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Case Report

Localized Lesion of Plasma Cell Gingivitis Mimicking Pyogenic Granuloma: A Case Report

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Abstract

Plasma cell gingivitis is a rare benign condition of unknown etiology postulated to be an immunologic reaction to allergens such as flavoring agents, mouthwash, dentifrices, cinnamon, and chewing gum. The diagnosis is usually made after histopathological examination which reveals inflammatory infiltrate in connective tissue composed predominantly of plasma cells. We present here a case of plasma cell gingivitis in a 22-year-old female which was diagnosed on basis of characteristic histopathological findings and was managed by conventional periodontal treatment. Plasma cell gingivitis usually affects gingiva in a more generalized manner, but this case reports an atypical presentation in form of a localized lesion similar to pyogenic granuloma. Through this case, we highlight the importance of proper history taking and histopathology to institute proper treatment for lesions which are refractory to conventional procedures alone.

Key words: Cartwheel, Gingivitis, Plasma, Pyogenic

INTRODUCTION

Plasma cell gingivitis (PCG) is a condition characterized by diffuse and massive infiltration of plasma cells into the subepithelial gingival tissue.[1,2] Exact etiology of PCG is still not known but according to many authors, due to the presence of plasma cells, it is considered to be an immunological reaction to allergen such as mint candy, herbal toothpastes, red pepper, cinnamon clove, khat leaves, and food flavoring agents.[2,3] Because of its allergic nature, it is also known as atypical gingivitis, plasma cell gingivostomatitis, allergic gingivostomatitis, and stomatitis venenata.

Clinically, it is characterized by macular lesions that are bright red, velvety, sharply circumscribed, and flat to slightly elevated.[4] In most cases, these lesions are asymptomatic, but some patients may complain of burning, pain, or pruritus.

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Histologically, it is defined by a dense, band-like plasmacytic infiltrate in the upper dermis.[4] Usually, PCG is not associated with loss of attachment. Here, we present a case of plasma cell gingivitis with loss of attachment and alveolar bone loss, but without any identifiable source of allergy.

CASE REPORT

A 22-year-old female patient reported to the department of oral medicine and radiology with the chief complaint of swelling of gum in maxillary right quadrant for 6 months. According to the history, it was insidious in onset and bleed occasionally on brushing. There was no associated pain and burning. Medical history including drug history was non-contributory.

Extraoral examination was unremarkable. On intraoral examination, there was bright red, elevated lesion in relation to marginal and attached labial gingiva of maxillary right lateral incisor, measuring approximately 5 × 5 mm in size [Figure 1a and b]. It was edematous, soft, and friable in consistency. There was bleeding on probing with exudate through gingival sulcus. The probing depth was found to be 7 mm with no associated mobility of teeth. The probing depth and erythema were disproportionate with

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the amount of local factors present as evidenced by oral hygiene index with total score of 2.1. Based on clinical findings, a provisional diagnosis of periodontal abscess was made with pyogenic granuloma as the differential diagnosis.

The patient was advised routine blood investigations and intraoral periapical radiograph (IOPA) in relation to 12. Results of routine blood investigations revealed lowered hemoglobin levels with increased mean corpuscular volume and mean corpuscular hemoglobin. IOPA radiograph was suggestive of alveolar interdental bone loss [Figure 1c]. The lesion was excised and sent for histopathological examination.

On histopathological examination, sections showed parakeratinized stratified squamous epithelium with moderate hyperplasia overlying a cellular connective tissue stroma. Underlying stromal tissue showed numerous plasma cells with eccentric nuclei having cartwheel pattern of chromatin arrangement [Figure 2a], arranged in sheets and large nests. Numerous budding capillaries surrounded by plump endothelial cells were noted throughout the lesion. Bands of fibrous collagen were seen in between the plasma cells. Immunohistochemistry for kappa and lambda bodies was positive suggesting polyclonal nature of the lesion [Figure 2b and c]. Overall findings were suggestive of plasma cell gingivitis.

Based on histopathology, diagnosis of plasma cell gingivitis was made. To find out the possible allergen, the patient was enquired about habitual use of chewing gum, mouthwash, and herbal toothpaste but no definite etiology could be found. However, there was recurrence of lesion 10 days after complete excision [Figure 3a and b]. The patient was referred to the department of periodontology for further management. The lesion was completely excised and thorough curettage was done followed by a periodontal pack. Complete healing was evident in 7 days and no recurrence was noted after 1 month of follow-up [Figure 3c and d].

DISCUSSION

Plasma cell gingivitis is a benign inflammatory condition that is uncommon and of unclear etiology. Clinical appearance of PCG is striking; it mostly affects maxillary labial gingiva and presents as fiery red erythematous lesion involving the attached gingiva extending to mucogingival junction.[5,6] In the present case also, lesion is present on maxillary labial gingiva as bright red lesion. Although the precise cause of it is not known, is thought to be caused because of exposure to an allergen. Diagnosis is formed by selective exclusion through hematological screening, histopathological examination, and identification of allergen.

Gorgillo and Timms *et al.*[3,7] divided plasma cell gingivitis into three types:

1. Caused by an allergen
2. Neoplastic
3. Unknown origin

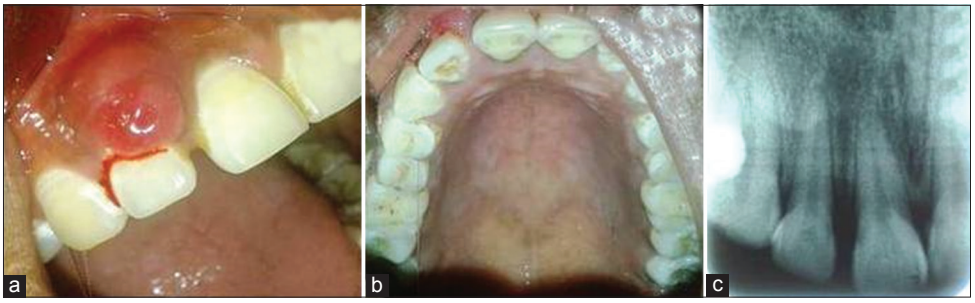

Figure 1: Clinical intraoral photograph of the patient showing well-circumscribed lesion on maxillary labial gingiva i.r.t 12 (a and b) and intraoral periapical radiograph of the patient showing interdental bone loss between 11 and 12 (c)

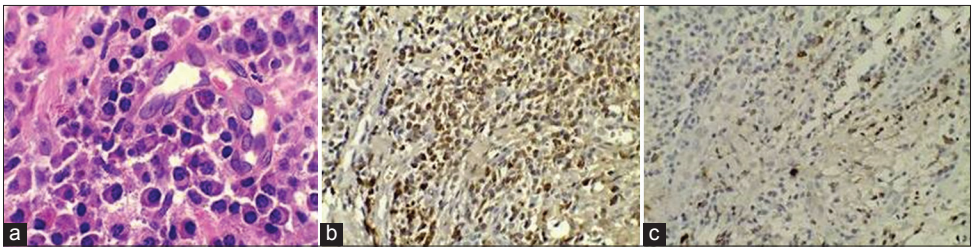

Figure 2: Photomicrograph (×40) showing plasma cells with cartwheel arrangement of chromatin (a), positive immunohistochemical expression of kappa antibody with brown staining plasma cells (b), and positive immunohistochemical expression of lambda antibody with brown staining plasma cells (c)

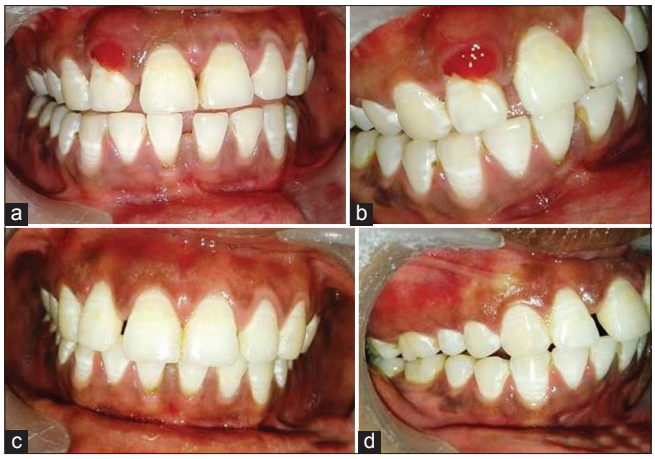

Figure 3: Clinical photograph of the patient with recurrence of lesion 10 days after complete excision (a and b) and follow-up photograph of the patient 1 month after periodontal treatment (c and d)

The present case belongs to type 3 as no known allergen was identified. PCG mimics lesions related to discoid lupus, lichen planus, cicatricial pemphigoid, and leukemia. However, in the present case, the lesion was slightly elevated clinically giving the appearance of periodontal abscess and pyogenic granuloma. Therefore, in addition to clinical and histopathological examination, the diagnosis requires hematological screening.

As already mentioned, from a histopathologic viewpoint, the intensely inflammatory infiltrate in the dermis and dermoepidermal border with infiltrate consisting mainly of plasma cells is considered characteristic of this lesion. Plasma cells are identified by eccentric nuclei with a cartwheel appearance.[8] However, the histopathological changes with predominance of plasma cells mimic conditions such as multiple myeloma, plasmacytoma, and plasma cell granuloma. Hence, to rule out plasmacytoma, immunohistochemistry with kappa and lambda antibody is often diagnostic.[9] In the present case, there was positivity for both kappa and lambda antibody, thereby eliminating plasmacytoma.

Since PCG is a benign lesion, for complete remission of the condition, it is essential to detect and eliminate any exposure to the etiologic agent.[2] The patient must, therefore, be advised to record complete dietary history, including food, dentifrice, mouthwash, alcohol, chewing gum, candy, and medication.

In this case, the patient's thorough history was taken but no possible allergen was identified. All the relevant hematological investigations were performed to rule out other probable lesions. Comprehensive history taking, clinical examination, and appropriate diagnostic tests form the key to diagnosis of PCG. Histopathological examination forms the basis for differentiating plasma cell gingivitis from other mimicking lesions. Hence, the present case highlights the importance of comprehensive history to arrive at a definitive diagnosis as well as appropriate management of lesions which are refractory to conventional therapy alone.

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Case Report

Tooth-Supported Overdenture: A Case Report

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Abstract

For elderly patients with few remaining teeth, overdenture is one of the successful treatment modality as it decreases residual ridge resorption and also aids in retention and stability of denture. Roots maintained under the denture base preserve the alveolar ridge, provide sensory feedback, and improve the stability of the dentures. The concept of overdentures may not be the elixir, but it helps in delaying process of complete edentulism and also helps in bone preservation. To top it all, it gives the patient the satisfaction of having prosthesis with his natural teeth. The concept of conventional tooth-retained overdentures is a simple and cost-effective treatment than the implant overdentures. In this case report, rehabilitation of an edentulous patient with a tooth-supported overdenture is discussed.

Key words: Overdenture, Prosthesis, Residual Ridge Resorption, Stability

INTRODUCTION

Overdenture is a removable partial or complete denture that covers and rests on one or more remaining natural teeth, roots, and/or dental implants, a dental prosthesis that covers and is partially supported by natural teeth, tooth roots, and/or dental implants (GPT 8).[1] It is also called as overlay denture, overlay prosthesis, and superimposed prosthesis.[2] Tooth retained overdenture option, as preventive prosthodontics treatment modality becomes a boon for edentulous patients due to its innumerable advantages and also due to a simple and cost-effective treatment than the implant overdentures.[3] Overdenture takes advantage of few firm teeth that are present in an otherwise compromised dentition, which can be retained and used as abutments for overdenture fabrication.[4] This helps to improve the retention and stability of the final prosthesis significantly as the bone is a dynamic tissue.[5] The extraction of teeth results in the initiation of the bone resorption pattern. An additional bone formation occurs when bone receives tensile stress. Such stresses occur when occlusal forces are transmitted to the alveolar bone by the periodontal ligament of the preserved teeth, which are used as abutment teeth for overdentures, and prevent residual ridge resorption and this principle helps preserve bone. Hence, we can say the concept of overdenture helps in bone preservation and also delays complete edentulism.

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Indications	Contraindications
Dental arch having four or less than four retainable teeth	Patients who cannot be motivated to develop the desired level of oral hygiene
Loss of teeth in one dental arch while the other is dentulous.	Severe systemic complications as it can make treatment unsatisfactory for the patient.
Those with unfavorable tongue positions, muscle attachments, or residual ridges.	There is inadequate interarch distance.
Patients who may encounter problems with retention and stability of conventional complete dentures.	Inadequate attached gingiva

GENERAL CONSIDERATIONS DURING DIAGNOSIS AND TREATMENT PLANNING

Periodontal Consideration

Periodontal inflammation, pocket formation, and bony defect must be eliminated before starting treatment. An important periodontal requisite with overdenture abutment is an adequate zone of attached gingiva.

Endodontic Consideration

There are advantages of treating the abutment endodontically. Few to mention include:

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1. By endodontic treatment, we can make the crown – root ratio favorable.
2. By tooth preparation, interocclusal clearance is also provided for the arrangement of artificial teeth.
3. For securing attachments.

Location of abutment teeth: Two teeth in each quadrant present an ideal situation, for example,

1. Cuspids, second premolars, or second molars in each quadrant
2. Mandibular cuspids are most often utilized since they are usually the last teeth to be lost
3. Mandibular incisors can be used as overdenture abutments if the mandibular arch is intact.[2]

CASE REPORT

A 72-year-old male patient reported to the Department of Prosthodontics, Teerthanker Mahavir Dental College and Research Centre, Moradabad, with the chief complaint of difficulty in chewing due to missing teeth. The medical history of the patient was taken, and it was irrelevant affecting prosthodontic treatment. Intraoral examination revealed well-formed maxillary and mandibular ridges in Class I ridge relationship. Only teeth that were present 13, 22, 23 in the maxillary arch, and 43 in the mandibular arch and radiographic examination revealed good bone support and long roots.

The different treatment options available for this patient's mandibular arch were – extraction of the remaining teeth followed by conventional complete denture, implant-supported overdenture, and tooth-supported overdenture. The patient denied implant-supported overdenture due to additional surgery and long treatment time as well as high expenditure. It was planned to construct a tooth-supported maxillary and mandibular overdenture. Hence, it was decided to retain 13, 22, 23, and 43, proceed with intentional root canal treatment (RCT) followed by coping with all four teeth.

After the intentional root canal treatment of all four teeth, they were prepared with tapered round end diamond point with a chamfer finish line. Impression was made with additional silicone for the fabrication of copings. The copings obtained were checked for fit in the patient's mouth and finally cemented with glass ionomer cement. The thickness of the copings should not be more than 1 mm [Figure 1].

Primary impressions for the maxillary and mandibular arches were made with alginate. The impressions were poured and special trays were fabricated with self-cure acrylic resin with double spacer over abutment teeth. Border molding was done for both the arches with low fusing compound. Final impressions for the maxillary and mandibular arches were made with light body addition silicones [Figure 2]. Master casts were prepared by pouring the impressions in Type IV gypsum products.

Fabrication of record bases was done after the application of separating medium and copings was covered with wax. Placement of wax over abutments prevents the fracture of abutment during removal and placing of denture bases during different laboratory procedures. Fabrication of occlusal rims was done; jaw relations were recorded and transferred onto the semi-adjustable articulator with the help of face-bow.

Teeth arrangement was done and evaluated in the patient's mouth for phonetics, vertical and centric relation, and esthetics. Verification of vertical dimension and also centric and eccentric contacts was checked [Figure 3]. Patient's approval was taken, and the curing of the final denture was done in Lucitone acrylic resin. The denture was cured and polished. Adjustment of denture bases was done with articulating paper and pressure indicator paste. The patient was satisfied as the denture was very retentive and stable [Figure 4].

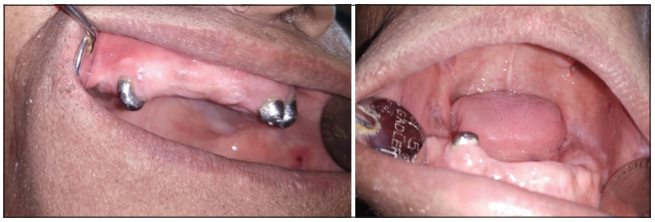

Figure 1: Copings cemented after endodontic treatment and tooth preparation

Figure 2: Border molding and final impression with green stick compound and light body addition silicone

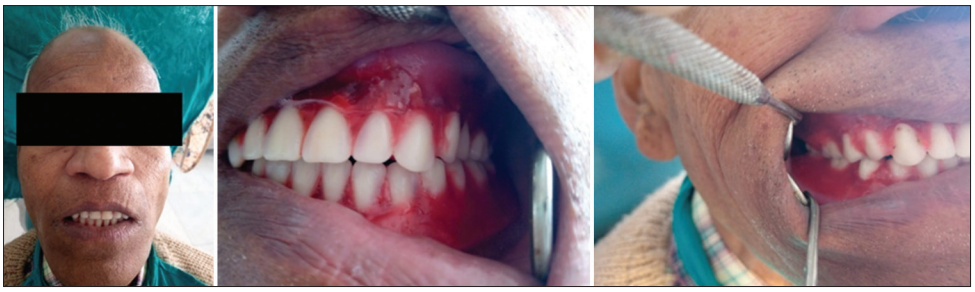

Figure 3: Trial with respect to maxillary and mandibular denture bases

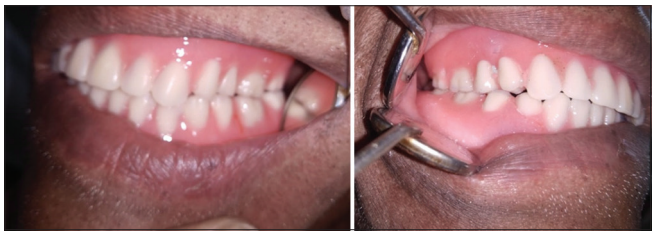

Figure 4: Final denture insertion

DISCUSSION

Tooth-supported overdentures help in the preservation of natural teeth and supporting structures. In many instances, teeth that would otherwise be removed can be retained to provide support for complete dentures. Frequently, only even one natural tooth can successfully help support a denture.[6] Rissin *et al.*, in 1978, compared natural dentition, conventional complete denture, and overdenture and it was found that the over-denture patients had a better chewing efficiency and it was about one-third higher than the complete denture patients. Crown and Rooney, in 1975, also found that preservation of alveolar bone occurs when the mandibular canine is retained for overdenture.[2]

CONCLUSION

The success of the tooth-supported overdenture treatment depends on the proper selection for the particular case. Overdenture patients have a chewing efficiency higher than the complete denture patients[7] which suggest that tooth-supported overdenture is very much effective both functionally as well as esthetically; moreover, it does not put heavy burden on patients pocket. Hence, this treatment modality should be considered in our regular clinical practice.[8]

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Case Report

Surgical Management of Masseter Muscle Hypertrophy – A Case Report

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Abstract

Masseter muscle hypertrophy (MMH) is considered to be a very rare entity with no known cause. The swelling can be seen in the mandibular angle region where the muscle is inserted. The cause of MMH includes several factors, for which several treatment modalities are mentioned in the literature. Botulinum toxin type A injection is the most commonly used for the treatment because of its less invasive features as well as low-risk index. However, the pharmacological treatment modality has low prognosis than the surgical treatment. The combination of pharmacological and surgical treatment has been mentioned in the literature. This article emphasizes on the surgical treatment aspect.

Key words: Angle of mandible, Hypertrophy, Masseter muscle

INTRODUCTION

Masseter hypertrophy (MH) is associated with nursing uncommon condition that may cause aesthetic and purposeful issues. Aesthetic issues carry with it distinguished facial muscle within the face, rectangular face form, and wide jaw angle. Patients could suffer psychological problems thanks to associate in nursing unattractive look.[1] Medical diagnosis needs clinical history and physical examination and should even embody complementary imagination resources such as resonance (magnetic resonance [MR]) and computed tomography (CT) scans to exclude different disorders. Medical diagnosis should include secretory organ disorders, intrinsic facial muscle pathology, parotitis, salivary gland tumor, lipoma, benign or malignant muscle tumors, benign, and malignant jaw tumors. Because the facial muscle is inserted within the jaw angle region, it causes the overgrowth of this region thanks to torsional forces. It is essential to create the medical diagnosis of head and neck mass, unilateral mass placed within the cheek. The potential underlying pathologic factors ought to be assessed fastidiously with elaborated patient history and imaging techniques before picking treatment.[2] A hypertrophied facial muscle can alter facial lines, generating discomfort, and negative cosmetic impact in several patients. Treatment of MH is disputed. Various degree of success is reported for a few of the treatment choices for MH that vary from easy pharmacotherapy to a lot of invasive surgery. Reduction of the masticatory muscle, osteotomy, neurotoxin, and splint medical aids measure choices for managing this problem.[3] Injection of neurotoxin A into the facial muscle is taken into account as a less invasive modality and has been reportable to be with success used for cosmetic sculpting of the lower face.[4] The normal methodology of treatment for MH is the partial surgical excision of the muscle and osteotomy of the jaw angle region and reshaping the curvature of the bone under general anesthesia.[5] The employment of associate in nursing intraoral approach was first advised by Wood. He suggested the removal of bone enlargement of

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the jaw angle with none muscle manipulation. Tabrizi *et al.* advocated an intraoral approach together with facial muscle reduction and part monocortical and bicortical osteotomy within the jaw angle in the treatment of MH.[6]

CASE REPORT

A 14-year-old female reported with a chief complaint of swelling on the right lower border of the jaw since 6 months [Figure 1a and b]. The history of the patient revealed the absence of any parafunctional habits, mouth opening was adequate and no recent history of trauma. There was no relevant medical history or family history. On palpation, the swelling was hard, non-tender, and temperature, which was not raised, firm in consistency and no associated lymph nodes were palpable. Temporal mandibular joint examination revealed no abnormal finding. The patient's concern was limited only to her facial asymmetry and she desired to have more attractive facial appearance.

Ultrasonography (USG) and panaromic radiographs were taken to make a differential diagnosis [Figure 2a and b]. USG report revealed enlargement of the right masseter muscle. There was also no pathological formation in the muscle and significant bone deposition seen on the right gonial notch on the panoramic view. The patient was diagnosed with the right masseter muscle hypertrophy (MMH).

Following all aseptic conditions and precautions, an intraoral incision was made using 15 number blade supraperiostally, slightly lateral to the external oblique line, and extending up to mandibular first molar region [Figure 3a]. The muscle was reduced and small amount of muscle mass ressected on the right side [Figure 3b]. At the same time, bone enlargements on the right side of the angulus of the mandible were reshaped. Satisfactory results have been achieved after 3 weeks follow-up [Figure 4a and b].

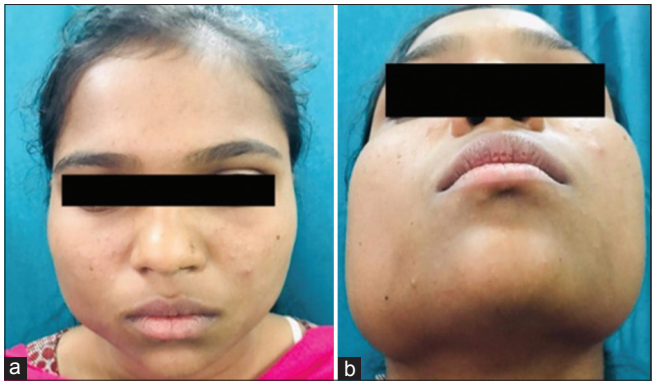

Figure 1: Pre-surgical photographs; (a) frontal and (b) worms view

DISCUSSION

There are many factors within the etiology of MH, like tensions and clenching caused by emotional stress and parafunctional habits. A congenital variety also exists, but acquired MH is more common. Unilateral occurrence is often seen when patients chew or clench totally on one side. Muscle function can also be impaired, thus causing conditions such as trismus, protrusion, and bruxism. Numerous factors, such as malocclusion, bruxism, clenching, or temporomandibular joint disorders, have been cited.[7] According to Teixeira *et al.*, there are two types of MMH, congenital or familial and acquired due to functional hypertrophy.[8]

The best diagnostic assay is to palpate the masseter muscle with fingers, while the patient clenches his/her teeth; therefore, the muscle is more prominent during contraction. It is observed that none of the etiologic factors within the literature are present in our patient like dental attrition, and thus, we will point out this condition as idiopathic MH. Especially within the diagnosis of the clinical situation in unilateral hypertrophy, the medical diagnosis of head and neck soft-tissue pathologies should be made.[2] Before deciding on the treatment plan, advanced

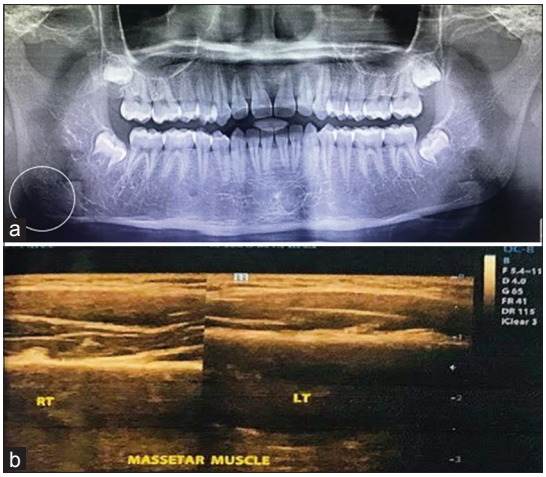

Figure 2: (a) Panoramic radiograph showing prominent right gonial notch (b) ultrasonography image showing hypertrophy of masseter muscle

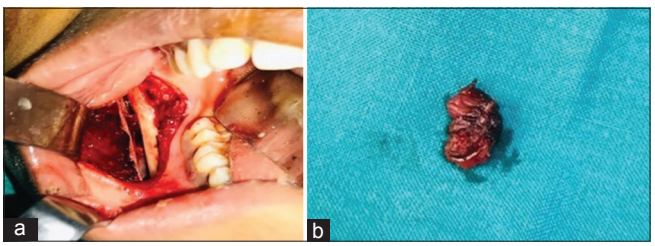

Figure 3: (a) Incision line and exposure of bone and masseter muscle (b) resected masseter muscle mass

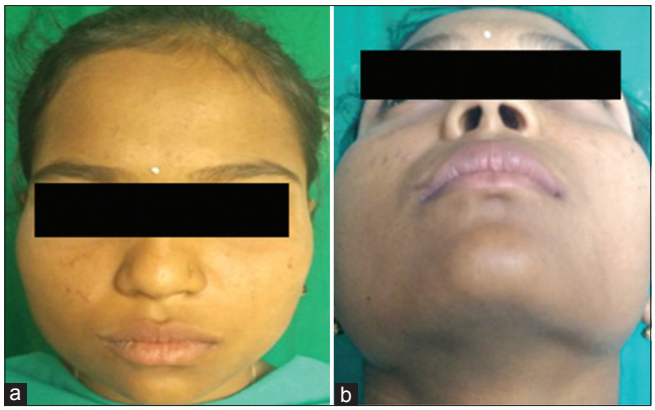

Figure 4: Follow-up after 1 month (a) post-operative frontal and (b) post-operative worms view

imaging such as MR and CT should be used to exclude possible pathologies such as muscle tumors, exocrine gland disorders, parotid tumors, parotid inflammatory diseases, and intrinsic masseter myopathy.[9]

USG images of the patient in our case showed that the masseter muscle and surrounding soft tissues had a regular structure, but the right masseter muscle was significantly larger than the left side. In orthopentomogram of the patient, hyperactive bone formation and significant asymmetry compared to the left side were observed in response to the abnormal activity of the masseter muscle within the mandibular angular region on the right side. The various treatment modalities for the management of MH are categorized into nonsurgical and surgical. Treatment of the idiopathic MH is based on psychological counseling, use of mouth guards, muscle relaxant, anxiolytic drugs, analgesics, physiotherapy, dental restorations, and occlusal adjustments to correct premature contacts.[2,3]

Honest result is often achieved within the patients with mild hypertrophy, but there is no reliable report on the literature on the success rates of isolated clinical therapy. In the literature, injection of botulinum toxin A into the masseter muscle is typically considered a less conservative modality and has been used for cosmetic purposes[4] Botox type A into the masseter muscle was first introduced by Smyth, Moore, and Wood in 1994 and thought of a conservative treatment of muscle hypertrophy.[10]

Botox A, when injected into a muscle, causes interference with the neurotransmitter mechanism producing selective paralysis and subsequent atrophy of the muscle. Perhaps, the foremost important disadvantage of neurotoxin therapy is that the treatment effect wears away and reverts to the primary condition in 6 months. According to some authors, the partial removal of the masseter muscle is enough to correct the hypertrophy. The insertion of hyperactive muscle causes an abnormal growing mandibular angle. Hence, authors confirmed that, to achieve satisfactory results, a mandibular angle resection is the appropriate treatment.

CONCLUSION

In case of facial deformities, the patient's expectations and physical findings should be evaluated thoroughly. It becomes important to make the differential diagnosis of head and neck mass, particularly unilateral mass located in the face area. In cases where MH causes appositional changes within the bone, the success rate with neurotoxin treatment alone is low, and therefore, the surgical option should be considered.

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Case Series

Socket Preservation – A Key for Success in Implants

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Abstract

Bone is a complex and constantly changing tissue. The healthy natural tooth stimulates the alveolar bone, thus maintaining its volume and density. The removal of a tooth begins a cascade of events within the socket that the final contour of the bone is reduced in width, height, or both. It often challenges the esthetics, retention and functions of the prosthetic restorations especially the implant supported restorations. When the bone width or height is compromised, augmentation becomes necessary to increase the bone volume. Bone augmentation is the cost involving and time consuming procedure which can be avoided if the timely care taken during extraction. Socket preservation is the procedure which will be helpful to retain the available bone that would otherwise be reduced during socket healing. It also helps to maintain the alveolar ridge in the labial aspect, thus improving the esthetic result of the reconstruction. Extraction sockets cannot be stereotype and every tooth socket should be managed according to clinical situation. In this case report, four different clinical situations with various management of socket preservation are well discussed.

Key words: Closed socket preservation, Extraction socket, Immediate implant, Onlay grafting, Open socket preservation, Socket preservation, Symphysis block graft

INTRODUCTION

Tooth extraction is a traumatic procedure often resulting in immediate destruction and loss of alveolar bone and surrounding soft tissues. It can lead to problem in future replacements due to reduction in alveolar bone height, width, or both.[1]

Bianchi and Sanfilippo[2] stated that the progressive involution of the alveolar bone begins following tooth loss, and it is accompanied by a reduction in both the quality and quantity of hard and soft tissues. Araujo *et al.*[3] showed that after extraction of natural teeth, the greatest reduction of the alveolar bone occurs in the first 6 months to 2 years.

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According to longitudinal study by Tallgren[4] it was found that after 1st year of extraction there was 25% reduction in alveolar bone width and 4 mm reduction in alveolar bone height. Within 2–3 years, 40–60% reduction was expected in mean ridge volume with greater amount of horizontal bone loss compared to vertical bone loss.

Socket Preservation

A procedure to reduce bone loss after tooth extraction to preserve the dental alveolus in the alveolar bone.[5]

Advantages:[6]

- It prevents immediate bone resorption after extraction
- Keep the contour and integrity of the socket with natural looking appearance
- It provides good bone support for dental prosthesis
- It maintains the facial soft-tissue esthetics.

Drawbacks:[7]

- It requires at least 4–6 months of healing period for implant placement.
- Technique sensitive

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- It requires special materials and instruments which increases the cost of the treatment
- Secondary surgical site needed in certain cases, for harvesting the soft- and hard-tissue grafts
- Risk of failure – due to membrane exposure or graft necrosis
- Contraindicated in acute inflammatory conditions.

Classification

According to Misch,[8] classified based on number of osseous walls remaining after extraction, the sockets or ridge defects into five wall, four wall, three wall, two wall, and one wall defects.

For better understanding, the extracted tooth socket can be compared to an open box, which has a mesial wall, distal wall, labial/buccal wall, palatal/lingual wall, and an apical wall.

- Five wall defects is a healthy extraction socket in which all the five walls are intact
- In four wall defect, any one of the walls may be missing. It may be due to peri-apical pathology or trauma or anatomical factors such as dehiscence
- In a three wall defects, only three walls are present and in two walled defects only two walls present. These are the usual findings in periodontally affected tooth
- In one wall defects, only one wall will be present.

Management

- Five wall defects are managed by immediate implant placement
- Four wall, three wall, and two wall defects of the sockets can be preserved by either open or closed socket seal technique
- In case of one wall defect, onlay grafting is an ideal treatment of choice.

CASE REPORTS

Case 1

A 37-year-old male patient reported with a fractured maxillary right central incisor due to trauma. On clinical examination, it was found to be periodontally sound [Figure 1a]. Radiographic examination also revealed the same without peri-apical pathology and in cone-beam computed tomography (CBCT) intact alveolar topography was present [Figure 1b]. Hence, it was considered as a five wall defect and planned to manage by immediate implant placement.

Under aseptic condition, local anesthesia was administered. Atraumatic extraction of 11 was done using periotomes [Figure 1c]. After extraction, socket was found to have intact walls and the socket was curetted thoroughly. Sequential osteotomy was performed to receive the implant. Implant was wrenched into the prepared osteotomy site and the primary implant stability of 40 N/Cm was achieved. Then, the implant abutment was customized and placed [Figure 1d].

10 ml of venous blood was drawn from the patient and centrifuged to obtain the platelet-rich fibrin (PRF). PRF was mixed with demineralized bone allograft material (Osseograft, Encoll, U. S. A).This mixture was used to fill the space between the implant surface and the socket wall [Figure 1d].

Temporary restoration was fabricated using preformed acrylic crowns and it was luted in non-functional occlusion. The patient was reviewed periodically for the past 4 months and final prosthesis to be given at the end of 6 months.

Case 2

A 33-year-old male patient came with complaint of pain in the upper front tooth region. On clinical examination, there was a decayed root stump of maxillary right central incisor [Figure 2a]. Intraoral periapical (IOPA) radiograph revealed peri apical pathology in relation to the affected tooth. CBCT confirmed the peri apical pathology with intact alveolar walls on other four sides [Figure 2b]. The case was diagnosed as four wall defect and planned to treat by closed socket seal technique.

Retained root stump of maxillary right central incisor was atraumatically extracted using periotomes under local anesthesia. On examination, the socket walls were found to be intact. Socket debridement was done and filled with demineralized bone graft material (Osseograft, Encoll, U. S. A) [Figure 2c]. Periosteal releasing incision was given to mobilize the buccal flap. The flaps were approximated and sutured with 3–0 black silk (Mersilk [Ethicon] – Johnson

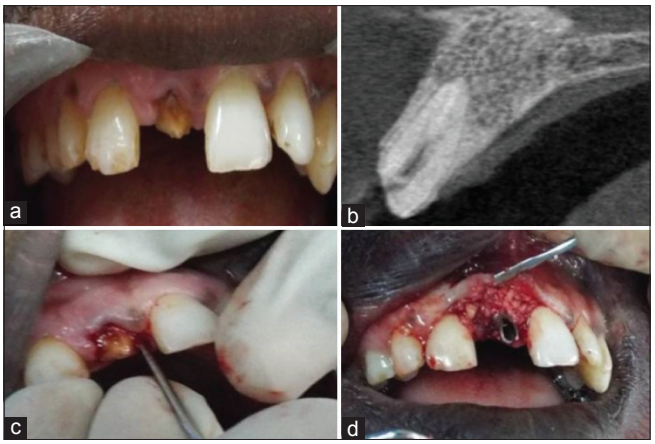

Figure 1: Five wall defect – immediate implant placement: (a) Pre-operative clinical view, (b) – pre-operative radiographic view, (c) atraumatic extraction, (d) immediate implant with platelet-rich fibrin + Bone graft mixture

& Johnson PVT Ltd., India) [Figure 2d] and periodontal dressing was given.

The sutures and the periodontal pack were removed after 10 days. The patient was periodically followed for past 2 months and implants were planned to be placed after 4 months of evaluation.

Case 3

A 27-year-old male patient came for the treatment of fractured maxillary left central incisor [Figure 3a]. On IOPA examination, it had periapical pathology. In CBCT, it was a three wall defect due to absence of buccal wall

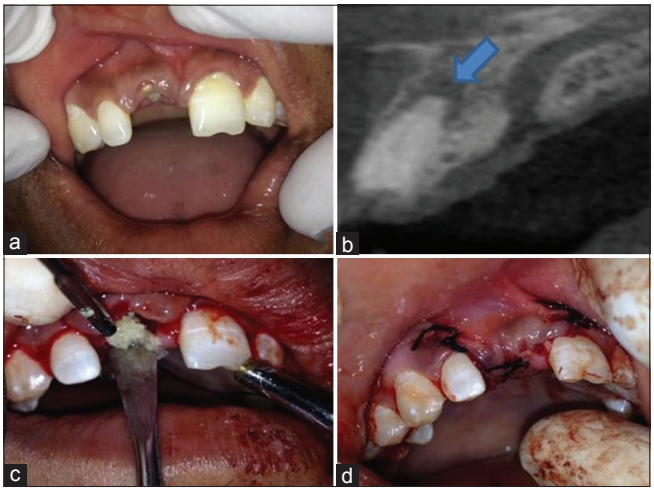

Figure 2: Four wall defect – closed socket seal technique; (a) pre-operative clinical view, (b) pre-operative cone-beam computed tomography view (Arrow- missing apical wall), (c) bone graft placement, (d) socket closure by simple suturing

[Figure 3b]. Hence, open socket seal technique was opted as the treatment for socket preservation.

Under local anesthesia, mucoperiosteal flap was elevated; and the root stumps were extracted carefully, to preserve the remaining walls. After extraction, examination revealed dehiscence in buccal socket wall [Figure 3c]. Debridement and degranulation of the socket were done. The socket was filled with demineralized bone allograft (Osseograft, Encoll, U. S. A) [Figure 3d] and covered with collagen membrane which was stabilized by 5–0 chromic catgut sutures [Figure 3e]. To prevent membrane exposure, the wound was covered with free gingival graft harvested from the palatal tissue and sutured with 5–0 chromic catgut [Figure 3f]. Periodontal pack placed and acrylic stent were used to protect the donor site.

Patient was reviewed every month for the past 4 months, and to be considered for prosthetic rehabilitation once the healing is completed.

Case 4

A 35-year-old male patient came for the replacement of maxillary right lateral incisor which had a history of traumatic extraction of the remaining root stump in relation to maxillary right lateral incisor about 6 month ago.

On clinical examination, the ridge width in relation to the edentulous region was very minimal, CBCT also showed a thin alveolar ridge which was inadequate for implant placement [Figure 4b]. As only the thin palatal plate was present, it is a one wall defect and planned to treat with onlay grafting by symphysis block graft.

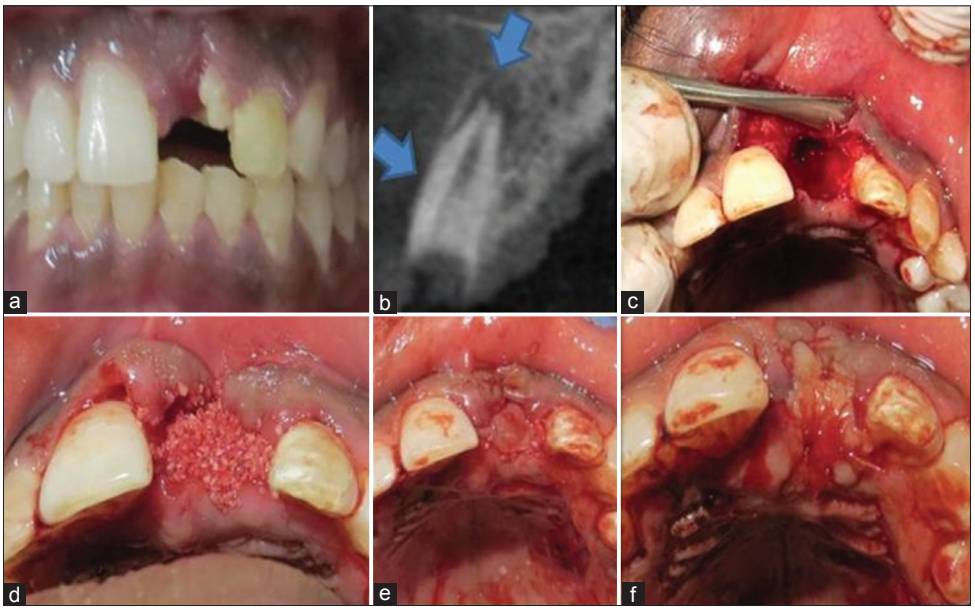

Figure 3: Three wall defect – open socket seal technique: (a) pre-operative clinical view, (b) pre-operative cone-beam computed tomography view (Arrow- missing labial and apical wall), (c) extraction socket with buccal dehiscence, (d) bone graft + platelet rich fibrin placement, (e) barrier membrane placement, (f) free-gingival graft suturing

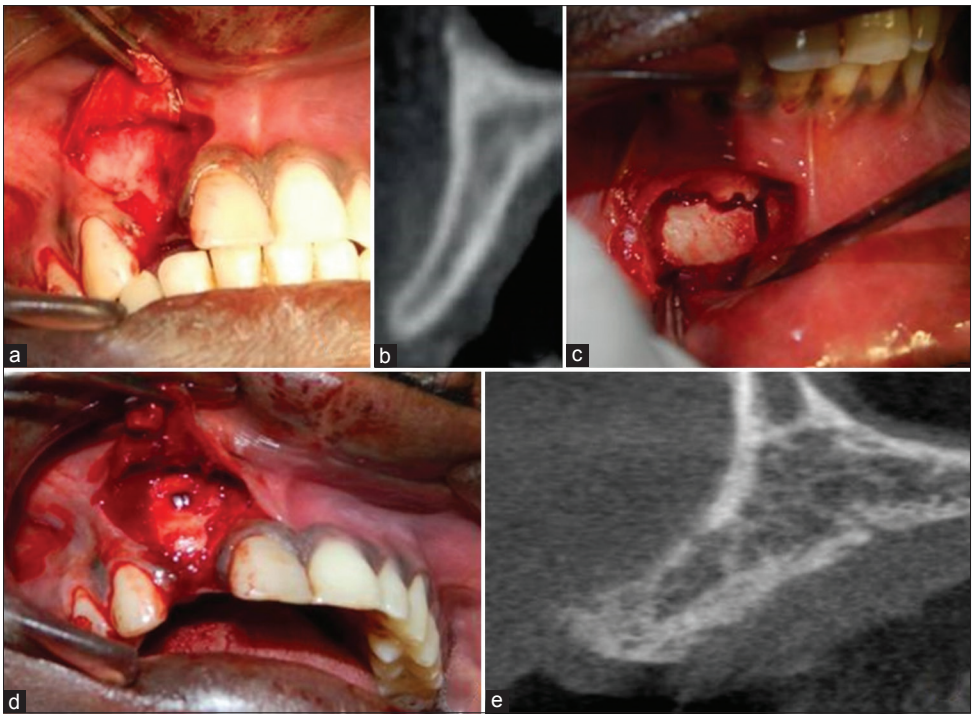

Figure 4: One wall defect – onlay grafting; (a) defect exposure, (b) pre-operative cone-beam computed tomography (CBCT) view , (c) graft harvesting, (d) blocked graft and osseous coagulum placement, (e) post-operative – CBCT view 5 months post-operative

Under local anesthesia, mid crestal incision made and mucoperiosteal flap was elevated to expose the defect [Figure 4a]. Block graft was obtained from the right symphysis region of mandible [Figure 4c]. Graft was trimmed and shaped according to the defect; decortication was done and stabilized at the defect site by titanium screw. Osseous coagulum was spreaded over the block graft [Figure 4d]. Flaps were mobilized to cover the graft and sutured by 5–0 catgut and donor site also sutured using the same. Patient was reviewed periodically.

After the satisfactory healing at the end of 5 months [Figure 4e], implant was placed by regular protocol. Patient is under regular review and the final prosthesis to be given after successful osseointegration.

DISCUSSION

In Case 1, the healthy extraction socket was a five wall defect, and thereby provided adequate space and protected environment for clot formation, implant stability, and osseous tissue formation. It also provided the best spatial relationship for defect bridging by vascular and cellular elements from adjacent osseous walls. It provided adequate space for graft retention and implant stability. Thus, five wall defects are ideal for regeneration with superior bone fill and implant success.[9]

In Case 2, less optimum anchorage of implants was expected due to the absence of apical wall of the socket. Hence, closed socket seal technique was followed in this case. Since all the 4 walls were intact, it helped in graft retention.[10]

In Case 3, it was difficult to gain primary implant stability and retain the graft in position as the buccal wall and the apical wall was missing. Hence, it was opted for open socket seal technique. The graft material was covered by graft membrane which acted as buccal wall and thereby retained the bone graft material in position. The bone graft material acted as a scaffold for the clot formation and maturation of granulation tissue. Placement of membrane isolated the intra bony healing compartment and prevented the intrusion of epithelium. Membrane exposure is the major cause for failure of augmentation; hence, it was covered with free gingival graft to prevent the membrane exposure.[11]

As only the palatal wall was remaining in Case 4, it was considered as one wall defect. Hence, onlay grafting was done with corticocancellous block graft from symphysis region.[12] Corticocancellous bone was opted since it increased the vascular ingrowth and resulted in rapid integration and delayed resorption. Shape and stability of the block graft ensured reliable space maintenance without collapse.[13] Rapid integration of block graft allows early re-entry for implant placement, often in 3–4 months compared to the particulate guided bone regeneration (GBR) techniques which require 6–9 months.[14]

CONCLUSION

Alveolar ridge resorption following tooth removal is a physiologically undesirable phenomenon but it can be avoided.

- Socket preservation procedures, as they can limit bone changes of the alveolar process; the use of grafts and barriers, both together and alone, might help to interfere in the normal sequence of biological events leading to resorption in wound healing
- Clinician should decide the treatment at the right time with adequate knowledge for the overall success.

The key points to all the clinicians

- "Please do extraction as atraumatic as possible!"
- "Please do not compress the socket after extraction!!"

" It is more important to preserve what already exists than to replace what is missing!!"

- De Van.

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Original Article

Anatomical and Functional Outcomes of Canal Wall Down Mastoidectomy with Cavity Obliteration and Posterior Canal Wall Reconstruction

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Abstract

Objectives: We evaluated the anatomical and functional outcomes of canal wall down mastoidectomy (CWDM) with cavity obliteration (CO) by superiorly based musculoperiosteal pedicled flap and posterior canal wall reconstruction (PCR) using free cartilage graft.

Materials and Methods: This hospital-based randomized control trial (RCT) included 60 subjects allocated into two groups (30/group). "Cases" underwent CWDM with CO-PCR and "controls" underwent CWDM. Post-operative anatomical and functional outcomes, including hearing, were assessed at 1st, 3rd, and 6th month and compared.

Results: One (3.33%) subject of the control group found frank cholesteatoma and 1 (3.33%) in the case group had a retraction pocket on examination under microscope (EUM). Three (10%) cases had distorted external auditory canal (EAC) and 100% controls had distorted EAC. Ten (33.3%) controls and 2 (6.7%) cases had complaints of post-operative otorrhoea. One (3.33%) case and all (100%) controls needed water precautions. Four (13.33%) controls experienced caloric induced vertigo, 15 (50%) required timely EUM cleaning, 3 (10%) showed depression in post-aural area, and 1 (3.33%) had a post-aural fistula. No, any case had vertigo, requirement of frequent ear cleaning, and had any other complications except 1 (3.33%) case who had temporary facial paresis. Among cases mean post-operative AC threshold was 40.70 ± 5.26 dB with a gain of 10.73 dB. In controls, AC threshold was 43.67 ± 4.31 dB with a gain of 8.47 dB. Cases had a mean post-operative A-B gap (ABG) of 21.13 ± 7.69 dB with a reduction of 9.30 dB. In controls, mean ABG was 25.30 ± 8.26 dB with a reduction of 8.60 dB.

Conclusion: CWDM with CO-PCR is significantly reduces post-operative morbidity and overall it is found to be a cost-effective procedure.

Keywords: Canal wall down mastoidectomy, Canal wall reconstruction, Cavity obliteration, Neo-external auditory canal

INTRODUCTION

Chronic otitis media (COM) with cholesteatoma is a potentially dangerous disease because it can lead to life-threatening intracranial complications. There are two surgical treatment options for cholesteatoma: The canal-wall-down mastoidectomy (CWDM) and the intact canal-wall mastoidectomy (ICWM). Recurrence of disease is the most evidenced complication associated with ICWM. The CWDM had been found to overcome this problem but with the occurrence of cavity problems along with it as a disadvantage. Mastoid cavity is unnatural and anatomically and physiologically unsatisfactory.[1]

A consensus is emerging among otologists that obliteration of the mastoid cavity that creates after CWDM can be a sound option to prevent cavity related problems such as frequent otorrhoea, recurrent infection, requirement of regular cleaning by surgeon, caloric induced dizziness, tinnitus, unsightly appearance due to presence of wide meatoplasty, and difficulty in using hearing aids. Cavity obliteration (CO) was first introduced by Mosher in

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1911 using superiorly based postauricular soft tissue flap. Subsequently, various methods were introduced using a variety of materials used to fill the cavity such as fat, cartilage, bone, dust, variety of flaps, hydroxyapatite, and bio-active glass.[2-4]

To avoid the presence of an open mastoid cavity, canal wall reconstruction (CWR) has been described. CWR is another technique for the elimination of mastoid cavity problems after CWDM. Various materials have been used for CWR, such as conchal cartilage, costal cartilage, bone pate, bone chip, or silicon block.[5-8]

We performed a surgical procedure that includes CO by superiorly based musculoperiosteal pedicled flap and posterior CWR (PCR) using free conchal cartilage graft [Figure 1]. In this study, we aimed to assess the outcomes of CWDM with and without CO and posterior canal wall reconstruction (CO-PCR).

MATERIALS AND METHODS

After the approval of institutional ethics committee, this hospital-based randomized control trial (RCT) was carried out in the department of otorhinolaryngology and head and neck cancer, SMS Medical College and Hospitals, Jaipur, Rajasthan, India, from June 2018 to July 2019. A total of 60 cases of unsafe (squamous) COM were enrolled in the study and allocated into two groups, including 30 patients in each group. One group included "cases" who underwent CWDM with CO by superiorly based musculoperiosteal pedicled flap and bone pate and PCR using free conchal cartilage graft (CO-PCR) and another group included "controls" who underwent CWDM without CO-PCR. Tympanoplasty and/or ossiculoplasty were done simultaneously in all subjects on the basis of intraoperative findings if required.

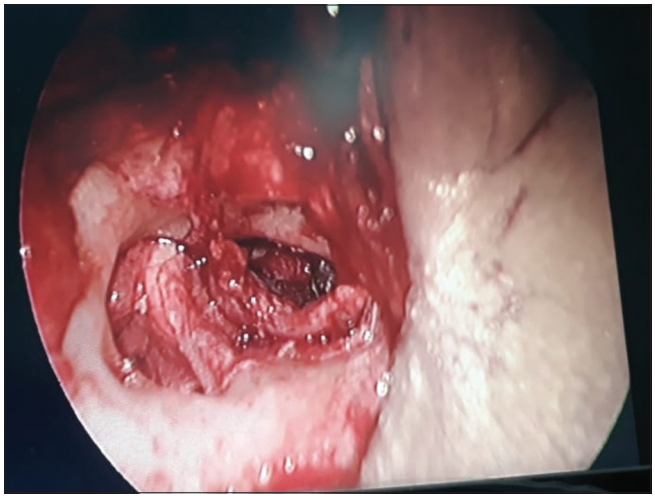

Figure 1: Intraoperative image of CWDM with cavity obliteration with canal wall reconstruction

All subjects presented with COM with active/inactive squamous disease planned for surgery after taking written and informed consent were included in the study. Patients with a mucosal type of COM, COM with complications, previously operated cases, and those who were not willing to participate in the study were excluded from the study.

All eligible patients were approached by the investigator himself. The nature and aim of the study were explained. Detailed history was taken. Thorough general and local examination was done. Routine investigations for surgery along with baseline pure tone audiometry (PTA) to assess hearing status and examination under a microscope (EUM) was done.

Patients were randomized and divided into groups. Surgeon who is a recognized otolaryngologist of ENT department of our institute remained same throughout the study to minimize the inter-surgeon variation.

Patients were discharged and called after a period of 7–10 days for suture removal then at 1st, 3rd, and 6th month post-operatively for follow-up. Follow-up at 1st, 3rd, and 6th month done by EUM. Post-operative PTA was done at the end of 6th month for hearing assessment. Data thus generated was recorded and outcomes were compared in terms of hearing status, post-operative complaints of discharge, recurrent infections, caloric induced dizziness, post-operative external auditory canal (EAC) anatomy, residual/recurrence of disease, and requirement of ear cleaning.

RESULTS

A total of 60 patients fitted with the inclusion criteria were enrolled in the study. Both male and female patients were included with a mean age 23.9 ± 9.53 years. There were 30 male and 30 female subjects, that is, male:female ratio was 1:1. Fifty patients had an active squamous type of COM and rest 10 had an inactive squamous type of disease.

On EUM done 6 months after surgery, of 60 subjects, 2 were presented with signs of recidivism. One subject out of 30 in the control group was found to have frank cholesteatoma. On the other side, in case group 1 subject had a retraction pocket with minimal keratin debris which was cleaned by EUM.

EAC status was examined on post-operative follow-up at the end of 6 months. In the control group, we did

meatoplasty along with CWDM so, in all subjects (100%), both inner and outer anatomy of EAC got distorted (EAC looking widened). On the other hand, in the case group, after CWDM, we reconstructed the posterior wall of EAC along with CO. Hence, anatomy of EAC was well maintained as neo-EAC was reconstructed. Only three cases (10%) in the case group had distorted EAC. Among those three, one had widened EAC (subject with secondary infection of obliterated material), one had non-significant widening and one developed narrowing of neo-EAC. P-value for this between both groups was found to be significant ($P = 0.000$).

Ten (33.3%) subjects in the control group had persistent otorrhoea, which may have been due to secondary infection or persistence of infection. This type of cavity is also called a discharging cavity. However, in the case group, only 2 (6.7%) subjects had complaints of post-operative otorrhoea. Among these two, one recovered by a short course of medical treatment but other had persistence of discharge due to secondary infection of obliteration material. *P* value for this was found to be significant ($P = 0.024$).

During the period of 6 months, follow-up in the case group, only one subject needed water precautions who suffered from secondary infection of obliteration material and was not cured successfully after initial medical treatment, whereas in the control group, all patients needed water precautions. *P* value for this comparison was found to be 0.000, which is significant.

In the case group, no one (0%) experienced vertigo due to caloric stimulation by water or air entry into the canal as semicircular canals were not exposed. On the other hand, in the control group, four subjects (13.33%) complained about this because of the exposed canal ($P = 0.236$).

After the initial period of epithelization (2–3 months), frequent cleaning was usually not required. In the control group, 15 subjects (50%) required timely EUM cleaning for which they depend on the surgeon. Out of 15, 10 (33.33%) were due to discharging cavity and the rest 5 (16.66%) due to the accumulation of wax/epithelial debris. However, in the case group, only one subject (3.33%) was surgeon dependent for regular ear cleaning (subject with secondary infected obliterated material). *P* value for this is 0.000, so it is a significant distribution.

In the control group, three subjects (10%) showed depression in post-aural area and one subject (3.33%) had a post-aural fistula in early post-operative period. In the case group, no subject (0%) showed any abnormality in the post-aural area. However, one subject (3.33%) had facial paresis in an immediate post-operative period which got relieved merely by releasing the dressing and EAC pack pressure with a short course of steroid therapy.

