBS

The concept of Human Blood Banking system is not a newer device, but appears to be reviewed again and again. A group of people will be registered as an “individual living bank” to serve people as and when necessary. The system should be interconnected by the telephone or by mail. The recent mode of WhatsApp also goes as a powerful engine for area wise services. This is one way to minimize the load of stored blood in a bank.

In the text of the open truth, no one is immune from criticism or from comparison of their results with those of their peers. The act in terms of professionalism is on the other side of justification in the text of a critical





management. The object is one that is life is first and limb second. In a subject of an injury by a bullet the common and the important steps are followed that points toward the life-saving approach than to concentrate on the act of removal of bullet that may be more damaging to the system even with risks in life care. The common causes of professionalism in the subject to objective assessment are four Cs. Common sense, competence, commitment, and compassion. All that is true to its nature is to adhere to the legal side of the fact.<sup>[10]</sup>

Again it is said that success is not always a sign of good judgment, equally failure may result from factors you could not have anticipated.<sup>[11]</sup>

Observations in our ER [COM and JNMH] with a simulation in of rural set up in COMJNMH with discharged [D] and admission [A] of a random control [irrespective of time, disease, and major assessment for risk].

Age group (years)	Man [M]	Woman [F]	<1 hr [D]	<2 hrs [D]	[A] M/F
1–10	4	6	8	2	0/0
11–20	5	9	11	2	0/1
21–30	21	8	23	2	3/1
31–40	23	12	18	8	6/3
41–50	12	9	10	5	4/2
51–60	12	4	4	0	7/5
61–80	9	3	2	0	8/2
81+	3	1	0	1	2/1
Total [1–8 1+]	89	52	76	21	30/15

A: Admission, D: Discharge, F: Woman, M: Man

## CONCLUSIONS

The results allowed us to conclude that the ED nurses and physicians in our study had overall good QWL, and allowed

us to identify targets for potential interventions. However, the results also confirm that recruitment for this type of study is difficult and that a larger study will require strategies to improve recruitment. The results of the larger study will yield a greater understanding of the factors associated with work-related quality of life in ED professionals, and of the factors associated with recruitment and retention of ED personnel.

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# Out-look of Comparative Evaluation of Intraperitoneal Instillation of Bupivacaine and Bupivacaine with Dexmedetomidine in Laproscopic Surgeries

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## Abstract

**Introduction:** Intraperitoneal injections of local anesthetic have been proposed to minimize post-operative pain after laparoscopic surgery.

**Aim:** The aim of this study was to comparing the antinociceptive effect of intraperitoneal instillation of bupivacaine and bupivacaine with dexmedetomidine after laparoscopic surgeries in post-operative pain management.

**Materials and Methods:** The study was conducted in the age group of 18–60 years on 120 adult patients of American Society of Anesthesiologists physical status 1 and 2, scheduled for elective laparoscopic surgeries under general anesthesia. Patients were randomly allocated into two groups of 60 each: Group A: ( $n = 60$ ) Intraperitoneal bupivacaine (50 ml 0.25% + 5 ml normal saline) and Group B: ( $n = 60$ ) Intraperitoneal bupivacaine (50 ml 0.25%) + dexmedetomidine 1  $\mu\text{g/kg}$  (diluted in 5 ml normal saline).

**Results:** The mean visual analog score in our study for the bupivacaine group was  $2.95 \pm 0.675$  when compared to bupivacaine and dexmedetomidine group  $2.30 \pm 0.830$  over a period of 24 h. However, it was statistically significant from 6 h postoperatively.

**Conclusion:** VAS was observed at 2, 4, 6, 8, 12, 16, 20, and 24 h and we found that Group B has less score (VAS <3) compared to Group A (VAS >3) which was statistically significant ( $P < 0.05$ ).

**Key words:** Bupivacaine hydrochloride, Dexmedetomidine hydrochloride, Intraperitoneal injection, Pain, Post-operative

## INTRODUCTION

Laparoscopic surgery is a modern surgical technique used for various surgeries such as cholecystectomy, appendectomy, and hernia repair. There are a number of advantages of this technique including reduced pain and bleeding, shorter recovery time and hospital stay, and over all reduced healthcare costs.<sup>[1]</sup>

The pain intensity usually peaks during the 1<sup>st</sup> post-operative period and usually declines over the following

2–3 days.<sup>[2]</sup> The pain after laparoscopic surgery results from the stretching of the intra-abdominal cavity,<sup>[3]</sup> peritoneal inflammation, and phrenic nerve irritation caused by residual carbon dioxide ( $\text{CO}_2$ ) in the peritoneal cavity. The pain can prolong hospital stay and lead to increased morbidity. Intraperitoneal injections of local anesthetic have been proposed to minimize post-operative pain after laparoscopic surgery.<sup>[4]</sup>

The  $\alpha_2$ -adrenergic agonist provides sedation, anxiolysis, analgesia, and sympatholysis. Dexmedetomidine has become one of the frequently used drugs in anesthesia due to its hemodynamic, sedative, anxiolytic, analgesic, neuroprotective, and anesthetic sparing effect. Bupivacaine is an anesthetic that blocks nerve impulses in your body. Bupivacaine is used as a local (in only one area) anesthetic.

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## MATERIALS AND METHODS

After getting approval from the Institutional Ethical Committee, written informed consent was obtained from all the patients before surgery. One hundred and twenty patients of American Society of Anesthesiologists (ASA) physical status I-II of both sexes, aged between 18 and 60 years undergoing laparoscopic surgeries, were included in this prospective, and randomized study conducted.

Patients with the previous abdominal surgery, drug allergy, cardiac patients, significant pulmonary diseases, and leaving intra-abdominal drain at the end of the surgery were excluded from the study.

### Exclusion Criteria

The following criteria were excluded from the study:

- Patient refusal
- Patients belonging to ASA grade 3 and grade 4
- Patients physically dependent on narcotics
- Patients with history of drug allergy
- Patients with gross spinal abnormality, localized skin sepsis, hemorrhagic diathesis, or neurological involvement/diseases.

Pre-anesthetic check-up was carried out preoperatively with a detailed history, general physical examination, and systemic examination. Airway assessment examination was done.

The following laboratory examinations were done in all the subjects in study – hemoglobin, urine analysis, blood sugar, blood urea, serum creatinine, coagulation profile, blood grouping and Rh typing, electrocardiography (ECG)-for patients over 40 years of age, and chest X-ray.

On arrival to the operation theater, a peripheral intravenous line was established with an 18G cannula on the non-dominant hand. The patients were monitored with standard five-lead ECG, heart rate, non-invasive blood pressure, and pulse oximeter. Patients were induced with 2 µg/kg fentanyl and propofol until the verbal response was lost. The muscle relaxation was achieved with atracurium 0.5 mg/kg and the trachea was intubated with an appropriate size endotracheal tube after 3 min. The anesthesia was maintained with admixture of oxygen + nitrous oxide and sevoflurane to achieve the MAC of 1.3 and maintained with top up of injection atracurium (0.1 mg/kg) as a muscle relaxant.

The intraperitoneal instillation of the test drug (bupivacaine 0.25%, 50 ml and bupivacaine 0.25, and 50 ml with dexmedetomidine 1 µg/kg) was done by the same operating surgeon after the gallbladder was taken out and the peritoneal wash had been done. At

the end of the surgery, residual neuromuscular blockade was reversed with injection neostigmine 0.05 mg/kg with injection glycopyrolate 0.01 mg/kg and tracheal extubation was performed as per standard anesthesia protocol.

Data were collected after the patient was shifted to post anesthesia care unit (PACU). Heart rate, systolic and diastolic blood pressure, MAP, and SpO<sub>2</sub> were recorded at 0, 1, 2, 4, 6, and 8 h of intervals after surgery. The time 0 started when the patient was shifted to PACU. If heart rate was <50 beats/min, injection atropine was given. Injection mephentermine was given in 3 mg bolus if the mean arterial pressure was <20% of the baseline.

## RESULT AND DISCUSSION

In the present study, we elicited significant difference in the study groups with respect to the rescue analgesic consumption and total dose analgesics consumption.<sup>[5]</sup> The present study results correlate with study done by Ahmed *et al.*,<sup>[6]</sup> which has shown that intraperitoneal instillation of dexmedetomidine in combination with bupivacaine 0.25% significantly decreases the post-operative analgesic requirements and decreased incidence of shoulder pain in patients undergoing laparoscopic cholecystectomy surgeries. Intraperitoneal instillation of bupivacaine in combination with dexmedetomidine is superior to bupivacaine alone.

In the present study, results vital parameters such as heart rate and blood pressure are important indicators of patients comfort as the values correlated well with high visual analog score (VAS) scores. In the present study, only 8 (13.33%) patients in Group A suffered from shoulder pain as compared to 3 (5%) patients in Group B. Incidence of shoulder pain was also lower in dexmedetomidine group in study done by Ahmed *et al.*<sup>[6]</sup>

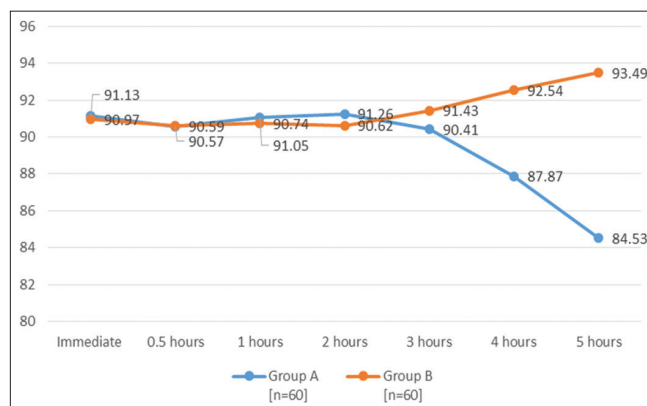


Figure 1: Mean arterial pressure (mmHg) in study group

**Table 1: Demographic distribution in the study**

Patients Characteristic	Group A (n=60)	Group B (n=60)	P-value
Age in years	42.35±11.040	42.12±10.577	0.96 (NS)
Body weight in kg	58.28±4.819	57.95±5.444	0.72 (NS)
Height in cm	156.97±6.142	154.17±5.773	0.07 (NS)
ASA* I/II			
Duration of surgery (min)	47.13±5.861	47.63±5.995	0.64 (NS)

Data presented as mean±standard deviation or Number: \*P<0.05 was considered significant

**Table 2: Comparison of mean duration of analgesic in two group**

Variable	Group A (n=60)	Group B (n=60)	P-value
Mean duration of analgesic	184.43±23.545	198.30±36.065	0.01 (S)

**Table 3: VAS post-operative period up to 24 h**

VAS score	Group A (n=50)	Group-B (n=50)	P-value
Immediate	123.00±6.936	120.02±4.773	0.007 (S)
0.5 h	122.37±7.052	119.52±4.649	0.01 (S)
1 h	119.98±6.307	118.37±6.112	0.15 (NS)
2 h	120.28±5.508	118.67±4.444	0.08 (NS)
3 h	117.08±7.495	117.57±7.263	0.71 (NS)
4 h	117.57±5.838	118.70±5.878	0.29 (NS)
5 h	114.40±6.129	119.27±4.940	0.001 (S)

VAS: Visual analog score

**Table 4: Analgesic requirement**

Analgesic profile	Group A (n=50)	Group-B (n=50)	P-value
Number of patients given rescue analgesia	32 (53.33%)	27 (45.00%)	-
Mean time for first dose (hours)	347.88±4.301	455.19±9.262	0.01 (S)
Mean total dose	3.75±0.440	2.26±0.447	0.01 (S)

**Table 5: Adverse effects**

Side effect	Group A (n=60) (%)	Group B (n=60) (%)
Nausea/Vomiting	4 (6.67)	5 (8.33)
Shoulder pain	8 (13.33)	3 (5.00)
Sedation	0 (0.00)	0 (0.00)
Diarrhea	0 (0.00)	0 (0.00)
Pruritis	0 (0.00)	0 (0.00)
Urinary retention	0 (0.00)	0 (0.00)
Constipation	0 (0.00)	0 (0.00)
Shivering	0 (0.00)	0 (0.00)

The adverse effects noted by us were nausea and vomiting, only 4 (6.67%) patient experienced PONV in Group A as compared to 5 (8.33%) patients in Group B.<sup>7-10</sup> This present study confirms earlier evidence that, in patients with gallbladder diseases undergoing laparoscopic cholecystectomy, intraperitoneal local anesthetic instillation

is more effective when applied at the end of an operation than at the start.

Limitation of the present study is the post-operative pain, which is a subjective experience and can be difficult to quantify objectively and compare when comparing various treatment options [Tables 1-4 and Figure 1].<sup>7-10]</sup>

## CONCLUSION

The following conclusions were drawn after discussion from the study.

1. Demographic data (e.g., age, sex, diagnosis, distribution, and BMI) were comparable in both the groups
2. Mean time taken for the duration of analgesia and total rescue analgesia in Group A was  $3.75 \pm 0.440$  and Group B was  $2.26 \pm 0.447$  min, which was concluded that rescue analgesic requirement was high in Group A than in Group B
3. Mean duration of analgesia (Minutes) in Group A was  $184.43 \pm 23.545$  and in Group B was  $198.3 \pm 36.065$ , which showed that Group A had higher mean duration of analgesia than in Group B after instillation of the drugs respectively
4. Significant changes were seen in hemodynamics (SPO2 and MAP) when both the groups were compared and Group A showed effective analgesic response with minimum hemodynamic alternations
5. No significant complications were observed VIZ, Hypotension, and Bradycardia. Only eight patients suffered from shoulder pain in Group A and three patients in Group B

VAS was observed at 2, 4, 6, 8, 12, 16, 20, and 24 h and we found that Group B has less score (VAS <3) compared to Group A (VAS >3) which was statistically significant ( $P < 0.05$ ).

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# Comparative Assessment of Push-Out Bond Strength of Two Different Root Canal Sealers to Root Dentin: An *In vitro* Study

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## Abstract

**Introduction:** Sealers are an important component for root canal obturation. They bind the gutta-percha to the root canal wall. As a binder, the most important property of the sealer is to have high bond strength. This study will evaluate the bond strength of two experimental sealer and will help to choose the one with high bond strength for successful root canal treatment.

**Aim:** The aim of this study is to do a comparative analysis of the push-out bond strength of two different root canal sealers to root dentin.

**Materials and Methods:** Twenty human permanent anterior teeth with one root and one canal were selected for this study. The teeth were decoronated and roots were biomechanically prepared with rotary ProTaper system, and obturated using two types of sealers: AH plus (Group 1,  $n = 10$ ) and Sure-Seal root canal sealer (Group 2,  $n = 10$ ), along with gutta-percha. The specimens were then divided into three parts (coronal, middle, and apical) by sectioning them horizontally using a diamond disk and a middle third of each section of 1 mm thickness was obtained from each sample and was subjected to the universal push-out test. The values were statistically analyzed using one-way analysis of variance and *t*-test.

**Results:** AH plus sealer showed a higher push-out bond strength than Sure-Seal root canal sealer that was statistically significant ( $P < 0.001$ ). The push-out bond strength was higher in the apical and middle segment when compared to the coronal segment for both groups.

**Conclusion:** It was concluded that AH plus sealer has better bond strength to root canal dentin and helps in reducing endodontic failure.

**Key words:** AH plus, Push-out bond strength, Sure-Seal root

## INTRODUCTION

The current century has run over numerous up to date headways in endodontics, such as in materials and techniques. Nonetheless, the significant objective of non-surgical endodontic treatment stays the same, that is, there should be comprehensive biomechanical preparation and

complete disinfection of the root canal system to achieve a successful three-dimensional hermetic seal.<sup>[1]</sup> The life span of a root canal treated tooth is extraordinarily improved once complete debridement that eliminates the pathogenic organism is achieved. A three-dimensional seal of the root canal space and a good post-obturation restoration ensures prevention of further recontamination from the oral environment, if broken which may lead to failure of the root canal treated tooth.<sup>[2]</sup> The physical properties of the sealer that is vital in fulfilling this objective, include appropriate adaptation and bond of filling material to the wall of the root canal. Since gutta-percha does not directly adhere to the dentinal surface so an adequate and long-lasting bond must be produced by the sealer. It is

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also suggested that, if the sealer bonds to the root canal walls, it will limit the movement of the filling due to the presence of chemical bonding which will further improve the push-out bond strength of the sealer to the dentinal walls of the root canal.<sup>[3]</sup>

AH plus sealer (Dentsply DeTrey, Konstanz, Germany) is measured as a benchmark material for all root canal sealers, as it is been successfully used for many years and also due to its advantages with good adaptation and bond strength.<sup>[4]</sup> An epoxy resin-based sealer by composition that it is supplied as a two pastes system consisting of: paste A (bisphenol-A epoxy resin, bisphenol-F epoxy resin, calcium tungstate, zirconium oxide, silica and iron oxide pigments) and paste B (dibenzyl diamine, tricyclodecane-diamine, amino adamantane, calcium tungstate, zirconium oxide, silica, and silicone oil). The advantageous properties of the AH plus sealer are that it is biocompatible and more radiopaque, has a shorter setting time (approximately 8 h), and decrease solubility, low shrinkage, and higher dimensional stability. The research has, additionally, proven that it has good flow characteristics and it is able to penetrate up to a considerable depth into the dentinal tubules. Sure-Seal (Sure Dent Corp, Gyeonggi-do, Korea) is a hydrophilic bioceramic sealer containing calcium silicate material. It is mainly composed of calcium silicate, calcium sodium phosphosilicate, zirconium oxide, and thickening agent and is available as premixed hydrophilic injectable paste having excellent flowability and is dimensionally stable with high antibacterial properties.<sup>[5]</sup>

Bond strength of endodontic sealers to dentin surface is of important significance since it reduces the chances of debonding of filling from the dentinal surface during an operative procedure or while mastication ensuring that the sealing is perfectly maintained.<sup>[6]</sup> The strength of the bond between the filling material and the root canal wall has been assessed frequently. It has been suggested that for evaluation of bonding strength the push-out test holds more weightage than the conventional shear test, because in push-out test, fracture takes place parallel to dentin bonding interface making it a true shear test.<sup>[7]</sup> This study aims to evaluate the push-out bond strength of AH plus and Sure-Seal root canal sealers to root canal dentin using the universal testing machine.

## MATERIALS AND METHODS

Twenty permanent maxillary incisors that were periodontally compromised and thus extracted were selected. The root surfaces were thoroughly cleaned and teeth were subjected to surface disinfection by completely immersing in 2.5% sodium hypochlorite (Prime Dental, India) for 4 h, after

which they were stored in distilled water till further use. A diamond disk was used to cut the crown of each sample at the cemento-enamel junction. The roots were standardized at 13 mm length. The endodontic access cavity was prepared and a working length 1mm short of the apex, was established using a 15 K file (Mani Inc. Japan). Coronal preflaring was done for all roots using Gates Glidden Drills #2 and #3 in each canal. Biomechanical preparation was done using ProTaper rotary instruments (Dentsply), till #F2 size of ProTaper rotary system for all teeth. Disinfection and debridement of the canal were achieved using copious amounts of irrigant such as 17% aqueous Ethylenediaminetetraacetic acid (EDTA) (Prevest Dentsply) and 5 ml of 2.5% sodium hypochlorite, along with saline irrigant which were used during instrumentation. Final irrigation was completed using 5 ml of aqueous 17% EDTA (Prevest Dentsply) for 1 min, followed by a copious amount of saline (Nirlife NIRMA LIMITED). Each sample was dried with paper points (Dentsply-Tulsa Dental, Tulsa, OK). The sample teeth were divided into two experimental groups (10 each) according to the sealer used for obturation:

- Group 1 – Resin-based sealer [AH plus sealer]
- Group 2 – Bioceramic sealer [Sure Seal Root].

The samples of each group were obturated with the allocated experimental sealer using 0.6, #25 gutta-percha point (Dentsply-Tulsa Dental, Tulsa, OK) single cone obturation technique. Post-obturation, the samples were stored in a moist environment at 37°C for 1 week. Then, each sample was divided into three parts by sectioning them horizontally using a diamond disk and a middle 3<sup>rd</sup> section of 1 mm thickness was obtained from each sample. One section of 1 mm from the middle of each third of the root was obtained for evaluation. Thus, we obtained 30 sections in each group. All samples were evaluated for assessment of their push-out bond strength, using a universal testing machine (UTM; Instron). The plunger tip of the universal testing machine end had a thickness of 0.5 mm diameter. A vertical load was applied at the dentin-sealer interface in an apical to the coronal direction at 0.5 mm/min rate. The maximum load applied to the material was recorded in Newton at the time of dislodgement by the computer. Bond strength was evaluated using the following formula:

$$Mpa = N / 2\pi rh$$

(Mpa: Bond Strength, N: The maximum load for each specimen, r: Root canal radius in millimeters, h: Thickness of root dentin in millimeters,  $\pi$ : 3.14).

## Statistical analysis

Descriptive and inferential statistical analyses were carried out in the present study. Results on continuous measurements were presented on Mean  $\pm$  SD. The level of

significance was fixed at  $P = 0.05$  and any value  $\leq 0.05$  was considered to be statistically significant. Student *t*-tests (two tailed, unpaired) were used to find the significance of the study parameters on continuous scale between two groups. Analysis of variance was used to find the significance of the study parameters between the groups (intergroup analysis).

## RESULTS

Table 1 shows the comparative push-out bond strength for Group 1 and Group 2. Using the unpaired *t*-test, it was observed that there was a statistically significant difference in the push-out bond strength for the middle ( $P = 0.004$ ) and apical ( $P < 0.001$ ) segments, whereas, there was no statistically significant difference seen for the coronal segment ( $P = 0.098$ ) in both the groups. Group 1 (Resin-based sealer) shows a higher push-out bond strength than Group 2 (Bioceramic sealer). It was also observed that push-out bond strength was higher in the middle (Group 1 = 3.14) (Group 2 = 1.73) and apical segments (Group 1 = 4.98) (Group 2 = 2.32) in comparison to the coronal segment in both groups. (Group 1 = 1.98) (Group 2 = 1.05).

## DISCUSSION

The prerequisite for a well obturated tooth is the complete adhesion of the sealant to the root canal dentinal wall and gutta-percha ensuring a hermetic seal.<sup>[8]</sup> Adhesion inherently plays an important role in establishing a three-dimensional seal which, in turn, affects the root strength. Comprehensive adhesion eliminates gaps between the filling material and the dentin wall, thus inhibiting fluid penetration and secondary bacterial contamination.<sup>[9]</sup> The core material and sealant must form a uniform chemical substance that adheres to the wall of the root canal to minimize leakage.<sup>[10]</sup> Gutta-percha, due to its following properties such as biocompatibility, chemical stability, radiopacity, and its ease of manipulation has been the material of choice for obturation. The bonding inability of gutta-percha puts it at a disadvantage when compared

to those obturating materials that now bond to the root dentin.<sup>[2]</sup> A varied number of endodontic sealers have been used with gutta-percha to bond it to root dentin. AH plus is an epoxy biphenyl resin-based sealer that also contains adamantane which helps in mechanical adhesion to the root dentin.<sup>[11]</sup> Sure-Seal (Sure Dent Corp., Gyeonggi-do, Korea) is a premixed, injectable bioceramic sealer containing calcium silicate material with osteogenic and antibacterial properties (pH = 12) and is hydrophilic in nature.<sup>[10,12]</sup> It exhibits excellent physical properties (does not shrink on setting) and has good dentinal bond strength. Sealer-dentin adhesion is necessary under dynamic conditions to prevent sealer dislodgement under mechanical stresses caused by the operative procedure, tooth flexure, and post space preparation.<sup>[13]</sup> Bond strength can be measured using various tests such as push-out bond test, pull-out bond test, shear bond strength test, and micro-tensile bond strength test. Push-out bond strength test has the advantage of evaluating the bond strength at several root levels.<sup>[14]</sup> The force application was in an apicocoronal direction to avoid interference brought about as a result of canal taper.<sup>[6]</sup> A study conducted by Gade *et al.* compared the root-filled teeth using Endosequence BC, AH Plus, and Endomethasone N sealers on the basis of their bond strength and the result of the study showed that the bond strength of Endosequence BC sealer was lower than the AH plus root canal sealer.<sup>[15]</sup> The performance of resin-based sealer was better than the bioceramic-based sealer in the present study. This can be explained by the covalent bonds formed between the amino groups of the dentinal collagen and the epoxy resin of AH plus which resulted in a stronger link to dentin as compared to the interaction of calcium silicate of Sure-Seal root to dentin.<sup>[16]</sup> In this study, both the groups exhibited the lowest push-out bond strength in the coronal third and a highest strength in apical third followed by middle third. Mannocci *et al.* conducted a similar study, where they concluded that the high bond strength value was attributed due to the presence of low dentin tubule density within the apical dentin area.<sup>[17]</sup> The results are also in accordance with the study of Mishra *et al.*<sup>[18]</sup> This being an *in vitro* study, the bond strength of sealers which can be affected by a multitude of factors of the oral environment such as oral fluids, tissue fluids, or periapical fluids has not been accounted. Hence, further investigations are warranted to validate an ideal sealer to be used during obturation.

## CONCLUSION

The resin-based sealer [AH plus] demonstrates a higher bond strength to root dentin than the bioceramic sealer [Sure Seal Root]. Furthermore, for both groups, apical third segment showed a higher push-out bond strength to root

**Table 1: Comparative evaluation of the push out bond strength at different levels using unpaired *t*-test between AH plus and sure seal root sealers**

Sample Segment	Group	n	Mean value	Standard Deviation	t-value	P-value
Coronal	Group 1	10	1.9840	1.44572	1.745	0.098
	Group 2	10	1.0530	0.87040		
Middle	Group 1	10	3.1430	0.64579	3.353	0.004*
	Group 2	10	1.7350	1.16008		
Apical	Group 1	10	4.9890	0.74395	4.957	<0.001**
	Group 2	10	2.3260	1.52710		

$P < 0.05$  – Significant\*,  $P < 0.001$  – Highly significant\*\*



dentin when compared to the middle and coronal third segment of root dentin.

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# Comparison of Microleakage and Cariostatic Properties of Two Commercially Available Pit and Fissure Sealants: An *In vitro* Study

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## Abstract

**Introduction:** Glass-ionomer cement (GIC) is known to have an ion exchange and fluoride release activity, which results in interfering with cariogenic bacteria and has remineralization potential. One such modification was addition of surface pre-reacted glass-ionomer (S-PRG) particles in GIC as fillers. The S-PRG filler particles are formed by an acid-base reaction between fluoroaluminosilicate glass and polyacrylic acid.

**Aim:** The aim of the present study was to compare the microleakage and cariostatic properties of BeautiSealant with S-PRG particles (Mfg. Shofu) and Helioclear F (Mfg. Ivoclar Vivadent) resin sealants.

**Materials and Methods:** A total of 60 caries-free premolar teeth indicated for extraction for orthodontic purposes were collected and divided into two groups; Group A containing 40 randomly selected premolars for the assessment and comparison of the microleakage properties and Group B containing 20 randomly selected premolars for the assessment and comparison of the cariostatic properties. In Group A, the dye leakage of all the 40 specimens was measured using the software under stereomicroscope. The extent of penetration depth of both the materials was determined using stereomicroscope. In Group B, all the 10 specimens from each group were sectioned longitudinally across buccolingual surface and were finally subjected to scanning electron microscopic assessment of sealant-tooth surface interface.

**Results:** There was no significant difference seen in the microleakage of the Shofu BeautiSealant and Ivoclar Helioclear F ( $P > 0.05$ ), whereas the wt.% of the contents of the BeautiSealant (33.45) was found to be more than that of Ivoclar Helioclear F (30.73), which showed a better remineralization potential of BeautiSealant compared to Helioclear F.

**Conclusion:** In future, due to the bioactive properties of the S-PRG particles, they can be used in clinical restoration of early carious lesions in a biomimetic, atraumatic, and non-cavitated manner due to its excellent remineralization potential.

**Key words:** BeautiSealant, Cariostatic, Helioclear F, Microleakage, Remineralization, Scanning electron microscope

## INTRODUCTION

Dental caries and periodontitis are two major causes of tooth loss in adults. To reduce dental caries, it is necessary to prevent demineralization of the intact tooth surface and to

promote remineralization of early stage tooth decay. With the evolution of dentistry and the progress in preventive and adhesive technologies, new techniques are applied for preventing and stopping the carious process.<sup>[1]</sup> Glass-ionomer cement (GIC) is known to have an ion exchange and fluoride release activity, which results in interfering with cariogenic bacteria and has remineralization potential.

One such modification was addition of surface pre-reacted glass-ionomer (S-PRG) particles in GIC as fillers. These fillers have been tried because of its ability of high fluoride release. The S-PRG filler particles are formed by an acid-base reaction between fluoroaluminosilicate glass and

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polyacrylic acid.<sup>[2]</sup> S-PRG is also known to release several types of ions, including Al, B, Na, Si, Sr, and F.<sup>[3]</sup>

S-PRG particles have been shown to deliver caries resistant properties by various earlier studies. These particles when added to pit and fissure sealants will work synergistically and may improve sealing ability.

Among the diverse kinds of bioactive glass filler, S-PRG filler has already been used for a relatively long time in some specific commercial resin-based composites. Therefore, we are carrying out this study to evaluate the microleakage and cariostatic properties of S-PRG-containing resin sealant.

## MATERIALS AND METHODS

The study was conducted in the Department of Pediatric Dentistry, Bharati Vidyapeeth Dental College and Hospital, Pune, after obtaining approval from the Institutional Research Committee and Institutional Ethics Committee. A total of 60 caries-free premolar teeth indicated for extraction for orthodontic purposes were collected from the Department of Pediatric Dentistry, Bharati Vidyapeeth Dental College and Hospital, Pune. The teeth specimens were cleaned ultrasonically to rid them off cellular debris. These teeth were stored in a thymol solution till the experimentation. Then, specimens were removed from the solution, washed, and thoroughly dried.

The samples were divided into two groups; Group A containing 40 randomly selected premolars for the assessment and comparison of the microleakage properties and Group B containing 20 randomly selected premolars for the assessment and comparison of the cariostatic properties.

### Group A: Assessment and Comparison of Microleakage Properties

Group A was divided into two subgroups; Group A1 (Shofu BeautiSealant) and Group A2 (Ivoclar Helioclear F) with 20 samples in each group. The occlusal surfaces on pit and fissure areas of all teeth were etched using 37.5% phosphoric acid gel for 30 s. Subsequently, the etching gel was thoroughly washed using a water spray and the application of adequate amount of primer on the enamel surface of pit and fissure was done using a brush. It was left undisturbed for a second and the surface was light cured for 20 s until a thin and uniform bonding layer was obtained. Later, the application of necessary amount of conventional resin sealant on 20 samples and the resin sealant containing S-PRG particles on other 20 samples was done directly on the pit and fissures. The excess material was removed using a cotton pellet and the surface was light cured for 40 s using a dental light curing unit.

