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Case Report

Adenomatoid Odontogenic Tumor of Follicular Variant Affecting the Anterior Maxilla: A Case Report

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Abstract

Adenomatoid odontogenic tumor (AOT) is uncommon lesion of odontogenic origin which is benign and non-invasive. Young female patients are commonly affected. Lesion is slow growing, asymptomatic, and mainly involved maxillary anterior region. In this case report, this lesion is of follicular variant and is in association with maxillary impacted 13. Enucleation and curettage are the treatment of choice. There is 0.1% recurrence rate observed in this lesion. However, in this case, we did 3 years follow-up of the patient, but reoccurrence was not observed. The early intervention and diagnosis can prevent patient's esthetics and stops further destruction of adjacent structure. Any swelling of longer duration associated with deciduous teeth present in maxillary anterior region should be suspected as odontogenic lesion.

Key words: Follicular AOT, Adenomatoid odontogenic cyst, Hamartomas

INTRODUCTION

Steensland, in 1905, considered adenomatoid odontogenic tumor (AOT) lesion as a variation of ameloblastoma.[1] AOT accounts for 3–7% of all odontogenic tumors.[2] In 1948, Stafne considered it as a separate entity.[2] In 1971, the World health organization (WHO) accepted the term AOT.[3] Philipsen *et al.* classified AOT into types follicular, extrafollicular, and peripheral.[4] This lesion is slow growing, non-invasive, and asymptomatic. This lesion is common in the 2nd and 3rd decades of life, which accounts for 88% cases.[5] Female-to-male ratio is 2:1 and affects upper anteriors.[6] Lesion has very distinct capsule surrounding it and structures resembling ducts (adenomatoid) within epithelial lesion.[7] It rarely reoccurs even if it is treated with a conservative curettage.

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CASE REPORT

A 11-year-old female patient reported to our department with chief complaint of swelling in the right maxillary front region since 1 year. Swelling was painless, initially small in size gradually grew to present size. There was no relevant medical history and history of trauma.

On extraoral examination [Figures 1-3], facial asymmetry was present. On the right side of maxilla, there was a solitary, localized, and spherical-shaped swelling approximately 4 × 4 cm in size present with center 1 cm posterior to alae of the nose obliterating nasolabial fold. Overlying skin was normal, movable, and not fixed with the swelling suggestive of intraoral swelling without involving skin. The swelling was non-tender and bony hard in consistency. Anteroposteriorly, the swelling was extending from alae of nose to perpendicular line drawn from outer canthus of eye. Superoinferiorly, the swelling was extending from 1 cm inferior to infraorbital margin until commissure tragus line.

On intraoral examination [Figure 4], the swelling was present in the right maxillary buccal region extending

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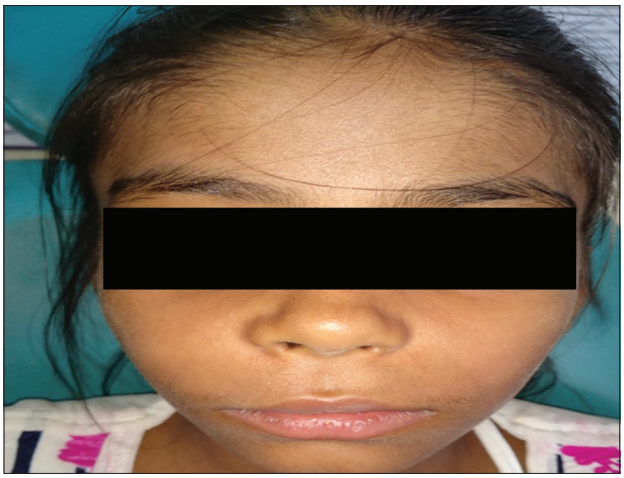

Figure 1: Shows facial asymmetry on right side of maxilla

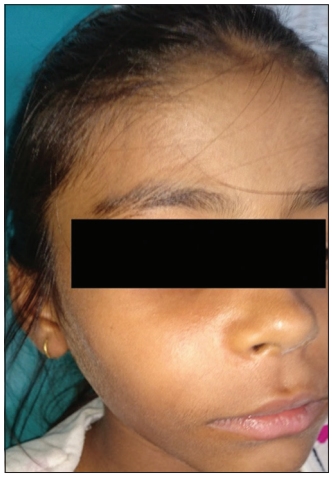

Figure 2: Shows extraoral swelling present on the right side of maxilla, there is a solitary, localized, and spherical-shaped swelling approximately 4 × 4 cm in size present with center 1 cm posterior to alae of the nose obliterating nasolabial fold

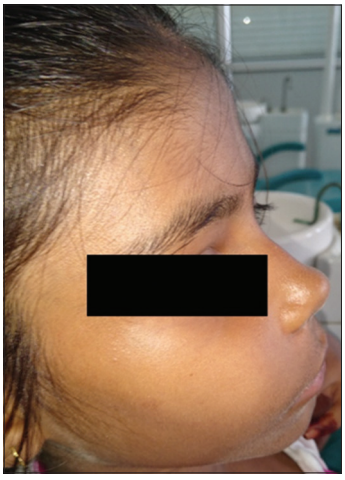

Figure 3: Shows extraoral swelling present on the right side of maxilla, there is a solitary, localized, and spherical-shaped swelling approximately 4 × 4 cm in size present with center 1 cm posterior to alae of the nose obliterating nasolabial fold

from mesial margin of 11 until mesial margin of 16. Superoinferiorly, it was from gingival margin to the depth of the vestibule causing vestibular obliteration. Overlying mucosa was normal in color. Swelling was hard in consistency suggesting expansion of buccal cortex.

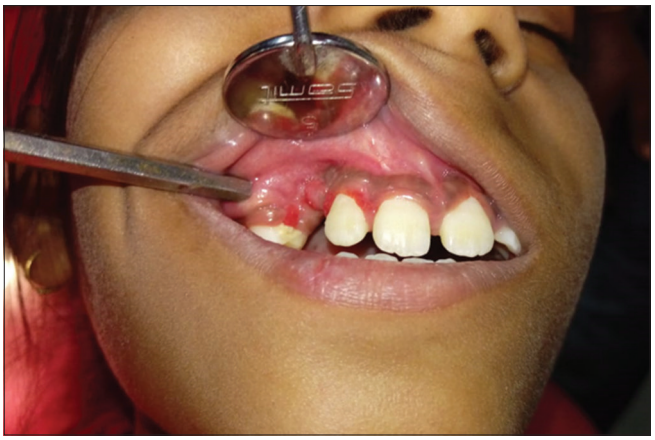

Figure 4: Intraoral swelling present on right maxillary buccal region extending from mesial margin of 11 until mesial margin of 16

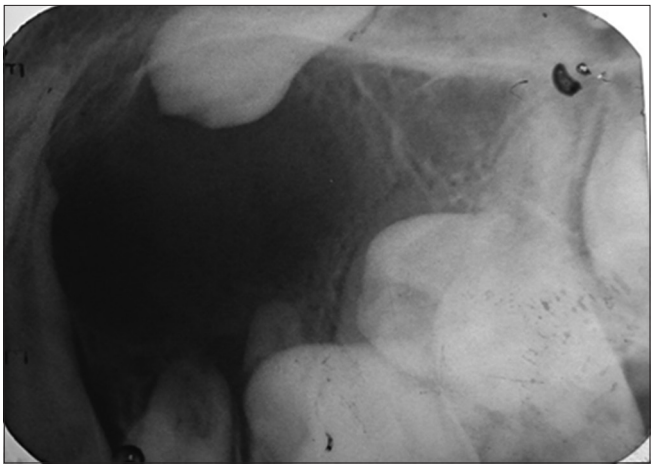

Figure 5: IOPA shows a well- defined radiolucency in periapical region extending from mesial border of 12 without involving apex of 11 until mesial border of 16

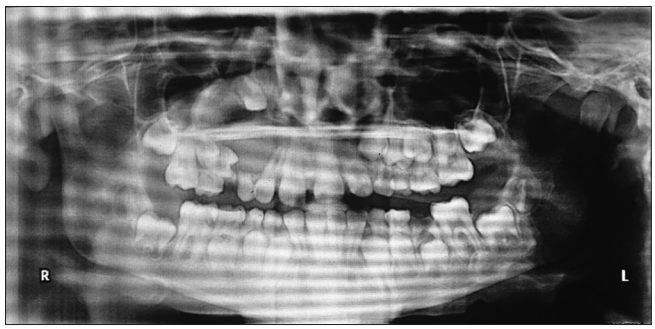

Figure 6: Superoinferiorly, radiolucency was extending from crest of alveolar bone of 12, 53, 54, and 55 region to lifting floor of the maxillary sinus. 13 was impacted and superiorly displaced. Root apex of 12 was mesially tilted causing space between crown of 11 and 12. The right central incisor was slightly extruded. Root resorption was seen in 53 and grossly carious 54

Aspiration was found negative. Electric vitality test of 12 demonstrated negative response. Provisional diagnosis of Adenomatoid odontogenic tumor with differential diagnosis of dentigerous cyst was considered.

IOPA and OPG [Figures 5 and 6] showed a well-defined radiolucency in periapical region extending from mesial border of 12 without involving apex of 11 until mesial border of 16 anteroposteriorly. Superoinferiorly, radiolucency was extending from crest of alveolar bone of 12, 53, 54, and 55 region to lifting floor of the maxillary sinus. Thirteen was impacted and superiorly displaced. Root apex of 12 was mesially tilted causing space between crown of 11 and 12. The right central incisor was slightly extruded. Root resorption was seen in 53 and grossly carious 54. Roots of developing premolars were pushed posteriorly causing anterior inclination of crowns.

Occlusal view [Figure 7] showed a well-defined corticated radiolucency causing buccopalatal expansion without displacing nasal septum. Cone-beam computed tomography [Figures 8 and 9] showed a well-defined corticated expansile lesion approximately 4.5 × 3.5 cm lifting the anteroinferior floor of maxillary sinus without perforating it. Thirteen was pushed superoanteriorly and completely enveloped by the lesion. Lesion was expanded until lateral wall of the nose without its displacement or perforation.

Lesion was surgically enucleated [Figures 10 and 11] with extraction of 13, 53, and 54. Based on clinical, radiological, and histopathological findings, a diagnosis of Adenomatoid odontogenic tumor was made. The patient visited to the department after 12 months [Figure 12]. The patient is still under follow-up.

DISCUSSION

AOT has been given variety of terminologies such as adenoameloblastoma, ameloblastic adenomatoid tumor, odontogenic adenomatoid tumor, and pseudoadenoma adamantinum.[8] AOT occurs 2/3rd in young females, maxilla,

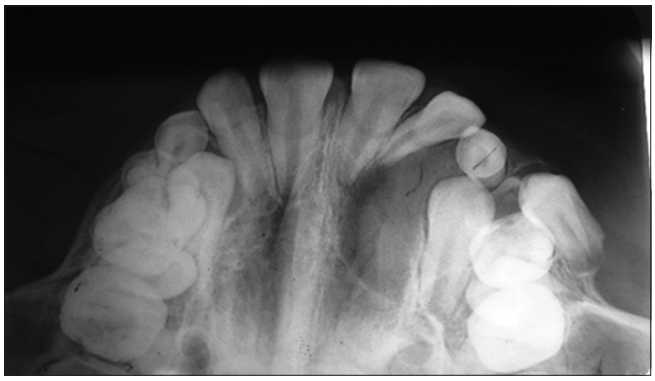

Figure 7: Occlusal view showed a well defined corticated radiolucency causing buccopalatal expansion without displacing nasal septum

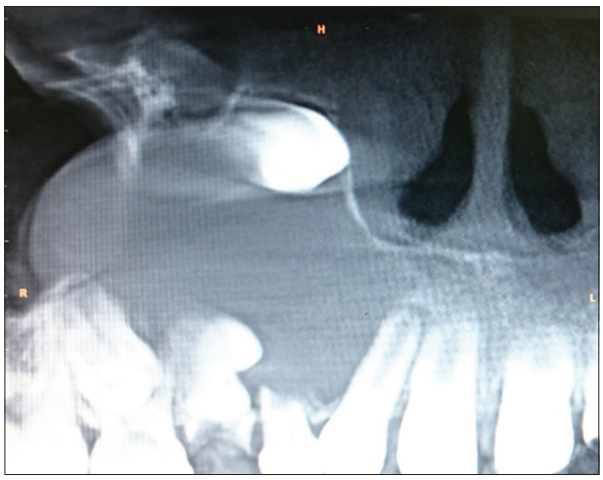

Figure 8: CBCT showed a well defined corticated expansile lesion approximately 4.5 x 3.5 cm lifting the anteroinferior floor of maxillary sinus without perforating it

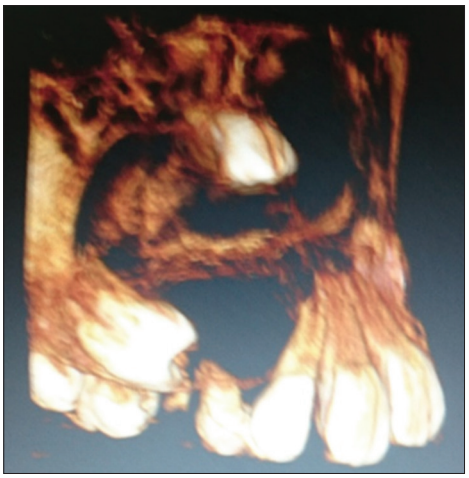

Figure 9: CBCT showed a lesion was expanded until lateral wall of the nose without its displacement or perforation