We observed pre- and post-operative PTA of all subjects and AC threshold, BC threshold, and A-B gap (ABG) was compared among both study groups. After CO and CO-PCR, significant improvement was noted in hearing with 10.73 dB in AC threshold ($P < 0.001$) and 9.3 dB in ABG ($P < 0.003$). In control group, improvement in AC threshold was 8.47 dB ($P < 0.001$) and 8.60 dB in ABG ($P < 0.001$).

Among cases mean post-operative AC threshold was 40.70 ± 5.26 dB. Hearing gain was 10.73 dB. On the other hand, in control group post-operative mean AC threshold was 43.67 ± 4.31 dB and gain was 8.47 dB. On the basis of P value, post-operative AC threshold was found to be significant ($P = 0.02$) but hearing gain was non-significant ($P = 0.245$) [Figure 2].

The case group had a mean post-operative ABG of 21.13 ± 7.69 dB. The ABG reduction was 9.30 dB. Whereas, in the control group, post-operative mean ABG was 25.30 ± 8.26 dB. Reduction in ABG was 8.60 dB. On the basis of *P*-value calculation, post-operative ABG was found to be significant ($P = 0.048$), but ABG reduction was non-significant ($P = 0.462$). Pre-operative ABG in most subjects of both study groups was above 20 dB (in case group 80% and in the control group 100%). After surgery in both study groups, a significant number of subjects shifted to below the level of 20 dB (in case group 63.3% and in the control group 43.4 %) [Figure 3].

DISCUSSION

A chronic discharging ear has been a perpetual problem and a challenge to the otologists for centuries. The objectives

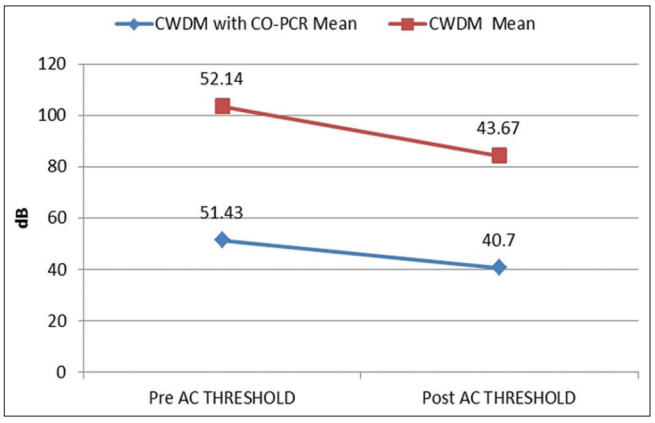

Figure 2: Comparison of audiometric finding (AC threshold) in the two study groups

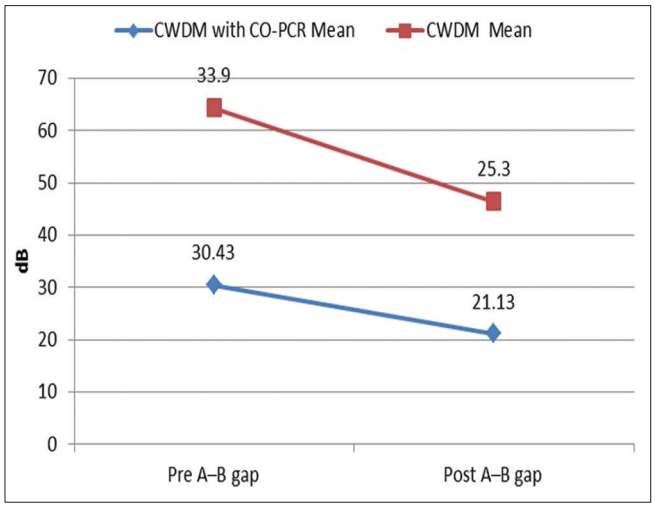

Figure 3: Comparison of audiometric findings (A-B gap) in the two study groups

of mastoidectomy in cholesteatoma are disease-free dry ear (primary), to create anatomic conditions to prevent recurrence and to restore the functional capacity of the ear, that is, the hearing (secondary).

The open mastoidectomy technique has been the mainstay of management of chronic ear disease; however, this type of surgery has its own disadvantages. The major problem is the creation of a large cavity and problems associated with it. To overcome these problems after mastoidectomy, CO and PCR can be done.

A canal wall down mastoidectomy, if not obliterated, can result in persistent otorrhea (discharging cavity) not responding to topical management. Sade, in his landmark article in 1982, proposed the causes of persistent otorrhea as high facial ridge, large cavity, small meatus causing inadequate drainage, tympanic membrane perforation leaving middle ear mucosa and eustachian tube opening open to the discharging cavity, and inadequate clearance of the disease.[9]

Obliteration of mastoid cavity thus leaves a smaller surface requiring epithelization and as a result, healing is fast. The exposed bone is covered with flap which reduces the likelihood of granulation and discharge. The cavity being smaller is also more likely to retain its epithelial migration potential and is self-cleaning. In patients with a successfully obliterated cavity, the smaller surface area and protection of lateral canal by the obliterating material allows most patients to swim free of complications. Hearing aids if required are better tolerated in an obliterated cavity than an open cavity.

In our study, we assessed and compared the outcomes of the two study groups in the form of cavity problems, requirement of frequent otomicroscopic cleaning, rate of secondary infections (discharge), rate of recurrence or residual (recidivism) disease, effect on hearing, and the effect on lifestyle.

Uçar C observed no recurrence in any of subject.[10] Similarly, Kim *et al.* observed in his study that there was no recurrence of disease.[11] Yamamoto *et al.* concluded that no residual cholesteatoma or cystic lesions were detected in the obliterated mastoid cavity. However, residual cholesteatoma in the tympanic cavity was observed in 9 (7.6%) ears.[12] Whereas, Suzuki *et al.* observed that cholesteatoma recidivism was seen in 8 ears (11.0%), residual cholesteatoma in 7 ears (9.6%), and recurrent cholesteatoma in 1 ear (1.4%). Of the 7 residual cholesteatomas, 3 occurred in the attic, and 4 in the mesotympanum. They all were the post-operative case of CWDM with partial CO and soft wall reconstruction.[13]

Liu *et al.* conducted a study on 47 patients who underwent mastoidectomy with obliteration and canal wall reconstruction. They observed that recurrent cholesteatoma was found on post-operative follow-up in two of the revision patients (7.4%) but none in the primary patients.[14] Hence, CWDM with CO-PCR shows better results in terms of recidivism but requires longer follow-up time for more accurate and conclusive results.

In our study, EAC status shows a significant difference between the two study groups and CWDM with CO-PCR results were far better in terms of neo-EAC status. In the control group, we performed meatoplasty along with CWDM so, in all subjects (100%), both inner and outer anatomy of EAC got distorted. Whereas, in "cases," after CWDM, we reconstructed the posterior wall of EAC along with CO. Hence, anatomy of EAC was well-maintained in most as neo-EAC was reconstructed.

Similar to our study, Uçar observed in his study that EACs were smooth and healthy. Epithelization was complete after the 2nd month of the operation.[10] Lee *et al.* observed that in a total of 20 of 22 patients (90.9%), the EAC wall healed well and maintained its cylindrical shape. Of the two remaining patients, in one case, the reconstructed posterior canal wall totally collapsed due to infection and the resultant autogenous bone pate infection. In the other case, the reconstructed posterior wall was exposed and partially reabsorbed, which eventually resulted in posterior wall hollowing. There was no EAC wall stenosis.[15] Kim *et al.* observed that the EAC was well maintained in all patients and no patient experienced a cavity problem; moreover, there was no bone pate infection. The posterior ear canal was well maintained and the retroauricular skin depression was minor, which caused no functional or

cosmetic problems.[11] Yamamoto *et al.* observed that a total of 113 ears (95.8%) achieved the nearly physiologic appearance of the EAC, and these conditions were maintained throughout the follow-up period.[12]

The present study showed that the most significant advantage of CWDM with CO-PCR over CWDM is in terms of relief from post-operative recurrent otorrhea (persistent infection/secondary infection). In the study by Yamamoto *et al.*, post-operative otorrhea was observed in 2.5% cases; however, most patients had good epithelization on the EAC and could cease water restriction 6 months after surgery.[12] Walker *et al.* found that the overall severe post-operative infection rate was 5.6% (16/285) which caused otorrhea. Infection of the bone pate necessitates admission and IV antibiotics.[8] Kim *et al.* and Liu *et al.* also observed no otorrhea in mastoidectomy with CO and canal wall reconstruction.[11,14]

Disease clearance is good after CWDM, but it gives a lot of cavity problems in terms of requirement of post-operative water precautions (restricted water activity, e.g., swimming), calorically induced vertigo by air/water, dependence on doctor for frequent cavity cleaning, and inability to use conventional hearing aids/earphones (problematic mainly for call-center workers). Meatoplasty is an essential part of CWDM. This wide meatoplasty also causes cosmetic/esthetic issues in subjects, mostly in females. Depression of the post-aural area in patients either due to large cavity or post-op infection, also leads to similar concerns. These affect the post-operative lifestyle of the subjects.

Uçar observed that in all patients, epithelization was complete after the 2nd month of the operation. Yamamoto *et al.* observed that most patients had good epithelization on the EAC and could cease water restriction 6 months after surgery. Similarly, Lee *et al.* observed that the average time required for complete epithelialization of the fascial surface and EAC wall was 30.7 days (range 7–84 days). After this period of epithelization, there was no need to take water precautions. In the study of Liu *et al.*, over 86.4% of all cases were water-resistant.

Uçar observed that none of their patients returned with vertigo induced by cold air or swimming. Similarly, in the study of Lee *et al.*, none of patient's complains of dizziness with pressure or temperature changes after CO and canal reconstruction. Liu *et al.* and Kim *et al.* also observed the same.

Kim *et al.* and Liu *et al.* observed that after CO and canal wall reconstruction, there was no need of frequent visits to the surgeon for ear cleaning as was required in CWDM.[11,14]

We observed some other complications in our study. In the "control" group (CWDM), three subjects (10%) developed depression in the post-aural area and one subject (3.33%) had a post-aural fistula in the early post-operative period. In the case group, one subject (3.33%) had facial paresis in the immediate post-operative period which got relieved just by releasing the dressing and EAC pack pressure with a short course of steroid therapy.

Lee *et al.* observed that minor postauricular wound infection (13.6%) was the most common surgical complication. Obliterating material got infected in two patients and consequently mastoid skin fistulas developed.[15] Walker *et al.* in his study observed that four (1.4%) of 285 ears had post-operative facial nerve weakness with two presenting after the CWR procedure and two after ossiculoplasty and CSF leak in 14 (4.9%) cases. These issues resolved either with conservative management or by surgical correction. One (0.4%) had post-operative mild to moderate SNHL.[8] Kim *et al.* and Liu *et al.* observed no any such complications in their studies.[11,14]

Lee *et al.* studied 18 cases that underwent staged operation with follow-up PTA. Thirteen (72.2%) of those showed an improved ABG value of >10 dB hearing level (HL). Stratified hearing results were as follows; seven patients had a post-operative ABG value of <10dB HL and five patients had a post-operative ABG value that fell between 10 and 20 dB HL. A post-operative ABG value>20 dB HL was reported in the remaining six patients. The average ABG value before the staged operation was 35.4 dB HL (range 20–48.8) and after the staged operation, 17.8 dB HL (range 1.5–41.5).[15]

Walker *et al.* observed that pre-operative ABG for the entire cohort (n = 285) was 27.8 dB. 253 (89%) patients underwent a second look with ossiculoplasty. Of those, 148 ears had audiometry performed 1 year or more after the second look surgery. The average ABG for these 148 ears was 23.4 ± 11.7 dB, an improvement of 4.2 dB from pre-operative ABG of 27.6 ± 12.9.[8] Kim *et al.* studied "outcomes of modified canal wall down mastoidectomy and mastoid obliteration using autologous materials;" of the 76 patients that underwent a one-stage operation and PTA at the 12-month follow-up, 11 (14.5%) showed a post-operative ABG value of 0–10 dB hearing level (HL), and 28 (36.8%) showed a post-operative ABG value of 10–20 dB HL. A post-operative ABG value of 20–30 dB HL was observed in 23 patients (30.3%) and a value 30 dB HL was observed in 14 patients (18.4%). The average ABG values were 26.7 ± 10.9 dB HL before the operation and 20.8 ± 10.8 dB HL after the operation (P = 0.001). Post-operative hearing outcomes improved significantly after the operation.[11]

Liu *et al.* revealed a mean gain on PTA of 4.5 and 2 dB, at 1- and 4-year post-operative, respectively. The mean improvement in the ABG at 1- and 4-year post-operative follow-up was 4.4 and 2.2 dB, respectively. ABG improvement at 1-year follow-up was statistically significant ($P < 0.05$), as compared to the pre-operative value. About 70.4% patients experienced excellent (0–10 dB) or a good (11 to 20 dB) gap closure one-year after surgery. About 63.7% had excellent or good gap closure in the operated ear at the 4-year follow-up. Those improvements, both 1 and 4 years after surgery, were statistically significant as compared to that before surgery ($P < 0.05$). In some patients, conductive hearing loss persisted.[14]

CONCLUSION

We conclude that mastoid CO-PCR is a cost-effective surgery which gives better outcomes with respect to cavity problems, recurrent infections, recidivism, surgeon-dependence for frequent otomicroscopic cleaning, hearing improvement, and effect on lifestyle as compared to those in canal wall down mastoidectomy. In addition, it provides a safe, dry, and "self-cleaning" ear.

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Original Article

A Study of Knowledge, Attitude, and Practice of Contraception among Antenatal Mothers Attending Antenatal Clinic of a Tertiary Institute in India

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Abstract

Objective: The objective of the study was to assess the knowledge, attitude regarding family planning, and the practice of contraceptives among antenatal women.

Materials and Methods: It was a cross-sectional study done over a period of 18 months in the Dept. of Obstetrics and Gynaecology of a hospital in India, involving 1000 women attending the antenatal clinic of this hospital. Their knowledge, attitude, and practice of contraception were studied.

Results: Out of 1000 women studied, 659 (65.9%) were primi and 351 (35.1%) were multigravida; most women (75.3%) belonged to 20–29 years of age group, had secondary education (38.1%), and were house-wives (69.3%). Eight hundred seventy-nine women (87.9%) had knowledge about contraception. Among those 879 women, 340 women had a positive attitude toward birth spacing, 98 had negative attitudes, 70 were undecided, and 365 women had no idea about the necessity of birth spacing. Most of the primigravida (212, 36.3%) prefer contraceptive pills, whereas most of the multigravida (102, 34.58%) prefer tubectomy. Most of the women (474), both users and non-users, depend upon the health workers regarding the choice of contraceptives.

Conclusion: Most of the women studied had some knowledge about contraception. Majority of them have a positive attitude toward contraception and birth spacing, but it is also noteworthy that a large number had no idea about the utility of birth spacing. Most of the primigravida prefer contraceptive pills, whereas most of the multigravida prefer tubectomy. They mainly depend upon the health workers for the selection of contraception.

Keywords: Attitude, Contraception, Knowledge, Practice

INTRODUCTION

It is rightly said that "The greatest shortcoming of the human race is our inability to understand the exponential function." For countries such as Spain, Canada, and Italy, where the population is decreasing, population explosion might be considered as a boon. However, for a developing country like India, population explosion is nothing but a curse which is damaging the development of the country. With 17.74% of world's population, India is the second most populated country in the world. Even though 2001–2011 decadal growth rate has reduced to 17.6 %, compared to 21.5% recorded during 1991–2001, suggesting slowing down of growth, there is an urgent need for the XII Five Year Plan to further accelerate the stabilization of India's population by repositioning family planning within the broader framework of reproductive health and primary health care.[1] The antenatal clinic was selected as the present study area as it suggests the best environment within the hospital for meeting females in the reproductive age group along with providing a forum for the dissemination of family planning information, correction of wrong perceptions as well as the opportunities for exchange of ideas between mothers.

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MATERIALS AND METHODS

It was a cross-sectional observational study done in the Department of Obstetrics and Gynaecology of a tertiary

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hospital in India, from January 2018 to June 2019 involving 1000 pregnant women, both primigravida and multigravida, attending antenatal clinic, after getting approval from Clinical Research Ethics Committee. Analysis was done regarding their knowledge, attitude, and practice of contraception. Informed consent was obtained from those women included in the study.

Objective

The objective of the study was to assess the knowledge, attitude toward family planning and the practice of contraceptives among antenatal women.

RESULTS AND ANALYSIS

Statistical analysis was done using percentage, Chi-square test. $P < 0.05$ was considered statistically significant.

Sociodemographic features of the study population are depicted in Table 1. Of 1000 women, 649 (64.9%) were primigravida and 351 (35.1%) were multigravida. Most of the women belonged to the age group of 20–29 years (75.3%), had secondary education (38.1%), and were housewives (69.3%).

Of 1000 women, 879 (87.9%) women had some knowledge about contraception. This is elaborated in Table 2.

Among those 879 women, 340 women had positive attitudes toward contraception, 98 women had a negative attitude, 70 women undecided, 365 women had no idea regarding the necessity of birth spacing. This is elaborated in Table 3. $P = 0.021$ is statistically significant.

Most of the primigravida (212, 36.3%) prefer contraceptive pills, whereas the majority of multigravida (102, 34.58%) prefer tubectomy as a mode of contraception. This is illustrated in Table 4. $P < 0.001$ is statistically significant.

Most of the women (474), both users and non-users, depend upon health workers for the selection of contraceptive methods. This is illustrated in Table 5. $P < 0.001$ is statistically significant.

Table 1: Distribution of cases according to sociodemographic features

Gravidity	Frequency	Percentage
Primigravida	649	64.9
Multigravida	351	35.1
Total	1000	100
Age (Years)		
15-19	83	8.3
20-24	398	39.8
25-29	355	35.5
>=30	164	16.4
Total	1000	100
Educational status		
Illiterate	244	24.4
Primary education	273	27.3
Secondary education	381	38.1
Graduate	102	10.2
Total	1000	100
Occupation		
Govt/Pvt employee	86	8.6
Farmers	174	17.4
House wife	693	69.3
Others	47	4.7
Total	1000	100

Table 2: Distribution of cases according to knowledge about contraception

Knowledge about contraception	Frequency	Percent
No	121	12.1
Yes	879	87.9
Total	1000	100

DISCUSSION

The global population today stands at 7.7 billion and is expected to reach 9 billion by the year 2045.[2] Increasing population is a global problem today and India having one-fifth of the world population and a growth rate of 16 million each year is the second most populated country in the world.[3] Uncontrolled population growth has been recognized as the most important impediment to our national development, despite the fact that India was the first country in the world to adopt a national population control program in 1952.[4,5] Hence, it is important at a global as well as national scale to ensure that all pregnancies are wanted or intended.

Family planning is defined by WHO as "a way of thinking and living that is adopted voluntarily, upon the basis of knowledge, attitudes, and responsible decisions by individuals and couples, to promote the health and welfare of family groups and thus contribute effectively to the social development of a country."[6]

It is quite evident from our study that the majority of antenatal women (879 of 1000 women studied) had at least some knowledge regarding contraception. This corresponds to the findings of the studies of Mustafa *et al.*[6], Kara *et al.*[7], Sherpa *et al.*[8], Renjhen *et al.*,[9] Lavanya *et al.*[10] who also found that most women of the reproductive age group had some degree of knowledge about contraception.

It was noted that among 879 women, both users and non-users of contraception, who had some knowledge about

Table 3: Distribution of cases according to attitude toward birth spacing method

		Attitude toward birth spacing				Total (%)	*P* value	Significance
		No idea (%)	Negative (%)	Undecided (%)	Positive (%)			
Used contraceptive before this pregnancy	No	251 (68.77)	55 (56.12)	41 (53.95)	213 (62.65)	560 (63.71)	0.021	Significant
	Yes	114 (31.23)	43 (43.88)	35 (46.05)	127 (37.35)	319 (36.29)		
Total		365(100)	98(100)	76 (100)	340 (100)	879 (100)		

Table 4: Distribution of cases according to the method of contraception used before this pregnancy between Primi and Multi gravida

		Gravidity		Total (%)	*P* value	Significance
		Multi (%)	Primi (%)			
Type of contraception	Condom	28 (9.49)	155 (26.54)	183 (20.82)	<0.001	Significant
	Pill	40 (13.56)	212 (36.3)	252 (28.67)		
	IUCD	48 (16.27)	126 (21.58)	174 (19.8)		
	Tubectomy	102 (34.58)	0 (0)	102 (11.6)		
	Injectables	77 (26.1)	91 (15.58)	168 (19.11)		
Total		295 (100)	584 (100)	879 (100)		

Table 5: Distribution of cases according to dependency on person for selection of method of contraception

		Dependency on person for choice of contraception			Total	*P* value	Significance
		Family (%)	Husband (%)	Health personnel (%)			
Used contraceptive before this pregnancy	No	65 (60.19)	218 (73.4)	277 (58.44)	560 (63.71)	<0.001	Significant
	Yes	43 (39.81)	79 (26.6)	197 (41.56)	319 (36.19)		
Total		108 (100)	297 (100)	474 (100)	879 (100)		

contraception, 340 women had positive attitudes toward birth-spacing, 98 had negative attitudes, and 70 women were undecided. A large number of women (365) had no idea about the necessity of birth-spacing. $P = 0.021$ which is statistically significant. This finding corresponds to the findings of Mustafa *et al.*,[6] Kara *et al.*,[7] Sherpa *et al.*,[8] Renjhen *et al.*,[9] Thapa *et al.*[11] Pegu *et al.*[12] These studies also show that majority of women had a positive attitude toward contraception as well as birth spacing, but also a large number of women had no idea about the utility of birth spacing.

From our study, we also found that while most of the primigravida prefer hormonal pills, most of the multigravida prefer tubectomy as a method of contraception. $P < 0.001$ is statistically significant. This corroborates with studies by Kara *et al.*[7] and Sherpa *et al.*,[8] which found that most women prefer hormonal pills followed by condoms. Renjhen *et al.*[9] also found that most women prefer hormonal pills followed by condoms followed by tubectomy. Thapa *et al.*[11] found that most women prefer Inj. medroxyprogesterone followed by tubectomy followed by hormonal pills and condoms with equal frequency.

We found that most of the women depend upon health workers for the choice of contraception rather than their husbands or other family members. $P < 0.001$ is statistically significant. This finding matches with the studies by Sherpa *et al.*[8] and Pegu *et al.*[12] However, Renjhen *et al.*,[9] Lavanya *et al.*,[10] Idonije *et al.*,[13] and Tajure [14] found that the source of information on contraception was social circle followed by media rather than health personnel. Thapa *et al.*[11] found that the source of information was mass media in most of the cases followed by health workers.

Mustafa *et al.*[6] conducted a cross-sectional study on 100 non-pregnant rural women of 15–45 years age group in the gynecological outpatient clinic of a hospital in Karachi, Pakistan, from July to December 2005. Of 100 interviewed women with a mean age of 29.7 years, 81 (81%) had some knowledge about family planning methods. The media provided information of contraceptives in 52 out of 81 (64%) women. Regarding the usage of contraceptive methods, only 53 (53%) of the respondents were using some sort of contraception. Barrier method (condoms) was in practice by 18 (33.9%) and 12 (22.6%) of women had already undergone tubal ligation. The women using injectables and intrauterine contraceptive devices were 10 (18.8%) and 7 (13.2%), respectively. Six were using oral contraceptive pills (11.3%). Positive attitude toward contraception was shown by 76 (76%) of them, while

41 (41%) stated their husbands' positive attitude toward contraception.

Sherpa *et al.*[8] conducted that a descriptive survey of 136 females between 18 and 45 years of age was done using a structured knowledge questionnaire, structured attitude scale, and opinionnaire on practice and preference during the month of January 2012 to February 2012 at Moodu Alevoor village, Udupi district, Karnataka. It was shown that 98.5% got information through health personnel. The majority (67.60%) had moderate knowledge on contraceptive methods and 17.60% had high knowledge. The majority (87.50%) had a favourable attitude and 12.50% had an unfavorable attitude toward contraceptive methods. From the group of studied women, 38.23% did not use any contraceptive methods, 19.85% used OCPs, and minimum 1.47% used injection as a contraceptive method. In this study, 37.5% preferred OCPs as Rank 1, male condom (22.1%) as Rank 2, and injection (16.3%) as Rank 3. There was no association between attitude and the studied variables.

Renjhen *et al.*[9] conducted a cross-sectional descriptive study in the Obstetrics and Gynaecology Department of a Hospital in Sikkim, India. The study group included 443 women of reproductive age group (15–44 years) attending the two hospitals during the month of January 2004 to March 2005. Their knowledge, attitude, and practice on contraceptives were evaluated with the help of a pre-designed questionnaire. It was found that 98% of the women had knowledge about family planning and 94.2% of them had knowledge about contraceptives. Over 50% had gained information from media. The majority (98%) thought that contraceptive use was beneficial, but only 55.2% had used contraceptives and 84% of them were satisfied. Sixty-two percent were currently using contraceptives, 37.9% of them were using oral contraceptives, 37.9% of them were using oral contraceptive pills, and 31% were using condoms.

A cross-sectional descriptive study was conducted by Thapa *et al.*[11] among 209 married women of reproductive age in selected wards of Dharan Sub-Metropolitan City, Nepal. Most (53.1%) of the respondents were of the age group 20–34 years. The majority (92.3%) of the respondents had ever heard of contraception. Popular known method was Inj. Depo-Provera (92.7%). Mass media (85.8%) was the major source of information. Mean percentage score of knowledge was 45.23%. The majority (90.4%) of the respondents had a positive attitude and only (64.6%) were using contraceptives currently.

Bhabani Pegu *et al.*[12] conducted a cross-sectional study in a hospital in Shillong, Meghalaya, a state in the North-Eastern part of India. Two hundred married women aged between 15 and 45 years were included in this study. Along with the sociodemographic characteristics of the women, their knowledge, attitude, and practices on contraception were evaluated with the help of a pre-designed questionnaire. It was observed that of 200 women, 174 (87%) had knowledge about contraceptive methods and it was mainly obtained from health workers (58.6%) followed by media (24.1%) and social circle (15.5%). Seventy-six (38%) women were practicing contraceptive methods, of which most of them were using a condom (38.2%) followed by oral contraceptive pills (OCPs) (27.6%), intrauterine contraceptive device (15.8%), etc. Although most of the women had knowledge about contraceptive methods, the majority of male 55.5% and female 51.5% were showing a negative attitude toward family planning.

Hence, it is evident that the findings of our study are similar to the findings of the aforementioned studies.

CONCLUSION

From our study, we can conclude that most of the women among the study group had some degree of knowledge about contraception and also had a positive attitude about family planning. The majority of primigravida prefer hormonal pills, whereas multigravida prefers tubectomy. They mostly depend upon health personnel for the selection of contraceptives. It is noteworthy that a large number of women had no idea about the necessity of birth-spacing. Hence, we must take proper initiative to increase awareness on the utility of birth-spacing.

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Original Article

Dermatological Manifestations of HIV Patients on Antiretroviral Therapy in a Tertiary Care Hospital

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Abstract

Background: Mucocutaneous diseases are among the first recognized clinical manifestation of acquired immunodeficiency syndrome. They function as visual markers in assessing the progression of HIV infection given the ease of skin examination. It remains the important tool in the diagnosis of HIV infection.

Aim: This study aims to determine the pattern of dermatological manifestations in HIV patients on antiretroviral therapy and to correlate their presence with CD_4 count.

Materials and Methods: We conducted single-center study of 100 human immunodeficiency virus-infected patients attending outpatient department for various dermatological problems over a period of 1 year. They were screened by dermatologists and data were analyzed for correlation between CD_4 count and various dermatological disorders.

Results: Infective diseases were more than non-infective dermatoses in HIV-positive patients with CD4 count <200 and between 200 and 350, whereas both were almost equal when CD4 count > 350. The most prevalent infections were staphylococcal infections (12), dermatophytoses (11), herpes simplex infection (4), herpes zoster (5), scabies (4), Hansen (2), Wart (2), and molluscum contagiosum (2). The non-infectious dermatoses noted were eczema, pruritus, insect bite allergy, drug eruption, psoriasis, miliaria rubra, etc.

Conclusion: Our study suggests that dermatological findings occur throughout the course of HIV infection. Surely the effective and early initiation of antiretroviral therapy (ART) has decreased the dermatological manifestations in such a way that it is no longer different from non-HIV patients.

Key words: Acquired Immunodeficiency Syndrome, Human Immunodeficiency Virus, CD4 count, Antiretroviral Therapy

INTRODUCTION

Dermatological manifestations of HIV/AIDS constitute a major health problem worldwide. There were around 36.9 millions of people living globally with HIV in 2017. As per HIV estimates 2017, there were an estimated 2.14 million people living with HIV/AIDS in India with adult HIV prevalence of 0.22%.[1] This raised to 38 million people (adults – 36.2 and children – 1.8) in 2019.

Dermatological manifestations during HIV infection are numerous. They may be the initial sign of immunosuppression or reflection of the progress of HIV infection. Evaluation of skin remains an important tool in the diagnosis of HIV infection. This study was conducted to determine the pattern of dermatological manifestations in HIV-positive patients on ART and to correlate their presence with CD4 cell counts.

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MATERIALS AND METHODS

This study was conducted in Govt. Theni Medical College, Tamil Nadu, over a period of 1 year. There were no specific eligibility criteria.

One hundred HIV-positive patients who attended our skin OPD for various dermatological problems were included in the study. Information regarding age, sex, occupation, mode of transmission, duration of disease, ART status, and CD4 count were noted. A complete medical history and physical examination of patients were done by dermatologists.

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The clinical diagnosis was confirmed with laboratory procedures such as microscopy (KOH, Tzanck Smear) and histopathological evaluation where ever necessary. Data were analyzed for establishing correlation between CD4 cell count and various dermatological disorders.

RESULTS

A total of 100 HIV-infected patients were enrolled in the study and the following observations were made.

Among 100 patients, 52 were male and 48 were female. Of these, most patients were in 21–40 years age group 44% (19 males and 25 females) while male prevalence was highest in the age group of 41–60 years (23 males and 16 females) [Figure 1].

Regarding the occupation of the patients, the largest group was constituted by labourers (39), followed by farmers (16), students (15), housewives (11), business people (9), and drivers (6) [Table 1].

The predominant mode of transmission was heterosexual contact (85), 12 patients acquired the infection through vertical (mother to child transmission), 1 patient through homosexual practice, and 2 patients through bisexual contact. There was no history of acquisition of infection through blood transfusion or needle prick injury [Figure 2].

Table 1: Occupation-wise distribution of patients

Occupation	Male	Female
Government servants	1	1
Housewives	-	11
Farmers	7	9
Business people	6	3
Drivers	6	-
Student	9	6
Labourers	24	15

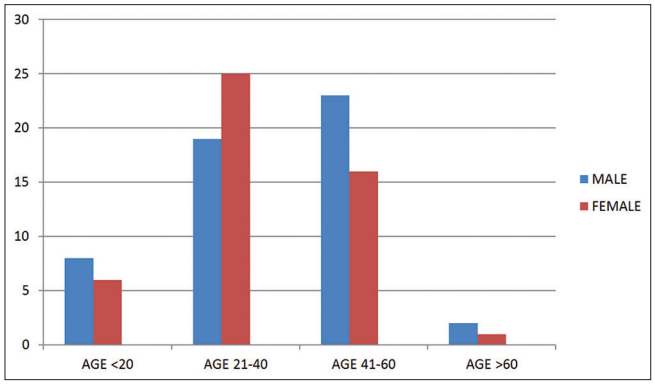


Figure 1: Age and sex distribution of patients

The duration since disease identification in 54 patients was < 5 years, 6–10 years in 37 patients, 11–15 years in 6 patients, and >15 years in 3 patients [Figure 3].

Out of 100 patients, 20 had their CD4 count less than 200/µl, between 200 and 350/µl in 24 patients and in 53 patients, CD4 count valve was more than 350/ µl, CD4 count report was not known in 3 patients [Figure 4].

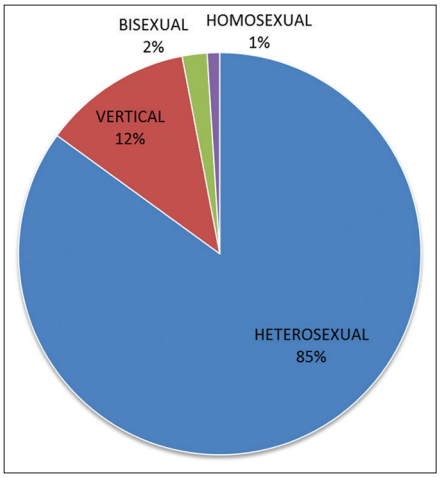


Figure 2: Mode of transmission

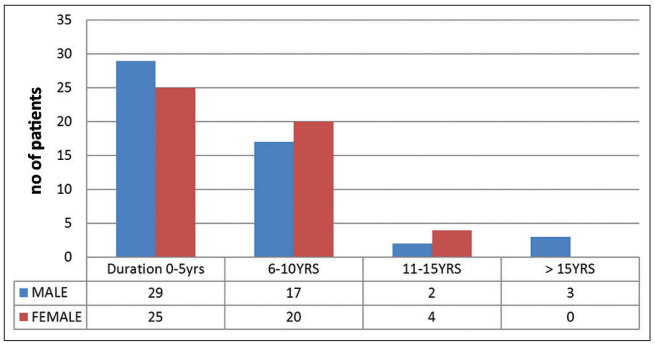


Figure 3: Duration of disease

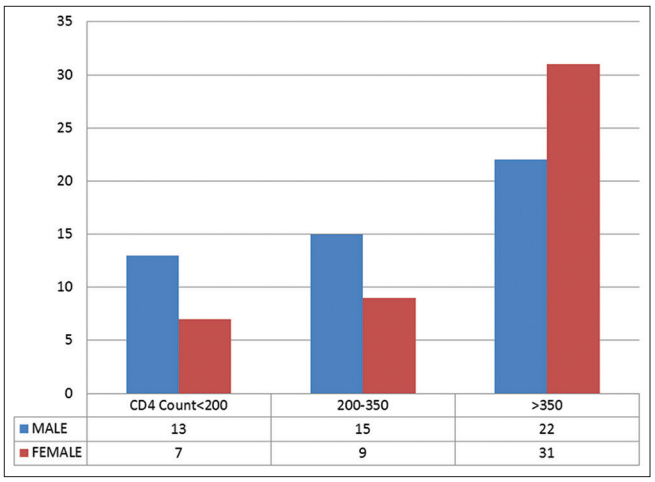


Figure 4: CD4 count of patients

Regarding antiretroviral therapy (ART), 80 out of 100 patients were already on ART, 14 patients were not on ART, and 6 patients were under investigation to be started on ART.

The common infection noted in the study was staphylococcal infection (impetigo, folliculitis, and furunculosis) (12), followed by dermatophytosis (11) [Picture 1], tinea versicolor (2), oral and vulval candidiasis (6), herpes labialis (4), herpes zoster (6), verrucae vulgaris (1), scabies (4), pediculosis capitis (1), and borderline tuberculoid Hansen's disease (2).

Among the sexually transmitted infection, herpes genitalis (5) was the most common manifestation. Other STIs noted were genital wart (1), genital molluscum contagiosum (1), latent syphilis (1), scrotal swelling (1), and genital ulcer (1).

Eczema was the most common non-infective dermatoses which was present in 16 patients (out of which 8 patients had photosensitive eczema). Others were insect bite allergy (9), miliaria rubra (5), adverse drug eruption (3) [Picture 2,2a], pruritus (3), and psoriasis (2). Xerosis (2), prurigo nodularis, seborrheic dermatitis, actinic cheilitis, cutaneous amyloidosis, systemic lupus erythematosus, and pemphigus vulgaris one patient each pemphigus vulgaris.

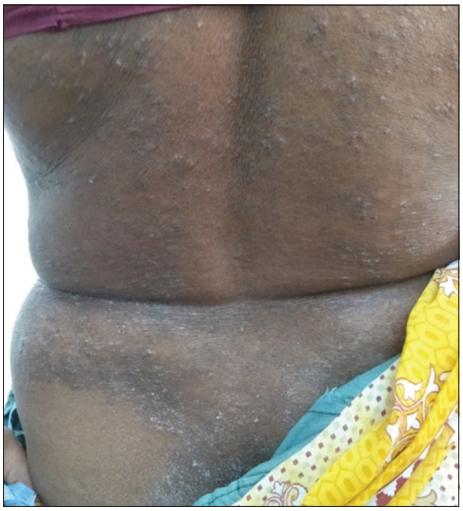
Hyperpigmentation in oral mucosa was noted in 12 patients, oral ulcer in 2 patients, longitudinal melanonychia in 15 patients, subungual hyperkeratosis, onycholysis, and nail dystrophy in 1 patient each. Diffuse hair loss was seen in 1 patient [Table 2].

NK-CD4 COUNT NOT KNOWN

Dermatological manifestations	CD4 correlation		
	<200	200–350	>350
Non-infectious conditions			
Insect bite allergy	3	2	4
Psoriasis	-	-	2
Eczema	-	2	6
Photosensitive eruption	-	3	5
Prurigo nodularis	-	-	1
Miliaria rubra	1	1	3
Seborrheic dermatitis	-	1	-
Xerosis	-	-	2
Pruritis	1	-	2
Actinic cheilitis	-	-	1
Systemic lupus erythematosus	1	-	-
Pemphigus vulgaris	-	-	1
Fixed drug eruption	-	1	-
Stevens–Johnson syndrome	1	-	-
Maculopapular drug eruption	-	-	1
Cutaneous amyloidosis	-	-	1
Mucosa			
Oral pigmentation	3	4	5
Nails			
Nail pigmentation	5	4	6
Nail dystrophy	-	-	1

DISCUSSION

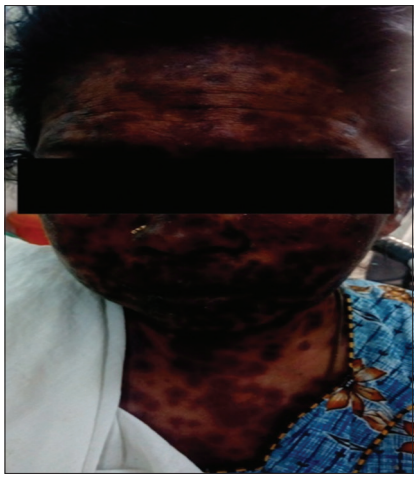
During this study period, 100 patients were seen. The male-to-female ratio is 1:0.8. This is consistent with



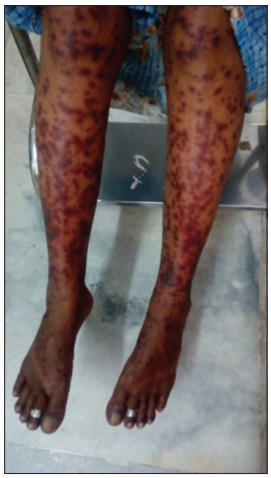
Picture 1: Dermatophytosis

Table 2: Dermatological manifestation and CD4 correlation

Dermatological manifestations	CD4 correlation		
	<200	200–350	>350
Bacterial	Infectious	Conditions	
Furunculosis	--	4	4 NK-1
Folliculitis	-	-	1
Impetigo	-	1	1
Fungal			
Dermatophytosis	2	2	7
Taenia versicolor	-	-	2
Candidiasis			
Oral	2	-	2
Vulval	-	1	1
Viral			
Herpes labialis	1	1	2
Herpes genitalis	-	2	2 NK-1
Herpes zoster	3	1	2
Common wart	-	-	1
Genital wart	1	-	-
Molluscum contagiosum	-	1	-
Viral exanthem	1	-	-
Parasites			
Scabies	2	1	1
Pediculosis capitis	-	-	1
STD			
Latent syphilis	1	-	-
Scrotal swelling	1	-	-
Genital ulcer	-	1	-
Leprosy			
Borderline tuberculoid	-	-	1 NK-1



Picture 2: Stevens–Johnson syndrome (Adverse Drug Reaction)



Picture 2a: Stevens–Johnson syndrome (Adverse Drug Reaction)

NACO–HIV Sentinel Surveillance and HIV estimation 2006.[2] Increase trend in females is due to less educated, financially dependent on men, fail to use protective measures, and also due to effective partner and children screening.

The predominant mode of transmission was heterosexual contact (85%) unlike the results of Spira *et al*.[3] where it was of 35.3% by homosexual, 27.8% by intravenous drug use, and 24.4% by heterosexual.

In our study also, infectious diseases constitute the largest category consistent with the previous studies,[4-7] the majority being bacterial, fungal, and viral. Staphylococcal infection is the single most common bacterial infections.[8] The prevalence of dermatophytosis in our study was similar to that reported previously by Kumarasamy *et al*.[5] The most common viral infection is herpes zoster, consistent with the previous study by Mignard *et al*.[3] Decrease prevalence of candidiasis in our study is in consistent with the study by Hengge in which the prevalence decreases after ART administration.[9] Most of these opportunistic infections of the skin and mucosa occurring in HIV patients represent overgrowth of resident flora, extend beyond sites of colonization, reactivation of latent infection, and transformation of subclinical infection.[10]

Herpes genitalis being the most common STI seen in 5% in contrast to 18% in the study by Sarna *et al*.[11] The lower incidence of chancroid and syphilis could be due to the fact that most of the patients referred to us had already been given multiple course of antibiotics which taken care of bacterial STIs.

Photosensitivity eruption is seen in eight patients in our study which correlates well with the study by James *et al*.[12]

Exaggerated response to mosquito bite has been reported in HIV infection[13] which is also noted in our study. This could be due to the result of reactivation to antigens to which they were earlier desensitized (by repeated insect bites).

The prevalence of pigmentary disorder in our study was 15%. An increased pigmentation was noted in oral mucosa and nails. Some cases were related to zidovudine therapy. Others were due to increased pigment production by melanocytes and increased levels of melanocyte-stimulating hormone in HIV patients. The most common pattern of nail discoloration was longitudinal melanonychia.

Coexistence of psoriasis in HIV infection in our study may be by chance.[14] Seborrheic dermatitis prevalence was low similar to the study by Sharma *et al*.[15]

The prevalence of xerosis in this study was 2% in contrast with high report by smith *et al*.[16]

Adverse drug reactions were seen only in three patients in contrast to the report by Dover[17] in which the incidence of drug reaction is high. We did not notice any case of Kaposi sarcoma in our study.[18]

Infectious diseases were common when CD4 count <200 and 200–350, whereas non-infectious dermatoses were high when CD count > 350. Meanwhile, even patients with high CD4 count are not free from infection. Hence, there was no significant correlation between CD4 count and dermatological manifestations in HIV patients in our study.

Most of our patients nearly 80% were on ART at the time of presentation to our department. This may be the reason why cutaneous manifestations were not different in both HIV and non-HIV patients.

CONCLUSION

Result of our study suggests that dermatological manifestations occur throughout the course of HIV infection. There is no significant correlation between CD4 count and cutaneous manifestation in HIV patients on ART. Definitely early initiation of ART has decreased the dermatological manifestations in such a way that it is no longer different from non-HIV patients.

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Original Article

Profile of Skin Diseases – A Stratified Analysis

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Abstract

Introduction: The skin diseases are the most easily detectable diseases in a community. The profile of skin diseases vary with respect to non-modifiable factors such as age, gender, and genetics and modifiable factors such as geographical location, climate, and socioeconomic status.

Aim: This study aims to understand and analyze the profile of skin disease in patients, attending a tertiary care hospital in Central Kerala.

Materials and Methods: All regional language speaking adult patients of age category 18–36 and 37–60 attending the skin outpatient department of Government Medical College, Ernakulam, were interviewed and examined, the data collected were analyzed using SPSS version 21.

Results: Age is categorized into two groups 18–36 and 37–60. Both age groups were equally represented. Skin infections were more in the younger age group (36.8%). Females outnumbered males in the study. Fungal infections were more in females. About 72.7% were married. In all groups (married, unmarried, separated, and widow or widower), infections were more. Fungal infections were more in married group. About 67.4% of patients studied were above poverty line. Fungal and parasitic infections were more in patients of low socioeconomic status. Muslims constituted the majority in our study (43.1%).

Conclusion: Non-infectious diseases were more common in the older age group. Eczema was the most common. Among infections, fungal infection was the most common. The decrease in infections may be because of the fact that these are being treated by general practitioners. The increase in non-infectious cases can be taken as an increase in awareness among patients about the disease conditions and its treatment options and accessibility to health-care centers. However, as the burden of skin diseases at present is the same as in the previous studies, a little more planning may be needed to reduce the brunt, like training health-care providers and conducting awareness classes for the public.

Key words: Infectious, Non-infectious, Skin diseases

INTRODUCTION

Skin diseases are common and accounts for the fourth leading cause of non-fatal disease burden at the global level.[1] Skin diseases carry significant morbidity leading to disfigurement, disability, or symptoms such as intractable itch, which can reduce the quality of life leading to isolation and economic burden.[2] The prevalence of skin diseases in the general population varies from 6.3% to 11.2%. Skin diseases, which are commonly encountered in the community, are an important disease group in health-care set-up. The development of skin disease is influenced by external factors, such as geographic region, climate, socioeconomic status, and personal habits, and internal factors, such as age, gender, and heredity.[3] The prevalence of skin disease differs between regions as a result of these factors. The recognition of the skin disease profile of a region is important in planning therapeutic and preventive health-care services.[3] Such a study was conducted in Kerala 9 years back and the present study was also meant to compare it with the findings received then.[4]

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MATERIALS AND METHODS

An institutional observational study was conducted in the Skin Department of Government Medical College, Ernakulam, after getting the approval of the Institutional Ethics Committee. The study participants were, all regional

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language speaking and new patients of the age group (18–60 years) attending the skin outpatient department for a period of 6 months from February 2016 to July 2016. Those who consented for the study were given a questionnaire which included the personal, occupational, and sociodemographic variables such as age, sex, marital status, educational status, and geographic location. The data were collected and analyzed using SPSS version 21.

RESULTS

Of all the total new patients attending the hospital, 10% attended skin outpatient department. There were 4017 participants in this study group of the age 18–60 years. Taking the age 36.10 as mean age, it was found that both categories 18–36 and 37–60 were almost equally represented [Table 1].

The skin diseases were classified as non-infectious and infectious. Bacterial, viral, fungal, parasitic, and protozoal diseases were considered under infectious category. Under the non-infectious group comes psoriasis, eczema, hair and nail disorders, pruritus, autoimmune conditions, and miscellaneous. Non-infectious diseases were marginally more in the 37–60 age group (33.3%) and infections in the 18-36 age group (36.8%). Viral and parasitic infections were more among the 18–36 age group about 5% and 2% when compared to 1.7% and 0.9% in the other group [Table 2].

There were about 63% of females in the study group. Both males and females showed a higher incidence of non-infectious disease around 60%, but infections seemed to be more by 1.1% in the males. Except for the fungal infection, the rest of the infections were more in male gender [Table 3].

When considering the marital status, 72.7% were married and almost quarter were unmarried. Non-infectious diseases were the common skin disease in all the categories. Bacterial and viral infections were more in the separated category. Fungal infections were the common skin infection affecting the married and parasitic infection in the unmarried groups [Table 4].

More than half (67.4%) of the participants belonged to the upper socioeconomic status. Irrespective of their socioeconomic status all patients suffered from non-infectious diseases. Fungal and parasitic infections were more in the BPL (below poverty line) category, but viral infections more in the APL (above poverty line) group. Bacterial infections were almost the same in both the groups [Table 5].

Religion-wise Muslims were about 43.1%, Hindus, 39.7%, and Christians smaller in number about 17.1%. All the infections except viral infections were more in Muslims.

Table 1: Age correlation

Age	Age category				Total
	Non-infectious	Infectious	Both	Miscellaneous	
18–36	569	764	39	705	2077
	27.4%	36.8%	1.9%	33.9%	100.0%
37–60	646	661	28	605	1940
	33.3%	34.1%	1.4%	31.2%	100.0%
Total	1215	1425	67	1310	4017
	30.2%	35.5%	1.7%	32.6%	100.0%

Table 2: Sex correlation

Sex	Sex				Total
	Non-infectious	Infectious	Both	Miscellaneous	
Male	458	554	25	426	1463
	31.3%	37.9%	1.7%	29.1%	100.0%
Female	757	871	42	884	2554
	29.6%	34.1%	1.6%	34.6%	100.0%
Total	1215	1425	67	1310	4017
	30.2%	35.5%	1.7%	32.6%	100.0%

DISCUSSION

The multitude of skin problem as represented by 10% of the outpatient attendance in our study which was similar to that in studies conducted in Nepal in 2014[5] and in Trichur in 2009.[4] This shows that the burden of skin diseases has remained the same in spite of advances made in the field. It is important to study the burden of skin disease in low resource setting which help in delivering high quality care in improving the prevalence of skin disease.[6] A study in Kolkata showed a slightly less percentage 4.16% only.[2] Non-infectious diseases (65.4%) were found to be more than infectious. Of this, eczema is the most common. This is in par with studies conducted in Kumaon region, Northwest India, Kolkata, Central Iran, and Faridpur [2,7,5,8] but against that found in Trichur, Chennai, and hilly areas of Uttarakhand.[9,4,10] The increase in eczema may be because the infectious diseases may be treated by the general practitioners due to the ease in the diagnosis. Nowadays, because of the various awareness programs going on, the knowledge about skin diseases, especially non-infective diseases, encourages the patients to self-report. Studies conducted in Indore and Maharashtra[11] showed that patients in younger age group came forward to seek medical help compared to older age group. However, in this study, the representation of both groups was almost the same. Jayanthi and Anandan[10] also found that patients of the age category 20–50 years attended the outpatient department

Table 3: Skin disease and marital status

Marital status	Marital status				Total
	Non-infectious	Infectious	Both	Miscellaneous	
Unmarried	265	380	15	371	1031
	25.7%	36.9%	1.5%	36.0%	100.0%
Married	926	1026	51	917	2920
	31.7%	35.1%	1.7%	31.4%	100.0%
Separated/divorced	5	6	0	3	14
	35.7%	42.9%	.0%	21.4%	100.0%
Widow	19	13	1	19	52
	36.5%	25.0%	1.9%	36.5%	100.0%
Total	1215	1425	67	1310	4017
	30.2%	35.5%	1.7%	32.6%	100.0%

Table 4: Skin disease and socioeconomic status

Socioeconomic status	Non-infectious	Infectious					Total
		Bacterial	Viral	Fungal	Parasitic	Protozoal	
APL (above poverty line)	1786	165	99	616	32	11	2709
	65.9%	6.1%	3.7%	22.7%	1.2%	.4%	100.0%
BPL (below poverty line)	828	78	37	332	27	6	1308
	63.3%	6.0%	2.8%	25.4%	2.1%	0.5%	100.0%
Total	2614	243	136	948	59	17	4017
	65.1%	6.0%	3.4%	23.6%	1.5%	0.4%	100.0%

Table 5: Skin disease and religion

Religion	Non-infectious	Infectious					Total
		Bacterial	Viral	Fungal	Parasitic	Protozoal	
Hindu	1092	94	51	334	15	9	1595
	68.5%	5.9%	3.2%	20.9%	0.9%	0.6%	100.0%
Muslim	1079	111	52	451	34	6	1733
	62.3%	6.4%	3.0%	26.0%	2.0%	0.3%	100.0%
Christian	443	37	33	163	10	2	688
	64.4%	5.4%	4.8%	23.7%	1.5%	0.3%	100.0%
Others	0	1	0	0	0	0	1
	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	100.0%
Total	2614	243	136	948	59	17	4017
	65.1%	6.0%	3.4%	23.6%	1.5%	0.4%	100.0%

the most. A probable reason could be because of inability to come due to age restraints in elderly and to avoid loss of attendance at school in the younger ones. Viral and parasitic infections were more in the 18–36 category, because they are the floating population and have to stay away from home for pursuing studies and seeking jobs. In two studies conducted in North India, Uttarakhand,[7] and in Maharashtra,[11] males outnumbered females. However, studies in Central Iran, Nepal, Kolkata, and Chennai[12,13,5,10] were at par with our finding of more females than males. This could be because of the awareness among females and accessibility of medical services. We found that infections were more in males, when compared to females, but fungal infections were more in females which is not the case in Uttarakhand,[7] where males outnumbered females. However, a study in Turkey[3] showed a female preponderance in case of fungal infections. Increase trend in fungal infections in females can be attributed to their attire and their involvement in household chores. More bacterial, viral, and parasitic infections in males could be due to their outdoor activities. When it comes to the marital status, fungal infections were more in the married. The interactions with the family members and if employed, balancing between workplace and home and lack of time for personal needs and self-care may be cited as the reasons. An increase in fungal and parasitic infections in the patients belonging to the low socioeconomic status was noted in our study. This was not the finding in a study in Kolkata[2] where both infectious and non-infectious cases were the same in lower class and upper class showed more of infections. The reason for increase of infection in the lower strata could be due to overcrowding, lack of facilities for basic amenities, and lack of awareness. Muslims formed the majority of the patients enrolled in

the study. The occurrence of fungal, bacterial, and parasitic infections was more in this category. The reason could be the religious practices which need frequent washing, close interactions between people of same community at different meeting places at different times of the day.

CONCLUSION

The profile of skin disease in a region gives an insight into the distribution and magnitude of skin problems in that area. This knowledge is an index to health-care facilities available. Hence, to reduce the disease burden, in addition to proper recognition and treatment of various skin disorders, educating the patients about the disease condition, the need to comply, proper follow-up, and against misuse of medications should be carried out promptly. This study did not include all the patients attending the skin outpatient clinic so maybe lacking the true depth of the situation. The study period was only 6 months which covered only summer and monsoon. Hence, an overview of the proper situation could not be obtained.

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Original Article

Knowledge, Awareness, and Practices about Ergonomics among Dental Postgraduate Students – A Cross Sectional Study

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Abstract

Introduction: The knowledge pertaining to ergonomics is vital for preventing musculoskeletal disorder. A proper work posture should be inculcated in dental clinical practice to prevent such health hazards.

Purpose: To evaluate knowledge and practices about ergonomics among postgraduate students.

Materials and Methods: A survey was conducted among the dental postgraduate students for the duration of 3 months. The questionnaire was validated and online Google forms were prepared and circulated among the postgraduate students of various dental institutes. Questionnaire was divided into three parts. Part 1 includes the demographic variables and knowledge towards ergonomics. Part 2 questions are related to awareness toward ergonomics. Part 3 being the practices of ergonomic principles by postgraduates. The resultant responses were recorded in Microsoft Excel format which formed the basic data for the study. The correlation between the source of information related to knowledge and practices about ergonomics was statistically evaluated using the Chi-square test. A *P* value < 0.05 was measured as statistically significant.

Results: On statistical analysis, there was a statistically significant correlation observed among the second and the third-year postgraduate students toward basic ergonomics compared to the 1st year.

Conclusion: Comprehensive understanding and awareness regarding the types of ergonomically equipped chairs for practicing in dental clinics among postgraduate was lacking. A proper emphasis on chair side exercise and training should be initiated to prevent any sort of musculoskeletal pains.

Key words: Ergonomics, Musculoskeletal Disorder, Postgraduates, Work posture, Ergonomic Assessment

INTRODUCTION

Dental practice requires knowledge and experience of dental procedures with greater precision and accuracy. That necessitates the dental operator's focus, concentration, and patience along with physical and mental resilience. In an ergonomic setting, performing a therapeutic approach and effective practice involve clear working conditions for the dentist and the assistant.