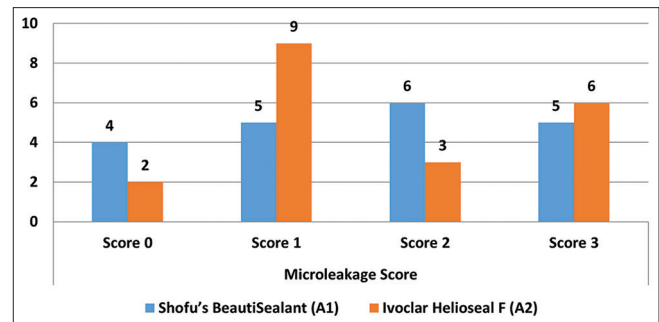
**Table 1: Distribution of microleakage scores among the study groups, n (%)**

Groups	Microleakage score				Total
	0	1	2	3	
Shofu BeautiSealant (A1)	4 (20)	5 (25)	6 (30)	5 (25)	20 (100)
Ivoclar Helioclear F (A2)	2 (10)	9 (45)	3 (15)	6 (18)	20 (100)

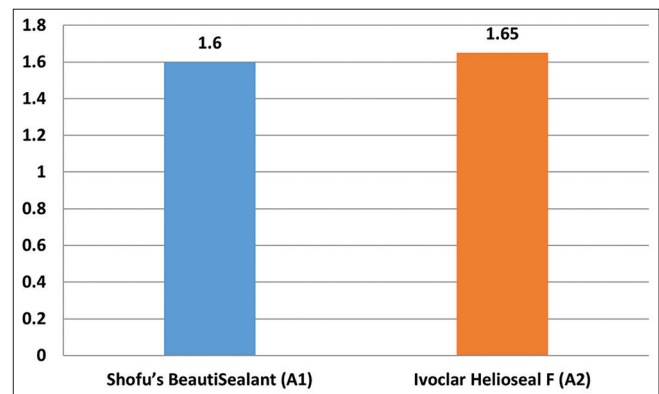
**Table 2: Comparison of mean microleakage score among the study groups**

Groups	Mean±SD	Median	Difference	z value	P-value
Shofu BeautiSealant (A1)	1.60±1.10	2.00	-0.05	-0.099	0.921 (NS)
Ivoclar Helioclear F (A2)	1.65±1.04	1.00			

Mann-Whitney U-test; NS: Non-significant,  $P > 0.05$  – not significant,  $*P < 0.05$  – significant,  $**P < 0.001$  – highly significant



**Graph 1: Distribution of microleakage scores among the study groups**



**Graph 2: Mean microleakage scores of both the study groups**

The restored teeth were stored for 1 week in water at room temperature and then thermocycling was carried out 500 times at 5°C and 55°C with 20 s dwell time. The teeth were then soaked in methylene blue dye for 24 h at room temperature and longitudinally sectioned in buccolingual direction. The dye leakage was measured using the software under stereomicroscope. The extent of penetration depth of both the materials was determined using stereomicroscope.



All the 40 specimens, which included the buccal and lingual halves, were then observed under the stereomicroscope at  $\times 15$  for determining both the depth of penetration (in microns) and microleakage [Figures 1 and 2]. The Williams and Winter scoring criteria were used to calculate the dye penetration for marginal microleakage along the wall.

### Group B: Assessment and Comparison of the Cariostatic Properties

The Group B was divided into two subgroups; Group B1 (Shofu BeautiSealant) and Group B2 (Ivoclar Helioclear F) with 10 samples in each group. The specimens were entirely covered with dental wax, leaving exposed only the area to be restored later and 2 mm area around their margins. They were immersed in lactic acid gel to create artificial demineralized lesions on occlusal enamel.

After the white spot lesions are seen on the enamel surface, the occlusal surfaces on pit and fissure areas of all teeth were etched using 37.5% phosphoric acid gel for 30 s.

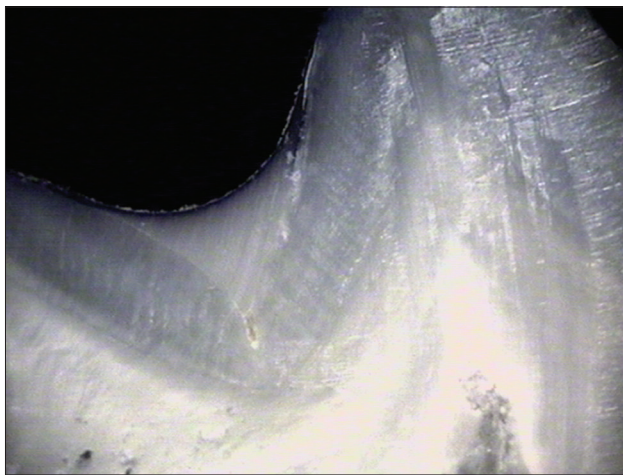


Figure 1: Image under stereomicroscope for Shofu BeautiSealant (Group A1)

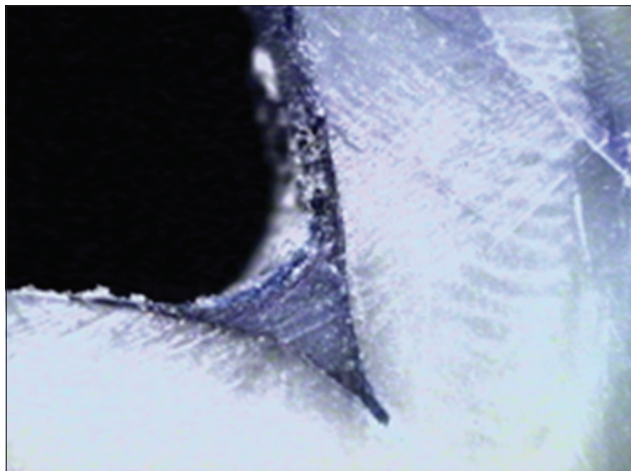


Figure 2: Image under stereomicroscope for Ivoclar Helioclear F (Group A2)

Subsequently, the etching gel was thoroughly washed using a water spray. An adequate amount of primer was applied on the enamel surface of pit and fissure using a brush. It was left undisturbed for a second and the surface was light cured for 20 s until a thin and uniform bonding layer was obtained. Later, the application of necessary amount of conventional resin sealant on 10 samples and the resin sealant containing S-PRG particles on other 10 samples was done directly on the pit and fissures. The excess material was removed using a cotton pellet and the surface was light cured for 40 s using a dental light curing unit.

Ten specimens from each group were sectioned longitudinally across buccolingual surface and were finally subjected to scanning electron microscopic assessment of sealant-tooth surface interface [Figures 3-5].

## RESULTS

The following results can be extrapolated from the above tables –

- There was no significant difference seen in the microleakage of the Shofu BeautiSealant and Ivoclar Helioclear F (\*\* $P > 0.05$ )

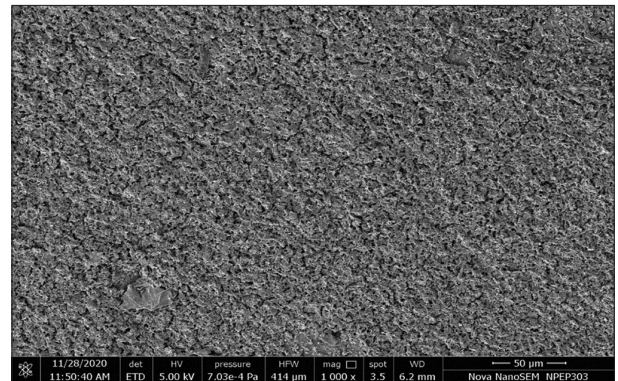


Figure 3: Group B1 showing the compact deposition of the elements on the demineralized enamel surface after the application of Shofu BeautiSealant

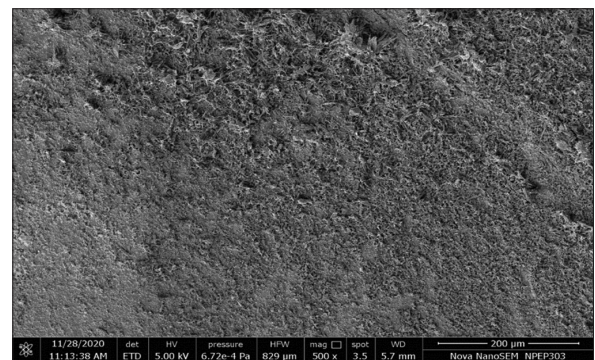
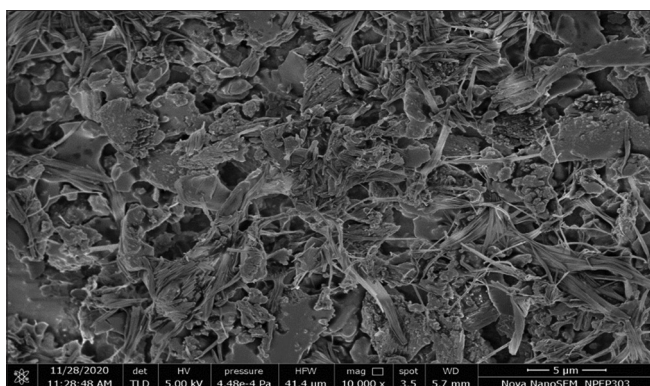


Figure 4: Group B2 showing open/loose deposition of the elements on the demineralized enamel surface after the application of Ivoclar Helioclear F





**Figure 5: Resin tag formations after the application of pit and fissure sealants**

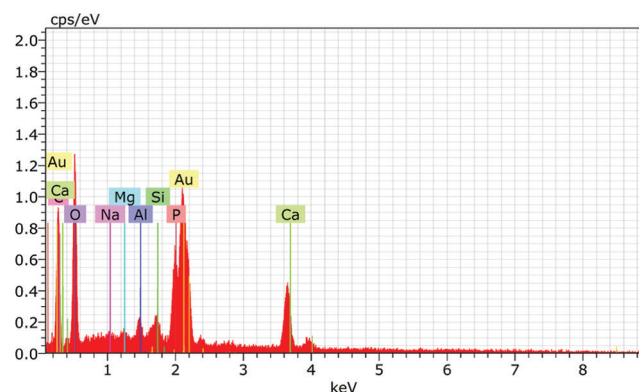
- The mean average microleakage of Shofu BeautiSealant was  $1.60 \pm 1.10$  than the microleakage of Ivoclar Helioclear F ( $1.65 \pm 1.04$ ) with a difference of  $-0.05$  [Tables 1,2 and Graphs 1, 2].

## RESULTS OF CARIOSTATIC PROPERTIES BETWEEN GROUP B1 (BEAUTISEALANT) AND GROUP B2 (HELIOSEAL F)

Savitribai Phule Pune University, Central Instrumentation Facility, EDS Report  
Group B1 – Shofu BeautiSealant

### Spectrum: Objects 10069

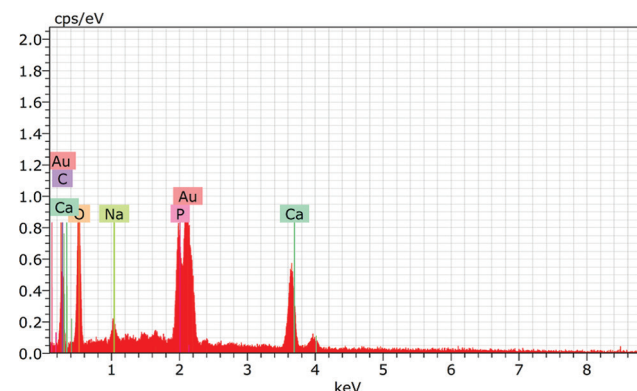
El	AN	Series	Unn.	C norm.	C Atom.	C Error
[wt.%]	[wt.%]		[wt.%]	[at.%]	[wt.%]	(1 Sigma)
O	8	K-series	13.28	39.66	44.63	2.43
C	6	K-series	9.00	23.98	35.95	1.73
Ca	20	K-series	5.31	17.42	7.83	0.30
P	15	K-series	3.83	12.57	7.31	0.22
Si	14	K-series	1.04	3.09	1.98	0.10
Al	13	K-series	0.56	1.84	1.23	0.08
Mg	12	K-series	0.32	1.07	0.79	0.07
Na	11	K-series	0.11	0.37	0.29	0.05
Au	79	M-series	0.00	0.00	0.00	0.00
Total			33.45	100.00	100.00	



## Group B2 (Ivoclar Helioclear)

### Spectrum: Objects 10068

El	AN	Series	Unn.	C norm.	C Atom.	C Error
[wt.%]	[wt.%]		[wt.%]	[at.%]	[wt.%]	(1 Sigma)
O	8	K-series	12.05	37.18	46.22	2.30
Ca	20	K-series	7.31	27.76	13.78	0.42
C	6	K-series	5.46	16.84	27.88	1.32
P	15	K-series	5.30	16.36	10.50	0.27
Na	11	K-series	0.61	1.87	1.62	0.09
Au	79	M-series	0.00	0.00	0.00	0.00
Total			30.73	100.00		



- The following energy-dispersive X-ray spectroscopy (EDS) results suggest that the elements such as Si, Al, and Mg were found additionally in Group B1
- The wt.% of the contents of the BeautiSealant (33.45) was found to be more than that of Ivoclar Helioclear F (30.73), which shows a better remineralization potential of BeautiSealant compared to Helioclear F.

## DISCUSSION

Fissure sealants provide a mechanical barrier against microorganisms and plaque by sealing the pits and fissures and are an effective way for the prevention of caries.<sup>[4]</sup> They protect pits and fissures from caries by preventing food and bacterial impaction.<sup>[5]</sup> Young permanent molars are at an increased risk of decay due to the complicated morphology of the occlusal surface and increased percentage of organic component.

Glass-ionomer sealants bond chemically to enamel without acid etching. The setting reaction of this type of sealant is initiated by the photoactivation of the resin component followed by the acid-based reaction for the ionomer component.

The resin-based pit and fissure sealants present polymerization shrinkage and have different linear coefficients of thermal expansion compared to the tooth. These factors affect the

clinical performance of resin-based sealants by disrupting the adhesive interface, resulting in microleakage.<sup>[6]</sup> In the present study, microleakage was evaluated using dye penetration technique. The scoring criteria used to evaluate the level of dye penetration at the tooth restoration interface which was the criteria described by Williams and Winter and we found no such difference between the microleakage of the S-PRG-containing sealant and the conventional resin sealant.<sup>[7]</sup>

The results of the present study are in accordance to a study done by Indira and Archana in 2016 with similar results where they concluded that there was no statistically significant difference between nano-ionomer and resin-modified GIC.<sup>[8]</sup> Furthermore, in our study, we did not observe any difference in microleakage between S-PRG-containing filler and conventional resin sealant with  $P = 0.921$ .

Another study done by Shin *et al.* in 2013 showed similar results in accordance to our study with no significant difference in the microleakage between an S-PRG filler-containing pit and fissure sealant, BeautiSealant® (Shofu, Japan), and a composite resin sealant, Concise® (3M ESPE, USA).<sup>[9]</sup> The S-PRG filler-containing pit and fissure sealant also showed higher anticariogenic effect than that of flowable resin sealant.

Furthermore, in the present study, the mean average microleakage scores were 1.60 for Group A (Shofu BeautiSealant) and 1.65 for Group B (Ivoclar Heliaseal). This depicts that there was no significant difference seen in microleakage of S-PRG fillers containing sealant compared to conventional resin-based sealant ( $P > 0.05^*$ ), which concludes that addition of S-PRG particles to resin sealants does not have any effect on bonding abilities.

There have been several resin-based sealants with anti-demineralization properties, of which one of them is the S-PRG-containing fillers resin sealant. S-PRG is also known to release several types of ions, including Al, B, Na, Si, Sr, and F. The functions of these ions are summarized in Table 3.

Moreover, the mechanical properties of glass-ionomer sealants are reportedly inferior to those of resin-based sealants.<sup>[10]</sup> However, the procedure for resin-based sealant

application involves placement of the etching material, waiting time, rinsing, and drying followed by sealant application and exposure to the curing light. These time-consuming steps increase the risk of saliva contamination during the procedure, which may have a deleterious effect on bonding if it occurs after etching.<sup>[11,12]</sup> Consequent microleakage and gaps may result in the formation of secondary caries around the sealed fissure. Consequent microleakage and gaps may result in the formation of secondary caries around the sealed fissure.

The results of this study had similar results with our study, where the S-PRG-containing fissure sealant (Shofu' BeautiSealant) showed better remineralization properties with the release of additional elements such as Si, Al, and Mg in comparison to conventional resin sealant (Ivoclar Heliaseal F) as seen according to the EDS report.

In the present study, the sealant bonded by self-etching primer showed an excellent preventive effect on demineralization compared with conventional resin-based sealant. The findings suggest that an S-PRG filler-containing sealant bonded by self-etching primer can prevent demineralization and provide a good cariostatic effect to the tooth enamel. On the basis of the present results, a fissure sealant containing S-PRG filler and bonded by self-etching primer can inhibit enamel demineralization regardless of the enamel condition. S-PRG fillers release several types of ions into distilled water or lactic acid solution, such as Sr, B, Na, Al, and Si ions, implying that a sealant containing S-PRG filler can release and recharge fluoride. A long-term follow-up study is necessary to confirm the remineralization – promoting effect of fissure sealants containing S-PRG fillers.

## CONCLUSION

In the present study, it has been found that the BeautiSealant release ions such as Sr, B, Na, Al, and Si ions, implying that a sealant containing S-PRG filler can release and recharge fluoride. Due to the release of these additional elements, the S-PRG-containing fissure sealant has even proved to show good caries preventive effect and better remineralization potential compared to the conventional resin sealant.

In future, due to the bioactive properties of the S-PRG particles, they can be used in clinical restoration of early carious lesions in a biomimetic, atraumatic, and non-cavitated manner. They can be used in varnishes as coating materials, creating a solid film after physical or chemical changes, which show excellent remineralization and antimicrobial effects. The S-PRG fillers can be incorporated with the silver nanoparticles to have an additional antibacterial effect to the restoration.

**Table 3: Functions of S-PRG ions**

Ions	Functions
F	Fluorapatite production, antibacterial effect, remineralization of demineralized lesions
Sr	Improvement of bone formation and mineralization
Al	Suppression of hypersensitivity
Si	Remineralization of tooth
B	Antibacterial effect, promotion of bone formation

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# Treatment of Giant Cell Tumor around Knee Joint by Modified Sandwich Technique Using Autograft, Hydroxyapatite, Polymethylmethacrylate Cement, and Local Bisphosphonates

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## Abstract

**Introduction:** Treatment of Giant cell tumors (GCT) remains challenging till date because of high recurrence rate of the disease and also notorious post-operative complications which may lead to significant morbidity in patients. Among the various type of surgical procedures, curettage followed by packing with bone graft, bone substitute, and bone cement separated in layers (sandwich technique) is one of the latest procedure done by surgeons.

**Materials and Methods:** In this study, we did a follow-up of 17 cases treated between 2016 and 2019 by modified sandwich method using autograft, hydroxyapatite (HA), polymethylmethacrylate (PMMA) cement, and local zoledronic acid as adjuvant. All of the tumors studied involved more than 50% of the bone diameter and they were classified based on Campanacci grading system. Patients were treated using meticulous curettage followed by subchondral bone grafting using autograft from iliac crest and layers of HA over it as bone substitute. PMMA bone cement was used to fill the rest of cavity after gel foam was placed. Fixation with buttress plate was done in case of impending fracture. Local zoledronic acid was used as adjuvant.

**Results:** The mean follow-up period was 2.5 years and functional outcomes were evaluated using the Musculoskeletal Tumor Society Score (MSTS). All patients continue to be monitored and none lost to follow-up. The MSTS score was studied at 1 year as described by Enneking *et al.* We got a total mean of 22.94 (76.46%) among 17 patients we studied. Only 1 (5.88%) patient had recurrence at 2-year follow-up.

**Conclusion:** Our modified method of the treatment of GCTs around the knee not only achieved a good functional outcome with improved standard of living but also reduced the recurrence rate to 5.88%.

**Key words:** Giant cell tumor, Sandwich technique, Zoledronic acid

## INTRODUCTION

Giant cell tumor (GCT) of bone is a locally aggressive benign neoplasm which can be highly recurrent and occasionally metastatic malignant.<sup>[1]</sup> They accounts for 4–5% of all bone tumors and 21% of benign tumors of

bone<sup>[2]</sup> occurring around metaphyseal area of long bone in contact with joint cartilage.<sup>[3]</sup> Patients presents most often in their third decade of life, with approximately 80% of lesions occurring between 20 and 55 years of age with slight female predilection.<sup>[4,5]</sup> The most common site is distal femur (23–30%) followed by proximal tibia (20–25%) and distal radius (10–12%).<sup>[5]</sup> Depending on the involvement of the articular surfaces, the tumor can be removed either by resection or with curettage. Compared to *en bloc* resection, curettage presents with higher recurrence rates but less morbidity and functional impairment for the patients.<sup>[6,7]</sup> Curettage alone has the worst recurrence rates while using local adjuvants such as polymethylmethacrylate (PMMA)

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cementation, hydrogen peroxide, alcohol, phenol, local application of zoledronic acid, cryoablation with liquid nitrogen, speed burr drilling, and combinations have reduced local recurrence rates.<sup>[7-10,11]</sup> According to Turcotte *et al.*, the curettage and cementation technique with acrylic cement have the advantages of preservation of dynamic stability, thus allowing rapid loading, early detection of recurrence with radiological observation of lysis at the cement bone interface, as well as the heat generated by cement during polymerization has necrotic effect. It can also be used at the onset of pathological fracture. However, the contact of cement with cartilage can damage the cartilage and can possibly generate osteoarthritis as studied by Steryern *et al.*<sup>[12]</sup>

Here, in our study, we treated the GCT around knee joint by meticulous curettage of the tumor using power burr and local application of zoledronic acid was done as adjuvant. Autograft from iliac crest and hydroxyapatite (HA) followed by PMMA bone cement was put in layers and prophylactic fixation was done in cases of impending fracture.

## MATERIALS AND METHODS

A total of 17 subjects including ten women and seven men of age ranging from 21 to 45 years (mean 30.6) were selected for operative intervention after they were provisionally diagnosed clinically and radiologically (X-Ray and magnetic resonance imaging) with GCT around the knee joint and the diagnosis was later confirmed by biopsy. Most common site of tumor was distal femur ( $n = 9$ ) followed by proximal tibia ( $n = 8$ ).

Campanacci *et al.*<sup>[13]</sup> grading system was used to classify tumors, according to which two tumors were classified as Grade 1 (well defined margin and an intact cortex), nine were Grade 2 (with a relatively well defined margin but no radiopaque rim, and thinned and moderately expanded cortex), and seven were of Grade 3 (with indistinct border and cortical destruction).<sup>[13]</sup> Of our patients were having pathological fracture at time of presentation and in all of them, tibia was involved. All of the tumors studied involved more than 50% of the bone diameter in both AP and lateral dimensions. Prophylactic fixation was done in Grades 2 and 3 fractures.

Functional outcomes were evaluated using the Musculoskeletal Tumour Society Score (MSTS)<sup>[14]</sup> at serial interval of 3 months, 6 months, and 1 year. Recurrence was defined as progressive lysis of more than 5 mm at the bone-cement interface or absence of the sclerotic rim at the bone cement interface.<sup>[15]</sup>

## Surgical Procedures

All patients were operated under spinal anesthesia. The operation had three parts. One is excision of the tumor, curettage, and site preparation. Other part is bone graft harvesting and the third part is filling the gap with appropriate materials. For first part, a large cortical window was osteotomized in the cortex depending on the tumor size, so that it can be curetted adequately without any iatrogenic fracture. Window was made by doing multiple drill hole over cortex and adding then with osteotome. Tumor materials were scooped out thoroughly. Power burr was used for completion of meticulous curettage. Following curettage, 4 mg (1 vial) of zoledronic acid was locally administered in the cavity as adjuvant. The second part, that is, autograft was harvested from iliac crest in tricortical layers. Now, the third part started with packing of bone grafts in layers adjacent to the subarticular surface followed by layer of HA over it. Autograft was given for its osteoinductive property while HA served the osteoconductive one. Gel foam was placed above as a layer of separation between hydroxyapatite and PMMA bone cement. Before polymerization of the cement, the curetted zone filled with substitutes was fixed with an internal fixator to ensure mechanical stability and early weight bearing. Internal fixators, mostly buttress plating, were done in cases of impending fracture which are Grade 2 and 3 of Campanacci<sup>[13]</sup> classification system. Pathological bone curetted in every case was sent for histopathological examination.

Post-operative non-weight bearing mobilization using crutch and active knee ROM exercises was started immediately. Partial weight bearing was allowed after 8–12 weeks as tolerated. Nasal calcitonin was advised for every patient at dose of 200 IU every day in alternate nostrils for maximum 3 months.

## RESULTS

The mean follow-up period was 2.5 years (1–4 years). None of the patients lost to follow-up. One patient had local infection over incision site and was managed by debridement and iv antibiotics. Implant was removed for one patient at 2 years due to hardware prominence. Other post-operative complication included stiffness of the knee joint in one patient due to inadequate follow-up and lack of adherence to treatment. Three patient developed early osteoarthritis and one of them had genu varum at 4-year follow-up but with little progression. Conservative management was done for these patients.

The MSTS score was studied at 3 months, 6 months, and 1 year as described by Enneking *et al.*<sup>[14]</sup> Pain, function,

**Table 1: Musculoskeletal tumor society score**

P	Pain	Function	Emotional	Support	Walking	Gait
5	No pain	No restriction	Enthusied	None	Unlimited	Normal
4	Intermediate	Intermediate	Intermediate	Intermediate	Intermediate	Intermediate
3	Modest/non disabling	Recreational restriction	Satisfied	Brace	Limited	Minor cosmetic
2	Intermediate	Intermediate	Intermediate	Intermediate	Intermediate	Intermediate
1	Moderate/Disabling	Partial restriction	Accepts	One cane or crutch	Inside only	Major cosmetic
0	Severe disabling	Total restriction	Dislikes	Two canes or crutches	Not independently	Major handicap

and emotional acceptances were common domains while use of supports, walking ability, and gait were lower limb specific domains taken into account. We got a total mean of 22.94 (76.46%) among 17 patients we studied. Table 1 shows details of MSTS scoring system for the lower limb. Table 2 showing details of our patient.

Only one patient of the upper tibia neoplasm had recurrence at 2-year follow-up and was treated with second curettage and cementation procedure. The recurrence was in contact with cartilage but with none extension to soft tissue. This particular patient was followed up up to 5 years without any recurrence [Figures 1-6 ].

## DISCUSSION

GCTs are locally aggressive benign neoplasm with a large biological spectrum. Treatment for GCTs around the knee includes curettage alone with a high recurrence rate of about 42% (range 21–65%),<sup>[7,16]</sup> curettage with adjuvant therapy such as phenol, PMMA cement, hydrogen peroxide, argon laser photocoagulation, liquid nitrogen, and bisphosphonates and marginal or wide resection. Resection alone leads to functional impairment and may be followed by reconstruction, arthrodesis, or mega-prosthetic joint replacement. Preservation of joint function is an advantage of curettage compared to wide resection. Treating GCT with curettage and cementation was described by Vidal in 1969, and since then this technique has become current practice for a large number of surgeon. Although use of the cytotoxic properties of cement reduces the recurrence between 0% and 29%;<sup>[7,17]</sup> however, the toxic effect of cement in cartilage and surrounding normal tissue still remains question. The use of local adjuvants is not without complications. Chemical burns can occur by phenol, if the application is not carefully performed, and special attention must be given to the neighboring neurovascular structures and soft tissues.<sup>[18]</sup>

Keeping all the above points in our mind, we treated the patients with modified sandwich technique where we used autograft laid in subchondral region, followed by ceramic based HA over it due to its better osteoconductive property.<sup>[19]</sup> Allograft was not used due to its high cost

**Table 2: Musculoskeletal tumor society score – our study finding at 1 year**

S. No.	Pain	Function	Emotional	Support	Walking	Gait	Total (/30)
1	4	3	5	4	3	4	23
2	5	4	4	4	4	3	24
3	4	4	3	4	5	4	24
4	3	4	4	3	4	4	22
5	4	5	3	5	4	4	25
6	3	3	3	4	4	4	21
7	4	4	3	4	3	4	22
8	5	4	5	4	5	4	27
9	4	3	4	5	5	4	25
10	2	3	3	3	3	4	18
11	5	4	4	4	5	4	26
12	3	4	3	4	4	5	23
13	4	4	3	3	4	4	22
14	2	3	3	4	4	4	20
15	3	3	3	3	3	4	19
16	5	4	3	4	4	5	25
17	4	5	4	3	4	4	24
Mean							22.94/30

**Figure 1: Pre-operative X-ray**

and concerns about transmission of pathogens.<sup>[20]</sup> The subchondral autograft helps maintain joint function and prevents articular degeneration.<sup>[21]</sup>

We used zoledronic acid as adjuvant instead of phenol or hydrogen peroxide which are commonly used to reduce any chemical burns or accidental damage to surrounding neurovascular structure. Post-operative fracture, skin

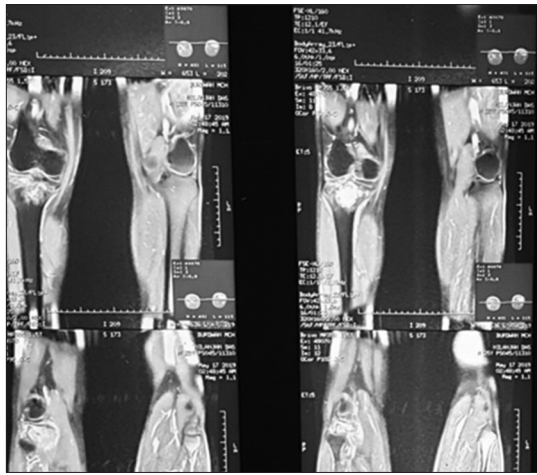


Figure 2: Pre-operative magnetic resonance imaging



Figure 5: Post-operative 6 months



Figure 3: Just post-operative X-ray

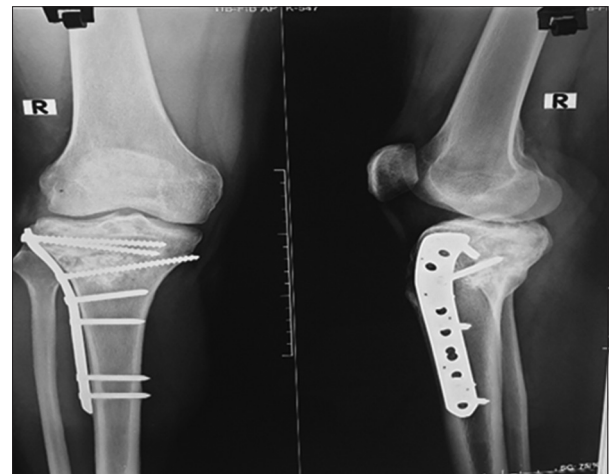


Figure 6: Post-operative 1 year

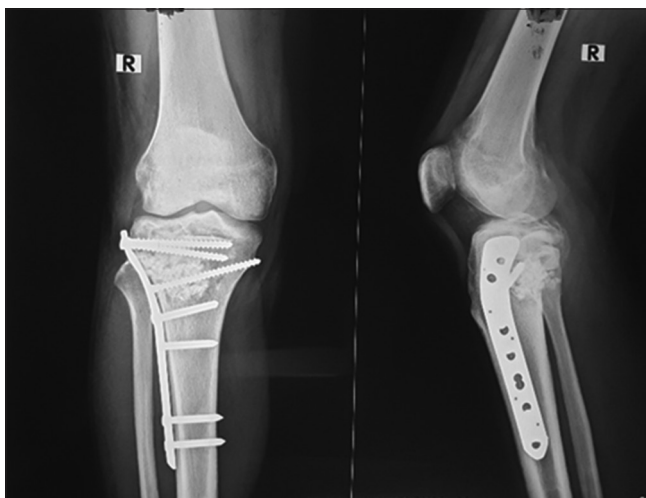


Figure 4: Post-operative 3 months

necrosis, transient nerve palsy, and infection are some of the complications reported with chemical ablations.<sup>[22]</sup> Due to their anti- resorptive properties, some exploratory studies

tested the efficacy of bisphosphonates in GCT of bone. It was shown that nitrogen containing bisphosphonate induces apoptosis in both giant cells and stromal cells *in vitro*.<sup>[23]</sup> We modified the mode of administration and applied locally instead of oral or intravenous route. Although local administration of zoledronic acid as adjuvant is not widely used due to lack of enough evidence but there are case reports of successful use of the same.<sup>[10]</sup> Bisphosphonates do not have any adverse effect on osteoblasts or reparative mechanisms of bone.<sup>[24]</sup> Care was taken to apply zoledronic acid to maximum pathological tissue possible inside the cavity.

Bone cement was used for better mechanical stability and early weight bearing. The heating effect of cement destroys remaining tumor cells. Buttress plating was done in Type 2 and 3 tumors and fixation of the implant was completed before complete polymerization of the cement. Care was taken during cementation to avoid spillage of cement to surrounding soft tissue. Posterior cortex of the cavity

was meticulously curetted to prevent iatrogenic fracture and leak of cement. However, the drawback of our study included low sample size and lack of comparative group.

## CONCLUSION

Our modified method of the treatment of GCTs around the knee not only achieved a good functional outcome with improved standard of living but also reduced the recurrence rate to 5.88%.