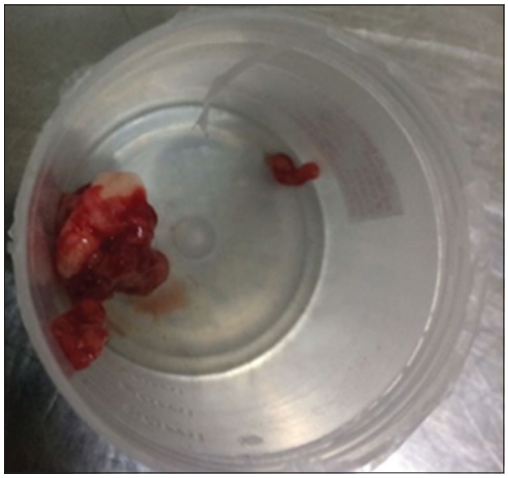

Figure 10: Extracted 13, 53, 54

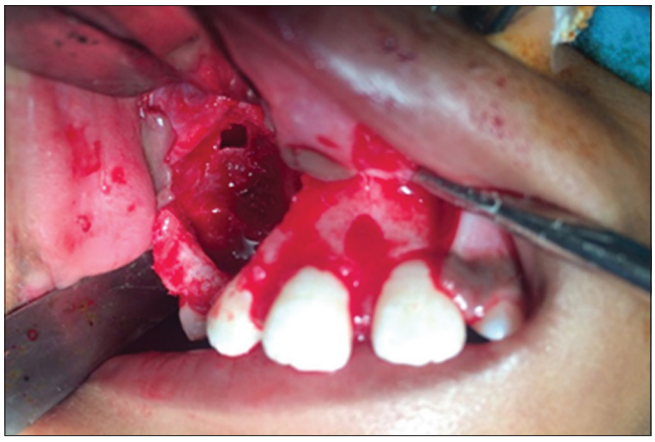

Figure 11: Lesion was surgically enucleated and 13, 53, 54 were extracted

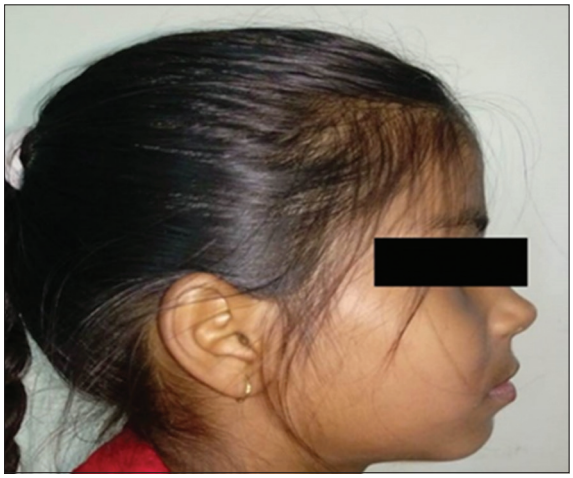

Figure 12: Post op follow up after 1 year

and its association with unerupted teeth especially canine, so it is also known as "two-thirds tumor."[9] About 73% cases of AOT are follicular type, in which there is central lesion in association of impacted tooth as seen in this case; 24% of cases are extra follicular type, in which there is no connection of central lesion with the tooth; and 3% of cases are of peripheral type that is present in gingival tissue of tooth bearing areas.[4] Odontogenic sources such as enamel organ, reduced enamel epithelium, dental lamina, and their remnants are thought to be the cause of AOT. Features of AOT include asymptomatic nature, cortical expansion which is present often and lesion involving the tooth is commonly impacted with slight displacement of adjacent tooth. All these features mentioned were seen in this case.

AOT shows resemblance with many odontogenic lesions such as dentigerous cysts, calcifying odontogenic cysts, ameloblastomas, odontogenic keratocysts, and calcifying epithelial odontogenic tumor. It can be distinguished from dentigerous cyst as radiolucency circumscribing the tooth shows apical displacement from CEJ, while in dentigerous cyst, it never crosses CEJ.[10] Histopathologically, AOT shows spindle-shaped or polygonal cells which form sheets and whorled masses in scarce connective tissue stroma. Duct such as structures is lined by single row of columnar epithelial cells and nuclei are polarized away from central lumen. Dystrophic calcification is mostly seen in AOT.[11,12]

CONCLUSION

Impacted permanent teeth or retained deciduous teeth for longer duration when associated with swelling should always be suspected for odontogenic lesion.

ACKNOWLEDGMENT

General support by assisting staff.

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Case Report

Autotrasplantation of Mandibular Third Molar after Enucleation of Radicular Cyst: A Case Report

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Abstract

Rapidly evolving implantation and alveolar ridge reconstruction techniques created a new area in modern dentistry where tooth loss is no longer a problem. Endless variations of implant's length, diameter, surface, and design along with autogenous, alogenous, aloplastic, or xenogenous bone substitutes made it possible to recreate physiological occlusion, esthetic, and masticatory function. However, none of nowadays technologies in implant dentistry have the potential to adapt to a growth and development changes of a child's jaw. Therefore, patient's young age is a restriction for implantation and a particular challenge for a dentist willing to restore missing tooth. Thus, tooth auto-transplantation can be a good choice for treatment.

Key words: Auto-transplantation Bone substitutes, Ridge reconstruction

INTRODUCTION

The major goal of dentistry is to maintain the harmony of dentition. Transplantation of tooth has been a method to restore the masticatory function and esthetics. Dental autotransplantation is can be defined as "movement of one toothor's dental germ from one position to another within the same person." Tooth transplantation can be classified into three categories: (1) Homogenous: when tooth of same species is used for transplantation, (2) heterogenous: When tooth from different species is used for transplantation, and (3) autogenous: When tooth of same individual is used for transplantation.[1]

Autotransplantation has an crucial role in the substituting missing teeth in young patients as osseointegrated implants are contraindicated in them. The tooth which is autotransplanted has the capacity of preserving the alveolar ridge and functional adaptation, which is very important and advantageous in comparison to osseointegrated implants as they remain stationary in the oral cavity and do not erupt, resulting in infraoccluion. Successful transplantation of teeth results in improved esthetics, dentofacial development, arch form, arch integrity, mastication, and speech.[1,2] The purpose of the paper is to describe the auto transplantation of left mandibular third molar to replace cyst i.r.t 36.

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CASE REPORT

A 25 years old patient reported to the department of oral and maxillofacial surgery with a chief complaint of pain and swelling in lower left back tooth region since 1 month. Patient had undergone root canal treatment for the same tooth 6 months back. Inspectory findings revealed swelling of buccal and lingual mucosa in respect to 36. OPG showed a well-defined radiolucency with sclerotic border involving periapical region of 36. Routine blood examinations reports were normal. After analyzing clinical and radiographic features provisional diagnosis of radicular cyst was made. At the same time radiographs also showed partially erupted 38 and it was decided to extract 36 followed by enucleation of the cyst followed by autotransplantation of 38 with packing of PRF at the extraction site of 36. Complete medical history of the patient was taken and was found to be noncontributory.

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Treatment plan and postoperative consequences were postoperative consequences were explained to the patient. An informed written consent was taken.

The procedure was started by asking the patient to rinse with Betadine gargles and proper surgical disinfection was followed. About 2% lignocaine hydrochloride was administered to anesthetic inferior alveolar, lingual, and long buccal nerves. It was decided to enucleate the cyst first and so 36 was extracted and the cystic cavity was explored and the cyst was enucleated. Once the cystic lining was removed a gauze was places at the socket of 36, after this and incisions was placed and 38 was disimpacted, at the same time while the disimpaction was being performed blood was withdrawn from the patient and PRF was prepared. When 38 was successfully disimpacted PRF was packed in the socket of 36 followed by autotranplantation of 38 at 36 position. 38 got snugally fit in the socket of 36 after that splinting was done.

The patient was instructed to avoid the use of operated site, to have soft diet and to perform warm saline rinse trice till

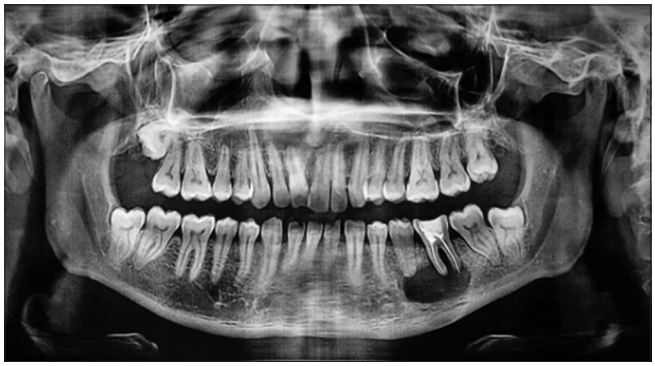

Figure 1: Pre-operative picture of patient

Figure 2: Profile pic of the patient

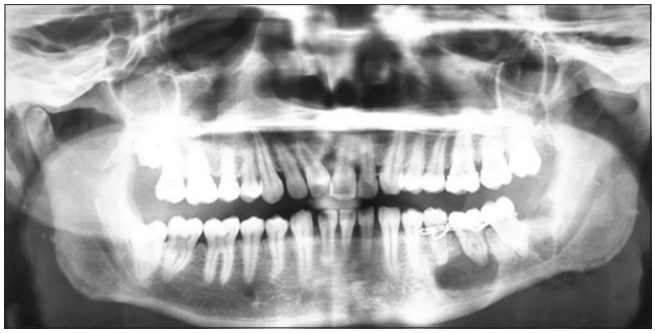

Figure 3: Immediate post-operative of the patient

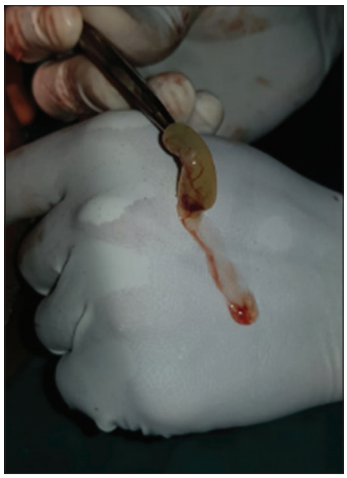

Figure 4: PRP formation

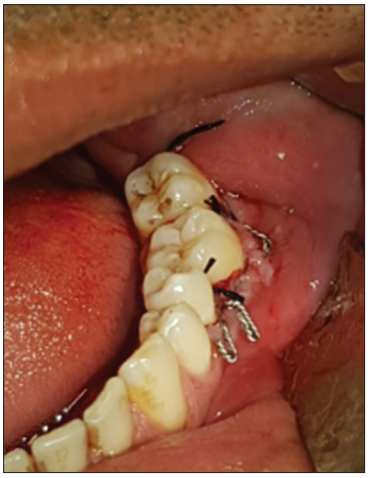

Figure 5: Immediate post-operative

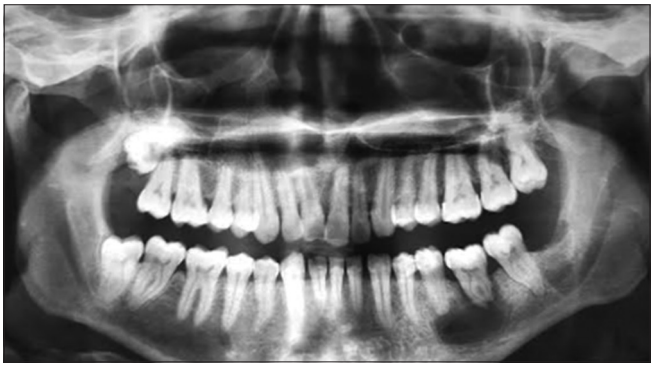

Figure 6: OPT after 5 months of treatment

first follow up. Pt was given antibiotics and analgesic for 5 days in the first follow-up the healing was satisfactory.

At 1 month follow-up, intraoral examination showed adequate stability of the transplanted tooth and OPG revealed resolution of the cystic cavity was seen [Figures 1-6].

DISCUSSION

The earliest evidence of tooth transplantation is found with ancient Egypt, where slaves were forced to donate their teeth to their rulers. The surgical method of dental tooth transplantation was first explained by Abulcassis in 1950, Moreover, it was in year 1564, a French dentist Ambroise, who performed and explained tooth bud transplantation. In the year 1956 transplantation method for molar was described. Since then the basic treatment guidelines have remained the same but the newer developments have like usage of cone beam computed tomography in treatment planning, two stage procedure and three dimensional prototyping have decreased the complications and have improved the prognosis.[3,4]

Many studies have evaluated the treatment outcome for autologous transplantation. Jonsson and Sigurdsson recorded 92% success rate after 2.5–26 years of follow-up. A large sample size was evaluated by Kvint *et al.* and they reported a success rate of 81% success rate after a mean duration of 4.8 months. Moreover, several recent articles have recorded 100% of success rate for immature autotranplanted teeth after a follow-up for 4 years. The major factor for success of autotranplantation depends on healing of periodontal ligament that depends on number of viable cells preserved at root surfaces.[3-5]

Autotransplantation of tooth are advantageous over osseo-integrated implants. Autotranplants helps in maintaining accomplishable periodontal ligament and thereby they continue to erupt in the oral cavity during growth, thereby making it best suitable for growing child. These teeth can also be moved orthodontically using fixed orthodontic appliances. Moreover, they help in preserving the volume of alveolar bone and in case of failure, they provide option for osseo-integrated implants.[4,5]

Autotransplantation can be indicated in patients with no relevant medical history in repositioning of ectopically positioned teeth to their position in arch, first molars with a bad prognosis which can be autotranplanted by third molar, loss of anterior teeth due to trauma or pathology that can be replaced by mandibular second premolars, hypodontia in one arch and crowding in the other arch. The approximation of size and shape of the donor site and receptor site are prerequisite for effective transplantation root resorption and attachment loss is major complications of Autotransplantation. Moreover, autotransplantation ensures maintenance and regeneration of periodontium.[5,6]

CONCLUSION

Autogenous transplantation should always be considered as a treatment plan when indicated.it is an uncomplicated and affordable treatment modality with good success rates. When performed with full efficacy it ensures biocompatibity in oral cavity helps in preservation of periodontium and provides better functional and esthetic adaptation.