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"Ergonomics" is defined as a collection of multidisciplinary knowledge applied to the organization of labor activities and elements that make up work. The key purpose behind the ergonomic principles is to establish a safe, healthy, and comfortable working atmosphere for dental practitioners, thereby preventing health problems which in turn improve productivity.[1] When ergonomic principles are applied in dentistry, it aims to minimize cognitive and physical distress, prevent occupational diseases related to dental practice, and increase efficiency with enhanced quality and comfort for both the professional and patient.[2]

Maintaining a proper posture imparts the dentist with more energy to work, reduced stress level, and increased comfort. It is understood that a "good" posture produces more working energy, lowers the stress level, increases comfort, and lowers the risk for therapeutic errors. A "bad"

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posture is known to cause fatigue, stress, and a negative attitude to work, high-risk for musculoskeletal disorders, and a poor job quality.[2]

Musculoskeletal disorders are characterized by the presence of discomfort, and persistent pain in the joints, muscles, tendons, and soft parts, aggravated by repeated movements and prolonged awkward or forced body postures.[3] Work-related musculoskeletal disorders are one of the primary occupational health risk affecting dentists.[1] Studies demonstrate that among the wide range of musculoskeletal disorders, back pain is the most common among dentists.[4] Incorrect working posture can potentially lead to loss of productivity and earning. Therefore, it is essential to install an appropriate working condition and magnification to improve visibility.[5] Despite the huge risk to the health of dentist, as well dental students, they show unsafe work practices and lack basic ergonomics knowledge.[6] Good ergonomic practice can prevent the dentist from early retirement.[1]

Postgraduates undergo a complex educational experience in dental sciences. The residents of the entire specialty are expected to be trained well clinically on patients. All these factors add on to ergonomic circumstances. After a literature search was performed to find the topics pertaining to knowledge, attitude, and awareness among postgraduate toward ergonomics was at sparse. Hence, the objective of the present study is to evaluate the knowledge, attitude, and awareness of postgraduate students toward ergonomics and to compare the practices followed by different postgraduate across various dental institutes in day to day practice.

MATERIALS AND METHODS

The present study is a cross-sectional questionnaire-based study which was conducted among the dental postgraduate students of various dental colleges across India for the duration of 3 months. Ethical clearance was obtained from the Institutional review board of KAHER'S KLE VK Institute of Dental Sciences and Hospital, Belagavi. A total of 240 postgraduates made up the sample for the study. The study objectives were explained and informed consent was obtained from the participants before the questionnaire through online forms. Participants who did not give their consent to participate in the study were excluded from the study. A self-prepared questionnaire was given to the participants in the format of online forms and they were asked to fill the questionnaire as per their convenience. If any problem arises while filling the questionnaire form, it was immediately solved by the investigator during the period of the study.

The questionnaire consists of 25 closed-ended questions and one open-ended question to evaluate their knowledge, awareness, and attitude toward ergonomics. The questionnaire was divided into two parts, first part contains the demographic details which include gender and professional background. Second part includes a general understanding of ergonomics, application of ergonomics in clinical practice, effective methods and tools in implementing proper ergonomics in clinical practice, and some suggestions related to ergonomics were also invited. The individual responses from each participant were recorded and tabulated on an excel template and subjected to statistical analysis to draw the conclusion from the resultant data. The data were analyzed and Cronbach's alpha coefficient was used to test the alpha value and reliability. Chi-square test was used to assess the relationship between demographic profile with the levels of knowledge, awareness, and attitude among postgraduate with a significance level of $P < 0.05$.

RESULTS

A total of 240 participants answered the questionnaire. As mentioned in Table 1, about 148 (61.67%) were female and about 92 (38.33%) were male. The highest number of subjects were from 1st year of MDS 113 (47.08%) followed by 3rd-year 67 (27.92%) and 2nd-year 60 (25.00%).

The distribution of questions and scores related to knowledge are shown in Table 2. While comparing the association between the gender and knowledge regarding the use of poor fitting gloves used in the dental procedure,

Table 1: Demographic details

Demographic profile	No of respondents	% of respondents
Gender		
Female	148	61.67
Male	92	38.33
Year of MDS course		
1st year	113	47.08
2nd year	60	25.00
3rd year	67	27.92
Total	240	100.00

Table 2: Questionnaire regarding Knowledge toward ergonomics

Questions	Correct answers
What is the preferred position of operator while working in maxillary arch	84.17%
What is the preferred position of operator while working in mandibular arch	73.33%
Does poor fitting gloves hinder during your treatment procedure	79.17%
How ergonomics can be applied in dentistry	80.83%

there is a statistically significant difference found between them when calculated according to the Chi-square test, as shown in Table 3 ($P = 0.003$).

Subjects when asked questions related to awareness, about 121 (67.22%) female responders believed that emphasis regarding the equipment ergonomics is less in the present dental curriculum and a statistically significant difference was found between the subjects [Table 4] ($P = 0.004$). Furthermore, when questioned regarding the correct chair positing while operating on the patient, 2nd- and 3rd-year postgraduates were more aware when compared to 1st-year postgraduates [Graph 1]. Of 240 male and female subjects, only 211 (87.92%) participants were aware of correct chair positing, nearly 2 (0.83%) participants were unaware of chair positing and unfortunately, 9 (3.75%) subject choose the option that correct chair positing does not matter to them. However, as such, there is no statistically significant difference found in the responses between male and female ($P = 0.1603$) [Graph 2].

Table 3: Association between gender and knowledge about ergonomics

Does poor fitting gloves hinder during your treatment procedure?	Male	%	Female	%	Total	%	Chi-square	*P* value
Yes	62	32.63	128	67.37	190	79.17	14.249	0.0030*
No	5	83.33	1	16.67	6	2.50		
Maybe	3	50.00	3	50.00	6	2.50		
Sometimes	22	57.89	16	42.11	38	15.83		

$P < 0.05$

Table 4: Comparison between gender and awareness about equipment Ergonomics

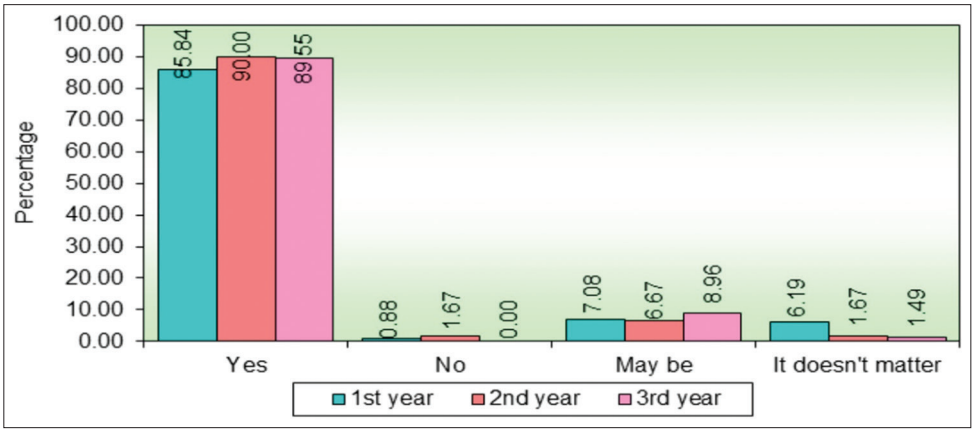
Emphasis about equipment ergonomics is less in the present dental curriculum	Male	%	Female	%	Total	%	Chi-square	*P* value
Don't know	25	51.02	24	48.98	49	20.42	11.191	0.0040*
No	8	72.73	3	27.27	11	4.58		
Yes	59	32.78	121	67.22	180	75.00		
Total	92	38.33	148	61.67	240	100.00		

$P < 0.05$

Table 5: Association of gender and attitude about Ergonomics

Do you prefer taking rest in between the procedures?	Male	%	Female	%	Total	%	Chi-square	*P* value
Yes	40	33.06	81	66.94	121	50.42	10.881	0.0040*
No	26	60.47	17	39.53	43	17.92		
Sometimes	26	34.21	50	65.79	76	31.67		
How do you prefer to work?								
Depends on procedure	38	32.76	78	67.24	116	48.33	12.110	0.0070*
Sitting	25	45.45	30	54.55	55	22.92		
Standing	7	22.58	24	77.42	31	12.92		
All of above	22	57.89	16	42.11	38	15.83		

$P < 0.05$



Graph 1: Assosiation between year of MDS couse and awareness about the correct chair positioning while operating a patient

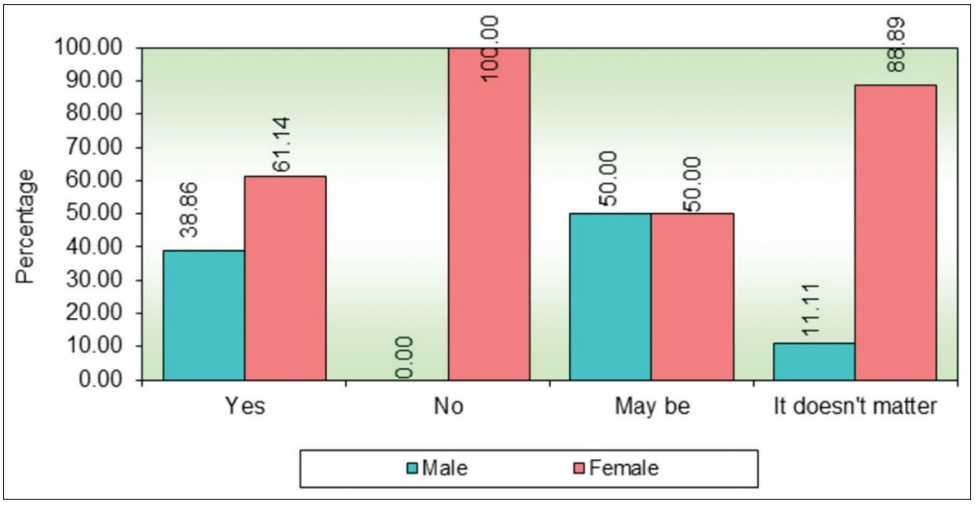
Distribution of questions related to attitude, as shown in Table 5. Using the Chi-square test, a statistically significant difference was found between male and female subjects ($P = 0.004$) when enquired if the subject prefers taking rest in between the dental procedure. Most of the respondents, 116 (48.33%) prefer working according to the dental procedure performed by them in dental clinics, 55 (22.92%) subjects preferred to sit and perform the routine dental procedures, 31 (12.92%) subjects prefer to stand and perform the dental procedure.

Of 240 postgraduates, most of the postgraduates work for more than 2–4 h daily. The average time taken by 2nd- and 3rd-year students for routine dental treatment was more than 2–4 h [Graph 3]. When the compared association between gender and average time taken by them for routine dental treatment, no statistically significant difference was found between them [Graph 4] ($P = 0.4800$).

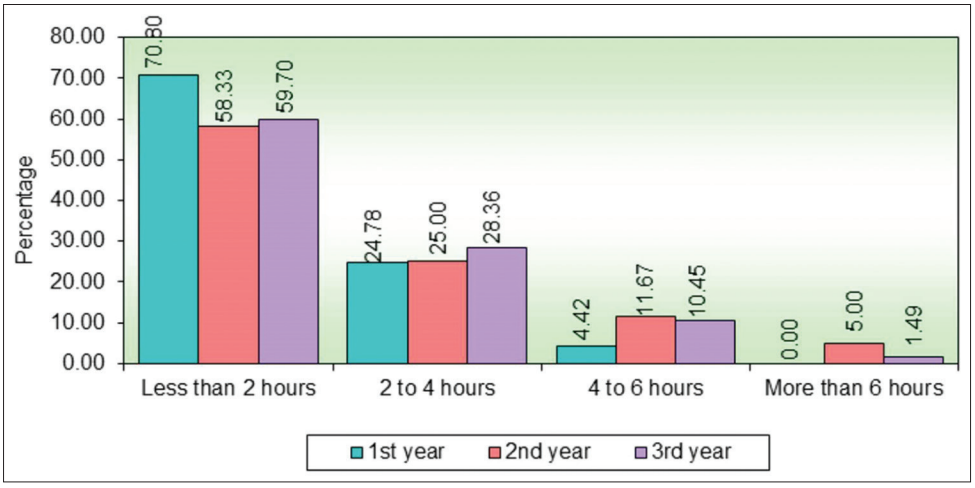
DISCUSSION

Maintaining good body postures helps to reduce the energy expenditure, improves function, and protects the individual from an occupational hazard.[7] When applied to dentistry, ergonomics aims reducing the cognitive and physical stress, prevent occupational conditions linked to the practice of dentistry, and increases the performance, with improved quality and superior comfort for both the dental professionals and the patients.

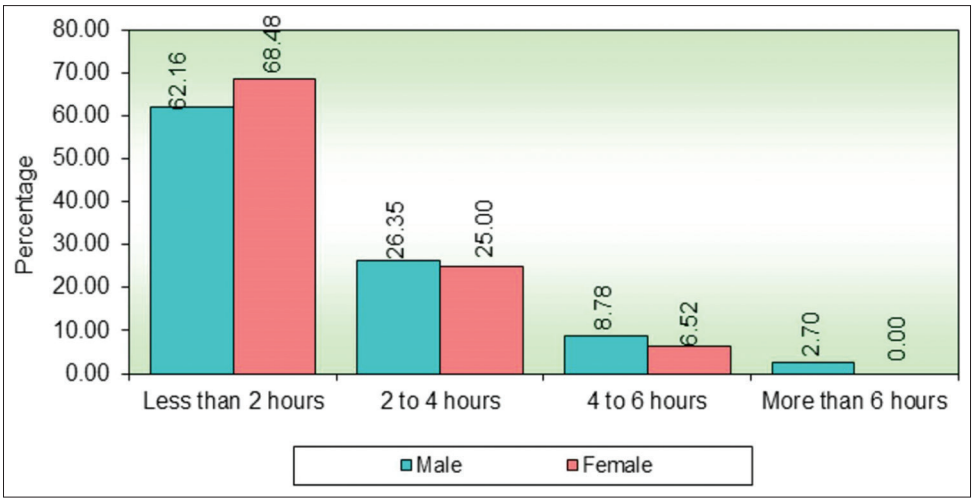
In the recent dental literature, musculoskeletal injuries related terminologies have arisen with an increased frequency. A symptom for musculoskeletal pain includes pain, swelling, tenderness, numbness, and loss of strength. Mechanism of musculoskeletal pain includes prolong static posture of the human body which initiates pain, causes injury, and ceases the workflow. To prevent the occurrence of musculoskeletal injuries, self-contemplation and



Graph 2: Association between gender and awareness about the correct chair positioning while operating a patient



Graph 3: Association between the year of MDS course and average time taken for routine dental treatment



Graph 4: Association between the gender and average time taken for routine Dental treatment

recognition by the dentists in relation to their own postures, practicing positions, and equipment usage pattern is the first critical step. Such identification will aid in avoiding these risk factors.[8]

In the Indian context, where the number of practicing dentist is increasing, there is a continuous prevalence of musculoskeletal injuries.[4] Ergonomics has always been neglected as a knowledge and attitude point of view, as well it is not the part of dental curriculum in undergraduate as well as postgraduate as proposed by Dental Council of India.[9] As a result, the knowledge of ergonomics is dissipated using informal means only.[4] This necessities the evaluation of knowledge, awareness, and practices toward ergonomics among postgraduate students during their routine dental procedures. Therefore, the current cross-sectional questionnaire study was conducted to assess the postgraduates regarding the ergonomic principles and has uncovered interesting and hidden areas of this dynamic field. In our study, we found that about 62.50% of responders were aware of the ergonomic principles.

When noticed, the majority of the respondents (80.83%) applied ergonomics to dentistry as instruments, equipment, and work posture. This, in general, demonstrates that postgraduate students understand ergonomics as something important, which may benefit their health in the near future.[10] Many postgraduates did recommend that the ergonomic should be supervised by the professors specializing in the area during their clinical activities.

The use of operating stool is complex and is misunderstood among the postgraduates. Dental professionals sit for more than 80–100% of the day in a chair with weak lumbar support and inadequate adjustability, which predisposes them to lower back pain.[11] In our study, about 43.01% of postgraduate were unaware of the saddle and triple-shaped ergonomically designed stool.

Following a correct work posture is fundamental in delivering optimal dental treatment.[12] About 78.75% of respondents in our study had a proper knowledge of the operator's positing while working in maxillary as well as mandibular arch.

In the present study, about 50.42% responders preferred taking microbreaks in between the procedures and which improved their work productivity and about 25% of the responders did practice chairside exercise in between the procedures. Certain chair side exercise was emphasized by *Shipra Gupta* such as un-twister, trunk rotation, and reversal exercises that can be practiced as microbreaks to improve the working efficiency.[13]

Rhodej *et al.* emphasized the use of proper size and fit gloves does influence hand comfort.[14] It has been sited that the use of improper gloves does cause carpel tunnel syndrome.[15] The risk factor prevailing this condition is the repetitiveness of work, mechanical stress, posture, temperature, and vibration.[16] In this study, when queried, about 79.19% responded that the use of ill-fitting gloves does hinder the treatment procedure.

Long-term maintenance of poor posture can result in chronic muscle pain. Standing involves a different group of muscles, alternating two positions allows one group to rest and the workload is shifted to another group of muscles. Practicing alternative methods between standing and sitting can be an effective tool in reducing fatigability.[17]

Many of the participants in our study were right-handed. A correct seating position is between 9'o clock to 12'o clock

for a right-handed operator, whereas for the left-handed operator, 3'o clock to 12'o clock position is preferred.[18]

Many responders in our study did agree that working in an incorrect posture can affect in the long run. Hence, a proper postural parameter should be followed. Sitting in an upright symmetrical position, legs slightly apart, and forearms lightly elevated ensures a correct working posture.

In our study, it was found that many of the postgraduates were interested in learning about the recent ergonomic posture through various platforms. Many of them recommended for live demonstrations, workshops, and training to reduce work fatigability. Few responders also mentioned that the ergonomics should be a part of the daily curriculum and should be included as a syllabus in undergraduate as well postgraduate. Further studies must be conducted among the postgraduate on practical training workshops to prevent the early establishment of postural vices.

CONCLUSION

Four-handed dentistry is an ergonomically efficient way to provide good dental care, leading to an increase in efficiency and productivity of a person in improving the workability toward dental treatment.[19]

Our study concluded that there is an acceptable level of knowledge and awareness found regarding ergonomics in various dental institutes. The attitude of participants regarding ergonomics is appreciable. Postgraduates should work toward the proper establishment of ergonomic posture in clinics and should influence others too in practicing dentistry in an effortless way.

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Original Article

Clinical Study of Amoebic Liver Abscess

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Abstract

Background: A clinical study of amoebic liver abscess was chosen because it is the most common cause of liver abscess in a tropical country like India. An attempt was made in this study to define the various symptom complexes, modes of presentation, methods used in diagnosis, treatment options, and complications occurring in amoebic liver abscess. This study showed that the mortality and morbidity were reduced significantly by antiamoebic chemotherapy and minimal invasive ultrasound-guided needle aspiration of the abscess.

Study Design: Case series.

Aim of the Study: To study the etiopathogenesis, various clinical presentations, various investigations to evaluate amoebic liver abscess, treatment options available for management of patients with amoebic liver abscess, and its complications.

Methodology: A series of 50 cases of amoebic liver abscess admitted to our MGM Hospital, Warangal, between January 2015 and September 2016 were studied, inclusive of a follow-up period of 6 months.

Results: The mainstay of management of amoebic liver abscess consisted of antiamoebic chemotherapy and surgical intervention involving ultrasound-guided aspiration, Malecot Catheter drainage, exploratory laparotomy, and drains under local anesthesia. In our study of 50 cases with amoebic liver abscess, complications encountered in 4 cases (8%) with subdiaphragmatic rupture of amoebic liver abscess, 4 cases (8%) with acute renal failure, and 2 cases (4%) with rupture into the peritoneal cavity causing peritonitis. Computed tomography scan established the diagnosis in these complicated cases except for one case in which exploratory laparotomy was directly done for peritonitis and was found to have ruptured amoebic liver abscess. Four cases of subdiaphragmatic rupture with a localized collection of amoebic liver abscess were also treated by Malecot Catheter insertion into the subdiaphragmatic collection. Two patients had ruptured liver abscess, one underwent exploratory laparotomy and drainage of pus. In the other patient, drains were kept under local anesthesia and antiamoebic chemotherapy was given for both of them. There was no mortality in our study. Recurrence was nil up to 6 months of follow-up.

Conclusion: Prompt diagnosis, aggressive medical treatment along with minimal intervention can keep morbidity and mortality associated with this condition to a bare minimum. The scope of surgery in this condition is minimal and limited to cases not responding to medical management and with complications like a rupture. Preventive measures at the individual level and community level can help in eliminating the disease.

Key words: Amoebic liver abscess, Antiamoebic chemotherapy, Ultrasound-guided needle aspiration of abscess

INTRODUCTION

Liver abscess is a common condition in India. India has 2nd highest incidence of liver abscess in the world. Liver abscess is caused by bacterial, parasitic, or fungal infection.

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Amoebiasis is presently the second most common cause of death from parasitic diseases. The World Health Organization reported that *Entamoeba histolytica* causes approximately 50 million cases and 100,000 deaths annually. India being a tropical country and home to 400 million people harboring *E. histolytica*, the causative organism of amoebic liver abscess, it assumes immense importance for a thorough understanding of the same. The vast majority

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of these infections are acquired in the developing world. In a country like India, where the majority of population lives below the poverty line, basic sanitary facilities are lacking. This coupled with overcrowding and urban slums and also outdoor unhygienic eating habits sets the stage for communicable diseases like amoebiasis.

Amoebic liver abscess is not an abscess in the true sense, as pus does not contain pus cells and bacteriologically sterile.

Liver abscess continues to be a disease with considerable mortality in our country. The rising incidence in alcoholics has become a matter of grave concern, as complicated rates are high in this subgroup, leading to increased morbidity and mortality. Locally made alcoholic drinks such as neera and arrack may be the routes of faeco-oral transmission of amoebic cysts.

Primary prevention by improving sanitation, health education, early diagnosis, and prompt treatment preventing complications may result into lowering mortality/morbidity associated with the disease. With the advent of imaging modalities such as ultrasonography (USG), computed tomography (CT) scan, serological tests diagnosis, and management has become easier with a resultant decrease in mortality and morbidity.

This study has tried to delineate the clinical profile, risk factors, and management strategies of amoebic liver abscess.

METHODOLOGY

A series of 50 cases of amoebic liver abscess admitted to our MGM Hospital, Warangal, between January 2015 and September 2016 were studied, inclusive of a follow-up period of 6 months.

Inclusion Criteria

1. All cases of amoebic liver abscess diagnosed clinically, ultrasonographically, and confirmed serologically. 2. Culture and sensitivity of the aspirate were done in all the cases. 3. All cases of liver abscess (evolving, liquefied, and ruptured stage) with or without peritonitis.

Exclusion Criteria

1. Age <18 years not included.
2. Traumatic liver abscess.
3. Recurrent pyogenic liver abscess.

A detailed history, clinical examination, and laboratory profile of the patients were recorded in a predesigned pro forma. Alcoholism was screened as per CAGE questionnaire[1] depending upon the frequency of alcohol intake, patients were divided into non-drinkers, occasional drinkers (alcohol intake <3 times a week), and regular drinkers (alcohol intake >3 times a week). Using modified Kuppuswamy's socioeconomic status scale,[2] patients were divided into three socioeconomic classes: Upper, middle, and lower. All the patients were subjected to complete hemogram, liver function test, kidney function test, and coagulation profile (prothrombin time and international normalized ratio).

The patients were treated depending upon the clinical presentations, response to medical therapy, and size of the abscess, as seen on USG.

A) Patients with abscess size <5 cm were given anti amoebic chemotherapy only. Antiamoebic chemotherapy consisted of metronidazole 800 mg, 8th hourly for 10 days or 30 mg/kg body weight per day in three divided doses for 10 days, and doxycycline 200 mg orally initially followed by 100 mg daily for 5 days. These patients were managed on an outpatient (OP) basis followed up by USG, except for a few patients who were toxic were admitted.
B) Surgical intervention in the form of ultrasound-guided aspiration was done for patients with
    1) Abscess size more than 5 cm and no clinical response to medical therapy even after 72 h.
    2) Patients with impending rupture.
    3) Left lobe abscess of any size.

Aspiration was done using 18G lumbar puncture needle and a 20 ml syringe. About 2% lignocaine was used for local anesthesia. Every case was followed up by ultrasound to see the complete evacuation of the abscess. If the aspiration was found incomplete, the position and depth of the needle were changed or even the puncture site was changed till there was adequate evacuation.

C) Malecot Catheter drainage was done for abscesses >10 cm in loculated ruptured abscess and abscesses which filled up despite repeated aspiration (2–3 times). 8–10 Fr Malecot Catheter was inserted under ultrasound guidance.
D) Exploratory laparotomy was done for abscess, which had ruptured intra peritonially causing peritonitis. Abdomen was opened by a midline incision, pus was sucked out, following which warm saline wash was given. Abdomen was closed after keeping two drains in the abdominal cavity, one in the pelvis and another drain at the site of the abscess cavity. Patients were given broad-spectrum antibiotics in addition to anti amoebic chemotherapy, intravenous fluids, and blood transfusions as and when necessary.
E) Drains under local anesthesia were inserted for patients who were not fit for surgery.

The patients were examined daily for clinical improvement. Improvement in pain, fever, anorexia, and hepatomegaly was considered criteria for successful treatment. Mean hospital stay was recorded in each group. Ultrasound was repeated twice a week to look for recurrence or residual collection of the liver abscess.

RESULTS

In our institute, 7243 patients were admitted in the surgery unit between the study period, that is, from January 2015 to September 2016. Among them, the number of cases of amoebic liver abscess was 50 (incidence 0.69%).

In this study, 72% of the patients were between 21 and 50 years. The highest incidence was between 41 and 50 years. The mean age was 48 years in our study.

In this study, there was male preponderance and there were no female patients. Male preponderance may be due to chronic alcoholism in most of the patients.

The highest incidence of amoebic liver abscess is observed in rural areas 37 patients (94%) attributed to lack of proper sanitation, personal hygiene due to low socioeconomic conditions when compared to urban areas-3 patients (6%).

About 94% of patients were from the low socioeconomic class with regard to education, occupation, and per capita income. Alcohol consumption was also more common in low socioeconomic class. The rest were from the middle class.

Alcoholism is one of the major predisposing factors for amoebic liver abscess. Majority of the patients were chronic alcoholics (64%).

Distribution of Symptoms in Patients Studied

Pain (100%) and fever (90%) were the two most common symptoms compared to jaundice (30%) and dysentery (12%) in this study. Dysentery is less common because almost 90% of them are asymptomatic carriers, only 10–12% of them gave a history of dysentery.

Distribution of Clinical Signs in Patients Studied

Right-sided intercostal tenderness was seen in 90% of the patients because amoebic liver abscess is common in the posterosuperior surface of the liver. It is one of the diagnostic signs of amoebic liver abscess. Remaining 10% elicited epigastric tenderness with the involvement of the left lobe of the liver.

Investigations Hematological, Biochemical, and Microbiological Studies in Patients

Neutrophilic leukocytosis was seen in about 72% of the patients.

Alkaline phosphatase (58%), bilirubin (44%), and serum glutamic-oxaloacetic transaminase/serum glutamic pyruvic transaminase (>40 U/L) (44%) were elevated in most of the patients indicating altered liver function.

ELISA test was positive in all cases.

Pus aspirated from abscess was sent for culture and sensitivity in all the cases. Only one case was positive for Gram-negative organisms on culture.

HIV was done in all the cases and was negative.

Amoebic liver abscess is commonly observed in the right lobe (84%) and is a mostly solitary abscess (94%). Multiple abscesses (3%) are rare in amoebic liver abscesses.

Most of the patients who presented with amoebic liver abscess were between 5 and 10 cm size (68%) as they presented late due to low socioeconomic background and treated initially by local quacks. Size is important in the management of amoebic liver abscess.

Management

The mainstay of management of amoebic liver abscess consisted of antiamoebic chemotherapy and surgical intervention involving ultrasound-guided aspiration, Malecot Catheter drainage, exploratory laparotomy, and drains under local anesthesia.

Management of Amoebic Liver Abscess

- Antiamoebic chemotherapy – only antiamoebic chemotherapy was given in 19 patients and remaining 31 patients needed surgical intervention along with antiamoebic chemotherapy 8 patients were <5 cm and 11 patients were 5–10 cm size of liver abscess.
- Ultrasound-guided aspiration was done for all cases on admission with liver abscess >5 cm and liquefied. Out of 42 patients with amoebic liver abscess >5 cm, 34 were between 5 and 10 cm and 8 were >10 cm. All the 8 cases with >10 cm size were treated by Malecot Catheter drainage. Out of 34 patients between 5 and 10 cm, 11 were treated with antiamoebic chemotherapy and responded to it. In the remaining 23 patients, 17 were managed by ultrasound-guided aspiration and out of the remaining 6 patients, 4 had localized rupture among them 1 had undergone direct Malecot drainage, 3 underwent ultrasound-guided aspiration first, not responding to it were followed by Malecot Catheter drainage. Remaining 2 patients had ruptured amoebic liver abscess with peritonitis.
- Malecot Catheter drainage – 8–10 Fr Malecot Catheter was inserted under ultrasound guidance and local anesthesia. Twelve patients underwent Malecot Catheter drainage. Eight were >10 cm and remaining

4 had localized rupture among them 1 had undergone direct Malecot drainage, 3 underwent ultrasound-guided aspiration first, not responding to it were followed by Malecot Catheter drainage.
- Explorative laparotomy was done in a single case of the ruptured liver abscess into the peritoneal cavity with peritonitis.
- Drains under local anesthesia were inserted for one patient as the patient was not fit for surgery from the anesthesia point of view.

Complications of Amoebic Liver Abscess

Out of 50 patients, four presented with rupture into the subdiaphragmatic space (8%) and acute renal failure (8%). Two presented with rupture into the peritoneal cavity with peritonitis (4%).

Duration of Hospital Stay

Patients were categorized into three groups depending on the abscess size on USG:
- Group – A (<5 cm) – Out of 8 patients in this group, 4 were treated on OP basis and 4 were admitted, as they were toxic with an average duration of stay about 6.7 days.
- Group – B (5–10 cm) – The average stay of 34 patients was 14.7 days.
- Group – C (>10 cm) – The average stay of these 8 patients was 20.1 days

DISCUSSION

The WHO estimates that *E. histolytica* causes 50 million cases and 100,000 deaths annually, making this disease the second leading cause of death from protozoal diseases.[3,4] Although infection with *E. histolytica* occurs worldwide yet, liver abscess is the most common extraintestinal complication in 3–9% of patients.[5-10] Diagnosis of amoebic liver abscess is straightforward on the basis of epidemiological, clinical, serological, and ultrasonographic findings. Amoebic liver abscess arises from the hematogenous spread of trophozoites of *E. histolytica* from the intestinal mucosa to the liver through the portal vein.

Age

In our study, 72% of the patients were between 21 and 50 years of age.

The youngest being 21 years and oldest 72 years of age.

The highest incidence was between 41 and 50 years of age group (32%) because of the high incidence of chronic alcoholism in this age group coming from rural backgrounds.

Gender

In our study, there was preponderance among the male population (100%).

Rollestan[11] suggested that the increased incidence in males is probably due to increase alcohol intake predisposing to hepatic congestion.

Alcohol

Alcohol is one of the most common predisposing factors for forming amoebic liver abscess and many patients gave a past history of consuming alcohol (64%).

Dysentery

Dysentery with the passage of blood and mucus in the stool was encountered in only 12% of our cases. About 90% of the infections are asymptomatic and 10% produced a spectrum of clinical symptoms ranging from dysentery to abscess of liver [Table 1].

The most common symptom noted in our series was abdominal pain (100%) followed by fever (90%) and Jaundice (12%). Pain was most commonly felt in the right hypochondrium and intercostal tenderness. Our study is comparable with other studies [Table 2].

Local tenderness confined to the right hypochondrium and intercostal tenderness was the most common elicited clinical sign in 90% of our cases because amoebic liver abscess is common in the right lobe. Remaining 10% had left lobe abscess and 72% had hepatomegaly comparable with other studies [Table 3].

The important hematological and biochemical investigations carried out in our study-included hemoglobin, leukocyte count, and liver function tests.

Hemoglobin <10 g% was found in 22% of our patients.

White blood cells count more than 11,000 cells/mm^3 was seen in 72% of the patients. Raised alkaline phosphatase was seen in 58% of the cases in our study and raised bilirubin more than 1.2 g% was found in 44% of the cases in our study.

Pus aspirated from the abscess was sent for culture and sensitivity, only one case was positive for Gram-negative organisms on culture, remaining were sterile [Table 4].

X-ray chest was done in all the cases. In 26% of the patients, the dome of the diaphragm was raised on the right side and 26% of the patients showed associated pleural effusion.

USG was done in all our cases, in 76% of the cases, the abscess was in the right lobe of the liver, in 10% of the cases, the abscess was in the left lobe of the liver and 14% of the cases had multiple abscesses, comparable with other studies [Table 5].

Most of the patients who presented with amoebic liver abscess were 5–10 cm size (68%), as they presented late due to low socioeconomic background, went to local quacks for management initially, by the time they came to the tertiary care, size was 5–10 cm.

Table 1: Symptoms

Studies	Abdominal pain (%)	Fever (%)	Jaundice (%)
Mukhopadhyay *et al.* (2010)[12]	83	81	14
Mathur *et al.* (2002)[13]	83	87	30
Khulna *et al.* (2015)[14]	90	94	13
Present study	100	90	30

Table 2: Clinical signs

Studies	Right hypochondrial and intercostal tenderness (%)	Hepatomegaly (%)
Khulna *et al.* (2015)[14]	90	88
Mukhopadhyay *et al.* (2010)[12]	75	82
Present study	90	72

Table 3: Investigations

Studies	Leukocytosis (%)	Alkaline phosphatase (%)	Bilirubin (%)
Qin *et al.*[15]	61		
Yoo *et al.*[16]	78	55	7
Present study	72	58	44

Table 4: X-ray chest

Study	Chest X-ray raised dome of the diaphragm (%)
Mukhopadhyay *et al.* (2010)[12]	32
Present study	26

CT scan was done for 7 patients who were suspected rupture of amoebic liver abscess.

ELISA for amoebiasis was done in all patients and all showed positive results [Table 6].

The management given in our series of 50 patients includes

1) Only antiamoebic chemotherapy in 38% of the patients.
2) Majority of the patients (34%) were treated by ultrasound-guided aspiration and antiamoebic chemotherapy for abscess size >5 cm, as seen on USG.
3) Malecot Catheter drainage was done in 24% of the cases for abscess size >10 cm and complicated localized ruptured amoebic liver abscess with minimal extrahepatic contamination, excluding peritonitis.
4) Exploratory laparotomy was done in 2% of the patients for a ruptured liver abscess with peritonitis and
5) Drains under local anesthesia were inserted in 2% of patients not fit for anesthesia.

In our study of 50 cases with amoebic liver abscess, complications encountered in 4 cases (8%) with subdiaphragmatic rupture of amoebic liver abscess, 4 cases (8%) with acute renal failure, and 2 cases (4%) with rupture into the peritoneal cavity causing peritonitis. CT scan established the diagnosis in these complicated cases except for one case in which exploratory laparotomy was directly done for peritonitis and was found to have ruptured amoebic liver abscess. Four cases of subdiaphragmatic rupture with a localized collection of amoebic liver abscess were also treated by Malecot Catheter insertion into the subdiaphragmatic collection.

Two patients had ruptured liver abscess, one underwent exploratory laparotomy and drainage of pus. In the other patient, drains were kept under local anesthesia and antiamoebic chemotherapy was given for both of them.

Duration of STAY

All the 50 cases in our study responded to the treatment given to them and were discharged. The average hospitalization time in patients with abscess size <5 cm

Table 5: Ultrasonography

Studies	Yoo *et al.*[16] (%)	Rajak *et al.* 2008[17] (%)	Mukhopadhyay *et al.* (2010)[12] (%)	Present study (%)
Solitary abscess	89	84	94	94
*Right lobe abscess	69	72	84	84
*Left lobe abscess	20	12	10	10
Multiple abscesses	11	16	6	6
Size of liver abscess (cm)				
<5	45	34	17	16
5–10			48	68
>10	55	66	35	16

Table 6: Management

Treatment modality	Alpesh *et al.* (2015)[18] (%)	Naveen *et al.*[19] (%)	Present study (%)
Conservative antiamoebic chemotherapy	28	58	38
USG aspiration	57	25	34
Catheter drainage	10	14	24
Exploratory laparotomy	5	5	2
Drains under local anesthesia			2

was 6.7 days, patients with abscess size 5–10 cm was 14.7 days, and patients with abscess size more than 10 cm was 20.1 days. In our study, the mean hospital time was 13.8 days.

CONCLUSION

Amoebic liver abscess is the most common extraintestinal complication of intestinal amoebiasis and occurs fairly frequently in Indian population.

High index of suspicion is mandatory for early clinical diagnosis. With the advent of newer imaging modalities such as USG and CT scan, diagnosis has become easier.

Serological tests like ELISA are very useful in the diagnosis of amoebic liver abscess. It has a high sensitivity of 95–100%. The pus aspirated was sterile in 98% cases indicating secondary infection is rare. Early diagnosis and treatment has led to a reduction in morbidity and mortality. High incidence was observed among the lower socioeconomic group and among patients coming from rural areas because of poor sanitary habits, personal hygiene, and history of alcoholism which indicates the need for preventive measures at individual and community levels.

Prompt diagnosis, aggressive medical treatment along with minimal intervention can keep morbidity and mortality associated with this condition to a bare minimum. The scope of surgery in this condition is minimal and limited to cases not responding to medical management and with complications like a rupture.

Preventive measures at the individual level and community level can help in eliminating the disease.

SUMMARY

A clinical study of amoebic liver abscess was chosen because it is the most common cause of liver abscess in a tropical country like India. An attempt was made in this study to define the various symptom complexes, modes of presentation, methods used in diagnosis, treatment options, and complications occurring in amoebic liver abscess. This study showed that the mortality and morbidity were reduced significantly by antiamoebic chemotherapy and minimal invasive ultrasound-guided needle aspiration of abscess.

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Original Article

Effect of Aqueous and Acid-based Coloring Solutions on Microhardness and Translucency of Monolithic Zirconia

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Abstract

Introduction: Zirconia has encountered a rapid development of metal-free dentistry because of its biological, mechanical, and esthetic properties. The white opaque color of zirconia limits the possibility of natural-looking restoration. Pre-colored blocks and green stage coloring liquids are used to obtain shaded zirconia. Coloring may affect mechanical and optical properties.

Purpose: The purpose of the study was to evaluate the effect of aqueous and acid-based coloring solutions on microhardness and translucency of monolithic zirconia.

Materials and Methods: A total of 30 specimens (15 × 12 × 0.5 mm) were divided into three groups. Non-colored zirconia specimens, Group A, were used as a control group. Acid-based coloring liquid treated zirconia, Group B, and aqueous coloring liquid treated zirconia, Group C, as experimental groups. Coloring liquids were applied to the specimens 1 time using a brushing technique. A micro Vickers hardness tester was used to evaluate the surface microhardness. Translucency values were measured by UV visible spectrophotometer. The results were analyzed using a one-way analysis of variance (ANOVA) and 2-way ANOVAs, followed by post hoc comparison by Tukey's method.

Results: The mean values of surface microhardness (in HV) of all three groups, Group A, B, and C, were 1077.34, 1192.51, and 1222.64, respectively. The mean values of translucency (in %) of all three groups, Group A, B, and C are 40.06, 70.41, and 48.71, respectively. There was a statistically significant improvement in surface microhardness and translucency of monolithic zirconia after coloring with acid based and aqueous coloring solutions.

Conclusion: The surface microhardness and translucency of both monolithic zirconia treated with acid based and aqueous coloring solution was significantly increased as compared with non-colored monolithic zirconia. Monolithic zirconia treated with acid-based coloring solution has the highest translucency. Aqueous colored monolithic zirconia has the highest surface microhardness.

Key words: Monolithic zirconia, Prettau A3 coloring liquid, Prettau Aquarell A3, Surface microhardness, Translucency

INTRODUCTION

A good face is a letter of recommendation. Media projected perfect appearance has a strong impact on the behavior and thinking of our beauty-conscious society. Moreover, it has led to an increased demand for esthetic treatment from public.[1] Good dental appearances are thought to be a requirement of prestigious occupations among some professional groups.[2]

Metal-ceramic restoration has been used successfully in dentistry. Although it provides favorable results in terms of strength, form, and function, it shows unesthetic appearance from metal underneath, especially at the cervical part of the restoration or from the opaque porcelain layer.[3] Ceramic materials, also named bioceramics, are especially

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developed for dental use to solve the esthetic problems related to metal-ceramic fixed dental prosthesis.[3,4]

The modern era, which is encountering an ever-increasing assortment of ceramic material, could be characterized as the "ceramic age."[5] Over the last decade, zirconia has encountered a rapid development of metal-free dentistry because of its biological, mechanical, and esthetic properties. The mechanical properties of zirconia are the highest ever reported for any dental ceramics.[6] The high strength and fracture toughness of zirconia result from transformation toughening.[7,8] Due to its white opaque color, it has to be veneered with feldspathic porcelain, but cohesive failure of feldspathic porcelain has been identified as the main complication.[8] Clinical studies have reported that the use of weak veneering porcelain, differences in the coefficient of thermal expansion, low core veneer bond strength, and undesirable zirconia framework design are the main reason for chipping or fracture on veneering porcelain.[9-12] One approach to overcome this problem is to fabricate complete contour zirconia without any veneering. Since zirconia is opaque, coloring must be done for zirconia.

Two main coloring techniques are additive and painting technique.[13] In additive techniques, metal oxides are mixed with zirconia powder at a stage of zirconia block manufacturing and the colored block is sintered.[13] In the painting technique, color is superficially applied with a brush before being dried and sintered.[13] Two commonly used zirconia coloring liquids are acid based and aqueous coloring solutions. Acid-based coloring solution imparts color to zirconia through acid-base reaction,[14] whereas aqueous coloring solution imparts color by filtering metal cations into a porous zirconia framework.

In this context, the present study was conducted to evaluate the effect of microhardness and translucency of monolithic zirconia after the application of acid based and aqueous coloring solution as compared with non-colored monolithic zirconia.

MATERIALS AND METHODS

Fabrication of Test Specimens

Monolithic zirconia blocks (Alpha Z 0; DMAX) were used in this study. Green stage zirconia blocks were milled into 15 × 12 × 0.5 mm using a milling machine [Figure 1]. All the specimens were polished with 1000 grit silicon carbide paper to produce a uniform surface profile [Figure 2]. A total of 30 specimens were divided into three groups. Non-colored zirconia specimens (Group A) were used as a control group. Acid-based coloring liquid (Group B) treated zirconia and aqueous coloring liquid treated (Group C) zirconia as experimental groups. Prettau A3 coloring liquid was used for acid based and Prettau Aquarell A3 for the aqueous coloring techniques [Figure 3]. Coloring liquids were applied to the specimens 1 time using the brushing technique [Figure 4]. The specimens were then dried for 30 min in an oven at 130°C and sintered in a sintering furnace according to manufactures instructions [Figures 5-7].

Figure 1: Zirconia milling machine

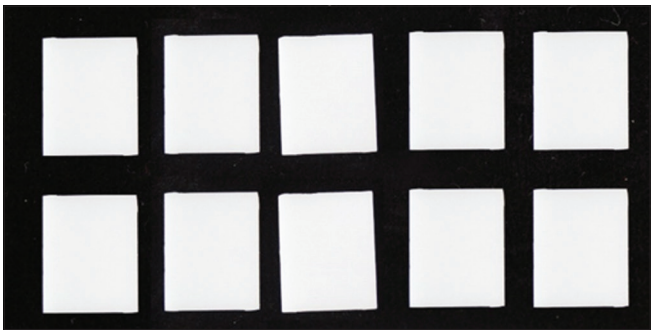


Figure 2: Finished zirconia blocks

Figure 3: Prettau A3 and Prettau Aquarell

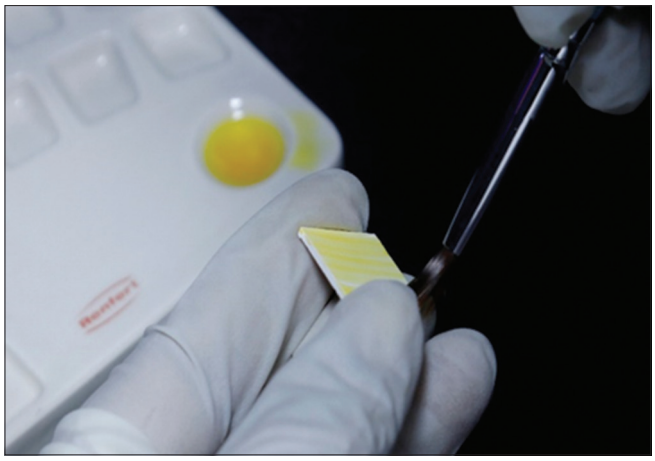


Figure 4: Coloring of zirconia using brushing technique

Figure 5: Sintering unit

Figure 6: Sintering

Testing of Specimens for Surface Hardness

A micro Vickers hardness tester (HMV SCHIMADZO, model HMV 2T ADW) was used to evaluate the surface hardness of specimens for each treatment [Figures 8 and 9]. Surface hardness was measured using the indentation technique to determine the Vickers hardness number of specimens. Specimens were mounted in the horizontal stage of the tester, then the indenter was lowered under a load of 9.8 N for 15 s. Three indentations will be placed in the center of each specimen. For each tested sample, all indentations were measured and an average Vickers microhardness number HV was determined.

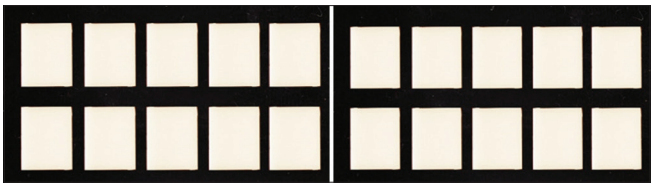


Figure 7: Monolithic zirconia colored with acid-based coloring solution (A3 Shade) and aqueous coloring solution (A3 Shade)

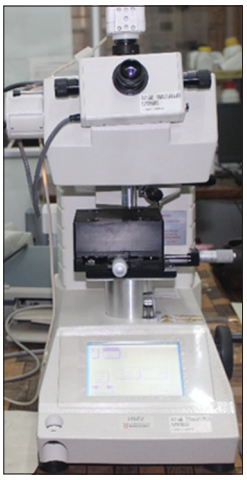


Figure 8: Micro Vickers hardness tester (HMV SCHIMADZO, model-HMV 2T ADW)

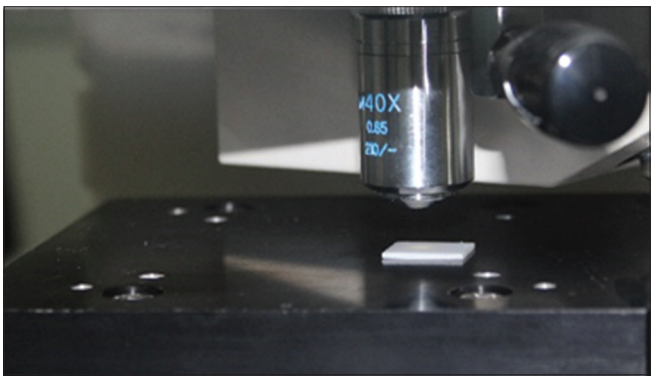


Figure 9: Specimen *in situ*

Testing of Specimens for Translucency

Light transmittance was measured using UV visible spectrophotometer (Varian, model CARY100BIO) [Figures 10 and 11].

Since translucency is the characteristic of a substance that is partially able to allow light to pass through it, light

transmittance was considered as a translucency parameter. UV/VIS spectroscopy is based on the absorption of light by a sample. Depending on the amount of light and its wavelength absorbed by the sample, valuable information can be obtained.

The spectrophotometer consisted of two instruments: A spectrometer with a double prism monochromator to produce the light of any selected wavelength, a photometer with a silicon photodetector to measure the intensity of light and a sample holder. The instruments were arranged so that specimens could be placed between the spectrometer beam and the photometer at the entrance port of the integrating sphere in order that the total amount of light transmitted and scattered through it could be measured.

Fabricated specimens were placed in a spectrophotometer with the help of a holder and working wavelength ranged from 400 to 800 nm of the visible light spectrum was arranged. The readings were obtained on the computer connected to spectrophotometer. The amount of light transmittance was recorded in percentage and a UV/VIS spectrum is graphically represented as absorbance as a function of wavelength.

RESULTS

Data were analyzed using computer software, Statistical Package for the Social Sciences version 16.0. Data were expressed in its mean and standard deviation. Analysis of variance (one-way ANOVA) was performed as a parametric test to compare different groups. To facilitate multiple comparisons between groups, Tukey's method was employed as a post hoc test along with ANOVA. For all statistical evaluation, a two-tailed probability of value <0.05 was considered significant.

Graphical representation of the mean values of surface hardness and translucency, comparison of surface microhardness and translucency among groups is shown in Graphs 1-4, respectively.

Mean and standard deviation values of the surface microhardness are presented in Table 1. As per this study, maximum mean surface microhardness was obtained for monolithic zirconia colored with aqueous-based coloring liquid (Group C) and non-colored monolithic zirconia is minimum (Group A) [Table 1]. One-way ANOVA showed a statistically significant difference between mean values [Table 2]. Multiple comparisons with post hoc by Tukey's method revealed that comparison between groups (A and B) and (A and C) were statistically significant as $P < 0.001$. Since P-value is 0.529 (>0.005), comparison between Groups B and C was not statistically significant [Table 3].

Mean and standard deviation values of the translucency are presented in Table 4. As per this study, maximum mean

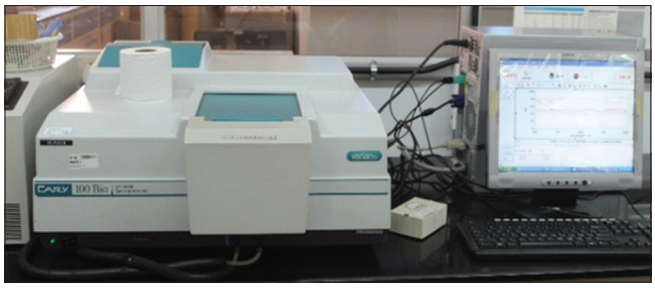


Figure 10: UV visible spectrophotometer (Varian, model CARY 100 BIO)

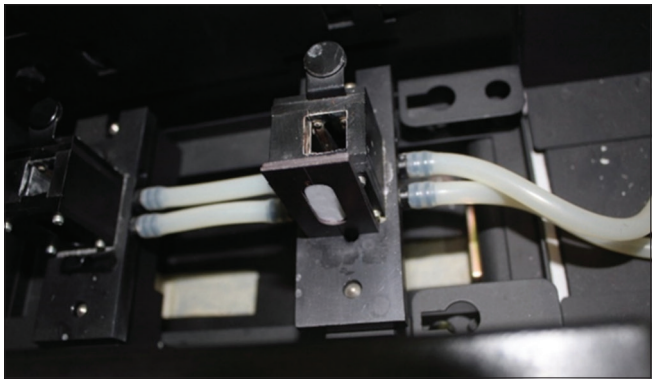
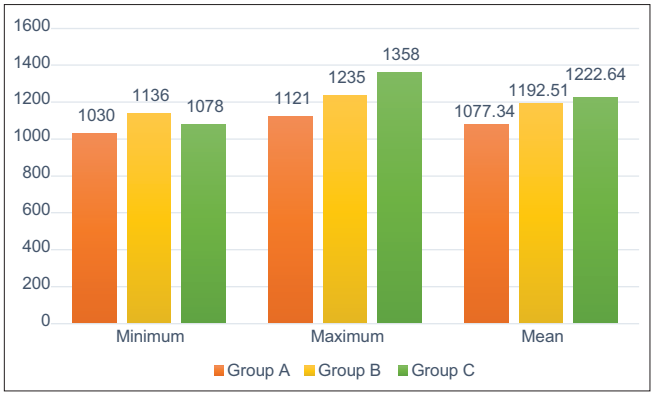
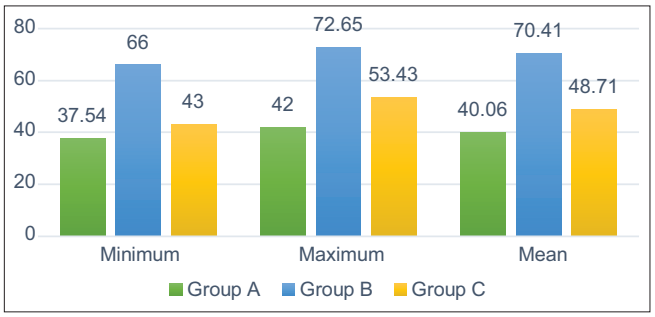


Figure 11: Specimen *in situ*

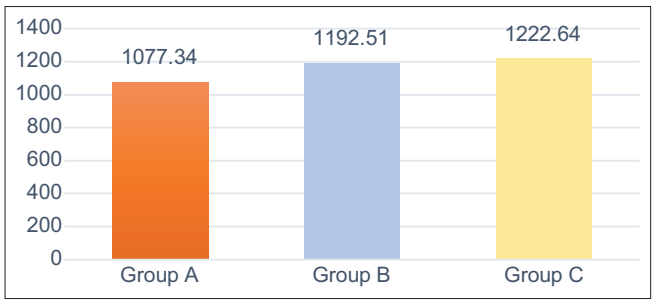


Graph 1: Surface microhardness in HV unit

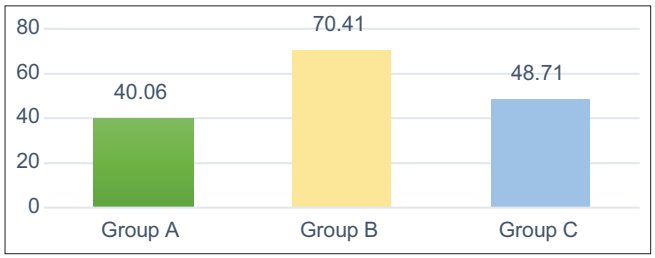


Graph 2: Transmittance in percentage

translucency was obtained for monolithic zirconia colored with acid-based coloring liquid (Group B) and non-colored monolithic zirconia is minimum (Group A) [Table 4]. One-way ANOVA showed a statistically significant difference between mean values [Table 5]. Multiple comparisons with post hoc by Tukey's method revealed that comparison between Groups (A and B), (A and C), and (B-C) were statistically significant as $P < 0.001$ [Table 6].