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# Study of Psychological Morbidity in Hyperemesis Gravidarum

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## Abstract

**Background:** Hyperemesis gravidarum (HG) is one of the most common causes of repeated antenatal admissions in the first trimester giving rise to both physical symptoms and psychological problems. Unfortunately, psychological problems are not identified and addressed appropriately. The objective of this study is to determine the severity of anxiety and depression in women with HG.

**Materials and Methods:** This was a cross-sectional study. A total of 51 cases admitted in antenatal ward, JSS Hospital, Mysore, with HG for the 1<sup>st</sup> time were screened for depression using Beck's depression inventory (BDI) scale and anxiety using Hamilton Anxiety Scale. The data obtained were analyzed statistically using Microsoft Excel and SPSS Microsoft version 21.

**Results:** Of the total number of cases, majority (60.8%) of the study subjects were primigravida, 9 (17.7%) were suffering from mild to moderate anxiety disorder, 3 (3.9%) were suffering from moderate to severe anxiety disorder, 6 (11.8%) were suffering from borderline depression, 18 (35.3%) were having mild depression, 9 (17.6%) had moderate depression, and 2 (3.9%) had severe depression. Moderate-to-severe anxiety was found only in women aged <24 years. The severity of anxiety was found to be more between 13 and 16 weeks of gestation. The prevalence of depression was more in women with a history of HG in the previous pregnancy.

**Conclusion:** Anxiety was found in 21.5% of pregnant women with HG and 3.9% had severe anxiety. Depression was found in 68.6% of women with HG, of whom 3.9% had severe depression.

**Key words:** Anxiety, Beck's depression inventory score, Depression, Hamilton Anxiety Scale score, Hyperemesis gravidarum

## INTRODUCTION

Pregnancy, although a physiological process, is often associated with minimal to severe risk factors. These risks are usually seen in all groups of people irrespective of the socioeconomic class and the setting and might affect the physical as well as mental health of the pregnant woman. Special care toward mental health and well-being during pregnancy is available in developed countries but women

in the developing and underdeveloped countries are often deprived of this. Hence, a vast majority of women in these countries even though physically healthy are found to suffer from one or the other type of mental disorders such as anxiety, depression, mood disorders, and many more.<sup>[1]</sup>

About 90% of women experience nausea and vomiting during pregnancy.<sup>[2]</sup> Hyperemesis gravidarum (HG), reported to affect 0.5–2% of pregnant women, is a severe form of nausea and vomiting where women cannot tolerate anything orally. It is the most common reason for hospitalization in early pregnancy. "It generally begins around 4–7 weeks of gestation, peaks at 11–13 weeks, and resolves in most cases by 12–14 weeks. About 10% of women continue to suffer throughout the pregnancy."<sup>[3–6]</sup> The most common cause of nausea and vomiting during pregnancy is increased blood levels of human chorionic

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gonadotropin hormone which is secreted from the placenta. Persistent vomiting may result in weight loss, nutritional deficiencies, dehydration, ketosis and electrolyte, and acid-base imbalance.<sup>[7]</sup>

Psychological problems are more common with this disorder of pregnancy. Hence, these problems should be identified and addressed appropriately.<sup>[8]</sup> Along with major depression and generalized anxiety disorder, other psychiatry problems such as avoidant personality disorder and obsessive-compulsive personality disorders are also higher in women with HG. “Even though psychosomatic symptoms are more common in HG, the psychological components of the disease are not fully understood yet.”

There are many factors that may put a woman at an increased risk for developing antenatal depression or anxiety, including but not limited to: The amount of emotional support she receives, history of depression and/or anxiety, and financial issues.<sup>[9]</sup> Antenatal depression is the presence of a major depressive disorder during pregnancy.<sup>[10]</sup> Incidence of depression usually increases during pregnancy as compared with other times in their lives, which could be because of their altered hormone level. Incidence is between 10% and 19%.

The prevalence of anxiety during pregnancy also varies. A study by Teixeira *et al.*<sup>[11]</sup> found that the prevalence of anxiety fluctuates according to trimester. A total of 270 participants were recruited to complete the State Anxiety Inventory (STAI-S) by Spielberger *et al.*<sup>[12]</sup> in the first, second, and third trimesters of pregnancy. STAI-S is used to measure the anxiety a person experiences in a particular state or situation (i.e., pregnancy). They found that 15.0% of the participants had anxiety in their first trimester, 12.3% in the second trimester, and 18.2% in the third trimester. The prevalence of anxiety peaked in the third trimester.

Research also shows that the prevalence of anxiety can be substantially higher during pregnancy compared to depression.

## MATERIALS AND METHODS

All the patients with HG admitted in the antenatal ward of JSS Hospital, Mysore, during the study period from October 2017 to July 2019 were included in the study. Only women who were hospitalized for the 1<sup>st</sup> time in the current pregnancy for the treatment of HG were included in the study. Confirmation of pregnancy was done with ultrasound or a positive urine pregnancy test, if ultrasound was uninformative due to very early pregnancy.

Women with multiple pregnancy, thyroid disease, gestational trophoblastic disease, and established psychiatric illness or any other acute illness that could cause nausea and vomiting which may confound the diagnosis of HG were excluded from the study. Sample size was calculated using the formula  $S = Z^2pq/d^2 = 1.96 \times 1.96 \times 0.02 \times 0.98/0.05 \times 0.05 = 30$ . Hence, a minimum of 30 patients with HG were considered for the study. However, during the study period, a total of 51 cases of HG were admitted in the Department of OBG at JSS Medical College and Hospital, Mysuru, and all of them were included in the study. Ethical clearance was obtained from Ethical Committee of JSSAHER, Mysuru.

The study subjects were counseled regarding the nature of the study. The sociodemographic data, history of present pregnancy, obstetric history, and past and family history of HG were collected in a pretested, semi-structured questionnaire method by interview technique. Translation was done in local language by an interpreter for those who did not know English. The level of anxiety and depression was measured using Hamilton Anxiety Rating Scale (HAM-A) for anxiety and Beck's depression inventory (BDI) for depression. The completed questionnaires were collected and data were analyzed using Microsoft Excel and SPSS Microsoft version 21. Categorical data were represented in the form of frequencies and proportions. Chi-square test was used as the test of significance for qualitative data. Continuous data were represented as mean and standard deviation.  $P < 0.05$  was considered as statistically significant.

## RESULTS

The mean age of the study group was  $23.65 \pm 3.48$  years in our study with nearly 60% of them aged  $<24$  years and 31 (60.8 %) of the study participants were primigravida. Majority (45.1%) of the study subjects were between 9 and 12 weeks, 14 (27.5%) were between 6 and 8 weeks of gestation, and 12 (23.5%) were between 13 and 16 weeks. Only 2 (3.9%) women presented with HG after 16 weeks of gestation.

Out of the 20 multigravida in our study, 10 (50%) had a history of HG in the previous pregnancy. Only 3.9% of the study subjects reported family history of HG.

When we analyzed the HAM-A questionnaire, it was found that 9 (17.6%) of the study subjects were suffering from mild to moderate anxiety disorder and 2 (3.9%) of them were suffering from moderate to severe anxiety disorder [Table 1].

BDI questionnaire analysis revealed that 6 (11.8%) of the subjects were suffering from borderline depression,

18 (35.3%) were having mild depression, 9 (17.6%) had moderate depression, and 2 (3.9%) had severe depression following HG [Table 2].

When the subjects were divided into different age groups and then analyzed for severity of anxiety, it was found that moderate-to-severe anxiety was found only in women aged <24 years. Mild-to-moderate anxiety was found in women of all age groups. The difference was statistically significant [Table 3]. There was no statistically significant difference in the occurrence of depression in different age groups. When the association between anxiety and period of gestation was analyzed, the severity of anxiety was found to be more between 13 and 16 weeks of gestation. Majority of the study subjects suffered from anxiety during the end of the first trimester and the start of the second trimester [Table 4]. The association between depression and the period of gestation is shown in Table 5. There was no statistically significant difference with respect to the same.

In spite of similar experience in the past, among the study subjects who had a history of HG during previous pregnancy, nearly half had an episode of anxiety ranging from mild to severe and 90% were suffering from depression even in the present pregnancy. Only two women

with HG had a positive family history of HG and both of them were suffering from anxiety as well as depression in the present pregnancy.

## DISCUSSION

Mild-to-severe nausea and vomiting in pregnancy usually affects approximately 50–60% of the pregnant women and 0.2–2.5% of them may progress into HG. HG is more common in women of younger age group. In the studies done by Wilkins.<sup>[13]</sup> and Aksoy *et al.*,<sup>[14]</sup> the mean age was 25.6 years and 25.19 years, respectively, which is almost similar to the present study. However, in the studies done by Kjeldgaard *et al.*<sup>[15]</sup> and Poursharif *et al.*,<sup>[16]</sup> the mean age was 30.2 years and 30.9 years which is much higher.

The experience of a pregnant lady during her first pregnancy is different when compared to subsequent pregnancies. Hence, most of the signs and symptoms are more common among primigravida when compared with multiparous women. Similar to the findings of our study, parity predominance was seen in many other studies done by Depue *et al.*,<sup>[17]</sup> Kjeldgaard *et al.*,<sup>[15]</sup> and Kejela *et al.*<sup>[18]</sup>

HG is more common in the first trimester, that is, before 12 weeks of pregnancy and the same was noted in our study (72% of women were in the first trimester). Similar results were seen in the studies done by Kejela *et al.*<sup>[18]</sup> and Magtira *et al.*<sup>[19]</sup>

It is reported in numerous studies that the severity of depression and anxiety could be more in pregnant cases with HG than it is in the healthy pregnant cases.<sup>[20]</sup> In the study by Uguz *et al.*,<sup>[21]</sup> “the prevalence of mood disorders such as major depression and anxiety disorders was detected to be higher in pregnant cases with HG than it is in healthy control group.” It has been suggested that “psychiatric diseases comorbid to HG could be the consequence of trauma and stress of a physical illness.”<sup>[22]</sup>

Mitchell-Jones *et al.*<sup>[23]</sup> demonstrated association between anxiety and HG in their meta-analysis. In studies done by Simsek *et al.*<sup>[24]</sup> and Kender *et al.*<sup>[25]</sup> using Beck’s anxiety

**Table 1: Classification of anxiety disorder among the study subjects**

Severity of anxiety	Frequency (n=51)	Percentage
Anxiety (HAM-A)		
Mild to moderate	9	17.7
Moderate to severe	2	3.9
No	40	78.4

HAM-A: Hamilton Anxiety Rating Scale

**Table 2: Classification of depression disorder among the study subjects**

Severity of depression	Frequency (n=51)	Percentage
Depression (BDI)		
Borderline	6	11.8
Mild	18	35.3
Moderate	9	17.6
Severe	2	3.9
No	16	31.4

BDI: Beck’s depression inventory

**Table 3: Association between anxiety and the age group of study subjects**

Anxiety grade	Age group							
	Between 18 and 21 years		Between 22 and 24 years		Between 25 and 27 years		Between 28 and 37 years	
	Frequency	%	Frequency	%	Frequency	%	Frequency	%
Anxiety (HAM-A)								
Mild to moderate	2	13.3	0	0.0	4	36.4	3	60.0
Moderate to severe	1	6.7	1	5.0	0	0.0	0	0.0
No	12	80.0	19	95.0	7	63.6	2	40.0

Chi-square=13.882, P=0.031\*, HAM-A: Hamilton Anxiety Rating Scale

**Table 4: Association between anxiety and the period of gestation of study subjects**

Anxiety grade	Period of gestation							
	Between 6 and 8 weeks		Between 9 and 12 weeks		Between 13 and 16 weeks		Between 16 and 27 weeks	
	Frequency	%	Frequency	%	Frequency	%	Frequency	%
Anxiety (HAM-A)								
Mild to moderate	2	14.3	1	4.3	5	41.7	1	50.0
Moderate to severe	0	0.0	0	0.0	2	16.7	0	0.0
No	12	85.7	22	95.7	5	41.7	1	50.0

Chi-square=17.24,  $P=0.008^*$ , HAM-A: Hamilton Anxiety Rating Scale

**Table 5: Association between depression and the period of gestation**

Depression grade	Period of gestation							
	Between 6 and 8 weeks		Between 9 and 12 weeks		Between 13 and 16 weeks		Between 16 and 27 weeks	
	Frequency	%	Frequency	%	Frequency	%	Frequency	%
Depression (BDI)								
Borderline	2	14.3	2	8.7	1	8.3	1	50.0
Mild	6	42.9	9	39.1	3	25.0	0	0.0
Moderate	3	21.4	2	8.7	4	33.3	0	0.0
Severe	0	0.0	0	0.0	2	16.7	0	0.0
No	3	21.4	10	43.5	2	16.7	1	50.0

Chi-square=16.50,  $P=0.169$ , BDI: Beck's depression inventory

inventory scale, patients with HG had significantly higher anxiety score and the association was also found to be statistically significant. In our study, HAM-A was used and the study subjects were further classified into mild, moderate, severe, and no anxiety depending on the score obtained by the individual subject. This scale was used based on previous research studies and operational feasibility in the ward with respect to time spent in data collection and quicker responses. Lee *et al.*<sup>[26]</sup> in their study found that anxiety was seen in 26.6% of women with HG which is almost similar to the findings of the present study (21.57%). In the study done by Jennifer Kramer *et al.*,<sup>[27]</sup> nearly 14.2 % of pregnant women suffered from anxiety which is lesser than our study.

Depression component of the pregnant mothers with HG was assessed and evaluated using BDI scale and study subjects were classified from borderline to severe depression. Simsek *et al.*<sup>[24]</sup> and Kender *et al.*<sup>[25]</sup> concluded that patients with HG had significantly higher depression score as per the BDI score and found the difference to be statistically significant. In the study done by Tan *et al.*<sup>[28]</sup> also, depression was found to be significantly associated with HG.

In the study done by Kramer *et al.*,<sup>[27]</sup> 12% had mild and 10% had major depression while in a study by Lee *et al.*,<sup>[26]</sup> 11% had mild and 29% had major depression based on EPDS scores among the pregnant women with HG. Mitchell-Jones *et al.*<sup>[23]</sup> also demonstrated association between depression and HG in their study.

In a study done by Bazarganipour *et al.*,<sup>[29]</sup> 27.5% of the pregnant women were suffering from mild, 11% from moderate, and 2.5% from severe type of depression which is almost similar to our study finding. In the study done by Tan *et al.*<sup>[28]</sup> also, depression was found to be significantly associated with HG. In the study done by Aksoy *et al.*,<sup>[14]</sup> 33.3% had mild, 38.5% had moderate, and 15.4% had severe depression which were statistically significant. Scores of mild depression were similar to our study findings whereas moderate and severe depression was found to be much more when compared to other studies.

When our study result was compared with other epidemiological data, patients with HG were found to have higher levels of depression disorders compared to women without HG.<sup>[30,31]</sup> In contrast to our findings, Bozzo *et al.*<sup>[32]</sup> and Jahangiri *et al.*<sup>[33]</sup> found no association between depressive disorders and HG.

One of the reasons for the variation in the prevalence of various degrees of severity of depression in different studies could be the use of different scores for quantifying depression. According to some studies, BDI depression scale shows more depression when compared to Edinburgh depression scale, because it has more questions related to the somatic symptoms of depression which might lead to misdiagnosis of depression. This discrepancy in result might also be due to differences in sample size and period of gestation “because the incidence and severity of nausea and vomiting in HG varies according to the gestational week.”



## CONCLUSION

Our study suggests that anxiety was found in 21.5% of pregnant women with HG of whom 3.9% had severe anxiety (HAM-A score >25). Depression was found in 68.6% of women with HG, of whom 3.9% had severe depression (BDI score >29). Hence, spending time with patients and understanding their emotional needs as well as creating awareness among medical fraternity about psychological basis of HG are important aspects in caring for patients with HG. Understanding mind-body relationship is a complex task; research regarding the same is the need of the hour.

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# Assessment of the Drug Utilization Pattern of Meropenem in a Tertiary Care Super Specialty Hospital, Telangana: An Observational Study

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## Abstract

**Introduction:** Drug utilization evaluation is a quality-improvement activity to ensure rational use of medications. High empirical prescription of meropenem in the hospitals may lead to the prevalence of resistance, rising the necessity for evaluation of its utilization pattern. Meropenem is a broad-spectrum  $\beta$ -lactam antibiotic of the carbapenem clan. This study aims to evaluate the appropriateness of meropenem utilization pattern in the hospital.

**Purpose:** The main objectives of this study are to assess prescribing pattern of the meropenem and to observe its efficacy among the study participants.

**Methods:** This is a single-centered, observational, and cross-sectional retrospective study done in a tertiary care super-specialty hospital. This study was conducted by reviewing the case files of the patients who received meropenem from April 2021 to September 2021.

**Results:** Meropenem was prescribed to a total of 104 patients including 78 males and 26 females in 6 months. It is observed that meropenem is used for an appropriate indication in 80.76% of the patients. Culture and sensitivity tests were conducted for 88.47%. Duration of antibiotic therapy for more than half of the patients in between 1 and 5 days. Continuation of the therapy is justifiable only in 53.8% of the total patients. About 87.5% of the patients met the therapeutic success.

**Conclusion:** Meropenem is used in appropriate indication for most patients but, considerable inappropriateness is noted in the continuation of meropenem therapy. An increase in adherence to standard treatment guidelines can maximize the rationality in antibiotic therapy and decrease antibiotic resistance.

**Key words:** Antimicrobial resistance, Drug utilization evaluation, Meropenem, Rational use of antibiotics

## INTRODUCTION

According to the WHO, evaluation of drug utilization pattern is a continuous quality-improvement activity, defined as an ongoing, systematic program to ensure rational use of medications.<sup>[1]</sup> It is classified into three categories, that is, prospective, concurrent, and retrospective. Drug utilization

evaluation is specific to a disease or a drug that will assess the pattern of prescription, dispensing, or administration of medications in the hospital.

Antibiotics are the most frequently and imprudently prescribed drugs in hospitals. Approximately 40% of hospitalized inpatients receive antibiotics either for prophylactic or empirical use.<sup>[2]</sup> Inappropriate use of antimicrobials may lead to resistance. Antimicrobial resistance is a widespread health issue accelerated by the excess use of antimicrobials worldwide. An increase in antimicrobial resistance can cause severe infections, complications, increased hospital stays, and mortality.<sup>[3]</sup> Rational use of antibiotics should include compliance with

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the standard treatment guidelines for specific infections. As a broad-spectrum antibiotic of the carbapenem family, meropenem is mostly used to treat a wide variety of infections.

### Spectrum and Mechanism of action of Carbapenems

Carbapenems are beta-lactam antibiotics having bactericidal activity. Amid hundreds of antimicrobials, they possess the broadest spectrum of activity against Gram-negative and Gram-positive aerobes and anaerobes. After the penetration into periplasm through outer membrane proteins, carbapenems bind with the penicillin-binding proteins and enzymes that are crucial for the formation of peptidoglycan chain in the bacterial cell wall. The reason for the efficacy of carbapenems is their ability to bind with multiple penicillin-binding proteins. They are often referred to as last-line agents as they are only used in sternly ill patients or if the suspected organism is multi-drug-resistant.<sup>[4]</sup> Meropenem therapy is highly efficient in the treatment of various infections in adults and children.<sup>[5]</sup> It is a key option for some serious bacterial infections as empirical treatment.

### Indications of Meropenem

Meropenem is mostly prescribed as an empirical therapy prior the identification of causative organisms or after the identification of causative organisms for the treatment of a disease. It is approved for indication in complicated intra-abdominal infections, complicated skin infections, complicated urinary tract infections, respiratory tract infections, pneumonias, septicaemia, febrile neutropenia, bacterial meningitis, obstetric and gynecological infections, and also in cystic fibrosis.<sup>[6]</sup>

As stated by Salehifar *et al.* in an evaluation study on meropenem therapy, high evident empirical prescriptions of meropenem in the hospitals may increase the resistance of meropenem, rising the necessity for evaluation of its utilization pattern.<sup>[7]</sup>

To maximize benefits from meropenem therapy, its utilization in the hospitals must fully comply with the standard guidelines. This study aims to study and analyze the appropriateness of the utilization pattern of meropenem in the hospital and suggest recommendations if necessary.

## STUDY METHODOLOGY

### Idea Conceptualization

The idea of evaluating the utilization pattern of an antibiotic in our hospital originated due to the observation of high empirical prescription of antibiotics without de-escalation by the clinical pharmacist during the regular prescription audits.

### Study Setting

Tertiary care super-specialty hospital located in Hyderabad city, South India. The study was started after the approval of the hospital management with vide acknowledgement number SLGH/CLAD/CPI/002/2021-22

### Study Type

This is a retrospective observational study.

### Study Tool

An annexure was designed to collect the data. The collected data include demographics of the patient, medical and medication history, current diagnosis, duration and dosing of meropenem, clinical outcomes, microbial culture and sensitivity reports, and the type of infection.

### Study Population and Source of Data

All the hospital in-patients who received meropenem during 6 months, that is, from April 2021 to September 2021 were included in the study. A total of 104 files were gathered. All files including the clinical case records, laboratory values, culture, and sensitivity test reports of the hospitalized patients prescribed with meropenem.

### Statistical Analysis

The data which have been collected are compiled in a Microsoft Excel spreadsheet after coding and sorting, the results are exported in the form of frequency and percentages and represented in the form of tables and graphs.

## RESULTS

A total of 104 files of the patients under meropenem therapy during the study period were analyzed. The ratio of male and female patients is observed as 3:1 with 75% male and 25% females. Table 1 shows the distribution of the study population based on age and gender. The total number of patients was divided into five age groups. In the age group of 21–40 year, the number of male and female patients was equal. The age group of 41–60 year contains the highest number of patients in which 16 are female and 32 are male patients. The age group above 80 year has the least numbers of two male patients.

**Table 1: Distribution of the patients in accordance to age and gender**

Age Group (in years)	Gender		Grand Total (n=104)
	Female	Male	
<20	0	0	0
21–40	8	8	16
41–60	16	32	48
61–80	2	36	38
>80	0	2	2
Total	26	78	104

Table 2 presents the comorbid illness that was observed in 60% of total patients. The remaining 40% of the patients had no comorbid illness. Hypertension and diabetes mellitus were most commonly observed in the study participants. Ten of them are post-COVID pneumonia patients.

Graph 1 shows the antibiotic used before meropenem. About 50% of the patients were on a combination of Cefoperazone and Sulbactam before changing to meropenem and 40.4% of patients were started directly with meropenem, respectively. Table 3 presents the final diagnosis of the patients prescribed with meropenem. COVID viral pneumonia is the most common diagnosis among the study population. Septic shock with multiple organ dysfunction syndrome (MODS) is seen in 12 patients.

### Evaluation of Meropenem Therapy

Initially, all the patients received meropenem as empirical treatment. 84 (80.76%) cases were deemed appropriate for indication and 20 (19.24%) were inappropriate. COVID viral pneumonia and urosepsis were the most common indications for meropenem therapy in the present study.

The frequency and dosing duration were analyzed in Table 4. Dosing frequency of meropenem in 53.8% of the total patients was 8<sup>th</sup> hourly, 42.30% of patients was 12<sup>th</sup> hourly, and 3.9% patients was 24 hourly. The dosing duration analysis of the total study population is as follows. One day was considered as minimum time duration and 14 days as maximum time duration. The duration of

meropenem therapy for most of the patients, that is, 63.46% was in between 1 and 5 days.

A clear analysis of sensitivity patterns among the study population is summarized in Table 5. Meropenem indication in all the patients was empirical. Out of 104 study subjects, 11.53% of the patients were not ordered for culture and sensitivity tests. In the remaining 88.47%, it is observed that the study drug was sensitive against the particular organism in 44.23% population and 9.63% of the patients were continued with the drug despite its resistance.

A total of 56 patients were isolated with microorganisms. Out of the identified organisms for which meropenem was used, *Klebsiella pneumoniae* is most prevalent and was isolated in 18 patients through culture and sensitivity tests [Table 6]. Continuation of the therapy was evaluated in all the 104 patients. It is observed that 53.8% of the cases were justified for the continuation of antibiotic [Flowchart 1].

Among the total study population, 87.5% of them were well recovered after using this antibiotic [Table 7].

## DISCUSSION

The rational use of antibiotics is a key element for preventing resistance to antimicrobials. This evaluation was attempted

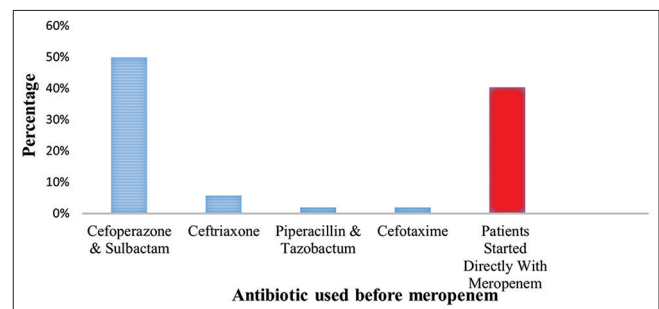
**Table 2: Distribution of the patients on basis of comorbid illness**

Comorbid illness	Number of Patients
Chronic kidney disease	14
Hypertension	40
Diabetes Mellitus	42
Cerebral vascular accident	2
Post-COVID pneumonia	10
Coronary artery disease	12

**Table 3: Frequency of patients based on the diagnosis**

Diagnosis	Number of patients
COVID viral pneumonia	18
Septic Arthritis	2
Urosepsis	16
Septic Shock with MODS	12
Intra-abdominal Infections	8
Skin Infections	14
Dengue Shock Syndrome	6
ENT Infections	8
Melioidosis	2
Cancer of Buccal Mucosa	4
Others	14

MODS: Multiple organ dysfunction syndrome, ENT: Ear, nose, and throat



**Graph 1: The distribution of patients based on the antibiotic used before meropenem**

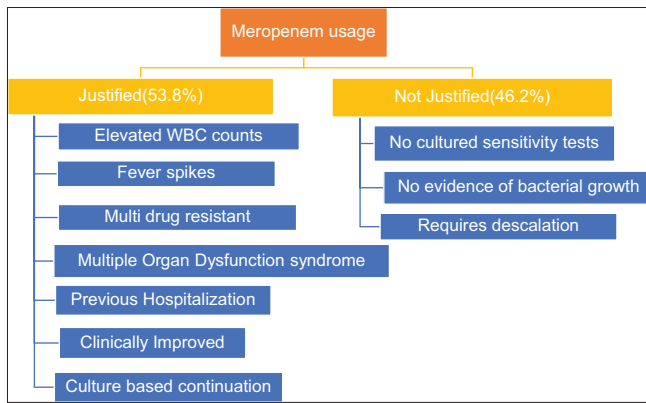
**Table 4: Dosing frequency of meropenem in the patients**

Dosing frequency	Number of Patients (n=104)	Percentage
8 <sup>th</sup> hourly	56	53.8
24 hourly	4	3.9
12 <sup>th</sup> hourly	44	42.30

### Duration of meropenem in the patients

Duration of Antibiotic	Number of Patients (n=104)	Percentage
1–5 days	66	63.46
6–10 days	30	28.84
11–15 days	8	7.7





**Flowchart 1: Flowchart representing evaluation for continuation of meropenem therapy**

**Table 5: Assessment of the sensitivity pattern**

Condition	Number of patients (n=104)	Percentage
No microbial growth	36	34.61
Sensitive to meropenem	46	44.23
Multidrug Resistant cases	10	9.63
Empirical therapy	12	11.53

**Table 6: List of organisms isolated in the culture and sensitivity tests**

Name of the Organism	No of Patients
<i>Burkholderia pseudomonas</i>	2
<i>Pseudomonas aeruginosa</i>	6
<i>Burkholderia cepacia</i>	2
<i>Candida</i> Species	2
<i>Escherichia coli</i>	8
<i>Enterobacter cloacae</i>	2
<i>Enterobacter aerogenes</i>	2
<i>Klebsiella pneumoniae</i>	18
<i>Proteus mirabilis</i>	2
<i>Providencia rettgeri</i>	2
<i>Staphylococcus aureus</i>	2
<i>Staphylococcus hemolyticus</i>	4
<i>Stenotrophomonas maltophilia</i>	4

**Table 7: Clinical outcome of the patients**

Condition	Number of Patients (n=104)	Percentage
Improved	91	87.5
Left against medical advice	4	3.85
Death	9	8.65

to gather basic data for the examination of antibiotic usage in our hospital. This study includes the data of patients administered with meropenem admitted to intensive care unit, surgical, and medical wards in the hospital.

A total of 104 case files were evaluated during the study period, similar to the evaluation carried out in Kolkata by Bera *et al.* on 173 patients, prospectively.<sup>[8]</sup> As presented

in Table 1, the patients who received meropenem were above 20 years and there is no pediatric population in the study. Among the study participants, 75% are males due to the high admission of male patients in the hospital during the study period. Meropenem utilization in 80.76% of the cases was deemed as appropriate for indication and 19.24% were inappropriate. The results are relatively higher in our center compared to results of a similar drug utilization study conducted by Foroughinia *et al.* having 64.8% appropriateness indication, respectively.<sup>[9]</sup>

In a retrospective evaluation by Farzad *et al.*, 41.9% of meropenem prescriptions were inappropriate.<sup>[10]</sup> Culture and sensitivity tests results have a key role in the optimization of the antibiotic regimens and detection of antibiotic resistance among isolated organisms. While assessing the data, it is observed that 88.45% of patients were ordered for microbial culture and sensitivity tests similar to the observations of Mahini *et al.* in which 89.7% were tested for microbial culture.<sup>[11]</sup> Out of the identified organisms, *Klebsiella pneumoniae* is most prevalent which was similar to the study conducted by Bera *et al.*<sup>[8]</sup> Gram-negative bacteria were the predominant isolates and most of them were sensitive to cephalosporins, penicillin's, and aminoglycosides.

The dosing duration analysis shows that 53.8% of the patients were given meropenem thrice daily. More than half of the patients, that is, 63.46% received meropenem therapy in the duration of 1–5 days which was in correlation to Bera *et al.* where 63% had the duration of 1–4 days.<sup>[8]</sup> During this observational study, we found that the continuation of meropenem therapy is justifiable in 53.8% of patients. A study conducted by Al-Hadithi *et al.* in Oman retrospectively has a justification of 55% for the continuation of therapy.<sup>[12]</sup>

Appropriateness of antibiotic use includes termination or de-escalation of antimicrobial treatment when required. About 46.2% of inappropriateness in meropenem utilization is observed when the drug was used as an empirical therapy without any evidence of culture and sensitivity tests was constant to the study conducted by Sanhoury *et al.*<sup>[13]</sup> Overall meropenem therapy was initiated without evidence of culture tests depending on the knowledge and experience of the prescribers.

Meropenem was administered to patients with septic shock and MODS among which 8.65% were deceased. About 87.5% of the total study population were well recovered after meropenem therapy while in Sanhoury *et al.*, 20% of patients died and 65.2% were well controlled. Most of the deaths are due to COVID viral pneumonia.<sup>[13]</sup>

A high clinical outcome of 87.5% was observed after meropenem administration. Our study has higher results

compared to the results reported by Sanhoury *et al.*, where 65.2% met the therapeutic success after meropenem therapy.<sup>[13]</sup>

Our study highlights that about 80% of patients were prescribed with meropenem for appropriate indication and continuation of meropenem therapy was justifiable in more than half of them. We also present deviation from the standard guidelines in meropenem prescription including a high rate of empirical use, inadequate culture and sensitivity tests for some patients, and lack of de-escalation of antibiotic regimen in some cases. The appropriateness can be maximized by the implementation of standard guidelines for the usage of antibiotics.

De With *et al.* stated that implementation of standard treatment guidelines for usage of antimicrobials enhances their rational use and prevents antimicrobial resistance which maximizes clinical outcomes of the patients.<sup>[14]</sup> Data analysis by a single observer to reduce the inter-observer variation is the major strength of the study. As this study is retrospective, it has a few limitations. The data were collected from the available inpatient medical records and the proper reasons for the continuation of meropenem therapy after the culture and sensitivity reports cannot be completely investigated in some of the patients.

## CONCLUSION

Meropenem is used for appropriate indication as per the guidelines in most patients. Considerable inappropriateness is noted in the continuation of meropenem therapy. An increase in adherence to standard treatment guidelines maximizes the rationality in antibiotic therapy and decreases antibiotic resistance.