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Case Report

Fabrication of Silicone Hand Prosthesis: A Case Report

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Abstract

Prosthetic restoration of facial defects is an ancient art. Nowadays, maxillofacial prosthodontics has been tremendously integrated with oral oncology, trauma, and deformity. It has not only limited to face but progressing toward make-over and also toward rehabilitating other parts of body such as a hand and a foot. Success of prosthesis has always been limited to the availability of material fulfilling the ideal requirements along with skill of the specialist concerned. Fabrication of prosthesis for a child is even more challenging considering the growth and psychology of a child. Silicone has been integral part of maxillofacial prosthodontics armamentarium for many years. This case report is an attempt to rehabilitate congenitally missing hand of a child, with silicone as a material of choice.

Key words: Hand prosthesis, Missing hand, Silicone material

INTRODUCTION

Prosthesis refers to an artificial replacement of an absent part of the human body[1] that enhances patient's esthetics, benefits the psychological well-being, and to great extent removes the social annihilation associated with lost part of a body.

Reconstructive surgery has limited role in rehabilitation of the lost body parts. The major role in rehabilitating the patient is, thus, played by the maxillofacial prosthodontist and the anaplastologist.[2] Injuries and amputations due to trauma, accidents, or congenital absence of limbs were treated as something to be covered by a sleeve, or made to look similar to the missing limb or a missing part.

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People, generally, associate the hand with a function. Hands also have an esthetic representation; they are a symbol; and they can emphasize the beauty of a gesture or the grace of a movement.[3] In current days, there is a trend of showing off the amazing materials and engineering that goes into the creation of state of the art prosthesis.

This case report describes the rehabilitation of congenitally missing hand, with silicone hand prosthesis.

CASE REPORT

A 13-year-old male patient reported Department of Prosthodontics. He gave a history of congenitally and partially missing parts of the left hand [Figure 1]. On examination partially missing left hand appeared normal with no signs of infection, fully developed thumb and not so well developed four fingers.

Technique

Impression [Figures 2 and 3]

A wax mold was fabricated to contain the hydrocolloid impression material and the patient's hands were lubricated

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with petroleum jelly, to prevent adhering of impression material to the skin. The patient was instructed to keep his hand in normal resting position and not to strain or fold the thumb. Then, the impression material was placed on palmer side of hand first to record the fine details and then on dorsal side of hand. Impression of opposite hand was also made in similar fashion, which served as guide in fabrication of wax pattern. The impression was then poured with type III dental stone, and thus, a positive replica was obtained.

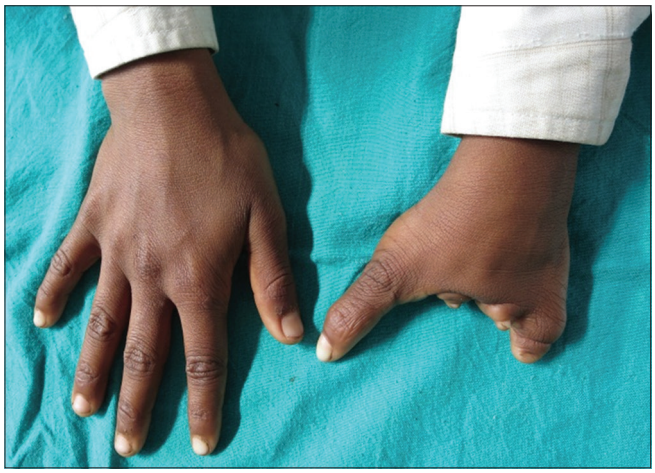

Figure 1: Pre-treatment

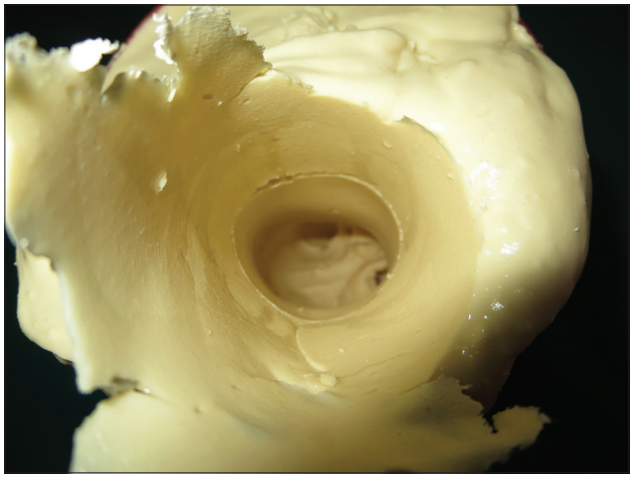

Figure 2: Impression of a left hand

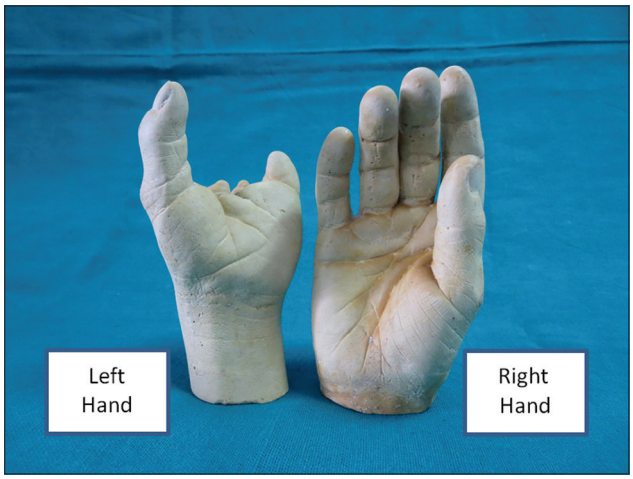

Figure 3: Positive replica obtained after pouring of impression

Wax-up and nail fabrication [Figures 4 and 5]

Prosthesis for the left hand was sculpted in modeling wax, taking normal hand (right side) as a guide.

Nails were fabricated using chemically activated polymethyl methacrylate resin (combination of clear, white, and pink) and characterized using acrylic stains.

Flasking and de-waxing [Figure 6]

The wax pattern was then flasked, first pour was done covering complete dorsal aspect of wax pattern of hand and all undercuts were eliminated. De-waxed and the mold thus obtained facilitate easy packing of silicone material.

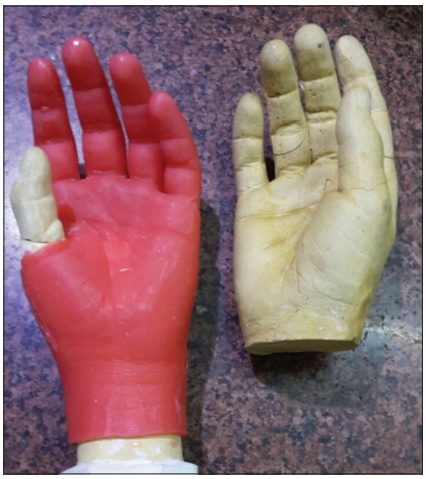

Figure 4: Left hand with carved wax pattern, taken right hand as guide for carving details

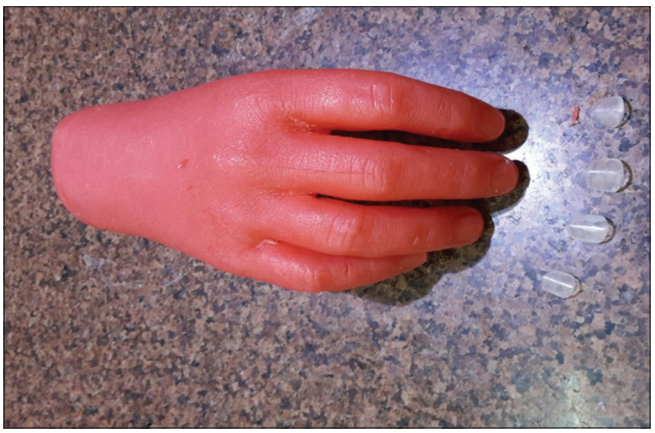

Figure 5: Nails were fabricated using clear acrylic resin

Shade matching and packing [Figure 7]

The shade matching was done in patient's presence under natural day light. Shade matching for the dorsal and ventral surface was done separately.

Silicone (Cosmesil) was packed in the mold obtained after dewaxing, the base color was dispensed, and intrinsic stains were mixed to achieve the desired shade. The dorsal part and sole of foot were packed separately and characterized individually.

Curing

The material was allowed to cure for 24 h at room temperature. Residual silicone outside the flask was used to check for polymerization.

Finishing

Final prosthesis was retrieved and sharp blade was used to trim the excess flash.

Final finishing was accomplished using silicon burs.

Nail implantation[4]

To complete, the prosthesis artificial nails which were fabricated earlier were implanted. A cyanoacrylate adhesive was, then, applied on the under surface of the nail for bonding with silicone surface to achieve a realistic look.

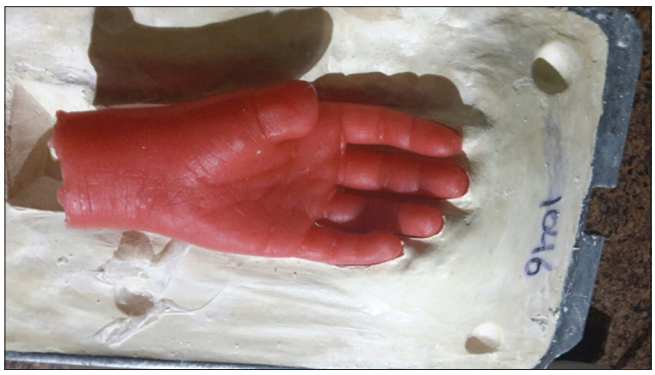

Figure 6: Flasking of wax pattern

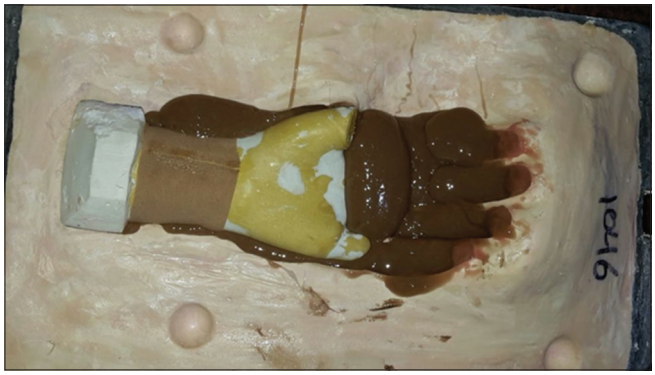

Figure 7: Silicone packing and characterization

Final insertion [Figure 8]

The final prosthesis was placed on the patient's hand. The patient was instructed about the use and maintenance of prosthesis.

Follow-up was done. The patient was able to use the prosthesis well, which was comfortable and happy.

DISCUSSION

Finger absence can cause marked psychological trauma. Reconstruction of such defect has gained importance in recent years. When surgical restoration is unsuccessful, contraindicated, or unavailable, prosthesis definitely provides great psychological help.

Over the past decade, silicone elastomers have proven to be the most promising material. Silicones are preferred due to their improved texture, light weight, and life-like appearance. These silicones are a combination of organic and inorganic compounds. Antioxidants and vulcanizing agents transform the raw mass from a plastic to a rubbery resin during processing.

Retention is of prime concern and is important for esthetics, function, and comfort, thus enhancing quality.

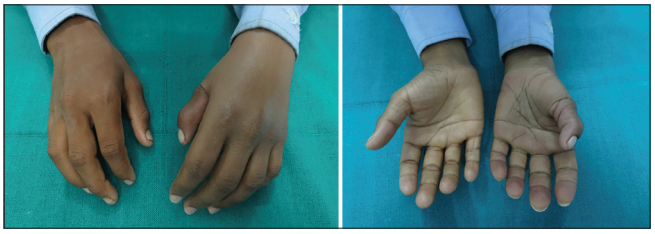

Figure 8: Post-insertion of prosthesis

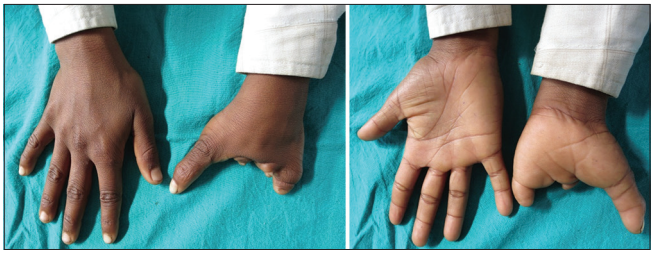

Figure 9: Before

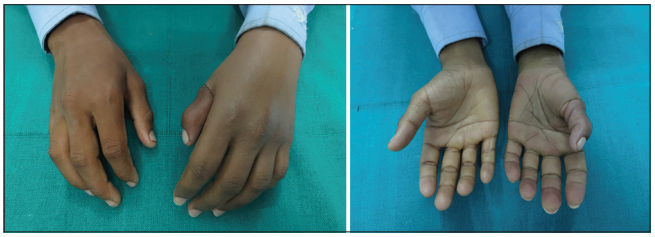

Figure 10: After

At present, the methods for prosthesis retention to the remaining part of the finger include ring, double ring, adhesives, and osseointegrated implants. Normally, the vacuum effect on the stump is sufficient to retain the finger.[5] In the present case report, vacuum has been used as an aid for retention, which has yielded a satisfactory retention of prosthesis [Figures 9 and 10].