Graph 3: Comparison of surface microhardness in HV unit



Graph 4: Comparison of transmittance in percentage

Table 1: Surface microhardness in HV unit

Variable	Groups	*n*	Minimum	Maximum	Mean	Std. Deviation
Surface micro hardness in HV unit	Group A	10	1030.00	1121.00	1077.34	34.19
	Group B	10	1136.00	1235.00	1192.51	35.95
	Group C	10	1078.00	1358.00	1222.64	94.93

Table 2: Comparison of surface microhardness in HV unit among the three groups using one way ANOVA

Groups	*n*	Mean	Std. Deviation	Std. Error mean	*P*-value
Group A	10	1077.34	34.19	10.81	0.001*
Group B	10	1192.51	35.95	11.37	(significant)
Group C	10	1222.64	94.93	30.02	

*Significant at the 0.05 level using one way ANOVA

Table 3: Pairwise comparison of surface microhardness in HV unit among the three groups using Tukey post hoc test

Groups	Groups	Mean Difference (I-J)	Sig.
Group A	Group B	–115.17200*	0.001* (significant)
	Group C	–145.30200*	0.001* (significant)
Group B	Group C	–30.13000	0.529 (not significant)

*Significant at the 0.05 level using Tukey post hoc test

DISCUSSION

The use of an esthetic material for the restoration of missing tooth structure has been a long-standing goal in dentistry. Patients are expecting to have several options for esthetically pleasing, functional, and durable restorations in all areas of the dentition. To remedy this, new materials that combine strength, esthetics, and biocompatibility have been developed and brought to market.[15]

Metal ceramic restorations are a type of ceramic system for fixed prosthetic rehabilitation that has been widely used since the early 1960s.[16] Light-reflecting from the opaque porcelain used to mask the metal, particularly at the cervical third of the restoration, causes a light gray appearance of the adjacent gingival tissue. This phenomenon led to the development of metal-free ceramics. Some of the mechanical properties of these materials, such as brittleness, crack propagation, fracture toughness, low tensile strength, wear resistance, marginal accuracy, and difficulty of repair, have limited their clinical use.[7]

Zirconia was introduced in dentistry in the early 1990s and has been used as a core material to support more esthetic ceramic materials. Zirconia shows similar mechanical properties to stainless steel[10] and the highest ones among

Table 4: Transmittance in percentage

Variable	Groups	*n*	Minimum	Maximum	Mean	Std. Deviation
Trans mittance in percentage (%)	Group A	10	37.54	42.00	40.06	1.64
	Group B	10	66.00	72.65	70.41	2.32
	Group C	10	43.00	53.43	48.71	2.88

Table 5: Comparison of transmittance in percentage among the three groups using one way ANOVA

Groups	*n*	Mean	Std. Deviation	Std. Error mean	*P*-value
Group A	10	40.06	1.64	0.52	0.001*
Group B	10	70.41	2.32	0.73	
Group C	10	48.71	2.88	0.91	

*Significant at the 0.05 level using one way ANOVA

Table 6: Pairwise comparison of transmittance in percentage among the three groups

Groups	Groups	Mean difference (I-J)	Sig.
Group A	Group B	–30.35100*	0.001* (significant)
	Group C	–8.65200*	0.001* (significant)
Group B	Group C	21.69900*	0.001* (significant)

*Significant at the 0.05 level using Tukey post hoc test

ceramics used in dentistry. As the strongest and toughest of all dental ceramics,[17] zirconia has 900–1200 MPa flexural strength.[18] Since of their lack of translucency, zirconia cores are generally veneered with porcelain. Differences in the coefficient of thermal expansion between the zirconia substructure and the veneering ceramic improper framework design, rapid cooling rates, and low fracture toughness and flexural strength of veneering ceramic compared to the zirconia core have been considered as the cause of this cohesive failure.[19] Recently, there has emerged a trend of fabrication of full-contour zirconia restoration to avoid veneering failure. To increase the translucency and esthetics of full-contour zirconia, coloring liquids have been applied. Two main coloring techniques are additive and painting technique.[13] In additive techniques, metal oxides are mixed with zirconia powder at a stage of zirconia block manufacturing and the colored block is sintered.[13] In the painting technique, color is superficially applied with a brush before being dried and sintered.[13] Two commonly used zirconia coloring liquids are acid based and aqueous coloring solutions. Acid-based coloring solution imparts color to zirconia through acid-base reaction,[14] whereas aqueous coloring solution imparts color by filtering metal cations into porous zirconia framework. The coloring procedure may affect the mechanical and optical properties of zirconia.[20]

The present *in vitro* study investigated the effect of aqueous and acid-based coloring solutions on translucency and microhardness of monolithic zirconia. The first property evaluated in this study was surface microhardness. A micro Vickers hardness tester (HMV SCHIMADZO, model HMV 2T ADW) was used to evaluate the surface hardness of specimens for each treatment. There was a statistically significant increase in the surface microhardness of monolithic zirconia colored with aqueous-based coloring liquid and monolithic zirconia colored with acid-based coloring liquid as compared with non-colored monolithic zirconia was obtained. Among these, monolithic zirconia colored with aqueous-based coloring solution showed the highest value of surface microhardness.

Surface hardness can be used as an index to predict the resistance of materials to surface crack formation. Surface cracks can be due to reduced fatigue strength and produce early fractures of restorations.[12] This difference in surface microhardness is due to the chemical composition of coloring liquids and the mechanism of imparting color to zirconia. The addition of metal oxides for zirconia coloring may cause crystallographic and microstructural modifications which in turn could affect the mechanical properties of zirconia. Nature of grain form and concentrations of the coloring liquids can have a considerable effect on the mechanical properties of zirconia materials.

The coloring solution contains a solvent, coloring agents, and additives. The coloring agents contain rare earth metals and transition metals. The coloring agents are a combination of two or more rare earth metal compounds such as praseodymium (Pr) ions, erbium (Er) ions, cerium (Ce) ions, and neodymium (Nd) ions. Solvent can dissolve the coloring agents (water and alcohol). The additives preferably are organic additives that do not leave any harmful residue after sintering. Additives are polyethylene alcohol and polyethylene glycol-600.

Acid-based coloring liquids typically contain 0.1 wt% HCl (pH 1 to 3), a strong acid which imparts colors to zirconia through an acid-based reaction, whereas aqueous coloring solution imparts color by filtering metal cations into porous zirconia framework. Certain metal salts can only be liquefied in acid, and the acidification of coloring liquid helps them to infiltrate deeper into the zirconia framework. Scanning electron micrograph analysis revealed that the entire surface of the acid-based coloring liquid specimens was coated with coloring liquid. Hence, the metal ions can enter into the crystal lattice of the zirconia. Coloring liquid was observed mainly at the grain boundary for the aqueous coloring liquid. This difference in the distribution of metal ions in the crystal lattice of colored zirconia is the reason for increased surface microhardness of aqueous colored zirconia than acid colored zirconia.

Various authors have a different opinion regarding microhardness of colored zirconia.

In a study conducted by Nam and Park,[12] a statistically significant difference in hardness was found between acid-colored zirconia and aqueous colored zirconia. They also found that increasing the number of applications decreased the hardness value of acid colored zirconia but had no effect on aqueous colored liquid zirconia. This can be attributed to the change in the distribution of metal ions of coloring solution in the crystal lattice of zirconia. According to Hjerppe *et al*.,[21] biaxial strength and surface microhardness of zirconia framework were reduced after shading. The reduction was due to a difference in shading time and composition of coloring solution. Investigation done by Ban *et al*.[22] reported that various ions in the coloring liquid may act as impurities in the sintered zirconia block and can affect its properties. Their studies concluded that coloring liquids containing Er and/or Nd should be avoided for dental prostheses. Furthermore, coloring with Fe and Co showed no remarkable changes in mechanical property, indicating little reaction with zirconia.

The second property assessed in this study was translucency. Translucency was measured using a UV visible spectrophotometer (Varian, model CARY100BIO). Optical

properties such as light transmittance and reflectance have important roles in the esthetics of restorations, and the translucency of the material can ensure the natural appearance of the restorations. There was a statistically significant increase in the translucency of monolithic zirconia colored with acid-based coloring liquid and monolithic zirconia colored with aqueous-based coloring liquid as compared with non-colored monolithic zirconia was obtained. Among these, monolithic zirconia colored with acid-based coloring solution showed the highest value of translucency. This difference in translucency is due to the chemical composition of coloring liquids and the distribution of metal ions in the crystal lattice of zirconia. Since the entire surface of the acid-based coloring liquid specimens was coated with coloring liquid, the metal ions can enter into the crystal lattice of the zirconia. Coloring liquid was observed mainly at the grain boundary for the aqueous coloring liquid specimens. Hence, the metal ions maintained at the crystal boundary may scatter the incident light. This difference in the distribution of metal ions in the crystal lattice of colored zirconia is the reason for increased translucency of acid colored zirconia than aqueous colored zirconia.

An *in vitro* study conducted by Nam and Park[12] found that aqueous coloring liquid on zirconia produced a greater redness or yellowness compared to acid-coloring liquid. They also concluded that the coloring of zirconia lowered its brightness and imparted a red/yellow hue to zirconia. They attributed that this can be due to a change in the composition of coloring liquids. However, many of the researchers found that coloring procedures can decrease the translucency of zirconia. According to Sulaiman *et al*.[14] staining decreased the transmittance of zirconia due to change in chemical nature of the coloring liquid. This lead to more absorption of light energy and thus decreasing the amount of light transmission.

The result of the present study states that monolithic zirconia colored with acid based and aqueous coloring solution increased translucency and surface microhardness. Monolithic zirconia colored with aqueous coloring solution has the highest microhardness and monolithic zirconia colored with acid-based coloring solution has the highest translucency.

According to Nam and Park,[12] aqueous coloring liquids have long-term stability without the need for pigment-stabilizing agents, as high pH values are required for hydrolysis of rare earth metal ions. Compared with acid-based zirconia coloring liquids, aqueous coloring liquids are safer and more convenient for dental technicians because less acidic fumes are emitted during the application and sintering processes of aqueous coloring solution. Furthermore, they have more enhanced drying time. Therefore, aqueous coloring liquids could be a good substitute for acid-based coloring liquids.

The results of the study were limited to 1-time application of aqueous colorant (A3 shade) and an acid-based colorant (A3 shade). Therefore, it is necessary to study the effect of various coloring agents and multiple applications on the coloring of zirconia. Furthermore, the study evaluated only the changes in two properties that are translucency and surface microhardness. The change in other esthetic and physical properties of the material should be evaluated. The effect of coloring on various components of the zirconia block among the manufacturers also be evaluated. Moreover, as per the present study, no correlation exists between microhardness and translucency of colored specimens. Hence, further investigations are required.

CONCLUSION

The present study was conducted to evaluate the effect aqueous and acid-based coloring solutions on microhardness and translucency of monolithic zirconia.

Within the limitations of the study, the following conclusions were drawn

1. The surface microhardness and translucency of both monolithic zirconia treated with acid-based coloring solution and aqueous coloring solution were significantly increased as compared with non-colored monolithic zirconia
2. Monolithic zirconia treated with aqueous coloring solution has the highest surface microhardness
3. Monolithic zirconia treated with acid-based coloring solution has the highest translucency.

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Original Article

Color Doppler-based Evaluation of Lower Limb Arteries for Suspected Peripheral Arterial Disease in Patients of Diabetes Mellitus

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Abstract

Aims and Objectives: This study aims to study the patterns of vascular affection using Doppler sonography with spectral analysis and ankle brachial index in patients of diabetes mellitus as well as to detect site, severity of vessel narrowing, in those with peripheral arterial disease and assess the functional status of limb in diabetics who are at a risk of peripheral arterial disease. This study emphasizes the role of arterial Doppler in identifying the functional compromise in the diabetic patients, who are at risk of developing PAD and the prime role of the modality in preventing the long-term complications of PAD patients, who end-up having limb amputation surgeries, due to limb ischemia.

Materials and Methods: The study was carried out in the Department of Radiodiagnosis and Imaging, Government Medical College and New Civil Hospital, Surat, over a duration of 12 months on a total of 50 cases. The equipment used was Philips Affiniti 50 USG and Doppler machine by a linear 3–12 MHz L12-5 probe and a curvilinear 3–5 MHz C9-4V probe.

Results: In our study, we found that ulceration, burning sensation, intermittent claudication, and numbness were found to be among the most common clinical features in patients with PAD. The elderly age group (age group 41–50 and 50–60), males with hyperlipidemia, hypertension, and smoking are at increased risk. The infrapopliteal vessels were found to be most adversely affected, showing spectral broadening and speckled waveform pattern. Involvement of femoropopliteal segment was mainly in the form of atheromatous plaque and raised intimomedial thickness, whereas the involvement of anterior and posterior tibial arteries was in the form of mural calcification type of plaque formation. Most of the atheromatous plaques found were echogenic.

Key words: Peripheral arterial disease, Plaque, Stenosis

INTRODUCTION

The term "peripheral arterial disease" broadly encompasses the vascular diseases caused primarily by atherosclerosis and thromboembolic pathophysiological processes that alter the normal structure and function of the aorta, its visceral arterial branches, and the arteries of the lower extremity.[1] By early detection of the vascular changes in the hemodynamic parameters, end-stage complications related to peripheral arterial disease can be prevented and its morbidity reduced, thereby preventing functional compromise of the limb. Therefore, this study emphasizes on the early detection of these changes by means of arterial Doppler study and relevance of Doppler parameters in evaluating limb ischemia and claudication.

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Risk Factors[2-4]

Modifiable

- Dyslipoproteinemia (unhealthy patterns of serum proteins carrying fats and cholesterol):+
- High serum concentration of low-density lipoprotein (LDL) and/or very low-density lipoprotein particles, that is, "lipoprotein subclass analysis"
- Low serum concentration of functioning high-density lipoprotein (HDL)
- An LDL:HDL ratio greater than 3:1

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- Tobacco smoking
- Having hypertension
- Elevated serum C-reactive protein concentrations.

Non-modifiable

- Advanced age
- Male sex
- Having close relatives who have had some complication of atherosclerosis.

Clinical Presentation[5,6]

- The most common symptom is muscle pain in the lower limbs on exercise (intermittent claudication)
- Ischemic rest pain
- Sores, wounds, or ulcers.

MATERIALS AND METHODS

The study was carried out after the approval of the Institutional Review Board, in the Department of Radiodiagnosis and Imaging, Government Medical College and New Civil Hospital, Surat, over a duration of 12 months. The equipment used was Philips Affiniti 50 USG and Doppler machine by a linear 3–12 MHz L12-5 probe and a curvilinear 3–5 MHz C9-4V probe.

Number of Patients

50.

Inclusion Criteria

Patients with diabetes mellitus referred from medicine OPD or surgery OPD for lower limb arterial Doppler with suspected peripheral arterial disease (any of the following symptoms/signs: Tingling/numbness, cold leg/feet, and abnormal lower extremity pulse examination).

Exclusion Criteria

Patients <18 years and >70 years of age; patients with lower limb swellings due to surgical causes (e.g., filariasis) or with leg ulcers which would impair Doppler quality; and patients with H/O trauma were excluded from the study.

Observations

A total of 50 patients were taken for the study.

From Table 1, ulceration, burning sensation, intermittent claudication, and numbness were found to be among the most common clinical features in patients with PAD, whereas rest pain and gangrene with burning sensation were found to be the least common.

Among the 50 patients studied, most of them were above 40 years of age (90%) as shown in the Table 2.

In the study, majority of the patients were male, comprising about 76% as shown in the Table 3.

From Table 4, it can be inferred that infrapopliteal vessels are more adversely affected than the proximal vessels as indicated by spectral broadening and speckled waveform patterns.

From the above-mentioned Table 4 and Graph 1, it can be inferred that SFA is most commonly involved by atheromatous plaque lesions. Example of SFA involvement is shown in Figure 1.

Table 5 shows, among the patients with atheromatous plaques, 41.3% were moderately echogenic, 37.9% were severely echogenic, and 20.6% showed low echogenicity.

From the above-mentioned graph and Table 6, it can be inferred that majority of the patients (70%) had a normal ankle brachial index (ABI) (>0.9) while only 3% of the cases had severely reduced ABI values (<0.7). About 20% of patients had ABI in the range of 0.8–0.89.

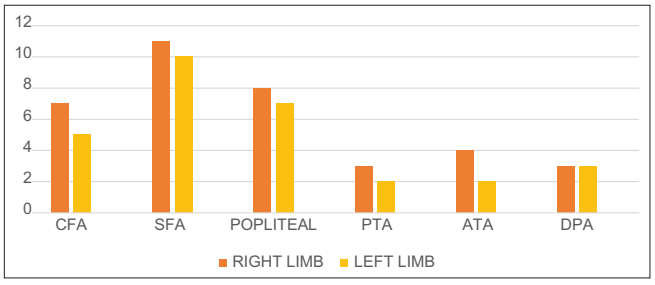
In the study, hemodynamically significant stenosis, that is, >50% stenosis is mostly found in femoropopliteal

Table 1: Signs and symptoms distribution of cases

Sign/Symptom	No. of cases
Ulcer	28
Gangrene	17
Intermittent claudication	20
Rest pain	5
Numbness	20
Burning sensation	32
Gangrene and numbness	10
Gangrene and burning	3

Table 2: Age-wise distribution of patients

Age (years)	Male	Female	No. of patients	Percentage
18–30	1	2	3	6
31–40	2	0	2	4
41–50	9	6	14	30
51–60	17	3	20	40
61–70	8	2	10	20



Graph 1: Atheromatous plaque distribution of cases

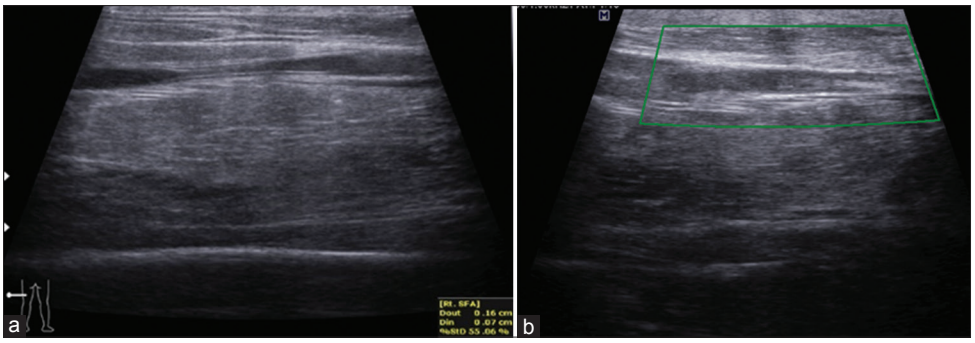


Figure 1: (a and b) The two images show atheromatous plaque in SFA causing nearly 55% luminal occlusion with no color filling seen on color Doppler interrogation. Findings likely represent chronic thrombosis of SFA.

Table 3: Sex distribution of cases

Sex	No. of patients	Percentage
Male	38	76
Female	12	24
Total	50	100

Table 4: Waveform pattern analysis distribution of cases

Vessel	Good	Spectral broadening	Speckled	Nil
CFA	94	-	6	-
SFA	87	6	7	-
PA	84	8	8	-
ATA	59	19	20	2
PTA	56	14	26	4
DPA	59	19	19	3

Table 5: Plaque characterization

Plaque characteristic	No. of patients (*n*=29)	Percentage
Low echogenicity	6	20.6
Moderate echogenicity	12	41.3
Severe echogenicity	11	37.9

segments followed by dorsalis pedis artery as shown in Table 7.

It can be inferred that intimomedial thickening and atheromatous plaque type of involvement are predominantly seen in the superficial femoral arteries and popliteal arteries, whereas anterior and posterior tibials show mural calcification type of plaque involvement. Hemodynamic patterns of the stenosis are shown in Figures 2 and 3.

From the above-mentioned Table 8, it can be inferred that dorsalis pedis followed by posterior tibialis artery was found to show maximum affection and showed significant hemodynamic changes, as indicated by mono/biphasic waveform patterns and absent color filling. Figure 4 shows the same.

Table 6: Ankle brachial index distribution

Ankle brachial index values	Frequency	Percentage
>0.9	35	70
0.8–0.89	10	20
0.7–0.79	3	7
0.6–0.69	1	3

Table 7: Vessel distribution based on site of significant stenosis

Significant stenosis >50% artery	No. of patients (n = 35)	Percentage
CFA	9	17.1
SFA	26	57.1
Popliteal A	12	28.5
PTA	5	11.4
ATA	5	11.4
DPA	6	14.2

Table 8: Case distribution based on flow patterns

Vessel involved	Triphasic	Biphasic	Monophasic	Nil
CFA	43	6	0	1
SFA	26	16	6	2
PA	15	18	13	4
ATA	7	10	28	5
PTA	2	16	28	4
DP	0	7	35	8

DISCUSSION

Age Distribution

In our study, 90% of the cases were above the age of 40 years and 10% of the cases were between the age of 18 and 40 years. It is well accepted fact that the lower extremity arterial disease is the disease of middle and older age groups as cited by Cossman *et al.*[7] and Hughson *et al.*[8]

Plaque Characterization and Percentage of Stenosis

In patients who had complete occlusion, collaterals were noted in significant number of cases but exact site of origin, number of collaterals, and distal reformation site could not

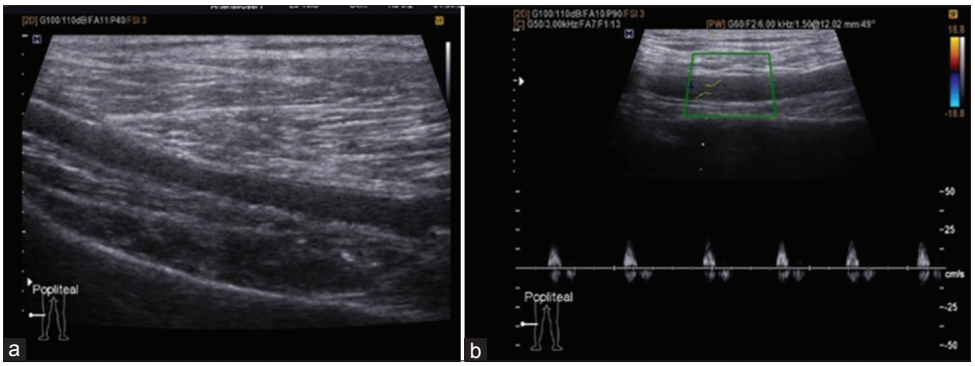


Figure 2: (a and b) Above-mentioned gray scale and pulse Doppler modes reveal atherosclerotic wall thickening and calcification in the popliteal artery with biphasic waveform patterns on pulse Doppler analysis

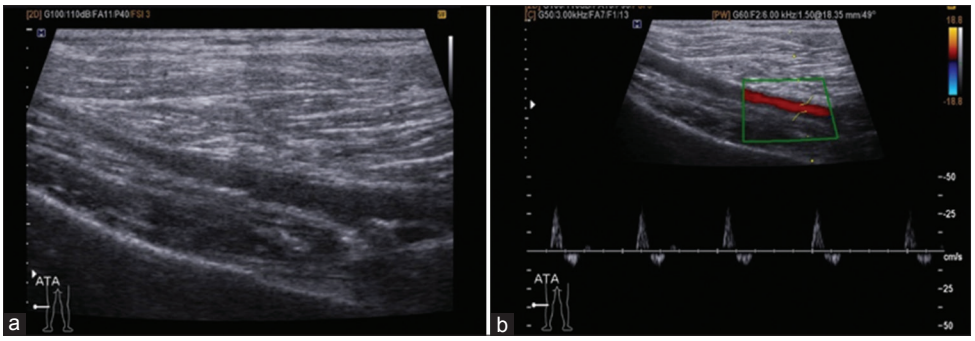


Figure 3: Above images show atherosclerotic wall thickening and calcification in ATA with biphasic waveform patterns. Distal flow from SFA being maintained through collaterals in this case

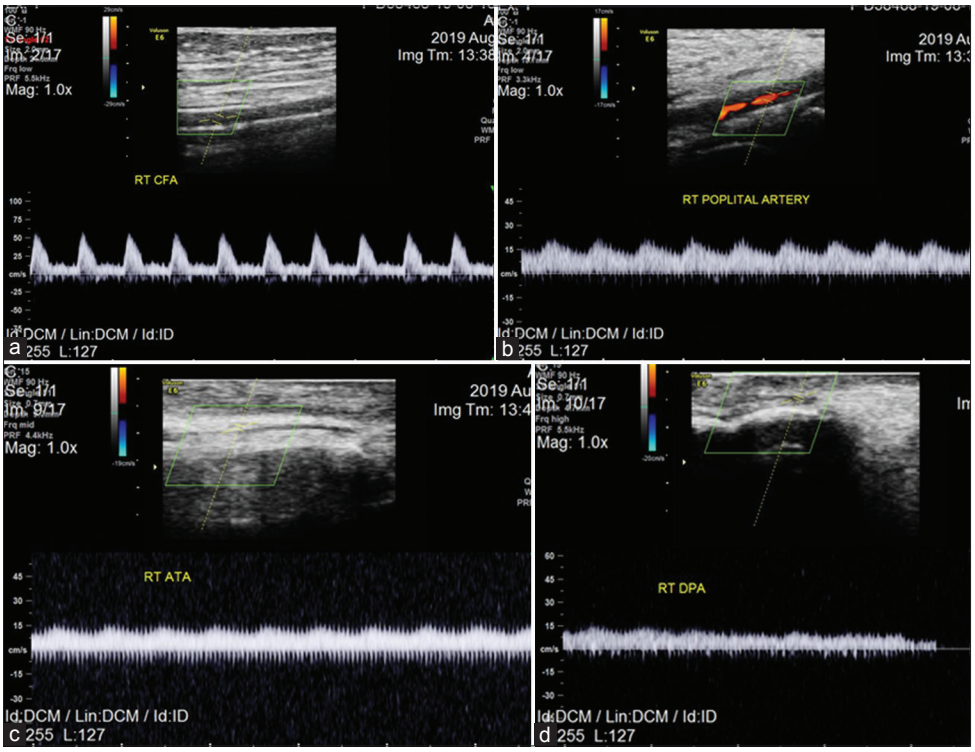


Figure 4: (a-d) Above images show chronic thrombosis in posterior tibial artery and severely reduced flow in rest of the arteries of the right lower limb with dampened monophasic waveform pattern with approx. 40% luminal narrowing in popliteal and 30% in anterior tibial and dorsalis pedis arteries. Findings represent changes of peripheral vascular disease

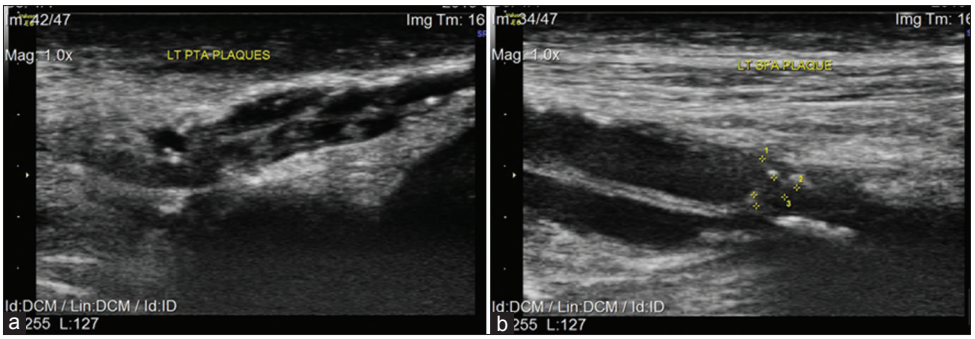


Figure 5: (a and b) Few atherosclerotic plaques as seen in above image in the left SFA and PTA causing nearly 30% luminal compromise

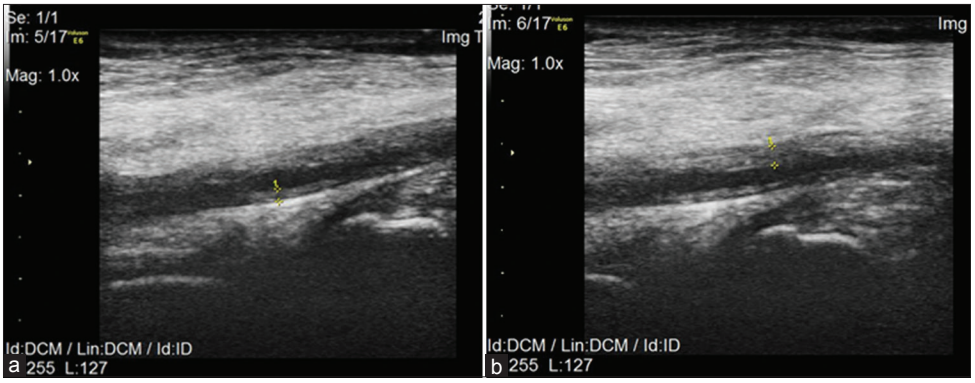


Figure 6: (a and b) Above two images show diffuse atherosclerotic wall thickening involving entire right lower limb arterial tree causing variable degree of luminal compromise

be demonstrated in all cases. Figures 5 and 6 exemplarily show plaques causing luminal stenosis.

Sacks *et al.* in their study observed the gradual decrease in peak systolic velocity from iliac to popliteal artery.[9] Resistance index (RI) is a quantitative analysis of the waveform and reflects resistance to blood flow. The lowest RI suggesting distal ischemia was most commonly seen in dorsalis pedis artery followed by posterior and anterior tibial artery. Das *et al.* demonstrated the low resistance pattern to be more common in dorsalis pedis artery (25.5%) followed by anterior tibial (23%) and posterior tibial (21.5%) artery.[10] Our present study findings were found to be consistent with it.

The earliest signs (gray scale) of atherosclerotic disease are thickening of intima and media followed by wall changes (luminal narrowing and soft or hard plaques) and turbulence and flow irregularities on color Doppler flow images. In our study, plaque variants intima thickening and atheroma were more common in popliteal (18.21% and 17.29%, respectively) and superficial femoral arteries (17.68% and 17.29%, respectively). Calcifications were more common in anterior and posterior tibial arteries (17.89% and 17.57%, respectively). Das *et al.* in their study stated that femoral artery was the most common site of plaque deposition.

Therefore, pattern of vessel narrowing varies in supra versus infrapopliteal vessels.

CONCLUSION

- Arterial Doppler study plays a central role in the management of the patients with peripheral arterial disease by early detection of the changes in the hemodynamic parameters long before limb ischemia sets in and identifying the functional compromise in the diabetic patients who are at risk of developing PAD, thereby decreasing disease morbidity. It can be implemented as an easily available screening tool in the management of these patients to identify the at-risk patients
- Doppler can also be useful in the post-interventional management of the patient as it can be repeated without exposure of the patient to any radiations
- In patients with diabetes mellitus, the elderly age group (age group 41–50 and 50–60) is at increased risk of peripheral arterial disease. Males are more commonly affected with hyperlipidemia, hypertension, and smoking being the most common associated comorbidities
- The infrapopliteal vessels were found to be most adversely affected, showing spectral broadening and

speckled waveform patterns. The most common site of pathology is femoropopliteal segment

- Involvement of femoropopliteal segment was mainly in the form of atheromatous plaque and raised intimomedial thickness, whereas the involvement of anterior and posterior tibial arteries was in the form of mural calcification type of plaque formation
- Most of the atheromatous plaques found were echogenic, showing moderate or severely increased echogenicity
- Duplex color Doppler sonography can accurately locate the site and extent of stenosis/occlusion
- Duplex sonography can be used to assess the peripheral arterial disease into hemodynamically non-significant and significant using PSV, PSV ratios, and spectral waveforms which will help in management
- Duplex Doppler imaging is safe, cost-effective, repeatable, non-invasive procedure for investigating lower limb arteries. Hence, it is the primary investigation of choice in all cases of lower extremity arterial disease
- Duplex sonography allows the evaluation and quantification of arterial disease
- Color Doppler study also helps in the follow-up of the arterial diseases.

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Original Article

Proximal Femoral Locking Compression Plating in Trochanteric and Subtrochanteric Fractures of Femur

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Abstract

Background: Intertrochanteric and subtrochanteric fractures are very common and difficult to treat specially the unstable types. Controversies still exist regarding the choice of implant for the fixation of these fractures. For the last 15 to 20 years different modifications of both the extramedullary and intramedullary devises have been done.

Objectives: Evaluation of results of intertrochanteric and subtrochanteric fractures fixed with proximal femoral locking compression plate.

Materials and Methods: In our study forty cases (26 males and 14 females) of intertrochanteric and subtrochanteric fractures were managed with proximal femoral locking compression plate. Among the forty patients 32 had intertrochanteric and eight had subtrochanteric fractures.

Results: Average time of union was 14.9 weeks (range 12-24 weeks); in 87.5% cases union occurred in12-16 weeks. Final results analyzed based on Modified Schantzker-Lambert score out of 40 cases, excellent to good results were found in 35 cases (87.5%) [excellent 57.5%, good 30%]. fair results were in 12.5%.

Conclusion: In view of the above observations, the proximal femoral locking compression plating may be suggested as one of the options for the treatment of intertrochanteric and subtrochanteric fractures of femur, specially the unstable type of fractures.

Key words: Intertrochanteric fracture, Proximal femoral locking plate, Subtrochanteric fracture

INTRODUCTION

Hip fractures are a leading cause of death and disability in the elderly. Epidemiological studies have suggested that the incidence of fractures of proximal femur is increasing, not unexpectedly, since the general life expectancy of the population has increased significantly during the past few decades. These fractures are associated with substantial morbidity and mortality; approximately 15–20% of patients die within 1 year of fracture.[1]

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Fractures of the proximal femur are relatively common injuries in adults, especially in the elderly. Approximately 50% of proximal femoral fractures are intertrochanteric fractures, a large percentage of which are unstable[2,3] and 5–11% are subtrochanteric fractures; they constitute about 73.3% and 26.7% of extracapsular proximal femur fracture, respectively.[4]

Intertrochanteric fractures of the femur readily unite no matter what treatment is used because most of it is the cancellous bone, have a good blood supply and covered by muscles. These fractures usually unite and satisfactory results obtained if reduction and fixation are adequate, otherwise complications are frequent especially in unstable type of fractures. If non-union occurs, it is always due to interposition of soft tissues. On the other hand, subtrochanteric fractures have long been recognized as the most difficult to treat[4] and remain technically challenging,

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even to experienced fracture surgeons till date. These fractures are associated with high rates of nonunion and implant failure because of the cortical bone and high stresses in this region.[5]

Stable trochanteric femur fractures can be treated successfully with conventional implants. However, comminuted and unstable inter- or subtrochanteric fractures and fractures with extension into the pyriform fossa are challenging injuries that are prone to complications.[6-8] Despite improved techniques and devices, failure of fixation is still a problem with unstable intertrochanteric and subtrochanteric fractures. A high incidence of secondary implant failure ranging between 3% and 17% has been reported.[9-14] The complication rate for unstable fractures treated with a dynamic hip screw, dynamic condylar screw plate or intramedullary nails has shown to be as high as 3–15%.[9-14] Ongoing efforts to find an acceptable implant have resulted in a wide variety of implants having some advantages and disadvantages. Many new devices, both extramedullary and intramedullary, had been introduced but still there is lack of a single implant of universal acceptance which can be used with confidence and full reliability.

In recent years, the minimally invasive surgical techniques have led to a wide spread use of many new implants which can reduce operative complications and post-operative morbidity.[9,15,16,17] The locking compression plates were introduced in the 21st century as a solution that allows angular-stable plating for the treatment of complex comminuted and osteoporotic fractures.[18-22] Despite promising results with the use of the locking compression plate for complex fractures in different anatomic regions, until recently locked plating had not been applied to treatment of unstable proximal femur fractures.

Extensive biomechanical studies have shown inferior stiffness and lower load to failure for extramedullary devices compared to intramedullary devices.[23] However, technical difficulties are common with the cephalomedullary nail because of the flexion, abduction, and external rotation of the proximal fragment in subtrochanteric fractures and comminution of the entry point in unstable trochanteric fractures. Traditional blade plate fixation is a suitable option for the subtrochanteric femur fracture. However, this technique demands expertise and allows a narrow margin of error, requiring precise plate placement in all planes.[24,25] Moreover, chances of failure are higher with extramedullary devices (sliding hip screw) especially in unstable, comminuted osteoporotic peri-trochanteric fracture.[26-29] To combat the technical difficulties of the nail and promising results with the use of the locking compression plate for complex fractures in different anatomic regions, recently locked plates are being used to treat extracapsular proximal femur (peri-trochanteric) fractures. The development of the LCP introduced a new treatment option for unstable and highly comminuted fractures and for periprosthetic fractures.[18,30-41]

MATERIALS AND METHODS

We have conducted a longitudinal observational study comprising 40 patients of 20 years and above from 2011 to 2015, all having closed intertrochanteric and subtrochanteric fractures, who were treated by internal fixation with proximal femoral locking plates. Patients who were having pathological fractures, open fractures, polytrauma, neglected fractures of more than 4 weeks old, fractures with neurovascular compromise, and unfit for anesthesia were excluded from our study.

Protocol

Patients were evaluated regarding preinjury mobility status on the basis of their ability to walk within their place of residence, their ability to walk outside, and their ability to go shopping and each activity was assigned a score on the basis of its level of difficulty. History of any other comorbid disease was obtained.

Each patient was thoroughly evaluated to rule out any associated intra-abdominal, intra-thoracic, head and neck injuries, and to rule out other associated osteoporosis related fractures such as a distal radius or proximal humeral fracture. The affected limb was thoroughly examined to rule out vascular or neurological insufficiency. The ipsilateral knee was examined for associated injury. Anteroposterior radiograph of pelvis showing both hips and lateral view of involved proximal femur obtained, though it was not always possible to take true lateral view preoperatively.

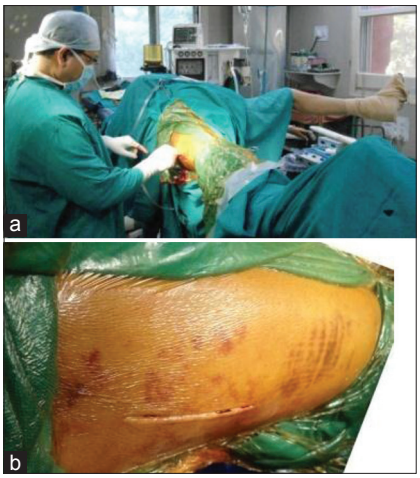


Figure 1: (a) Position in fracture table, (b) Drapping and skin incision

Figure 2: (a) Exposure and plate placement, (b) Provisional fixation with k-wires, (c) Closure

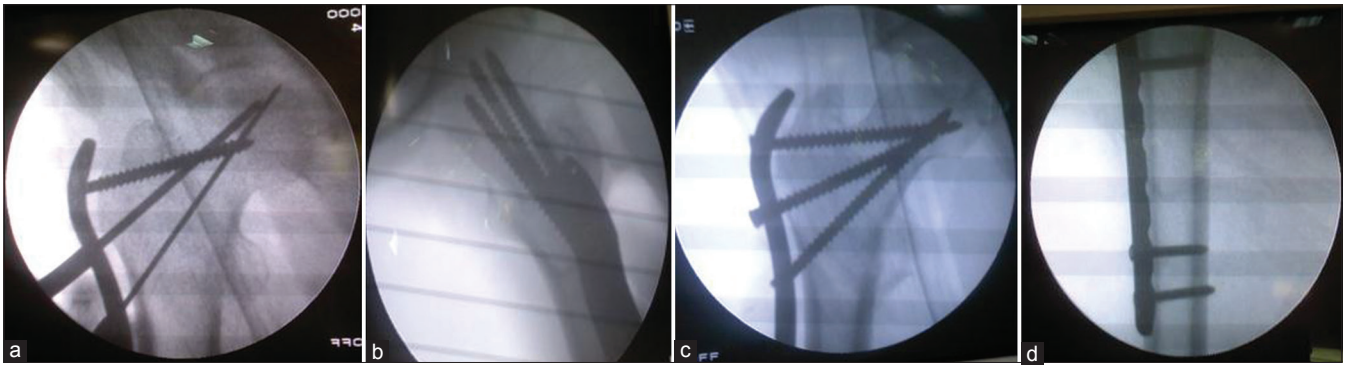


Figure 3: (a-d) Intraoperative C-arm picture AP and lateral view

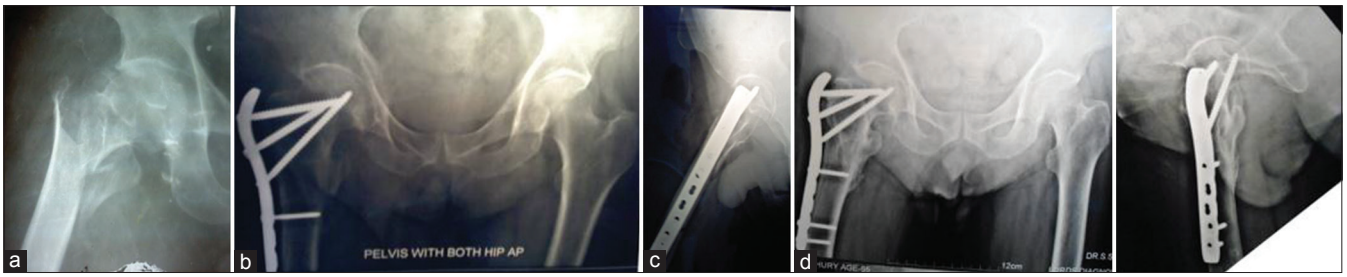


Figure 4: (a) Case 1 Pre-operative X-rayfig, (b) Immediate post-operative AP view, (c) Immediate post-operative lat view, (d) 3 months post-operative AP and lat view

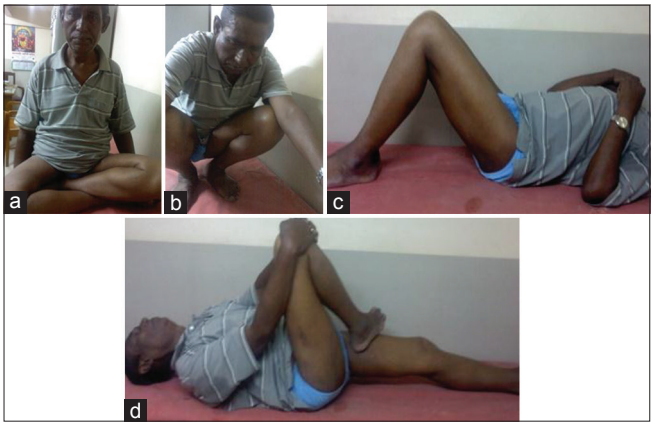


Figure 5: (a-d) Case 1 Clinical outcome at 3 months, (a) Cross legged sitting, (b) Squattingfig, (c) Hip knee flexon showing no shortening (d) Hip flexon

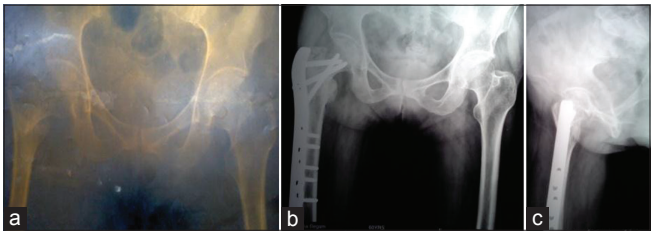


Figure 6: (a) Case 2 Pre-operative, (b) Case 2 Post-operative AP viewfig (c) Case 2 Post-operative lat view

Surgical Technique

In cases, where a closed reduction was successful and MIPO technique feasible, the proximal part of the femur was exposed through the conventional lateral approach [Figure 1a and b]. Perfect placement of the plate was ensured (special care was taken to avoid any off ending of the plate) in both the anteroposterior and lateral views. The plate was temporarily held in this position with K-wires, one in proximal and one in the distal small "K-wire holes" [Figure 2a-c]. After ensuring perfect anatomic placement of the plate, three 2.5-mm drill tip guidewires were inserted through locking sleeves within the three proximal holes at predetermined angles of 95°, 120°, and 135°, respectively,

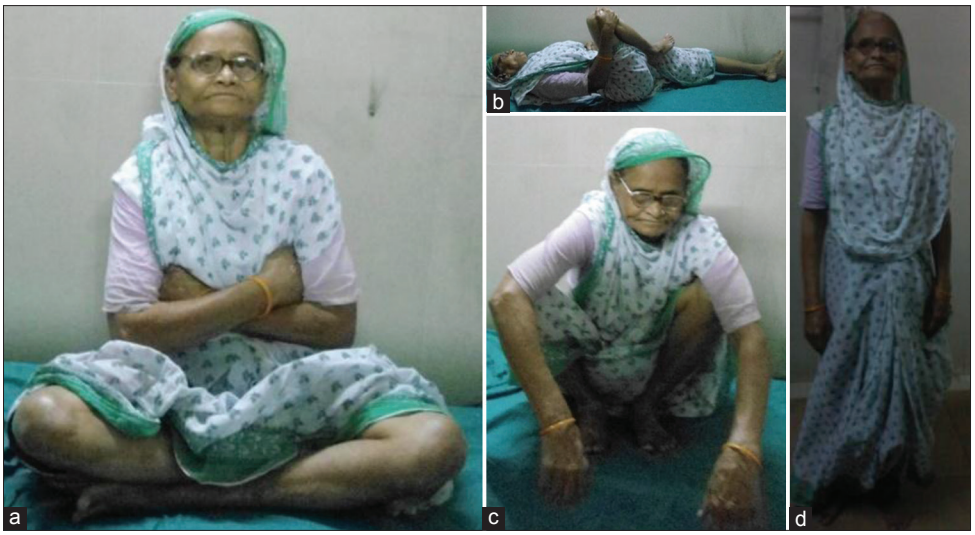


Figure 7: (a-d) Case 2 Clinical outcome at 3 months, (b) Hip flexon, (c) Squatting, (d) Standing

up to the subchondral bone, drilled appropriately, and followed by introduction of proximal locking head screws of appropriate length. Correct alignment of the plate with the femur, correct placement of drill bits, and screws were checked at all the steps. The plate was then distally fixed with an additional 3–4 bicortical locking screws (5 mm). All the K-wires were removed [Figure 3a-d].

For subtrochanteric fractures, where most difficulties are encountered to achieve and maintain the reduction, the plate was be used as a reduction device, by first fixing the proximal part of the plate to the proximal fragment, and then reducing the distal fragment to the plate. This manoeuver was possible due to the angle stabilized interface between the plate and the locking head screws in the proximal fragment.

The convergence of the three locking head screws in the AP plane and the divergence in the lateral plane allows an angular stable buttress that increases the stability of fracture fixation [Figure 3a-d].

In case of failed close reduction especially in unstable intertrochanteric and subtrochanteric fractures, open reduction of the same was done and supplementary iliac crest bone grafting done when there was bone loss. In metaphyseal comminution, at least 3–4 holes of the plate were left empty at the level of the fracture. This allows for a larger working length of the plate and larger area of stress distribution on the plate and simultaneously reducing the strain at the fracture.

Assessment

Pre-operative patient's demographic profile, pre-injury mobility, fracture pattern, bone quality and medical profile, and delay in operation were recorded. Intra-operative data such as type of reduction, quality of reduction, any difficulties or complication, blood loss, and time of operation were recorded. Post-operative medical complication, blood collection in drain, need for blood transfusion, infection, and post-operative hospital stay were recorded.

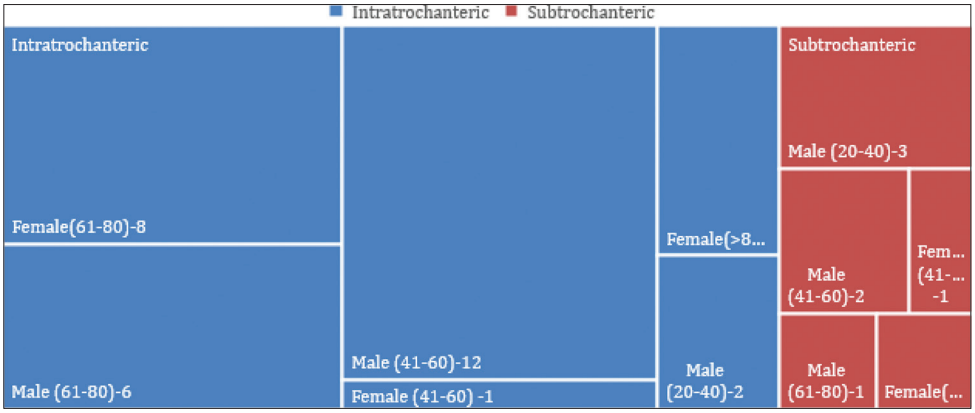
After discharge patients were assessed clinicoradiologically at 6th and 12th weeks, followed by monthly assessment till union of fracture. Then, they were asked to report every 3 months. In every follow-up visit patient was assessed for hip/thigh pain, walking ability, abnormal gait/limp (abductor lurch, and short limb gait), limb length discrepancy (shortening), any deformity, range of movement at hip and knee joint, and muscle strength. Radiographs were taken to assess union and residual angulation at fracture, change of neck shaft angle difference in respect to the normal side, hip joint congruency, and any evidence of implant failure [Figures 4-7].

Fracture union was defined as that period between injury and full weight bearing with a roentgenographical evidence of healing of fracture (characterized by ¾ cortical bridging and fading of fracture lines on two views) and absence of pain. Delayed union was considered present if roentgenographs did not demonstrate fracture consolidation by 9 months. Malunion was defined as limb shortening or lengthening greater than 1 cm, 10° angulation in any plane or rotational malignment greater than 15° and neck shaft angle difference of more than 5 degree.

RESULTS AND ANALYSIS

In our study, 53.13% of intertrochanteric fractures were in the age group of >60 years and 46.87% were < 60 years age. Average age was 66.41 years and male:female was (1.7:1).

Table: 1 Age and sex distribution



However, the ratio was (M: F= 1:1.84) in more than 60 years age group.

In our study, 75% of subtrochanteric fractures were in the age group of 60 years or less and average age was 49.89 years and male:female = 3:1. Taking both the intertrochanteric and subtrochanteric fractures together average age were 63.1 years (range 26–86 years) and male:female was 1.86:1. [Table 1].

In our study, 80% of the extracapsular proximal femoral fractures were intertrochanteric and 20% were subtrochanteric variety.

Average perioperative blood loss was 171.56 ml and 213.75 ml in intertrochanteric fractures and subtrochanteric fractures, respectively.

Average follow-up period was 10.78 months (minimum 6 months, and maximum 18 months). There was no loss of follow-up within 6th post-operative months, but seven cases (3 deaths, and 4 loss of f/u) were lost to follow-up after their 6th post-operative months.

Average time of union was 14.9 weeks and majority of the cases (87.5%) union occurred in 12–16 weeks**.** In intertrochanteric fractures, average tine of union was 14.4 weeks. In subtrochanteric fractures, average tine of union was 16.5 weeks [Table 2].

Significant shortening of more than 1 cm occurred in two (5%) cases.

Average neck shaft angle in the injured hip [in final X-ray of pelvis (AP)] was 131.2° [range 127°–137°].

Average neck shaft angle difference was (−1.25°). Excluding the two 10° varus malreduction, the neck shaft angle differences were in the range (−4°) to (+3°). There was no change of the neck shaft angle difference when the final X-rays were compared with the patients' immediate post-operative X-rays [Table 3].

Table 2: Time taken for union of fracture

Time taken for union of fracture	Intertrochanteric	Subtrochanteric	*P* value
≤16 weeks	13	4	
More than 16 weeks	19	4	
Total	32	8	

Table 3: Varus/valgus malreduction

Difference of neck shaft angle from opposite side	No.	Percentage
No change	7	17.5
0–5° varus	23	57.5
0–5° valgus	8	20
More than 5° varus or valgus angulation	2	5
Total	40	100

Table 4: Results of inter and subtrochanteric fractures

Inter trochanteric fractures			Sub trochanteric fractures		
Results	No.	Percentage	Results	No.	Percentage
Excellent	19	59.38	Excellent	4	50
Good	8	25	Good	4	50
Fair	5	15.62	Fair	0	0
Poor	0	0	Poor	0	0

Table 5: Overall results of extracapsular proximal femur fractures

Results	No.	Percentage
Excellent	23	57.5
Good	12	30
Fair	5	12.5
Poor	0	0
Total	40	100

All fractures united, though there were malunion in four cases (two cases of Varus and two cases of shortening >1 cm.)

In our study, excellent and good results were obtained in 87.5% of the cases [Tables 4 and 5].

DISCUSSION

The sliding hip screw is a tried and tested device for fixation of stable intertrochanteric fractures with excellent results reported.[42] However, the complication rate for unstable fractures treated with a dynamic hip screw or dynamic condylar screw plate has shown to be as high as 3–15%. Primary or secondary varus collapse and hardware failure by "cut-out" of the femoral head screw are the most frequently reported complications.[9,11,43] Jacobs *et al.*[26] have reported an average sliding of 5.3 mm in stable fractures and 15.7 mm in unstable fractures. Steinberg *et al.*[27] have reported an average sliding of 9.3 mm in his study and sliding more than 15 mm is associated with higher rate of fixation failure. Parkar *et al.*[28] have reported that medialization of the femoral shaft of greater than 1/3rd diameter of the femur is associated with 7 times increase in fixation failure.

The common causes of fixation failure are instability of the fractures, osteoporosis, lack of anatomical reduction, failure of the fixation device, and incorrect placement of the lag screw in femoral head.[44-47]

For example, when a fracture extends to the piriformis fossa or greater trochanter, intramedullary nails are unsuitable because it is difficult to achieve stable fixation of the proximal bony fragment. The surgical technique with the nails has been known to be demanding particularly for the less experienced surgeons with high intra-operative and post-operative complications.[48,49]

The development of the LCP introduced a new treatment option for unstable and highly comminuted fractures and for periprosthetic fractures.[18-22,30,31]

The PFLCP system is an extramedullary internal fixator which combines the advantages of both interlocked intramedullary nailing techniques and the early advances of the so-called biological plating technique into one system. Biomechanics are inherently different from conventional plating techniques since it does not rely on friction at the bone-plate interface for compression of the plate to bones unlike conventional plates and hence periosteal blood is not compressed and vascularity of the fracture is maintained. It acts as a stable fixed angle plate. Moreover, by supporting the lateral trochanteric wall especially in unstable trochanteric fracture it prevents significant fixation failure (22% fixation failure reported by Henrik *et al.*[29]). The PFLCP does not allow collapse at the fracture site (excessive collapse is a major cause of fixation failure in SHS) thus minimize the risk of implant failure.

The plate is anatomically precontoured to lateral wall of proximal femur. The contour of proximal femur in Indian population especially female patients was found to mismatch with that of the plate. In such cases, when the tip of the plate was flushed with the tip of greater trochanter, guidewire through 120° hole of the plate passed below the neck or along the inferior border of neck of the femur. In an attempt to put all the three head screws perfectly through neck into the head of femur, in some cases, especially in four-part intertrochanteric fractures having greater trochanteric fragment, the tip of the plate was shown to be higher up than the tip of the greater trochanter.

Hip and knee physiotherapy in bed started within 2–5 days toe-touch partial weight bearing with the help of a pair of axillary crutches or walker was started as per pain tolerance usually 2 weeks onward. Unsupported full weight bearing was allowed after clinic-radiological evidence of healing/union and absence of pain.

In our study, all fractures were united with an average duration of 14.9 weeks (range 12–24 weeks), majority of the cases (87.5%) union occurred in 12–16 weeks. In the Sodowski series[11] union occurred within 16 weeks in 36.84% and 60% cases, within 16–24 weeks in 15.78% and 25% cases, within 24–36 weeks in 10.52% and 10% cases, and nonunion in 36.84% and 5% cases of intertrochanteric and reverse oblique fractures treated with sliding hip screw and proximal femoral nail, respectively. There was no case of back out and breakage of head screw, head screw cut-out, hip joint penetration of screw, plate breakage, or shaft –screw back out/breakage. In the study of Boldin *et al.*[49] "Z" effect in PFN group and head screw cut out in DHS group were 5.45% and 3.63%, respectively. In our study, 57.5% excellent, 30% good, and 12.5% fair functional results were obtained based on Modified Schantzker-Lambert score. Overall, excellent and good results were obtained in 87.5% of the cases and they could achieve their pre-injury locomotor activity. The PFLCP we used did have some limitations (1) the plate was found not to be well fitted for all the patient, especially short height Indian females, (2) non-cannulated devices, head screws insertion were more time consuming, and (3) when using long plate, it was necessary to bend the distal portion to adapt the femur well.

We are also aware of some limitations of our study. The sample size was small. We had not compared the

results with the patients having similar fractures treated with alternative fixation during the same study periods. We had included the patients of wide age groups. No attempt had been made in our study to compare the results between young patients and the old patients and also results obtained in individual types of fractures because of short sample size. The longer-term outcome analysis is not there in our study. Additional prospective and randomized comparative studies are needed to fully describe the role of this method in the treatment of patients with trochanteric or subtrochanteric femoral fractures.