## RECOMMENDATIONS

Based on results obtained by the above study, the following recommendations are proposed

- Functional pharmacy and therapeutic committee programs could aid in achieving rationality in antimicrobial use
- To revise and implement the treatment guidelines to reduce inappropriate use of antimicrobials
- Regular studies on utilization patterns of antibiotics by clinical pharmacists to obtain definitive outcomes
- To implement antibiotic stewardship forms for monitoring the use of antibiotics

- To decrease the rate of empiric prescriptions and increase the advice of microbial culture and sensitivity tests for the patients
- Conducting awareness programs for the health-care professionals regarding antibiotic resistance to promote rational use of antibiotics
- To conduct cost-effective studies on various antibiotics for further evaluation.

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# Comparison between Esmolol and Intravenous Lignocaine for Attenuating Hemodynamic Response to Laryngoscopy and Endotracheal Intubation

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## Abstract

**Introduction:** Laryngoscopy and tracheal intubation are usually associated initially with bradycardia followed by sympathetic stimulation characterized by increase in heart rate and blood pressure. The cardiovascular changes appear within a few seconds and can last for 5–10 min. In this study, we are comparing the effectiveness of esmolol with lignocaine in blunting the cardiovascular response to intubation.

**Materials and Methods:** After obtaining the Institutional Ethics Committee, the patients were divided into three groups with 20 patients in each group. Patients in Group A were given esmolol 0.5 mg/kg 30 s before intubation, while Group B patients received lignocaine 1.5 mg/kg approximately 90 s before intubation. Group C patients did not receive any drug. The heart rate and blood pressure were noted down at each minute after intubation for 5 min in all the groups and tabulated.

**Results:** From our observations, we found that the heart rate variability was minimal in both Groups A and B, with no statistical significance. However, after laryngoscopy, the 1<sup>st</sup> min and 2<sup>nd</sup> min observations showed a significant difference when compared between the two groups. The blood pressure control was better in the esmolol group, compared to the lignocaine group with  $P < 0.05$ .

**Conclusion:** The present study concluded that esmolol definitely achieves better control of the hemodynamic response, compared to lignocaine, especially in the first few minutes after intubation.

**Key words:** Blood pressure, Esmolol, Heart rate, Lignocaine

## INTRODUCTION

Laryngoscopy and intubation are essential skills to be mastered by the anesthetist. This intervention is usually associated initially with bradycardia followed by sympathetic stimulation characterized by increase in heart rate and blood pressure. The cardiovascular changes appear within a few seconds and can last for 5–10 min.<sup>[1,2]</sup> Unlike in healthy patients, they can cause adverse outcomes in patients with comorbidities such as cardiac disease, hypertension, and kidney disease. Various

agents have been tried in the past to prevent sympathetic stimulation including opioids, B-blockers, local anesthetic infiltration of airway, intravenous lignocaine, calcium channel blockers, and magnesium.<sup>[3]</sup> Lignocaine is a commonly used drug for attenuating the intubation response. Esmolol is a short-acting  $\beta$ -adrenergic blocker which has been found to be very effective to control the heart rate and blood pressure increase after intubation.<sup>[4]</sup> In this study, we are comparing the effectiveness of esmolol with lignocaine in blunting the cardiovascular response to intubation.

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## MATERIALS AND METHODS

After obtaining Institutional Ethics Committee, the patients were divided into three groups with 20 patients in each group (in accordance with the power of the study). All patients belonged to ASA I or II and were between the

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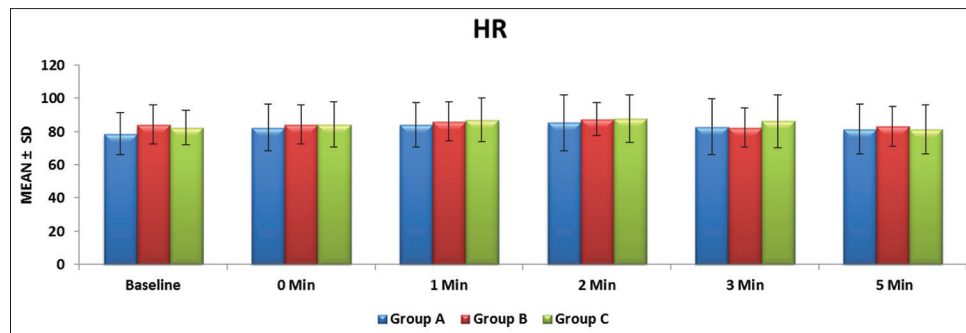


Figure 1: Changes in heart rate

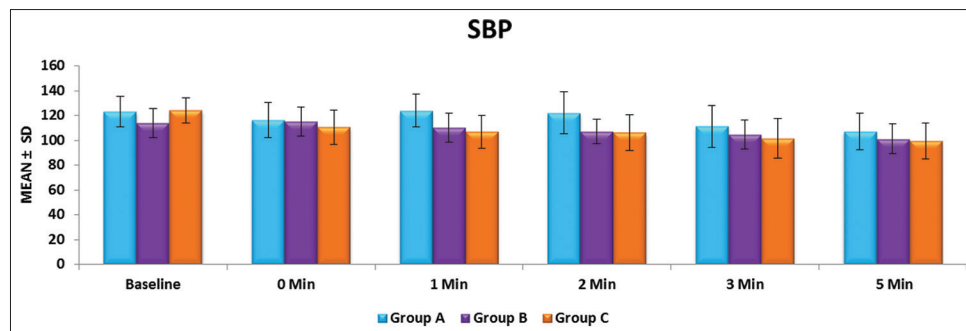


Figure 2: Changes in systolic blood pressure

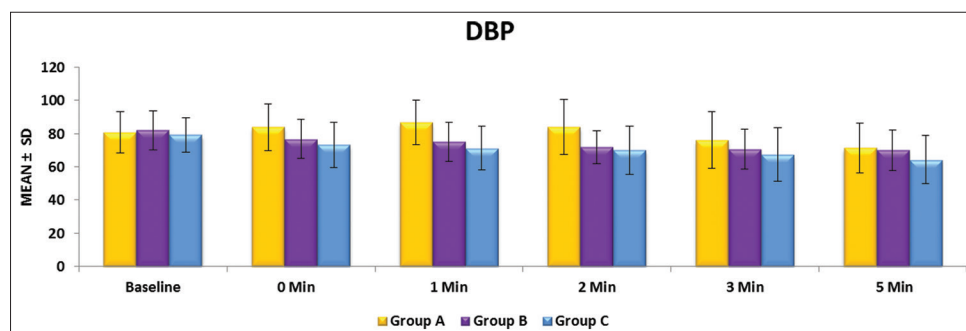


Figure 3: Changes in diastolic blood pressure

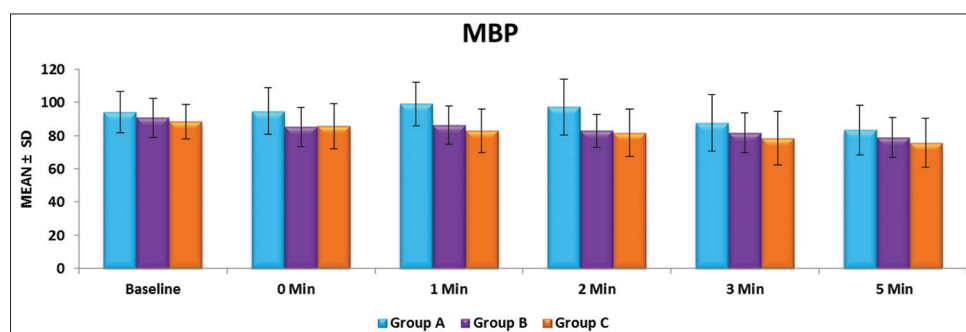


Figure 4: Changes in mean arterial pressure

ages of 20 and 45 years. The baseline heart rate and blood pressure were obtained before induction.

Exclusion criteria included patients with multiple comorbidities, ASA III or more, cardiac surgeries,

emergency surgeries, and laryngoscopy time of >30 s. Patients in Group A were given esmolol 0.5 mg/kg 30 s before intubation, while Group B patients received lignocaine 1.5 mg/kg approximately 90 s before intubation. Group C patients did not receive any drug. The heart rate



**Table 1: Changes in heart rate**

Parameters	Mean±standard deviation			
	Group A	Group B	Group C	P-value
Baseline HR	78.80±12.539	84.25±11.787	82.40±10.415	0.327
HR 0 mins	82.30±14.057	84.30±11.721	84.25±13.649	0.861
HR 1 mins	84.15±13.287	86.05±11.741	86.95±13.193	0.779
HR 2 mins	85.35±16.819	87.60±9.848	87.80±14.439	0.829
HR 3 mins	82.95±16.925	82.50±11.905	86.25±16.039	0.694
HR 5 mins	81.40±14.905	83.10±12.109	81.30±14.553	0.900

**Table 2: Changes in systolic blood pressure**

Parameters	Mean±standard deviation			
	Group A	Group B	Group C	P-value
Baseline SBP	123.20±20.172	114.00±23.143	124.05±21.135	0.270
SBP 0 mins	116.45±17.310	115.00±17.137	110.55±25.353	0.634
SBP 1 mins	123.95±23.119	110.00±13.401	106.95±23.175	0.025
SBP 2 mins	122.15±24.071	106.90±14.205	106.15±16.155	0.013
SBP 3 mins	111.40±19.685	104.70±14.412	101.50±13.197	0.146
SBP 5 mins	107.00±19.714	101.15±13.838	98.40±10.096	0.257

**Table 3: Changes in diastolic blood pressure**

Parameters	Mean±standard deviation			
	Group A	Group B	Group C	P-value
Baseline DBP	80.85±14.755	82.15±16.187	79.35±13.096	0.835
DBP 0 min	83.90±14.567	76.80±15.966	73.25±17.597	0.112
DBP 1 min	86.80±18.412	75.05±9.997	71.25±18.669	0.010
DBP 2 min	84.05±17.721	71.85±13.433	70.05±11.776	0.007
DBP 3 min	76.15±15.675	70.60±10.976	67.35±9.298	0.081
DBP 5 min	71.35±17.055	70.10±11.544	64.35±6.596	0.117

DBP: Diastolic blood pressure

**Table 4: Changes in mean arterial pressure**

Parameters	Mean±standard deviation			
	Group A	Group B	Group C	P-value
Baseline MAP	94.25±15.437	90.90±12.371	88.45±11.468	0.384
MAP 0 min	94.75±15.338	85.40±15.024	85.80±19.856	0.150
MAP 1 min	99.15±19.911	86.40±10.620	82.85±20.142	0.012
MAP 2 min	97.35±18.230	83.00±13.872	81.80±13.121	0.003
MAP 3 min	87.80±16.976	81.65±11.156	78.55±10.081	0.084
MAP 5 min	83.35±17.966	79.00±11.494	75.75±6.703	0.184

MAP: Mean arterial pressure

and blood pressure were noted down at each minute after intubation for 5 min in all the groups and tabulated.

## RESULTS

The heart rate baseline in Group A had a mean of 78.80 ± 12.539, while in Group B, the mean was 84.25 ± 11.787 and  $P = 0.327$ . At 0 min, Group A mean was 82.30 ± 14.057, and in Group B, the mean was 84.30 ± 11.721, and  $P = 0.861$ . At 1 min, Group A had a mean of 84.15 ±

13.287, while in Group B, the mean was 86.05 ± 11.741, and  $P = 0.779$ . At 2 min, the mean of Group A was 85.35 ± 16.819, and Group B mean was 87.60 ± 9.848, and  $P = 0.829$ . At 3 min, Group A mean was 82.95 ± 16.925, while in Group B, the mean was 82.50 ± 11.905, and  $P = 0.694$ . At 5 min, the mean of Group A was 81.40 ± 14.905, and Group B mean was 83.10 ± 12.109, and  $P = 0.900$  [Table 1 and Figure 1].

The systolic blood pressure baseline in Group A had a mean of 123.20 ± 20.172, while in Group B, the mean was 114.00 ± 23.143, and  $P = 0.270$ . At 0 min, Group A mean was 116.45 ± 17.310, and in Group B, the mean was 115.00 ± 17.137, and  $P = 0.634$ . At 1 min, Group A had a mean of 123.95 ± 23.119, while in Group B, the mean was 110.00 ± 13.401, and  $P = 0.025$ . At 2 min, the mean of Group A was 122.15 ± 24.071, and Group B mean was 106.90 ± 14.205, and  $P = 0.013$ . At 3 min, Group A mean was 111.40 ± 19.685, while in Group B, the mean was 104.70 ± 14.412, and  $P = 0.146$ . At 5 min, the mean of Group A was 107.00 ± 19.714, and Group B mean was 101.15 ± 13.838, and  $P = 0.257$  [Table 2 and Figure 2].

The diastolic blood pressure baseline in Group A had a mean of 80.85 ± 14.755, while in Group B, the mean was 82.15 ± 16.187, and  $P = 0.835$ . At 0 min, Group A mean was 83.90 ± 14.567, and in Group B, the mean was 76.80 ± 15.966, and  $P = 0.112$ . At 1 min, Group A had a mean of 86.80 ± 18.412, while in Group B, the mean was 75.05 ± 9.997, and  $P = 0.010$ . At 2 min the mean of Group A was 84.05 ± 17.721, and Group B mean was 71.85 ± 13.433, and  $P = 0.007$ . At 3 min, Group A mean was 76.15 ± 15.675, while in Group B, the mean was 70.60 ± 10.976, and  $P = 0.081$ . At 5 min, the mean of Group A was 71.35 ± 17.055, and Group B mean was 70.10 ± 11.544, and  $P = 0.117$  [Table 3 and Figure 3].

The mean arterial pressure baseline in Group A had a mean of 94.25 ± 15.437, while in Group B, the mean was 90.90 ± 12.371, and  $P = 0.384$ . At 0 min, Group A mean was 94.75 ± 15.338, and in Group B, the mean was 85.40 ± 15.024, and  $P = 0.150$ . At 1 min, Group A had a mean of 99.15 ± 19.911, while in Group B, the mean was 86.40 ± 10.620, and  $P = 0.012$ . At 2 min, the mean of Group A was 97.35 ± 18.230, and Group B mean was 83.00 ± 13.872, and  $P = 0.003$ . At 3 min, Group A mean was 87.80 ± 16.976, while in Group B, the mean was 81.65 ± 11.156, and  $P = 0.084$ . At 5 min, the mean of Group A was 83.35 ± 17.966, and Group B mean was 79.00 ± 11.494, and  $P = 0.184$  [Table 4 and Figure 4].

The ASA classification in Group A was 70% of patients belong to ASA I and 30% belong to ASA II. While in

Group B, 45% of patients belong to ASA I and 55% of patients belong to ASA II.

## DISCUSSION

General anesthesia associated with laryngoscopy and intubation is painful, associated with acute increase in hemodynamic responses, which lasts for around 5–10 min. This sympathetic stimulation can be deleterious in patients with comorbidities and high-risk patients (ASA III or more). Various agents have been tried previously such as opioids, alpha-2 agonists, N-Methyl-D-aspartate receptor antagonists, beta-blocker, and lignocaine.<sup>[2,3]</sup>

Intravenous lignocaine is a conservative free local anesthetic that can be used to suppress the intubation response. Lignocaine has the ability to cause direct myocardial suppression and peripheral vasodilation. Its significance lies in the fact that it can suppress the airway irritation to tracheal mucosa during intubation and hence can blunt the adrenergic response.<sup>[5,6]</sup>

Esmolol hydrochloride is a relatively cardioselective, beta-antagonist. It has a rapid onset of action, has a peak hemodynamic effect within minutes, and possesses a short elimination half-life of 9 min. Hence, it is believed to be an ideal agent to be used for the intubation response.<sup>[7,8]</sup>

From our observations, we can find that the heart rate variability was minimal in both Groups A and B, with no statistical significance. This is in accordance with the study done by Singh *et al.* which showed that both lignocaine and esmolol are effective in controlling the heart rate during intubation.<sup>[6,9,10]</sup>

Blood pressure observations showed no significance in pre-induction baseline values. However, after laryngoscopy, the 1<sup>st</sup> min and 2<sup>nd</sup> min observations showed a significant difference when compared between the two groups.<sup>[11,12]</sup> The blood pressure control was better in the esmolol group, compared to the lignocaine group with  $P < 0.05$ .<sup>[13,14]</sup> This observation is supported in the study by Ugur *et al.* which showed that esmolol provided better control of blood pressure compared to lignocaine.<sup>[7,15]</sup>

## CONCLUSION

Comparing the two most common drugs used for intubation response, we find that both esmolol and lignocaine play a role in preventing the sympathetic stimulation. However, esmolol has definitely been shown to achieve better control of the hemodynamic response, especially in the first few minutes after intubation. Its pharmacokinetic profile makes it a suitable agent in this regard.

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# Study of Inguinoscrotal Swellings in Children using Clinical Assessment and Radiological Evaluation at a Tertiary Care Hospital

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## Abstract

**Introduction:** Inguinoscrotal swellings are one of the most common congenital anomalies observed in children majority of them being attributed to inguinal hernia and hydrocele. The main cause being patent processus vaginalis which fails to obliterate. Although clinical examination itself establishes the diagnosis in various inguinoscrotal swelling, ultrasonography (USG) is recommended as to rule out contralateral hernia and to prognosticate chances of developing hernia on the other side depending on the size of deep ring.

**Materials and Methods:** This study was conducted as an observational study on pediatric patients presenting with inguinoscrotal swelling in Department of Surgery, at our hospital during the study period. Detailed history and clinical examination of swelling was done followed by radiological evaluation using USG.

**Results:** A total of 53 patients fulfilling inclusion criteria were enrolled. The majority of children belonged to age range of 1–5 years (62.3%) and we observed male predominance in our study with male: female ratio of 12.3:1. USG findings revealed inguinal hernia in 39 (73.5%) children. Hydrocele and undescended testis was observed in USG in 11 (20.8%) and 3 (5.6%) of children, respectively.

**Conclusion:** Inguinal hernia does not resolve spontaneously and should be repaired as soon as possible to avoid the risk of incarceration or strangulation.

**Key words:** Hernia, Hydrocele, Inguinoscrotal swelling, Radiology, Ultrasonography

## INTRODUCTION

Inguinoscrotal swellings are one of the most common surgical problems in infancy and childhood worldwide. Among various causes, hydrocele and hernia are most common causes of inguinoscrotal swelling.<sup>[1]</sup> Inguinoscrotal swelling may also be due to other causes such as testicular torsion, epididymo-orchitis, retractile testis, undescended testis, inguinal lymphadenitis, paratesticular, and other

tumors in inguinal region.<sup>[2]</sup> Normally, testis descends in the inguinal region by approximately 28 weeks of gestation and then by 29 weeks, testis descends into the scrotum among males. Along with descent of testes, lining of peritoneum covering the testis extends into the inguinal canal and scrotum which is called processus vaginalis. However, in females, processus vaginalis extends into the labia majoris through the inguinal canal with descent of ovaries and is called canal of Nuck<sup>[3]</sup> The processus vaginalis closes spontaneously at the area of inguinal ring few weeks before birth or immediately after birth. Inguinal hernia in pediatric age group results due to patent processus vaginalis through which abdominal contents protrude into inguinal region.<sup>[2,3]</sup>

The reported incidence of hernia among infants varies from 1% to 4% and it can be as high as 30% among premature

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infants. Most common age of presentation of inguinal hernia among infants is within first 6 months of life.<sup>[4,5]</sup> The majority of inguinal hernia are unilateral among term infants whereas the majority of inguinal hernias among preterm neonates are bilateral.<sup>[2]</sup> Developmentally, the right testis descends late as compared to left testis and thus inguinal hernias among infants are more common on the right side. Unilateral hernias are more common in male infants whereas bilateral hernias are more common in female infants.<sup>[6]</sup> Other common cause of inguinoscrotal swelling is hydrocele which may be of three types, communicating, non-communicating, and hydrocele of cord. In case of communicating hydrocele, processus vaginalis is patent which allow movement of the fluid between peritoneal cavity and tunica vaginalis whereas in case of non-communicating hydrocele, obliteration of processus vaginalis occurs proximally.<sup>[7]</sup>

Usually, the hernias are asymptomatic but typically, the child may present with intermittent swelling in groin, scrotum, or labia which appear during crying, straining, and other activities causing increased intra-abdominal pressure and may disappear spontaneously or manually. Child may also present with vague, chronic sharp pain in groin which increases during the exercise.<sup>[8]</sup> Clinically, a child is assessed for appearance of inguinoscrotal swelling during crying or straining. Cord is palpated to determine its thickness which is called silk glove sign. Both the testis must be examined. Hydrocele may present as a translucent non-tender inguinal swelling.<sup>[8]</sup>

It is important to differentiate between different types of swelling as the management strategy for individual diagnosis differs. The diagnosis of swelling is based on history and clinical examination. However, in few cases, who present with history suggestive of hernia, but the examination reveals inconclusive findings, radiological investigations such as ultrasonography (USG), computed tomography, and magnetic resonance imaging play an import role. USG is a safe and inexpensive tool that may help in improving the diagnosis in case of inguinoscrotal swelling. Furthermore, it may be helpful in deciding the management strategy in case of inguinoscrotal swelling.<sup>[9]</sup> The present study was conducted at a tertiary care center to assess different types of inguinoscrotal swelling in children using clinical assessment and radiological evaluation at tertiary care center. Objectives of the study were to study the demographic pattern, clinical presentation, and radiological differentiation of inguinoscrotal swelling among children presenting at tertiary care hospital.

## MATERIALS AND METHODS

This study was conducted as an observational study on pediatric patients presenting with inguinoscrotal swelling

in Department of Surgery, People's Hospital Bhopal during the study period of 18 months, that is, from November 1, 2019 to April 30, 2021. All the patients with inguinoscrotal swelling, belonging to age range of 6 months–14 years and whose guardians consenting for the study, were included in the study. However, patients with exstrophy of bladder, prune belly syndrome, and intersex patients were excluded from the study. After obtaining ethical clearance from Institute's Ethical Committee, all the patients presenting at the study area during the study period with inguinoscrotal swelling belonging to age range of 1 day–14 years and fulfilling the inclusion criteria were included using purposive sampling. Written consent was obtained from the guardians. Data regarding sociodemographic profile such as age and gender were obtained from guardians and entered in pretested questionnaire. Detailed history regarding the inguinoscrotal swelling such as onset, duration, laterality, reducibility along with birth history, period of gestation, and family history was obtained and entered in questionnaire. History regarding presence of congenital anomalies was also enquired and entered in questionnaire. Detailed physical examination of swelling was conducted to assess the nature, type, and reducibility of swelling. Location of testis was also assessed to rule out undescended testes. Transillumination test was also done to establish the diagnosis. Furthermore, detailed general and systemic examination was conducted to assess the presence of associated congenital anomalies. All the patients were subjected to complete blood examination and other relevant investigations. Further, all the patients were subjected to radiological examination using USG to establish the accurate diagnosis and to assess associated congenital anomalies. Radiological examination was also done in case of unilateral presentation to rule out possibility of contralateral hernia.

## Statistical Analysis

Data were compiled using MsExcel and analyzed using IBM SPSS software version 20. Data were grouped and expressed as frequency and percentage whereas numerical data were expressed as mean and standard deviation. Appropriate statistical test was applied and  $P < 0.05$  was considered statistically significant.

## RESULTS

A total of 53 patients fulfilling inclusion criteria were enrolled. The majority of children belonged to age range of 1–5 years (62.3%) and we observed male predominance in our study with male: female ratio of 12.3:1. Out 53 children, 37 (69.8%) children were delivered at term whereas 16 (30.2%) were premature [Table 1].



**Table 1: Distribution according to the baseline variables**

Baseline variables	Frequency (n=53)	Percentage
Age		
<1	14	26.4
1–5	33	62.3
>5	6	11.3
Gender		
Male	49	92.5
Female	4	7.5
Period of gestation		
Preterm	16	30.2
Term	37	69.8

About 100% children in our study had swelling in inguinoscrotal region and 1 child (1.9%) had pain. About 58.5% children presented with swelling at inguinoscrotal region followed by 32.1% and 9.4% children with swelling at inguinal and scrotal region, respectively. In majority of the children (52.8%), the duration of swelling was found to be between 1 month and 1 year [Table 2].

USG findings revealed inguinal hernia in 39 (73.5%) children. Hydrocele and undescended testis was observed in USG in 11 (20.8%) and 3 (5.6%) of children, respectively [Figure 1].

Inguinal hernia was observed as a unilateral swelling in 37 (94.8%) cases out of 39 whereas it was bilateral in 2 (5.1%) cases only. However, swelling due to hydrocele (100%) and undescended testes (100%) was usually unilateral. In the present study, the observed association of inguinoscrotal swelling with laterality was found to be statistically insignificant ( $P > 0.05$ ). In the present study, we observed no significant association of diagnosis with laterality in both males and females ( $P > 0.05$ ). About three cases had associated epididymal cyst whereas renal agenesis was observed in one case [Table 3].

## DISCUSSION

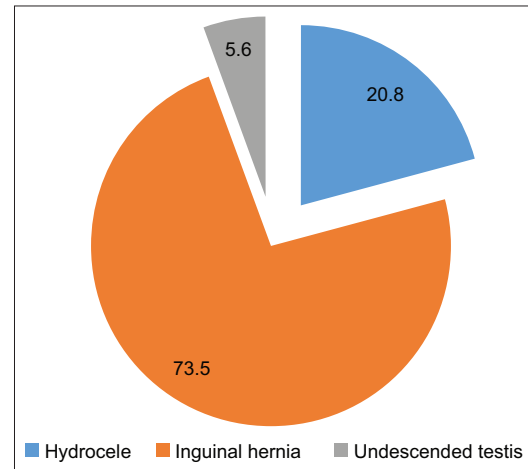
Inguinoscrotal swellings are commonly encountered condition in pediatric surgery. These swellings often necessarily arise due to persistent funicular process or in the constituents of spermatic cord.<sup>[10]</sup> Among all the causes of inguinoscrotal swellings, the most common causes are inguinal hernia and the hydrocele.<sup>[11]</sup> Inguinal hernia in the childhood may not be the sole presentation, there are certain associated conditions which may be observed with inguinal hernias. These associated anomalies include hypospadias, epispadias, cryptorchidism, ambiguous genitalia, prune belly syndrome, and bladder exstrophy. The incidence of such conditions is higher in preterm neonates, that is, about 30% preterm neonates may have these

**Table 2: Distribution according to the characteristics of clinical features**

Characteristics of Clinical features	Frequency (n=53)	Percentage
Clinical features		
Swelling	53	100
Pain	1	1.9
Site of swelling		
Inguinal	17	32.1
Inguinoscrotal	31	58.5
Scrotal	5	9.4
Duration of swelling		
<1 month	3	5.6
1 month–1 year	28	52.8
>1 year	22	41.5

**Table 3: Gender-wise association of diagnosis with laterality**

Gender	Diagnosis	Side			P-value
		Right	Left	Bilateral	
Male	Inguinal hernia	20 (57.1)	13 (37.1)	2 (5.7)	0.9
	Hydrocele	7 (63.6)	4 (36.4)	0 (0)	
	Undescended testis	1 (33.3)	2 (66.7)	0 (0)	
Female	Inguinal hernia	2 (50)	2 (50)	0 (0)	NA
Total	Inguinal hernia	22 (56.4)	15 (38.4)	2 (5.1)	
	Hydrocele	7 (63.6)	4 (36.4)	0 (0)	
	Undescended testis	1 (33.3)	2 (66.7)	0 (0)	

**Figure 1: Distribution according to the ultrasonography diagnosis**

conditions along with inguinal hernias.<sup>[12,13]</sup> We aimed to study different types of inguinoscrotal swelling in children using clinical assessment and radiological evaluation.

The previous studies have reported that maximum cases of inguinoscrotal swelling especially inguinal hernias present in children below 5 years of age.<sup>[14]</sup> In our study, the majority of children (62.3%) belonged to 1–5 years of age group. Similarly, in a study of Wani *et al.*, maximum children with

inguinoscrotal swelling belonged to 3–6 years of age at the time of presentation (30%).<sup>[15]</sup> Approximately 50% cases with inguinoscrotal swellings in a study by Verma *et al.* belonged to toddler and preschool age group.<sup>[8]</sup> The age of presentation was similar in a study of Charles *et al.*, where it was reported that >70% cases with inguinal hernia present before 6 years of age.<sup>[16]</sup>

Male predominance for inguinoscrotal swelling has been reported by the previous literature.<sup>[17,18]</sup> In the present study, about 92.5% cases with inguinal swellings were males. Thus male predominance was observed with male: female ratio of 12.3:1 in our study. Jadhav *et al.* documented male predominance for inguinoscrotal swellings with male: female ratio of 11.5:1.<sup>[19]</sup> Verma *et al.* documented male predominance of inguinal swelling with a ratio of 7:1.<sup>[8]</sup>

Preterm delivery and prematurity are identified as a significant risk factor associated with inguinal hernias and congenital hydrocele.<sup>[20]</sup> Rao *et al.* reported the incidence of inguinal hernia in premature infants as 13%.<sup>[20]</sup> In our study, about 30.2% cases with inguinoscrotal swellings were born preterm. However, in studies conducted by Honeyपालsingh *et al.*<sup>[2]</sup> and Jadhav *et al.*,<sup>[19]</sup> prematurity was associated with inguinoscrotal swellings in 2 (10%) cases.

We conducted the study in 53 cases with inguinoscrotal swellings. About 35.1% cases had inguinal swellings whereas 8.8% had scrotal swellings. Apart from swelling, pain was associated with 1.9%, that is, one child experienced pain. The pain may also represent complications such as loop entrapment and torsion of testes.<sup>[8]</sup> Verma *et al.* (2018) noted inguinal swellings in 77.3% cases whereas 13.6% and 9.1% cases had scrotal and inguinoscrotal swellings, respectively.<sup>[8]</sup> Jadhav *et al.* documented incarceration in 4% cases and that too on the right side presenting with severe pain.<sup>[19]</sup> The duration of swelling may help in determining the complication in cases with inguinoscrotal swellings and also depicts the health seeking behavior of parents or guardians of the children. In our study, as per the history, the duration of swelling was found to be between 1 month and 1 year (52.8%) in maximum cases, followed by 41.5% cases in whom swelling was present for more than 1 year. Similarly, Jadhav *et al.* observed swelling with duration of 1 month–1 year in maximum number of cases (46%) followed by swelling for 1–5 years (40%).<sup>[19]</sup>

Our study aimed at evaluating inguinoscrotal swellings clinically as well as radiologically. USG was done for fulfilling this objective. USG has been considered as a safe and inexpensive tool which can be utilized in children and infants without the risk of radiation hazard. This tool might help in improving the diagnosis in case of inguinoscrotal

swelling and in deciding the management strategy in case of inguinoscrotal swelling.<sup>[9]</sup> Based on the findings of clinical examination and radiological diagnosis, final diagnosis was established. USG was suggestive of inguinal hernia in maximum cases 73.5% and hydrocele in 20.8% cases. USG revealed undescended testes in 5.6% cases which was in concordance with the clinical diagnosis. Our study findings were supported by findings of Meena *et al.*, in which the authors recommended the use of USG in all cases of inguinoscrotal swellings irrespective of the mode of presentation of the child.<sup>[21]</sup> Youssef *et al.* highlighted the role of color Doppler USG for guiding in diagnosis as well as management of inguinoscrotal/inguinolabial swelling. The USG revealed hydrocele in majority of cases (35) and among them, hydrocele was of non-communicating type in maximum cases. Hydrocele was followed by hernia and undescended testes in 30 cases each.<sup>[9]</sup>

The literature suggests inguinal hernia and hydrocele as a most common causes of inguinoscrotal swelling in children.<sup>[2]</sup> In our study, inguinal hernia was the most common cause of inguinoscrotal swelling in 73.5% cases followed by hydrocele (20.8%) cases. Our study findings were concordant with the findings of Verma *et al.* in which 72.7% of the swellings were due to inguinal hernia followed by hydrocele in 11.4% cases.<sup>[8]</sup> Koranga *et al.* observed inguinal hernia in all the cases with inguinoscrotal swellings and of them 10 (out of 40) cases had associated hydrocele.<sup>[6]</sup> Congenital inguinal hernias may be predominantly observed on the right side as developmentally, the right testes descend late as compared to the left testes. Unilateral hernias are more common in male infants whereas bilateral hernias are more common in female infants.<sup>[6]</sup> However, it has been suggested that hernias may be bilateral in 10–15%.<sup>[8]</sup> Out of various causes, inguinal hernia was observed as bilateral as well as unilateral swellings whereas other swelling was unilateral. Inguinal hernia was bilateral in 5.2% cases in males and none in females. Inguinal hernia was predominantly observed on the right side in males, whereas in females, the laterality showed no difference. Hydrocele was predominantly right-sided whereas undescended testes were commonly observed on the left side. Our study findings were concordant with the findings of the previous studies.<sup>[6,8]</sup>

The limiting factor in our study was the sample size because of a worldwide COVID-19 pandemic. Although a fair sample size could be achieved and had there been no pandemic in the duration of the study, we could have recruited a significant more number of patients. Due to the limited time period of the study, children could not be followed in case they developed hernia on the contralateral side.