CONCLUSION

One among the various extraoral defects are amputed fingers. Loss of a finger has been found to affect the person psychologically. In such situations restoring esthetics with sufficient, retention becomes the prime concern. Thus, a custom-made prosthesis using silicone polymers is esthetically acceptable, which partially restores some degree of functionality and comfort for patient.

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Case Report

Venous Malformation (Cavernous Hemangioma) of Great Saphenous Vein: A Rare Entity

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Abstract

Cavernous hemangioma is a collection of dilated blood vessels that form a lesion. These are more common in the liver followed by brain and in the eye. Cavernous hemangioma in the region of the great saphenous vein is a very rare occurrence. According to the International Society for the study of vascular anomalies, cavernous hemangiomas are slow flow venous malformations. Here, we are reporting a rare case of cavernous hemangioma of great saphenous vein and how we managed it.

Key words: Cavernous hemangioma, Great saphenous vein, Rare

INTRODUCTION

Cavernous hemangiomas are also called cavernous angiomas, cavernomas, or cerebral cavernoma (when referring to the presence in the brain). They may be sporadic or familial. In familial form, it may be due to loss of one of three genes – CCM1/KRITI, CCM2/Malcavernin, and CCM3/PDCD10.[1] They commonly involve regions of the head, neck, and viscera but saphenous vein cavernous hemangioma is a rare condition.[2]

According to the International Society for the Study of Vascular Anomalies (ISSVA), cavernous hemangiomas are considered as slow flow venous malformations.[3]

CASE REPORT

A 60-years-old male patient presented with complaints of swelling in the left leg which started as a small swelling insidious onset, gradually progressed to the present size of 5 × 3 cm for 6 years. Swelling increases on standing/walking and reduces on lying down. Not associated with pain or loss of sensation.

On Examination

A solitary and oval-shaped swelling of size 5 × 3 cm located approximately 10 cm proximal to medial malleolus over the medial aspect of the right leg [Figure 1a].

The swelling was soft, compressible [Figure 1b], non-tender, and non-pulsatile swelling. The skin over the swelling was normal and free from swelling. Magnetic resonance angiogram was done which showed peripheral nerve sheath tumor/venous malformation.

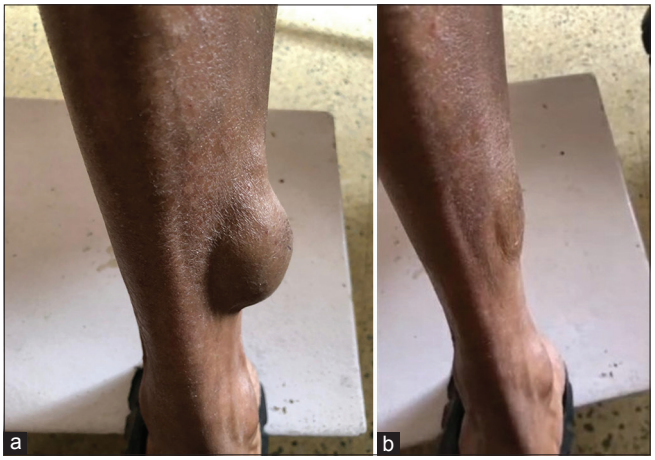

Figure 1: (a) Swelling over the left lower limb (b) Demonstration of compressibility of swelling

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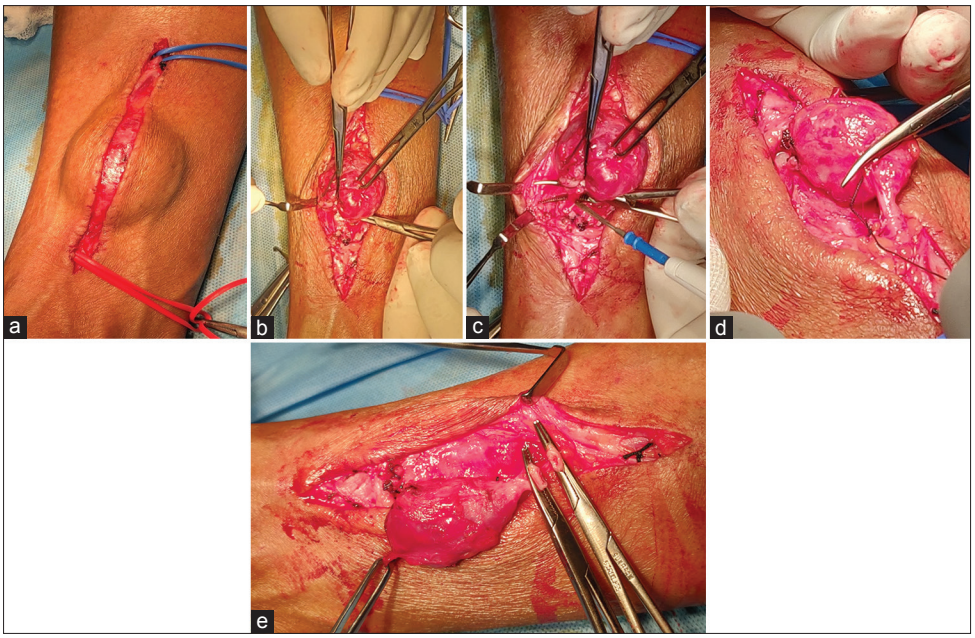

Figure 2: Operative procedure of cavernous hemangioma: (a) Incision over the swelling. (b) Swelling was isolated from the surrounding tissues. (c) Separation of base of the swelling through blunt dissection. (d) Ligation of proximal and distal ends of the swelling. (e) Demonstration that proximal and distal ends of swelling is having a lumen indicating that it is vein

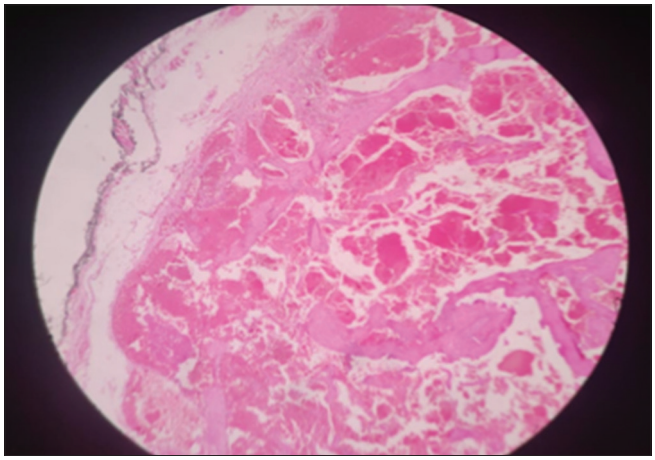

Figure 3: Histopathology demonstrating thick walled blood filled channels

Surgery

Excision biopsy under spinal anesthesia was done.

Operative Findings

5 × 3 cm single cystic swelling was continuous with great saphenous vein with some feeding vessels above and below [Figures 2a to 2e].

Histopathology

A well-circumscribed benign lesion composed of thick and thin blood-filled vascular channels of varying calibers lined by plump endothelial cells which suggests that it is cavernous hemangioma (venous malformation) of the right leg [Figure 3].

DISCUSSION

Cavernous hemangioma is a collection of dilated blood vessels that form a lesion. They can arise nearly anywhere in the body where there are blood vessels. Most cases are thought to be congenital and when there is no definitive cause, research shows that genetic mutations result in onset. They develop due to abnormal cell proliferation, which is influenced by hormonal and growth factors.

These are most common in the liver and can also occur in the brain, spinal cord (cerebral hemangiomas), and the eyes (eye cavernous hemangiomas).[4] They can be seen in any age group, but the majority are found in those between the ages of the third to sixth decade of life.[4-6] Cavernous hemangioma in the region of the Great saphenous vein is a very rare occurrence.[2,7]

Ultrasonography is the first line in diagnostic imaging. Gradient T2WI magnetic resonance imaging is the most sensitive method for diagnosing cavernous hemangiomas.[4] Resection is the mainstay treatment for this condition. Sclerotherapy is the non-operative management of cavernous hemangioma. Sclerotherapy is performed with lesser formulations (95% or 90%) of concentrated ethanol and sodium tetradecyl sulfate.[2,8]

Cavernous hemangioma is not a vascular tumor but rather a vascular anomaly. According to the ISSVA, vascular malformations are subdivided into a high and low flow and

within these categories, lesions are defined by components as arterial, venous, and mixed. By definition, venous malformations are slow flow and low-pressure venous spaces. Based on this, cavernous hemangioma is termed as slow venous malformation.[9,10]

CONCLUSION

Venous malformations of the great saphenous vein are a rare condition. Diagnosis will be based on clinical and radiological findings combined. One should not depend on radiological findings as they are not always reliable, which is seen in our case. A strong clinical suspicion should be present even though it is a rare entity.

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Review Article

Papilla Preservation Flap: A Novel Surgical Approach

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Abstract

The periodontal therapy includes nonsurgical periodontal therapy, surgical periodontal therapy, and the correction mucogingival problems. Non-surgical approach is most common for maxillary anterior dentition. However, in specific cases, surgical therapy is the treatment of choice, for obtaining favorable outcome. The aim of surgical periodontal therapy is to eliminate pocket and to create a stable, easily maintainable state, and to promote periodontal regeneration. Periodontal surgical therapy used in periodontal defects with maxillary anterior dentition in an esthetic manner is possible only when integrity of the papilla is preserved. This article discusses the different papilla preservation flap designs.

Key words: Conventional papilla preservation, Esthetics, Modified papilla preservation, Simplified papilla preservation, Whale's tail technique

INTRODUCTION

An ideal periodontal therapy must necessarily consider esthetic appearance, which means an effort to maintain gingival marginal anatomy and as much height of papilla as possible along the course of the periodontal therapy. Often, non-surgical approach is encouraged for maxillary anterior dentition. However, there are situations, in which surgical therapy is unavoidable. A surgical approach that splits the papilla certainly contribute to shrinkage and decrease in the height of interdental papilla leading to exposure of the interproximal embrasures and recession. This led to the development of a flap technique which intended to spare the papilla instead of splitting it. Probably, the first report of a papilla preservation procedure was by Kromer in 1956 which was designed to maintain osseous implants.[1] App, in 1973, reported a similar technique and termed it as intact papilla flap, which retained the interdental gingival in the buccal flap.[2] Evian *et al.* modified this technique to preserve the anterior esthetics after flap surgery.[3] Genon and Bender, in 1984, also reported a similar technique indicated for esthetic purposes. Takei *et al.*, in 1985, introduced a detailed description of the surgical approach reported earlier by Genon and named the technique as papilla preservation flap, which ensured optimal interproximal coverage and facilitated placement and retention of bone grafts which prevented exfoliation of the graft material.[4]

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There are various surgical approaches available to obtain primary closure of flap and to preserve interdental tissue.

a. Conventional papilla preservation technique[5] (Takie *et al.* 1985)
b. Modified papilla preservation[6] (Cortellini *et al.* 1995)
c. Simplified papilla preservation flap[7] (Cortellini *et al.* 1999)
d. Whale's tail technique (Bianchi and Basseti 2009).

CONVENTIONAL PAPILLA PRESERVATION FLAP

Takei *et al.*, in 1985, introduced conventional papilla preservation technique. It incorporates the entire papilla in one of the flaps by means of crevicular interdental incisions to detach the connective tissue attachment and a horizontal incision at the base of the papilla, leaving it connected to one of the flaps.

- Step 1 – Intrasulcular incision at the facial and proximal aspects of the teeth
- Step 2 – Intrasulcular and semilunar incisions at lingual/palatal aspect of teeth

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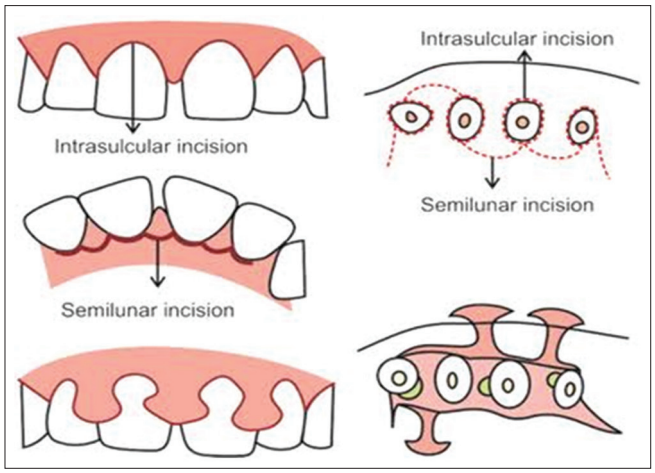

Figure 1: Conventional papilla preservation flap

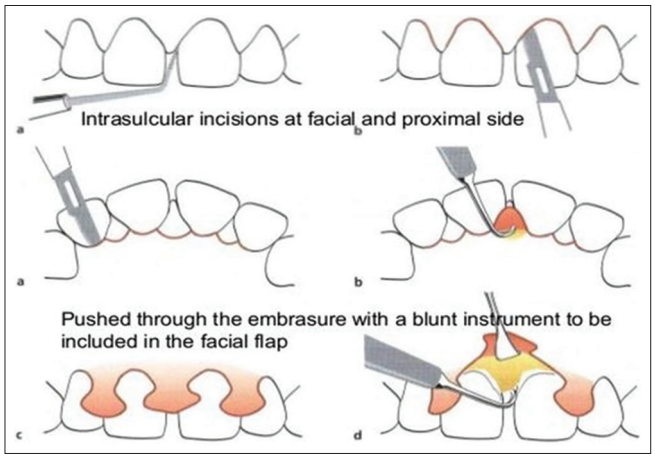

Figure 2: Conventional papilla preservation flap

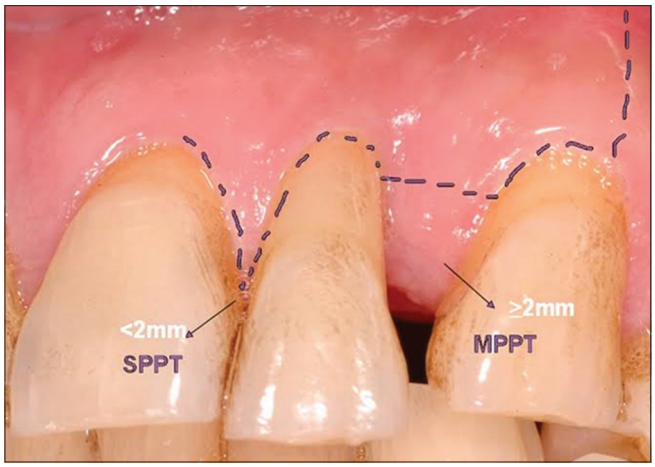

Figure 3: Simplified papilla preservation flap and modified papilla preservation flap

- Step 3 – Semilunar incision should dip apically by 5 mm from line angles of teeth
- Step 4 – A curette/interproximal knife is used to free the interdental papilla from underlying tissue and a blunt instrument is used to push the detached interdental tissue through embrasure
- Step 5 – A full thickness flap is reflected by periosteal elevator on facial and lingual/palatal surfaces.