SUMMARY

In view of the above observations, the proximal femoral locking compression plating may be suggested as one of the options for the treatment of intertrochanteric and subtrochanteric fractures of femur, specially the unstable type of fractures, combining the benefits of intramedullary and angle stable implant but avoiding the complications of a surface implant.

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Original Article

Neonates Born to Mothers with SARS-CoV-2 Infection: A Prospective Observational Study

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Abstract

Objectives: To assess the clinical presentation and risk of mother-to-infant transmission of SARS-CoV2 in infants born to mothers with COVID-19 infection.

Design: Prospective observational study.

Setting: Tertiary care centre and a dedicated covid hospital in central India.

Participants: Infants born to mothers diagnosed to have COVID-19 at the time of delivery, born between 1 June and 25 September 2020.

Results: 40 infants were born to mothers with COVID-19 at the time of delivery. Three neonates tested positive for SARS-CoV2 after birth-one had mild respiratory symptoms and the other two infants remained well. A preterm baby who was negative for covid died due to extreme prematurity with sepsis (early onset) with respiratory failure on day 4 of life and another baby who was negative died due to Hypoxic ischaemic encephalopathy stage 3 with Meconium aspiration syndrome with respiratory failure. Remaining 38 neonates and their mother roomed in while in hospital and all were breast fed. None of the other neonates developed any significant health issues or developed symptoms attributable to SARS CoV2.

Conclusions: The risk of mother-to-infant transmission of SARS-CoV2, in the perinatal period is very low. Breast feeding and rooming in can be practiced safely with adequate infection control precautions with negligible clinical risk to the infant.

Key words: Breastfeeding, COVID19, Newborn

INTRODUCTION

The novel SARS-CoV-2 which leads to the clinical syndrome now labeled as COVID-19 was first detected in the Wuhan – Hubei Province of China in December 2019. Since then, it has spread across the world with the WHO declaring it as a global pandemic on March 11, 2020.[1] Knowledge about the epidemiology and clinical presentation of COVID-19 is rapidly evolving. Although the virus affects individuals across the age spectrum, it is becoming increasingly apparent that outcomes in adults are worse than in children.[2,3] The vast majority of subjects infected display only mild symptoms or remain asymptomatic.[4] Women are deemed to be in an immunocompromised state and data from previous coronavirus epidemics (SARS-CoV and MERS-CoV) have shown that they were at a high risk of morbidity and mortality.[5] The literature published so far on COVID-19, however, suggests that hospitalized pregnant women do not seem to be at a higher risk of adverse outcomes compared with hospitalized non-pregnant individuals.[6,7] The risk of vertical transmission to infants born to mothers with COVID-19 seems low.[7-11] In the few infants who tested positive following birth, it was not certain whether the transmission was vertical or postnatal and further, the majority of these infants had only mild-to-moderate disease.

Here, we present the short-term outcomes of infants born to mothers infected with SARS-CoV-2 and the safety of a policy of rooming in and breastfeeding such babies at our hospital.

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MATERIALS AND METHODS

All neonates born to mothers who tested positive for SARS-CoV-2 during pregnancy from June 1, 2020, to September 20, 2020, were eligible to be included in the study. SARS-CoV-2 virus was diagnosed by real-time reverse transcriptase PCR in nasopharyngeal swab taken up by an expert on day 2 of life or at admission for neonates referred from other centers as COVID suspect. Interpretation of the result was performed according to the manufacturer's recommendation. Once a negative result was obtained, babies were labeled as COVID negative and test was not repeated for asymptomatic neonates as per the institutional protocols. Neonates who were well enough to be cared on the postnatal ward were allowed to room in with their mothers except where mother or child was too critical and required admission in intensive care unit. Neonates who roomed in were allowed to breastfeed with adequate droplet and contact precautions in accordance with recommendations from professional bodies. This included caring for the infant in a separate baby cot which is placed at least 6 ft from the mother's bed, mother wearing a mask when in close proximity to the infant and performing hand hygiene with either soap and water or alcohol-based gel prior to handling the baby. No visitors apart from health personnel with appropriate personal protective equipment were permitted into the rooms while in hospital. The parents were advised to continue the same precautions at home after discharge till the mother was considered negative for COVID-19 and had been in isolation for 14 days.

Data Collection and Analyses

The baseline characteristics (age at admission, sex, birth weight, and gestational age), clinical details which included term/preterm, clinical diagnosis (transient tachypnea of newborn), hypoxic ischemic encephalopathy Stage 3, meconium aspiration syndrome, hypoglycemia, sepsis (early onset), roomed in with mother in hospital, breastfed at the time of discharge, and results of COVID-19 screening were collected from the patient record. Informed consent was obtained from the parents for inclusion in the study. Data were collected on an electronic database and analyzed.

Table 1: Baseline characteristics

Baseline characteristics	Median (range)* Number (percentage)†
Day of admission	4 days (1 PND-22 days)
Birth weight in grams	2508 (1200–3600)*
Gestation (weeks)	38 weeks (28–42)*
Normal vaginal delivery	18 (45%)
Cesarean section	22 (55%)
Male:female	1.2:1 (22 M 18F)
Full term (AFD)	36 (90%)
Full term (SFD)	3 (7.5%)†
Preterm (SFD)	1 (2.5%)†

RESULTS

A total of 40 neonates born to COVID-positive mothers were included in the study period of June 1–September 25. The baseline characteristics are summarized in Table 1.

Out of the 40 neonates as summarized in Table 2, 7 were admitted to intensive care unit – most of these 5 (12.5%) for transient tachypnea and/or prematurity (2.5%). There were 2 (5%) deaths out of total 40 neonates born to COVID-positive mother till 25 of September both were negative for COVID (A preterm baby died due to extreme prematurity with sepsis (early onset) with respiratory failure on day 4 of life and another baby died due to hypoxic ischemic encephalopathy Stage 3 with meconium aspiration syndrome with respiratory failure. Thirty-eight of the 35 infants (95%) received breast milk either directly if rooming in with mother or through expressed breast milk if admitted to NICU. At the time of writing the report, the discharge outcomes of 24 neonates were known while 8 infants are still in the hospital.

Three neonates tested positive [Table 3] for SARS-CoV-2, out of these 3 the first one who was born through LSCS admitted for mid cough and fever on day 20 of life and a history of contact with COVID-positive mother after almost 15 days of her delivery came positive for COVID-19, received supportive treatment, and discharged successfully on day 10 of isolation in stable condition, and other two came positive for COVID-19 on day 3 and day 10 of life both were asymptomatic discharged successfully after 10 days of isolation.

Table 2: Indication for admission in HDU

Indication for admission in HDU (isolation ward)	Number (percentage)
Indication for admission in HDU	
Prematurity	1 (2.5)†
Transient tachypnea of newborn	5 (12.5)†
Hypoxic ischemic encephalopathy stage 3	1 (2.5)†
Meconium aspiration syndrome	1 (2.5)
Hypoglycemia	2 (5)†
Sepsis (early onset)	2 (5)

†Number (percentage)

Table 3: Short-term outcome of neonates

Neonates positive for RT-PCR	3 (7.5)
Roomed in and breastfed with mother‡	38 (95)
Discharged	28 (70)
Still admitted	10 (25)
Mortality	2 (5)
HIE stage 3 meconium aspiration syndrome	1 (2.5)
Extreme prematurity with NEC Stage 3 with septic shock	1 (2.5)

DISCUSSION

Despite initial concern that pregnant women and the newborn may be high-risk groups compared with the general population based on outbreaks of other coronavirus diseases in the past, it has become increasingly clear that this is not the case with the SARS-CoV-2 pandemic.[6-11] The risk of vertical transmission of the virus from mother to infant before or during delivery has been shown to be low.[7-12] This has been confirmed based on virus testing and clinical features in our cohort, with the estimated risk being only 7.5% (3/35). This figure seems to be similar to previously published data.[6,9,13] The low risk of vertical transmission has been hypothesized to be due to paucity of ACE2 receptors in the placenta which may be necessary for transplacental transfer to the fetus.[9] Regardless of the above, it would appear from our series that the short-term clinical risks to the infant from maternal COVID-19 at the time of delivery are minimal. Due to the uncertainty surrounding the outcomes of mothers affected by COVID-19 and their infants, recommendations on the postnatal management of the mother-infant dyad from professional bodies have been inconsistent.[12,14-17] Some guidelines advocate caring for the affected mothers and their infants in separate rooms when feasible to reduce the risk of mother-infant transmission postnatally and also recommend avoiding direct breastfeeding while mother is still infected, unless mother expresses her wish to directly breastfeed.[16,17] At our hospital, we found that the benefits of both rooming in and breastfeeding with good infection control precautions, for mother-infant bonding and long-term breastfeeding far outweighed the small risk of mother-infant transmission. Thus, we strongly recommended rooming in and direct breastfeeding for all well mother-infant dyads while in hospital as well as after discharge. Our study has validated this approach with no clinically or laboratory-proven mother to infant transmission of the virus during the hospital stay, even with a very high rate of breastfeeding in the discharged infants.

To the best of our knowledge, this study is the single largest series on the outcomes of infants born to mothers with COVID-19 with follow-up of their health status post-discharge. However, our study has limitations. The diagnosis of COVID-19 and virus carriage was based on NP swabs. Although the absolute sensitivity of detecting SARS-CoV2 with NP swabs is unknown, the modality is only around 70% sensitive for diagnosing respiratory viral infections.[18] The universally good clinical outcomes in all the infants are nevertheless encouraging. The follow-up of infants was conducted by telephonic interview of the parents. There is a chance that asymptomatic and mildly symptomatic infants infected with the virus may have been missed in the absence of testing, although we would suggest that this is of limited clinical significance.

CONCLUSION

The risk of mother-to-infant transmission of SARS-CoV-2, in the perinatal period, is very low. Breastfeeding and rooming in can be practiced safely with adequate infection control precautions. The risk of adverse outcome to infants born to mothers who have SARS-CoV-2 infection at birth is minimal aside from the risk of premature delivery due to iatrogenic/maternal causes. However, there are no published long-term outcome data on these infants and further follow-up studies will be needed to fully ascertain adverse outcomes in this group of infants.

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Original Article

Double-blind Randomized Control Study to Compare the Efficacy of Incisional 0.25% Bupivacaine versus both Intraperitoneal and Incisional 0.25% Bupivacaine for Post-operative Pain Relief and Effect on Recovery after Laparoscopic Cholecystectomy

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ABSTRACT

Objective: The objective of the study was to (1) compare the efficacy of incisional 0.25% bupivacaine versus both intraperitoneal and incisional 0.25% bupivacaine for post-operative pain relief after laparoscopic cholecystectomy and (2) compare the effect on recovery to normal activity and feeling of well-being.

Materials and Methods: This is a prospective, double-blind, randomized control study of 60 cases. Sixty patients were divided into group intraincisional (IC) 4–5 ml of 0.25% bupivacaine was infiltrated at each trocar insertion site and group (ICP) patients received intraperitoneal instillation of 20 ml of 0.25% bupivacaine along with 4–5 ml of 0.25% bupivacaine at each trocar insertion site. Patients were evaluated for visual analog score (VAS), immediately after extubation and at 1, 2, 4, 6, 12, 24, and 48 h postoperatively. Feeling of well-being (FOB) was assessed using an ordinal one-5 scale for 5 days postoperatively. All statistical analyses were performed using SPSS version 21 for Windows® 10.0. The Chi-square ($\chi 2$) test and Student's *t* test were used.

Results: VAS scores are significantly less at one (4.13 vs. 1.43), 2 (3.23 vs. 2.47), and 4 (3.33 vs. 2.80) h in group ICP as compared with group IC. Recovery room stay in ICP is significantly less, that is, 21.3 min vs. 29.9 min. Post-operative day one in group ICP FOB is significantly better (1.87 ± 0.881 vs. 2.6 ± 0.621, $P < 0.001$).

Conclusion: A combination of intraperitoneal and incisional bupivacaine at the end of the LC results in better pain relief, shorter stay in the recovery room, decreased cumulative analgesic consumption, and decreased incidence of PONV. This also fastens recovery and improves patient's sense of well-being.

Key words: Bupivacaine, Intraperitoneal instillation, Laparoscopic cholecystectomy, Post-operative pain, Recovery

INTRODUCTION

Post-operative pain is still the most important independent factor affecting patient's recovery after laparoscopic cholecystectomy.[1] It is one of the most common reasons for re-admission after daycare laparoscopic cholecystectomy.

Local anesthetic infiltration and intraperitoneal instillation are commonly used techniques of pain relief. Their effectiveness in reducing post-operative pain is well established, but their effect on recovery after surgery is not fully evaluated.[2,3] This study compares the efficacy of a combination of intraperitoneal and incisional 0.25% bupivacaine versus incisional 0.25% bupivacaine in reducing post-operative pain, improving sense of well-being, and fastening recovery.

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MATERIALS AND METHODS

This is a prospective randomized study of sixty cases conducted from August 2016 to July 2017. Institutional Ethics approval was taken. Informed consent was secured from patients who fulfilled the inclusion criteria. The inclusion criteria were age between 18 and 65 years, ASA I-II patients and patients in which laparoscopic cholecystectomy was done using three-four ports. Patients were recruited from the general surgery and surgical gastroenterology department. We excluded patients with a history of allergic reactions to local anesthetic drugs, pregnant and lactating mothers, acute pancreatitis or cholecystitis (<6 weeks), any past or present history of chronic pain treatment, history of alcohol addiction or drug addiction, extreme overweight (BMI > 35), cognitive impairment or communication problems, and patient with h/o psychiatric illness.

Sample size calculation was done on the basis of VAS scores of 4, 8, 12, and 24 h postoperatively, we calculated that minimum 23 patients are needed in each group to obtain 5% type one error and an 80% power. The sample size for VAS scores (1) 4, 8, 12, and 24 h calculated separately highest was 23. It was calculated with the help of OpenEpi, Version three. Considering dropout rate of 15% sample size taken as 30.

Patients were divided randomly into two groups using computer generated random number table. Group (IC) patients received post-procedure 4–5 ml of 0.25% bupivacaine at each site of trocar insertion with a 23G needle and intraperitoneal instillation of 20 ml of 0.9% normal saline. Group (ICP) patients received both intraperitoneal instillation of 20 ml of 0.25% bupivacaine and 4–5 ml of 0.25% bupivacaine at each site of trocar insertion with a 23G needle.

Preoperatively, these participants were given an explanation of the visual analog scale (VAS) and ordinal scale of feeling of well-being which was used postoperatively.

The operating room (OR) nurse staff not involved in the study opened the sealed opaque envelope and followed instructions for the solution preparation. Intravenous access was taken after applying non-invasive monitoring using a continuous electrocardiogram (ECG), pulse-oximetry (SpO_2), end-tidal CO_2, and non-invasive systolic and diastolic blood pressure monitoring (NIBP) including mean arterial pressure (MAP). All parameters were monitored at five minutes interval. General anesthesia was given by standard technique using intravenous (IV) fentanyl 2 μg kg^{-1} as analgesic, midazolam 0.03 mg kg^{-1} as sedative, induction agent propofol 2 mg kg^{-1}, and muscle relaxant vecuronium 0.1 mg kg^{-1}. Anesthesia was maintained with MAC one sevoflurane in oxygen:nitrous oxide mixture (50:50) and intermittent vecuronium boluses.

Maximum allowable dose of bupivacaine was a maximum dose of 2 mg kg^{-1} in all groups. All patients received IV paracetamol 15 mg kg^{-1} intraoperatively. This study was double-blind as a patient were not aware of group and one research staff (accessor) blinded to the details of the study was scheduled to collect the post-operative data. Patients were evaluated using VAS, immediately after extubation and at 1, 2, 4, 6, 12, 24, and 48 h postoperatively. Incidence of nausea, vomiting in 24 h post-operative period was noted. Feeling of well-being (FOB) was assessed using an ordinal one-5 scale (one-feeling sick, two-not so good, three-Okay, four-fine but not normal, and five-feeling normal) from day one till 5 days postoperatively. The number of patients requiring post-operative analgesia was noted. Rescue analgesic used was IV diclofenac 75 mg for patients demanding post-operative analgesia if VAS was more than four. Not more than three doses of IV diclofenac were given in 24 h and it was not repeated for 6 h. If laparoscopic cholecystectomy gets converted to open cholecystectomy by surgeon or surgical complications like major bleeding or rupture of gall bladder intraoperatively, the patient will be withdrawn from the study.

If there was no relief after IV diclofenac 75 mg, then opioids were given for pain relief and patients have been excluded from study statistics.

Following parameters such as time of discharge (days), duration of surgery – (in minutes), duration stay in recovery room – (in minutes), time to resume walking around without support after surgery (hours), and doing daily routine activities without help (like going to toilet, dressing up in days) were also noted during the study.

Statistical Analysis

All statistical analyses were performed using SPSS version 21 for Windows® 10.0. The Chi-square (χ^2) test was used to compare proportions (No. of patients requiring post-operative analgesic drug). Student's *t* test was used to compare the mean VAS score and FOB score. Results were given as percentages or mean ± SD where appropriate. $P < 0.05$ was considered statistically significant.

RESULTS

All 60 patients successfully completed the study. The mean age of patients in IC was 40.5 ± 13.505 and ICP was 43.6 ± 11.566 in both the groups, there is female predominance (M:F 2.3:2.8). Duration of surgery (min)

was comparable in both groups (IC 83.07 ± 13.759, ICP 80.70 ± 15.139; $P = 0.529$)

VAS score has been calculated at the end of 1, 2, 4, 6, 12, 24, and 48 h. The mean of these scores is calculated for these scores in each group. The "*P*" value is also calculated for each reading in both the group. There are VAS scores significantly less at 1, 2, and 4 h in group ICP as compared with group IC [Table 1]. The rescue was required in only five (16.7%) patients in the ICP, whereas 17 (56.7%) patients required rescue analgesic in only IC group. This difference is significant as $P < 0.05$.

On day one, there was a significant difference in FOB score [Table 2]. The score was significantly better in ICP group. The second day even though the score was still better in ICP group, difference did not reach the level of significance. Day three onward score in both the groups was found to be comparable to each other.

Only nine (30%) patients had nausea in ICP group as against 13 (43.3%) in IC group. Only one (3.3%) patients had vomiting in ICP group as against 04 (13.3%) in IC group. In both, the groups mean duration of surgery is almost same, that is, 83 and 80.7 min. $P = 0.52$ is not significant.

While comparing duration in the recovery room (RR), the mean time taken by patients in ICP is significantly less, that is, 21.3 min as against to 29.9 min in the other group [Table 3] *P*-value (0.001). The mean time taken by patients to walk without support in the ICP group was 9.7 h, whereas in other groups, it was 14.5 h. This difference is significant as $P = 0.01$. The mean time taken by patients for starting daily routine activities in the ICP group was 2.2 days, whereas in other groups, it was 2.4 days. This difference is not significant as $P = 0.053$. The mean time taken to discharge the patients in ICP group was 2.1 days, whereas in other groups, it was 2.27 days. This difference is not significant as $P = 0.098$.

DISCUSSION

Age and sex in both groups were comparable. However, in our study there was female preponderance, F:M was 2.5:1. It could be because of cholelithiasis being more common in females.

Table 1: VAS score at various interval postoperatively

VAS score interval postop (h)	Intra-incisional		Intra-incisional + Intra-peritoneal		*P* value
	Mean and confidence interval	Standard deviation	Mean and confidence interval	Standard deviation	
1	4.13(1.53–6.7)	1.279	1.43 (−0.6–3.43)	1.040	<0.001
2	3.23(2–4.5)	0.626	2.47 (0.93–4)	0.776	<0.001
4	3.33 (2.2–4.4)	0.547	2.80 (1.8–3.8)	0.484	<0.001
6	4.10 (1.8–6.5)	1.185	3.37 (1.1–5.6)	1.129	0.015
12	3.07 (0.73–5.4)	1.172	2.70 (0.9–4.5)	0.915	0.171
24	2.13 (3.7–0.6)	0.776	1.73 (0.8–2.6)	0.450	0.028
48	1.00 (0.1–1.9)	0.455	1.10 (0–2.2)	0.548	0.433

Table 2: Comparison of feeling of well-being scores postoperatively

Day	Intra-incisional		Intra-incisional + Intra-peritoneal		*P* value
	Mean (confidence interval)	Std deviation	Mean (confidence interval)	Std deviation	
1	1.87 (0.11–3.63)	0.881	2.6 (1.35–3.8)	0.621	<0.001
2	2.87 (4–1.73)	0.571	3.17 (1.9–4.5)	0.648	0.062
3	3.63 (2.6–4.6)	0.490	3.73 (2.8–4.6)	0.450	0.414
4	4.07 (2.9–5.23)	0.583	4.0 (2.9–5.1)	0.55	0.999
5	4.77 (3.9–5.6)	0.430	4.83 (5.56–4.0)	0.379	0.527

Table 3: Comparison of recovery parameters

Parameter	Intra-incisional		Intra-incisional + Intra-peritoneal		*P* value
	Mean (confidence interval)	Standard deviation	Mean (confidence interval)	Standard deviation	
Recovery room stay (min)	29.90 (19.7–40.3)	5.189	21.37 (15–27.4)	3.011	0.001
Walking without support (h)	14.57 (7–22.2)	3.794	9.73 (4.7–14.7)	2.504	0.01
Daily routine activities (days)	2.43 (1.4–3.4)	0.504	2.20 (1.4–3)	0.407	0.053
Time to discharge (days)	2.27 (1.37–3.17)	0.450	2.10 (1.5–2.7)	0.305	0.098

We used both instillation and infiltration at the end of surgery. There is collective evidence which suggests that intraperitoneal instillation[4,5] and incisional infiltration[6-8] of local anesthetic at the end of laparoscopic cholecystectomy have better pain relief than at the beginning of surgery.

Etiology of pain after laparoscopic cholecystectomy is multifactorial. Incisional pain, visceral pain, and shoulder tip pain are the various components which have been hypothesized. Few studies state that incisional pain is the most predominant type[9,10] while there are others who believe the shoulder tip is most predominant.[11] Various methods for pain relief have been used for post-operative pain in laparoscopy. Efficacy of intraperitoneal bupivacaine instillation in reducing post-laparoscopic cholecystectomy intra-abdominal pain has been well-established. It has been proposed that intra-abdominal pain after laparoscopic cholecystectomy is caused by the formation of carbonic acid, especially in the subdiaphragmatic area and irritation of the peritoneum due to carboperitoneum.[12] Intraperitoneal instillation of bupivacaine relieves this pain and acts also on the raw area in gall bladder bed. VAS scores of in-group IC for 1st 8 h are significantly more than group ICP which suggests that intraperitoneal bupivacaine reduces the visceral component of post-operative pain significantly. Studies suggest that pain after laparoscopic cholecystectomy peaks around 4–8 h.[12,13] VAS score after 12 h postoperatively was comparable in both the groups. Rescue analgesia requirement was significantly more in group IC. It was maximum in the first 6–7 h postoperatively, coinciding with previous study findings suggesting pain intensity maximum during 4–8 h postoperatively. No side effects or adverse events related to intraperitoneal or intraincisional bupivacaine were noted during this study. By reducing the requirement of rescue analgesia, it further decreases the risk of side effects associated with them. The duration of surgery in our study is group IC and group ICP is 83.07 (13.76) and 80.70 (15.12), respectively. This is significantly longer compared to other studies.[14] Reason behind this finding is our hospital being a state-run teaching hospital with surgeons of varied of the degree of experience in performing laparoscopic cholecystectomy.

In our study, stay in the recovery room in group IC and group ICP is 29.90 (5.12) and 21.37(3.01), respectively, which are comparable to a similar study using ropivacaine.[15] Stay in the recovery room was significantly shorter in group ICP because of better pain relief and lesser incidence of nausea, vomiting.

In our study, we assessed walking without support as a measure of recovery because it reduces the need of attendant and also eases the attendant's burden. This has a huge psychosocial impact on patient's recovery and well-being. Group ICP showed significantly less time to resume walking around without support as compared to group IC. This difference of around 4–5 h is of great financial importance in private hospitals. This can be attributed to better pain relief, less nausea, and vomiting which fastened patient's recovery. Pain is a very important factor affecting patient's sense of well-being and post-operative recovery.[14] Multimodal analgesia is known to result in better pain relief postoperatively,[16] facilitate early recovery, discharge, and early resumption of daily activities;[11,17] earlier resumption of walking around without support, better pain relief, and lesser nausea improve patient's confidence and sense of well-being in the early post-operative period. In our study, on day 1, the sense of well-being was significantly better in group ICP, on day 2, the difference did not reach the level of significance, while day 3–5 were comparable. Pain aggravates nausea and vomiting through neurohormonal mechanisms. It also increases nausea due to the increased consumption of opioids.[11] This explains the significantly more incidence of nausea and vomiting in group IC. There is enough evidence to support that laparoscopic cholecystectomy can be performed as daycare surgery.[18-24] But in a developing country like India patient prefers to stay overnight after surgery. This could be because of psychosocial factors or infrastructure available.[25] In our study, the duration of hospital stay was similar in both the groups. The reason behind this finding is our hospital is a government-run hospital and in our hospital discharge is governed by surgical unit protocol.

Limitation

In our study, we have excluded cases which had surgical complications such as major bleeding or rupture of gall bladder intraoperatively to avoid bias, so the efficacy of a combination of intraperitoneal and incisional bupivacaine needs to be further explored in these scenarios.

CONCLUSION

A combination of intraperitoneal and incisional bupivacaine at the end of the LC results in better pain relief, shorter stay in the recovery room, decreased cumulative analgesic consumption, and decreased incidence of PONV. This also fastens recovery and improves patient's sense of well-being.

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Original Article

Impact of Prenatal and Post Natal Factors on the Eruption Time of First Primary Tooth among Healthy Infants in Kottayam, Kerala – A Longitudinal Study

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ABSTRACT

Introduction: Eruption of primary teeth is an orderly, sequential, and age-specific event. A wide range of variation is seen in eruption time as a part of human evolutionary changes in different populations and geographic areas. Although this variation is strongly controlled by genes, certain environmental factors also play a significant role in it.

Purpose: The standards for tooth eruption time and pattern derived from one group of children of different genetic pools and environmental conditions cannot be extrapolated to another group residing at other geographic locations. Hence, the present study was carried out to find the impact of certain pre-natal and post-natal factors on the first tooth eruption time in the Kerala population.

Methods: This prospective study was carried out among 250 healthy infants of 3-month-old who were randomly selected from the vaccination center. Pre-natal factors (socioeconomic status, maternal age, gestational age, and self-reported maternal systemic diseases) and post-natal factors (gender of child, birth weight, feeding practice, use of pacifiers, milestones of developments, and history of oral intubation) were collected by questionnaire. Children were followed up in 6, 9, 12, and 15 months until the first primary tooth eruption. Statistical analysis was done by Pearson's correlation, *t*-test, ANOVA, and multivariate linear regression.

Results: The mean age of first tooth eruption was found to be 10.28 ± 2.627 months. Bivariate analysis showed maternal age, gestational age, and self-reported maternal systemic disease, birth weight, feeding practice, and history of oral intubation had a statistically significant association with eruption time. On multivariate linear regression analysis, maternal, gestational age, birth weight, and history of oral intubation were found to be a good predictor of time of tooth eruption. The first erupted tooth for a greater proportion of children was lower central incisors (80%).

Conclusion: There was a significant delay in primary tooth eruption. Maternal age, gestational age, birth weight, and history of oral intubation was found to be a good predictor of time of tooth eruption.

Keywords: Delayed eruption, Eruption time, First primary tooth, Pre-natal, Post-natal

INTRODUCTION

Deciduous teeth are important biological markers of maturity and they play a significant role in dentomaxillofacial complex.[1] Tooth eruption is a natural physiologic process involving the interplay of regulating genes and a series of interactions between the cells of dental follicles and alveolus.[2] It is an orderly, sequential, and age-specific event. Dental age is utilized in various studies of the relationship between dental and skeletal maturation rates for anthropological as well as clinical use in dentistry. Developmental norms of the emergence of teeth are important for child health care planning and for accurate diagnosis of local and systemic growth disturbances, preventive dentistry procedures, archaeological, anthropological, and paleontological studies and may have

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legal as well as forensic applications.[3] Alteration in tooth eruption trend cause suspicion of underlying systemic disease[4] which evoke parental anxiety which leads to futile laboratory investigations as well as radiographs. Late eruption may cause nutritional problem,[5] malocclusion, and crowding which can cause poor oral health.[6]

Human dentition has undergone several evolutionary changes and children are maturing earlier than they did at the beginning of this century.[7,8] It is reported that a wide variation is seen in the eruption time in the present generation.[9,10] Several variables are thought to be influencing the eruption time such as race, gender, ethnicity,[11] genetic factor,[5] nutritional status,[5] socioeconomic status,[12] feeding practice,[13] gestational age,[14] birth weight,[14] post-natal growth,[15] obesity,[15] and head circumference.[16] Many studies were focused to find the eruption time and factors associated to it in various populations and geographic locations. The standards for tooth eruption time and pattern derived from one group of children of different genetic pools and environmental conditions cannot be extrapolated to another group residing at other geographic locations. Hence, the present study was carried out to find the impact of certain pre-natal and post-natal factors on the first tooth eruption time in the Kerala population.

MATERIALS AND METHODS

This longitudinal study was conducted among 3-month-old infants with their mothers who attended the Vaccination Centre at Government Medical College, Kottayam, from November 2018 to November 2019. The study protocol was approved by the Institutional Ethical Committee. Informed consent was taken from all parents of children who were participating in the study in their preferred language either in Malayalam or English. The study participants were selected by a random sampling method from the vaccination clinic which was accessed by a wide range of people seeking treatment from a rural and urban area with different cultural backgrounds and having low and high socioeconomic levels. The minimum sample size was 172. The sample number was increased up to 250 to compensate for missing cases and dropouts. The selected children were planned to examine on subsequent visits to find out the primary tooth eruption time in each subject. Hence, we adopted a longitudinal study design. Three-month-old infants who were natives, without any systemic disease, were included in this study. Infants with congenital birth defects, chronic illness, and with natal or neonatal teeth and mothers who were not willing to participate in this study were excluded from the study.

Data Collection

A semi-structured questionnaire was developed and validated based on the factors influencing first tooth eruption according to previous study reports. The questionnaire contained demographic data collection followed by pre-natal and post-natal variables which may influence the eruption time of first primary tooth in infants. Self-reported socioeconomic status was recorded by the Kuppuswamy scale based on the modification 2019. Pre-natal factors considered in this study were socioeconomic status, maternal age, gestational age (<37 weeks and more than 37 weeks), and self-reported maternal systemic diseases (none, nutritional, endocrine, and others). Post-natal factors such as gender of child, birth weight (less than 2.5 kg, 2.5–3.5 kg and more than 3.5 kg), feeding practice up to 6 months (breastfeeding, bottle feeding, and combination) use of pacifiers, milestones of developments, and history of oral intubation were also recorded by interviewing mother. Data were also collected and verified from children's health records which mothers bring during their routine vaccination.

Parents were instructed to examine children's mouth frequently. A pictorial tooth eruption record chart was given and parents were asked to mark the date on which the edge of tooth was seen on gums. Eruption of teeth was defined as any tooth with any part of its crown penetrating the gingiva and visible in the oral cavity. Recording of parents was checked for accuracy by clinical examination in the next follow-up visit. The child was made to sit on mothers lap and tooth eruption was checked in daylight by the investigator in the vaccination clinic. Site of tooth erupted first, either in the maxillary or mandibular arch, was also recorded. Children were followed up in 6, 9, 12, and 15 months until the eruption of the first primary tooth. On each visit, oral health instructions were given to mothers along with oral hygiene demonstration.

Statistical Analysis

Data obtained were coded, entered in, and analyzed using IBM SPSS version25. Frequency distribution of pre-natal and post-natal factors was explained by descriptive analysis. Considering bivariate analysis, the association between eruption time with categorical pre-natal and post-natal variables were analyzed using independent *t*-test and ANOVA. *Post hoc* Tukey test was used to assess the significance of the difference between the risk factors and eruption time. Pearson's correlation test was used to explore the correlation between the age of the mother and first tooth eruption time. Multivariate linear regression model was employed to determine the significant predictors linked to the eruption time of the first tooth. The minimum significant level adopted was 5% (0.05).

RESULTS

The study participants comprised 250 healthy children of 3-month-old who were reported for routine vaccination. The mean age of mothers of the participants included in the study was 28.68 ± 5.650 years. There was the statistical significance of the correlation between age of the mother and the age of eruption of the first tooth (Pearson's correlation, $r = 0.777$) [Table 1]. There was no significant association between socioeconomic status and eruption time ($P = 0.693$). Among study participants, 45.6% had gestational age <37 weeks and 54.4% reported more than 37 weeks. The mean eruption time (MET) of the first tooth was found to higher (12.65 ± 1.563) among the children with <37 weeks of gestation when compared to those with more than 37 weeks of gestational age (8.29 ± 1.393) which was significant ($P = 0.000$). When the self-reported maternal systemic disease was taken into account, 37.6% mothers reported themselves to have nutritional disorders during pregnancy. Endocrine problems and other diseases were 31.2% and 15.6%, respectively. About 15.6% mothers were free from any illness and MET was 8.28 ± 1.905 in their children. MET was more in children with mothers having an endocrine problem (11.03 ± 2.711). In the case of nutritional problems, MET was 10.54 ± 2.500 and in other diseases (10.13 ± 2.441). There was statistically significant association between systemic disease of mothers and eruption time of first tooth ($P = 0.000$). Among pre-natal factors, maternal age, gestational age, and self-reported maternal systemic disease showed statistically significant association with mean eruption time of the first tooth in children on bivariate analysis [Table 2] and [Table 3].

Table 1: Correlation values between maternal age and first tooth eruption time

		Age of mother	Time of first tooth eruption
Age of mother	Pearson correlation	1	0.777
	Sig. (2-tailed)		0.000*
	N	250	250
Time of first tooth eruption	Pearson correlation	0.777	1
	Sig. (2-tailed)	0.000*	
	N	250	250

r=0.777. *Significance

The current sample consists of 49.2% boys and 50.8% which demonstrate almost equal gender distribution. There was no significant difference ($P = 0.473$) in MET between boys (10.15 ± 2.580) and girls (10.39 ± 2.676). About 34.4% children included in the study weighed above 3.5 kg at birth and 27.6% were having 2.5 kg to 3.5 kg at birth. About 38.4% were reported birth weight <2.5 kg. MET was found to be highest for participants with birth weight between <2.5 kg (12.84 ± 1.510) followed by weight between 2.5 and 3.5 kg (9.32 ± 1.867) and the lowest for birth weight above 3.5 kg (8.15 ± 1.484). Weight at birth was found to be significantly associated with the mean eruption age of first tooth ($P = 0.000$). When the association between feeding practice up to 6 months and eruption time are considered, statistically significant result was obtained ($P = 0.004$). Different feeding practices such as breastfeeding, bottle feeding, combinations were considered. A greater proportion of the children included in the study was practiced exclusive breastfeeding (75.2%) and MET was 9.96 ± 2.536. Only 2.8% children were bottle-fed (MET 11.43 ± 2.299) and combination feeding was practiced by 22.0% (MET 11.20 ± 2.751). The participants were almost equally distributed in terms of their use of pacifiers (50.4% and non-user 49.6%) and there was no significant association with eruption time ($P = 0.782$). The majority of the participants (94%) had normal milestones of development (MET 10.22 ± 2.632) and there is no significant association between eruption time ($P = 0.193$). History of oral intubation was seen in 18.4% (MET 13.52 ± 1.225) and 81.6% of children were not orally intubated (MET 9.54 ± 2.281). History of oral intubation was found to have a significant association with the mean age of eruption of first tooth ($P = 0.000$). Among post-natal factors, birth weight, feeding practice, and

Table 2: Relationship between pre-natal factors and first tooth eruption time

Variable		*n* (%)	Mean±SD	SE	Sig.
Socioeconomic status	Upper	19 (7.6)	10.47±2.756	0.632	0.693
	Upper middle class	28 (11.2)	9.93±2.734	0.517	
	Lower middle class	45 (18.0)	10.64±2.664	0.397	
	Upper lower class	145 (58.0)	10.16±2.527	0.210	
	Lower class	13 (5.2)	10.77±3.320	0.921	
Gestational age	<37 weeks	114 (45.6)	12.65±1.563	0.146	0.000*
	>37 weeks	136 (54.4)	8.29±1.393	0.119	
Systemic disease of mother	None	39 (15.6)	8.28±1.905	0.305	0.000*
	Nutritional	94 (37.6)	10.54±2.500	0.258	
	Endocrine	78 (31.2)	11.03±2.711	0.307	
	Others	39 (15.6)	10.13±2.441	0.391	

N: Number, SD: Standard deviation, SE: Standard error, *Significance

history of oral intubation showed statistically significant association with mean eruption time of the first tooth in children on bivariate analysis [Tables 3 and 4].

Table 3: ANOVA *post hoc* Tukey HSD analysis of pre-natal and post-natal variables

Variable	Mean±SD	Tukey HSD		
Systemic disease		None	Nutritional	Endocrine
None	8.28±1.905			
Nutritional	10.54±2.500	0.000*		
Endocrine	11.03±2.711	0.000*	0.581	
Others	10.13±2.441	0.006*	0.816	0.254
Birth weight		<2.5 kg	2.5–3.5 kg	>3.5 kg
<2.5 kg	12.84±1.510			
2.5–3.5 kg	9.32±1.867	0.000*		
>3.5 kg	8.15±1.484	0.000*	0.000*	
Feeding practice		Breast feeding	Bottle feeding	Combination
Breastfeeding	9.96±2.536			
Bottle feeding	11.43±2.299	0.304		
Combination	11.20±2.751	0.006*	0.973	

SD: Standard deviation. *Significance

Multivariate linear regression analysis pointed out that maternal age and gestational age were significant predictors among pre-natal factors. Among post-natal factors, birth weight and history of oral intubation were found to be a significant predictor of time of tooth eruption. [Table-5]. The mean age of first tooth eruption was found to be 10.28 ± 2.627 months. It was also noted that lower central incisors was erupted first in 80% of children.

DISCUSSION

Variation in the eruption time of primary teeth may potentially indicate pathology of local tooth relating factors as well as a link to systemic imbalance at a cellular, molecular, or genetic level. These variations are multifactorial of which events occur simultaneously, consecutively or intermittently in the pre-natal or post-natal period of child.

The current longitudinal study was designed for easy subject recruitment and retention by reducing inconvenience to

Table 4: Relationship between post-natal factors and first tooth eruption time

Variables		*n* (%)	Mean±SD	SE	Sig.
Gender	Male	123 (49.2)	10.15±2.580	0.233	0.473
	Female	127 (50.8)	10.39±2.676	0.237	
Birth weight	<2.5kg	96 (38.4)	12.84±1.510	0.154	0.000*
	2.5 kg–3.5 kg	69 (27.6)	9.32±1.867	0.225	
	>3.5 kg	85 (34.4)	8.15±1.484	0.161	
Feeding practice	Breastfeeding	188 (75.2)	9.96±2.536	0.185	0.004*
	Bottle feeding	7 (2.8)	11.43±2.299	0.869	
	Combination	55 (22.0)	11.20±2.751	0.371	
Use of pacifier	yes	126 (50.4)	10.23±2.623	0.234	0.782
	no	124 (49.6)	10.32±2.640	0.237	
Milestones of development	Normal	235 (94.0)	10.22±2.632	0.172	0.193
	Delayed	15 (6.0)	11.13±2.475	0.639	
History of oral intubation	yes	46 (18.4)	13.52±1.225	0.181	0.000*
	No	204 (81.6)	9.54±2.281	0.160	

N: Number, SD: Standard deviation, SE: Standard error, *Significance

Table 5: Multiple regression analysis for various predictors of first tooth eruption time

		Unstandardized coefficients		Standardized coefficients			95% confidence interval for B	
		Beta	Std. error	Beta	t	Sig	Lower bound	Upper bound
(Constant)		5.385	0.560		9.616	0.000*	4.282	6.488
Age of mother		0.121	0.021	0.260	5.703	0.000*	0.079	0.162
Gestational age	<37 weeks	1.935	0.295	0.368	6.569	0.000*	1.355	2.515
	>37 weeks[a]	-	-	-	-	-	-	-
Systemic disease	None[a]	-	-	-	-	-	-	-
	Nutritional	0.330	0.240	0.061	1.374	0.171	−0.143	0.802
	Endocrine	0.189	0.255	0.033	0.740	0.460	−0.314	0.692
	Others	0.069	0.282	0.009	0.243	0.808	−0.486	0.623
Birth weight	<2.5 kg	0.899	0.278	0.167	3.230	0.001*	0.351	1.447
	2.5–3.5 kg[a]	-	-	-	-	-	-	-
	>3.5 kg	−0.501	0.205	−0.091	−2.444	0.015*	−0.905	−0.097
Feeding practice	Breastfeeding[a]	-	-	-	-	-	-	-
	Bottle feeding	−0.396	0.479	−0.025	−0.826	0.409	−1.339	0.547
	Combination	−0.148	0.195	−0.023	−0.759	0.448	−0.533	0.236
Oral intubation	Yes	1.210	0.242	0.179	4.993	0.000*	0.732	1.687
	No[a]	-	-	-	-	-	-	-

A: Reference group r^2-0.798, adjusted r^2-0.789. F-24.928 P = 0.000

them and thus tried to reduce the possibility of missing cases. Although this study design requires long time interval and frequent examinations, it was the best design for reducing recall bias.

The present study revealed that maternal childbearing age had an important role in primary tooth eruption time. The correlation between the mean age of the mother and the mean age of eruption of the first tooth was good and was statistically significant ($r = 0.777$). This is in accordance with the findings of Savage *et al.*[17] and Un Lam *et al.*[18] However, the reports of Alnemer *et al.*[19] and Vejdani *et al.*[20] suggested that there was no association between maternal childbearing age and eruption time of first primary tooth. Many studies reported a well-established relationship between maternal age and child growth parameters. Moreover, skeletal growth influence on eruption was also studied.[21] Hence, the correlation between maternal age and eruption may due to the interplay of growth factors and underlying metabolic pathways.

The findings of this study showed no significant association between mean age of eruption of the first tooth and the socioeconomic status ($P = 0.693$). The results were similar to previous studies presented by Ahmadi-Motamayel *et al.,*[22] Sing *et al.,*[23] and Bambach *et al.*[24] In contrast to this finding, Clemens *et al.* reported that early tooth eruption in the high socioeconomic status group.[25]

Maternal systemic disease was also considered as a pre-natal factor for this study and it was found that there was a statistically significant association with a mean age of tooth eruption ($P = 0.000$). A similar finding was reported by many authors.[26-30] Majority of the mothers reported themselves to have nutritional disorders during pregnancy which reinforces the hypothesis that maternal nutritional problems can cause alteration in the eruption of tooth germ in the oral cavity. Multiple linear regression analysis indicated that maternal systemic disease is not a good predictor of tooth eruption time statistically. It may be due to the confounding effect of maternal age on the eruption time of teeth in their children. The importance of this pre-natal factor is very relevant in a clinical scenario. Categorization of various systemic diseases and inclusion of all maternal illness was not done and exact vitamin D as well as calcium level was also not checked in mothers, which was a limitation of our study. Further research is needed to explore the significance of maternal systemic disease on tooth eruption time of their children.

The result of this study explored that gestational age acts as a strong predictor of eruption time ($P = 0.000$). The finding of this study is consistent with several previous studies.[31,32] Seow *et al.* reported that infants with the lowest birth weight and shortest gestational age had the lowest rates of dental development.[33] Viscardi *et al.* studied the low birth weight and preterm babies and cited that there was a significant delay of first tooth eruption among children of gestational age <30 weeks.[34]

Considering sexual dimorphism, our study showed that the difference in MET between boys and girls was not found to be statistically significant ($P = 0.473$). Similar results were reported by Liversidge *et al.,*[35] Woodroffe *et al.,*[36] and Un Lam *et al.*[18] which showed no gender predilection in tooth eruption time. In contrast, Huaying *et al.*[37] among Chinese children, Al-Jasser *et al.*[38] among Saudi children, and Gunashekhar *et al.*[39] among Indian children reported that male child having early eruption time. However, in studies of Agarwal *et al.*[40] and Kaul *et al.*,[41] it was reported that girls exhibit early eruption. Hence, sexual dimorphism of primary tooth eruption needs further research.

Infant's birth weight was widely used as a marker for assessing the intrauterine environment and low birth weight was indicative of poor fetal nutrition. Multivariate analysis showed that birth weight was a strong predictor for tooth eruption time ($P = 0.000$). Our study finding is running with several studies when birth weight is taken into consideration.[42-46]

A number of different studies tried to investigate the link between eruption time and feeding practice. Our study observed that on bivariate analysis, feeding practice up to 6 months such as breastfeeding, bottle feeding, and combination had a significant association with tooth eruption time ($P = 0.004$). It was evident that early sucking activity influences the total growth of craniomaxillofacial complex. It was also proposed that breastfeeding is an ideal stimulus for the physiological development of musculoskeletal components of dentofacial complex. However, results of multivariate analysis showed that feeding practice is not a good predictor of tooth eruption time, it may be due to the confounding effect of birth weight on eruption time. This is in accordance with the study report of Folayan *et al.*[47] and Zarabadipour *et al.*[42] Contrary to the results of our study, Holman *et al.*[48] cited that late eruption of some teeth in children who were not breastfeed. Ahn *et al.*[49] suggested that exclusive breastfeeding had an overall role in child's growth and development. Sahin *et al.*[50] reported that feeding with cow or formula milk feeding in the 1st year of life has affected tooth eruption time negatively.

On the basis of our data, post-natal factors such as the use of pacifiers ($P = 0.782$) and the status of milestones of development ($P = 0.193$) were not found to have any significant association with the mean age of eruption of

the first tooth. This result is in accordance with the findings of Varma *et al.*[51] who reported no significant correlation between developmental milestones and tooth eruption. Our study, however, focused on healthy children who were medically fit, could have been the reason for this finding. History of oral intubation during the neonatal period was found to have a strong impact on the time of tooth eruption ($P = 0.000$). In a study, Viscardi *et al.*[32] reported that the duration of oral intubation is significantly related to tooth eruption time. In the present study, we did not record the duration of oral intubation which was a limitation of our study.

The mean age of first tooth eruption was found to be 10.28 ± 2.627 months. A similar finding is reported by Patil *et al.*[52] and Indira *et al.*[53] that there was a delay in eruption age in Indian children. In a longitudinal study, Gunashekhar *et al.*[39] also concluded the same result among Indian children. The first erupted tooth for a greater proportion of children was lower central incisors (80%) which were in accordance with findings of Gunashekhar *et al.*[39] but it in disagreement with the report of Patil *et al.*[52]

CONCLUSION

From the current study, it is evident that primary tooth eruption time is delayed in the Kerala population as compared to the standard eruption chart, which is commonly used in our clinical, academic, and research fields. This study also indicates that maternal age, gestational age, birth weight, and history of oral intubation are good predictors for the delayed eruption of a deciduous tooth. Medical, dental, and other paramedical professionals along with the general public should be made aware of the current evidence-based trend in eruption time of deciduous teeth. This study can be a useful basis for comparison with future studies. There is a need for further analytical studies using large sample size, including special children in order to enhance the evidence.

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Original Article

Comparative Evaluation of the Antimicrobial Efficacy of a Herbal Mouthwash and Chlorhexidine Mouthwash on Oral Pathogens: An *in vitro* Study

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Abstract

Introduction: Tea tree oil (TTO) is an ethereal oil widely used due to its curative nature. The topical use of TTO has shown great results due to its antibacterial as well as antiviral properties.

Purpose: This study was carried out to see the effect of TTO on oral pathogens.

Materials and Methods: Blood and MacConkey agar plates were prepared to inoculated the test organism, that is, *Streptococcus mutans*. Streak plate method is used in this study for the antimicrobial assessment. The plates were incubated at 37°C for 24–48 h. The readings were subjected to statistical analysis using the Wilcoxon signed-rank test and Chi-square test. *P*-value was considered significant at $P < 0.05$.

Results: Maximum antibacterial efficacy was exhibited by 2% chlorhexidine (CHX), followed by herbal mouthwash and least was shown by placebo.

Conclusion: According to this study, herbal mouthwash can be used as an alternative to CHX mouthwash although long-term *in vivo* studies are needed.

Key words: Antibacterial efficacy, *Melaleuca alternifolia*, *Streptococcus mutans*

INTRODUCTION

Tea tree (*Melaleuca alternifolia*) oil is well known and used as it has numerous therapeutic properties.[1] Tea tree oil (TTO) also known as melaleuca oil, is an essential oil obtained by the process of steam distillation of leaves and terminal branches of tea tree plant. TTO is volatile in nature and is made up of terpene hydrocarbons, mainly monoterpenes, sesquiterpenes, and their associated alcohols. Terpenes are aromatic hydrocarbons and are contemplated as polymers of isoprene, with chemical formula C_5H_8. The antimicrobial activity of TTO is attributed mainly to terpinen-4-ol. The minimum inhibitory concentration of TTO against *Streptococcus mutans* and *Streptococcus salivarius* is equivalent to 1940.16 μg/ml and 3977.34 μg/ml, respectively.[2] Various studies conducted in the past have shown antimicrobial properties of *M. alternifolia*.[3-6] During the initial stage of development, biofilm comprises mainly of streptococci and actinomyces which acts as commensals. However, further colonization leads to rapid increase in lactobacillus species, or Gram-negative anaerobes resulting in the beginning and development of dental caries and periodontal diseases.[7] Ethereal oils have abundant biologically active compounds.[8] Clinically, TTO has shown the capability to put a stop on the hospital acquired infections caused by Gram-positive as well as Gram-negative microorganisms.[9] Due to the presence of antimicrobial terpenes, *M. alternifolia* is well known to fight against acne. The essential oil is popularly used for the treatment of dermatophyte infection or tinea, tinea pedius, and fungal nail infections.

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Increasing evidence of microbicidal, fungicidal, antiviral, and anti-inflammatory effects of *M. alternifolial* in various *in vitro* studies presents a need to determine its efficacy as a mouthwash on oral pathogens. Hence, this study was conducted aimed to discover and compare the result of an herbal mouth wash preparation containing TTO in controlling microbial growth with chlorhexidine (CHX) mouthwash which is considered as the gold standard.

MATERIALS AND METHODS

An *in vitro* study was executed in the department of public health dentistry. The Institutional Ethical Committee Clearance (Ref. No: TMDCRC/IEC/SS/19-20/PHD01) and informed consent were obtained from all the participants before commencement of the study. Forty samples of saliva were taken to determine the antimicrobial effect of herbal (tea tree) mouthwash on bacterial strains.

Herbal mouthwash was prepared using tea tree essential oil (pure TTO) purchased from Moradabad (India), baking soda, 80% alcohol, methylparabene, sodium chloride, propylparabene, peppermint flavor, and distilled water to study the antibacterial activity. Various aerobic and anaerobic strains of bacteria that are associated with distinguishable phases of periodontal disease were selected to study the antimicrobial effect of the herbal preparation. To compare the antimicrobial efficacy, three groups were formed Group 1, Group 2, and Group 3 representing CHX mouthwash, tea tree mouthwash, and placebo, respectively. Each saliva sample collected was mixed with three mouthwashes placed in different test tubes. To determine the antimicrobial activity against aerobic and anaerobic bacteria, the samples from test tubes were inoculated on blood and MacConkey agar plates. Then, the samples were incubated at a temperature of 37°C for 24-48 hours.

Inclusion Criteria

The following criteria were included in the study:

- Subjects aged between 20 and 30 years
- Subjects having at least 22 teeth were selected.

Exclusion Criteria

The following criteria were excluded from the study:

- Subjects who showed allergic reactions to test products were excluded
- Any systemic illness
- Antibiotic and periodontal therapy in the past month
- Subjects with destructive periodontal disease.

Intervention

Preparation of tea tree/herbal mouth rinse: Herbal mouth wash was prepared by dissolving 1 ml of TTO in 5 ml of 80% alcohol. In second beaker, 20 ml of distilled water was taken and 0.5 ml of methylparaben and 1 ml of propylparaben were added with constant stir. After that, 1 g of baking soda and 1.5 g of sodium chloride were added. In second beaker, peppermint flavoring agent was dissolved in 10 ml of water. Alcoholic solution of TTO was added in the second beaker and stirred for 10 min. Finally, the preparation was filtered with muslin cloth.

Preparation of placebo mouth rinse: Placebo mouth rinse was prepared by dissolving peppermint flavoring agent in distilled water.

Preparation of CHX: Commercially available 0.2% CHX mouth rinse was used.

Statistical Analysis

The results were tabulated and statistically analyzed using Wilcoxon signed-rank test and Chi-square test. $P < 0.05$ was considered significant.

RESULTS

Table 1 shows that the qualitative count of bacteria detected by both the mouthwashes was significantly different. The qualitative count of bacteria with CHX mouthwash was none in 36 samples. However, Herbal Mouthwash was able to detect moderate and heavy bacterial growth in two samples, respectively. The qualitative count of bacteria was mild in 32 out of 40 samples with herbal mouthwash. The Chi-square test of association shows that there is an association between the qualitative bacterial count and the kind of mouthwash used as the $P < 0.05$.

Table 2 shows the difference between the two mouthwashes to detect the qualitative count of bacterial

Table 1: Qualitative bacterial count by different mouthwashes

Crosstab						
Groups	Nil	Qualitative count				Total
		No Growth	Mild	Moderate	Heavy	
Group						
Chlorhexidine						
Count	4	36	0	0	0	40
% of Total	5.0	45.0	0.0	0.0	0.0	33.3
Herbal mouthwash						
Count	4	0	32	2	2	40
% of Total	5.0	0.0	40.0	2.5	2.5	33.3
Placebo						
Count	4	0	0	0	36	40
% of Total	5.0	0.0	0.0	0.0	0.0	33.3
Total						
Count	12	36	32	2	38	120
Chi-square (*P* value)			4.235 (0.037)			

growth. There were 4 cases where the qualitative count with Herbal Mouthwash is more than the qualitative count with CHX, while 36 samples where the qualitative count with Herbal Mouthwash is equal to the qualitative count with CHX. The Wilcoxon signed-rank test shows that there is a difference in the two mouthwashes in the detection of the qualitative count of bacterial growth as $P < 0.05$, herbal mouthwash was more efficient in the detection of the more moderate and heavy count of bacterial growth.

DISCUSSION

S. mutans is the most commonly isolated microorganism from the mouth. It possesses various virulence factors which enable it to survive and persist as a pathogen in the oral cavity. Hence, *S. mutans* was chosen as the test organism for this study and was obtained using the subculture method. Streak plate method was used in this study for antimicrobial assessment. The streak plate method is a rapid qualitative isolation method. This method is used for segregation into pure culture from a mixed population of microorganisms. In this study, the experiment was repeated 40 times making the results more reliable, and there were four dropouts due to contamination of the samples. In our study, we found that the qualitative growth of bacteria with CHX mouthwash was none in 36 samples. However, herbal mouthwash was able to detect moderate and heavy bacterial growth in two samples, respectively. The qualitative count of bacteria was mild in 32 out of 40 samples with herbal mouthwash. The qualitative count of bacteria was heavy in 36 out of 40 samples with a placebo as shown in [Figure 1]. CHX exhibited the best antibacterial efficacy followed by herbal mouthwash and least by placebo in our study as shown in [Figures 2-4] respectively, which is in support of previously published studies.