## CONCLUSION

Inguinoscrotal swellings are one of the most common congenital anomalies observed in children majority of them being attributed to inguinal hernia and hydrocele. The main cause being patent processus vaginalis which fails to obliterate. Although these swellings are termed as congenital, they may occur at any time during infancy till childhood, mostly before 5 years of age. The majority of inguinal hernias are right-sided due to delay in descent of the right testis; however, B/L inguinal hernias are not uncommon. Although clinical examination itself establishes the diagnosis in various inguinoscrotal swelling, USG is recommended as to rule out contralateral hernia and to prognosticate chances of developing hernia on the other side depending on the size of deep ring. Inguinal hernia does not resolve spontaneously and should be repaired as soon as possible to avoid the risk of incarceration or strangulation. Pain in inguinoscrotal swelling represents complication and needs to be managed promptly for successful clinical outcomes.

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# Prevalence of Dyslipidemia in Type 2 Diabetic Patients in Northern Kashmir

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## Abstract

**Background:** Diabetes mellitus (DM) is one of the most common chronic diseases globally. Dyslipidemia is highly prevalent among type 2 diabetic patients. Dyslipidemia in DM increases the risk of atherosclerosis, resulting in increased incidence of atherosclerotic cardiovascular disease. In view of the high prevalence of type 2 DM in Kashmir, the present study aimed to completely evaluate dyslipidemia in type 2 diabetic patients.

**Materials and Methods:** This was a descriptive cross-sectional study in 500 type 2 diabetic patients (210 – male and 290 – female) with the age range of 20–85 years, which was conducted in tertiary care hospital, Government Medical College Baramulla, in Northern Kashmir, in UT of J and K, India. Data collection includes recording of demographic parameters (age, gender, and sex), biochemical parameters including fasting blood glucose. Fasting blood samples of the patients were taken to measure serum lipid profile.

**Results:** The result shows hypercholesterolemia in 26% patients, hypertriglyceridemia in 60% patients, increased low-density lipoprotein levels in 38% patients, and reduced high-density lipoprotein levels in 20% patients. The present study shows 76% prevalence of dyslipidemia among type 2 diabetic patients. Mixed dyslipidemia was the most prevalent type of dyslipidemia.

**Conclusion:** There is an increased prevalence of diabetes and associated dyslipidemia in North Kashmir, with a relatively higher prevalence in women with higher age group. The regular screening of blood lipid levels and appropriate intervention programs, especially in type 2 diabetic mellitus person is needed to prevent cardiovascular complications of diabetes and dyslipidemia.

**Key words:** Atherosclerosis, Atherosclerotic, Diabetes mellitus, Dyslipidemia

## INTRODUCTION

India leads the world with largest number of diabetic patients and is often referred to as the diabetes capital of the world.<sup>[1]</sup> Diabetes has evolved into an epidemic all over the world.<sup>[1]</sup> This epidemic will be followed by a wave of cardiovascular disease (CVD).<sup>[2]</sup> Diabetes is in fact a serious vascular disease with poor prognosis, and not only a disease characterized by elevated blood glucose.<sup>[2]</sup> Diabetic patients are known to have high levels of serum low-density lipoprotein (LDL), serum

triglyceride (TG), and low levels of serum high-density lipoprotein (HDL).<sup>[3]</sup> People with diabetes comprise 8.8% of the world's population, and International Diabetes Federation (IDF) predicts that the number of cases of diabetes will rise to 642 million by 2040.<sup>[4]</sup> Diabetes mellitus (DM) is one of the most common chronic diseases globally and continues to increase in numbers.<sup>[1]</sup> It is among the top five causes of mortality.<sup>[1]</sup> The IDF estimates that worldwide, 415 million people have diabetes, 91% of whom have type 2 DM (T2DM).<sup>[4]</sup> Individuals with T2DM have a number of potentially modifiable risk factors, including dyslipidemia, hypertension, and hyperglycemia.<sup>[5]</sup> In persons with T2DM, the death rates are 15.4% for those without myocardial infarction (MI) and 42.0% in patients having a history of MI.<sup>[4]</sup> The prevalence of T2DM has been steadily increasing over time.<sup>[4]</sup> T2DM reduces life expectancy by as much as 10 years.<sup>[4]</sup>

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A lipid profile includes four basic parameters. Total cholesterol (TC), TG, HDL-cholesterol (HDL-C), and LDL-cholesterol (LDL-C) are all synthesized and excreted by the liver.<sup>[6]</sup> TGs are types of lipids constituted by a glycerol backbone and different fatty acids, while cholesterol is an unsaturated steroid alcohol lipid present in human diet.<sup>[6]</sup> Cholesterols are transported by very-LDL (VLDL), low-density lipoproteins, high-density lipoproteins, and chylomicrons.<sup>[6]</sup> Chylomicrons are carriers of large quantities of exogenous TG and a minute quantity of cholesterol from the small intestines to the liver.<sup>[6]</sup> Similarly, VLDL is responsible for carrying endogenous TG and cholesterol from the liver to body tissues.<sup>[6]</sup> LDL carries cholesterol and minute quantities of TG from the liver to body tissues.<sup>[6]</sup> HDL is responsible for the transportation of cholesterol from body tissues to the liver (reverse transport) for excretion.<sup>[6]</sup>

Dyslipidemia in DM increases the risk of atherosclerosis, resulting in increased incidence of atherosclerotic CVD, for example, coronary artery disease, cerebrovascular disease (CVD), and peripheral vascular disease.<sup>[4,7]</sup> In the presence of other cardiovascular risk factors, for example, smoking and hypertension, it increases the risk of CVD manifold.<sup>[4]</sup>

Diabetic dyslipidemia is characterized by:

1. High levels of LDL-C
2. Low levels of HDL-C
3. High levels of TGs
4. Predominance of small dense LDL particles
5. Postprandial lipemia
6. High cholesterol, which refers to high LDL and TG (www.medicalnewstoday.com).

The obesity/insulin-resistant metabolic disarray that is the root cause of the type 2 form of diabetes could, itself, lead to lipid abnormalities exclusive of hyperglycemia.<sup>[8]</sup> These lipid changes are aggravated by increased inflammatory cytokines.<sup>[9]</sup> These changes in lipids represent the major link between diabetes and the increased cardiovascular risk in diabetic patients.<sup>[10]</sup>

## MATERIALS AND METHODS

### Type of Study

This was a cross-sectional descriptive study conducted from August 01, 2021 to December 31, 2021 at a tertiary care hospital, Government Medical College (GMC) Baramulla in Northern Kashmir, in UT of J and K, India.

### Study Participants/Sample

A total of 500 patients with T2DM who visited Department of Medicine in GMC Baramulla participated in this study

and their records were collected according to their outpatient department number. Out of 500 diabetic patients – 210 were men and 290 were women with age range from 20 to 85 years. Patients data were collected regarding the demographic parameters (age of patient and gender), duration of type 2 diabetes (in years) since diagnosis, duration of hypertension (in years), duration of obesity (in years), duration of polycystic ovary disease (in years) and intake of any other oral anti-diabetic treatment, insulin and any lipid lowering drugs (in years), last lipid profile of the patient, and the pharmacologic treatment (s) he was on.

### Inclusion Criteria

The inclusion criteria were included in the study:

1. Age more than 20 years
2. Diagnosed with DM of more than 4 years
3. Patients who were on regular follow-up.

### Exclusion Criteria

The inclusion criteria were excluded from the study:

1. Age <20 years
2. Diagnosed with DM of <4 years
3. Patients with type 1 DM
4. Patients with coexisting diseases causing secondary dyslipidemia
5. Pregnant ladies
6. T2DM with uncontrolled sugars.

### Experimental Analysis

#### Patient's blood sample preparation

A 5 ml of venous blood was collected by venipuncture after an overnight fast for 8–12 h. After collecting the blood from the patients, 3 ml of blood was transferred into serum tubes for lipid profile and 2 ml of blood was transferred into sodium fluoride tubes or bulbs for blood glucose estimation.

### Diagnostic Analysis

The analysis was carried on an automated clinical chemistry analyzer; Beckman Synchron L ×20. Glucose concentrations were measured by oxygen rate method employing a Beckman oxygen electrode (glucose-oxidase). TC, LDL-C, HDL-C, and TG concentrations were measured by International Federation of Clinical Chemistry approved enzymatic methods. However, LDL-C can also be measured by Fried Ewald equation (TC- HDL -serum TG/5). VLDL-C was calculated by plasma TGs by 5.

### Statistical Analysis

The mean and standard deviations were calculated for fasting blood sugar, TC, TGs, HDL, and LDL in both males and females separately [Table 1]. The data were further categorized according to age group. Serum

lipids were categorized as per NCEP-ATP III (National Cholesterol Education Programmed Adult Treatment Panel) Guidelines. According to these standard guidelines, hypercholesterolemia is defined as TC >200 mg/dl, LDL-C as >100 mg/dl, hypertriglyceridemia as TG >150 mg/dl, and HDL-C <40 mg/dl. Dyslipidemia is defined by presence of one or more than one abnormal serum lipid concentration. Mixed dyslipidemia is defined by the presence of two or more than two abnormal value of the above-mentioned lipid parameters.

For serum Glucose levels, we referred to American Diabetes Association Guidelines. Persons with fasting blood glucose >126 mg/dl or who were on medication for diabetes were considered as having DM. 2-D column chart was applied in comparison of diabetic males and diabetic females.

## RESULTS

In the present study, the average age of the participants was 51.24 years. The average fasting blood glucose of the participants was 212.08 mg/dl. The average TC concentration, TG concentration, HDL levels, LDL levels, VLDL levels of the participants was 175.52 mg/dl, 236.88 mg/dl, 45.12 mg/dl, 95.75mg/dl, and 39.88 mg/dl, respectively [Table 2 and Figure 1].

In the present study, most of the participants were having dyslipidemia as one or two parameters of the lipid profile were outside the target recommended by the guidelines of National Cholesterol Education Program. Out of 500 diabetic patients, 130 (26%) patients were having hypercholesterolemia, 300 (60%)

patients were having hypertriglyceridemia, 190 (38%) patients were having increased LDL levels, and 100 (20%) patients were having reduced HDL levels and 210 (42%) patients were having VLDL s [Table 3]. Out of 290 females, 100 (34.5%) patients were having hypercholesterolemia, 150 (51.72%) patients were having hypertriglyceridemia, 120 (41.4%) patients were having increased LDL levels, 40 (13.79%) patients were having reduced HDL levels, and 130 (44.83%) patients were having VLDL levels [Table 3]. Out of 210 males, 30 (14.3%) patients were having hypercholesterolemia, 150 (71.43%) patients were having hypertriglyceridemia, 70 (33.33%) patients were having high LDL levels, 60 (28.57%) patients were having reduced HDL levels, and 80 (38.1%) patients were having VLDL levels [Table 3]. Thus, dyslipidemia was observed more in female diabetic patients [Figures 2-6].

- Total blood glucose concentration in all age groups in the diabetic males and females
- TC concentration in all age groups in the diabetic males and females
- TG concentration in all age groups in the diabetic males and females
- HDL concentration in all age groups in the diabetic males and females
- LDL concentration in all age groups in the diabetic males and females
- VLDL concentration in all age groups in the diabetic males and females.

## DISCUSSION

In the present study, 52% patients have mixed dyslipidemia with more than one lipid parameter out of range but with normal levels of HDL and 10% patients have mixed dyslipidemia with more than one lipid parameter out of range but with low levels of HDL [Tables 4 and 5]. The prevalence of dyslipidemia in the present study is found as 76% [Table 6], which is higher than the study conducted in Nepal, with prevalence (63.1%). Insulin resistance, relative insulin deficiency, and obesity are found to be associated with dyslipidemia in T2DM.<sup>[11]</sup> In the present study, the hypercholesterolemia was 26%, hypertriglyceridemia was 60%, increased LDL level was 38%, and lower HDL level was 20%. In the study conducted in Telangana, India by Dyakar *et al.* the prevalence of dyslipidemia in type 2 diabetic patients

**Table 1: Representation of various baseline clinical parameters in diabetic subjects**

Parameters	Male diabetic patient		Female DIABETIC PATIENT	
	mean (mg/dl)	SD	mean (mg/dl)	SD
Glucose	212.4286	101.118421	211.74	91.20295369
TC	165.3635	38.04574492	185.6803448	38.90981663
TG	282.1115	256.8900381	191.6485714	78.52334921
HDL-C	42.8605	8.401129665	47.3776	13.4388083
LDL-C	87.78	37.99093069	103.722	40.07806659
VLDL	41.41333	18.3708635	38.34428571	15.69686164

LDL-C: Low-density lipoprotein cholesterol, TG: Triglyceride, HDL-C: High-density lipoprotein cholesterol, TC: Total cholesterol, VLDL: Very low-density lipoprotein

**Table 2: Elaborative description of type 2 diabetic patients**

Gender	Age (Years)	No. of Patients	Glucose (mg/dl)	TC (mg/dl)	TG (mg/dl)	HDL (mg/dl)	LDL (mg/dl)	VLDL (mg/dl)
Male	53.380	210	212.428	165.363	282.111	42.860	87.78	41.413
Female	49.103	290	211.74	185.680	191.648	47.377	103.722	38.344

LDL: Low-density lipoprotein, TG: Triglyceride, HDL: High-density lipoprotein, TC: Total cholesterol, VLDL: Very low-density lipoprotein

**Table 3: Number of lipid parameters out of range in diabetic males and females**

Lipid Profile	Males (210)	Females (290)	Total Patients (500)
TC	30	100	130
TG	150	150	300
LDL	70	120	190
HDL	60	40	100
VLDL	80	130	210

LDL: Low-density lipoprotein, TG: Triglyceride, HDL: High-density lipoprotein, TC: Total cholesterol, VLDL: Very low-density lipoprotein

**Table 4: Prevalence of single and mixed dyslipidemia in female type 2 diabetic patients (n=290)**

S. No	Lipid Profile	No. of Patients
1	High TC only	0
2	High TG only	0
3	High LDL only	10
4	Low HDL only	10
5	Any one lipid parameter out of range with low HDL	0
6	Mixed with low HDL	30
7	Mixed without low HDL	150
8	All lipid parameters within range	90

LDL: Low-density lipoprotein, TG: Triglyceride, HDL: High-density lipoprotein, TC: Total cholesterol

**Table 5: Prevalence of single and mixed dyslipidemia in male type 2 diabetic patients (n=210)**

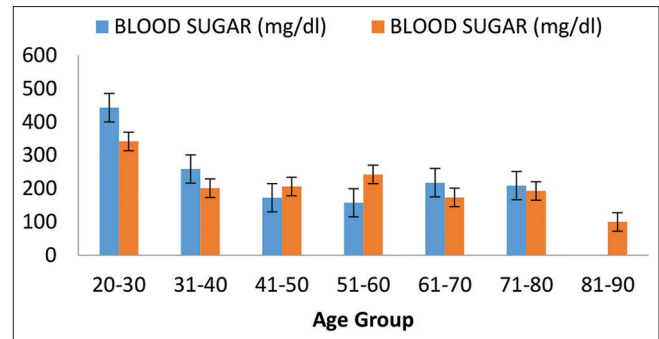
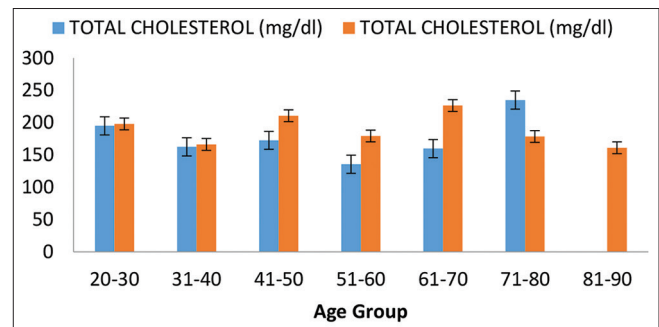
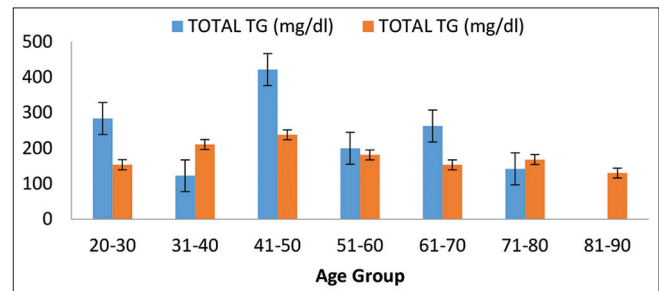
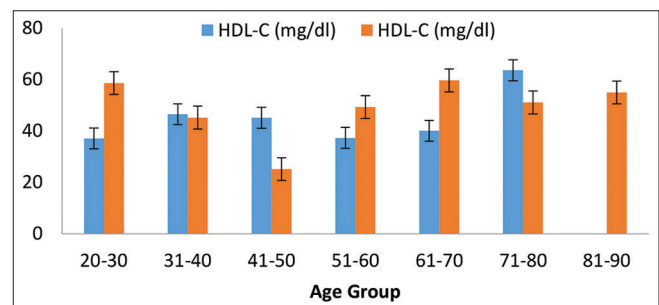
S. No	Lipid Profile	No. of Patients
1	High TC only	0
2	High TG only	10
3	High LDL only	0
4	Low HDL only	20
5	Any one lipid parameter out of range with low HDL	20
6	Mixed with low HDL	20
7	Mixed without low HDL	110
8	All lipid parameters within range	30

LDL: Low-density lipoprotein, TG: Triglyceride, HDL: High-density lipoprotein, TC: Total cholesterol

**Table 6: Prevalence of single and mixed dyslipidemia in type 2 diabetic patients (n=500)**

S. No.	Lipid Profile	No. of Patients
1	High TC only	0
2	High TG only	10
3	High LDL only	10
4	Low HDL only	30
5	Any one lipid parameter out of range with low HDL	20
6	Mixed with low HDL	50
7	Mixed without low HDL	260
8	All lipid parameters within range	120

LDL: Low-density lipoprotein, TG: Triglyceride, HDL: High-density lipoprotein, TC: Total cholesterol

**Figure 1: Fasting glucose concentration****Figure 2: Total cholesterol concentration****Figure 3: Triglyceride concentration****Figure 4: High-density lipoprotein cholesterol concentration**

was reported as 86.9% with 58.6% of type 2 diabetic patients had hypercholesterolemia, 36.9% had hypertriglyceridemia, 65.2% had increased LDL levels, and 93.4% had reduced HDL levels. Incidence of hypertriglyceridemia was low with

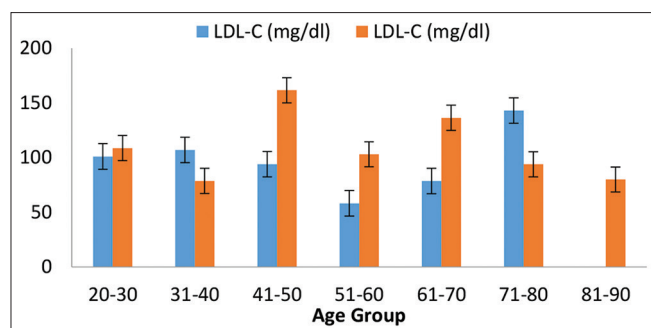


Figure 5: Low-density lipoprotein cholesterol concentration

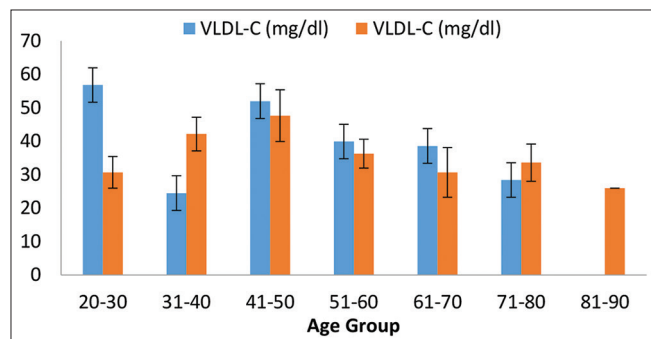


Figure 6: Very low-density lipoprotein cholesterol concentration

the present study results, but the incidence of increased hypercholesterolemia, LDL and reduced HDL were too high when compared with the present study. Similarly in the other study conducted in Western Cape, South Africa by Omodanisi *et al.*,<sup>[6]</sup> the prevalence of dyslipidemia in type 2 diabetic patients was reported as 89%, with 56% type 2 diabetic patients had hypercholesterolemia, 64% had hypertriglyceridemia, 61% had high LDL levels, and 65% had low HDL levels. Incidence of increased hypercholesterolemia, LDL, and reduced HDL was too high when compared with the present study, but the incidence of hypertriglyceridemia was coinciding with the present study results. The high prevalence of hypercholesterolemia (high TC), hypertriglyceridemia (high TG), and low HDL is a major cause of concern.<sup>[12]</sup> The contributing factor for hypertriglyceridemia in our population can be our diet rich in fat and carbohydrates.<sup>[12]</sup> High TG levels have been associated with increased levels of small low dense lipoprotein levels which are considered to be highly atherogenic.<sup>[12]</sup> Diet with high fat and calorie intake and lack of physical activity could be the major culprits of dyslipidemia in our population.<sup>[12]</sup> References have shown that our diets are rich in saturated fats.<sup>[12]</sup> Besides, it also involves overcooking of food which results in destruction of nutrients such as folate, deep frying, and refrying in the same oil leading to trans fatty acids formation which probably contributes to increase of dyslipidemia in our population.<sup>[12]</sup> Moreover, high glucose and low HDL-C are significant occurrences in type 2 diabetic patients which contributes to the worsening of diabetic

(glycemic) control.<sup>[6]</sup> Hence, the incidence of occurrence of dyslipidemia is very high in type 2 diabetic patients.<sup>[11]</sup> Health education should be provided to all the patients of T2DM about the dyslipidemia.<sup>[11]</sup> Along with the blood sugar levels, the lipid profile also should be monitored regularly to evaluate and treat dyslipidemia.<sup>[11]</sup>

## CONCLUSION

The study has been carried out in the GMC Baramulla and Associated Hospital. A large number of patients in this study shows uncontrolled blood glucose levels and have dyslipidemia with an increase in TC, TG, and LDL, VLDL and with a noticeable decrease in HDL. There is an increasing trend of diabetes and dyslipidemia in North Kashmir, with a relatively high prevalence among women with an increasing age. Dyslipidemia in this patient population was associated with gender and age. Majority of our diabetic patients failed to achieve all standard goals of dyslipidemia management. Combination lifestyle therapies, that is, enhanced physical activity and dietary modification and therapeutic intervention would help us in treatment and management of dyslipidemia. The optimal care of diabetic patients should include regular monitoring of blood sugar and full range serum lipid profile. Specific efforts to educate patients and increase their awareness regarding the need to change behaviors and regularly take medication would be a positive step toward decreasing dyslipidemia prevalence in diabetic patients. Thus, this result highlights the regular need for screening blood lipid levels and appropriate intervention programs, especially in type 2 diabetic mellitus person. I hope that the data in this study will help to demonstrate the importance of regular surveillance and screening of all the diabetic patients for dyslipidemia.

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# Barriers Experienced by Students in Conducting Research: A Web-based Cross-sectional Study among Indian Dental Population

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## Abstract

**Introduction:** Understanding research in health-care sciences can have a big impact on health care since it has a big impact on evidence-based diagnostic and therapy applications. There are multiple barriers which affect the investigator to take part in the study and also affect the outcome of the study.

**Aim:** The study was aimed to evaluate the obstacles faced by students on the subject of research conducted in dental colleges in India.

**Materials and Methods:** A web-based cross-sectional study was carried out from June 2021 to February 2022 covering Presence Across Nation India through zonal divisions. A closed-ended web-based questionnaire was formulated in English language. A template was provided by the Google Forms consisting of demographical data and nine questions through which participants were assessed.

**Results:** A total of 432 participants joined up for the study. The respondent rate showing maximum in western area (46%) accompanied by eastern region (16%) followed by central part (10%) and further followed as southern (10%), northern (9%), and north eastern (8%). Inadequate technical support (69.6%) is considerable as a major foundation problem whereas lack of time by adviser (59.1%) is considerable least among students. Among personal reasons cited, highly statistically significant difference was appreciated in terms of inadequate finance, lack of research course, and in terms of personal interest towards subject ( $P < 0.001$ ).

**Conclusion:** In this study, barriers of research were identified, and the ways to decrease the difficulties were suggested. The research would be further helpful for organizing training and continuing dental education program and modifications may be proposed in regard with research for the undergraduate curriculum.

**Key words:** Barriers, Dental, Education, Postgraduate, Research, Undergraduate students

## INTRODUCTION

Oral health-care investigation aims to keep the profession aware of scientific and technical breakthroughs, which have an immediate and long-term impact on the quality

of patient care and the further growth of dental practice, both of which are expected to have a considerable impact on dentistry.<sup>[1]</sup>

Understanding research in health care sciences can have a big impact on health care since it has a big impact on evidence-based diagnostic and therapy applications. Similarly, sufficient knowledge of sociological principles is required in academics to successfully perform a study and appropriately interpret data produced from clinical studies. For literature evaluation and evidence-based practice in dentistry, as well as for researchers seeking to have their publications accepted by international journals,

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understanding biostatistics and research design principles are critical.<sup>[2]</sup>

The search for facts in the pursuit of knowledge is what investigations are all about. It entails gathering and analyzing data to improve human description of the phenomenon under investigation. It comprises a systematic approach to data gathering, evaluation, observation, and assessment to find answers to a problem. According to the Organization for Economic Cooperation and Development, “research is methodical creative labor carried out with the goal of expanding knowledge and developing new applications.” It’s a common practice in academic and research organizations. In most situations, studies are done by researchers and postgraduate (PG) students, with the justification that education in institutions requires PG students to submit research projects, dissertation as part of their degree program.<sup>[3]</sup>

In the late 19<sup>th</sup> century, after the first academic revolution, research was done at universities in addition to learning. Since then, research has become one of the most important priorities in scientific societies. In the past few years, scientific research output has been evaluated and utilized to rate universities against one another. The publication of study results serves as proof of support for research investigations as well as a guarantee of future research funding to ensure the institute’s mandate and organizational goals are met.<sup>[4]</sup>

The trends in study are supported by knowledgeable members, whereas the lack of basic and essential research could be due to other variables influencing research. The three key factors that have been identified as having an impact on study give an insight into the literature are attitude, knowledge, and research barriers. Access skill barriers, attitudinal barriers, cultural barriers, infrastructural obstacles, and their sub-categories are examples of barrier elements that can be implemented. In universities, student research is extremely important, and university officials should be made aware of student research constraints. However, there are also some other obstacles faced by students which prevent them from conducting research which includes, lack of access to information sources, lack of English expertise, administratively tight regulations, limited research resources, and the inability to draught formal research proposals.<sup>[5]</sup>

Individual variations among students will be studied to improve the ability to plan curriculum, instruct, and advice learners. In part, we aim to learn more about whether students may encounter problems when conducting research, what those obstacles are, and how we might assist

individuals in their learning by better understanding and overcoming their specific challenges.<sup>[6]</sup>

Hence, the web-based study was commenced to evaluate the obstacles faced by students on research conducted in dental colleges in India.

## MATERIALS AND METHODS

This web-based cross-sectional study was carried out from June 2021 to February 2022 covering Presence Across Nation India through zonal divisions (northern, southern, eastern, western, central, and northeastern) after getting ethics approval from the Institutional Ethical Board (SVIEC/ON/DENT/SRP/21050).

### Calculation of Sample Size

$$\text{Formula: } n = \frac{N}{1 + N(e)^2}$$

Where,  $N$  is population size and  $e$  is the level of precision Where,  $N = 8000$  (considering participation of PG, undergraduate (UG), and interns students in various cities of India)

$e$  is 0.05 at 95% confidence interval  $n = 432$

Therefore, PG, UG, and interns’ participants are 432.

All the UG, interns, and PGs were included and those who were not willing were excluded from the study. A closed-ended web-based questionnaire was formulated by Sharma *et al.* in 2014 and was adapted for the present study.<sup>[6]</sup> The questionnaire was formulated in English language. Written consent was obtained from the author. A template was provided by the Google Forms (Google Inc., USA) consisting of demographical data and nine questions through which participants were assessed. Questionnaire was divided as demographic data, organizational (Question 1-5) and individual barriers (Question 6-9). Five-point (1–5) Likert scale was used in the study whose substitutes were as follows: (1) “Strongly agree,” (2) “agree,” (3) “neither agree nor disagree” (neutral), (4) “disagree,” and (5) “strongly disagree.”

Online generated link was forwarded through e-mail/ WhatsApp groups. The surveyor could access the link to the online questionnaire through a laptop and smart phone. To ensure maximum participation from various zones, snowball sampling (the participating students will be asked to forward the questionnaire to their colleagues) way was used. Once questionnaire has been filled by all the participants, data were entered into the Excel sheet and were subjected for statistical investigation.

### Statistical Analysis

The data were analyzed using IBM SPSS statistics 20.0 (IBM Corporation, Armonk, NY, USA) (Statistical Package for the Social Sciences, version 20.0, SPSS Inc., Chicago, IL, USA), and graphs, tables, and other graphics were created using Microsoft Word and Excel. The relevance of study parameters on a categorical scale was determined using Chi-square analysis. The significance of research parameters between the groups was determined using analysis of variance (intergroup analysis). The statistical significance level was set at  $P = 0.05$ , and any value less than or equal to that was considered statistically significant.

## RESULTS

Out of 432 participants (317 females and 115 males), 182 UG, 72 interns, and 178 PGs were enrolled for this study. Age (years) of the respondents was stated as  $21.43 \pm 2.82$  for UG,  $23.4 \pm 1.3$  for interns, and  $26.05 \pm 1.36$  for PG. Distribution of participants from various zonal divisions is shown in [Figure 1]. Maximum respondents were from western zone (46%) and least response was from northeastern zone (8%). For ease of understanding the results, strongly agree and agree have been mentioned in the results.

Numerous institutional problems faced by all three groups of students while undergoing research activities are mentioned in [Figure 2]. Inadequate technical support (69.6%) is taken into consideration as a major foundation problem whereas lack of time (59.1%) by counselor is less considerable obstacle among organizational reasons perceived by students.

Individual reasons are stated in [Figure 3]. Overall students stated that approximately 69.7% faced inadequate financial resources as the major barrier and personal commitments like marriage and family problems as least experienced obstacle (50.5%).

Year-wise distribution of UG, interns, and PGs showed that significant values are revealed in [Table 1]. Among institutional reasons cited, highly statistically significant difference was appreciated in terms of inadequate technical support, lack of research course in UG syllabus, and in terms of inaccessibility of mentors in the institution ( $P < 0.001$ ). However, lack of interest by faculty does not show statistically significant difference ( $P > 0.56$ ).

From the mentioned individual problems to research inadequate financial facilities, lack of interest and personal commitments such as family problem and marriage showed highly statistically significant difference ( $P < 0.001$ ) and significant difference was observed in learning regular subjects which took a lot of student's time ( $P = 0.01$ ).