Cortellini *et al.*, in 1995, proposed a modification in the papilla preservation flap and named it as modified papilla preservation flap.[6]

MODIFIED PAPILLA PRESERVATION FLAP

- Step 1 – Primary buccal and interproximal intrasulcular primary incision involving two teeth neighboring the defect is made
- Step 2 – A horizontal incision with slight internal bevel is given on buccal gingiva of interdental space at base of papilla
- Step3 – Connect the horizontal incision with mesiodistal primary intrasulcular incision
- Step 4 – A full-thickness flap is elevated on buccal aspect
- Step5 – The buccal and interproximal incisions are continued intrasulcular in interproximal space to reach palatal line angles on palatal aspect
- Step 6 – Dissect the papilla and push on palatal with blunt instrument
- Step 7 – A full thickness palatal flap with interdental papilla is then elevated
- Step 8 – To allow coronal positioning of buccal flap, a vertical releasing incision in coronoapical directions extending in to the alveolar mucosa can be placed in the interproximal spaces neighboring the defect.

SUTURING OF FLAP IS CARRIED OUT AS

- A horizontal internal mattress suture is placed between base of palatal papilla and the buccal flap coronal to MGJ
- A vertical internal mattress suture is placed between the buccal aspect of interproximal papilla and the most coronal portion of buccal flap
- The vertical releasing incisions are sutured with a apicocoronal suture
- Interproximal sutures are placed to close mesial and distal extension of the flaps, to obtain coronal positioning of the buccal flap and primary closure of interdental space over the membrane.

Wide interdental spaces as a pre-requisite to bring about appreciable functional and esthetic value, for both the papilla preservation flap and its modified flap design. To apply esthetic value to teeth having narrow interproximal

zone, Cortellini *et al*., in 1999, proposed the simplified papilla preservation flap technique.[8]

SIMPLIFIED PAPILLA PRESERVATION FLAP

A horizontal incision is replaced by an oblique incision and placed on the buccal aspect of the interdental papilla, and the papilla is elevated toward the palatal aspect.

- Step 1 – An oblique incision is placed along the defect associated papilla from the gingival margin at the buccal line angle of the involved tooth to reach the mid interproximal portion of the papilla of the adjacent tooth
- Step 2 – The oblique incision is continued intrasulcularly in the buccal aspect of the teeth adjacent the defect and extended to partially dissect the papilla of the adjacent interdental spaces
- Step 3 – This allows the elevation of a buccal flap with 2–3 mm exposure of alveolar bone.[8]

THE "WHALE'S TAIL" TECHNIQUE

Bianchi and Bassetti,[9] in 2009, introduced a surgical technique to preserve interdental tissue in guided tissue regeneration known as a "whale's tail" technique. It was used for the treatment of wide intrabony defects in the esthetic zone involving the elevation of a large flap from the buccal to the palatal side to allow accessibility as well as visibility of the intrabony defect maintaining interproximal tissue to recreate a functional attachment with esthetic results.[9] It was possible to elevate a large flap from buccal to palatal, which allowed the preservation of a large amount of soft tissue and resulted in good primary closure. Besides, positioning of incisions away from the defect area and placement of sutures distant from the regenerated defects decreased the chances of bacterial colonization of the biomaterials, which is often responsible for regenerative failures.

HEALING AFTER PAPILLA PRESERVATION FLAP

- Immediate response is clot formation
- At edge of flap numerous capillaries are seen
- 1–3 days after surgery, space between flap, and tooth surface and bone appears to be reduced and the epithelial cells along with border of the flap start migrating
- By 1 week after surgery, epithelial cells have migrated and established an attachment to root surface by means of hemidesmosomes
- The blood clot is replaced by granulation tissue proliferating from gingival connective tissue, alveolar bone, and periodontal ligament
- By 2nd week, collagen fibers begin to appear parallel to root surface
- By end of 1 month, the epithelial attachment is well formed and gingival crevice is also well epitheliased [Figures 1-3].

CONCLUSION

Papilla preservation flap surgery technique maintains esthetic value and a better approach for interproximal regenerative procedures.

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Review Article

Analgesics for the Dental Pain Management: A Comprehensive Review

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Abstract

Analgesics are the drugs which relieve pain as a symptom, without affecting its cause. Analgesics are most commonly prescribed in dentistry for pain relief which include the non-steroidal anti-inflammatory drugs (NSAIDs) and various opioid-containing analgesic combinations. Selection of an analgesic for the management of dental pain should be judicially planned. The literature was searched using "Pub Med" and electronic databases from 1981 to 2021. A total of 98 articles were retrieved from 1952 to 2021. Among the retrieved articles, most of them were case reports related to medical treatment procedures, seven were original research articles and five articles reviewed the use of NSAIDs in dentistry. Various medical therapies using NSAIDs are often prescribed by dentists. The literature review proves that the use of NSAIDs in the field of dentistry is very broad and is considered as safer drug. However, each drug has side effects and work power, each of which is adjusted to the needs and systemic conditions of patients who require administration of this drug. The present paper reviews the information currently available on NSAIDs, with special emphasis on those aspects related to dental practice. The dental practitioner has a wide range of drugs for analgesic/anti-inflammatory purposes. A rational prescription should be promoted, taking into account different aspects related to the drugs (pharmacodynamics and pharmacokinetics) and patients (medical history, type of procedure, and the like), leading to an individualized prescription for each patient. The accuracy of the use or administration of NSAIDs is supported by the knowledge and expertise of doctors or dentists.

Key words: Analgesics, Dental pain, Non-steroidal anti-inflammatory drugs in dentistry

INTRODUCTION

Most commonly non-steroidal anti-inflammatory drugs (NSAIDs) are the choice of drugs which are prescribed in dental practice to manage pain and swelling. Paracetamol and ibuprofen are the most widely used NSAIDs. Their mechanism of action is based on the inhibition of cyclooxegenase (COX), and therefore of prostaglandin synthesis. Side effects of all of these drugs are similar as they have similar mechanism of action. Symptoms vary from mild (e.g., nausea or vomiting) to serious gastric problems (such as gastric bleeding or perforation). Further side effects comprise of high risk of vascular accidents (specifically acute myocardial infarction), renal toxicity secondary to a decrease in perfusion, and the antiplatelet effect of these drugs enhances the risk of abnormal bleeding tendency. These drugs induce a premature ductus arteriosus closure, hence, contraindicated during third trimester of pregnancy. Broadly speaking, NSAIDs are classified into aspirin and non-aspirin NSAIDs. The ADA delegation house adopted a statement in 2016, that said, "Dentists should consider NSAIDs as a first-line therapy for the management of acute pain."[1]

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DISCUSSSION

Dental Indications for Analgesic Use

Odontogenic pain due to periapical and pulpal disease is considered as the most frequent in dental health settings[2] and it is a warning sign and subjective perception of altered pulpodentinal tissue and periapical tissue. Differentiation between these two influences the proper selection of analgesic drugs. The dental pain can be classified as mild, moderate, and severe according to the anticipated pain intensity. This classification of dental pain intensity

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influences the appropriate selection procedure of analgesic therapy for adequate pain relief.

NSAIDs are the first choice of drug in patients with mild dental pain. NSAIDs can be prescribed in amalgamation with other analgesics like paracetamol or it can be prescribed in over-the-counter doses.[3]

Ibuprofen 200 mg or naproxen 200–225 mg individual dose is the options of drugs from NSAIDs group for the management of mild odontogenic pain. The amalgamation of ibuprofen or naproxen with paracetamol (NAPROSYN P) tablet is found to be the most effective than individual NSAID agents in patients suffering from persistent mild dental pain.

Paracetamol 500–1000 mg is the drug of choice in patients where NSAIDs are contraindicated. Acetyl salicylic acid (ASPIRIN) is not the recommended option of drug for the treatment of dental pain because of its intervention with platelet aggregation. Patients suffering from heart disease should be treated with precautions with aspirin.

NSAIDs can be administered solitary or in amalgamation with aniline derivatives, such as mefenamic acid and meclofenamic acid. NSAID in its pharmacological full doses is the appropriate option of analgesic in patients having moderate dental pain. A weak opioid analgesic can be administered in some cases where NSAIDs combined with paracetamol does not provide an adequate relief.

The discrete dose of naproxen is 500–550 mg and the individual dose of ibuprofen is 400 mg. In the addition of full dose of paracetamol is advised in patients where pain is not controlled successfully. If pain is still present, the supplementation of weak opioid agents in full doses is recommended, that is, codeine 30 mg and hydrocodone 5 mg.[4]

The recommended pharmacological management of patients having severe dental pain is the combinations of strong opioid analgesics with high doses of NSAIDs with or without aniline derivatives. There is a higher probability of adverse drug reactions so these patients should be treated under close supervision of dental doctor.

Hydrocodone 10 mg, oxycodone 5 mg, codeine 60 mg, or tramadol 50–75 mg are the foremost options. Tramadol is not the drug of choice for the management of severe odontogenic pain because of the possibility of its misuse. The amalgamation of full dose opioid agents and NSAIDs is advised in patients having unsatisfactory level of pain control.

Utilization Pattern of Analgesic Use

The studies on consumption of drugs are empirical tools for the evaluation of analgesic usages and for recognizing the considerations of quality refinement of dental pain therapy. NSAIDs are the most desired analgesic drug group followed by acetaminophen. Opioid analgesics are earmarked for higher intensity dental pain. There is an increase in the prescribing of opioid analgesics or their combination with non-opioid analgesics in non-traumatic dental condition-related visits with more severe pain in the emergency departments.[5,6]

Opioids such as hydrocodone (78%), followed by oxycodone (15.4%), propoxyphene (3.5%), and codeine (1.6%) were delineated as the most commonly recommended analgesics after surgical extraction of teeth entailing dental care as per the new published study with enormous cohort of patients. Although, latterly disparate studies outlined a decline by 5.6% in the prescribing of opioids.[7,8] In this context, enormous studies should be done to stave off the opioid abuse and dentists perform a crucial role in this aspect, helping to slash the opioid abuse by vigilant patient education and significant prescribing practice.[9]

Paracetamol and NSAIDs are the best choices in cases of mild-to-moderate acute dental pain. Patients having gastrointestinal diseases or taking blood thinners such as warfarin may be considered at risk for prescribing COX-2 inhibitors. Doctor should prescribe shorter duration of treatment and he/she must be aware to limit the use of maximum recommended doses.[10]

Ibuprofen was found to dominate over other analgesics.[11-14] This also applies to pediatric dentistry, whereby ibuprofen and paracetamol predominate in prescription rates.[15]

Although there are tendentious studies which show that diclofenac or paracetamol may offer improved benefits. Nimesulide followed by diclofenac, ketoprofen, and ibuprofen was the most recommended NSAIDs in patients undergoing thirs molar surgery.

NSAIDs, Opioids, and their Mechanism of Action

Opioids show its effect in the central nervous system (CNS) through its depression while NSAIDs demonstrate its analgesic effects through inhibition of prostaglandin synthesis at the peripheral nerve endings.[16] NSAIDs mechanism of action is through the suppression of prostaglandin and thromboxane (eicosanoids) biosynthesis by impediment of activity of COX-1 discovered by John Vane or COX-2 from Daniel Simmons in reversible or irreversible pattern and dose-dependent manner competition of arachidonic acid.

Newer drugs such as piroxicam, flurbiprofen, diclofenac, naproxen, ibuprofen, etoricoxib, and celecoxib were started based on their COX activity in the past four decades. Their mechanism of action determines on whether they impede COX-1, COX-2, or both. COX-1 and COX-2 are in charge of synthesis of distinct prostaglandins found in pathological situations (COX-2 is more expressed in inflammatory conditions).