M. alternifolia is responsible for the disintegration and deprivation of membrane integrity and function by outflow of ions and the obstruction of respiration in bacterium. *M. alternifolia* shows broad-spectrum antimicrobic activity which can be chiefly ascribed to terpinen-4-ol.[10] In 2006, Carson *et al.*, Carson and Riley, and Cox *et al.* found that the *M. alternifolia* has shown obstructive results on bacteria with *Escherichia coli*.[1,11,12] In 2010, Fitzpatrick conducted a study on the effectiveness of TTO against five bacteria: *Bacillus subtilis*, *E. coli*, *Micrococcus roseus*, *Suillus luteus*, and *Serratia marcescens*. In his

Table 2: Difference between the two mouthwashes to detect qualitative bacterial growth

Ranks			
Qualitative count with herbal Mouthwash – qualitative count with Chlorhexidine	***n***	**Mean rank**	**Sum of ranks**
Negative ranks	0[a]	0.00	0.00
Positive ranks	4[b]	2.50	10.00
Ties	36[c]		
Total	40		

[a]Qualitative count with herbal mouthwash <qualitative count with chlorhexidine, [b]Qualitative count with herbal mouthwash >qualitative count with chlorhexidine, [c]Qualitative count with herbal mouthwash = qualitative count with chlorhexidinem, Z (*P* value)= −1.857 (0.034)

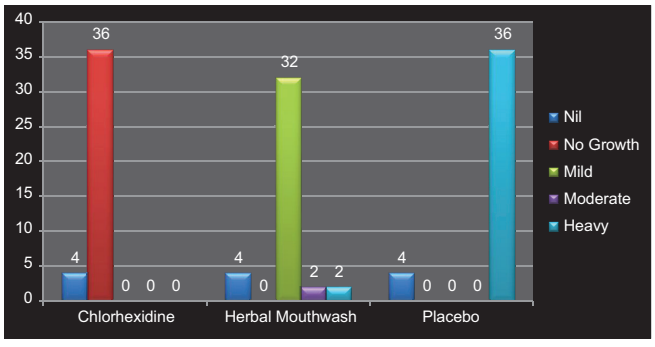

Figure 1: Bacterial growth in three different mouthwashes

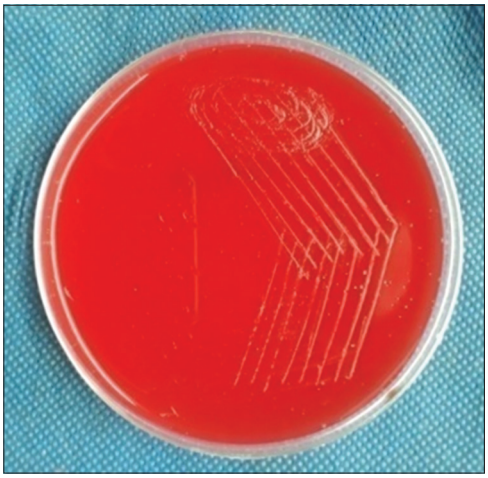

Figure 2: Antimicrobial activity by chlorhexidine

Figure 3: Antimicrobial activity by herbal/tea tree mouthwash

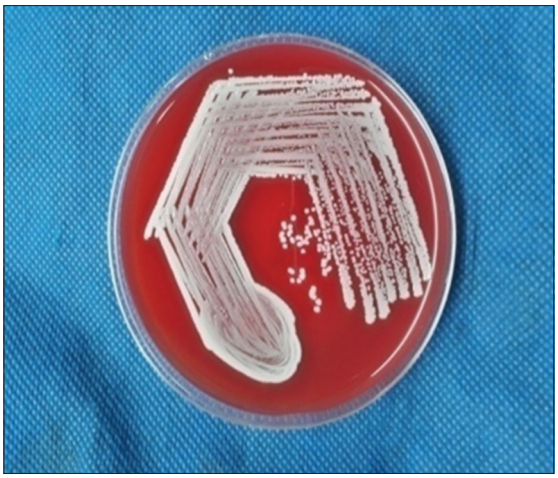

Figure 4: Antimicrobial activity by placebo

study, he found that TTO showed persistent preventive action in all bacteria, excluding *S. luteus*.[13] Results of our study show that TTO exhibits good antibacterial efficacy, which is in support of the study by Kamath *et al*., in 2013.[14] Studies like those conducted by Leite *et al*., in 2017, found that TTO presented antibacterial activity on oral microflora like *S. mutans*, *S. salivarius,* and Lactobacillus rhaminosus.

CONCLUSION

Based on the results of our study, it can be concluded that 2% CHX showed the maximum antibacterial activity. Herbal mouthwash demonstrated significant antibacterial activity in opposition to *S. mutans*. Thus, *M. alternifolia* can be employed as a substitute for CHX. Since herbal products are easily extracted and are cost-effective, this study opens new path for the use of herbal products. Further, preclinical and clinical trials are needed to be aware of the antimicrobial activity of numerous herbal products accessible and to encourage the unearthing of new natural resources.

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Original Article

Effect of Smoking on the Working Environment and Willingness to Quit Smoking among King Fahad Specialist Hospital-Dammam staff in the Eastern Province, Saudi Arabia

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ABSTRACT

Background: This study examines the prevalence of smoking among King Fahad Specialist Hospitals-Dammam and the effect of smoking on the working environment and their willingness to quit smoking. To increase the proportion of successful attempts to quit smoking, it is important to understand the needs of smokers and their concern. This study seeks to find out the smoking prevalence, the level of willingness to quit and reason influencing smoking cessation among King Fahad Specialist Hospital-Dammam staff.

Materials and Methods: This study is a descriptive cross-sectional study carried out among King Fahad Specialist Hospital-Dammam staff. A sample size of 350 was determined. The questionnaire was semi-structured, pre-tested, and self-administered. The analysis was performed, data were analyzed using a statistical program (SPSS version 21). Frequency tables and cross-tabulations were generated with a statistical significance *P*-value pre-determined at <0.05.

Results: The number of respondents that are current smokers was 110 (31.4%) and nonsmokers 240 (68.6%). Those willing to quit out of the 110 that currently smoke are 74 (67.3%) while 36 (32.7%) were not willing to quit. Reasons to quit smoking were expressed mainly by smokers concerned about their health 84.4%. Current smokers missed more days of work and experienced more unproductive time at work compared to nonsmokers.

Conclusions: Smoking prevalence is relatively high among our hospital workers. Most of the smokers tried to quit smoking but they did not succeed due to various reasons.Current smokers showed high percentage in productivity loss in compared to nonsmokers. There is an importance to developing a smoking cessation program to cover the needs of this disadvantaged population group.

Key words: Non-smoker, Smoker, Working environment

INTRODUCTION

Cigarette smoking is the leading preventable cause of mortality. Smokers who quit reduce their risk of developing and dying from tobacco-related diseases.[1]

Approximately 70% of smokers say that they want to quit, and over 50% of smokers report that they tried to quit in the past year. However, only 3–6% of smokers who make an unaided quit attempt are still abstinent 1 year later. Only 32% of smokers who try to quit seek help and even fewer use the most effective treatments.[2] With optimal treatment, 1-year abstinence rates after a single quit attempt can exceed 30%.

Cigarette smoking is a major modifiable health risk factor in the United States, significantly contributing to deaths from cancer and cardiovascular and pulmonary diseases. Although it is estimated that smoking-related illnesses lead to 443,000 premature deaths and almost $100 billion in lost productivity each year,[3] one in five American adults still smokes regularly (22% of men, 17.5% of women).[4]

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The harmful effects of smoking do not only affect smokers but extend far beyond the smoker. Exposure to secondhand smoke can cause serious diseases and death. Each year, an estimated 88 million nonsmoking Americans are regularly exposed to secondhand smoke and almost 41,000 nonsmokers die from diseases caused by secondhand smoke exposure.[5]

Aim of the Study

The aim of this study is to assess the effect of smoking on the working environment and to assess the need of an educational program to improve the environment and to establish a smoking cessation program at King Fahad Specialist Hospital-Dammam.

Objectives

The objectives are as follows:

1. To assess the effect of smoking on staff behavior at work
2. To assess the effect of smoking on work environment in general
3. To assess the need for a smoking cessation program
4. To assess the prevalence of smoking among the staff at KFSH-D
5. To establish the necessary knowledge to be able to assess the effectiveness of our smoking cessation program after implementation.

MATERIALS AND METHODS

Study Area

This study was conducted in King Fahad Specialist Hospital in Dammam city, Saudi Arabia.

Study Design

This was a cross-sectional descriptive study through a self-administered modified questionnaire.

Inclusion Criteria

All staff females and males in KFSH-D were included in the study.

Exclusion Criteria

None KFSH-D staff and patients were excluded from the study.

Study Variables

- Dependent variable: Effect of smoking on working environment and productivity
- Independent variable: Socio-demographic data: Age, gender, nationality, level of education, occupation, and marital status.

Sampling Size

There is around 4000 staff in KFSH-D and sample size was calculated to be 350.

Preparatory Phase

Official procedures

Approval of the study will be requested from IRB before implementation of the study.

Pilot study

A pilot study was done in December 2016 to some of the staff of King Fahad Specialist Hospital-Dammam. The questionnaire was extracted from some questionnaires from the previous studies with some modification according to the objectives of the study, culture, and community.

A total number of samples was 30 it was distributed to participants and the response was 100%. Collected data were revised immediately and computerized. Frequency tables were drawn to explore the findings with the biostatistician.

Data Collection

Data collection tools

Self-administered questionnaire structured by the researcher and was validated by three consultants.

Data collection techniques

Questionnaires were distributed to the staff during their visit to the employee health clinic in KFSH-D. Each eligible participant received a copy of an invitation letter that contains brief information about the aim of the study, its importance, the value of his/her participation, and instructions on how to fill the questioner ensuring their confidentiality. This was done over 3-month period.

Data management

Collection of data and double-checking was done by the primary investigator and then data were sorted by numbers. Data were computerized and analyzed by Health Research Center by using the SPSS program version 21 and double check by the primary investigator.

The data confidentiality was the Primary Investigator responsibility.

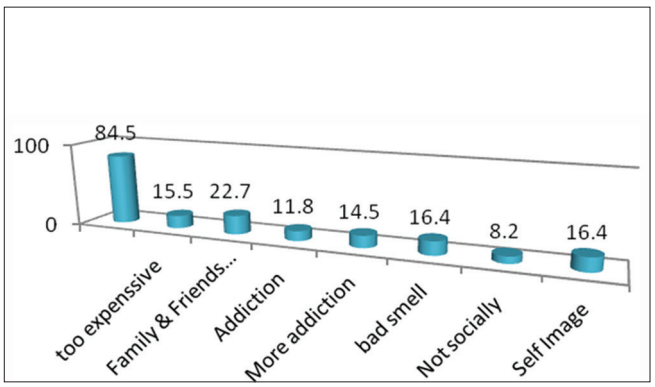

Figure 1: Possible reason for smokers to quit smoking

Data analysis and statistical considerations

Data were analyzed using a statistical program (SPSS version 21). Descriptive statistics (Mean, standard deviation, frequency, and percentages) were calculated for each variable. All independent variables were cross-tabulated with the dependent variable.

Limitation of the Study

This study enrolled only employees at KFSH-D, (tertiary hospital). It did not cover the other adult population in a different environment. As the study tool is a questionnaire, it will be subjected to possible recall bias.

Ethical Considerations

Approval of the study was requested from IRB before implementation of the study. As well as written consents for participation from each participant. Filling in the questioner was considered an approval of the information contained in it. Privacy and confidentiality were safeguarded throughout all phases of the study. The information used was for research purposes only.

RESULTS

Three hundred and fifty health workers met the criteria specified for the sample. All of the chosen health workers agreed to participate in the study. The response rate was 100%. Data collection began on March 1, 2017, and ended on March 29, 2017.

The results of data analysis are presented for each specific research question in the following sections.

Table 1: Demographic characteristics of healthcare workers (*n*=350)

Variable	Number (%)	Variable	Number (%)
Sex		Work	
Male	173 (49.4)	Physician	52 (14.9)
Female	177 (50.6)	Administrative	93 (26.6)
		Allied health	81 (23.1)
Age		Nurses	78 (22.3)
18–24	25 (7.1)	Others	46 (13.1)
25–29	79 (22.6)		
30—34	100 (28.6)	Monthly income	
35–39	73 (20.9)	SR <5000	26 (7.4)
40–44	45 (12.9)	SR 5,000 – SR 9,000	139 (39.7)
45–49	21 (6.0)	SA 10,000 – SR 19,000	121 (34.6)
50 plus	7 (2.0)	SA 20,000 – SR 29,000	27 (7.7)
		SR 30,000 – SR 39,000	12 (3.4)
Marital status		SR 40,000 – SR 49,000	14(4.0)
Single	112 (32.0)	MORE THAN SR 50,000	11 (3.1)
Married	225 (64.3)		
Divorced	13 (3.7)		
Widowed	0 (0)		
Nationality			
Saudi	227 (64.9)		
Non – Saudi	123 (35.1)		

Description of Sample

Health workers demographic characteristics

The results are summarized in Table 1. Of the 350 questionnaires distributed, 350 returned with a response rate of 100%. The male participants constituted 49.4% (173) while the females were 50.6% (177). Most of the participants age-range were 30–34 comprising 28.6% (100), followed by 25–29 years with 22.6% (79), 35–39 years 20.9% (73), and the least was 50 years and above.

More than half of the samples were married 64.3% (225), whereas single was 32% (112) divorced participants constituted 3.7% (13), and 0% widow/widower in our sample size.

The majority of the nationality in our sample was Saudis representing 64.9% (227/350) and non-Saudis were 35.2% (123/350). Their race was mainly Arabs counting for 70.9% (248/350), followed by Asians 24.9% (87/350) than African 1.7% (6/350) then North American 1.1% (4/350) then South American 0.6% and the least were European 0.3% (1/350).

Administrative comprised 26.6% (93), Allied Health was 23.1% (81), nurses were 22.3% (78), physicians were 14.9 % (52), and other fields were 13.1% (46). Out of the 350 participants, 64.9% (227) were Saudi, while 35.1 % (123) were non-Saudi of different nationalities. The majority race were Arabs counting for 70.9% (248), followed by Asians 24.9% (87).

The majority of our samples income was between the ranges SR 5,000 – SR 9,000 representing 39.7% (139/350), followed by SR 10,000 – SR 19,000 representing 34.6% (121/350) then SR 20,000 – SR 29,000 representing 7.7% (27/350) then <SR 5,000 representing 7.4% (26/350) and the least were between SR 30,000 – more than SR 50,000.

Smokers information

In Table 2, it shows out of 350 individuals 31.4% (110) were smokers, non-smokers 68.8% (240).

The majority of smokers have been smoking from 5 to 10 years which counts for 24.5% (35/110), followed by <5 years 27.3% (30/110) and the minority were more than 20 years 5.5% (6/110).

A number of packs smoked greater number showed that 48.2% (53/110) smokes less than half pack and 35.5% (39/110) smokes half pack to one.

When they were asked about do they think working in a tertiary care hospital affects their views to smoking 60.9%

Table 2: Smokers information

Variable	Number (%)	Variable	Number (%)	Variable	Number (%)
Smoker		Smoking policy		Attempt to quit smoking	
Yes	110 (31.4)	Not strict	19 (17.3)	Yes	74 (67.3)
No	240 (68.6)	Low strict	18 (16.4)	No	36 (32.7)
Years of smoking		Moderately	35 (31.8)	Ways to quit	
<5 year	30 (27.3)	Strict	30 (27.3)	N/A	34 (30.9)
5–10 years	35 (31.8)	Very strict	8 (7.3)	Personal effort	63 (57.3)
10–15 years	27 (24.5)	Family conflict		Nicotine patches	3 (2.7)
15	12 (10.9)	Never	20 (18.2)	Nicotine gum	2 (1.8)
>20 years	6 (5.5)	Rarely	18 (16.4)	Cessation clinic	2 (1.8)
Cigarette packs		Sometimes	42 (38.2)	Others	6 (5.5)
<Half pack	53 (48.2)	Often	10 (9.1)	Wish to quit	
Half pack to one pack	39 (35.5)	Always	20 (18.2)	Yes	82 (74.5)
One pack to two packs	17 (15.5)	Work conflict		No	7 (6.4)
>Two packs	1 (.9)	Never	45 (40.9)	I don't know	21 (19.1)
View of smoking		Rarely	22 (20.0)	Cessation program	
Yes	67 (60.9)	Sometimes	27 (24.5)	Yes	86 (78.2)
No	25 (22.7)	Often	4 (3.6)	No	12 (10.9)
I don't know	18 (16.4)	Always	12 (10.9)	I don't know	12 (10.9)
Hospital Image		Embarrassment		Join this program	
Yes	73 (66.4)	Never	20 (18.2)	Yes	58 (52.7)
No	28 (25.5)	Rarely	12 (10.9)	No	27 (24.5)
Others	9 (8.2)	Sometimes	28 (25.5)	I don't know	25 (22.7)
		Often	15 (13.6)		
		Always	35 (31.8)		

(67/110) answered yes and 22.7% (25/110) answered no and 16.4% (18/110) were not sure.

About 66.4% (73/110) of smokers think their habit affect the hospital's image, whereas 25.5% (28/110) do not and 8.2% (9/110) are not sure if their smoking habit affects hospital image.

Majority of smokers believe that the King Fahad specialist hospital's policy toward smoking is moderately strict 31.8% (35/110), whereas 27.3% (30/110) think it is strict and 33.7% (37/110) were between not strict and low strict. 7.3% (8/110) think it is very strict.

Family conflict over smoking, the majority 38.2% (42/110) had conflict sometimes, followed by 18.2% (20/110) said they never had and 18.2% (20/110) also said they always have conflict.

Conflict at work over smoking, the majority 40.9% (45/110) never had conflict, followed by 24.5% (27/110) said they sometimes have conflict and 20% (22/110) rarely have conflict.

When smokers were asked about feeling embarrassment regarding smoking, 31.8% (35/110) always felt embarrassed, 25.5% (28/110) sometimes felt embarrassed, 10.9% (12/110) rarely felt embarrassed, and 18.2% (20/110) never felt non-smokers.

About 67.3% (74/110) of smokers attempted to quit smoking, whereas 32.7% (36/110) did not attempt to quit smoking and mainly by personal effort 57.3% (63/110) least were nicotine patches nicotine gum, smoking cessation clinic.

Table 2 shows a great number of smokers willing to quit, 74.5% (82/110) while the minority 6.4% (7/110) are not willing and 19.1% (21/110) do not know if they want to quit.

Smokers wish that the hospital offers a smoking cessation program 78.2% (86/110) wish there was a program, 10.9% (12/110) do not want a program and same number 10.9% (12/110) were not sure if they wanted a program. Majority of smokers showed how willing they are to join a smoking cessation program 52.7% (58/110) answered they would join such program and 24.5% (27/110) do not want to join and 22.7% (25/110) do not know if they would join.

Graph 1 shows the possible reasons smokers want to quit smoking, the majority of smokers are concerned about their health 84.4%, followed by their friends or family do not want them to smoke 22.7% then they do not like the smell and Affect self-image represent 16.4%. And 15.5% think its too expensive, 14.5% do not want to be more addicts, 11.8% do not want get addicted, and least reason was its not socially accepted 8.2% Figure 1.

Cross-tabulation

Out of 350 individuals, 31.4% (110) were smokers and 68.8% (240) were non-smokers when considering the demographic data [Tables 3 and 4] smoking was highly significantly ($P = 0.000$) prevalent among males highest age-range of 35–39 years representing 38.4%.

Among the smokers subjects, a higher percentage of smoking was cited by administrative 45.2% (42), followed by Allied health 35.8 % (29), then physicians 26.9% (14) and the least were nurses 16.7 (13), and another field 26.1% (12) significant with a$P = 0.001$ [Table 5].

As for the marital status, divorced subjects showed a higher percentage than other groups representing 38.5%, as shown in Table 6.

In Table 7, it shows distribution of a number of packs by gender, the majority of female smokers smoke less than half a pack representing 26.9% while the majority of male smokers smoke one pack to two packs representing 88.2%, as shown in Table 3.

Nonsmokers' information

In Table 8, when asking non-smokers about how they feel about colleges who smoke, the majority answered it bothers them all the time 47.5% (114/240) while 10.8% (26/240) did not bother them at all.

About 99.8% (218/240) of non-smokers believe that smoking around the hospital affects the hospital's image. About 6.7% (16/240) did not think it affects the hospital's image and 2.5% (6/240) did not know if it affects the image of the hospital.

About 57.5% (138/240) of non-smokers which were the majority answered that they strongly agree that King Fahad Specialist Hospital should have a more strict policy regarding

Table 3: Distribution of smoking pattern by age groups

Age	Smoke	
	No	Yes
18–24	19	6
	76.0%	24.0%
25–29	51	28
	64.6%	35.4%
30–34	72	28
	72.0%	28.0%
35–39	45	28
	61.6%	38.4%
40–44	30	15
	66.7%	33.3%
45–49	17	4
	81.0%	19.0%
50 Plus	6	1
	85.7%	14.3%

Chi-square=5.926, *P*=0.432, insignificant

Table 4: Distribution of smoking pattern by gender

Gender	Smoke	
	No	Yes
Male	85	88
	49.1%	50.9%
Female	155	22
	87.6%	12.4%

Chi-square=59.979, *P*=0.000, highly significant

Table 5: Distribution of smoking pattern by work

Work	Smoke	
	No	Yes
Physician	38	14
	73.1%	26.9%
Administrative	51	42
	54.8%	45.2%
Allied Health	52	29
	64.2%	35.8%
Nurses	65	13
	83.3%	16.7%
Other	34	12
	73.9%	26.1%

Chi square=17.8, *P*=0.001, significant

Table 6: Distribution of smoking pattern by marital status

Marital status	Smoke	
	No	Yes
Single	80	32
	71.4%	28.6%
Married	152	73
	67.6%	32.4%
Divorced	8	5
	61.5%	38.5%

Chi-square=0.830, *P*=0.660, insignificant

Table 7: Distribution of number of packs by gender

Cigarettes pack	Gender	
	Male	Female
N/A	85	155
	35.4%	64.6%
Less than half packs	38	14
	73.1%	26.9%
Half (1/2) pack to one (1) pack	34	6
	85.0%	15.0%
One (1) pack to two (2) packs	15	2
	88.2%	11.8%
More than two (2) packs	1	0
	100.0%	0.0%

Chi-square=61.9, *P*=0.000, highly significant

Table 8: Non-smokers' information

Variable	Number (%)	Variable	Number (%)
Feel about colleges who smoke		Wish hospital provides smoking cessation program	
It bothers me all the time	114 (47.5)	Yes	216 (90.0)
It bothers me sometimes	75 (31.3)	No	12 (5.0)
It often bothers me	25(10.4)	I don't know	12 (5.0)
Doesn't bother me at all	26(10.8)		
		Would you volunteer	
Do you think smoking affects hospital image		Yes	119 (49.6)
Yes	218 (90.8)	No	78 (32.5)
No	16 (6.7)	I don't know	43 (17.9)
I don't know	6 (2.5)		
		Conflict with a smoker colleague	
Do you think KFSH should have more strict policy		Always	42 (17.5)
Strongly agree	138 (57.5)	Never	107 (44.6)
Agree	71 (29.6)	Sometimes	91 (37.9)
Uncertain	17 (7.1)		
Disagree	14 (5.8)	Do you think smoking affects productivity	
		Very much	114 (47.5)
Comfortable advising smokers to quit		Not much	63 (26.3)
Yes	151 (62.9)	Not sure	28 (11.7)
No	62 (25.8)	Very little	23 (9.6)
I don't know	27 (11.3)	Not at all	12 (5.0)

smoking, 29.6% (71/240) agreed and 7.1% (17/240) were uncertain and the minority disagreed with a 5.8% (14/240).

When non-smokers were asked about how comfortable are they advising a smoker to quit, 62.9% (151/240) felt comfortable advising and 25.8% (62/240) did not feel comfortable and 11.3% (27/240) were not sure.

A high percentage of non-smokers wished there was a smoking cessation program around 90% (216/240) and 5% (5/240) said no and 5% (5/240) were not sure.

A lot of non-smokers are willing to volunteer in a smoking cessation program 49.6% (119/240) and 32% (78/240) were not willing and 17.9% (43/240) don't know if they will volunteer.

When asked about how often do they have a conflict with a smoker college 44.6% (107/240) never had conflict and 37.9% (91/240) sometimes had conflict and 17.5% (42/240) always had conflict.

About 47.5% (114/240) think that smoking affects the productivity of their colleges, whereas 47.5% (114/240) were not much, not sure and very little effect and 5% (12/240) thinks it does not affect productivity.

MANAGERS QUESTIONNAIRE RESULTS

In Table 9, it shows 93 out of 350 were managers who answered the questionnaire when comparing non-smokers with smokers. When asked about causing trouble, 49.5% (46/93) caused trouble sometimes and 31.2% (29/93) believed it was neutral and 2.2%(2/93) believed they do not cause trouble at all.

Table 9: Manager's questionnaire

Variable	Number (%)	Variable	Number (%)
Compared to non-smokers, do smoker cause trouble?		Compared to non-smokers, are smokers moody?	
All the time	11 (11.8)	All the time	17 (18.3)
Sometimes	46 (49.5)	Sometimes	48 (51.6)
Neutral	29 (31.2)	Neutral	12 (12.9)
Very little	5 (5.4)	Very little	10 (10.8)
Not at all	2 (2.2)	Not at all	6 (6.5)
Compared to non-smokers, are smokers less productive?		Compared to non-smokers, do smoker cause trouble	
All the time	11 (11.8)	All the time	9 (9.7)
Sometimes	32 (34.4)	Sometimes	24 (25.8)
Neutral	21 (22.6)	Neutral	28 (30.1)
Very little	7 (7.5)	Very little	12 (12.9)
Not at all	22 (23.7)	Not at all	20 (21.5

Moreover, when asked about the productivity of smokers compared to non-smokers, the majority answered sometimes 34.4% (32/93) and 23.7% (22/39) thinks not at all and 11.8% (32/93) all the time.

When comparing smokers and non-smokers in being moody 51.6% (48/93) answered sometimes which was the majority and 6.5% (6/93) answered not at all.

The table presents absenteeism results by manager's opinion. The percentage of absenteeism in smokers had neutral absenteeism than did with non-smokers during

working days 30.1% (28/93) and 25.8% (24/93) think sometimes and 21.5% (20/93) answered that there is no difference at all.

DISCUSSION

There are no similar studies done in Saudi Arabia in the eastern province regarding the effect of smoking on the working environment and willingness to quit smoking among health-care providers. Most of the previous studies have addressed smoking habits and prevalence among students, general population, and different careers but not on health workers.

The result of our investigation showed that healthcare workers, although aware of the risk of smoking, had a quit prevalent smoking habit.[6] The prevalence of smoking among KFSH-D in our study (31.4%) as shown in Table 2, whereas the prevalence in similar studies ranged from 19% to 54% in different countries such as Kuwait, Bahrain, Netherlands, and Greece. For example, our results are comparable to findings reported in two studies, a study done on Tobacco Use among Health Care Workers in Southwestern Saudi Arabia who reported their prevalence of (26.3%) and another study on Prevalence of Smoking Among Health Care Providers in Eastern Province, Saudi Arabia showed the prevalence of 28.4% and mainly higher in males workers than females as.[6] In our study, it showed the prevalence of smokers in males are higher than in females with males counting for 50.9% and females 12.4%, as shown in Table 4.

The effect of smoking on productivity was not addressed in any of the studies conducted in Saudi Arabia. However, some international studies, for example, In the United States of America done on the effect of smoking status on productivity loss and results showed current smokers showed the high number in productivity losses in compared to former smokers and non-smokers.[8] Another study done among employees at a reservation office of a major US airline about impact of smoking status on workplace absenteeism and productivity results showed that productivity decreased and absenteeism increased among current smokers in compared to former smokers and nonsmokers at the workplace. Productivity among former smokers increases over time toward values seen among never smokers.[9]

Moreover, a study done on workplace smoking-related absenteeism and productivity costs in Taiwan that showed an estimate of increased absenteeism from work, male smokers took off an average of 4.36 sick days and male non-smokers took off an average of 3.30 sick days. Female smokers took off an average of 4.96 sick days and non-smoking females took off an average of 3.75 sick days. The time smokers spent taking smoking breaks amounted to 9 days/year resulting in productivity loss. Increased sick leave costs due to passive smoking.[10] Similarly in our study, as shown in Table 9, found variable effect of smoking on work-related issues addressed by their managers, for example, employees being moody was the most addressed issue followed by causing trouble followed by being less productive in means of taking extra break hours to smoke and lastly increase in absenteeism and sick leave requests compared to nonsmoker.

Moreover, regarding quitting smoking, current smokers' willingness to quit smoking in our study was found to be 74.5%, as shown in Table 2. Another study done among University Students in a Western Nigerian State showed the willingness to quit smoking 39.0% and another study done in north central Nigeria also showed a willingness to quit smoking by 39.4%. In all the previous studies and our study showed that the main reason current smokers wanted to quit smoking were that they were concerned about their health. Therefore, smoking cessation clinic and educational program regarding smoking should emphasize about the complication of smoking on health.[11]

Most of the smokers attempted to quit smoking 67.3% similarly in a study that was done in western Nigeria university students attempted to quit were 83.3%.[11] The results are high in these two studies may be cause of health problem and awareness of smoking complication. This would indicate that many smokers have tried quitting but, unfortunately, they have not succeeded in doing so.

CONCLUSION

Although most health workers were aware of the complication of smoking, and the effect on working environment smoking prevalence is relatively high among our hospital workers. Most of the smokers tried to quit smoking but they did not succeed due to various reasons.

Current smokers counted for high productivity loss in compared to non-smokers.

There is an importance to developing a smoking cessation program to cover the needs of this disadvantaged population group.

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Original Article

Psychological Distress and its Relation with Periodontitis among Patients Attending Outpatient Department in Moradabad – A Cross-Sectional Study

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Abstract

Purpose: The purpose of the study was to assess whether adolescents with periodontitis presented with higher scores for non-psychotic psychosocial disorders than control subjects without periodontitis.

Materials and Methods: A case–control study (*n* = 135) was performed using the 28-item Spanish version of the general health questionnaire (GHQ). The inclusion criterion for being a case was a clinical attachment level ≥3 mm in at least two teeth. Multiple logistic regression analyses were used to assess the association between periodontitis and psychosocial distress.

Results: The response rate was high and 81.8% of the participants answered all the items of the questionnaire. Similarly, the internal consistency of the instrument was high (Cronbach's alpha = 0.91). The results of multiple logistic regression analyses, adjusted for age and gender, suggested an association between case status and higher total scoring for psychosocial distress (odds ratio = 1.79). Among the four subdomains of the GHQ, the dimensions "somatic symptoms" and "severe depression" appeared positively associated with periodontal case status, albeit not significantly.

Conclusion: The findings of this study suggest that the association between periodontitis and psychosocial distress dimensions can be documented early in life. This calls for awareness on the part of health-care providers attending adolescents.

Key words: Coping, Depression, Periodontitis, Psychological distress, Stress

INTRODUCTION

Periodontitis is a disease affecting the supporting tissue of the teeth, that is, alveolar bone periodontal ligament and cement. Locally, the presence of predominantly Gram-negative biofilms triggers an inflammatory reaction of the bodies that result in the destruction of these tissues and eventually in tooth loss. Recent research reports document that the unfavorable outcome of periodontitis has a significant impact on the quality of life of adults and adolescents experiencing destruction of these tooth-supporting tissues.[1-3]

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The relationship between periodontitis and several dimensions of psychosocial distress such as stress,[4-10] depression,[4,5,9,11] anxiety,[4,6,8,9] life events,[11,12] and poor coping reactions[11] has attracted considerable attention from several groups of researchers during the past three decades. The list of plausible biological explanations for the observed association is long and includes psychologically induced modulation of the immune system, leading to increased blood levels of adrenocorticotropic hormones,[4,8,11,13] alteration of crevicular cytokine levels,[8,11,13] depressed polymorphonuclear leukocyte chemotaxis and phagocytosis,[8] reduced proliferation of lymphocytes,[5,10] changes in blood circulation and healing,[14] modifications of the salivary flow and its

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components,[9,11] and endocrine changes leading to immunosuppression.[7,10,11] The immunological modulation experienced as a consequence of stress, depression, anxiety and/or life events may partially explain the occurrence of psychological distress influences the behaviour of the subject towards less protective and riskier oral health related behaviour.[4,11]

Usually, the need to treat destructive periodontal diseases is based on observations made by dental professionals who suggest treatment, followed by reports of loss of clinical attachment or increased depth of probing pocket. Periodontal diagnosis is less often the result of individuals seeking care because of self-perceived periodontal problems. Nevertheless, it remains unclear if such professional observations of signs of periodontal damage are having an effect on the patient or to what degree.

Furthermore, most studies have focused on adult populations and only little attention has been devoted to the potential role of psychosocial distress in occurrence of periodontitis among the young. If the association is positive, it could have implications for the identification of a hitherto overlooked group of adolescents with undiscovered dental needs.

Aim of Study

The aims of this study were psychological distress is a general term that is used to describe unpleasant feeling or emotion that impact your level of functioning.

1. To assess the weather subject with periodontitis present with higher scores for non-psychotic psychological distress the control subject in a well-defined adolescent population
2. To investigate whether the dimensions "somatic symptoms," "anxiety and insomnia," "social dysfunction," and "severe depression" are associated with case status.

Objectives of Study

The aim of this research is to assess psychological distress and it's relation with periodontitis among patients attending outpatient department (OPD) of Teerthanker Mahaveer Dental College and Research Centre, Moradabad.

The objectives of this study are as follows:

1. To assess the psychological distress using 28-items Spanish version of the general health questionnaire (GHQ)
2. To measure pockets of more than 3 mm with the help of CPITN index
3. To assess impact of psychosocial distress (GHQ) on periodontitis
4. To recommended preventive measures.

MATERIALS AND METHODS

A case–control study was conducted among the patients attending OPD of Teerthanker Mahaveer Dental College and Research Centre, Moradabad, Uttar Pradesh, India, for a period of 2 months from September 2019 to November 2019. The participants were divided into two groups, cases and controls which comprise 135 subjects each.

Verbal informed consent was obtained, and the questionnaires were given at the individual level. Before commence of the study, an ethical clearance was obtained from the Institutional Ethical Committee of Teerthanker Mahaveer Dental College and Research Centre, Moradabad.

Sample Size Estimation

The sample size (n) was determined using the following formula:

$$n = \frac{Z^2 \times P \times q}{d^2}$$

Confidence interval=95%.
Relative precession=5%.
Z=Standardized normal deviate (Z value).
p=Proportion or prevalence of interest = 20%.
q=1- p (100-20 = 80).
d=clinically expected variation (5%).

Allowable error was 5% taken, keeping 95% confidence interval and 80% power of the study and 20%.

Prevalence of periodontitis, the sample size was determined to be:

$$n = \frac{(1.96)^2 \times (20) \times (80)}{5^2} = 245.86$$

=245

The sample size calculated was 245 using the above formula, but considering the dropouts, a total of 270 (n = 270) participants were selected; keeping in mind, dropout rate sample size is increase by 10.0%. A total of 135 participants were divided into cases and controls based on fulfilling the inclusion ad exclusion criterion.

Inclusion Criteria

1. All the patients attending OPD of Teerthanker Mahaveer Dental College and Research Centre who give the inform consent will be included in the study

2. The case definition adopted assigned case status to all subject presenting with the pathological pockets of ≥3 mm in at least two teeth recorded during the screening phase.

Exclusion Criteria

1. Physically challenged patients are not included in this study
2. Patients undergoing orthodontic treatment
3. Patients who had underwent any periodontal procedure for the past 6 months.

All participants took part in the study voluntarily and no incentives were used for the respondents. The questionnaire was adapted from pre-tested and pre-validated questionnaires from the previous studies, which was used to collect sociodemographic details. The following instruments are used plane mouth mirror, CPITN-C probe, tweezers, kidney trays, cotton holders, Korsolex, disposable mouth masks, disposable gloves, towels, soap, CPITN pro forma, and GHQ-28 questionnaire.[14-16]

The psychological distress 28-items Spanish version of the GHQ will be use. This was then converted into English vernacular language. The CPITN index was used to record periodontal status. In the study, the Likert scoring procedure (1, 2, 3, and 4) is applied and the total scale score ranges from **2**8 to **11**2 (1 – not at all, 2 – no more than usual, 3 – rather more than usual, and 4 – much more than usual). There are four subscales of the questionnaire, namely, somatic symptoms (item 1–7), anxiety/insomnia (8–14), social dysfunction (15–21), and severe depression (22–28).

The Likert scale used for final calculation was:
29–56: Feeling in need of a good tonic.
57–84: Run down.
85–112: Feeling ill.

Statistical Analysis

In the next stage, the distributed and completed questionnaires were collected and CPITN index was obtained and data were entered into MS Excel sheet (Windows 2007). Statistical analysis of the data was done using the Statistical Package for the Social Sciences (SPSS 20.0) using t-test to determine mean significant difference between the different variables, $P < 0.05$ and 95% confidence interval consider statistically significant.

RESULTS

A total of 330 questionnaires were distributed, among which 270 participants responded to the questionnaire. The overall response rate was 81.8% (270/330).

In Table 1, the present study was conducted among 270 participants out of whom 51 and 71 were female, respectively, in case and controls and 84 and 64 were male in case and controls, respectively. There was no significant difference in sex distribution of patients according to year of study.

In Table 2, the mean age of the respondents was 36.96 (±12.25) for cases and 33.71 (±10.07) for the controls. There was no significant difference in age distribution of patients according to year of study.

In Table 3, maximum responses of GHQ lie between 40 and 100. If you divide these into groups: 40–60, 61–80, and 81–100 with responses in cases 58, 72, and 5 and responses of controls are 89, 44, and 2, respectively. The Chi-square value came as 6.72. There was p-value came to be significant ($P = 0.03$) in distribution of GHQ score among the study subjects distribution of patients according to year of study.

In Table 4, the mean corruption perceptions index (CPI) score distribution score among the study subjects was recorded and it came to be 2.38 in cases and 1.26 in control. There results were highly significant and *t*-test value came as 6.72 in mean CPI score distribution of patients according to year of study. There was *P*-value came to be 0.01.

In Table 5, the mean GHQ score among the study subjects was recorded and it came to be 61.93 ± 10.27 in cases and 56.53± 9.30 in control. There results were highly significant

Table 1: Gender distribution of the study population

Group	Male		Female	
	n	%	*n*	%
Case	84	62.2	51	37.8
Control	64	47.4	71	52.6

Table 2: Age distribution of the study population

Group	Mean	SD
Case	36.96	12.25
Control	33.71	10.74

SD: Standard deviation

Table 3: Distribution of general health questionnaire score among the study subjects

Group	Case		Control	
	n	%	*n*	%
40–60	58	42.96	89	65.93
61–80	72	53.33	44	32.59
81–100	5	3.7	2	1.48
Chi-square		6.72		
P-value		0.03*		

*Statistically significant

Table 4: Corruption perceptions index score distribution among the study subjects

Group	Mean		SD
Case			
CPI 16/17	2.73		0.51
CPI11	1.55		0.75
CPI 26/27	2.71		0.68
CPI 46/47	2.72		0.76
CPI 31	2.02		0.82
CPI 36/37	2.57		0.78
Mean	2.38		0.73
Control			
CPI 16/17	1.84		0.38
CPI 11	1.11		0.58
CPI 26/27	1.04		0.44
CPI 46/47	1.23		0.53
CPI 31	0.99		0.67
CPI 36/37	1.36		0.74
Mean	1.26		0.56
t-test		9.11	
P value		<0.01*	

*Statistically significant. CPI: Corruption perceptions index, SD: Standard deviation

Table 5: Mean general health questionnaire score among the study subjects

Group	Mean		SD
Case	61.93		10.27
Control	56.53		9.30
t-test		8.91	
P-value		<0.01*	

*Statistically significant, SD: Standard deviation

(<0.01) and *t*-test value came as 8.91 in mean GHQ score distribution among the study subject.

In Table 6, the subdomain scores for "somatic symptoms," "anxiety and insomnia," "social dysfunction," and "severe depression" were similar for cases and controls.

In Table 7, the results of multiple logistic regression models adjusted for age and gender can be found. These analyses demonstrated a positive association between cases status and higher values for total GHQ score (odds ratio [OR] = 1.36, 95% confidence interval) and a positive but not significant association between the subdomains "somatic symptoms" (OR = 1.44) and "severe depression" (OR = 1.18) and case status.

Table 6: General health questionnaire score and its subdomains

Subdomains	Case		Control	
	Mean	SD	Mean	SD
Somatic symptoms	18.7	4.7	17.6	4.1
Anxiety and insomnia	16.8	3.96	16.9	4.05
Social dysfunction	14.87	3.17	13.84	3.24
Severe depression	11.56	3.76	11.54	3.65

SD: Standard deviation

Table 7: Regression analysis for total general health questionnaire score, its subdomains in relation to periodontitis

Subdomains	Reference	Moderate score	High score
General health questionnaire score	Low score	1.36	1.79
Somatic symptoms	Low score	1.44	1.41
Anxiety and insomnia	Low score	1.02	1.38
Social dysfunction	Low score	0.89	1.29
Severe depression	Low score	1.18	1.65

DISCUSSION

To the best of our knowledge, this study represents the first attempt by a young adolescent study population to investigate the association between periodontitis and non-psychosocial distress. The results of several studies conducted among adults have suggested the existence of a positive association[1,4-7,12,17,18] between measures of psychosocial distress and measures of periodontitis. A close inspection of the literature shows that some of the positive finding may be explained by the choice of parameter to assess periodontitis, for example, the use of probing depth as a measure of periodontitis.[6,12,17] Probing depth can be considerably influenced by poor oral hygiene, thus tending to represent the status of the gingival condition more than the presence of periodontal destruction. A look at the studies in which the investigators have employed "harder" measurements of periodontitis, for example, clinical attachment loss or bone loss, suggests a different picture, as only four studies support an association between periodontitis and anxiety/depression,[19] financially related stress,[19] or job-related stress,[5,7] whereas three studies could not confirm an association between periodontitis and anxiety,[6,9,12] depression,[6,11] stress,[6,9] psychiatric symptoms,[6] or negative life events by Castro *et al.* It should also be kept in mind that most of the evidence supporting the association originates from cross-sectional studies,[4,5] in which the temporal sequence of exposure and outcome cannot be disentangled.

The findings of our study suggest that psychosocial distress may be associated with periodontitis in young subjects. While the associations were not statistically significant, a clear dose–response gradient was found such that subjects scoring higher (1.38) and highest (1.79) were more likely to be a case than were subjects with lower totally GHQ scores [Table 7]. Moreover, the analyses showed that the subdomains "severe depression" and "somatic symptoms" were the main contributing dimensions underpinning the trend for an association between case status and psychosocial distress, as measured using the total GHQ score.

Two major plausible mechanisms may be suggested to explain the observed trend for an association between periodontitis and psychosocial distress. First, the nervous

and the immune systems work in interdependence, and an extensive body of literature suggests that distress may have indirect impacts on the immune function,[9,19,20] whereby the risk of periodontitis is increased. On the other hand, the association could also be mediated by psychosocial stress inducing behavioral changes, for example, by inducing or increasing smoking or by leading to deteriorated oral hygiene practices, which, in turn, are deleterious to periodontal health. Although our study is among the largest on the topic of the relationship between psychosocial distress and periodontitis,[4-6,10-12,21] this calculation shows that either much stronger association (higher estimates) is needed or the study groups need to be much larger.

According to Lopez *et al.,* they find out the finding of this study that the association between periodontitis and dimension of psychosocial distress can be documented in life. Too much of our knowledge, this research is the first attempt to investigate the association in a study population between periodontitis and non-psychotic psychosocial distress. The findings of our study suggest the psychosocial distress associated with periodontitis. The associations were statistically significant.

The most important limitation of this study is its cross-sectional design. Bias cannot be ruled out because information was collected from self-administered questionnaires. In this study, periodontal status was estimated by means of CPITN measurements. The CPITN is considered a "screening procedure for identifying actual and potential problems posed by periodontal disease both in the community and by the individual." Recent data on the bias resulting from examinations using a subset of sites (CPITN measurements) instead of full mouth recordings are scarce. Therefore, it is not clear whether a partial recording method leads to under- or overestimation of an actual periodontal status.[21]

CONCLUSION

The findings of this study suggest that the association between periodontitis and psychosocial distress dimensions can be documented early in life. This calls for awareness on the part of health-care providers attending adolescents. The evidence from the study conducted among adults suggests a significant interrelationship between periodontitis and dimensions of psychosocial distress. This warrants the awareness of health-care providers attending adults.

The results of the present study showed psychosocial stress to be related to lifestyle and lifestyle to levels of remaining periodontal support. The link between psychosocial stress and maintenance of periodontal health was supported in the present study.

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Original Article

Risk Factors and Clinical Outcomes of Acute Coronary Syndrome in Men: A Retrospective Study

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Abstract

Introduction: As the single largest cause of death on the planet, a cardiovascular disease including acute coronary syndrome (ACS) in all its forms is a vital, and more than that a matter of life or death. Despite the fact that the prevalence of ACS is higher in men; researches, up to now, have tended to focus more on the clinical outcomes of ACS in women rather than men.

Purpose: The present study aims to determine the risk factors and clinical outcomes of ACS in men, attended the tertiary health care center of Northwestern India.

Materials and Methods: In total, 500 male patients with age ≥18 years, who had the first-time presentation of ACS were included in this retrospective, observational study. A retrospective chart review was done, and demographic details, risk factors, coronary angiographic findings, and left ventricular ejection fraction were recorded.

Results: A total of 500 patients were involved in this study. Average age of the study population was found to be 53.4 ± 11.5 years. In men, diabetes (26.8%), followed by hypertension (24.2%), smoking (16.2%), and alcoholics (14.2%), was the most frequent factors associated with the development of ACS. In our study population, the majority of the patients (74.8%) had a single vessel disease and, the most commonly (77.8%) involved culprit vessel was left anterior descending artery. The maximum number of patients (80.2%) had achieved a good LV function at time of discharge.

Conclusion: Regardless of any gender bias, the prevalence of ACS has been continuously rising globally. Scrutinizing proper information with respect to risk factors and clinical presentation, ultimately aids in the management of therapy.

Key words: Acute coronary syndrome, Coronary angiogram, Coronary artery disease, Men, Risk factor

INTRODUCTION

Cardiovascular diseases (CVD) are major causes of mortality and morbidity worldwide, and these diseases have increased at an impressively fast rate in low- and middle-income countries. According to World Health Organization, an estimated 17.9 million people died due to CVD in 2016, represents 31% of all global deaths.[1] Acute coronary syndrome (ACS), a subset of CVD, refers to broad ranges of clinical condition include unstable angina, non-ST-segment elevation myocardial infarction (NSTEMI), and STEMI. The prevalence of ACS is predominant in men regardless of age specific groups.[2] In the last few years, there has been a growing interest in exploring the impact of gender difference in prognosis of ACS. This prognosis is a quite distinct among men and women mainly due to differences in baseline characteristics as well as physiopathological conditions; consequently, the diagnosis and management of ACS are also somehow distinct based on gender. In this context, Ayanian and Epstein[3] hold the view that men with ACS are more likely to undergo coronary angiography and invasive revascularization. In men, the risk factors associated with ACS are: Aging, high blood pressure, high blood cholesterol, smoking, lack of

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physical activity, unhealthy diet, obesity or overweight, type-2 diabetes, and family history of coronary artery disease.[4,5] A vast amount of literature focus on the clinical presentation of ACS in women, apart from this, only few studies compared the clinical presentation of ACS among men and women. There is, yet, a lack of evidence based data deals with clinical outcomes of ACS in men. Toward this end, we conducted this study to shed light on the risk factors and clinical outcomes of ACS in men.

MATERIALS AND METHODS

Study Design and Patient Population

This was a retrospective, observational study conducted at a tertiary-care center of the Northwestern India between August 2016 and December 2019. Men with age ≥18 years, who had first-time presentation of ACS were a main inclusion criteria for this study. Patients with known coronary artery disease (CAD), previous revascularization percutaneous transluminal coronary angioplasty, and coronary artery bypass graft, left main coronary artery (LMCA) disease, and men with prior ischemic heart disease/prior heart failure were completely rejected from the study. Informed consent was obtained from all patients.

Data Collection

Data regarding baseline demographic details, risk factors, and coronary angiographic findings were collected from the patient medical records. At discharge time, left ventricular ejection fraction was also noted. A selective coronary angiogram was done using standard technique within 48 h of admission unless the patient was not willing for a coronary angiography or has significant renal illness.

Definitions

In this study, hypertension is defined as systolic blood pressure ≥140, and/or diastolic blood pressure ≥90 mmHg. Dyslipidemia is defined as the presence of total cholesterol >240 mg/dl, triglycerides >150 mg/dl, low-density lipoprotein >130 mg/dl, and high-density lipoprotein <40 mg/dl for males. Diabetes is defined as the plasma glucose concentration ≥200 mg/dl or fasting blood sugar ≥126 mg/dl. Significant CAD is defined as a diameter stenosis >70% in each major epicardial artery. Normal coronary vessels are defined as the complete absence of any disease in the LMCA, left anterior descending (LAD), left circumflex (LCX), and right coronary artery (RCA) as well as in their main branches.

Statistical Analysis

The analysis was performed using Statistical Package for the Social Sciences (SPSS version 15; Chicago, Illinois, USA) software. Continuous variables were expressed as mean and standard deviation, and categorical variables were expressed as frequency and percentage.

RESULTS

A total of 500 patients were included in the study. Table 1 demonstrates the baseline characteristics of men with ACS. The mean age of men with ACS was found to be 53.4 ± 11.5 years. In men, diabetes (26.8%) was the most common risk factor associated with the occurrence of ACS, followed by hypertension (24.2%), smoking (16.2%), and alcoholics (14.2%). Chest pain (90%) was the most common symptoms present in men with ACS, followed by sweating (84.4%) shortness of breath (65%). Angiographic characteristics of the study population are displayed in Table 2. With regard to coronary angiographic findings, most of the patients (74.8%) had single vessel disease, followed by double vessel disease (19.6%) and triple vessel

Table 1: Baseline characteristics of men with acute coronary syndrome

Variables	Patients (*n*=500)
Age (mean±SD, years)	53.4±11.5
Risk factors	
Diabetes mellitus, *n* (%)	134 (26.8)
Hypertension, *n* (%)	121 (24.2)
Dyslipidemia, *n* (%)	62 (12.4)
Tobacco chewing, *n* (%)	22 (4.4)
Smoking, *n* (%)	81 (16.2)
Alcoholic, *n* (%)	71 (14.2)
Family history of CAD, *n* (%)	9 (1.8)
Symptoms	
Chest pain, *n* (%)	450 (90)
Shortness of breath, *n* (%)	325 (65)
Dyspnea, *n* (%)	255 (51)
Sweating, *n* (%)	422 (84.4)
Palpitations, *n* (%)	107 (21.4)
Syncope, *n* (%)	94 (18.8)
Vomiting, *n* (%)	57 (11.4)
Nausea, *n* (%)	82 (16.4)

†SD: Standard deviation, CAD: Coronary artery disease

Table 2: Angiographic characteristics of our study population

Variables	Patients (*n*=500)
Diseased vessels	
Single vessel disease, *n* (%)	374 (74.8)
Double vessel disease, *n* (%)	98 (19.6)
Triple vessel disease, *n* (%)	28 (5.6)
Target coronary artery lesions (*n*=735)	
Left anterior descending, *n* (%)	389 (77.8)
Left circumflex, *n* (%)	215 (29.2)
Right coronary artery, *n* (%)	131 (17.8)
LV function at discharge	
Good LV Function, *n* (%)	401 (80.2)
Mild LV Function, *n* (%)	58 (11.6)
Moderate LV Function, *n* (%)	41 (8.2)

†LV: Left ventricular

disease (5.6%). LAD is the most commonly involved culprit vessels, representing in 389 patients (77.8%), followed by LCA in 215 patients (29.2%) and RCA in 131 patients (17.8%). 2D echocardiography showed that the higher number of patients (401 patients; 80.2%) had a good LV function, and mild LV dysfunction was observed in 58 patients (11.6%), and moderate LV dysfunction in 41 patients (8.2%), but none of the patients had severe LV dysfunction at time of discharge.

DISCUSSION

Given the fact that the pattern of ACS in men has been remained unclear, and further there is no such evidence based report that compile the comprehensive details particularly in men, motivated us to conduct this study.

In this study, the mean estimated age of ACS onset was 53.4 ± 11.5 years. This findings have been in good agreement with the previously reported studies by Duan *et al.*[2] and Chen *et al.*,[6] the reported mean age was 54.61 ± 11.24 years and 59 ± 12 years, respectively. In contrast to our findings, Assiri[7] reported higher age of ACS onset in men compared to our findings, and it was 60 ±13.4 years. Furthermore, Udell *et al.*[8] (61.65 years) and Arslanian-Engoren *et al.*[9] independently reported the marked higher mean age for the development of ACS in men. More toward this side, EPIHeart cohort study included a total of 873 patients, of which 646 were men with mean age of 62.2 ± 12.7 years.[10] Altogether, overall we can say that men are more likely to develop ACS over the 5th decades of life. In brief, the prevalence of ACS has been growing with advanced age.

Regarding coronary risk factors, in this study, diabetes mellitus, hypertension, and smoking were the most common risk factors for the progression of ACS in men. The findings reported by Assiri[7] corroborate with our results. In one study, diabetes mellitus (35.6%) was the most common risk factor for ACS in men, and hyperlipidemia (60.4%) been a second common risk factor, and then hypertension (79.6%) got rank.[8] Controversially, another study reported smoking (69%) as the most common risk factor for ACS in men, followed by hypertension (62%) and dyslipidemia (62%).[9] It has been reported that hypercholesterolemia (88%), hypertension (53%), and smoking (71%) have contributed in the progression of ACS.[6] In his seminal article on sex differences in ACS, Khan *et al.*[11] reported that the majority of patients had hypertension as the first common risk factor, smoking was second one, and BMI >30 was third one; nevertheless, the younger men were involved in this study with mean age 49.0 years and ranged from 45 to 53 years.

The presence of diabetes worsens prognosis of ACS in both men and women, however, men is affected with lesser extent than women. For example, the relative risk of myocardial infarction (MI) is 3 times less in diabetic man compared to diabetic women (50% vs. 150%).[12] In men, another well-established leading risk factor of ACS is hypertension. It has been reported that hypertension has been noted in men younger than 65 years compared to women with similar age group.[13]

Smoking is regarded as a strong risk factor for all CVD including ACS. It contributes in premature atherosclerosis and cardiac death. Due to modern civilization, the number of smokers has been expected to be higher in recent decades than the previous time. Moreover, men more likely have a habit of smoking than women. To illustrate, the proportion of smokers in developed countries has been 35%, and it was 50% in developing countries. On the other hand, there has been a reversed pattern in women; around 22% women have been smokers in developed countries and 9% in developing countries.[14] To sum up, the earlier mentioned and other previously reported studies claimed diabetes, hypertension, and smoking as major risk factors for the progression of ACS, nonetheless, their predominance were distinct in these reports.[11,15,16]

Since the early 2000s, a shred of evidence has established a link between the presentation of symptom and gender differences. Experts have also agreed with that men with ACS have been less likely to present worsen symptoms than women. In women, nausea or vomiting, and pain between the shoulder blades, and shortness of breath have been reported as the typical presentation of ACS. On the other hand, men are more likely presented with chest pain (79% vs. 74%), shortness of breath (40% vs. 48%), diaphoresis (47% vs. 44%), nausea or vomiting (28% vs. 39%), and left arm and left shoulder pain (37% vs. 38%) than women.[17] Agreed with this findings, our study also demonstrated that chest pain was the most common complaint in men with ACS. In light of their findings, Assiri[7] reported the symptoms of chest pain in 71 percent of men. These findings are in line with earlier reported studies as well.[9,6,18]

On coronary angiography findings, most of the patients had single vessel disease, followed by double vessel disease (19.6%) and triple vessel disease (5.6%). One study reported single vessel disease in 31% and multi-vessels in 46.7% of men.[7] Another study reported that 49.3% patients had single vessel disease, 17.3% patients had double vessel disease, and 22.2% patients had triple vessel disease.[8] LAD was most commonly involved culprit vessel, followed by LCX and RCA among men in our study population. Regarding this context, there is a limited data available in the literature, especially for men

with ACS; however, results obtained from single study were in favor of our findings.[11] At time of discharge, almost patients recovered, and preserved improved left ventricular function. Fortunately, death was not reported in our subjects.