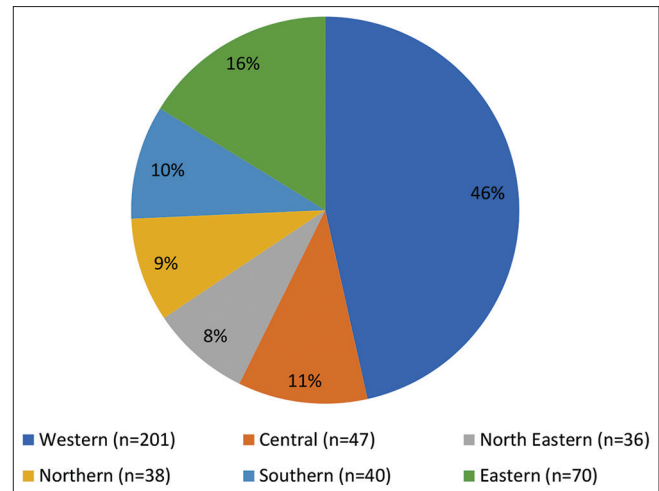


Figure 1: Distribution of participants from various zonal divisions

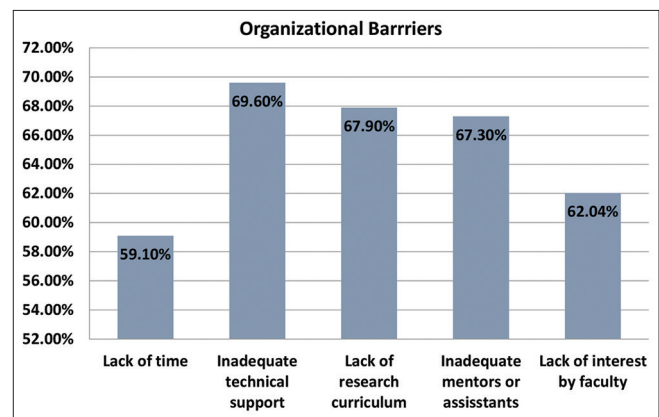


Figure 2: Distribution of overall students facing organizational obstacles

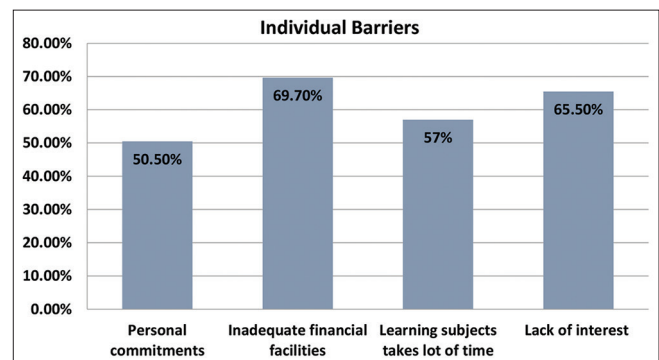


Figure 3: Distribution of overall students facing individual obstacles

## DISCUSSION

As research becoming a basic familiarity, not only PGs but also UG and interns should be motivated for taking part in research methods because it is important for dental students to have basic knowledge about research biostatistics.



**Table 1: Year-wise distribution of barriers**

S. No.	Obstacles	Undergraduates (%)	Interns (%)	Postgraduates (%)	P-value
Organizational barriers					
1	Lack of interest by faculty	61	62.5	62.9	0.56
2	Inadequate mentors/assistants in institutions	62.1	63.9	74.2	<0.001
3	Lack of research curriculum	63.2	62.5	74.8	<0.001
4	Inadequate technical support	62.6	68.1	77.5	<0.001
5	Lack of time	58.8	57	60.1	0.02
Individual barriers					
6	Lack of interest	61.5	58.4	72.5	<0.001
7	Learning subject's takes up a lot of time	54.9	52.8	60.7	0.01
8	Inadequate financial facilities	62.7	77.8	73.6	<0.001
9	Personal commitments like family problems; marriage	41.2	59.7	56.1	<0.001

The present study was conducted on Indian dental students from all the regions (northern, southern, eastern, western, central, and northeastern) for maximum participation, hence to evaluate the obstacles faced by them while doing research.

The student population in this crosssectional study included 432 students in the final sample and classified according to gender and year of study. The majority of the participants were females and similar demographic distribution was obtained by Sharma *et al.* in 2014.<sup>[6]</sup>

Although, its importance is well known and repeatedly stated in the field of medicine and dentistry, only a small proportion of research is done on obstacles faced by students.<sup>[7,8]</sup> There are many barriers that are responsible for this shortfall. In this study, we divided the questions into organizational and individual barriers. In organizational obstacles, we found inadequate technical support as the major one. However, in individual barriers, lack of finance is considered as a major obstacle. These results were consistent with the outcomes of another study conducted with Egyptian medical school in 2016.<sup>[9]</sup>

### Organizational Barriers

In this study, 62.1% of UG students, 63.9% of interns, and 74.2% of PG students considered that inadequate mentors in the institution are a hindrance from conducting research. Acquiring new skills such as conducting research is easy when one has an advisor that guides through the learning phase. Counselors not only facilitate in learning skills but also assess, progress, and advise corrective measures.<sup>[10]</sup> Similar results were shown in the study conducted on Egyptian medical students.<sup>[9]</sup> However, to overcome this difficulty, it is suggested by Heinicke *et al.* (2016) that unavailability of internal mentors can be overcome by approaching experts from other fields. The first step is conduction of literature search on topic in interest followed

by contacting corresponding authors in that field. The majority of researchers in our field will be eager to react and offer their advice and expertise.<sup>[11]</sup>

About 62% of dental UG students find difficulty in undergoing research activities due to lack of research curriculum in their course. These results were consistent with Sharma *et al.*<sup>[6]</sup> Research methods should be a compulsive activity due to growing era in fields of research. To get control over this obstruction, primarily research activities and modules should be made mandatory from the 1<sup>st</sup> year of graduation course by the statutory bodies. Secondly, one research/publication should be completed by the time students finish internship.

About 62% of UG, 68% of interns, and 77.5% of PG students considered that inadequate technical support from the foundation is considered a barrier. This finding is consistent with the study done by Farzaneh *et al.*<sup>[5]</sup> and Abushouk *et al.*,<sup>[9]</sup> Amin *et al.*,<sup>[12]</sup> Siemens *et al.*,<sup>[8]</sup> Majumder,<sup>[13]</sup> Sumathipala *et al.*,<sup>[14]</sup> and Majd *et al.*<sup>[15]</sup> It seems that the good training, research budget scarcity, lack of mentorship, and high publication cost of some specific journals are some of the underlying reasons for the current findings.<sup>[16,17]</sup> Unnikrishnan *et al.*<sup>[18]</sup> concluded that one of the barriers to conducting research and supporting students, as perceived by the faculty members, was limited sources, facilities, and limited access. Most of the colleges have a library resource center which has a computer laboratory where students have direct access to desktop and free WIFI. Other than this, the government has made designated areas for free WIFI accessibility.

Lack of interest on research by faculty members can be improved by giving them incentives toward their publication and presentation of their original research. Many universities have an incentive policy for their faculty members toward the research activities.

## Individual Barriers

In this study, 60% of respondents targeted lack of time and 69.7% considered lack of funding was considered as a chief barrier experienced by Indian dental students. Hegde *et al.* in 2017<sup>[15]</sup> reported that the most important barrier to conducting research was the lack of funding from the societies. However, similar findings were also stated in Alghamdi *et al.* in 2014 and Siemens *et al.* in 2010 considered lack of time as a significant barrier in conducting research due to busy academic schedule.<sup>[7,8]</sup>

Silvia (2017), his book about “finding time,” wrote that rather than “lack of time.” He mentioned about creating a schedule and stringently ensuring that it should not be canceled. He also stated to keep small goals while completing the task which would make the research more achievable.<sup>[19]</sup>

Various agencies that provide research funding can help overcome financial constraints or budget insufficiency. National organization such as the Science and Engineering Research Board, the Council of Scientific and Industrial Research, the Indian Council of Medical Research (ICMR), the Defence Research and Development Organization, and international organization such as the National Institute of Health and the World Health Organization assist in breaking down these barriers.

ICMR sponsors MD/MS/DM/MCh and MDS thesis and postdoctoral fellows in dental and medical research. Every year, it also grants 50 postdoctoral fellowships to work in ICMR institutes and centers with research and development resources. The ICMR funds the Short-Term Studentship Program for UG MBBS/BDS students to give them the opportunity to master research methods and methodologies.<sup>[20]</sup>

About 51% of respondents faced commitments such as marriages and domestic problems. This can be overcome by the college/institute making a schedule of one/two hours weekly in the time table; this will help in doing their research activity during college hours and it will not be a burden to students. Future perspectives on this topic of barriers in research are to increase the sample size of the population so as to generalize and validate the results of the study.

## CONCLUSION

Based on our current findings, the following suggestions will be implemented to improve the state of academic research, such as making it a mandatory component in

the dental curriculum. UG students must be encouraged to participate in workshops on study design to improve their skills. Externships to research laboratories or research institutes can be have added advantages to the students and can be included by dental colleges. Providing more financial support for students' research activities, holding theoretical and practical research methodology courses, forming a responsive and helpful research team assistant to support students and provide them with the necessary infrastructure, and carrying practical and theoretical methodology courses can all help to eliminate identified barriers to research. The takeaway message from this study is that students should be aware of and educated about research procedures, and that they should be given the time throughout their course to overcome these barriers.

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# Role of Diffusion-weighted Imaging in Differentiating Benign from Pathological Vertebral Collapse on the Basis of Apparent Diffusion Coefficients Values

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## Abstract

**Introduction:** Vertebral collapse is a common clinical problem. According to the demographic changes in our society, the incidence and prevalence of vertebral collapse are increasing. Vertebral collapse is associated with increased morbidity and mortality. Hence, vertebral collapse has a significant impact on the patient's overall quality of life and on the patient's life expectancy. The causes of vertebral collapse are manifold including benign and malignant causes. The differential diagnosis for a collapsed vertebra includes trauma, osteoporosis, infections, primary bone tumors, metastasis, and multiple myeloma.

**Materials and Methods:** Sixty-six patients with acute vertebral collapse were imaged using conventional MRI, fat-suppressed contrast-enhanced T1WI, and DWI sequence on a 1.5 T MR machine. Assessment of the abnormal signal intensity was done quantitatively by measuring apparent diffusion coefficients (ADCs). Furthermore, these areas of abnormal signal intensity were compared to adjacent normal marrow.

**Results:** The study comprised 66 patients, of which 46 cases (69.7%) were benign vertebral collapse and 20 cases (30.3%) were pathological collapse. Mean ADC ( $\pm$ SD  $\times 10^{-3}$  mm<sup>2</sup>/s) in the benign vertebral collapse was  $1.4578 \pm 0.2992$ , whereas the mean ADC ( $\pm$ SD  $\times 10^{-3}$  mm<sup>2</sup>/s) in the pathological vertebral collapse was  $0.8520 \pm 0.1786$ . We found out that the difference in mean ADC values between benign and pathological vertebral collapse was statistically significant.

**Conclusions:** DWI-ADC is a reliable adjunct parameter that supports conventional MRI in differentiating benign and malignant vertebral fractures.

**Key words:** Fractures, Metastasis, Multiple myeloma, Trauma, Vertebral

## INTRODUCTION

Vertebral collapse is a common clinical problem. According to the demographic changes in our society, the incidence and prevalence of vertebral collapse are increasing. Vertebral collapse is associated with increased morbidity and mortality. Hence, vertebral collapse has a significant impact on the patient's overall quality of life and on the patient's life expectancy. The causes of vertebral collapse

are manifold including benign and malignant causes. The differential diagnosis for a collapsed vertebra includes trauma, osteoporosis, infections, primary bone tumors, metastasis, and multiple myeloma. Osteoporosis is the leading cause of non-traumatic vertebral collapse. By the age of 80, 40% of women and 20% of men can be expected to have suffered osteoporotic spinal fracture. Less frequently seen is vertebral collapse following metastatic, hematologic, or neoplastic conditions. The spine represents the most frequent site of skeletal metastasis predominating in the thoracic and lumbar spine. Vertebral marrow lesions in patients with known primary malignancy are a common clinical problem, particularly in elderly patients. Despite osteoporosis being the most common cause at this age, the spine also is a common site of metastases, with about 39% of all bone metastases occurring in the spine. Such metastases may result in a pathologic fracture. Thus, it is

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essential to differentiate benign from malignant vertebral collapse because their medical management and their outcome are substantially different.

Conventional MRI has good sensitivity but lacks specificity in differentiating acute benign from pathological collapse. MR imaging findings such as abnormal signal intensity of the pedicle or posterior element, an epidural or paraspinal mass, and a convex posterior border of the vertebral body are useful for the differentiation of metastatic from acute osteoporotic compression fractures of the spine. Furthermore, multiple compression fractures, retropulsion of a posterior bone fragment, a low-signal intensity band on T1WI and T2WI, and spared normal bone marrow signal intensity of the vertebral body are suggestive of acute osteoporotic compression fractures. However, this differentiation can be problematic due to edema, hemorrhage, and the presence of repair tissue that accompanies acute benign collapse which results in bone marrow changes which resemble metastatic collapse. Even post-contrast T1WI MRI is also not very helpful because there is disruption of the blood-bone barrier in acute benign collapse leading to post-contrast enhancement. Adding diffusion-weighted imaging (DWI) sequence to routine, conventional MRI sequences are helpful.

DWI is a functional MR imaging sequence that relies on the detection of Brownian motion of free water molecules within voxel of tissue. It is based on the principle that water molecules in a tissue show a different Brownian motion depending on variations in microstructure. Signal attenuation reflects the degree of water motion with a proportional relationship. ADC value allows the quantification of this Brownian motion and is calculated from maps derived by diffusional signal attenuation. Briefly, tissues with high free water components, such as those with lower content of membranes and intracellular organelles or high free extracellular water content, show lower signal intensity on DWI and higher signal intensity on ADC maps in comparison to muscles. Conversely, tissues with restricted extracellular water content, such as those with high cellularity, as tumors, show higher signal intensity on DWI and iso-hypo intensity on ADC maps. Restricted diffusion on DWI shows low ADC value, whereas free diffusion on DWI shows high ADC values. ADC values can also be used to evaluate response to treatment as well as the progression of the disease. Thus, both qualitative as well as quantitative functional information concerning the microscopic movements of water at cellular level can be obtained from DWI. In addition to the characterization of lesions, DWI has also been used as a tumor screening technique for the whole body, such as positron-emission tomography (PET).

Some studies have suggested a significant role of DWI in the assessment of vertebral marrow pathologies, whereas few others have shown only equivocal results. In this prospective study, we evaluated the hypothesis that DWI and ADC values have a role in differentiating benign from pathological vertebral collapse. Hence, we carried out this study in our setup with the purpose of prospectively determining the value of adding qualitative and quantitative axial DW imaging to standard spine MR imaging to differentiate between acute benign and pathological vertebral collapse.<sup>[1-6]</sup>

## MATERIALS AND METHODS

This was a prospective study conducted from January 2020 to October 2021 in GSVM Medical College, Kanpur, India. Approval from the ethical committee was obtained before the study. The study includes 66 patients (33 women and 33 men) in the age groups of 13–79 years who were referred to the Department of Radiodiagnosis with a previous radiograph demonstrating vertebral collapse. Patients who were referred within 4 weeks of the onset of clinical symptoms were selected for the study. Informed consents were obtained from the patients.

The study was carried out on a 1.5T MRI machine using a standardized protocol on a phased-array spinal coil. All the patients will be subjected to conventional MRI sequences in the sagittal plane, which include T1 turbo spin-echo (TSE), T2 TSE, STIR (sagittal/coronal plane) sequences, and post-contrast fat-suppressed T1 as an optional sequence with a thickness (mm) 4 mm, TR/TET2-3500/103; T1-703/11; STIR-3500/78; T1-FS post-contrast-530/11.3800/82 Matrix size 384 × 384 92 × 180 FOV 330 350. DWI was carried out using single-shot echoplanar Imaging (SS-EPI) in a sagittal plane with a minimum of two b-values. The max b-value used was b 800. Sensitizing diffusion gradients were applied sequentially in the x, y, and z directions. ADC maps were generated with the software supplied by the manufacturer on a pixel-by-pixel basis from the DWI. ROI was defined in areas with abnormal signal intensity on max b-value DWI and copied to the ADC map.

In our study, a qualitative assessment was done by comparing diffusion images with ADC maps to look for the presence or absence of diffusion restriction in a collapsed vertebra. Quantitative assessment was done by placing at least two ROI in areas with abnormal signal intensity on max b-value DWI and copying to the ADC map. ROI was also placed in the marrow of normal vertebra to calculate their mean ADC values.

### Statistical Analysis

For statistical analysis, data were entered into a Microsoft Excel spreadsheet and then analyzed by the SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and GraphPad

Prism version 5. Data had been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables—two-sample t-tests for a difference in mean involved independent samples or unpaired samples. Paired t-tests were a form of blocking and had greater power than unpaired tests. Unpaired proportions were compared by Chi-square test or Fischer's exact test, as appropriate. Once a t-value is determined, a p-value can be found using a table of values from the Student's t-distribution. The  $P \leq 0.05$  was considered to be statistically significant.

### RESULT

The study comprised 66 patients, of which 46 cases (69.7%) were benign vertebral collapse and 20 cases (30.3%) were pathological collapse. In benign collapse, nine cases (19.5%) were due to osteoporotic compression fractures, nine cases (19.5%) were due to acute traumatic collapse, and 28 cases (61.0%) were due to Pott's spine. The mean age for osteoporosis compression fracture was 62 years,

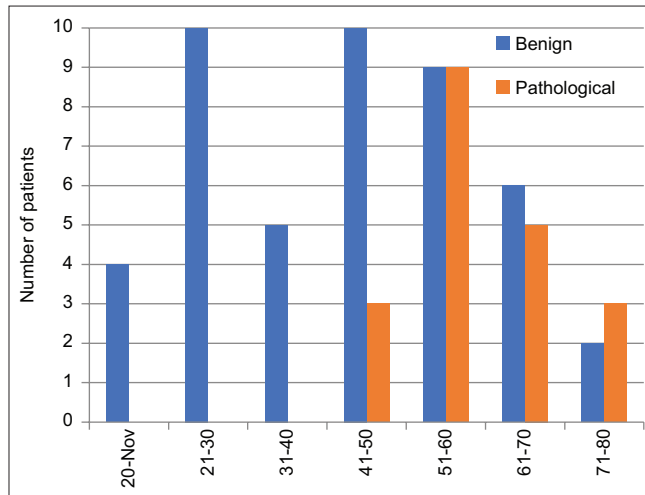


Figure 1: Association between ages in the group

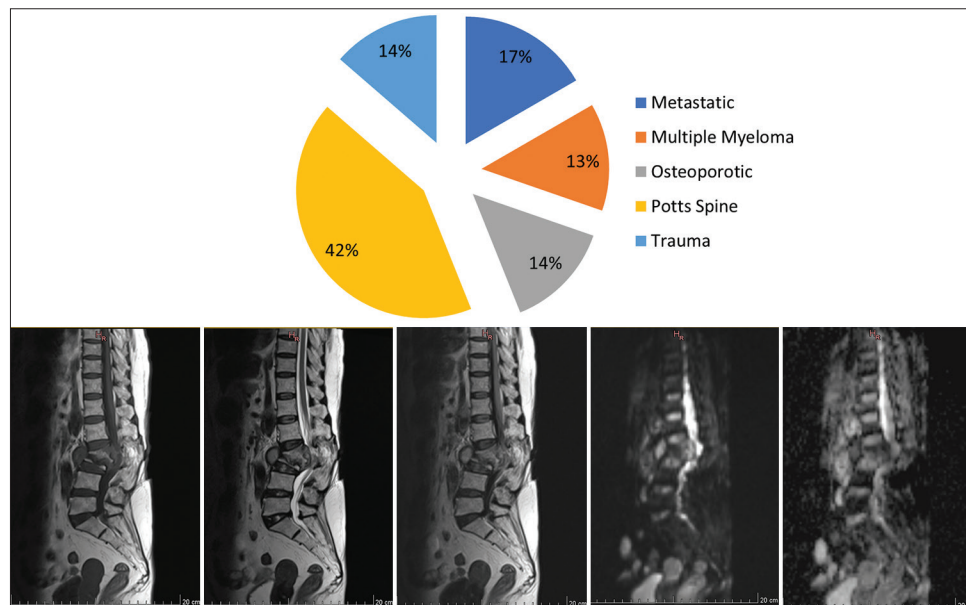


Figure 2: A 62-year-old female patient presented to emergency confirmed as a case of Pott's spine. On T1WI (a), T2WI (b), and STIR (c) showed altered marrow signal intensities seen as patchy and confluent areas of T1/T2 prolongation involving L2 and L3 vertebral bodies with the destruction of endplates and cortical margins. It also shows the partial collapse of the L2 and L3 vertebra. There is the partial destruction of the intervening disc with a reduction of disc space. The lesion shows diffusion restriction on DWI (d). On ADC map (e), ADC at this level is  $1.3 \times 10^{-3} \text{ mm}^2/\text{s}$

Table 1: Distribution of mean ADC-values ( $\times 10^{-3} \text{ mm}^2/\text{s}$ ) and ADC-values ( $\times 10^{-3} \text{ mm}^2/\text{s}$ )

	Number	Mean	SD	Minimum	Maximum	Median	P-value
ADC-values (×10 <sup>-3</sup> mm <sup>2</sup> /s)							
Benign	46	1.4578	0.2992	0.7200	2.1000	1.4600	<0.0001
Pathological	20	0.8520	0.1786	0.6100	1.3100	0.8400	
ADC-values (×10 <sup>-3</sup> mm <sup>2</sup> /s)							
Metastatic	11	0.8672	0.1635	0.6700	1.2600	0.8500	0.0009
Multiple myeloma	9	0.8333	0.2039	0.6100	1.3100	0.7900	

ranging from 45 to 75 years. The traumatic group's mean age was 25 years, ranging from 13 to 38 years. The mean age for vertebral collapse due to Pott's spine was 45 years ranging from 23 years to 70 years. Pathological collapse which included nine cases (45.0%) of multiple myeloma and 11 cases (55.0%) of metastatic compression fractures. The mean age in the multiple myeloma group was 60 years ranging from 50 to 71 years, and in the metastasis group was 60 years ranging from 46 to 79 years [Figure 1].

Mean ADC ( $\pm$ SD $\times 10^{-3}$  mm<sup>2</sup>/s) in normal vertebral marrow was  $0.326 \pm 0.121 \times 10^{-3}$  mm<sup>2</sup>/s, ranging from  $0.3\text{--}0.67 \times 10^{-3}$  mm<sup>2</sup>/s. Mean ADC ( $\pm$ SD  $\times 10^{-3}$  mm<sup>2</sup>/s) in the benign collapse was  $1.4578 \pm 0.2992$ . Mean ADC ( $\pm$ SD  $\times 10^{-3}$  mm<sup>2</sup>/s) in the pathological collapse was  $0.8520 \pm 0.1786$ . We found out that the difference in mean ADC values between benign and pathological vertebral collapse was statistically significant; however, within the pathological group, the difference in mean ADC values between multiple myeloma and metastatic vertebral collapse was statistically insignificant ( $P > 0.005$ ) [Table 1 and Figure 2].

## DISCUSSION

This was a prospective study conducted from January 2020 to October 2021 in GSVM Medical College, Kanpur, India. Approval from the ethical committee was obtained before the study. Differentiation between malignant and benign vertebral compression fracture is a common problem in the management of the patients: establishing the correct diagnosis is of great importance in determining treatment, surgical approach, and prognosis. Although MR imaging using conventional T1 WI and T2 WI has proved helpful in differentiating between benign and malignant causes of vertebral collapse, confident diagnosis is not always possible.

We conducted our study with a b-value of 800, which gave us reasonable SNR and ADC maps. Although multiple b-values give good SNR and accurate ADC values, scan times are prolonged, any movement during this time period can lead to motion artifacts.

In our study in the benign group, 4 (8.7%) patients were 11–20 years old, 10 (21.7%) patients were 21–30 years old, 5 (10.9%) patients were 31–40 years old, 10 (21.7%) patients were 41–50 years old, 9 (19.6%) patients were 51–60 years old, 6 (13.0%) patients were 61–70 years old, and 2 (4.3%) patient were 71–80 years old. In the pathological group, 3 (15.0%) patients were 41–50 years old, 9 (45.0%) patients were 51–60 years old, 5 (25.0%) patients were 61–70 years old, and 3 (15.0%) patients were 71–80 years old. Hence, we infer that benign vertebral collapse more frequently occurs

in the younger age group <50 years, accounting for 63% of patients in the benign group, whereas the malignant vertebral collapse most commonly occurs in the old age group of above 50 years comprising 85% of cases of the malignant group.<sup>[7–12]</sup>

In our study, benign vertebral collapse showed a mean ADC of  $1.4578 \pm 0.2992 \times 10^{-3}$  mm<sup>2</sup>/s, and pathological collapse showed a mean ADC of  $0.8520 \pm 0.1786 \times 10^{-3}$  mm<sup>2</sup>/s. According to Ajith Mahale *et al.*,<sup>[13]</sup> with b-values of 600 s/mm<sup>2</sup>, acute benign collapse showed a mean ADC of  $1.466 \pm 0.325 \times 10^{-3}$  mm<sup>2</sup>/s, and pathological collapse showed a mean ADC of  $0.959 \pm 0.288 \times 10^{-3}$  mm<sup>2</sup>/s. Furthermore, according to Arashdeep Kaur *et al.*,<sup>[14]</sup> the mean ADC value of benign pathologies was  $1.66 \pm 0.32 \times 10^{-3}$  mm<sup>2</sup>/s and malignant collapse showed a mean ADC of  $0.69 \pm 0.15 \times 10^{-3}$  mm<sup>2</sup>/s.

Vertebral metastases represent the secondary involvement of the vertebral spine by hematogenously disseminated metastatic cells. In general, these bone marrow vertebral metastases appear on DWI as high-signal intensity areas in an otherwise hypointense vertebral marrow. These areas correspond to low-signal intensities on ADC maps. It is well known that bone metastases can be prevalently lytic or sclerotic. Although in both types of metastases, the bone turnover is more pronounced than in normal bone marrow, in osteolytic metastases, the osteoclastic activity is prevalent as it is stimulated by the adjacent metastatic tumor cells. The osteoblastic metastases origin from the prevalent stimulation of osteoblasts. Osteolytic lesions are better detected on DWI imaging due to the higher content of water and cells with respect to the sclerotic ones.

Multiple myeloma is a primary malignant neoplasm due to abnormal proliferation of plasma B-cells leading to marrow infiltration. Diagnosis requires pathological, biochemical, and radiological evaluation. In multiple myeloma, the marrow cells are replaced by tumor cells which lead to diffusion restriction. ADC values of multiple myeloma are higher than normal bone marrow. MRI and DWI are helpful in assessing the tumoral burden in multiple myeloma. It also has a role in assessing treatment response. Multiple myeloma lesions appear T1 hypointense, T2 hypointense, and STIR hyperintense. In DWI, the lesions appear hyperintense and by calculating ADC values, it is even possible to assess treatment responders from non-responders.

The mean ( $\pm$ SD) ADC value in multiple myeloma was  $0.8333 \pm 0.2039 \times 10^{-3}$  mm<sup>2</sup>/s, whereas the mean ADC in metastatic compression fractures was  $0.8672 \pm 0.1635 \times 10^{-3}$  mm<sup>2</sup>/s. Furthermore, the difference in mean ADC values of both multiple myeloma and metastatic vertebral collapse was not statistically significant. This finding of our



study is seen in accordance with Ajith Mahale *et al.*<sup>[13]</sup> with b-values of 600 s/mm<sup>2</sup> where mean ADC values in metastatic compression fractures were  $0.970 \pm 0.237 \times 10^{-3}$  mm<sup>2</sup>/s and mean ( $\pm$ SD) ADC value in multiple myeloma was  $0.936 \pm 0.395 \times 10^{-3}$  mm<sup>2</sup>/s. With this result, we can conclude that DWI is not helpful in differentiating metastasis and myeloma. Hence, to distinguish metastasis and myeloma, other confirmatory tests should be performed.

Therefore, in our study, we observed that the mean ADC measurement of normal vertebrae was  $0.326 \pm 0.121 \times 10^{-3}$  mm<sup>2</sup>/s, and the mean ADC measurement of all the collapsed vertebrae (benign and malignant) was  $1.274 \pm 0.3872 \times 10^{-3}$  mm<sup>2</sup>/s, which was significantly greater than that of normal ones ( $P < 0.0001$ ), and this finding is indicative of diminished diffusivity of the normal fatty marrow. The tumor cells infiltrate and replace the bone marrow, thus also limiting free water diffusion. Accordingly, we found that the mean ADC measurement of vertebrae with malignant marrow lesions was less than those with benign pathologies. However, the mean ADC value of the vertebrae with malignant marrow pathologies was greater than those with normal fatty marrow. On the other hand, benign acute vertebral fractures have an increased quantity of free water in the interstitial region with an escalation of water diffusion and leading to high ADC values. Furthermore, in our study, we observed that the mean ADC value of benign pathologies ( $1.4578 \pm 0.2992 \times 10^{-3}$  mm<sup>2</sup>/s) was statistically greater than those of malignant ones ( $0.8520 \pm 0.1786 \times 10^{-3}$  mm<sup>2</sup>/s) ( $P < 0.0001$ ). Therefore, diffusivity (ADC values) was found to be highest in benign lesions, followed by malignant pathologies, and least in vertebrae with normal fatty marrow. Although the measured ADC may be indicative of benign or malignant lesions, a considerable overlap has been described in several studies. Our outcomes are in agreement with the many previous studies in the literature.

In our experience, according to the literature, we found that DWI and ADC values are very much useful in differentiation between benign and malignant vertebral collapse.

## CONCLUSION

DW-MRI of the vertebral marrow is a beneficial sequence that can be used for vertebral collapse. Quantitative ADC values can be useful in differentiating benign from pathological causes of vertebral collapse. The major

advantage of this sequence is that no ionizing radiation is administered, and no injection of isotopes or any contrast medium is required. Short data acquisition time is another advantage. Therapy assessment may be done by observing changes in extent, symmetry, and intensity of signal on high b-values, and corresponding alterations in ADC values is another exciting area of future research. Hence, DWI-ADC maps can be proposed to be done along with conventional MRI sequences so that early and accurate diagnosis can be sought for better management.

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# A Study on Socioeconomic, Nutritional, and Individual Factors on Prevalence of Myopia in School-Age Children

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## Abstract

**Introduction:** Myopia is a common refractive error of the eye, especially seen in children. The prevalence of myopia is high in India (6–22%) as well as in the whole world (4–12%). This study aimed at finding the prevalence of myopia as well as determining the factors relating to it.

**Materials and Methods:** The study commenced after obtaining ethical clearance. Sample size selected was 500. Three schools in Mysore, Karnataka, were chosen for the study. The participants were school-going children of 8–12 years of age (classes 5–7). Consent was taken from the headmasters/principals of the respective schools. The study model consisted of a survey and ophthalmologic examinations using Snellen chart and streak retinoscopy. The data collected were analyzed and presented in table forms.

**Results:** Many studies have been done on myopia and its prevalence and factors associated with it have been determined. This study supported many of the findings while contradicted some of them. The higher prevalence of myopia (30%) was found in this study compared to the previous studies. Myopia was found to be the most common cause for visual problems in children. The mean age of students with myopia was found to be 10.81. A statistically significant correlation was found between the symptoms of myopia and the presence of myopia.

**Conclusion:** This study indicated that symptoms could be used for early detection of the disease. No statistical socioeconomic and nutritional factors were linked with myopia. This information could help in better planning of eye care programs in schools.

**Key words:** Myopia, Prevalence, Refractive error

## INTRODUCTION

Myopia is the most common refractive error seen in children.<sup>[1-3]</sup> Although it is one of the easily correctable disorders of the eye, studies show that it is also one of the leading eye problems in India, where its prevalence 6–22%.<sup>[3-8]</sup> The prevalence of myopia in the world population is 4–12%.<sup>[2-5]</sup>

Myopia is mostly seen in the children. A possible reason behind this could be that children have to strain their eyes more than adults, especially for studying. Closely watching TV and playing computer games adds to the strain. Being in the actively growing age, they are more prone to nutritional deficiencies which could also have contributed to these defects of the eye. There are many factors which lead to myopia in school-going children and the determination of the most important among them could help in prevention or control of the condition. Early detection of myopia is important for its correction.