Although, this suppression results in the loss of few protective effects of prostaglandins with respect to the gastrointestinal (COX-1), cardiovascular, platelet, and renal function.[17] Taking this into contemplation, COX-1 inhibitors are more vulnerable to cause gastrointestinal bleeding. This can be intercepted by a switch to COX-2 inhibitors. Although, momentary use of the COX-2 inhibitors is advised based on their cardiovascular side effects which occurs due to disparity of PGI2 as antithrombic mediator and as one of the most crucial prostanoid in regulating homeostasis of the cardiovascular system and also TXA2 as prothrombic mediator.[18-20]

Opioid activity is arbitrated through its affinity for μ, κ, δ, and opioid receptor like-1 which are G-protein-coupled opioid receptors acting on GABAergic neurotransmission as agonists, weak agonists, and partial agonists in CNS and throughout the body. The mediated consequence is the dwindling of intracellular cAMP, which helps in modulating the release of substance P, a nociceptive neurotransmitter.[21]

Principles of Dental Pain Management

In adult patients

Dental doctors should give consideration to disease, patient, and to the available pharmacologically and non-pharmacologically effectual treatment modalities for effectual management of dental pain.

There are few researches that describe that premedication with NSAIDs such as ibuprofen and indomethacin remarkably rises the level of alveolar nerve block anesthesia in dental procedures (78 and 62%) compared to placebo (32%).[22]

It is recommended that analgesic drugs should be administered preoperatively to dwindle the post-operative pain and to decrease the need for post-operative analgesic while performing dental operative procedure.

Moreover, there is an obtainable fallacious information that naproxen sodium has a higher analgesic efficacy in contrast with ibuprofen at post-dose interval from 1 to 12 h.[23,24] Para-aminophenol derivative such as paracetamol (acetaminophen) is the most crucial analgesic agent for use in dentistry. Paracetamol can be prescribed individually for the treatment of mild form of dental pain when NSAIDs are contraindicated.

Ibuprofen in doses 200–512 mg versus paracetamol 600–1000 mg provides higher relief in post-operative pain as per the clinical corroboration. The amalgamation of ibuprofen and paracetamol is the most appropriate approach for the treatment of pain. This amalgamation is more effectual than the outcome of individual analgesic when taken at 6 h after dental procedure.

The most common amalgamation of doses of respective analgesics advised in clinical practice are 400 mg for ibuprofen and 1000 mg for paracetamol as per the studies.[25] Opioid and NSAIDs administration is advised for intense pain and when individual NSAID or combination of NSAID and paracetamol is not effective. The effect of this drug amalgamation is superior than doubling the dose of with analgesic prescribed individually.[26]

There are various prospects of amalgamation of non-narcotic and narcotic analgesics, which might be very effectual in dental pain.

Acetaminophen-codeine (300 mg + 30 mg), oxycodone-ibuprofen (5 mg + 400 mg), or hydrocodone-acetaminophen (5 mg + 325 mg or 7.5 mg + 500 mg) are the most widely used combinations for effectual dental pain management.[27]

The main prototype for the management of dental pain is the proper choice of effectual analgesic, at truncated doses with the lowest possibility for side effects.

ELDERLY PATIENTS

Paracetamol is the drug of choice for effectual pain relief in elderly patients. Paracetamol is contraindicated in patients with terminal hepatic insufficiency. Dosage modification is advised in patients with hepatic or renal functional disorders. These patients need close monitoring and NSAIDs are the preferred choice of drugs in these cases.

To decrease the chances of possible side effects of these analgesic drugs, NSAIDs should be administered in its lowest possible doses in short periods of time to elderly patients.

The use of opioid analgesic is advised in patients suffering from severe dental pain. Tramadol in its lowest possible dosage is recommended in these cases. The amalgamation of paracetamol and tramadol or codeine is prescribed to use the opioid analgesic drugs in the lowest doses.

The strongest opioid of choice in elderly cases with intense pain is MORPHINE.

CHILDREN

The progressive pain management approach depends on two main directions, comprehending the interventional pharmacological (incorporating the use of NSAIDs and other analgesics) and non-pharmacological strategy. Non-pharmacological strategy comprises of creating health awareness among children by educating them. Psychological approaches include emancipation of the perception of fear and other behavioral problems in children patients, breathing techniques, hypnosis, transcutaneous electrical nerve stimulation, guided imagery, acupuncture, relaxation, and other procedures for pain reduction.

There are various principles which are followed for the pain management in children patients, contemplating the difference between children and adult pain management. Prevention of pain should be focused which authenticate greater treatment outcomes before painful procedures. This is initiated by concocting the family and the child patient in advance, intending to ease fear and anxiety before procedure and enacting patient-controlled analgesia (PCA). Oral analgesics can be prescribed in cases of major surgical procedures according to the need of the patient.

Multimodal and multiapproach therapy is the cornerstone of pain management in children. These approaches utilize disparate analgesia and non-pharmacological supportive approaches intending to diminish the pain and drug-induced adverse effects. Coalescing non-opioid (NSAIDS, other analgesic agents, local anesthetics, alpha2-adrenergic agonists, and voltage-gated calcium channel alpha-2 delta-proteins) and opioid analgesics and other agents is in lowest possible doses intending to halt the clinical manifestations of drugs side effects.[28]

Analgesic dosages in children patients are formulated on the basis of mg/kg body weight. Intramuscular injections should be avoided in children patients. Pain management in severe cases by infusions, PCA, and other course of constant analgesic disburse is recommended.

The utilization of opioid analgesics is dodged in neonates and premature infants for the management of pain. Whenever there is no other choice left, in that case, opioid analgesics should be administered and monitored closely in intensive care units. Opioids are very vulnerable to cause dependency and depression of cardiorespiratory functions in this group of infants.

Prescribing the NSAIDs, paracetamol is the popular pharmacological pain management. In general, it is suggested to use paracetamol (infant dose is 10–15 mg/kg/dose every 6–8 h and pediatric oral dose 10–15 mg/kg/dose every 4 h), ibuprofen (10 mg/kg/dose every 6 h), and diclofenac (1 mg/kg/tds or 1.5 mg/kg/bd, maximum daily dose is 3 mg/kg). The utilization of naproxen (2 years or older: 5 mg/kg orally twice a day; 12 years or older: 220 mg orally every 8–12 h) is recommended more in inflammatory diseases. The dosages of individual analgesics are abated when it is amalgamated with other analgesics in treatment modalities. Opioids are advised for intense pain management. To enhance the effect of codeine (0.5–1 mg/kg every 4–6 h) (which is a weak opioid analgesic), it is amalgamated with paracetamol more often. The utilization of codeine in children should be closely monitored and should be used only in those cases where benefits exceed the risks as per the alert by FDA.[29]

Tramadol (1–1.5 mg/kg) is the other opioid analgesic for the management of mild-to-severe dental pain in children. The use of morphine (0.2–0.5 mg/kg q4–6 h) is advised for intense pain. Fentanyl, hydromorphone, methadone, and other opioid agents are considered as other substitutes to morphine. The use of regional analgesia such as local anesthetic administration, wound anesthetic infiltration, topical regional analgesia (lignocaine gel), and peripheral nerve block is the other choices to manage dental pain in children patients. Treatment of dental pain in children is intricate and supplemental data are required to revamp the success and safety of pain management.

Oral Analgesics Dosage for Healthy Adults and Children[30]

Drug Recommended Dose (Adult).

Mild-to-moderate Pain

- Acetamenophen 325 mg 2 tab.* q. 4 h #
- Aspirin 325 mg 2 tab.* q. 4 h #
- Ibuprofen 200 mg 1 tab. * q. 4 h#
- Naproxen Sodium 220 mg 1 tab. * q. 6-8 h".

Moderate-to-severe Pain

- Diclofenac potassium 50 mg 1 tab. * t.i.d†
- Ibuprofen 200 mg 2 tab. * q. 4 h# or 3 tab. q. 6 h"
- Ibuprofen 400 mg 1 tab. * q. 4 h#
- Ibuprofen 600 mg 1 tab. * q. 6 h"
- Ketorolac 20 mg 1 tab. * q. 6 h", not to exceed 5 days
- Rofecoxib 50 mg 1 tab. * q.d.¶

In Moderate-to-severe Pain, when NSAIDs are Contraindicated, Opioids are Prescribed

- Acetamenophen 325 mg + Codeine 30 mg 2 cap.ˆ q. 4 h#
- Acetamenophen 650 mg + Hydrocodone 10 mg 1 tab. * q. 4–6 h #

- Acetamenophen 650 mg + Oxycodone 10 mg 1 tab. * q. 4–6 h #
- Acetamenophen 325 mg + Tramadol 37.5 mg 2 tab. * q. 4–6 h #, maximum 8 tab/24 h.

Drug Recommended Dose (Children)

- Acetaminophen 10–15 mg/kg body weight 1 tab. * q. 4–6 h # (Also available in an elixir form)
- Ibuprofen Age 2 - 12–10 mg/kg body weight 1 tab. * q. 6–8 h" (Obtainable in an elixir form also)
- Over age of 12 - 200–400 mg 1 tab. * q. 4 h# (Also available in an elixir form)
  - * - Tablet
  - # - quaque quarta hora (every 4 h)
  - "- quaque sex- octa hora (every 6–8 h)
  - † - ter in die (a thrice-daily dosage)
  - ¶ - quaque die (every day)
  - ˆ - Capsule.

CONCLUSION

Numerous studies have been done to determine the safest analgesic but every medication comes with its benefits and risks. The accuracy of the utilization or administration of NSAIDs is supported by the knowledge and expertise of the dentists.

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Original Article

Evaluation and Correlation of Vision-Related Quality of life with Severity of Glaucoma

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Abstract

Introduction: Glaucoma significantly affects the quality of life (QoL) of a patient. QoL measures are important in understanding the impact of a disease. The aims of the study are to evaluate the vision-related quality of life in patients of primary open-angle glaucoma (POAG) and correlate it with severity of the glaucoma.

Materials and Methods: The study was done on 100 diagnosed cases of POAG and 100 normal subjects. All subjects underwent a comprehensive clinical examination. Visual field testing using Humphrey Field Analyzer was performed to obtain mean deviation, vision-related quality of life was assessed using orally administered glaucoma quality of life-15 (GQoL-15) questionnaire. Chi-square test was used to find association among categorical variables. One-way ANOVA test with *post hoc* Tukey HSD was used to compare mean values among different subgroups. All analyses were done using Social Science Software (SPSS) Program, version 23.0 (IBM).

Results: The mean glaucoma quality of life (GQL) score of glaucoma cases was 23.78 ± 7.072, and for controls, it was 15.19 ± 0.563 ($P < 0.001$). The mean GQL score in early cases was 17.50 ± 2.731, in moderate cases was 21.87 ± 4.529, and in cases with severe glaucoma was 32.7±3.826 ($P < 0.001$).

Conclusion: Patients with glaucoma had significantly poor glaucoma-related quality of life than controls. Patients of primary open-angle glaucoma had reduced quality of life in early stage of disease, with the increasing disease severity, there is corresponding decrease in vision-related quality of life.

Key words: Glaucoma, Glaucoma quality of life-15, Mean deviation

INTRODUCTION

Glaucoma is at the second number for causing irreversible blindness worldwide according to the World Health Organization.[1] Despite advances in therapy, the global burden of glaucoma remains high and will continue to rise. At present, 79.6 million individuals are living with glaucoma (2020) and this number will increase to 111.8 million by year 2040.[2]

Quality of life (QoL) is thus the sum of a range of objectively measurable life conditions experienced by an individual. These may include physical health, personal circumstances (wealth, living conditions, etc.), social relationships, functional activities and pursuits, and wider societal and economic influences.[3]

Loss of vision is the main cause of morbidity relating to glaucoma and it is the main determinant of health-related QoL for glaucoma patients. This can impact driving, walking, venturing from home, reading, seeing at night, adjusting to different levels of illumination, judging distances, and seeing objects coming from the side.[4] As vision decreases, the psychological burden increases, together with a growing fear of blindness, social withdrawal from impaired vision, and depression. Other debilitating medical conditions, psychological and social constraints may influence patient's visual morbidity. All these factors interact in a complex manner and can be reflected in holistic QoL assessment.[5]

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This study was undertaken to evaluate vision-related quality of life in primary angle glaucoma patients (POAG) and its relationship with severity of glaucoma.

MATERIALS AND METHODS

After taking permission from the Institution Ethical Committee, the study was conducted in outpatients visiting Glaucoma Clinic of Regional Institute of Ophthalmology in North India. A total of 200 subjects were enrolled for the study including 100 cases and 100 controls. Written informed consent from all the patients enrolled in the study was taken in their vernacular language, in accordance with the Declaration of Helsinki.

All subjects underwent a complete ophthalmic examination that included assessment of visual acuity (VA), intraocular pressure, gonioscopy, and dilated fundus examination with stereoscopic biomicroscopy of optic nerve head using slit lamp and indirect ophthalmoscopy. Glaucomatous eyes were defined as eyes exhibiting structural glaucomatous changes, such as a vertical cup-disk asymmetry between fellow eye of >0.2, cup-disk ratio >0.6, and neuroretinal rim narrowing, and retinal nerve fiber layer defect with glaucomatous VF loss in corresponding hemifield. Cases were classified into early, moderate, and severe glaucoma, respectively, depending on mean deviation (MD) on Humphrey Field Analyzer (HFA) using Hodapp-Parrish-Anderson criteria in more severely affected eye. Early visual field loss was defined as a mean deviation of ≤−6 decibels (dB), moderate visual field loss was defined as a mean deviation of more than -6 dB but <−12 dB, and severe visual field loss as mean deviation of more −12 dB.

Patients of POAG with 40 years or older and on medical therapy for primary open-angle glaucoma were enrolled as cases. Patients with high myopia (>6 diopters), patients with corneal opacities, patients with secondary causes of glaucoma, and patients with other ocular pathology such as visually significant cataract, diabetic retinopathy, hypertensive retinopathy, and age-related macular degeneration were excluded from the study.