It is plausible that a number of limitations might have affected the results obtained. To begin with, the study was retrospective in nature, and comprised limited sample size, hence, confounding factors might have influenced the final outcomes. Another possible source of error is a hospital based study design; thus, the obtained outcomes might not be an actual representation of the entire population.

CONCLUSION

This study has provided a deeper insight into risk factors and clinical outcomes of ACS in men. As concluded, diabetes, hypertension, smoking, and alcoholics were the primary risk factors in men with ACS. The almost patients had a single-vessel disease, and LAD was the most common culprit vessel. The maximum number of patients recovered with good left ventricular function.

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Original Article

Augmentation of Low-dose Atypical Antipsychotics along with Antidepressant in Mild-to-Moderate Depression – A Case–control Study

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Abstract

Introduction: Depression is the most common mental disorder in the world today, affecting 34 crore people in the world. 1:4 women and 1:10 men will develop depression sometime in their lifetime, 50% of cases are unrecognized. Various studies have shown adding our augmenting antidepressant with low-dose antipsychotic requires only in case of bipolar depression, recurrent depression, or resistant depression. Anxiety commonly associated with most of the depressive patients.

Aim: This study aims to study augmentation of low-dose atypical antipsychotics along with antidepressant in mild-to-moderate depression.

Materials and Methods: In this case–control study, mild-to-moderate depression cases were divided into 50 patients in each group. The study group treated with augmented antidepressant with low-dose antipsychotic olanzapine or amisulpride or quetiapine or levosulpiride or risperidone and in the control group treated with one or two different groups of antidepressant. Benzodiazepam has not been used in either of the group. Depression was diagnosed after meeting criteria as per DSM-5 (diagnostic and statistical manual of mental disorders) by clinical evaluation by a psychiatrist. The scale used was the Beck Depression Inventory scale for severity of depression, Brief Psychiatric Rating Scale to rule out any psychotic symptoms.

Results: Mean age of the control group was 32.48 ± 6.66 years and in the study group 33.22 ± 7.09 years (P = 0.0.592). Mean remission of the control group was 31.14 ± 3.55 days and in the study group 23.38 ± 2.42 days (P < 0.0001). Mean hospital stay of the control group was 44.16 ±3.91 days and in the study group 28.52 ± 1.82 days (P < 0.0001).

Conclusion: Augmentation of low-dose atypical antipsychotics along with standard antidepressants reduces the period of hospital stay and early remission from depressive symptoms.

Key words: Antidepressant, Augmentation, Combination, Depression

INTRODUCTION

Today, depression is the world's most prevalent mental illness, affecting 34 crore individuals in the world. Sometime in their lifetime, 1:4 women and 1:10 men may experience depression. This is unfortunate since one of the most treatable mental disorders is depression.[1] Substantial impairment is induced by depressive disorders, sometimes beyond that resulting from other chronic conditions such as cardiac disease and diabetes.[2] In the treatment of the major depressive disorder, atypical antipsychotic treatments are commonly utilized. There were an estimated 3.9 million treatment visits each year in the United States in 2007 and 2008 in which an antipsychotic medication was administered for depression, and almost all of these (96 percent) included the prescription of an atypical antipsychotic drug.[1] While aggregate figures obscure the precise indications for use (i.e., monotherapy vs. adjunctive therapy), this reprehensive therapy results are also consistent with industry market reports.[2] The US Food and Drug Administration has approved three atypical antipsychotic drugs as adjunctive treatments in adults for depression, although none are approved for monotherapy. These approvals (and subsequent marketing efforts), along with the number of prescriptions, indicate that adjunctive

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therapy utilizes a significant number of prescriptions for atypical antipsychotic drugs written for the treatment of depression.[3-5]

Over the last couple of decades, several antidepressant medicines have been established, but the mechanism of action of these medicines remains uncertain, and the proportion of patients who are not helped by these medicines remains large. Treatment with antidepressants and antipsychotics (including conventional antipsychotics, such as sulpiride, or atypical antipsychotics, such as clozapine, olanzapine, quetiapine, aripiprazole, risperidone, and ziprasidone) can involve the complete resolution of all symptoms of depression using several drugs with different mechanisms of action.

Various studies have shown adding our augmenting antidepressant with low-dose antipsychotic requires only in case of bipolar depression, recurrent depression, or resistant depression. Most of the psychiatrists still avoid augmenting antipsychotic in mild-to-moderate depression.

Aim

This study aims to study augmentation of low-dose atypical antipsychotics along with antidepressant in mild-to-moderate depression.

MATERIALS AND METHODS

This case–control study was conducted in the department of psychiatry of a large tertiary care hospital in Hyderabad with the urban population for 2 years from the year 2017 to 2019.

The required sample size is 100, in which 50 in the study group and 50 in the control group had been chosen randomly.

Inclusion Criteria

Selection criteria were the age group of 20–50 years, male, not on any psychoactive substance abuse, no family history of psychiatric illness, and no history of mental illness, no history of recent death or grief in the family, and no h/o any comorbid physical or surgical illness.

Exclusion Criteria

Those who have a history of substance abuse, a recent death in the family, family history of mental illness or suicide history in the family and recent death or grief in family, severe depression and too severe depression after clinical evaluation, depression with psychotic symptoms, recurrent depression, or bipolar depression were excluded from the study. Female patients were not included in this study because of the unavailability of inpatient female treatment.

The study group consisted of 50 patients of mild-to-moderate depression augmented antidepressant with low-dose antipsychotic olanzapine or amisulpride or quetiapine or levosulpiride or risperidone in randomly selected depression cases. The control group consisted of 50 patients, primarily case of depression mild to moderate and was exposed to one or two different groups of antidepressant. Benzodiazepine has not been used in either of the group.

After ethical clearance from all participants, informed consent had been taken, all participants examine by principal investigator who was blinded to the beck depression inventory (BDI) score, diagnosis made as per DSM-5.[6] Selected participants were subjected to a screening questionnaire BDI.[7] In BDI, score 11–18 considered as mild depression, score 19–25 considered as moderate depression, and any score 25 or above is severe or extreme severe depression.

Those who were selected assigned randomly in the study and control groups each of 50 patients over the next 2 years. After discharge from hospital, follow-up of all cases has been done for more than 8 months. In the study group, atypical antipsychotic gradually tapered down over the next 6–8 months and continued with a single antidepressant in adequate tolerable dose. The study group has been exposed to antidepressant mainly Cap fluoxetine 20 mg, Tab sertraline 50–150 mg, Cap venlafaxine 75–150 mg, and Tab mirtazapine 30 mg, with low-dose antipsychotics mainly; olanzapine (2.5–5 mg)/amisulpride (50–100 mg)/levosulpiride (50–100 mg) or Tab quetiapine (50–100 mg) and Tab risperidone (1 mg) randomly by the psychiatrist. No benzodiazepine has been added.

In the control group, single or combination of antidepressant had been added depends on the response after 21 days. The antidepressant used was mainly either of, Cap fluoxetine 20 mg or Tab sertraline 50–150 mg or Cap venlafaxine 75–150 mg or Tab mirtazapine 30 mg and if no response after 21 days second antidepressant use either of different drug of earlier mentioned antidepressant or Cap Doxepin (75–150 mg), in maximum recommended and tolerable dose. No benzodiazepine had been added in the control group also.

Remission has been considered after clinical examination by psychiatrist blinded to BDI score and further confirmed it with BDI score, reduced in BDI score <6 or 100% symptoms free, discharge has been considered, that is, hospital stay when the patient felt comfortable and self-reported for discharge and after clinical evaluation by two psychiatrists.

Statistical analysis was done by using SPSS Version 21 software. Pearson Chi-square used to calculate the

association of categorical variable and independent Student's t-test used to compare the continuous variables.

RESULTS

In this study, 100 male patients with mild-to-moderate depression were divided into two groups study and control, each group with 50 patients. No statistical difference noted between age in the control group and study group. A higher number of patients were in 31–40 years age group (48%). In the control group, 46% of patients and in the study group, 48% of patients are between 31 and 40 years age group. Mean age of the control group was 32.48 ± 6.66 years and in the study group 33.22 ± 7.09 years, statistically insignificant ($P = 0.592$) [Table 1].

In this study, 12% of patients were in the range of BDI score 11–15, 42% of patients were in the range of BDI score, and 42% of patients were in the range of BDI score 21–25. There is no statistical difference noted between BDI score in both groups. In the control group, 20% of patients were in the range of BDI score 11–15, 46% of patients in the range of BDI score 16–20, and 34% of patients were in 21–25 BDI score and study group 38% of patients were in 16–20 BDI score, and 34% of patients were in the range of BDI score 21–25, statistically insignificant ($P = 0.234$). Mean BDI score of the control group was 19.02 ± 3.62 and in the study group 20.06 ± 3.62 statistically insignificant ($P = 0.155$) [Table 2].

In this study, 36% of patients in mild depression in the control group and 30% of patients were in mild depression in the study group, 64% of patients were in moderate depression in the control group, and 70% of patients were in moderate depression in the study group [Table 3].

Mean remission of the control group was 31.14 ± 3.55 days and in the study group 23.38 ± 2.42 days ($P < 0.0001$). In this study, 50% of patients had remission in <30 days, in the study group, 100% of patients have had remission in <30 days, and in the control group, 86% of patients had remission in 31–40 days, statistically significant ($P < 0.0001$) [Table 4].

Mean hospital stay of the control group was 44.16 ± 3.91 days and in the study group 28.52 ± 1.82 days ($P < 0.0001$). In this study, 50% of patients had discharged in <30 days, in the study group, that is, 100% of patients were had discharged in <30 days. In the control group, 18% of patients discharge in 31–40 days, 72% of patients had discharged in between 41 to 50 days, and 10% discharge in 51–60 days, statistically significant ($P < 0.0001$) [Table 5].

About 100% of patients among the study group and 100% of patients of the control group could be followed up for next 1 year, and it was found out of 50 patients in the study group only 2 patients had a relapse of symptoms in 1 year and out of 50 patients of the control group 13 patients had a relapse of symptoms over 1 year. There is no drop out in either of the group during follow-up. Over 4–6 months, atypical antipsychotics gradually stopped, and the study group patient continued with a standard maintenance dose of single antidepressant. The control group patient continued with the same medication with the rationalization of dose as per evaluation during clinical follow-up. No patient in either of the group reported with any significant side effect or problem with medication. The main reason for relapse was stopping the medication when they were feeling better. Hence, it was difficult to say either of the group has any tendency for relapse because of poor drug compliance or unsupportive environment stressor among the study and control groups.

DISCUSSION

Depression is one of the common illnesses. Depending on the severity of symptoms, a depressive episode can be categorized as mild, moderate, or severe. In India, the National Mental Health Survey 2015–2016 reveals that nearly one in 20 Indian suffers from depression.[8]

In this study, we found no statistical difference noted between age in the control group and study group. There

Table 1: Age-wise distribution of the control and study groups

Group	Age group				Total	*P*-value
	<30	31–40	41–50	>51		
Control						
Count	20	23	6	1	50	0.592
% within group	40.00%	46.00%	12.00%	2.00%	100.00%	
Study						
Count	19	25	4	2	50	
% within group	38.00%	50.00%	8.00%	4.00%	100.00%	
Total						
Count	39	48	10	3	100	
% within group	39.00%	48.00%	10.00%	3.00%	100.00%	

Table 2: BDI score range in the control and study groups

Group	BDI score			Total	*P*-value
	November 15	16–20	21–25		
Control					
Count	10	23	17	50	0.155
% within group	20.00%	46.00%	34.00%	100.00%	
Study					
Count	6	19	25	50	
% within group	12.00%	38.00%	50.00%	100.00%	
Total					
Count	16	42	42	100	
% within group	16.00%	42.00%	42.00%	100.00%	

Table 3: Diagnosis in the control and study groups

Group	Diagnosis		Total
	Mild depression	Moderate depression	
Control			
Count	18	32	50
% within group	36.0%	64.0%	100.0%
Study			
Count	15	35	50
% within group	30.0%	70.0%	100.0%
Total			
Count	33	67	100
% within group	33.0%	67.0%	100.0%

Table 4: Remission in the day in the control and study groups

Group	Remission in days when BDI-0			Total	*P*-value
	<30	31–40	41–50		
Control					
Count	0	43	7	50	<0.0001
% within group	0.0%	86.0%	14.0%	100.0%	
Study					
Count	50	0	0	50	
% within group	100.0%	0.0%	0.0%	100.0%	
Total					
Count	50	43	7	100	
% within group	50.0%	43.0%	7.0%	100.0%	

is no statistical difference noted between BDI score in both groups. In this study, 36% of patients in mild depression in the control group and 30% of patients were in mild depression in the study group, 64% of patients were in moderate depression in the control group, and 70% of patients were in moderate depression in the study group. Mean remission of the control group was 31.14 ± 3.55 days and in the study group 23.38 ± 2.42 days ($P < 0.0001$). In the control group, 18% of patients discharge in 31–40 days, 72% of patients had discharged in between 41–50 days, and 10% discharge in 51–60 days, statistically significant ($P < 0.0001$).

Table 5: Hospital stay/discharge from the hospital in the control and study groups

Group	Hospital stay/discharge in days				Total	*P*-value
	<30	31–40	41–50	51–60		
Control						
Count	0	9	36	5	50	<0.0001
% within group	0.0%	18.0%	72.0%	10.0%	100.0%	
Study						
Count	50	0	0	0	50	
% within group	100.0%	0.0%	0.0%	0.0%	100.0%	
Total						
Count	50	9	36	5	100	
% within group	50.0%	9.0%	36.0%	5.0%	100.0%	

Low-dose atypical antipsychotics along with one standard antidepressant medicine reduced the remission time and reduced hospital stay compared to the control group who were on single or two different antidepressants with maximum recommended and tolerable dose. However, there is no statistically significant difference in mean BDI score of control and significant group.

Most of the study based on the augmentation of atypical antipsychotics in major or treatment-resistant depression. This is the first study which has been done to observe the effect of low-dose augmentation of atypical antipsychotics along with standard antidepressant from day 1 without adding benzodiazepine not only reduces the remission time but also decreases hospital stay, that is, discharge from hospital and found statistically significant result compare to control group those were on either one or two standard antidepressants without benzodiazepine, in mild-to-moderate depression.

Result of this study is in agreement with the study of the American Psychiatric Association 3rd Edition Practice Guidelines which was published in 2010.[9] They reported that adjunctive treatment with an atypical antipsychotic agent was significantly more effective than placebo in terms

of response and remission. The Canadian Network of Mood and Anxiety treatment guidelines were updated in 2016.[10] This guideline recommends adjunctive treatment with atypical antipsychotics as follows; aripiprazole, quetiapine, and risperidone are first lines, brexpiprazole and olanzapine second line, and ziprasidone third line. The NICE guidelines for the treatment of major depression[11] recommend adjunctive treatment as a treatment option and consider atypical antipsychotics such as aripiprazole, quetiapine, risperidone, and olanzapine, to be appropriate adjunctive treatment agents.

German National Clinical Practice Guidelines[12] are more conservative, not recommending atypical antipsychotics as an adjunctive treatment except in psychotic depression. However, the MPG (Max Planck Institute of Psychiatry) in German included quetiapine as a first-line, well-tolerated augmenter with a good evidence base, advising that it should be used in addition to an SSRI or serotonin-norepinephrine reuptake inhibitors. They advised that quetiapine is possibly more significant than lithium.

The World Congress of Biological Psychiatry included quetiapine as a first-line option, referencing a study in which it was significantly more effective than antidepressant monotherapy, though it has been associated with more weight gain and sedation (Komossa *et al*., 2010; Bauer *et al*., 2010).[13,14] Clinical studies in naturalistic settings consistently indicate that barely half of the depressed patients respond to initial antidepressant monotherapy (the most common recommendation in practice guidelines) and that only one third eventually achieve satisfactory remission of symptoms (the desired goal in most guidelines).[15] Shelton *et al*. reported that a combination of fluoxetine and olanzapine was superior to either drug alone in their non-psychotic depressed sample.[4]

Reviewing all the recommended studies of the different country this study is in close agreement that augmenting low-dose antipsychotics with standard antidepressant along with supportive therapy from day 1 not only helps in early remission but also reduces the hospital stay duration. Since this study population was less so it needs further study in the larger population without gender bias to formulate treatment guidelines and remove the stigma that atypical antipsychotics can only be used in treatment-resistant depression, major depression or depression with psychotic symptoms seeing the role of atypical antipsychotics in all type of receptors which help in early relief from depressive symptoms.

CONCLUSION

There was a significant improvement on remission in patients augmented with low-dose atypical antipsychotic along with one antidepressant from day 1 and reduced in the day of hospital stay with antidepressant augmented with low-dose atypical antipsychotics. At present, side effects are more predictable than treatment efficacy, so the relative risk of different types of side effects is the most important factor to consider. Future studies need to identify subgroups of depressive patients, categorized by genetics, neurophysiological markers, or family history.

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Original Article

Caudal Ketamine for Post-operative Analgesia in Pediatric Lower Abdominal Surgeries

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Abstract

Background: Caudal anesthesia is one of the most common regional anesthetic techniques used for lower abdominal and lower extremities surgery in pediatric group of patients. Various drugs other than local anesthetics have been tried for prolonging the duration of post-operative analgesia and also to enhance the quality of block. We aimed to study and compare the effect of ketamine and bupivacaine in caudal epidural block in pediatric patient.

Materials and Methods: This prospective, randomized, double–blind, and controlled study include 60 pediatric patient aged 2–12 years with ASA Grade I and II scheduled for lower abdominal surgery. The patient was randomly allocated to three groups of 20 each. The patient in Group K1 received caudal ketamine 0.5 mg/kg made up to 0.75 ml/kg. The patient in Group K2 received ketamine 1 mg/kg made up to 0.75 ml/kg. The patient in Group B received caudal bupivacaine (0.25%) with epinephrine 1:200,000 in a dose of 1.8 mg/kg made up to 0.75 ml/kg. Vital parameter including heart rate, blood pressure, respiratory rate, sedation score as well as the pain score of the patient was monitored hourly up to the 8th h postoperatively and compared between the groups.

Results: Ketamine and bupivacaine have practically, when given caudally have, no effect on vitals parameter. Bupivacaine (0.25%) and ketamine in doses of 1 mg/kg are better analgesic than ketamine 0.5 mg/kg ($P < 0.05$). There was no significant difference in between groups in sedation score.

Conclusion: In our study, it is concluded that ketamine in doses of 1 mg/kg made up to 0.75 ml/kg afford comparable analgesia to 0.25% bupivacaine when administered caudally in pediatric patient for lower abdominal surgery.

Key words: Bupivacaine, Caudal, Ketamine

INTRODUCTION

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage. During surgery, it occurs as result of direct tissue trauma and further aggravated by reflex muscular spasm or visceral distention.

Post-operative pain is likely to bring a term of unavoidable complications jeopardizing patient's recovery. Prolonged immobilization caused by pain can lead to deep vein thrombosis, bedsores, muscle wasting, hypostatic pneumonia, reduced functional residual capacity, inability for sputum clearance, and many other problems. Thus, the requirement of postoperative pain relief is more for therapeutic than for humanitarian reasons.

Parenteral administration of narcotics remains the most conventional method of post-operative pain relief. The larger dose requirement as compared to modern methods is associated with several side effects such as nausea, vomiting, itching, and respiratory depression early or delayed. When used for prolonged periods, the problems of tolerance and addiction cannot be ignored.

Extradural sacral block is one of the methods in conduction analgesia and provides differential spinal block. It has all

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the advantages of low spinal block and is outside theca. This method scores heavily on grounds of efficiency and largely avoids dangers of vomiting.

Caudal anesthesia has become widespread in pediatric surgery in recent years; especially for operations below the umbilicus since the "First pediatric report" in 1933. Several studies have described the indication for pediatric caudal block, the level of analgesia, recommended doses, and pharmacokinetics of local analgesics and anesthetics used in caudal anesthesia.[1-4]

The ketamine molecule (2-0-chloro-phenyl-2-methylaminocyclohexanone), which structurally resembles phencyclidine and cyclohexylamine, has a molecular weight of 238. Water soluble has a pka of 7.5 and contains a chiral center producing two optical isomers or enantiomers. The racemic mixture contains equal amounts of the two ketamine isomers.[5]

"Dissociative" anesthetic state which has been described as a functional and electrophysiological dissociation between the thalamoneocortical and limbic systems; catalepsy in which the eyes remain open with a slow nystagmic gaze while corneal and light reflexes remain intact, varying degree of hypertonus and occasional non-purposeful movements unrelated to painful stimuli; depression of thalamoneocortical pathways (producing hypersynchronous delta waves), and concomitant activation of limbic system.

Massopust *et al.*[6] showed that ketamine produces a selective depressant effect on the medial thalamic nuclei. This observation was supported by the work of Sparks *et al.*[7] who demonstrated that ketamine blocks afferent signals associated with the affective emotional components of pain perception (spinoreticular tracts) without significantly impairing conduction of signals related to localization of somatic stimuli (e.g., spinothalamic tracts). There are also evidence to suggest that ketamine binds stereospecifically to opiate receptors possibly competing with narcotic analgesics and endogenous morphine such as compounds for central nervous system and spinal cord receptors sites.[8]

Possible systemic toxicity after intravascular injection of local anesthetics or possible respiratory depression after spinal opioid administrations has been the motivation for caudal or epidural administration of ketamine.

It was assumed that ketamine exerts analgesic effects after epidural, caudal, or intrathecal administration because of its interaction with antinociceptive spinal receptors. Because the administration through epidural route would bring the drug closure to "the target organ," the effective doses can be reduced, thus decreasing possible adverse effects. Although some studies have shown sufficient analgesic effectiveness of epidural ketamine,[9] other study did not confirm these results. Hence, this study was conducted to document measurable analgesic effect of caudal epidural administered ketamine in varying doses.

Aims and Objectives

The objectives of the study were as follows:

1. To study the efficacy of caudal epidural administered ketamine as a post-operative analgesic
2. To study the efficacy of caudal epidural administered bupivacaine as a postoperative analgesic
3. To study the effects of caudal epidural administered bupivacaine and ketamine on cardiovascular and respiratory dynamics
4. To study the side effects of bupivacaine and ketamine

MATERIALS AND METHODS

This study was carried out on 60 children of either sex in the age group from 2 years to 12 years. The cases were selected from the routine operative list of pediatric surgery which were below umbilicus in N.S.C.B. Medical College and Hospital, Jabalpur. The duration of study was from 2000 to 2001.

The cases were chosen at random (ASA I and II) from different communities and status. They were examined to rule out any cardiorespiratory or systemic illness a day before surgery. Patients with a history of bleeding diathesis, pre-existing neurological and spinal diseases, or allergic tendencies were excluded from the study. The entire procedure was explained to the patients parents to gain confidence and written informed consent was taken.

Baseline parameters were recorded, that is, blood pressure, heart rate, and respiratory rate. All routine investigations were done and all patients were weighted preoperatively to calculate the dose of caudally administered drug to be given. The study comprised three groups.

- Group K1 consists of 20 patients of the either sex, who received caudal ketamine 0.5 mg/kg made up to 0.75 ml/kg
- Group K2 consists of 20 patients of either sex, who received caudal ketamine 1 mg/kg made up to 0.75 ml/kg
- Group B consists of 20 patients of either sex, who received caudal bupivacaine (0.25%) with epinephrine 1:200,000 made up to 0.75 ml/kg.

A patent vein was secured and patients pre-medicated by injection atropine in dose of 0.03 mg/kg. No narcotic was given. Then, the patients were induced with intravenous

thiopentone (2.5%) 4–7 mg/kg and intubation facilitated with succinylcholine. Anesthesia was maintained with 1–1.5% halothane and O_2, gas mixture (30:70). Muscle relaxation with atracurium and ventilation provided with JR modification of Ayre's T piece or Bain's circuit. An Isolyte P solution was infused at a rate of 5–10 ml/kg/h.

The anesthetized patient was placed in either right or left lateral position with the hip and knees flexed on abdomen with slight flexion of neck. All aseptic precautions were taken. The skin over the sacral hiatus was stretched with the left hand to facilitate puncture. Aspiration for blood and cerebrospinal fluid was done; if negative a test dose of 2 ml of selected drug was injected. The patient was watched for 5 min to detect any untoward effect. The total requisite dose of the drug was then slowly injected.

Immediately after injection of drug, the patient was turned supine. Vitals were obtained after induction of general anesthesia, immediately after caudal injection, and every 5 min thereafter during operation. Skin incision was allowed 15 min after caudal injection. At the beginning, of skin closure, anesthesia was discontinued.

When the surgery was over, the patient was shifted to recovery room and vitals along with sedation score and pain score were recorded before discharging the patient to surgical ward. On arrival to the surgical ward, the patient was observed until 8 h, after the caudal injection.

The efficacy of post-operative analgesia was documented by an observation pain/discomfort scale (OPS) and duration of analgesia after caudal block. Objective behavioral variables are as follows.

- Crying
- Facial expression
- Position of the torso
- Position of legs
- Motor restlessness.

Each variable was scored on a three point scale.

- 1 = None
- 2 = Moderate
- 3 = Severe.

Duration of analgesia was defined as the time between caudal injection of drug and first intravenous injection of paracetamol. If intravenous injection of paracetamol was not necessary within 6 h of observation period, the duration of analgesia was counted as 360 min. A four-point patient sedation score was assigned as follows —

- 1 = Asleep (not arousable by verbal contact)
- 2 = Asleep (Arousable by verbal contact)
- 3 = Drowsy (not sleepy)
- 4 = Alert, awake

Patient was observed closely for complications such as nausea, vomiting. itching, respiratory depression, retention of urine, bradycardia, and convulsion up to 8 h.

OBSERVATIONS AND RESULTS

Maximum number of children were in the age range of 5–8 years in Group B and age range 9–12 years in Groups K_1 and K_2. There was no significant difference between the three groups ($P > 0.05$).

Table 3 shows that children in all three groups had weight ranging from 5 to 28 kg. Difference between the three groups was statistically insignificant ($P > 0.05$).

The main indication of this block is to provide post-operative pain relief in operations below umbilicus. In this study, maximum number of cases were herniotomy (66.66%).

The mean heart rate decreased in all the three groups and there was no significant difference in heart rate among the groups after injection of drug ($P > 0.05$).

Although there was an increase in blood pressure after injection of drug in all the three groups, the difference

Table 1: Distribution of group

S. No.	Group	No. of cases	Drug for caudal epidural	Dose	Volume
1.	B	20	Bupivacaine	1.8 mg/kg	0.75 m1/kg
2.	K1	20	Ketamine	0.5 mg/kg	0.75 m1/kg
3.	K2	20	Ketamine	1.0 mg/kg	0.75 ml/kg

Table 2: Age-wise distribution of the patients

S. No.	Age in years	Group B (*n*=20)		Group K_1 (*n*=20)		Group K_2 (*n*=20)	
		Male	Female	Male	Female	Male	Female
1.	2–4	5	2	6	1	4	2
2.	5–8	7	2	4	2	4	1
3.	9–12	3	1	5	2	7	2
Total		15	5	15	5	15	5
Mean age±S.D.		6.25±2.78		6.6±3.37		7.8±3.39	

between groups was statistically insignificant ($P > 0.05$). The *Z*-test was applied to compare all three groups.

The change in respiratory rate at different hours in each group was found to be statistically insignificant ($P > 0.05$).

Table 8 shows four point sedation score. There was no significant difference between the three groups in mean hourly sedation score. *Z*-test applied to compare all three groups ($P > 0.05$).

Total duration of post-operative pain was observed using OPS. There were more patients requiring additional analgesic immediately after surgery in Group K1 compared with other two groups. In Group B, pain score significantly increased after 7 h. In Group K1, OPS was significantly increased after 4 h of observation. In Group K2, OPS was significantly increased after 5 h of observation. Mean OPS in Group B was significantly lower as compared with K1 ($P < 0.05$).

Table 10 shows mean duration of analgesia in three groups. In Group B, it was 5.10 ± 1.38 h. In Group K1, it was 3.21 ± 1.56 h, and in Group K2, it was 4.35 ± 2.01 h. Mean duration of analgesia for those patients who left the recovery area without first requiring addition analgesia did not differ significantly between groups ($P > 0.05$).

DISCUSSION

Caudal epidural analgesia has become wide spread in pediatric surgery in recent years, especially for pain management within the distribution of the T10–S5 dermatomes, covering the lower abdomen, perineum, and lower extremities. It is evident from various studies that intrathecal and epidural administration of local anesthetic drug and narcotic is a novel method for providing pain relief.

Discovery of caudal epidural space by Corning in 1885 started a new era of pain relief but did not achieve any success till the first successful attempt was done by Cathlein and Sicard (1901), to achieve pain relief by extradural administration of local anesthetic.

Although administration of bupivacaine in caudal epidural space has been the standard method for providing post-operative analgesia for below umblicus surgery; a single injection may have only a relatively short duration of action.

To obviate the need of narcotics, it was decided to determine if caudal ketamine could provide effective, long-lasting analgesia. Each group contains 20 patients posted for repair of inguinal hernia surgery; was given caudal epidural block to evaluate clinically the efficacy of ketamine by this route in children for the purpose of post-operative pain relief.

Group B contains 20 cases for caudal epidural bupivacaine in dose of 1.8 mg/kg, in volume of 0.75 ml/kg diluted with normal saline. Group K1 contains 20 cases for caudal epidural for ketamine in dose of 0.5 mg/kg in volume of 0.75 ml/kg diluted with normal saline and Group K2 contains 20 cases receiving ketamine in dose of 1 mg/kg in volume of 0.75 ml/kg diluted with normal saline.

In this study, 45 patients were male and 15 were female. The mean age of patients in this study was 6.25 ± 2.78 years in Group B, Group K1 was 6.6 ± 3.37 years, and Group K2 was 7.8 ± 3.39 years. The main indications of this block were inguinal herniotomy (66.66%) and herniorrhaphy (33.33%).

Mean weight of patients in Group B was 17.84 ± 5.30 kg, in Group K1 was 17.65 ± 6.28 kg, and in Group K2 was 20.15 ± 7.09 kg. Maximum number of patients were in weight range of 14–18 kg in Group B and weight range of 24–28 kg in Groups K1 and K2. The difference in mean weight of patients of three groups was found to be statistically insignificant.

In this study, patients were premedicated with injection atropine 0.03 mg/kg. After premedication, the patient was induced with intravenous thiopentone (2.5%) 4–7 mg/kg. Tracheal intubation was facilitated with succinylcholine 1–2 mg/kg and intraoperative muscle relaxation achieved using atracurium 0.5 mg/kg. Anesthesia was maintained with oxygen nitrous oxide mixture (30:70) + Halothane (0.5–1%). Patients were ventilated intraoperatively through J.R. modification of Ayre's T Piece or Bain's circuit. Patients received randomly one of the three solutions caudally, diluted with 0.9% saline as necessary so that volume injected into the caudal epidural space was 0.75 ml/kg.

Crighton *et al.*[10] studied 38 patients, the anatomy of the sacral extradural (caudal) space using magnetic resonance imaging. The sacrococcygeal membrane could not be detected in 10.8% of patients. In our study also, the sacral hiatus could not be felt in three children. These patients were excluded from the study.

After the patients were intubated and 15 min before the surgery was started, patients were given caudal block with the predetermined drug. Vital parameters including heart rate, blood pressure, and respiratory rate were observed preoperatively and hourly postoperatively for 8 hrs. Similarly, sedation score was also counted at an hourly interval postoperatively.

Table 3: Weight-wise distribution of the patients

S. No.	Wt. in kg	Group B (*n*=20)		Group K1 (*n*=20)		Group K2 (*n*=20)	
		n	%	*n*	%	*n*	%
1.	5-8	1	5	0	0	0	0
2.	9-13	2	10	6	30	6	30
3.	14-18	10	50	5	25	3	15
4.	19-23	3	15	3	15	2	10
5.	24-28	4	20	6	30	9	45
Mean ± S.D.		17.84±5.30		17.65±6.28		20.15±7.09	

Table 4: Indication of caudal epidural block

S. No.	Name of operation	No. of cases	Percentage
1	Herniotomy	40	66.66
2	Herniorrhaphy	20	33.34

Table 5: Mean heart rate

Time in hours	Group B (HR/min)±SD	Group K1 (HR/min±SD	Group K2 (HR/min)±SD
Pre-operative	102.3±16.64	113.5±16.93	112.1±11.04
0–1	107.7±12.72	108.1±11.15	97.1±11.76
1–2	104.7±7.17	106.4±10.43	98.4±11.38
2–3	103.9±7.44	105.3±10.34	98.3±10.86
3–4	99.2±7.95	104.8±9.87	98.9±9.34
4–5	98.8±5.99	104.6±10.28	99.1±8.49
5–6	98.6±6.77	103.8±10.3	99.5±8.04
6–7	98.9±7.93	103.2±9.58	100.6±7.42
7–8	98.1±7.41	102.9±10.23	99.7±6.90

Table 6: Mean blood pressure

Time in hours	Group B (mm Hg)±SD	Group K1 (mmHg)±SD	Group K2 (mmHg)±SD
Before injection	107.2±8.01	108.2±8.51	109.2±8.42
0–1	106.0±8.18	106.15±7.29	107.2±7.09
1–2	107.84±5.68	106.745±.38	110.325±0.00
2–3	108.11±5.61	109.79±6.29	111.0±4.01
3–4	108.84±4.72	111.89±5.52	111.793±0.39
4–5	108.51±4.80	110.63±4.95	112.214±0.05
5–6	110.11±4.14	111.26±5.34	112.63±2.98
6–7	110.47±4.45	110.47±4.45	112.0±3.46
7–8	110.71±3.22	111.71±3.22	113.16±2.24

Table 7: Mean respiratory rate per minute

Time in hours	Group B (RR/min) ±SD	Group K1 (RR/min) ±SD	Group K2 (RR/min) ±SD
Pre-operative	21.05±2.58	19.6±1.90	18.65±2.56
0–1	20.75±1.55	19.1±1.77	18.6±2.34
1–2	20.85±1.56	18.8±1.64	19.05±1.98
2–3	21.10±1.58	18.2±1.57	19.2+1.88
3–4	20.15±1.38	18.9±1.99	19.4±1.60
4–5	18.9±1.20	19±1.65	19.3±1.62
5–6	21.3±1.28	19±1.65	19.5±1.57
6–7	18.1±1.37	18.9±1.77	19.8±1.57
7–8	18.4±2.21	19.3±1.62	19.2±1.25

Mean heart rate decreased in all the three groups after injection of drug and there was no significant difference in heart rate among the groups. To compare these results, *Z*-test statistics was applied and it was observed that the difference among the three groups was statistically insignificant ($P > 0.05$). Similarly, blood pressure was recorded before injection and postoperatively. Blood pressure at different periods was slightly higher in all the three groups but the difference was statistically insignificant on each occasion ($P > 0.05$).

The findings of this study are consistent with those of Naguib *et al.*[11] They clearly demonstrate that both drugs are devoid of disturbances in circulatory parameters. Another reason for the stability of cardiovascular system from above may be due to less sympathetic activity due to good quality of pain relief.

Respiratory rate was closely observed preoperatively and 1 hourly in post-operative period. Mean respiratory rate before caudal block was 21.05 ± 2.58 per minute in Group B, Group K1 was 19.6 ± 1.90 per minute, and Group K2 was 18.65 ± 2.56 per minute. The change in

Table 8: Sedation score of the study group

Time in hours	Group B (Sedation score)±SD	Group K1 (Sedation score) ±SD	Group K2 (Sedation score)±SD
0–1	1.25±0.44	1.10±0.31	1.15±0.36
1–2	1.25±0.44	1.1±0.31	1.15±0.36
2–3	1.10±0.31	1.15±0.36	1.25±0.44
3–4	1.05±0.22	1.35±0.58	1.25±0.44
4–5	1.05±0.22	1.5±0.68	1.3±0.47
5–6	1.15±0.36	1.70±0.73	1.35±0.48
6–7	1.15±0.50	1.80±0.69	1.35±0.48
7–8	1.45±0.68	1.9±0.64	1.45±0.51

Table 9: Pain score of the study group

Time in hours	Group B (Mean pain score)±SD	Group K1 (Mean pain score)±SD	Group K2 (Mean pain score)±SD
0–1	1.3±0.57	1.3±0.47	1.2±0.41
1–2	1.1±0.31	1.5±0.60	1.35±0.58
2–3	1.15±0.37	1.75±0.71	1.45±0.68
3–4	1.15±0.37	2.4±0.72	1.5±0.76
4–5	1.45±0.60	2.85±0.67	1.85±0.93
5–6	1.6±0.68	3.0±0.85	2.0±0.73
6–7	1.8±0.77	3.1±0.91	2.1±0.79
7–8	2.55±0.69	3.25±0.72	2.2±0.77

Table 10: Mean duration of analgesia

Group	No. of cases	Mean duration of analgesia (hours) ±SD
B	20	5.10±1.38
K1	20	3.21±1.56
K2	20	4.35±2.01

Table 11: Complications

S. No.	Complication	Group B		Group K1		Group K2	
		n	%	*n*	%	*n*	%
1.	Flushing	4	20	4	20	4	20
2.	Pruritus	-	-	2	10	-	-
3.	Emesis	2	10	2	10	2	10
4.	Respiratory depression	-	-	-	-	-	-
5.	Retention of urine	-	-	-	-	-	-
6.	Convulsion	-	-	-	-	-	-
7.	Pain at puncture site	1	5	-	-	2	10

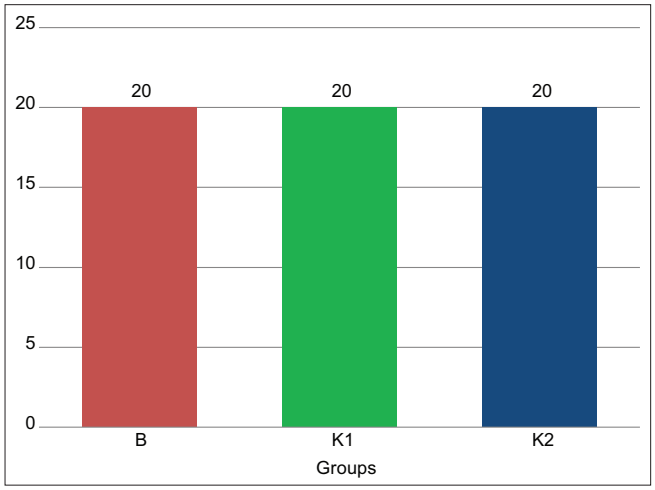

Chart 1: Distribution of group

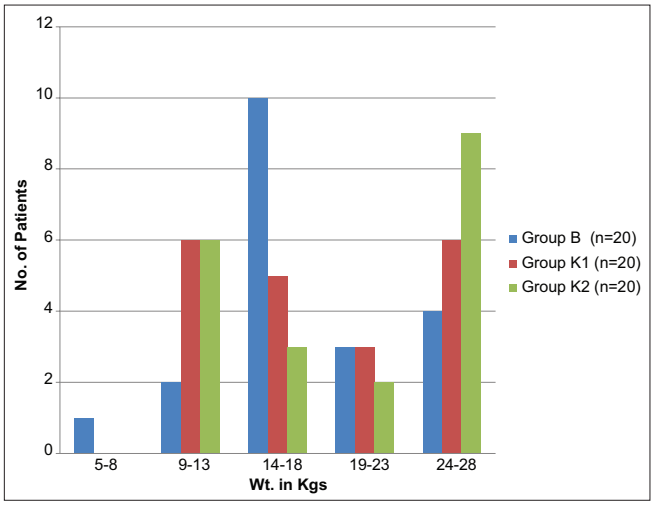

Chart 2: Weight-wise distribution of the patients

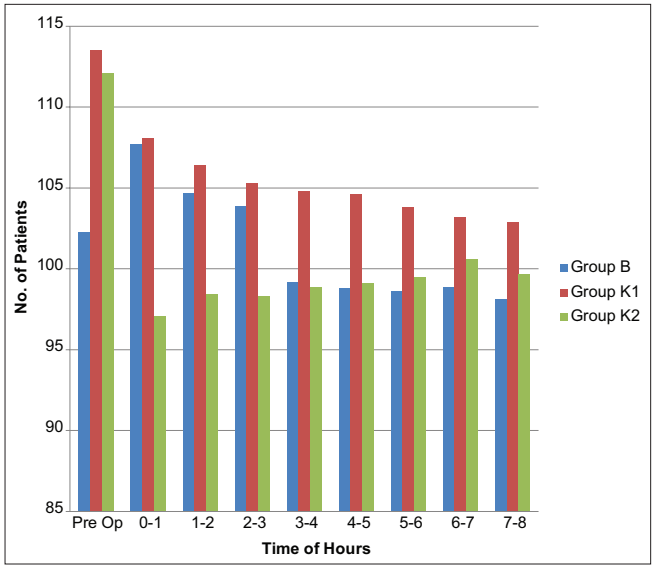

Chart 3: Mean heart rate per minute

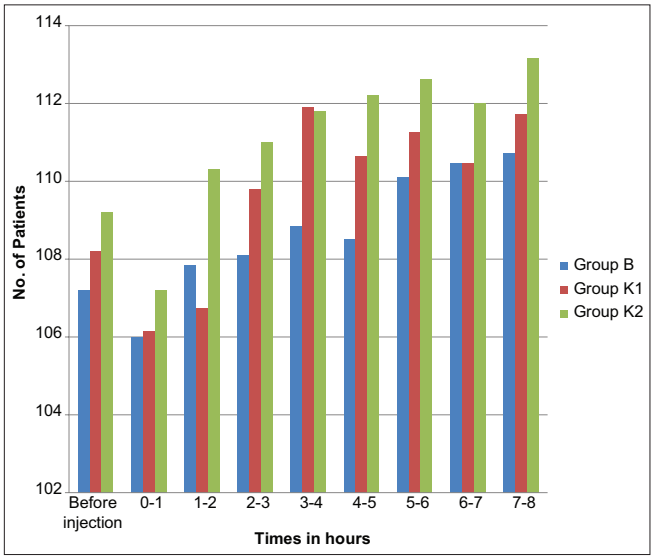

Chart 4: Average blood pressure

respiratory rate at different hours in each group was found to be statistically insignificant ($P > 0.05$). These findings were consistent with the finding of other workers like Marhofer *et al.*[12]

A four-point sedation score was also measured postoperatively at an hourly interval to the study the sedative property of drug. The score was slightly low in all the three groups. There was no significant difference between the three groups in mean hourly sedation score. Similar results were obtained by Marhofer *et al.*[12] The efficacy of post-operative analgesia was documented by an observational pain discomfort scale (OPS). We used the OPS to assess objective, behavioral variables (crying, facial

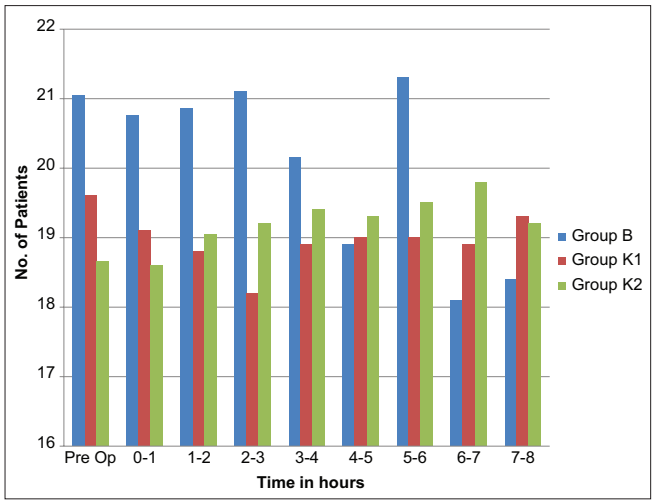

Chart 5: Mean respiratory rate per minute

expression, position of torso, position of legs, and motor restlessness). Each variable was scored on a 3-point scale.

1 = none, 2 = moderate, 3 = severe.

Marhofer *et al.*[12] also used the same pain score in their study. A pain score >11 in two subsequent measurement was considered as termination of pain relief and the patient was administered oral paracetamol 30 mg per kg. There were more patients who required additional analgesia in the recovery room immediately after surgery in Group K1 compared with other Groups B and K2. In Group B, pain score was significantly increased after 7 h. In Group K1, OPS was significantly increased after 4 h of observation. In Group K2, OPS was significantly increased after 5 h of observation. OPS in Group B was lower when compared with Group K2. However, the difference did not attain statistical significance ($P > 0.05$). These results are similar to that obtained Marhofer *et al.*[12]

The duration of analgesic action was taken as the time from caudal injection to first administration of supplementary analgesia. If by 8 h, no additional analgesia had been required, we assumed for sake of comparison that the duration of analgesia was 8 h. Although it is possible that useful analgesia may have continued for longer duration.

However, logistical problems dictated that further observations were impracticable and after 8 h observations were complete, there was a tendency for prophylactic paracetamol analgesia to be given by ward nurses to any patients, who were still awake. All patients were managed successfully with paracetamol alone after this time.

Mean duration of analgesia for those patients who left the recovery area without first requiring additional analgesia did not differ significantly between groups. The mean duration of analgesia in Group B was 5.10 ± 1.38 h, in Group K1 was 3.21 ± 1.56 h, and Group K2 was 4.35 ± 2.01 h.

Dhasmana *et al.*[13] reported duration of analgesia to be 273 ± 123 min. The study conducted by Marhofer *et al.*[14] with same drug ketamine and bupivacaine in pediatric patients for hernia repair, when given caudal epidurally demonstrated that the mean duration of analgesia in bupivacaine group was 300 ± 96 min, in ketamine Group K1 was 203 ± 117 min, and Group K2 was 273 ± 123 min. The dose used was similar to that of our study but the duration of analgesia in our study in Group B was 5.10 ± 1.38 h, in Group K1 was 3.21 ± 1.56 h, and in Group K2 was 4.35 ± 2.01 h.

There is a variation in duration of analgesia observed by different workers. This discrepancy is difficult to explain. Some explanation may be offered on the basis of methods of measurements of pain, type of surgery, individual reaction to pain, overall psyche of patients, and intelligence do have a definite influence, especially in our class of patients. All most all the patients in our study were from lower socioeconomic group and were illiterate. Their reaction was not like the patients from the affluent class. A higher mean pain score in Group K1 in early post-operative period demonstrate a slow set of action through ketamine N-methyl-D-asparate receptor antagonism (NMDA) receptors although it produces good quality of analgesia for an average 3.21 ± 1.56 h. If the operation was longer, adding ketamine to our usual dose of bupivacaine solves the purpose of enhancing the total analgesic period.

Ketamine, a derivative of phencyclidine, has a chemical structure similar to that of bupivacaine and therefore has local anesthetic effects. These local anesthetic effects are also caused by (NMDA receptors are in the substantia gelatinosa in spinal cord), opioid receptor agonism, and the voltage sensitive sodium channel interaction.

The incidence of side effects such as nausea, vomiting, pruritus, flushing, and others, if any, was recorded in post-operative period. Although incidence of facial flushing exceeded 20% in all the three groups, it was not obviously distressing to the individuals affected. No patient in any group had numbness, convulsion, or respiratory depression. Two patients complained of pain at the site of the puncture postoperatively. The pain was mild in nature and occurred in patients in whom manipulation was done to locate the sacral canal. The pain disappeared after 3–4 days.

Nausea and vomiting occurred in all three groups. The patterns of vomiting were similar. This did not appear to cause distress and no treatment was given. The difference was statistically insignificant.

SUMMARY AND CONCLUSION

The present study included a series of 60 patients of ASA Grade I and II of age ranging from 2 to 12 years who were selected randomly posted for operations below umbilicus.

Patients were premedicated with intravenous atropine (0.03 mg/kg), anesthesia was induced with thiopentone (2.5%) 4–7 mg/kg and tracheal intubation facilitated with succinylcholine 1–2 mg/kg. Anesthesia was maintained with oxygen nitrous oxide (30:70) + halothane (0.5–1%) + muscle relaxation achieved by atracurium. Patient received one of the three solutions diluted with normal saline as necessary to ensure a comparable volume of 0.75 ml/kg.

Group B received bupivacaine 1.87 mg/kg. Group K1 received ketamine 0.5 mg/kg and Group K2 received ketamine 1 mg/kg.

The vital parameters (respiratory rate, blood pressure, and heart rate) of the all patients in all the groups were observed preoperatively, during operation and in the post-operative period up to period of 8 hrs. The vital parameters remained stable throughout the operative and post-operative period in all patients of all the groups.

From the present study, it is concluded that:-

1. Ketamine 1 mg/kg, when given caudally in pediatric patients produces analgesia in post-operative period with a mean duration of 4.35 ± 2.01 h
2. Ketamine and bupivacaine both have practically no effect on vital parameter, that is, respiratory rate, heart rate, and blood pressure
3. Caudal ketamine has slow onset of action in Group K1
4. There was no significance difference between groups in sedation score
5. There is no cardiotoxicity associate with in advertent intravascular injection of ketamine when compared to bupivacaine
6. Bupivacaine and ketamine 1 mg/kg is better than ketamine 0.5 mg/kg for post-operative analgesia
7. There was no statistically significant difference in incidence of pain at puncture site and facial flushing (side effect)

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Original Article

Effect of Different Doses of Dexmedetomidine on Hemodynamic Response During Laryngoscopy and Tracheal Intubation in Endoscopic Neurosurgeries

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ABSTRACT

Background: Direct laryngoscopy and endotracheal intubation are the most frequently performed procedure. The noxious stimuli generated by the process of intubation leads to a period of extreme hemodynamic stress which is accompanied by intense sympathetic activity. This response mechanism to laryngoscopy and orotracheal intubation is somatovisceral reflexes.

Aim of the Study: The aim of this study is to assess the optimal dose of dexmedetomidine for the purpose of attenuation of hemodynamic response during laryngoscopy and tracheal intubation.

Materials and Methods: This study is prospective, randomized, and double-blind study on 144 patient divided into four groups. Groups I, II, III, and VI comprise dexmedetomidine 0.5 μg/kg, 0.75 μg/kg, 1 μg/kg, and 20 ml of NS. The study solution was infused 10 min before the standard general anesthesia in endoscopic neurosurgical procedure. Heart rate, blood pressure, and oxygen saturation were measured at specified time interval and analyzed. Sedation was also assess using Richmond Agitation Sedation Scale (RASS) just after dexmedetomidine infusion and at 10 min after completion of dexmedetomidine infusion.

Result: Neurosurgical patients are subset of patients in which induction from anesthesia is met with hemodynamic perturbations which, in turn, may lead to disastrous complication such as intracranial hematoma and raised intracranial pressure. Our study demonstrated that dexmedetomidine when used preoperatively as a premedicament in doses at 0.75 ug/kg in infusion from, provided the most acceptable hemodynamics in the peri induction period with an acceptable level of twilight.

Key words: Intubation, Laryngoscopy, Dexmedetomidine

INTRODUCTION

In 1921, Rowbatham and Magill had studied and practiced endotracheal intubation. The noxious stimuli generated by the process of intubation leading to a period of extreme hemodynamic stress which is accompanied by intense sympathetic activity.[1]

The hemodynamic changes brought about by laryngoscopy and intubation was first described by Reid and Brace.[2]

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Direct laryngoscopy and endotracheal intubation are the most frequently performed procedures, but their clinical benefits are not without a few undesirable effects due to afferent vagal stimulation and an efferent sympathoadrenal response.[3] These response mechanism to laryngoscopy and orotracheal intubation is somatovisceral reflexes.[4] Proprioceptors at the base of the tongue are stimulated during laryngoscopy leads to impulse dependent increases of systemic blood pressure, heart rate, and plasma catecholamine concentrations. Subsequent orotracheal intubation and passage of tube recruits additional receptor that elicit augmented hemodynamic and epinephrine responses as well as some vagus mediated inhibition of the heart.[5] The magnitude of response is directly proportional to the force and duration of laryngoscopy.[6] The response is initiated within 5 s of laryngoscopy, peaks in 1–2 min and returns to normal

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levels by 5 min. This is called vascular contraction reflex.[7] These changes are usually short lived and well tolerated by normal patients. However, in patients with cardiovascular disease, it can incite harmful effects such as myocardial ischemia, ventricular dysrhythmias, ventricular failure, and pulmonary edema. It can also lead to cerebrovascular accidents in susceptible patients.[8] The circulatory responses evolved by endotracheal intubation is not adequately suppressed by intravenous anesthetic induction agents.[9]

Alpha-2 agonists such as dexmedetomidine and clonidine reduce operational stimulus during surgery which is caused by sympathetic outflow and decreases cardiovascular behavior.[10] These drugs decreases sympathetic activity, which are beneficial for the cases.[11]

Its hemodynamic effects are predictable and dose-dependent. Dexmedetomidine, at clinically effective dosages, does not depress respiration, and therefore does not interfere with extubation. This pharmacological profile renders it suitable for premedication for general anesthesia in intravenous doses varying from 0.25 to 1 μg/kg for the attenuation of intubation responses, but the optimal dose not yet established.[12] Our study is to assess the effect of different doses of dexmedetomidine on hemodynamic response during laryngoscopy and tracheal intubation in endoscopic neurosurgeries at the Department of Anaesthesiology, N.S.C.B. Medical College Jabalpur (M.P.).

Aims and Objectives

Primary objectives

The primary objective of the study is to assess the optimal dose of dexmedetomidine for the purpose of attenuation of hemodynamic response during laryngoscopy and tracheal intubation.

Secondary objectives

1. The secondary objective of the study is to assess the sedation after 10 min of completion of dexmedetomidine infusion.
2. Any adverse effect of dexmedetomidine such as hypotension, bradycardia, respiratory depression, and fall in oxygen saturation.

MATERIALS AND METHODS

After obtaining approval from Institutional Ethics Committee, this study was conducted at Govt. N.S.C.B. Medical College and Hospital, Jabalpur.

Design of Study

- This was a prospective double-blind randomized study.

Conduct of Study

- The study was conducted in the Department of Anaesthesiology of N.S.C.B. Medical College, Jabalpur M.P.

Duration of Study

The duration of the study was from March 1, 2018, to August 31, 2019

Sample Size

- In our study, the total sample size of 144 was divided into four groups of 36 patients each. Following formula was used to estimate the require sample size in the study.

$$n = \frac{Z^2\ p\ q}{d^2}$$

where
n = Sample size
Z = 1.96 at 95% CI, 80% power and 5% alpha
p = Probability which was assumed 0.63
q = 1 − p
d = Marginal error which was 25% relative precision top, i.e. 0.16.

Selection Criteria of Cases

Inclusion criteria

1. Patient of ASA Grades I and II in the age group of 18–60 years of either gender was enrolled.

METHODOLOGY

After approval from the Institutional Ethics Committee, this study was conducted inside Neurosurgery operation theatre at N.S.C.B. Medical College and Hospital, Jabalpur. Written informed consent was obtained from all patients enrolled in the study.

All 144 patients of age 18–60 years, ASA physical Statuses I and II of either sex who were scheduled for elective neurosurgery were included in this study. Patient was equally divided into four groups of 36 patients each.