Children from specific schools in Mysore, Karnataka, were selected for this study, as schools are the most efficient means to approach children. The study model consisted of a survey and ophthalmologic examination using Snellen

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charts and streak retinoscopy. The intention of the survey was to collect data about the sociodemographic details, the lifestyle with respect to watching TV and reading habits, symptoms relating to myopia, and nutritional intake of the students. A questionnaire was prepared to interview the students based on it. Later, the ophthalmologic examinations were done.

Thus, this study presents the prevalence of refractive errors in relation to age, gender, economic status (type of school), TV viewing habits, reading habits, symptoms of myopia, and the nutritional status of the student. This information could help to plan for eye care programs for the students in school, which could help in early detection and correction and thus reduce the burden of visual impairment in the population, hence prevent the chances of amblyopia.

## MATERIALS AND METHODS

The aim of the project is to determine the prevalence of myopia in school-going children of 8–12 years of age (in classes 5<sup>th</sup> to 7<sup>th</sup>) in selected schools of Mysore district in Karnataka and to determine the major factors (socioeconomic, nutritional, or individual) contributing to it.

The study also aimed at determining the prevalence of myopia in pupils presenting with symptoms of myopia, so as to see how much well the symptoms can help in the early detection of the disease.

This was a cross-sectional type of study conducted in the schools of Mysore district, Karnataka, for 2 years. It started off after getting the ethical clearance certificate from K.R. Hospital, Mysore.

The sample size was calculated using the formula,

$$n = 4PQL^2$$

Where, n = Sample size,

P = Prevalence

Q = 100-P

L = Allowable error

From the previous Indian studies,<sup>[2,3,5,6,8]</sup> a good estimate of the prevalence of myopia among schoolchildren of India was taken as 16.6%. The calculated sample size was 483. The sample size was selected to be 500, considering 20% precision and 5% absolute error.

Three schools were selected randomly, two of which were government schools and one, a private school. Consent was taken from the headmasters/principals of the schools to carry out the study during class hours. The participants were students of classes 5–7, that is, of ages 8–12 years.

The schools chosen were Medar Public School, Medar Block, Mysore (101 students), St. Thomas High School-Government section (237 students), and St. Thomas High School-Private section (162 students), Vishweshwara Nagar, Mysore.

The students were interviewed with a questionnaire for the following:

- The sociodemographic details; age, sex, occupation of the parent, number of members in the household, the school – government school or private school, and if already diagnosed to be a myopic, the place of diagnosis.
- Habit of watching TV; the duration (<1/2 h or do not watch at all, around 2 h, 3–4 h, and more than 4 h), the distance they keep from the screen (<1 m, 1–2 m, 2–3 m, and >3 m), and the posture they have while watching TV (good and bad).
- Reading habits; the posture they have while reading (good and bad), the distance at which they keep the book (<10 cm, 10–20 cm, and more than 20 cm), and the lighting in the room where they read (tube light, CFL, and yellow light).
- Any eye straining work they do (yes/no)
- Whether their parents have myopia (yes/no)
- Whether they spend time on outdoors (yes/no)
- The symptoms related to myopia; frequent headaches, pain in the eyes, blurring of vision, watering of eyes, squinting while trying to see something that is not clear, discomfort in bright light (yes/no)
- Nutritional factors; food frequency of milk, starch, egg, fruits, and green leafy vegetables (taken every day of the week, more than 4 days, 2–4 days, and <2 days).

Then, ophthalmologic examination was done using Snellen chart, in which each student was asked to read the letters on the chart (which was kept at a distance of 6 m from the student) line by line, with one eye closed at a time. If they could read at least till the line corresponding to 20/20 vision (the metric equivalent of which is 6/6 vision), they were considered to have a normal vision. For the others with any other difficulty in vision, refraction test was done with streak retinoscopy for confirmation of myopia.

The data collected were entered into Microsoft Excel sheet. It was analyzed using SPSS version 13 software and tables were made. The Chi-square value and precision were checked in each table to see if the correlation was significant.

## Observations

Of the 500 students, 150, that is, 30% had myopia. The mean age of the children with myopia was found to be 10.81 with a standard deviation of 1.017. Male students showed a higher prevalence of myopia (30.6%) over female students (29%) but the correlation was found to

**Table 1: Sociodemographic distribution of the students**

Characteristics	Myopia		Total	Chi-square	P value
	Yes	No			
Age (in years)				6.080	0.193
8	2 (25.0%)	6 (75.0%)	8 (100%)		
9	14 (34.1%)	27 (65.9%)	41 (100%)		
10	52 (36.6%)	90 (63.4%)	142 (100%)		
11	37 (24.0%)	117 (76.0%)	154 (100%)		
12	45 (29.0%)	110 (71.0%)	155 (100%)		
Sex				0.132	0.716
Female	54 (29.0%)	132 (71.0%)	186 (100%)		
Male	96 (30.6%)	218 (69.4%)	314 (100%)		
Type of school				0.111	0.739
Government school	103 (30.5%)	235 (69.5%)	338 (100%)		
Private school	47 (29.0%)	115 (71.0%)	162 (100%)		

**Table 2: Association of TV viewing with the presence of myopia among the children**

Characteristics	Myopia		Total	Chi-square	P value
	Yes	No			
Difficulty in vision				61.484	>0.001
Yes	31 (88.6%)	4 (11.4%)	35 (100%)		
No	14 (34.1%)	27 (65.9%)	465 (100%)		
No. of TV viewing hours				1.565	0.667
Less than half an hour or do not watch at all	46 (29.9%)	108 (70.10%)	154 (100%)		
Around 2 h	70 (28.9%)	172 (71.1%)	242 (100%)		
3–4 h	22 (29.7%)	52 (70.3%)	74 (100%)		
More than 4 h	12 (40%)	18 (60%)	30 (100%)		
TV distance practiced				5.359	0.147
Less than 1 m	26 (32.5%)	54 (67.5%)	80 (100%)		
1–2 m	49 (26.8%)	134 (73.2%)	183 (100%)		
2–3 m	51 (28.3%)	129 (71.1%)	180 (100%)		
More than 3 m	24 (42.1%)	33 (57.9%)	57 (100%)		
Posture maintained while watching TV				0.475	0.290
Bad	24 (27.0%)	65 (73.0%)	89 (100%)		
Good	126 (30.7%)	285 (69.3%)	411 (100%)		

be statistically insignificant. A higher prevalence of myopia was seen among students of government school (30.5%) than private school (29%) [Table 1].

Among the students with difficulty in vision, a statistically significant number (88.6%) were myopic, indicating that myopia is the leading cause of defective eye in the children. In TV viewing habits, a higher prevalence of myopia was found among the students who watch TV for more than 4 h (40%). No relevant observation could be made out from the TV distance practiced by the students relating to the presence or absence of myopia. Moreover, the students who keep a good posture while watching TV were found to have a slightly higher prevalence of myopia among them. This could be because of interference of TV duration factor with the posture factor [Table 2].

In reading habits, myopia was more prevalent in students who keep a bad posture while reading (41.7%) over the students who keep a good posture while reading (29.4%) but this was not significant. A lower prevalence of myopia was found in students who read in tube light (28.1%) than

in CFL (32.8%) or yellow light (30.4%), but this also did not show any statistical significance. Reading distance practiced showed no correlation with the presence of myopia which could be due to the involvement of other factors such as posture and the lighting used while reading [Table 3].

About 42.9% of the students doing any eye straining work were found myopic, but it was not significant [Table 4].

If parents were myopic, 81% of their kids were also myopic. This was found to be statistically significant [Table 4].

Likewise, the finding that there is a lower prevalence of myopia among the children who play outdoor games (27.8%) over the ones who does not play (41.8%) was also statistically significant [Table 4].

The following symptoms could be correlated to the presence of myopia in children. About 56.3% with frequent headaches, 65.2% with pain in their eye, 75% with blurring of vision, 65.5% with watering of eye, and the only two

**Table 3: Association of reading habits with the presence of myopia among students**

Characteristics	Myopia		Total	Chi-square	P value
	Yes	No			
Posture while reading				1.634	0.201
Bad	10 (41.7%)	14 (58.3%)	24 (100%)		
Good	140 (29.4%)	336 (70.6%)	476 (100%)		
Reading distance practiced				4.985	0.083
Less than 10 cm	25 (32.5%)	52 (67.5%)	77 (100%)		
10–20 cm	77 (34.1%)	149 (65.9%)	226 (100%)		
More than 20 cm	48 (24.4%)	149 (75.6%)	197 (100%)		
Light used while reading				1.113	0.573
Tube light	75 (28.1%)	192 (71.9%)	267 (100%)		
CFL	58 (32.8%)	119 (67.2%)	177 (100%)		
Yellow light	17 (30.4%)	39 (69.6%)	56 (100%)		

**Table 4: Association of other risk factors, heredity, and physical activity with the presence of myopia among children**

Characteristics	Myopia		Total	Chi-square	P value
	Yes	No			
Eye straining work				0.559	0.4555
Yes	3 (42.9%)	4 (57.1%)	7 (100%)		
No	147 (29.8%)	346 (70.2%)	493 (100%)		
Parents myopic				27.100	<0.001
Yes	17 (81.0%)	4 (19.0%)	21 (100%)		
No	133 (27.8%)	346 (72.2%)	479 (100%)		
Outdoor games				6.192	<0.05
Yes	117 (27.8%)	304 (72.2%)	421 (100%)		
No	33 (41.8%)	46 (58.2%)	79 (100%)		

**Table 5: Association of various symptoms of myopia with the presence of myopia among children**

Characteristics	Myopia		Total	Chi-square	P value
	Yes	No			
Frequent headaches				11.218	>0.05
Yes	18 (56.3%)	14 (43.8%)	32 (100%)		
No	132 (28.2%)	336 (71.8%)	468 (100%)		
Pain in the eyes				14.239	<0.01
Yes	15 (65.2%)	8 (34.8%)	23 (100%)		
No	135 (28.3%)	342 (71.7%)	477 (100%)		
Blurring of vision				18.439	<0.001
Yes	19 (65.5%)	10 (34.5%)	29 (100%)		
No	131 (27.8%)	340 (72.2%)	471 (100%)		
Squinting while trying to see something that is not clear				4.685	<0.05
Yes	2 (100%)	0	2 (100%)		
No	148 (29.7%)	350 (70.3%)	498 (100%)		
Discomfort in bright light				0.016	0.899
Yes	1 (33.3%)	2 (66.7%)	3 (100%)		
No	149 (30.0%)	348 (70.0%)	497 (100%)		

who presented with squinting (i.e., 100%) had myopia. These were found to be statistically significant. Although, a slightly higher prevalence of myopia was seen among the students with discomfort in bright light (33.3%), it was not found to be significant [Table 5].

Considering the nutritional status, the students who used to take egg and green leafy vegetables for lesser number

of days of the week showed higher prevalence of myopia but this was not statistically significant. No such pattern could be made out from the food frequency of milk, starch, and fruits. This could be because food frequency tables are a very vague method of the assessment of nutritional status. Furthermore, other factors mentioned in the above tables could have interfered with these nutritional factors [Table 6].



**Table 6: Association of nutritional status through food frequency tables with the presence of myopia among schoolchildren**

Characteristics	Myopia		Total	Chi-square	P value
	Yes	No			
Food frequency of milk				0.637	0.959
Every day of the week	132 (30.3%)	304 (69.7%)	436 (100%)		
More than 4 days	4 (30.8%)	9 (69.2%)	13 (100%)		
2–4 days	7 (24.1%)	22 (75.9%)	29 (100%)		
Less than 2 days	6 (33.3%)	12 (66.7%)	18 (100%)		
0 days	1 (25.0%)	3 (75.0%)	4 (100%)		
Food frequency of starch				2.653	0.617
Every day of week	142 (30.3%)	327 (69.7%)	469 (100%)		
More than 4 days	3 (21.4%)	11 (78.6%)	14 (100%)		
2–4 days	4 (44.4%)	5 (55.6%)	9 (100%)		
Less than 2 days	1 (14.3%)	6 (85.7%)	7 (100%)		
0 days	0 (0.0%)	1 (100%)	1 (100%)		
Food frequency of egg				2.975	0.562
Every day of week	6 (23.1%)	20 (76.9%)	26 (100%)		
More than 4 days	9 (24.3%)	28 (75.7%)	37 (100%)		
2–4 days	25 (27.5%)	66 (72.5%)	91 (100%)		
Less than 2 days	60 (29.7%)	142 (70.3%)	202 (100%)		
0 days	50 (34.7%)	94 (65.3%)	144 (100%)		
Food frequency of fruits				7.984	0.092
Every day of week	61 (30.3%)	142 (70.0%)	203 (100%)		
More than 4 days	28 (44.4%)	35 (55.6%)	63 (100%)		
2–4 days	31 (26.1%)	88 (73.9%)	119 (100%)		
Less than 2 days	29 (26.1%)	82 (73.9%)	111 (100%)		
0 days	1 (25%)	3 (75%)	4 (100%)		
Food frequency of green leafy vegetables				2.154	0.707
Every day of week	58 (27.0%)	157 (73.0%)	215 (100%)		
More than 4 days	21 (32.8%)	43 (67.2%)	64 (100%)		
2–4 days	35 (30.2%)	81 (69.8%)	116 (100%)		
Less than 2 days	28 (33.7%)	55 (66.3%)	83 (100%)		
0 days	149 (30.0%)	348 (70.0%)	22 (100%)		

## DISCUSSION

The prevalence of refractive errors, obtained from done around the world, ranges from 4% to 12%.<sup>[4]</sup> From the studies conducted in various parts of India, the prevalence was found to be 6–22%.<sup>[2–6,8]</sup>

In this study, 150 subjects were found to be myopic out of 500, that is, 30%, which is slightly higher in comparison to the other studies. This variation could be because of the difference in lifestyles or living conditions (for example, time spent watching TV, reading habits, and nutrition) or the different diagnostic criteria used.

In a study done in Surat,<sup>[5]</sup> Gujarat, the mean age of the onset of refractive error was found to be 10.9 years. A study done in Ahmadabad found the mean age of myopia onset to be 11.22. The mean age of the students with in this study is 10.81, with a standard deviation of 0.017. These statistics indicate that myopia starts at a younger age, and therefore, screening should be done at an early age for proper detection and correction.

It was seen in this study that the male students had a higher prevalence of myopia (30.6%) than female students

(29%), but the small difference seems to be insignificant in statistical analysis. In the study done in Kathmandu too, similar observations were made but the study in Chandigarh showed a higher prevalence of myopia among female students.<sup>[9]</sup>

Proportion of cases with refractive error was found to be more in government schools compared to private schools in this study which was in contrast to a study done in Shimla<sup>[6]</sup> but it was found to be statistically insignificant in both the cases. In some other studies too, the same observations as the study in Shimla were made.<sup>[4–7]</sup> This could be because the students of good socioeconomic classes are the ones who spend more time with TV and computers. Furthermore, the burden of studies is more for them. The reason why this project gave a higher prevalence of myopia in government schools could be that the students of private schools are better off than the students of government school and so they get better nutritional and health facilities.

It was seen that among the students with difficulty in vision, 88.6% were myopic, indicating that myopia is the most common visual problem among these students and this was found statistically significant too. Other studies also

give a higher prevalence of myopia among the refractive errors in children.<sup>[5-8]</sup>

Other studies have shown significant association between watching computer or TV closely with the presence of refractive errors among schoolchildren.<sup>[6]</sup> In this study, a higher prevalence of myopia was found among students who watch TV more than 4 h/day (40%), and those who have a bad posture while doing it (41.7%) but both the correlations were found to be statistically insignificant. It was found that in students who keep an optimum distance from the screen while watching TV, the myopia prevalence is high, but this too was insignificant. Nevertheless, this could be because of the other factors involved while watching TV like the duration and posture.

This study showed a higher prevalence of myopia among the students who keep a bad posture (41.7%) while reading over the others (29.4%). It was found that the students who use tube light while reading showed a lower prevalence of myopia (28.1%) than the students who use CFL (32.8%) or yellow light (30.8%). However, these were not statistically significant. This study could not find any significant association between close study habits with the presence of refractive errors. The findings of the study done in Lahore showed a correlation between close study habits and studying in dim light with myopia and it was statistically significant.<sup>[2]</sup>

In a study done under Australian National University, it was found that hereditary myopia is influenced by environmental factors. Low hereditary values were seen when there is rapid environmental change between generations.<sup>[10]</sup> In this study, if the parent/s was myopic, the child was also myopic in 81% of the cases. This finding was statistically significant.

According to a study done by Rose *et al.*<sup>[11]</sup> in Sydney, the prevalence of myopia was seen to be lower among the students more involved in outdoor activities. In this study, a lower prevalence of myopia was seen in students who play outdoor games every day (27.8%) than the students who do not play outdoor games regularly (41.8%). This could be because outdoor gaming plays an important role in the physical development of children. Compulsory physical training in schools every day could help in the physical development of the kids as well as keep them healthier.

The prevalence of myopia was higher among the students who complained of frequent headaches (56.3%), pain in the eyes (65.2%), blurring of vision (75%), watering of eyes (65.5%), squinting while trying to see something that is not clear (100%), and discomfort in bright light (33.3%). In the study done in Surat,<sup>[5]</sup> blurring of vision and

watering of eyes (17.3%) was found to be present during the disease onset. These symptoms of myopia could help in its early detection. Being a correctable error of the eye, early detection is important in case of myopia. Therefore, health education activities regarding the symptoms of myopia should be carried out in schools.

The analysis of nutrition of the students, done by checking the food frequency of taking milk, starch, egg, fruits, and green leafy vegetables, did not show any correlation with the presence or absence of myopia except that the students who used to take egg and green leafy vegetables for lesser number of days of the week showed higher prevalence of myopia, which was not statistically significant. This could be because the food frequency is a vague estimation of the nutritional status. In a study done in Singapore and Chinese schoolchildren, higher saturated fat and cholesterol intake was found to be associated with longer axial length of the eye ball in otherwise healthy children.<sup>[12]</sup>

## CONCLUSION

The prevalence of myopia in this study was found to be 30% which confirms the high prevalence of myopia among the school-going children.

The mean age of onset of myopia observed is 10.81, which emphasizes the need for screening activities at a younger age.

Myopia was found to be the most prevalent among the visual disorders in the children.

A high prevalence of myopia was found in the students whose parents had myopia which confirms the role of hereditary factor in the disease.

The prevalence of symptoms of myopia such as frequent headaches, pain in the eyes, blurring of vision, watering of eyes, and squinting was high in the students with myopia. Timely detection of myopia is very important as it could progress if unnoticed. Hence, health awareness in schools with regard to symptoms of myopia could help in the early detection and correction of the condition. Even at the school level, the teacher can be trained to check for subnormal vision and refer the students for further refraction tests.

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# A Comparative Evaluation of Effect of Denture Cleansers on Color Stability, Surface Roughness, and Hardness of Polyether Ether Ketone

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## Abstract

**Introduction:** With the rising incidence of edentulousness, the need for dentures as well as their hygiene is of utmost importance. Very scarce data are available for effect of denture cleansers on color stability, surface roughness, and surface hardness of PEEK.

**Purpose:** This *in vitro* study was conducted to evaluate and compare the effect of different denture cleansers on color stability, surface roughness, and hardness of PEEK.

**Materials and Methods:** Thirty PEEK specimens were prepared with diameter of 20 mm and thickness of 3 mm by CAD/CAM milling process and divided into three groups ( $n = 10$ ). Specimens of each group were immersed in different denture cleansers of thyme oil, sodium perborate, and ozonated water for 10 min per day for 180 days. Initial and final color, surface roughness, and surface hardness of each specimen were measured after 180 days of immersion and difference was calculated. Data were tabulated and subjected to statistical analysis. Level of significance was set at  $P \leq 0.05$ .

**Results:** PEEK exhibited lowest color change and surface roughness, when immersed in thyme oil followed by sodium perborate and ozonated water. Increase in hardness was seen when PEEK specimens were immersed in ozonated water.

**Conclusion:** After immersion of PEEK specimens in different denture cleansers, the values of change in color and surface properties were within acceptable limits.

**Key words:** CAD/CAM, Color stability, Denture cleansers, Ozonated water, PEEK, Sodium perborate, Surface hardness, Surface roughness, Thyme oil

## INTRODUCTION

Due to continuous developments in dentistry, modification of materials is encouraged. The polymer modification and ceramic particles were included in it. Polyether ether ketone (PEEK) is one of such polymers, which is used in medical field. Moreover, due to tissue biocompatibility, it is

used for hip replacement. It was modified for dental use as alternative to metal framework and veneered by reinforced composite for optimum esthetics. PEEK was reported to have good mechanical properties and modulus of elasticity similar to denture.<sup>[1-3]</sup>

Dental prosthesis is an artificial replacement of missing oral structures restoring function, form, and esthetics. Thus, they should be manufactured using esthetically acceptable, precise, durable, and biocompatible dental materials. New researches and technologies in prosthetic dentistry are at its peak. Material researchers are continuously testing innovative materials to match the technological advancements and ever-increasing patient desires for function and esthetics as well.<sup>[4-7]</sup>

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A newer polymeric material polyether ether ketone (PEEK) has been introduced in recent times, which has unmatched strength, superior biocompatibility, low plaque affinity, esthetics, and characteristics structure.<sup>[8]</sup> PEEK is a close to the dental structure. PEEK is a polycyclic, aromatic, and thermoplastic polymer that are semi-crystalline and has a linear synthetic, tooth colored polymeric material, characterized by high mass-based stability, strong resistance against temperature loads, chemical and physical and radiological stress, and corrosion. Due to its outstanding properties in combination with outstanding biocompatibility and the high stability, it is used in variety of applications such as for the fixed dental prosthetic framework (FDP) or the removable partial denture abutment framework, and as a material for provisional implants abutments.<sup>[8,9]</sup>

In the clinical success of prosthesis, surface properties play an important central role. One of the most important clinical properties for all dental materials is that color stability and color changes are indicators of aging or damaging of the materials. Several factors may play a role for the discoloration of dental material after long-term use.<sup>[10]</sup>

For the longevity of the prosthesis, surface roughness, surface hardness, and color stability of the material are crucial. Therefore, the present study was taken up to evaluate and compare the effect of different denture cleansers on color stability, surface roughness, and hardness of PEEK.

## MATERIALS AND METHODS

Thirty specimens were prepared of PEEK denture base material with diameter of 20 mm and thickness of 3 mm [Figure 1]. Specimens of each group were immersed in different denture cleansers for 10 min per day for 180 days. Color measurement was done with the help of spectrophotometer. The surface roughness ( $R_a$   $\mu\text{m}$ ) measurement was done with the help of contact profilometer with a diamond stylus (tip radius of 2  $\mu\text{m}$ ). The surface hardness measurement was done with help of Shore D Durometer using 50-gf load for 30 s [Figure 2]. Thyme oil, sodium perborate, and ozonated water were selected as denture cleaners. Immersion procedure was carried for 180 days (6 months) to find out the long-term effects of different denture cleansers on color, surface roughness, and surface hardness of specimens [Figure 3].

After initial evaluation, the specimens were immersed in different denture cleansers. Ten specimens of each group were immersed in thyme oil, sodium perborate, and ozonated water, respectively [Figure 4a-c]. Each specimens were

immersed in thyme oil, sodium perborate, and ozonated water for 10 min/day. After 10 min, specimens were thoroughly washed and stored in distilled water. This procedure was repeated daily for 180 days. After immersion into a different denture cleansers, final color, surface roughness, and shore D surface hardness of all specimens were measured for the same surface as done before immersion. Difference between initial and final color, surface roughness, and shore D surface hardness was calculated.

## RESULTS

Table shows summary of mean and standard deviation of change in color, surface roughness, and hardness of PEEK specimens after immersing in different denture cleansers.

The result of the present study exhibited change in color of all specimens of PEEK denture base material immersed in all the denture cleansers evaluated. Least color change was seen in group II that was immersed in sodium perborate followed by group III (ozonated water) and I (thyme oil). There was statistically non significant change between all groups. ( $p > 0.05$ )

There was change in surface roughness of all specimens of PEEK denture base material immersed in all the denture cleansers evaluated. Least surface roughness change was seen in group II (sodium perborate) followed by group I (Thyme oil) and group III (Ozonated water). There was statistically non significant change between all groups. ( $p > 0.05$ )

Further, there was change seen in shore D surface hardness of all specimens of PEEK denture base material immersed

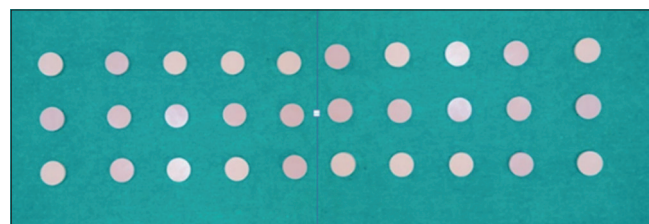


Figure 1: Test materials: PEEK samples



Figure 2: (a) Spectrophotometer, (b) Surface profilometer, (c) Shore D durometer, (d) Ozone generator

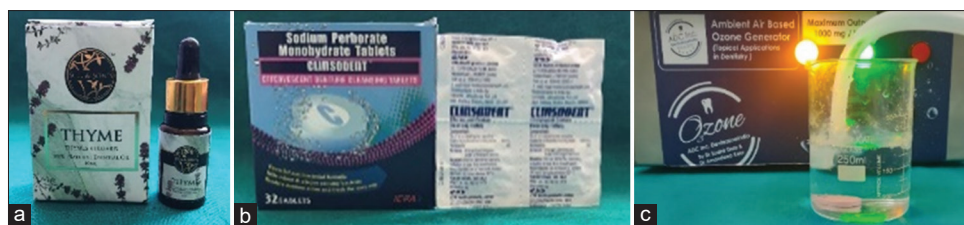


Figure 3: (a) Thyme oil, (b) Sodium perborate, (c) Ozonated water

in different denture cleansers evaluated. All the denture base resin specimens of group I and II in the present study exhibited decrease in hardness with immersion in denture cleansers. There was statistically significant change between groups. ( $p < 0.05$ ) [Table 1].

## DISCUSSION

In the last two decades, treatment options and materials used in dentistry progressed remarkably. The application of CAD/CAM (Computer-aided design/computer-aided manufacturing) technology contributes positively to comfortable and high quality dental services. CAD/CAM technologies have been introduced as an alternative to conventional processing techniques. The prosthesis fabricated through CAD/CAM is rated as promising for the successful long-term use. CAD/CAM polymers which have various cross-linking densities are used for fabricating prosthesis.<sup>[3,11]</sup>

The present study was conducted to evaluate and compare the effect of different denture cleansers on color stability, surface roughness and hardness of PEEK. Disc shaped test specimens were fabricated using PEEK with 20mm diameter and 3 mm thickness. These dimensions were used as it is compatible size for performing tests for color stability, surface roughness, and surface hardness, and this was similar to the dimensions used by Durkan *et al.*<sup>[12]</sup> and Sharabasy *et al.*<sup>[13]</sup> in their study.

Specimens of each group were immersed in different denture cleansers for 10 min per day for 180 days. Liebermann *et al.*<sup>[14]</sup> found that daily 10 min of immersion in any denture cleansers is needed for specimens to exhibit change in color and surface properties. Thyme oil, sodium perborate, and ozonated water were selected as denture cleaners. Immersion procedure was carried for 180 days (6 months) to find out the long-term effects of different denture cleansers on color, surface roughness, and surface hardness of specimens. This duration of immersion was similar to that of Liebermann *et al.*<sup>[14]</sup> Wieckiewicz *et al.*<sup>[15]</sup> and Stawarczyk *et al.*<sup>[16]</sup> After immersion for 10 min in, different denture cleansers specimens were stored in distilled water to prevent them from effect of drying.

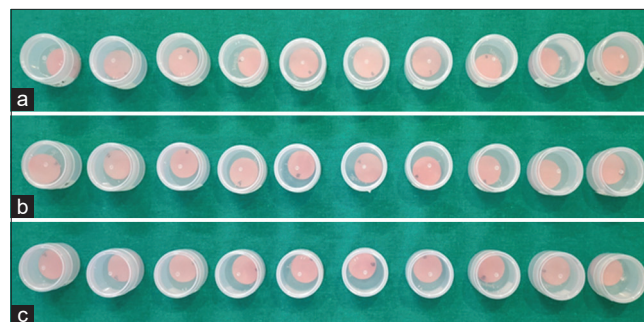


Figure 4: Specimens immersed in different denture cleansers. (a) Group I – Specimens immersed in thyme oil, (b) Group II – Specimens immersed in thyme oil, (c) GROUP III – Specimens immersed in thyme oil

Table 1: Summary table of mean change in colour, surface roughness and Shore D surface hardness of all groups after immersing in different denture cleansers

Group	Change in color ( $\Delta E$ ) (Mean $\pm$ S.D)	Change in surface roughness( $\mu m$ ) (Mean $\pm$ S.D)	Change in surface hardness (Mean $\pm$ S.D)
I	2.0310 $\pm$ .43041	0.057 $\pm$ 0.037	0.574 $\pm$ 0.622 <sup>a</sup>
II	1.8380 $\pm$ .70267	0.049 $\pm$ 0.038	0.529 $\pm$ 1.021 <sup>b</sup>
III	1.9250 $\pm$ .49887	0.079 $\pm$ 0.0538	-0.926 $\pm$ 0.755 <sup>b</sup>

Values with different lowercase superscript are statistically significant

After removing the specimen from different denture cleansers after a total of 180 cycles of immersion, the samples were cleaned with distilled water and wiped with dry clean cloth and air dried at room temperature. The surface to be examined was ensured by careful cleaning of each test specimen before the experiment. This technique of cleaning the test specimens was similar to study of Frederico Silva de Freitas Fernandes *et al.*<sup>[17]</sup> who used distilled water for 10 min to clean specimens. Color, surface roughness, and surface hardness were measured for each specimen before and after immersing procedure.<sup>[18]</sup>

CIELAB color system [Figure 3], most widely recognized order system, was developed in 1978. It is a uniform three-dimensional system that arranges the three dimensions of color at almost equal intervals and determines color changes.<sup>[19]</sup> The surface roughness ( $R_a \mu m$ ) measurement was done with the help of contact profilometer with a

diamond stylus (tip radius of 2 $\mu$ m). Contact profilometer was used in this study to measure change in surface roughness, because the stylus is in continuous contact with the surface and this method is not sensitive to surface reflectance or color unlike used in optical profilometer. The surface hardness measurement was done with help of Shore D Durometer using 50-gf load for 30 s.

The result of the present study exhibited change in color, surface roughness and shore D surface hardness of all specimens of PEEK denture base material immersed in all the denture cleansers evaluated. In this study, specimen of PEEK color change NBS range is range of 0 to 2 so it is considered as a perceivable by human eye but clinically acceptable. The measured values for surface roughness all test specimens after immersion in different denture cleansers were within acceptable limits of change. (0.15 to 2.0  $\mu$ m).

The change in color, surface roughness, shore D surface hardness can be attributed to their composition and the solution in which they were immersed. PEEK generates active radicals on its surface under heat and ultraviolet irradiation. The radical species subsequently induce functional monomer (such as vinyl monomer) polymerization, resulting in a functional group decorated PEEK surface. The changes of surface properties of the PEEK specimens can be attributed to the combination of monomers with free radicals species via oxygen bonding. However, because it exhibits a crystalline as well as an amorphous structure (which means strength and increased durability), the decrease was not statistically significant. Furthermore, the material has a slow rate of crystallization, so it is resistant to the effects of corrosive materials.<sup>[20]</sup>

The two main components of thyme oil showing antimicrobial properties are thymol (2-isopropyl-5-methylphenol) and carvacrol (5-isopropyl-2 methyl phenol). Thyme essential oil was used as the plant extract denture cleanser acts as antifungal and antimicrobial with least minimum inhibitory concentration (MIC) values. Sodium perborate denture cleansers act by releasing oxygen which has a high dissolving effect on plasticizers and loosen debris through mechanical means. Mode of action of ozone is attributed to lethal oxidation of bacterial protoplasm, membrane oxidation followed by lysis, cell electron transfer, or capture thus irreversibly altering the buffering mechanism and membrane alteration.