Patients with refractive errors <5 diopters of myopia and hypermetropia or <2 D cylinder of astigmatism, non-visual significant cataract and a best-corrected visual acuity (BCVA) of at least 20/30, normal appearing optic nerve head, normal visual fields, and no family history of glaucoma in a first degree relative were included as controls. Patients with BCVA <20/30; with history of glaucoma, ocular hypertension, and suspicious optic disk; and with other ocular morbidity affecting vision such as visually significant cataract, diabetic retinopathy, hypertensive retinopathy, and age-related macular degeneration were excluded from the control group.

Procedure

Vision-related quality of life was assessed using the glaucoma quality of life-15 (GQOL-15) questionnaire. It consists of list of daily activities with the strongest relationship with visual field loss in glaucoma. Patient is instructed to circle the correct answer, the scale ranging from 1 to 5 where [0] stands for not able to perform any of the activities for non-visual reasons, [1] stands for no difficulty, [2] for a little bit of difficulty, [3] for some difficulty, [4] for quite a lot of difficulty, and [5] for severe difficulty in performing the activity.

The glaucoma quality of life-15 questionnaire: List of daily activities with the strongest relationship with visual field loss in glaucoma.

	None	A little bit	Some	Quite a lot	Severe	Do not perform for Non-visual reasons
Reading newspapers	1	2	3	4	5	0
Walking after dark	1	2	3	4	5	0
Seeing at night	1	2	3	4	5	0
Walking on uneven ground	1	2	3	4	5	0
Adjusting to bright lights	1	2	3	4	5	0
Adjusting to dim lights	1	2	3	4	5	0
Going from light to dark room or vice versa	1	2	3	4	5	0
Tripping over objects	1	2	3	4	5	0
Seeing objects coming from the side	1	2	3	4	5	0
Crossing the road	1	2	3	4	5	0
Walking on steps/ stairs	1	2	3	4	5	0
Bumping into objects	1	2	3	4	5	0
Judging distance of foot to step/curb	1	2	3	4	5	0
Finding dropped objects	1	2	3	4	5	0
Recognizing faces	1	2	3	4	5	0

Total scores of the above-mentioned questionnaire for all patients and controls were compared with each other and statistical analysis was carried out. Higher subscale scores indicate greater difficulty in performing vision-related activities and poorer QoL.

RESULTS

The mean age in cases was 58.77 ± 10.5 years and in controls was 57.84 ± 9.18 years (P = 0.19). There was

predominance of males in our study but no statistical difference was observed between two groups for gender ($P = 0.773$) [Tables 1 and 2].

DISCUSSION

Glaucomatous visual field loss can significantly affect many daily activities, thereby affecting QoL of these patients.[6] Over the past several years, an increased awareness of the effect of glaucoma on the patient's quality of life has developed. This parallels an increased interest throughout ophthalmology in the impact of disease and therapy on QoL.[7]

In our study, on perimetric evaluation, the mean deviation (MD) in cases was 11.12 ± 6.39 dB and in controls was 2.79 ± 0.58 dB. The intergroup difference of mean deviation was found to be statistically significant. Based on the severity of glaucoma, the distribution of cases in our study was 26% with early glaucoma, 46% with moderate glaucoma, and 28% with severe glaucoma. In a study done by Kumar *et al*., the proportion of cases with mild glaucoma was 35.0%, moderate glaucoma was 39.28%, and severe glaucoma was 25.72%.[8]

In our study, patients with glaucoma had significantly poorer glaucoma-related quality of life than controls with the mean glaucoma quality of life (GQL) score in glaucoma cases which was 23.27 ± 5.31 and for controls was 15.19 ± 0.56 ($P < 0.001$). Our results are similar to the study done by Onakoya *et al.* and Dhawan *et al.* who reported the mean GQoL-15 score of 24.07 and 26.00 ± 10.84 in glaucoma subjects and 15.75 and 15.02 ± 0.14 in controls, respectively.[9,10] Our study was also in agreement with studies conducted by Jampel *et al.* and Nah *et al.* who also concluded that the quality of life in patients with glaucoma was compromised as compared to healthy controls.[7,11]

In the study, early glaucoma cases had a mean GQL score of 17.50 ± 2.731, moderate cases had a mean GQL score of 21.87 ± 4.529, and cases with severe glaucoma had a mean GQL score of 32.7±3.826 ($P < 0.001$). The results are summarized in Table 2. Our results are similar to the study done by Goldberg *et al.* and other studies which have also shown that QoL worsen with increase in severity of glaucoma.[10,12-14]

The mean GQL score value obtained in the control group was significantly different from the GQL score of early, moderate, and severe glaucoma. Hence, our study showed that patients with early, moderate, and severe glaucoma exhibited significantly poorer QoL relative to that observed in patients without glaucoma. As the difference between score obtained from early glaucoma cases and control was also significantly statistically, we were able to identify the patients in early stages of glaucoma. Our findings are consistent with the findings of Naveen *et al.* who also found that POAG reduces QoL even in early stages of the disease.[14]

Use of GQL-15 has certain limitations; first, it is subjective; two patients with similar losses of visual ability from glaucoma may rate their QoL differently on a QoL scale; second, it does not include personality and other psychological factors which may influence GQL; and third, it does not have any question regarding antiglaucoma medication; cost and side effects of antiglaucoma drugs may influence GQL score.

Table 1: Demographic and clinical characteristics of study participants

	Glaucoma (*n*=100)	Normal (*n*=100)	*P* value
Age	58.77±10.5	57.84±9.18	0.19
Male/female	61/39	59/41	0.773
Log MAR (BCVA)	0.254±0.235	0.040±0.080	<0.001**
IOP	21.01±10.72	14.66±2.13	<0.001**
VCDR	0.737±0.135	0.356±0.098	<0.001**
MD	13.378±8.446	2.795±0.590	<0.001**
GQL-15 score	23.78±7.072	15.19±0.563	<0.001**

BCVA: Best-corrected visual acuity

Table 2: Distribution of cases and association between vision-related quality of life and severity of glaucoma

Severity	No.	GQOL score		MD	
		Mean	±SD	Mean	±SD
Normal	100	15.19	0.563	2.795	0.589
Glaucoma					
Early	26	17.50	2.731	5.526	0.225
Moderate	46	21.87	4.529	10.374	1.058
Severe	28	32.75	3.826	25.602	5.475
Overall		<0.001**		<0.001**	
WNL versus early		0.001*		<0.001**	
Early versus moderate		<0.001**		<0.001**	
Early versus severe		<0.001**		<0.001**	
Moderate versus severe		<0.001**		<0.001**	

*P<0.05: Significant; **P<0.001: Highly significant

CONCLUSION

Patients of POAG had reduced quality of life in early stage of disease which continued to decrease with increase in severity of the disease. GQol is a useful and simple measure of vision related QoL in patients of POAG. Thus, physician for effectively treating a patient of POAG should not only aim at regulating quantitative measures such as IOP, visual field, and optic disk changes but also assess his qualitative and subjective measures like QoL. This would make patients more compliant and increase their level of

satisfaction which would allow physician and patient to share common realistic goals, leading to better treatment outcomes.

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Original Article

A Comparative Study of Lignocaine and Two Different Doses of Dexmedetomidine as an Adjunct to Lignocaine in Intravenous Regional Anesthesia for Upper Limb Orthopedic Surgeries – An Observational Study

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Abstract

Introduction: Intravenous regional anesthesia is a simple and cost reliable technique for providing anesthesia for extremity surgery. Dexmedetomidine which is about 8 times more potent than clonidine has been used in bier's block and was shown to improve the quality of anesthesia, tourniquet pain, and post-operative analgesic requirement.

Material and Methods: This study included 90 patients of ASA Class I and II of either sex aged between 20 and 60 years scheduled for various upper limb surgeries. Patients were divided into three groups 30 each. Group A received 40 ml of 0.5% lignocaine (preservative free). Group B received 0.5% lignocaine with 0.5 mcg/kg of dexmedetomidine to make a total volume of 40 ml. Group C received 0.5% lignocaine with 1 mcg/kg of dexmedetomidine to make a total volume of 40 ml.

Results: Sensory and motor block onset times were significantly shorter in Group B as compared to Group A and significantly shorter in Group C as compared to Group B. Recovery time of sensory and motor block was significantly prolonged in Groups B and C compared to Group A. Both the Groups B and C showed comparable low level of sedation. VAS score of Group C was statistically lower than VAS score of Group B and VAS score of Group B was statistically lower than Group A. Total amount of analgesic required was significantly lower in Group B than Group A and least in Group C. Quality of blockade in majority of cases of Groups B and C was excellent.

Conclusion: Addition of dexmedetomidine to lidocaine for IVRA shortens the onset times for both sensory and motor blockade, improves the quality of the anesthesia, and extends post-operative analgesia time. This study also demonstrated that addition of 1 μg/kg dexmedetomidine to lignocaine for IVRA showed significantly better improvement in the quality of anesthesia and post-operative analgesia in comparison to 0.5 μg/kg dexmedetomidine, without causing any significant side effects.

Key words: Biers block, Dexmedetomidine, Lignocaine

INTRODUCTION

Regional anesthesia was first used for surgical procedures at the turn of the 20th century. These central blocks were widely used worldwide until reports of permanent neurological injury appeared, most prominently in the United Kingdom. However, a large scale epidemiological study conducted in 1950s indicated that complications were rare when these blocks were performed skillfully, with attention to asepsis and newer, safer local anesthetics were used. Today, neuraxial blocks are widely used for labor analgesia, caesarian section, orthopedic procedures perioperative analgesia, and chronic pain management.[1] The earliest agent injected into the isolated vascular space was procaine. Lidocaine remains the standard local anesthetic agent for surgical procedures in North America[2]

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and prilocaine is used widely in Europe.[3] Intravenous regional anesthesia is an effective method of providing anesthesia for procedures expected to last <1 h and is widely used for minor operations in the extremities.[4] The technique includes applying a pneumatic tourniquet and injecting a local anesthetic distal to the tourniquet for delivering the local anesthetic directly to the core of the major nerves through the vasa nervosa. Intravenous regional anesthesia is easy to administer, reliable, and cost effective. Major nerve blocks such as brachial plexus block and femoral-sciatic block require technical expertise. Conversely, the administration of intravenous regional anesthesia requires only the skill necessary to perform a venipuncture.[5] It is quite safe for operations on the limbs especially in poor risk patient, in emergency situations such as full stomach, multiple facial injuries, and uninvestigated systemic problems or when general anesthesia might be hazardous. There is very little anesthetic hangover so that patient can go home and avoid hospitalization. The major disadvantages of this technique are occurrence of tourniquet pain, potential for local anesthetic toxicity, and minimal residual post-operative analgesia.[6] Different additives have been combined with local anesthetics[4] such as opioids, tramadol, NSAIDS, muscle relaxant, ketamine, and clonidine, to prolong post-deflation analgesia and reduce tourniquet pain, but there use is limited because of their side effects (e.g., mivacurium, which showed signs of local anesthetic toxicity,[7] and opioid) or limited efficacy (e.g., acetylsalicylate).[8]

The addition of clonidine to lignocaine during the Bier's block has shown to improve tourniquet pain tolerance but did not influence the speed and quality of bier's block. Its effect on prolonging post-operative analgesia is controversial. Reported side effects were post-deflation sedation and hypotension.[9,10] Dexmedetomidine, a potent alpha-2 adrenoceptor agonist, is about 8 times more potent than clonidine toward the alpha-2 adrenoceptors.[11] In addition to sympatholytic effects, dexmedetomidine has antihypertensive, anxiolytic, sedative/hypnotic, and analgesic effects.[12,13] It has been used clinically as an adjunct to anesthesia, as an analgesic agent, and is useful in painful surgical procedures and intensive care unit sedation.[14,15]

The present study was done to compare lignocaine and two different doses of dexmedetomidine (0.5 μg/kg and 1 μg/kg) as an adjunct to lignocaine in intravenous regional anesthesia for upper limb surgeries.

MATERIALS AND METHODS

The present study was undertaken on 90 patients in the Bone and Joints Hospital, Barzulla, an associated hospital of Government Medical College, Srinagar, during routine and emergency hours for various orthopedic surgical procedures involving upper extremities. An informed written consent was taken from all the patients in all the three groups after the approval of the Institutional and Ethics Committee in patients of ASA Class I and Class II of either gender aged between 20 and 60 years scheduled for various orthopedic procedures involving upper extremities. A detailed history, thorough physical examination, routine investigation, and any special investigation if required were done for the study.

All the patients observed were divided into three groups (30 patients each). Group A – received 40 ml of 0.5% lignocaine (preservative free). Group B – received 0.5% lignocaine with 0.5 μg/kg of dexmedetomidine to make a total volume of 40 ml. Group C – received 0.5% lignocaine with 1 μg/kg of dexmedetomidine to make a total volume of 40 ml.

A padded double cuff tourniquet was tested and positioned around the arm. A 20/22G intravenous cannula was placed for injecting drug in a peripheral vein distal to the operative site, preferably over the dorsum of the hand and secured in position. Now, the limb was elevated for exsanguination to 90° for 3 min along with an application of sterile bandage and it was followed by inflation of proximal tourniquet cuff to 250 mmHg. This criterion was fixed for all cases of the study. Then, a dose of 40 ml drug was given in each group slowly, Group A received 40 ml of 0.5% lignocaine, Group B received dexmedetomidine 0.5 μg/kg as adjuvant to 0.5% lignocaine, and Group C received 1 μg/kg dexmedetomidine as adjuvant to 0.5% lignocaine. The patients were asked frequently and were monitored continuously for any discomfort during the surgery. Throughout the procedure, tourniquet pressure was monitored. The hemodynamic parameters (HR, NIBP, RR, and SpO_2), visual analog scale (VAS), and Ramsay sedation scale were recorded every 10 min throughout the procedure. Vital parameters (heart rate, non-invasive blood pressure, and respiratory rate), sedation score, and visual analog scale (VAS) were recorded at 30 min after deflation of tourniquet and at 2 h, 4 h, 6 h, and 24 h after tourniquet deflation. Postoperatively, the pain score was recorded using visual analog pain scale (VAS), between 0 and 10 (0 – no pain and 10 – most severe pain). Diclofenac was given IM as rescue analgesia when VAS value was >4. Duration of post-operative analgesia was noted from deflation of tourniquet to VAS score of 4.