- Group I: Dexmedetomidine 0.5 μg/kg diluted with 0.9% NS to 20 ml IV.
- Group II: Dexmedetomidine 0.75 μg/kg diluted with 0.9% NS to 20 ml IV.
- Group III: Dexmedetomidine 1 μg/kg diluted with 0.9% NS to 20 ml IV.
- Group IV: 20 ml of 0.9% normal saline IV.

Careful pre-anesthetic evaluation was done and it was made sure that the patients met the inclusion

and exclusion criteria. Patients were kept nil per oral from midnight for at least 8 h before surgery. After shifting the patient to the operation theater, two large bore (18 G) intravenous access were obtained, and normal saline was started at the rate of 10 ml/kg/h. Monitors such as pulse oximeter, noninvasive blood pressure, and 3-lead electrocardiogram were connected and pulse rate (PR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), and oxygen saturation (SpO2) were recorded at that time.

The study solution was infused over 10 min. The general anesthesia technique was standardized in all four groups. Patients were premedicated with intravenous glycopyrrolate (0.2 mg) half an hour before induction. After preoxygenation for 3 min, general anesthesia was induced with inj. propofol (2–2.5 mg/kg) i.v, fentanyl (1.5 mcg/kg), followed by inj. vecuronium bromide (0.1 mg/kg) to facilitate direct laryngoscopy and orotracheal intubation (high-volume/low-pressure cuffed endotracheal tubes). The internal diameter of the endotracheal tube was 7–7.5 mm for women and 8–8.5 mm for men.

Heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, and oxygen saturation (SPO_2) were measured at:

- Baseline
- After 10 min of dexmedetomidine infusion (over 10 min) or just before intubation
- At 1 min after intubation.
- At 5 min after intubation.
- At 10 min after intubation.
- At 20 min after intubation.

Sedation was assessed using Richmond agitation sedation scale (RASS):

- Just after dexmedetomidine infusion.
- At 10 min after completion of dexmedetomidine infusion.

An event of hypotension (SBP <70 mm of Hg) was managed with 6 mg mephentermine IV and bradycardia (HR < 45 bpm) with 0.6 mg of atropine IV.

All the patients were mechanically ventilated at a fresh gas flow of 6 L/min and anesthesia was maintained with isoflurane (minimum alveolar concentration 0.8–1.0) and vecuronium (0.02 mg/kg every 20–30 min) throughout the surgical procedure. Intraoperative analgesia was supplemented with incremental doses of fentanyl every hour. Intraoperatively $etCO_2$ and urine output were also monitored. During mechanical ventilation, a respiratory rate and tidal volume were adjusted to keep normocapnia and normoxia with oxygen saturation ≥98%. Ringer lactate and normal saline were used for replacement and maintenance. Colloids, blood and blood products were used as and when required.

After surgery, reversal was achieved using IV neostigmine 0.05 mg/kg and IV glycopyrrolate 0.01 mg/kg. Once patient became conscious and responded to verbal commands, extubation was performed. After extubation, the patients were oxygenated with 100% oxygen for 5 min and after assessing adequate recovery, patient was shifted to post anesthesia care unit or wards and was monitored for 12 h.

Data Analysis and Statistics

Data were collected, summarized, and classified in the form of master chart in MS Excel worksheet. Quantitative data were expressed in Mean ± SD. Weightage of association of various factors was inferred by logistic regression. Data analyzed with the help of ANOVA test and other appropriate statistical test to find the significance of study parameters between the study groups.

Tools in the Study

The Richmond Agitation-Sedation Scale was used for assessment of sedation after dexmedetomidine infusion.

The Richmond agitation–sedation scale

	Term	Description
+4	Combative	Overtly combative or violent; immediate danger to staff
+3	Very agitated	Pulls on or removes tube(s) or catheter(s) or has aggressive behavior toward staff
+2	Agitated	Frequent nonpurposeful movement or patient–ventilator dyssynchrony
+1	Restless	Anxious or apprehensive but movements not aggressive or vigorous
0	Alert and calm	Spontaneously pays attention to caregiver
−1	Drowsy	Not fully alert, but has sustained (more than 10 s) awakening, with eye contact, to voice
−2	Light sedation	Briefly (<10 s) awakens with eye contact to voice
−3	Moderate sedation	Any movement (but no eye contact) to voice
−4	Deep sedation	No response to voice, but any movement to physical stimulation
−5	Unarousable	No response to voice or physical stimulation

OBSERVATION AND RESULTS

Table 1:Sex distribution

Sex		Group				Total
		Dexmedetomidine 0.5 mcg/kg	Dexmedetomidine 0.75 mcg/kg	Dexmedetomidine 1 mcg/kg	NS 0.9%	
Female	*n*	14	12	15	15	56
	%	38.9	33.3	41.7	41.7	38.9
Male	*n*	22	24	21	21	88
	%	61.1	66.7	58.3	58.3	61.1
Total	*n*	36	36	36	36	144
	%	100.0	100.0	100.0	100.0	100.0

Chi square = 0.701; *P* = 0.873

Table 2: Age distribution

Age group		Group				Total
		Dexmedetomidine 0.5 mcg/kg	Dexmedetomidine 0.75 mcg/kg	Dexmedetomidine 1 mcg/kg	NS 0.9%	
≤20 years	*n*	0	3	0	0	3
	%	0.0	8.3	0.0	0.0	2.1
21–30 year	*n*	3	8	10	8	29
	%	8.3	22.2	27.8	22.2	20.1
31–40 years	*n*	20	7	8	15	50
	%	55.6	19.4	22.2	41.7	34.7
41–50 years	*n*	6	11	12	12	41
	%	16.7	30.6	33.3	33.3	28.5
51–60 years	*n*	7	7	6	1	21
	%	19.4	19.4	16.7	2.8	14.6
Total	*n*	36	36	36	36	144
	%	100.0	100.0	100.0	100.0	100.0

Chi square = 28.86; *P* = 0.004

Table 3: ASA distribution

ASA		Group				Total
		Dexmedetomidine 0.5 mcg/kg	Dexmedetomidine 0.75 mcg/kg	Dexmedetomidine 1 mcg/kg	NS 0.9%	
I	*n*	21	23	22	20	86
	%	58.3	63.9	61.1	55.6	59.7
II	*n*	15	13	14	16	58
	%	41.7	36.1	38.9	44.4	40.3
Total	*n*	36	36	36	36	144
	%	100.0	100.0	100.0	100.0	100.0

Chi square = 0.577; *P* = 0.902

Table 4: RASS just after infusion

RASS 10 min after infusion		Group				Total
		Dexmedetomidine 0.5 mcg/kg	Dexmedetomidine 0.75 mcg/kg	Dexmedetomidine 1 mcg/kg	NS 0.9%	
−5	*n*	0	2	28	0	30
	%	0.0	5.6	77.8	0.0	20.8
−4	*n*	1	28	8	0	37
	%	2.8	77.8	22.2	0.0	25.7
−3	*n*	31	6	0	0	37
	%	86.1	16.7	0.0	0.0	25.7
−2	*n*	4	0	0	0	4
	%	11.1	0.0	0.0	0.0	2.8
0	*n*	0	0	0	36	36
	%	0.0	0.0	0.0	100.0	25.0
Total	*n*	36	36	36	36	144
	%	100.0	100.0	100.0	100.0	100.0

Chi square = 320.63; *P* < 0.0001

Table 5: RASS 10 min after infusion

RASS just after infusion		Group				Total
		Dexmedetomidine 0.5 mcg/kg	Dexmedetomidine 0.75 mcg/kg	Dexmedetomidine 1 mcg/kg	NS 0.9%	
−5	*n*	0	0	8	0	8
	%	0.0	0.0	22.2	0.0	5.6
−4	*n*	0	7	28	0	35
	%	0.0	19.4	77.8	0.0	24.3
−3	*n*	1	29	0	0	30
	%	2.8	80.6	0.0	0.0	20.8
−2	*n*	32	0	0	0	32
	%	88.9	0.0	0.0	0.0	22.2
−1	*n*	3	0	0	0	3
	%	8.3	0.0	0.0	0.0	2.1
0	*n*	0	0	0	36	36
	%	0.0	0.0	0.0	100.0	25.0
Total	*n*	36	36	36	36	144
	%	100.0	100.0	100.0	100.0	100.0

Chi square = 379.47; $P < 0.0001$.

Table 6: Changes in heart rate (mean, standard deviation) before and after intubation in different treatment groups

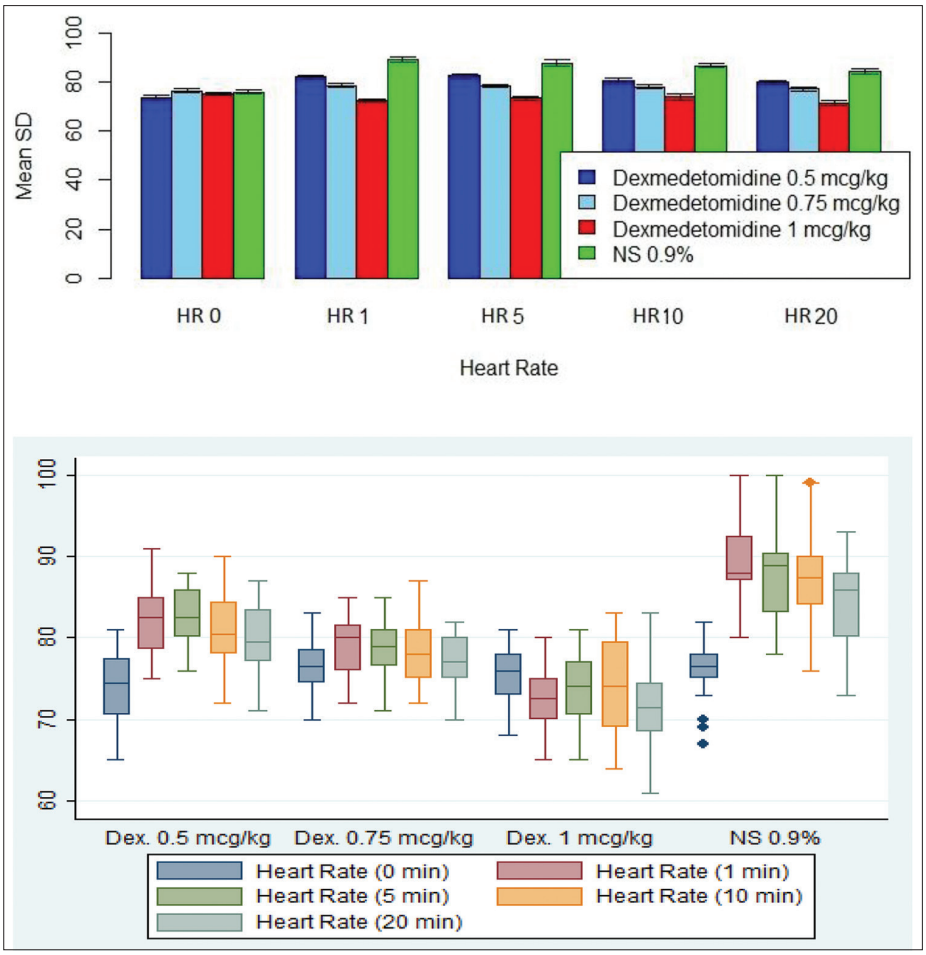
Variable	Follow-up	Dexmedetomidine 0.5 mcg/kg		Dexmedetomidine 0.75 mcg/kg		Dexmedetomidine 1 mcg/kg		Normal Saline 0.9%	
		Mean	SD	Mean	SD	Mean	SD	Mean	SD
Heart rate	Before intubation	73.75	4.43	76.58	3.29	75.25	3.45	76.11	3.59
Heart rate	1 min After intubation	82.11	4.52	78.75	3.49	72.69	3.57	89.31	5.77
Heart rate	5 min After intubation	82.67	3.71	78.44	3.15	73.61	4.28	87.94	5.86
Heart rate	10 min After intubation	80.67	4.51	78.17	3.78	73.97	5.86	86.78	4.71
Heart rate	20 min After intubation	79.94	3.76	77.28	3.23	71.58	5.15	84.42	4.81

Variables	Follow-up	ANOVA	
		F statistics	*P*
Heart rate	1	150.209	<0.0001
Heart rate	5	99.582	<0.0001
Heart rate	10	62.025	<0.0001
Heart rate	20	62.449	<0.0001

DISCUSSION

Derbyshire *et al.*[13] correlated the stress response to laryngoscopy and intubation with concomitant measurement of plasma adrenaline and noradrenaline. There was significant increase in plasma noradrenaline concentration and this was more when a non-depolarizer neuromuscular blocking agent is used for endotrachael tube placement (141% vs. 74% in depolarizer). Plasma adrenaline levels also increased significantly (18% vs. 39% in depolarizer group). The levels of the catecholamines did correlate well with rise in mean arterial pressure. Low *et al.*[14] also demonstrated significant adrenergic and noradrenergic response to laryngoscopy and intubation. They measured plasma catecholamine concentrations in 16 normotensive and 10 hypertensive patients undergoing elective vascular surgery. Following laryngoscopy, there was a moderate increase in arterial pressure in both normotensive and hypertensive patients. In normotensive patients, laryngoscopy was associated with a moderate increase in plasma noradrenaline concentration. There was no change in adrenaline concentration. By contrast, there was a marked increase in noradrenaline concentration, a moderate increase in adrenaline concentration and an arterial pressure response in the group of hypertensive patients. These data are consistent with transient sympathetic over activity in hypertensive patients following noxious stimuli such as laryngoscopy.

In patients with intracranial space-occupying lesion, induction agent alone will usually not attenuate the increases in MAP and CPP produced during laryngoscopy with tracheal intubation. Large increases in CPP can either increase intracranial blood volume, thereby increasing ICP, or disrupt the blood–brain barrier (BBB), causing cerebral edema. The previous studies demonstrated that there is no simple method to maintain a decreased ICP (compared with its awake baseline value) immediately following laryngoscopy and tracheal intubation in patients with intracranial hypertension. Although propofol is beneficial in attenuating the increase in ICP secondary to



Graph 1: Changes in heart rate (mean, standard deviation) before and after intubation in different treatment groups

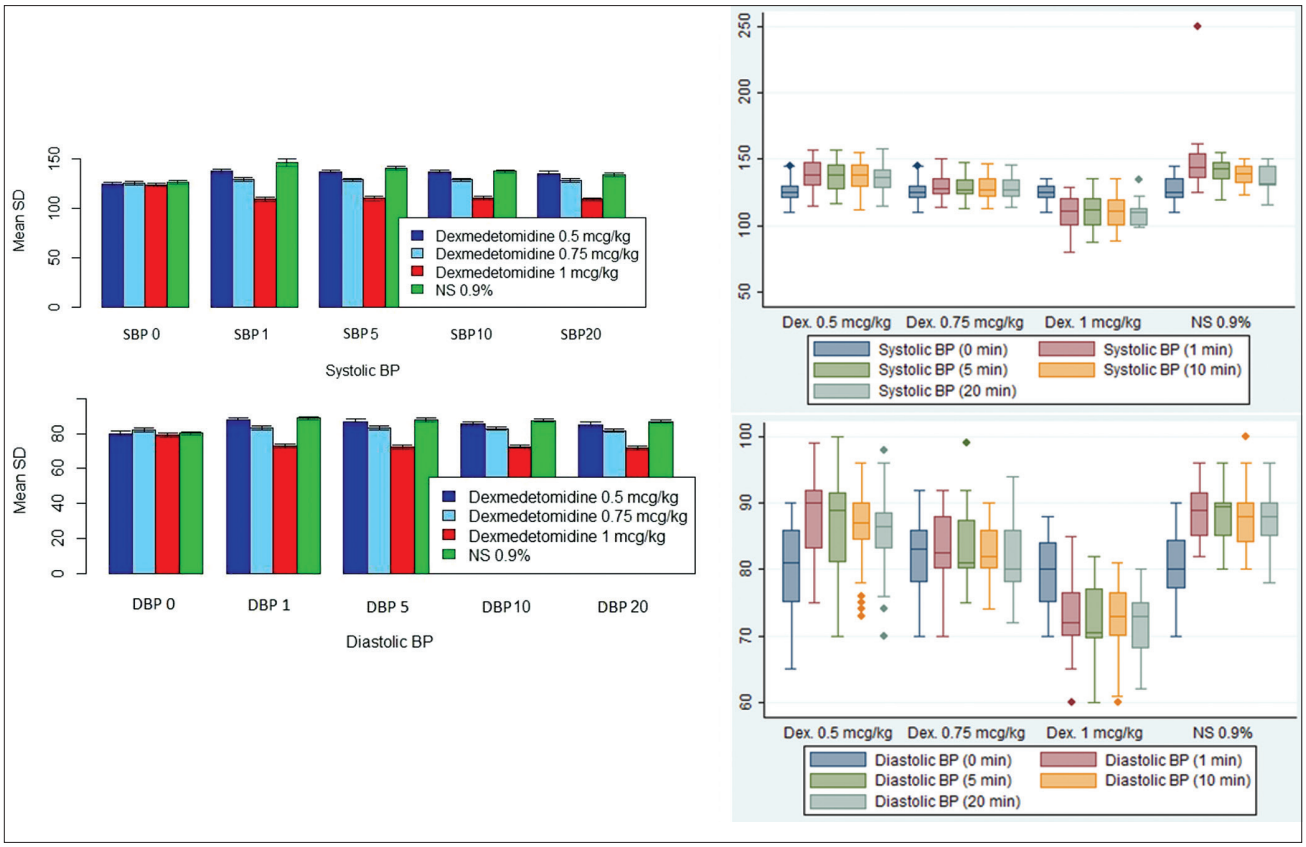
Table 7: Changes in blood pressure (mean, standard deviation) before and after intubation in different treatment groups

Variable	Follow-up	Dexmedetomidine 0.5 mcg/kg		Dexmedetomidine 0.75 mcg/kg		Dexmedetomidine 1 mcg/kg		Normal Saline 0.9%	
		Mean	SD	Mean	SD	Mean	SD	Mean	SD
Systolic BP	Before intubation	124.58	9.59	125.83	9.45	123.89	7.47	126.53	9.09
Systolic BP	1 min After intubation	137.81	11.69	129.14	8.98	109.11	12.36	146.42	20.71
Systolic BP	5 min After intubation	137.03	10.91	129.06	9.22	110.31	11.09	140.97	9.30
Systolic BP	10 min After intubation	136.94	11.44	129.03	8.94	110.42	10.95	137.67	7.72
Systolic BP	20 min After intubation	135.44	10.72	128.25	8.91	109.36	7.85	134.50	8.91
Diastolic BP	Before intubation	80.11	6.85	82.25	5.64	79.31	5.15	80.17	5.35
Diastolic BP	1 min After intubation	87.64	6.69	83.22	5.27	72.86	5.68	89.00	4.18
Diastolic BP	5 min After intubation	86.69	7.75	83.25	5.21	72.28	5.76	87.94	4.65
Diastolic BP	10 min After intubation	85.72	5.81	82.78	4.27	72.64	5.09	87.53	5.25
Diastolic BP	20 min After intubation	85.25	6.76	81.81	5.45	71.86	5.44	87.03	4.41

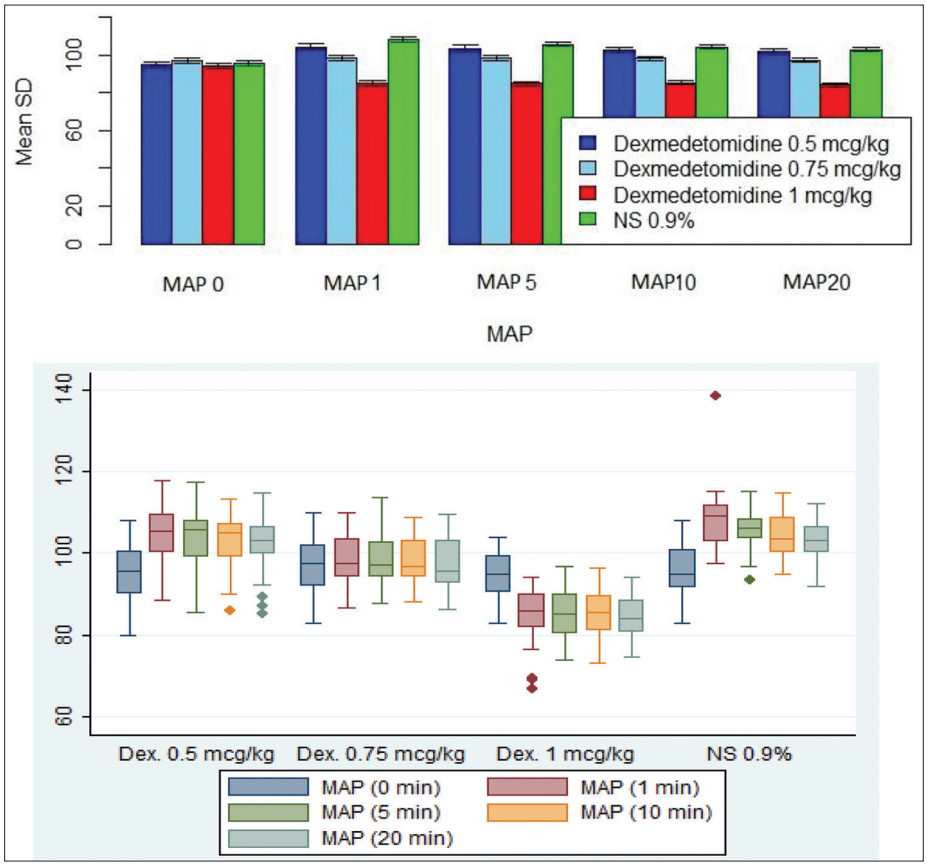
Variables	Follow-up	ANOVA	
		F statistics	P value
Systolic BP	1	63.757	<0.0001
Systolic BP	5	138.365	<0.0001
Systolic BP	10	109.691	<0.0001
Systolic BP	20	114.359	<0.0001
Diastolic BP	1	246.903	<0.0001
Diastolic BP	5	158.797	<0.0001
Diastolic BP	10	107.588	<0.0001
Diastolic BP	20	107.784	<0.0001

tracheal stimulation, it failed to show to maintain a decreased ICP effectively soon after intubation.

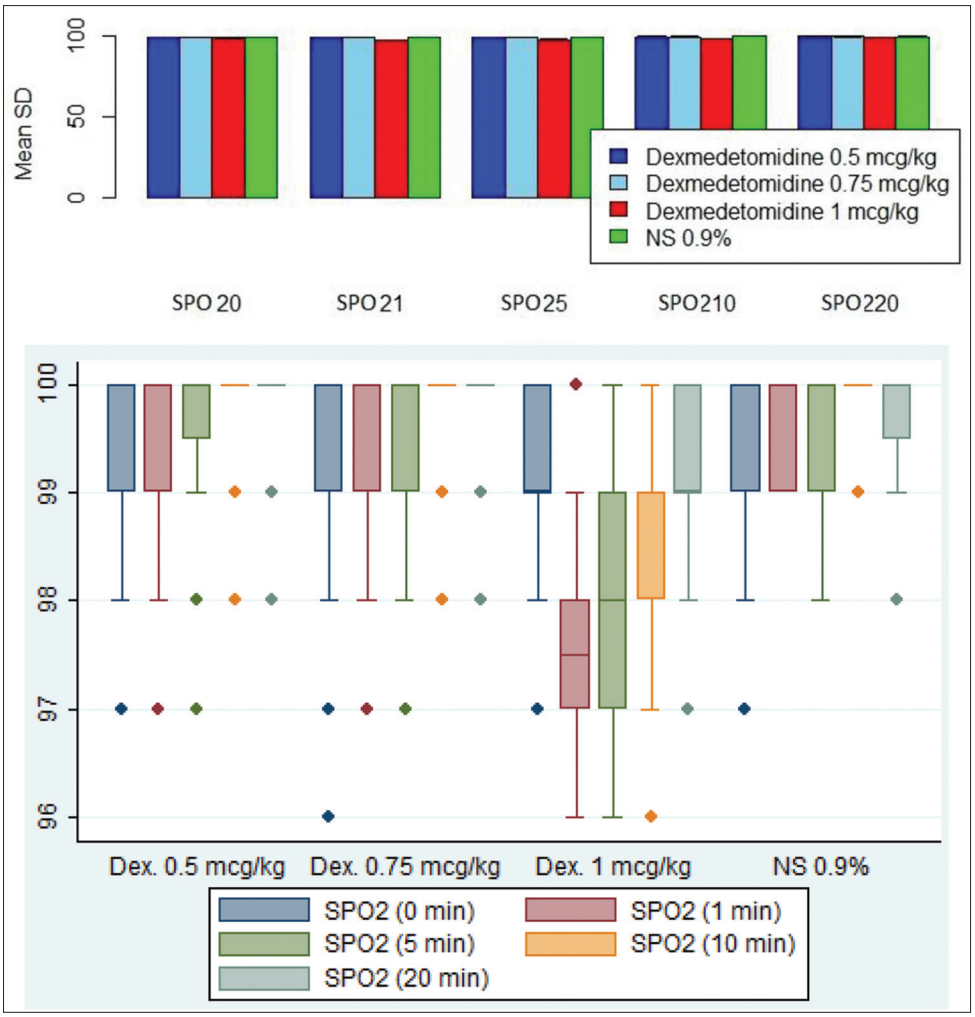
Dexmedetomidine has distribution half-life of approximately 6 min, so can be used successfully for attenuating the stress response to laryngoscopy. It has also been evaluated by several authors as an adjuvant to anesthesia for neurosurgery with favorable perioperative hemodynamic control.[15-20] Dexmedetomidine has been liberally and extensively used in



Graph 2: Changes in blood pressure (mean, standard deviation) before and after intubation in different treatment groups



Graph 3: Changes in mean arterial pressure (mean, standard deviation) before and after intubation in different treatment groups



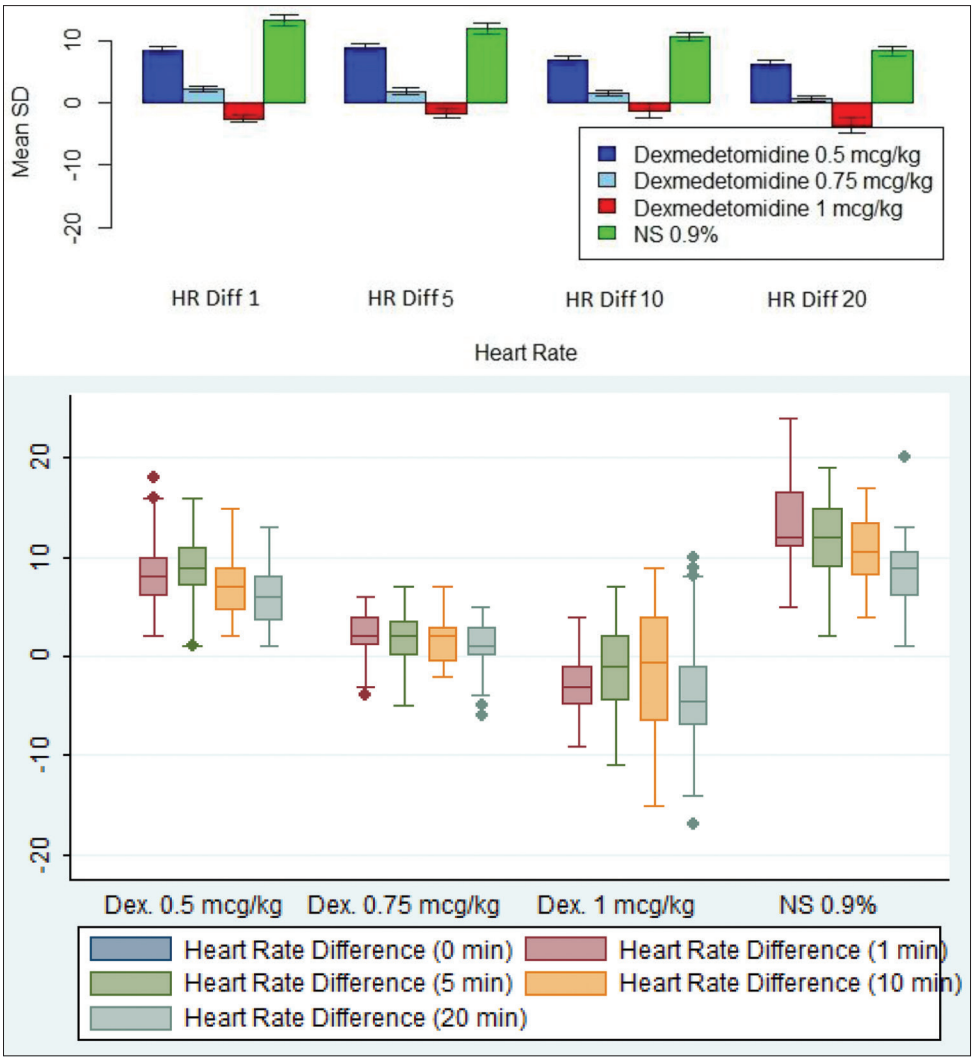
Graph 4: Changes in SPO_2 (mean, standard deviation) before and after intubation in different treatment groups

Table 8: Changes in mean arterial pressure (mean, standard deviation) before and after intubation in different treatment groups

Variable	Follow-up	Dexmedetomidine 0.5 mcg/kg		Dexmedetomidine 0.75 mcg/kg		Dexmedetomidine 1 mcg/kg		Normal Saline 0.9%	
		Mean	SD	Mean	SD	Mean	SD	Mean	SD
MAP	Before intubation	94.86	7.50	97.03	6.74	94.17	5.77	95.56	6.44
MAP	1 min after intubation	104.36	7.84	98.53	6.20	84.94	7.04	108.14	7.54
MAP	5 min after intubation	103.47	8.19	98.52	6.07	84.95	6.03	105.62	5.34
MAP	10 min after intubation	102.80	7.07	98.19	5.56	85.23	5.75	104.24	5.18
MAP	20 min after intubation	101.98	7.05	97.29	6.25	84.36	5.12	102.85	4.98

Variables	Follow-up	ANOVA	
		F statistics	*P*
MAP	1	188.847	<0.0001
MAP	5	283.434	<0.0001
MAP	10	174.723	<0.0001
MAP	20	190.556	<0.0001

neurosurgical operation due to its favorable profile to afford neuroprotection. Drummond *et al.*[21] evaluated the effect of dexmedetomidine on cerebral blood flow velocity (CBFV), cerebral metabolic rate (CMR), and CO_2 response in normal humans. The vasoconstrictive seems to occur principally at the level of plial arterioles and activation of intrinsic noradrenergic neural pathways originating in the locus ceruleus projecting to the microvasculature of the CNS. They found that CBFV and CMRe decreased in dose-related manner. CBFV/CMRe ratio remains unchanged. Georgia *et al.*[22] used transcranial Doppler imaging and tested the effect of loading dose of 1mcg/kg dexmedetomidine on cerebral hemodynamics in patients scheduled to undergo



Graph 5: Mean difference in heart rate before and after intubation in different treatment groups

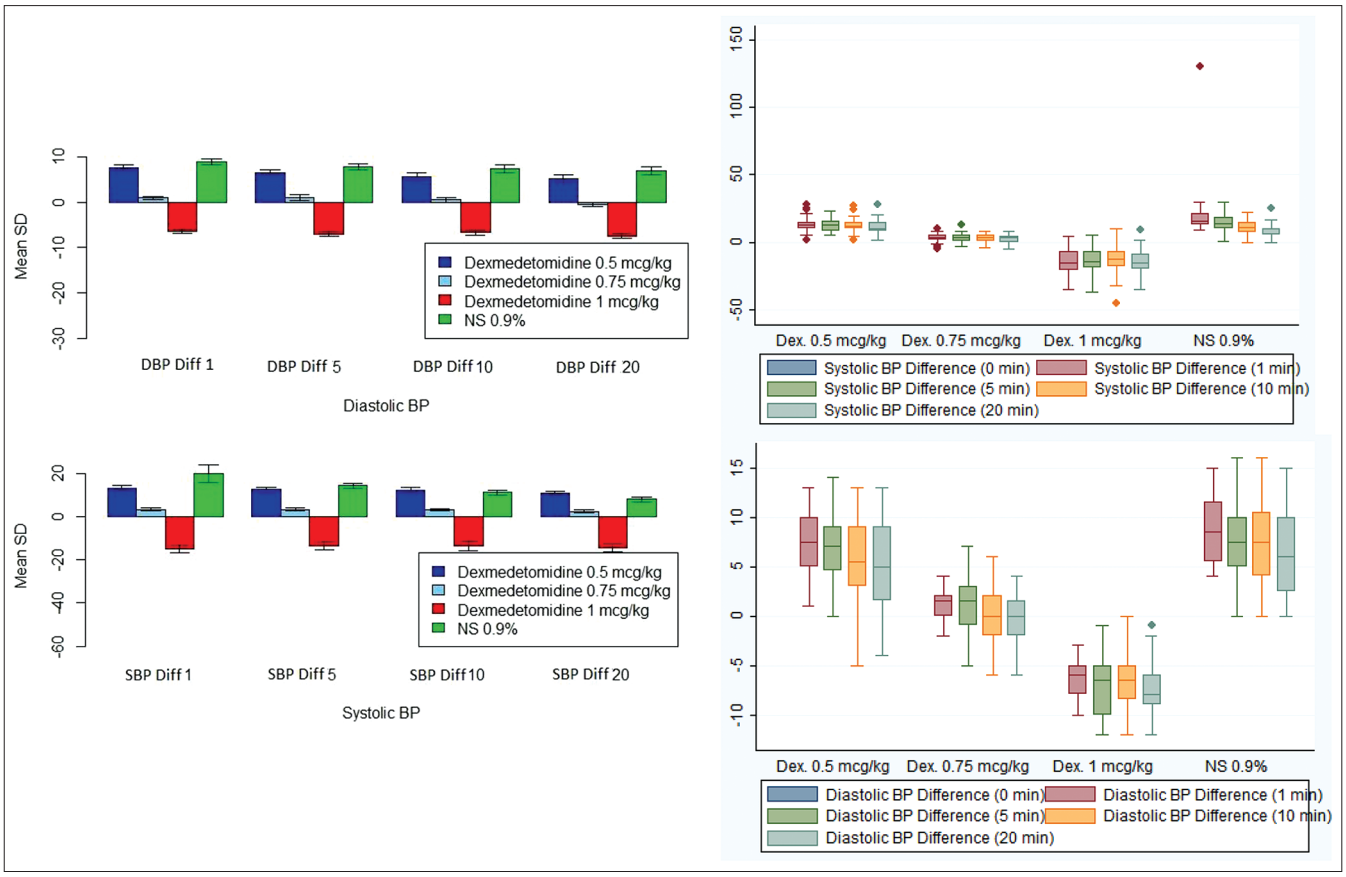
Table 9: Changes in SPO_2 (mean, standard deviation) before and after intubation in different treatment groups

Variable	Follow-up	Dexmedetomidine 0.5 mcg/kg		Dexmedetomidine 0.75 mcg/kg		Dexmedetomidine 1 mcg/kg		Normal Saline 0.9%	
		Mean	SD	Mean	SD	Mean	SD	Mean	SD
SPO_2	Before intubation	99.44	0.88	99.25	1.08	99.11	0.95	99.33	0.86
SPO_2	1 min after intubation	99.53	0.77	99.28	1.00	97.58	1.18	99.64	0.49
SPO_2	5 min after intubation	99.64	0.72	99.53	0.81	97.86	1.17	99.50	0.61
SPO_2	10 min after intubation	99.75	0.60	99.75	0.60	98.42	1.11	99.89	0.32
SPO_2	20 min after intubation	99.86	0.42	99.81	0.47	99.31	0.75	99.72	0.51

Variables	Follow-up	ANOVA	
		F statistics	*P*
SPO_2	1	41.10	<0.0001
SPO_2	5	35.44	<0.0001
SPO_2	10	33.70	<0.0001
SPO_2	20	7.47	0.0001

lumbar discectomy. They observed a decline of FV (flow velocity) in MCA along with augmentation of PI (pulsability index) and cerebral vascular resistance index. Prielipp *et al.*[23] evaluated the effect of dexmedetomidine on regional and global cerebral blood flow in healthy human volunteers. They used PET (positron emission tomography) to determine CBF. Global CBF decreased significantly from 91 ml/100 gm/min to 61 ml/100 gm/min.

Its hemodynamic effects are predictable and dose-dependent. Dexmedetomidine, at clinically effective dosages, does not depress respiration, and therefore does not interfere with extubation. This pharmacological profile renders it suitable



Graph 6: Mean difference in blood pressure before and after intubation in different treatment groups

Table 10: Mean difference in heart rate before and after intubation in different treatment groups

Variable	Follow-up	Mean difference from Intubation							
		Dexmedetomidine 0.5 mcg/kg		Dexmedetomidine 0.75 mcg/kg		Dexmedetomidine 1 mcg/kg		Normal Saline 0.9%	
		Mean	SD	Mean	SD	Mean	SD	Mean	SD
Heart rate	1 min after intubation	8.36	3.42	2.17	2.42	−2.56	3.1	13.19	4.31
Heart rate	5 min after intubation	8.92	3.15	1.86	2.55	−1.64	4.3	11.83	4.56
Heart rate	10 min after intubation	6.92	3.29	1.58	2.26	−1.28	6.18	10.67	3.5
Heart rate	20 min after intubation	6.19	3.22	0.69	2.67	−3.67	5.94	8.31	3.86

Table 11: Mean difference in blood pressure before and after intubation in different treatment groups

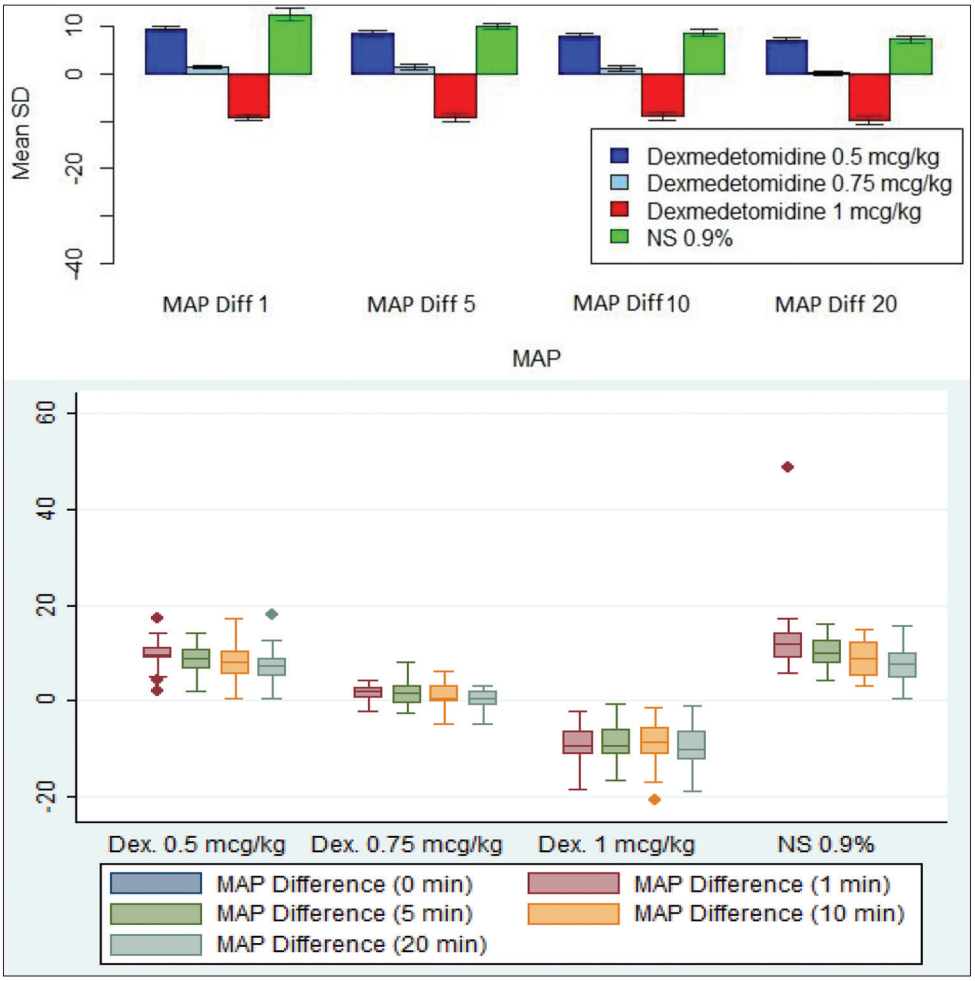
Variable	Follow-up	Mean difference from Intubation							
		Dexmedetomidine 0.5 mcg/kg		Dexmedetomidine 0.75 mcg/kg		Dexmedetomidine 1 mcg/kg		Normal Saline 0.9%	
		Mean	SD	Mean	SD	Mean	SD	Mean	SD
Systolic BP	1 min after intubation	13.22	5.28	3.31	2.9	−14.78	9.39	19.89	19.74
Systolic BP	5 min after intubation	12.44	4.99	3.22	3.31	−13.58	10	14.44	5.84
Systolic BP	10 min after intubation	12.36	5.05	3.19	2.7	−13.47	11.09	11.14	5.5
Systolic BP	20 min after intubation	10.86	5.17	2.42	3.28	−14.53	9.96	7.97	5.08
Diastolic BP	1 min after intubation	7.53	3.08	0.97	1.72	−6.44	2.24	8.83	3.35
Diastolic BP	5 min after intubation	6.58	3.25	1	3.02	−7.03	2.9	7.78	3.64
Diastolic BP	10 min after intubation	5.61	4.4	0.53	2.82	−6.67	2.8	7.36	4.22
Diastolic BP	20 min after intubation	5.14	4.69	-0.44	2.38	−7.44	2.59	6.86	4.61

Table 12: Mean difference in map before and after intubation in different treatment groups

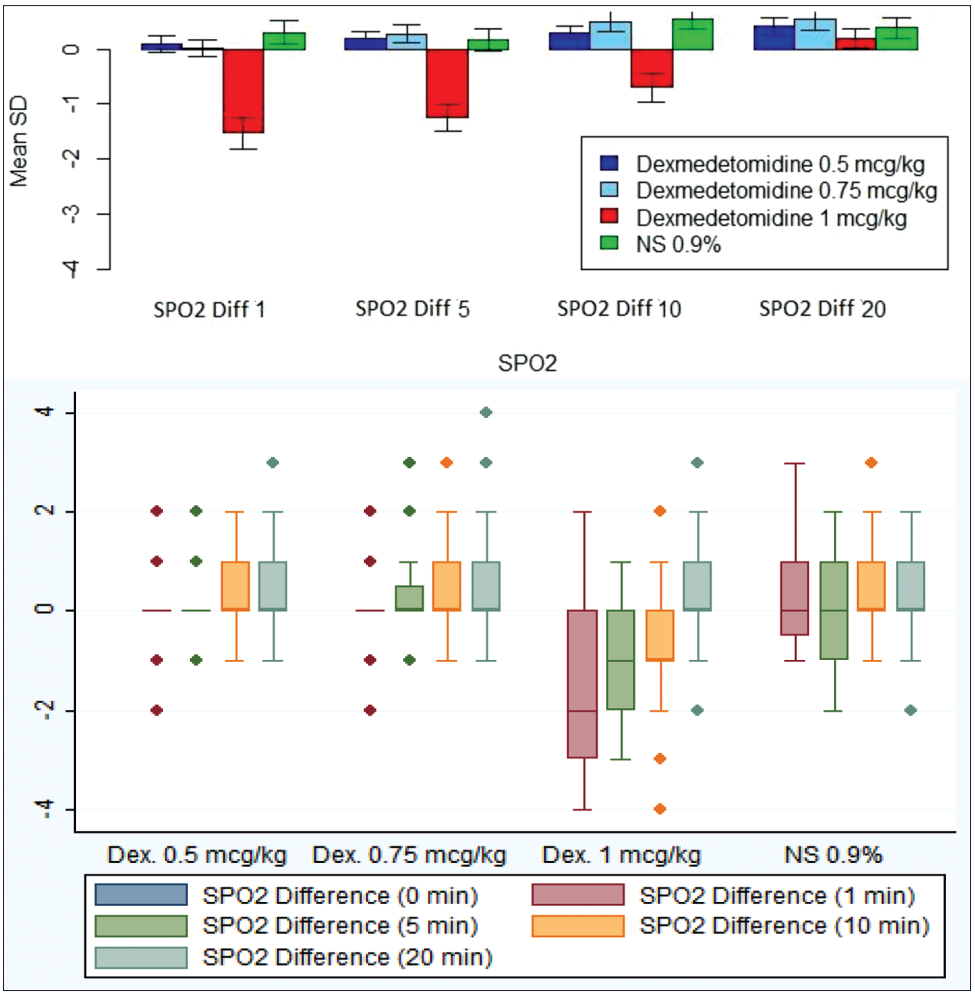
Variable	Follow-up	Mean difference from Intubation							
		Dexmedetomidine 0.5 mcg/kg		Dexmedetomidine 0.75 mcg/kg		Dexmedetomidine 1 mcg/kg		Normal Saline 0.9%	
		Mean	SD	Mean	SD	Mean	SD	Mean	SD
MAP	1 min after intubation	9.5	2.96	1.5	1.58	−9.22	3.67	12.58	6.9
MAP	5 min after intubation	8.61	3.01	1.49	2.35	−9.21	3.87	10.06	3.13
MAP	10 min after intubation	7.94	3.64	1.17	2.56	−8.94	4.58	8.69	3.77
MAP	20 min after intubation	7.12	3.61	0.26	2.11	−9.81	4.23	7.3	3.68

Table 13: Mean difference in SPO_2 before and after intubation in different treatment groups

Variable	Follow-up	Mean difference from Intubation							
		Dexmedetomidine 0.5 mcg/kg		Dexmedetomidine 0.75 mcg/kg		Dexmedetomidine 1 mcg/kg		Normal Saline 0.9%	
		Mean	SD	Mean	SD	Mean	SD	Mean	SD
SPO_2	1 min after intubation	0.08	0.77	0.03	0.77	−1.53	1.50	0.31	1.09
SPO_2	5 min after intubation	0.19	0.58	0.28	0.81	−1.25	1.18	0.17	1.06
SPO_2	10 min after intubation	0.31	0.62	0.50	0.97	−0.69	1.37	0.56	0.94
SPO_2	20 min after intubation	0.42	0.84	0.56	1.03	0.19	0.92	0.39	0.96



Graph 7: Mean difference in map before and after intubation in different treatment groups



Graph 8: Mean difference in SPO_2 before and after intubation in different treatment groups

for premedication for general anesthesia in intravenous doses varying from 0.25 to 1 μg/kg for the attenuation of intubation responses, but the optimal dose not yet established.[24] Our study is to assess the effect of different doses of dexmedetomidine on hemodynamic response during laryngoscopy and tracheal intubation in endoscopic neurosurgeries.

Our study was carried in neurosurgery operation theater of NSCB Medical College. It was a prospective double blind randomized study in which the study population of 144 was divided into four groups of 36 each. One was the control group and other three groups received dexmedetomidine in infusion form preoperatively in varying doses, namely, 0.5 mcg/kg, 0.75 mcg/kg, and 1.0 mcg/kg. We assessed the optimal dose of dexmedetomidine which attenuated the hemodynamic response during laryngoscopy and tracheal intubation as well as which provided the most stable hemodynamics.

Demographically all four groups were comparable, these were 38.6% female and 61.1% males of ASA physical Statuses I and II who were enrolled in our study. Most of the patients belong to the age group between 31 and 40 years.

On assessing the Richman Agitation Sedation Scores in different group just after completion of study drug infusion, it was found that the majority of patients receiving dexmedetomidine 1.0 mcg/kg, 0.75 mcg/kg, and 0.5 mcg/kg the scores were −5, −4, and −3, respectively, but when analyzed 10 min after infusion, the sedation scores of the respective groups rose to −4, −3, and −2, respectively, which depicts that patients were more arousable. Similarly Hall *et al.*[24] using a loading dose of 6 μg/kg/h for 1 min followed by constant infusion at two doses either 0.2 μg/kg/h or 0.6 μg/kg/h for 50 min observed significant sedation (in 50–60%) using BIS, VAS sedation, and OAA/S, impairment of memory in 50% using DSST and MEM and impairment of psychomotor performance in 28–41% using DSST in infusing dexmedetomidine to human volunteers. Yildiz *et al.*[25] observed Ramsay Sedation Score to be 6 in 56% of patients just after the infusion. Dhanachandra *et al.*[26] observed significant sedation using 0.75 μg/kg

dexmedetomidine. Thus, there was discrepancy between our study and the study done by Dhanachandra *et al.*[26]

Analysis of variance showed that heart rate after 1, 5, 10, and 20 min compared from before intubation changed significantly in all treatment groups except for the group using normal saline. Dexmedetomidine group using 0.75 mcg/kg dose showed most stable heart rate when compared with other groups ($P < 0.0001$). Group wise multiple comparison also showed significance except for dexmedetomidine 0.5 mcg/kg and normal saline at 20 min which were not different ($P > 0.05$) in our study. Dexmedetomidine in 0.75 μg/kg showed minimum deviation from mean (beats/min). Smitha *et al.*[27] showed highly significant reduction in heart rate using 1microgram/kg dexmedetomidine when compared to 0.5 μg/kg. This is congruent to our study results. Yildiz *et al.*[25] observed after 1 μg/kg dexmedetomidine the postoperative heart rate to be less than preoperative levels but it did increase after intubation. Sebastian *et al.*[28] when compared 0.75 μg/kg with 0.5 μg/kg dexmedetomidine showed that heart rate was better controlled with 0.5 μg/kg dose. This was in contrast to the results of our study in which the most stable heart rate was provided with dexmedetomidine 0.75 μg/kg. Kumari *et al.*[29] used 0.5 μg/kg to show significant reduction in heart rate (19.6) till 15 min postoperatively on inter comparison among the study groups. Mahajan *et al.*[30] showed that dexmedetomidine 1 μg/kg was more effective in controlling heart rate when compared to 30 mg/kg magnesium sulfate. Hall *et al.*,[24] when compared two regimens of infusing dexmedetomidine (0.2 or 0.6 μg/kg/h), found a significant reduction in heart rate (16% and 20%) and at higher concentration, the drug paradoxically resulted in increase of blood pressure due to alpha-2 stimulation. Saraf *et al.*[31] using pre-operative 0.6 μg/kg dexmedetomidine found a mean drop of heart rate of 2.86 bpm and a significant fall in heart rate at 2, 5, and 8 min of drug infusion. Talke *et al.*[32] while infusing dexmedetomidine throughout the perioperative period observed that heart rate was slower than placebo (73+ 11 bpm vs. 83+ 20 bpm).

Systolic blood pressure after 1, 5, 10, and 20 min when compared from before intubation changed significantly in all treatment groups except for normal saline, moreover dexmedetomidine 0.75 mcg/kg doses showed most stable systolic blood pressure. Group wise multiple comparison also showed significant change from baseline during follow-up period except for dexmedetomidine 0.5 mcg/kg and normal saline at 1, 5, 10, and 20 min which did not significantly differ ($P > 0.05$).

Diastolic blood pressure after 1, 5, 10, and 20 min when compared from before intubation changed significantly in all treatment groups except for normal saline, moreover dexmedetomidine 0.75 mcg/kg doses showed most stable diastolic blood pressure. Group wise multiple comparison also showed significant changes during follow-up period except for dexmedetomidine 0.5 mcg/kg and normal saline at 1, 5, 10, and 20 min which did not significantly differ ($P > 0.05$).

Mean arterial pressure (MAP) after 1, 5, 10, and 20 min when compared from before intubation changed significantly in all treatment groups except for normal saline, moreover dexmedetomidine 0.75 mcg/kg doses showed most stable mean arterial pressure. Group wise multiple comparison also showed significant changes during follow-up period except for dexmedetomidine 0.5 mcg/kg and normal saline at 5, 10, and 20 min which did not significantly differ ($P > 0.05$).

Smitha *et al.*[27] when comparing 0.5 and 1.0 μg/kg dexmedetomidine showed that the values of SBP, DBP, and MAP were statistically lower at all-time intervals especially 1 min after intubation by 1 μg/kg dexmedetomidine. This is in accordance to our study where dexmedetomidine at 1 μg/kg significantly attenuated the hemodynamic response. Gulabani *et al.*[33] exhibited that dexmedetomidine 1 μg/kg was better than linocaine 1.5 mg/kg and esmolol 100 mg in controlling specifically the diastolic blood pressure. Yildiz *et al.*[25] when infused 1 μg/kg dexmedetomidine proved that the drug was effective in controlling hemodynamic variables. Keniya *et al.*[34] when preloaded the patients with 1 μg/kg dexmedetomidine followed by infusion at 0.2–0.7 μg/kg/h in the operative period found that it better controlled diastolic pressure (11%) than systolic (8%). Thus, the studies by Gulabani *et al.*[33] and Keniya *et al.*[34] showed that dexmedetomidine was more effective in controlling the diastolic blood pressure. Sulaiman *et al.*[15] compared dexmedetomidine 0.5 μg/kg with normal saline and showed that there was statistical difference between them at 1st, 2nd, and 3rd min post-intubation in terms of attenuating SBP, DBP, and MAP. Sebastian *et al.*[28] when comparing normal saline and dexmedetomidine in doses 0.5 and 1.0 μg/kg showed that by 1 μg/kg dose the hemodynamic variables fell below baseline at 3rd min post-intubation. Our study is in accordance to the study by Sulaiman *et al.*[15] and Sebastian *et al.*[28] where the use of dexmedetomidine was better than the placebo in attenuating the hemodynamic response and when used at 1 mcg/kg, maximally abolishes the pressor response to laryngoscopy and intubation. Ravikumar Keshari *et al.*[35] on comparing 0.5 and 1 mcg/kg dexmedetomidine showed that mean SBP was significantly low using 1 mcg/kg dose at 5 and 10 min post-intubation. Thus, all the above studies have pointed out that whenever dexmedetomidine was used in the dosages of 1.0 μg/kg, the hemodynamic variables fell considerably below the baseline and if such doses are used in the perioperative

setting of neurosurgical cases, there is potential chance of CPP (cerebral perfusion pressure) reaching to critical levels. Similar to our study, Dhanachandra *et al*.[26] showed that dexmedetomidine when used in dosage of 0.75 μg/kg provided the most stable hemodynamics.

SPO_2 after 1, 5, 10, and 20 min when compared from before intubation changed significantly in all treatment groups except for normal saline ($P < 0.0001$). Group wise multiple comparison also showed that statistical change in SPO_2 observed with dexmedetomidine 1 mcg/kg dose was most significant from all other treatment groups Aho *et al*.[36] using 2.4 μg/kg, Yildiz *et al*.,[25] Sagiroglu *et al*.,[37] and Ying *et al*.[38] in their study observed elevated sedation scores with 1 μg/kg dexmedetomidine which lowered the SPO_2 values just after the commencement of infusion.

SUMMARY AND CONCLUSION

Neurosurgical patients are subset of patients in which induction from anesthesia is met with hemodynamic perturbations which, in turn, may lead to disastrous complications such as intracranial hematoma and raised intracranial pressure.

The control of hemodynamics in the peri induction period can be met with judicious use of various anesthetic protocols.

This study was planned to evaluate the control of pressor response to laryngoscopy and intubation in neuroendoscopic procedures and avoidance of neurological complications such as raised intracranial tension in immediate peri induction period, provision of stable hemodynamic variables, and early recovery from anesthesia.

Our study demonstrated that dexmedetomidine when used preoperatively as a premedicament in doses at 0.75 μg/kg in infusion form, provided the most acceptable hemodynamics in the peri induction period with an acceptable level of twilight.

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