## CONCLUSION

PEEK is a supreme material and has become extremely widespread in dental field. This suggests its wide application in fabrication of FDP and CPD framework, in

implantology for fabrication of implant abutments, implant supported prosthesis framework, etc. PEEK specimens exhibited changes in color, surface roughness, and surface hardness when immersed in different denture cleansers (sodium perborate, thyme oil, and ozonated water). The change in color, surface roughness, and surface hardness of PEEK after immersion in denture cleansers was well within clinically acceptable limits. Sodium perborate, thyme oil, and ozonated water can be used as denture cleansers with PEEK denture base material. It is necessary on the part of the dental professional, to ensure that the denture wearing population knows how to select and use the appropriate denture cleanser so as to improve denture home care protocol.

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# Effect of Carbonated Beverages on Hard Tissue of Teeth and Light-Curing Filling Materials

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## Abstract

**Introduction:** In recent years, consumption of soft drinks increased among young people. The substance of dental hard tissues changes under the conditions of constant exposure to dyes drinks. Our enamel is constantly exposed to dyes contained in carbonated beverages. It is the right choice of filling materials, which maintains the appearance of existing tooth fillings, taking into account the consumption of staining beverages.

**Materials and Methods:** Thirty teeth were prepared by cavities of 5 class by Black on maxillary incisors. Company 3M Espe – Vitremer and composite Filtek Z 550 were used as filling materials. Sealed teeth in equal amounts were placed for a month in carbonated beverages “Tarhun” (Group 1) and “Baikal” (Group 2). After careful washout of dye and drying, the thin sections were produced in the longitudinal direction of the teeth on the border of the filling material and hard tissue. Photomicrographs were taken of each slice, and the comparative histological characteristics were made.

**Results:** The most coloration was in the first group teeth which were sealed by Vitremer, especially in the hard tissues of tooth. Microcracks were found in Group 1 and Group 2, which were sealed by Vitremer also.

**Conclusion:** The research showed a negative effects of carbonated beverages containing coloring agents on the hard tissue of teeth and filling materials. The nanocomposite Filtek Z 550 is most resistant to the effects of food dyes than Vitremer. This is due to its chemical composition and characteristics.

**Key words:** Enamel, Light-curing filling materials, Soft drinks

## INTRODUCTION

In recent years, consumption of soft drinks increased among young people. This is seen in the survey of 153 students of the Volgograd State Medical University which showed that carbonated beverages consumed almost all young people (96.7% of responses). About daily use of drinks reported 64 people (41, 8% of responses). A third of the respondents consume carbonated drinks not more than

1 time a week (37, 2% of responses), 17.6% – not more than ones a month. Most students consume drinks between meals (43.8% of responses).<sup>[1]</sup> Furthermore, children use a lot of sugar that reduces personal oral hygiene and increases incidence of dental caries.<sup>[2]</sup>

The substance of dental hard tissues changes under the conditions of constant exposure to dyes drinks. Ions of strontium, copper, aluminum, and potassium uniformly distributed throughout the thickness of the enamel.<sup>[3-7]</sup> According to the data of conventional, inorganic materials comprise 98.7% of the dry weight of the enamel, and the share of organic substances account for 1.3%.<sup>[8]</sup> Our enamel is constantly exposed to dyes contained in carbonated beverages. Speaking about the chemical composition of the enamel, it is necessary to mention anameloid – phase at the boundary between the enamel and dentin.<sup>[6]</sup> Enamel is

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a buffer system for acids, acting on its surface. Displacing calcium and ions  $H^+/H_3O^+$  bind to hydroxyapatite. This reduces the ability of hydroxyapatite counteract acid due to reduction of excess calcium.<sup>[4]</sup> The age of the tooth, enamel demineralization, acidity, oral fluid, properties permeate, the structure, and composition of the enamel effect on the enamel permeability.<sup>[5]</sup> Speaking of dental enamel permeability, it should be noted that the level of the enamel permeability changes under the influence of organic acids, primarily lactic, acetic, and propionic. Due to ion exchange, protons can be absorbed by enamel without destruction of its structure until certain point.<sup>[3]</sup> The permeability of the enamel depends on the concentration of hydrogen ions. This may be due to changes in the structure of the enamel, because increasing of acid concentration in the solution, it increases the solubility of enamel. Hybrid restorative and cosmetic material Vitremer, marketed by 3M ESPE consists of tinting glass ionomer powders, glass-liquid primer, and varnish to give shine. Restorative and cosmetic glass ionomer Vitremer material have all the basic virtues of the glass ionomer cements – adhesion to tooth structure, release of fluoride in them, and biocompatibility. Filtek Z 550 – light-curing restorative material developed by 3M Corporation known as based on nanocomposites. Due to the high density of the composite, it is well adjacent to the edges of teeth. Actively elastic material is used for sandwich technique. Based on the foregoing, it is the right choice of filling materials maintains the appearance of existing tooth fillings, taking into account the consumption of staining beverages.

### Aim

The aim of the study was to provide a comparative analysis of morphological changes in the hard tissue of teeth and light-curing filling materials that have arisen under the influence of various carbonated drinks containing food dyes.

## MATERIALS AND METHODS

Thirty teeth were prepared by cavities of 5 class by Black on maxillary incisors. Company 3M Espe – Vitremer and composite Filtek Z 550 were used as filling materials. Sealed teeth in equal amounts were placed for a month in carbonated beverages “Tarhun” (Group 1) and “Baikal” (Group 2). A selection of drinks was chosen due to dyes, for example, in the “Tarhun” includes tartrazine and brilliant blue, and the drink “Baikal” – Eleutherococcus extracts, black tea and sugar color (E 150d). Carbonated water “Essentuki” was selected as the control group (Group 3).

After careful washout of dye and drying, the thin sections were produced in the longitudinal direction of the teeth

on the border of the filling material and hard tissue. Photomicrographs were taken of each slice, and the comparative histological characteristics were made.

## RESULTS

Results of survey of 153 students of the Volgograd State Medical University which showed that carbonated beverages consumed almost all young people (96.7% of responses) Table 1.

This survey shows that the most popular drinks are bottled tea, Pepsi, and Sprite.

The most number of students drink carbonated beverages between meals or after meal [Table 2].

Effects of carbonated drinks to the hard tissue of teeth and filling materials are shown in Table 3.

The most coloration was revealed in the first group of tooth, which were sealed by Vitremer and placed in “Tarhun” drink. Microcracks were found on the boarder of filling material and hard tissues of tooth of 1 and 2 groups, which were sealed by Vitremer also.

**Table 1: Types of carbonated beverages consumed**

Name of drink	Number of people	% answers
Pepsi, Coca- Cola	39	25.5
Bottled tea	46	30.1
Sprite	28	18.3
Mineral water	9	5.9
Fanta	7	4.6
Juice	7	4.6
Nothing	9	5.9

**Table 2: The time of consumption of drinks**

Time	Number of people	% answers
Before meal	3	2.0
At the same time	20	13.1
After meal	63	41.2
Between meals	67	43.8

**Table 3: Effects of carbonated drinks to the hard tissue of teeth and filling materials**

Property	Coloration			Microcracks		
	Group 1	Group 2	Group 3	Group 1	Group 2	Group 3
Vitremer	++	+	-	+	+	-
Filtek Z550	-	-	-	-	-	-
Cement of teeth	+++	+++	-			
Enamel	++	++	-			

-: The absence of signs; +: A sign expressed slightly; ++: A sign clearly expressed; +++: A sign intensity expressed

## DISCUSSION

Filtek Z 550 – light-curing restorative material developed by 3M Corporation known as based on nanocomposites. Due to the high density of the composite, it is well adjacent to the edges of teeth. We believe that it is the chemical composition and properties of nanocomposite Filtek Z 550 can stand to the impact of different food dyes, which are contained in carbonated beverages. At the same time, the hard tissue of teeth staining causes permeability of enamel and cement, their properties. Restorative and cosmetic glass ionomer Vitremer material has all the basic virtues of the glass ionomer cements – adhesion to tooth structure, release of fluoride in them, and biocompatibility. You can also assume that the acid resistance of the nanocomposite Filtek is more than the Vitremer. From this, it can be assumed that the resistance, adhesion, and also the quality of the fillings deteriorate in Vitremer under the influence of the dyes.<sup>[9,10]</sup>

## CONCLUSION

The research showed a negative effects of carbonated beverages containing coloring agents on the hard tissue of teeth and filling materials. The nanocomposite Filtek

Z 550 is most resistant to the effects of food dyes than Vitremer. This is due to it's chemical composition and characteristics.

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# Demographic Profile of Patients Presenting with Cervical Lymphadenopathy: A Cross-sectional Study

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## Abstract

**Background:** Tuberculosis (TB) is one of the major public health problems, being the ninth leading cause of death. Extra pulmonary TB (EPTB) contributes to the burden of the disease, with lymph node TB being the commonest form of EPTB. The incidence of TB is at an increase due to poor hygiene, poverty, and overcrowding. TB contributes to 2 million deaths worldwide every year. It has been reported that host risk factors for EPTB include younger age, female sex and non-white race.

**Aim:** The aim of the study was to study the demographic profile of patients presenting with cervical lymphadenopathy.

**Materials and Methods:** Patients with TB cervical lymphadenopathy attending out-patient departments of Pulmonary Medicine, Otorhinolaryngology, General surgery in SVS Medical College and Hospital were reviewed from May 2019 to May 2021. 100 patients with tuberculous cervical lymphadenopathy who were satisfying the inclusion criteria were included in the study.

**Results:** The most common presenting age group was between 20 and 40 years. Mean age was found to be around 25.82 years with a standard deviation of around 12.089, with the youngest in the present series was 5 years old. Higher incidence of disease was seen in females. There were 64% females and 36% males, ratio being approximately 1.7:1. Majority of the patients in this study were found to belong to class 3 and class 4 of Modified Kuppuswamy's classification.

**Conclusion:** Female gender with age 20–40 years, belonging to class 3 and class 4 of Modified Kuppuswamy's classification was common factor among the patients who developed cervical lymphadenopathy.

**Key words:** Cervical lymphadenopathy, Demographic details, Extra pulmonary tuberculosis

## INTRODUCTION

Tuberculosis (TB) is one of the major public health problems, being the ninth leading cause of death.<sup>[1]</sup> Extra pulmonary TB (EPTB) contributes to the burden of the disease, with lymph node TB being the commonest form

of EPTB.<sup>[2,3]</sup> TB lymphadenitis is seen in nearly 35% of EPTB of which cervical LN region is the most common to get involved, seen in 60–90%. The incidence of TB is at an increase due to poor hygiene, poverty, overcrowding.<sup>[4]</sup> TB contributes to 2 million deaths worldwide every year.<sup>[5]</sup> It has been reported that host risk factors for EPTB include younger age, female sex and non-white race.<sup>[6,7]</sup> The most common presentation is neck swelling with other presenting signs and symptoms being generalized weakness, weight loss, fever, and headache.<sup>[8]</sup>

The present study was taken up with the objective of studying the demographic profile of patients presenting with cervical lymphadenopathy.

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**Table 1: The age distribution of study population**

Age group	Frequency	Percentage
1–10 years	6	6
11–20 years	35	35
21–30 years	35	35
31–40 years	13	13
41–50 years	7	7
>50 years	4	4
Total	100	100

**Table 2: The gender distribution**

Gender	Frequency	Percentage
Females	64	64
Males	36	36
Total	100	100

**Table 3: The socio-economic status**

Socio-economic status	Frequency	Percentage
Class I	7	7
Class II	15	15
Class III	29	29
Class IV	47	47
Class V	2	2
Total	100	100

### Aim

The aim of the study was to study the demographic profile of patients presenting with cervical lymphadenopathy.

## MATERIALS AND METHODS

Patients with TB cervical lymphadenopathy attending out-patient departments of Pulmonary Medicine, Otorhinolaryngology, General surgery in SVS Medical College and Hospital were reviewed from May 2019 to May 2021. 100 patients with tuberculous cervical lymphadenopathy who were satisfying the inclusion criteria were included in the study.

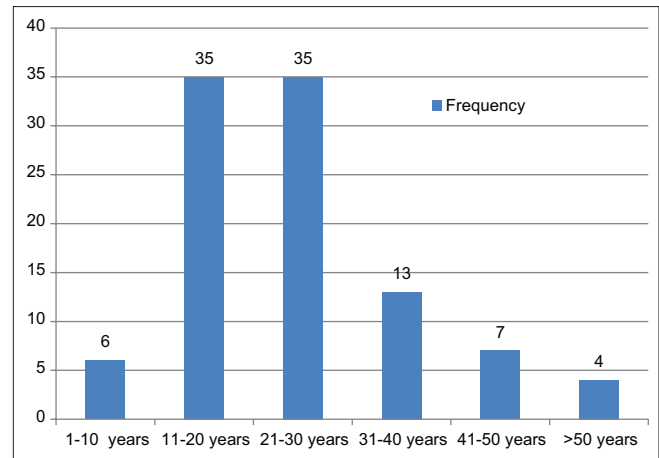
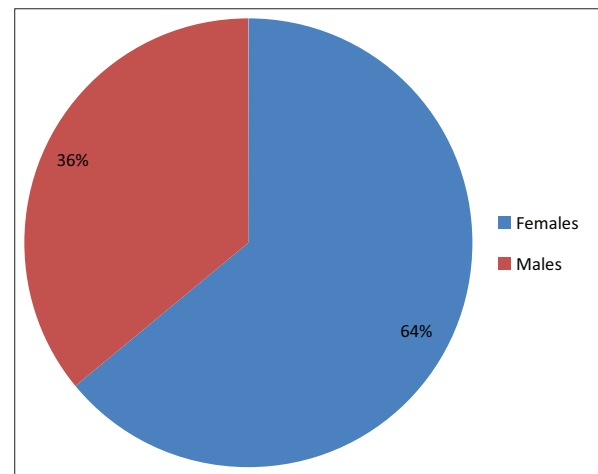
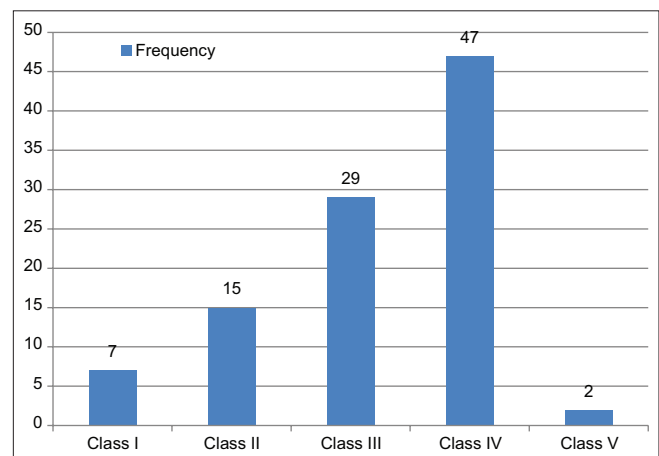
### Inclusion Criteria

All patients with tubercular lymphadenopathy above 1 years of age were included in the study.

### Exclusion Criteria

All patients with age <1 year and patients diagnosed with HIV were excluded from the study.

The patients were diagnosed to have cervical tubercular lymphadenopathy based on history, clinical examination and confirmed by either FNAC or EB with histopathological examination (when FNAC was inconclusive). All the demographic details were entered in Microsoft excel and data were analyzed using Epi info 7.2.1.0.

**Figure 1: The age distribution of study population****Figure 2: The gender distribution****Figure 3: The socio-economic status**

## OBSERVATIONS AND RESULTS

### Age Distribution

The most common presenting age group was between 20 and 40 years. Mean age was found to be around 25.82 years with a standard deviation of around 12.089, with the youngest in the present series was 5 years old.

**Table 4: Comparison of age incidence with the other studies**

Author	Age group in years					
	1–10 years	11–20 years	21–30 years	31–40 years	41–50 years	>50 years
Present study	6%	35%	35%	13%	7%	4%
Biswas and Begum <sup>[16]</sup>	--	10 cases	9 cases	3 cases	3 cases	--
Muhammad and Bukhari <sup>[17]</sup>	--	44%	31%	11%	8%	2%

**Table 5: Comparison of gender with the other studies**

Author	Gender (%)	
	Male	Female
Present study	36	64
Biswas and Begum <sup>[16]</sup>	36.6	63.4
Muhammad and Bukhari <sup>[17]</sup>	38	62
Salman <i>et al.</i> <sup>[18]</sup>	42	8

**Table 6: The comparison of socio-economic status with other studies**

Author	Socio-economic status (%)		
	Low	Middle	High
Present study	49	44	7
Biswas and Begum <sup>[16]</sup>	60	30	10

### Gender Distribution

Higher incidence of disease was seen in females. There were 64% females and 36% males, ratio being approximately 1.7:1.

### Socio-economic Status

Based on “Updated Kuppaswamy socioeconomic scale 2021, the patients were categorized into 5 classes, where 1 - upper, 2 - upper middle, 3 - lower middle, 4 - upper lower, and 5 - lower. Majority of the patients in this study were found to belong to class 3 and class 4 [Figures 1-3] [Tables 1-6].

## DISCUSSION

TB is one of the major public health problems, being the ninth leading cause of death, contributing to 2 million deaths worldwide every year.<sup>[9,10]</sup> EPTB contributes to the burden of the disease, with lymph node TB being the commonest form of EPTB.<sup>[11,12]</sup> TB lymphadenitis is seen in nearly 35% of EPTB of which cervical LN region is the most common to get involved, seen in 60–90%. The incidence of TB is at an increase due to poor hygiene, poverty, overcrowding.<sup>[13]</sup> It has been reported that host risk factors for EPTB include younger age, female sex and non-white race.<sup>[14,15]</sup> 100 cases of tuberculous cervical lymphadenopathy in this study are compared to other series in literature.

From the above table, the most common age group to be involved in the present series is 11–20 and 21–30. There are also six cases reported in the present series who belong to 1–10 years of age group. In Biswas and Begum study of 30 cases, 9 cases are in the age group between 21 and 30 years. In Muhammad and Bukhari study of 96 cases, 31 cases are in the age group of 21–30 years. In the present series studied, 35 cases are in the age group of 21–30 years which is almost equal to the studies in the literature. Cases above 60 years of age seemed to be unreported from all the three studies.

In the present series, the ratio is 1.77:1. The ratio according to the Biswas and Begum study is 1.73:1 whereas in Muhammad and Bukhari series it is 1.63:1. The ratio in Salman *et al.* study is 1.4:1. The reason behind the female preponderance of the disease could be due to under nutrition, repeated and early pregnancies. Socially, in developing countries women often have a low socioeconomic and nutritional status, which can affect the immune response to the disease.

The present series is compared using the Modified Kuppaswamy SE scale 2021.<sup>[19]</sup> (which divides patients into upper, upper middle, lower middle, upper, and lower), to the Biswas and Begum series categorizing the patients into low, middle, and high SES. Majority of the patients in the present series belong to the lower and middle SE status. Overcrowding, poor ventilation, poverty, malnutrition, and unhygienic environment are the predisposing factors for the increased incidence in the low socio-economic status group.

## CONCLUSION

Cervical lymphadenitis was more common among females with 1.7:1 ratio with low socio-economic status.

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# Clinical Profile of Cervical Lymphadenopathy: An Observational Study

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## Abstract

**Background:** Tuberculosis (TB) is one of the major public health problems, being the ninth leading cause of death. Extrapulmonary tuberculosis (EPTB) contributes to the burden of the disease, with lymph node TB being the most common form of EPTB. TB lymphadenitis is seen in nearly 35% of EPTB of which cervical LN region is the most common to get involved, seen in 60–90%. The incidence of TB is at an increase due to poor hygiene, poverty, and overcrowding.

**Aim:** This study aims to study the clinical profile of patients presenting with cervical lymphadenopathy.

**Materials and Methods:** Patients with TB cervical lymphadenopathy attending outpatient Departments of Pulmonary medicine, Otorhinolaryngology, and General surgery in SVS Medical College and Hospital were reviewed from May 2019 to May 2021. One hundred patients with tuberculous cervical lymphadenopathy who were satisfying the inclusion criteria were included in the study.

**Results:** Swelling was the presenting chief complaint in 87% of patients, with associated fever in 43% of patients. Weight loss and cough were reported in 9% and 11%, respectively. The right side was found to be a more common side of involvement than left. Bilateral involvement was found in 28% of patients. Matted nodes were seen in 69% of patients, with 43% not maintaining hilum.

**Conclusion:** Matted lymph nodes on the right side of the cervical region were the most common presentation.

**Key words:** Clinical profile, Cervical lymphadenopathy, Extrapulmonary TB

## INTRODUCTION

Tuberculosis (TB) is one of the major public health problems, being the ninth leading cause of death.<sup>[1]</sup> Extrapulmonary tuberculosis (EPTB) contributes to the burden of the disease, with lymph node TB being the most common form of EPTB.<sup>[2,3]</sup> TB lymphadenitis is seen in nearly 35% of EPTB of which cervical LN region is the most common to get involved, seen in 60–90%. The

incidence of TB is at an increase due to poor hygiene, poverty, and overcrowding.<sup>[4]</sup> TB contributes to 2 million deaths worldwide every year.<sup>[5]</sup> It has been reported that host risk factors for EPTB include younger age, female sex, and non-White race.<sup>[6,7]</sup> The most common presentation is neck swelling with other presenting signs and symptoms being generalized weakness, weight loss, fever, and headache.<sup>[8]</sup>

The present study was taken up with the objective of studying the clinical profile of patients presenting with cervical lymphadenopathy.

## Aim

- This study aims to study the clinical profile of patients presenting with cervical lymphadenopathy.

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## MATERIALS AND METHODS

Patients with TB cervical lymphadenopathy attending outpatient Departments of Pulmonary medicine, Otorhinolaryngology, and General surgery in SVS Medical College and Hospital were reviewed from May 2019 to May 2021. One hundred patients with tuberculous cervical lymphadenopathy who were satisfying the inclusion criteria were included in the study.

### Inclusion Criteria

All patients with tubercular lymphadenopathy above 1 years of age were included in the study.

### Exclusion Criteria

All patients with age <1 year and patients diagnosed with HIV were excluded from the study.

**Table 1: The clinical profile of patients**

Clinical presentation	Frequency	Percentage
Swelling	87	87
Fever	43	43
Weight loss	9	9
Cough	11	11

**Table 2: The history of tuberculosis**

History	Frequency	Percentage
History of pulmonary TB	9	9
History of extrapulmonary TB	4	4
No history of tuberculosis	87	87
Total	100	100

**Table 3: The side of lymph node involvement**

Side of involvement	Frequency	Percentage
Right	37	37
Left	32	32
Bilateral	28	28
Total	100	100

**Table 4: The USG findings of lymph nodes**

USG findings	Frequency	Percentage
Necrotic maintaining hilum	31	31
Matted maintaining hilum	26	26
Matted without hilum	43	43
Total	100	100

**Table 5: The mode of diagnosis**

Mode of diagnosis	Frequency	Percentage
FNAC	81	81
EB	19	19
Total	100	100

The patients were diagnosed to have cervical tubercular lymphadenopathy based on history, clinical examination, and confirmed by either FNAC or EB with histopathological examination (when FNAC was inconclusive). All the demographic details were entered into Microsoft Excel and data were analyzed using Epi Info 7.2.1.0.

## OBSERVATIONS AND RESULTS

### Clinical Profile

Swelling was the presenting chief complaint in 87% of patients, with associated fever in 43% of patients. Weight loss and cough were reported in 9% and 11%, respectively as shown in Table 1 and Figure 1.

### History of TB

About 87% of patients had no previous history of Koch's pathology, with only 4% of patients with previous history of extrapulmonary Koch's pathology. It has been represented in Tble 2 and Figure 2.

### Side of Lymph Node Involvement

The right side was found to be a more common side of involvement than left. Bilateral involvement was found in 28% of patients as shown in Table 3 and Figure 3.

Number of lymph nodes involved: Multiple node involvement was seen in 66% of patients.

### USG Findings of Lymph Nodes

Matted nodes were seen in 69% of patients, with 43% not maintaining hilum. None of the cases in the present

**Table 6: The comparison of clinical features**

Clinical feature	Present study	Jha <i>et al.</i> <sup>[16]</sup>
Swelling	87%	94.6%
Fever	43%	10.7%
Weight loss	9%	14.3%
Cough	11%	10.7%
Others	--	16% (sinus tracts)

**Table 7: The comparison of lymph node characteristics**

Lymph node characteristic	Present study	Salman <i>et al.</i> <sup>[17]</sup>
Fixed	--	--
Matted	69%	72%
Others	--	6% (sinus tracts)

**Table 8: The history of pulmonary tuberculosis**

History of pulmonary TB	Present study	Jha <i>et al.</i> <sup>[16]</sup>	Maharajan <i>et al.</i> <sup>[18]</sup>
Present	4%	26.66%	16.86%
Absent	94%	83.33%	83.14%

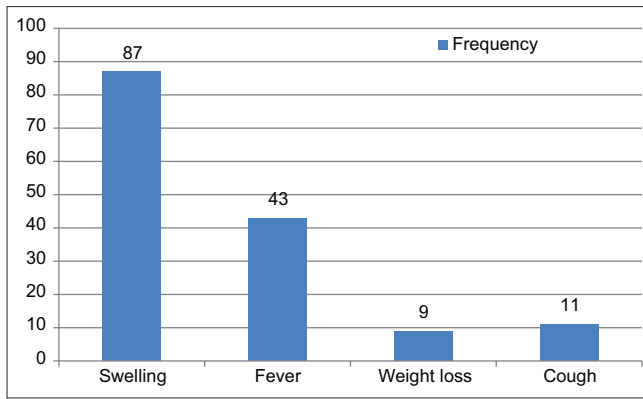


Figure 1: Clinical profile of patients

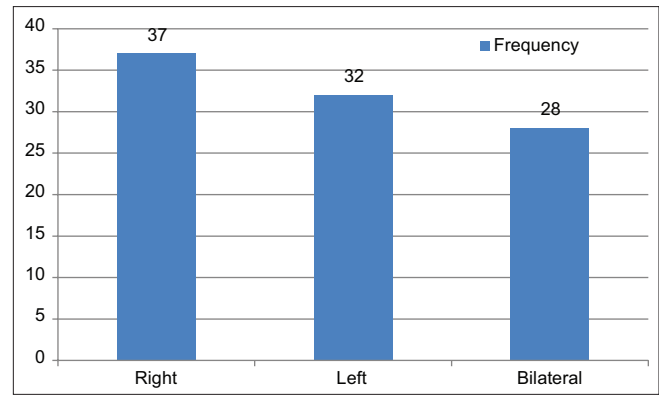


Figure 3: The side of lymph node involvement

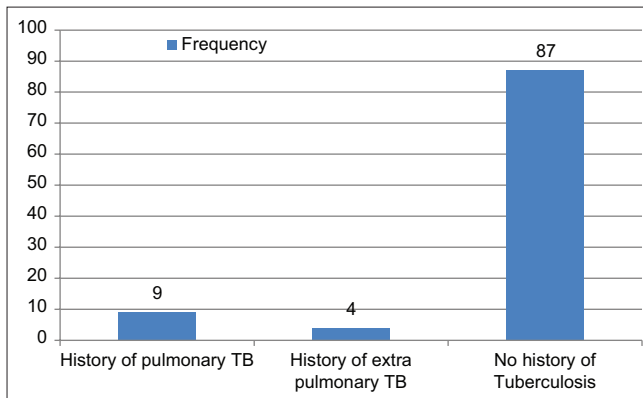


Figure 2: The history of tuberculosis

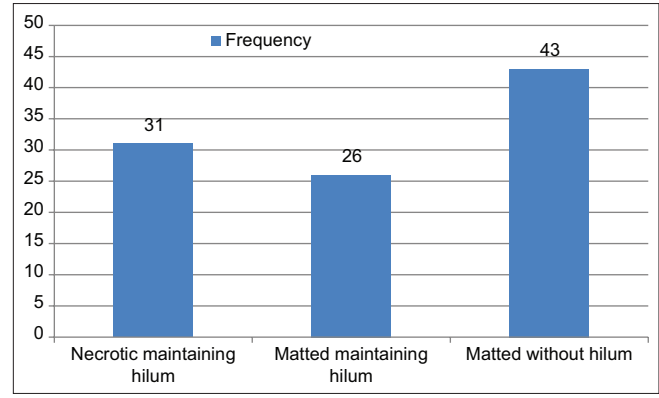


Figure 4: USG findings of lymph nodes

Table 9: The results of FNAC and excision biopsy in various studies

Mode of diagnosis	Present study	Muhammad and Bukhari <sup>[19]</sup>	Salman <i>et al.</i> <sup>[17]</sup>
FNAC	81%	69%	82%
Excision biopsy	100%	--	18%

study presented with sinuses as represented in Table 4 and Figure 4.

### Diagnosis

Mode of diagnosis is represented in Table 5 and Figure 5. Nineteen patients with inconclusive FNAC reports were subjected to EB with HPE, of which 11 patients showed positivity with no rifampicin resistance noted.

## DISCUSSION

TB is one of the major public health problems, being the ninth leading cause of death, contributing to 2 million deaths worldwide every year.<sup>[9,10]</sup> EPTB contributes to the burden of the disease, with lymph node TB being the most common form of EPTB.<sup>[11,12]</sup> TB lymphadenitis is seen

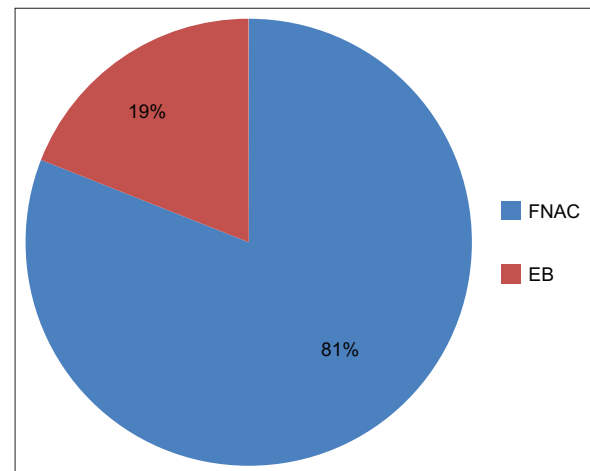


Figure 5: The mode of diagnosis

in nearly 35% of EPTB of which cervical LN region is the most common to get involved, seen in 60–90%. The incidence of TB is at an increase due to poor hygiene, poverty, and overcrowding.<sup>[13]</sup> It has been reported that host risk factors for EPTB include younger age, female sex, and non-White race.<sup>[14,15]</sup> One hundred cases of tuberculous cervical lymphadenopathy in this study are compared to other series in literature.

The most common symptom with which the patient presents to the hospital is neck swelling which is seen in 87% of cases. These results were compared with Jha *et al.* study, as shown in Table 6 which are almost similar to the present study which accounts for about 94.6% of cases presenting with swelling, but differ in presentation of fever, where almost half of the patients in the present series had complains of fever. Cough is due to the upper respiratory tract involvement and is not a specific feature of tuberculous adenitis, seen in nine patients.

The results of the present series are compared with those in Salman *et al.* study as shown in Table 7. None of the cases in the present study had fixed nodes or sinuses.

In the present series, 4% of cases had associated pulmonary TB which is about 16.86% in Maharajan *et al.* study and 26.66% in Jha *et al.* study as represented in Table 8.

In the present study, FNAC revealed caseating granuloma in 81% of cases compared to 69% in Muhammad and Bukhari series and 82% in Salman *et al.* study as mentioned in Table 9. FNAC showed inconclusive evidence in 19% of the cases in the present series. According to Salman *et al.* study, excision biopsy revealed caseating granuloma in 18% of the cases. After confirmation of diagnosis, patients were put on antitubercular drugs and were followed up. The cure rate was 100%. This result is similar to that of Jha *et al.* study and Maharajan *et al.* study.

## CONCLUSION

Swelling was the most common form of presentation involving the right-sided lymph nodes with matting in 69%.

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