Statistical Methods

The recorded data were compiled and entered in a spreadsheet (Microsoft Excel) and then exported to data editor of SPSS Version 20.0 (SPSS Inc., Chicago, Illinois,

Table 1: Gender distribution of study patients

Gender	Group A		Group B		Group C	
	No.	%age	No.	%age	No.	%age
Male	14	46.7	11	36.7	13	43.3
Female	16	53.3	19	63.3	17	56.7
Total	30	100	30	100	30	100

Chi-square=0.638; *P*=0.727 (not significant)

Table 2: Age, weight, and duration of surgery, among various groups

	n	Mean	SD	Range	*P*-value
Age (years)					
Group A	30	40.4	11.48	20–59	0.961
Group B	30	39.6	13.13	20–60	
Group C	30	39.6	12.57	21–59	
Weight (kg)					
Group A	30	61.8	6.94	51–74	0.758
Group B	30	60.7	7.87	48–74	
Group C	30	62.1	7.98	48–75	
Duration of surgery (min)					
Group A	30	30	49.8	5.52	0.722
Group B	30	30	49.5	6.02	
Group C	30	30	50.6	5.30	

USA). Continuous variables were summarized in the form of means and standard deviations and categorical variables were expressed as frequencies and percentages. Graphically, the data were presented by bar and lie diagrams.

RESULTS

The present observational study was conducted at Bone and Joints Hospital, Barzulla, an associated hospital of Government Medical College, Srinagar, over a period of 1½ years. Ninety (90) patients of ASA Class I and II of either sexes, between 20 and 60 years of age were observed and divided into three groups (30 patients each). Group A – received 40 ml, 0.5% lignocaine (preservative free). Group B – received 0.5% lignocaine with dexmedetomidine 0.5 μg/kg to make final volume 40 ml. Group C – received 0.5% lignocaine (preservative free) with dexmedetomidine 1 μg/kg to make final volume 40 ml. The parameters studied were onset of sensory and motor block, recovery of sensory and motor block, quality of block, visual analog scale (VAS), rescue analgesia, hemodynamic parameters, and any adverse effects. There were no significant differences in age, sex, weight, duration of surgery, and tourniquet time. The mean onset of sensory and motor blockade in Group A was 5.7 ± 0.757 and 10.8 ± 0.741 min, Group B was 3.7 ± 0.726 and 8.1 ± 0.686 min, and Group C was 1.4 ± 0.453 and 3.9 ± 0.460 min, respectively. Difference in mean onset of sensory and motor block between Group A and between Group B and C was statistically highly significant ($P < 0.001$).

Table 3: Comparison based on tourniquet duration among various groups

	Mean	SD	Comparison	*P*-value
Tourniquet duration (min)				
Group A	51.17	3.19	A vs. B	0.286
Group B	52.10	3.16	B vs. C	0.176
Group C	53.17	2.93	A vs. C	0.052
Onset of sensory block (min)				
Group A	5.7	0.757	A vs. B	<0.001*
Group B	3.7	0.726	B vs. C	<0.001*
Group C	1.4	0.453	A vs. C	<0.001*
Onset of motor block (min)				
Group A	10.8	0.741	A vs. B	<0.001*
Group B	8.1	0.686	B vs. C	<0.001*
Group C	3.9	0.460	A vs. C	<0.001*
Recovery time of sensory block (min)				
Group A	4.1	0.568	A vs. B	<0.001*
Group B	7.3	0.626	B vs. C	<0.001*
Group C	9.7	0.551	A vs. C	<0.001*
Recovery time of motor block (min)				
Group A	5.4	0.592	A vs. B	<0.001*
Group B	8.6	0.623	B vs. C	<0.001*
Group C	10.9	0.574	A vs. C	<0.001*
Time request for first analgesic (min)				
Group A	45.7	11.15	A vs. B	<0.001*
Group B	181.9	17.12	B vs. C	<0.001*
Group C	327.2	24.71	A vs. C	<0.001*
Total analgesic consumption in 24 h				
Group A	115	51.12	A vs. B	<0.001*
Group B	52.5	44.69	B vs. C	0.012*
Group C	22.5	34.96	A vs. C	<0.001*

Table 4: Quality of block among various groups

Quality of block	Group A		Group B		Group C	
	No.	%age	No.	%age	No.	%age
Poor	1	Xc 83.3	0	0.0	0	0.0
Fair	4	13.3	1	3.3	0	0.0
Good	5	16.7	2	6.7	1	3.3
Excellent	20	66.7	27	90.0	29	96.7
Total	30	100	30	100	30	100

Chi-square=12.21; *P*=0.031*

Table 5: Complications among various groups

Complications	Group A		Group B		Group C		*P*-value
	No.	%age	No.	%age	No.	%age	
Dry mouth	0	0.0	2	6.7	3	10.0	0.227
Bradycardia	0	0.0	1	3.3	2	6.7	0.355
Tinnitus	0	0.0	0	0.0	1	3.3	0.364
Perioral numbness	0	0.0	0	0.0	1	3.3	0.364

In our study, the mean recovery of sensory and motor blockade in Group A was 4.1 ± 0.568 and 5.4 ± 0.592 min, Group B was 7.3 ± 0.626 and 8.6 ± 0.623 min, and Group C was 9.7 ± 0.551 and 10.9 ± 0.574 min,

respectively. Difference in mean recovery of sensory and motor block between Group A, Group B, and Group C was statistically highly significant ($P < 0.001$). Quality of blockade was excellent in 66.7% cases in Group A, 90% of cases in Group B, and 96.7% of cases in Group C. It was good in 16.7% of cases in Group A, 6.7% of cases in Group B, and 3.3% of cases in Group C. The quality of block was not found poor in any case of Group B and Group C. In our study, the visual analog scale (VAS) was lowest and statistically significant in patients who received dexmedetomidine as adjuvant in IVRA as compared to the patients received lignocaine only. Comparing the VAS among the two groups who received dexmedetomidine in IVRA in our study, the VAS was lowest and statistically significant in group who received 1 μg/kg dexmedetomidine as compared to group received 0.5 μg/kg of dexmedetomdine in IVRA. Total analgesic consumption (diclofenac) in 24 hours postoperatively was 115 ± 51.12 mg in Group A, 52.5 ± 44.69 mg in Group B, and 22.5 ± 34.96 mg in Group C, respectively. Difference in analgesic consumption in 24 h was statistically significant between the three groups. There were only few incidence of side effects which we encountered in our study like, dryness of mouth which was observed in 2 (6.7%) cases in Group B and 3 (10%) cases in Group C ($P > 0.227$), bradycardia was noted in 1 (3.3%) in Group B and 2 (6.7%) in Group C ($P > 0.355$), and tinnitus in 1 (3.3%) ($P > 0.364$) and perioral numbness were noted in 1 (3.3%) ($P > 0.364$) case only in Group C. All the results regarding the adverse effects were statistically insignificant among the groups. Hemodynamically, all patients were stable during both intraoperative and post-operative period, and statistically insignificant differences were found regarding systolic blood pressure, diastolic blood pressure, mean arterial pressure, and mean pulse and respiratory rate [Tables 1-5].

DISCUSSION

In our study, the mean onset of sensory and motor blockade in Group A was 5.7 ± 0.757 and 10.8 ± 0.741 min, Group B was 3.7 ± 0.726 and 8.1 ± 0.686 minutes, and Group C was 1.4 ± 0.453 and 3.9 ± 0.460 min, respectively. Difference in mean onset of sensory and motor block between Group A and between Groups B and C was statistically highly significant ($P < 0.001$). Memis *et al.* (2004)[16] in his study also found that the addition of dexmedetomidine to lignocaine for IVRA leads to significant decrease in sensory and motor blocks onset time compared with control group. Gupta *et al.* (2014)[17] in their study also found that adding 1 μg/kg of dexmedetomidine to lignocaine for IVRA leads significant decrease in sensory and motor block onset time as compared to adding 0.5 μg/kg of dexmedetomidine. Abdelkader *et al.*[18] in their study also found that addition of dexmedetomidine to lignocaine for IVRA leads to significant decrease in sensory and motor block onset times. Study also correlates with Bhaumik *et al.* (2016)[19] who in their study also found that adding dexmedetomidine to lignocaine as an adjuvant in intravenous regional anesthesia significantly shortens the onset of sensory and motor block as compared to lignocaine alone. Our study is also in agreement with the study of Jewliker and Suryawanshi (2017)[20] who also concluded that addition of dexmedetomidine to lignocaine provides intravenous regional anesthesia with quicker onset of sensory and motor block.

In our study, the mean recovery of sensory and motor blockade in Group A was 4.1 ± 0.568 and 5.4 ± 0.592 min, Group B was 7.3 ± 0.626 and 8.6 ± 0.623 min, and Group C was 9.7 ± 0.551 and 10.9 ± 0.547 min, respectively. Difference in mean recovery of sensory and motor block between Group A and between Groups B and C was statistically highly significant ($P < 0.001$). Jewliker and Suryawanshi (2017)[20] in their study also concluded that addition of dexmedetomidine as an adjuvant to lignocaine in IVRA prolongs the recovery time of sensory and motor block as compared to lignocaine alone. Bhaumik *et al.* (2016)[19] also showed prolonged regression of sensory and motor block when dexmedetomidine was used as adjuvant to lignocaine in IVRA. Our study results were also in agreement with the results of Abdelkader *et al.* (2015)[18] who found that adding 0.5 μg/kg of dexmedetomidine to lignocaine prolonged the recovery time of sensory and motor block in the group in which dexmedetomidine was used as adjuvant as compared to group in which only lignocaine was used. Another study done by El–Shalakany and Salah[21] also reported prolonged regression of sensory and motor block in group having 0.5 μg/kg of dexmedetomidine as an additive in comparison to group in which only lignocaine was used. Our study results are also in agreement with those of Memis *et al.*[16] who found prolonged recovery of sensory and motor block in dexmedetomidine group in IVRA block.

The mean duration of post-operative analgesia in our study was 45.7 ± 11.15 min in Group A, 181.9 ± 17.12 min in Group B, and 327.2 ± 24.71 min in Group C. Duration of analgesia was significantly longer in Group B than Group A which is statistically highly significant ($P < 0.001$) and also in Group C than Group B ($P < 0.001$). This result correlates well with the study conducted by Memis *et al.* (2004)[16] and Esmaoglu *et al.* (2005),[22] they found significantly prolonged duration of analgesia with dexmedetomidine group when compared with control group. Gupta *et al.* (2014)[17] also found prolonged duration of analgesia in group containing 1 μg/kg of dexmedetomidine as an additive when compared with group containing 0.5 μg/kg

of dexmedetomidine as additive. Similar results were found in study conducted by Abdalkader *et al.*[18] in which they found that addition of dexmedetomidine decreased postoperative analgesic requirements. Prolonged duration of postoperative analgesia was also confirmed by Bhaumik *et al.*[19] in their study group in which dexmedetomidine was used as an adjuvant to lignocaine in IVRA as compared to study group in which only lignocaine was used. Our study results are also in agreement with that of Jewliker and Suryawanshi[20] who also found prolonged postoperative analgesia in the group in which dexmedetomidine was used as an adjuvant.

In our study, the visual analog scale (VAS) was lowest and statistically significant in patients who received dexmedetomidine as adjuvant in IVRA as compared to the patients received lignocaine only. Comparing the VAS among the two groups which received dexmedetomidine in IVRA in our study, the VAS was lowest and statistically significant in group that received 1 μg/kg dexmedetomidine as compared to group that received 0.5 μg/kg dexmedetomidine in IVRA. Total analgesic consumption of diclofenac in 24 h postoperatively was 115 ± 51.12 mg in Group A, 52.5 ± 44.69 mg in Group B and 22.5+34.96 mg in Group C respectively. Difference in analgesic consumption in 24 h was statistically significant between Group A, Group B- and Group C ($P < 0.001$). Analgesic consumption was maximum in Group A and least consumption was seen in Group C. Bhaumik *et al.* (2016) [19] in their study of bier's block for upper limb surgery concluded that the patients who received dexmedetomidine as adjuvant in bier's block showed prolonged post-operative analgesia and lower requirement of rescue analgesia in post-operative period. Our study also correlates with the study conducted by El-Shalakany and Salah (2015)[21] who also found that low total analgesic was consumed in 24 h postoperatively in group containing 0.5 μg/kg of dexmedetomidine with lignocaine as compared to group containing only lignocaine. Abdalkader *et al.* (2015)[18] in their study also found that adding dexmedetomidine to lignocaine provided satisfactory intraoperative analgesia, lower VAS score, extended post-operative analgesia, and reduced the amount of post-operative analgesic.

Quality of blockade was excellent in 66.7% cases in Group A, 90% of cases in Group B, and 96.7% of cases in Group C. It was good in 16.7% of cases in Group A, 6.7% of cases in Group B, and 3.3% of cases in Group C. No patient showed poor quality of block in Group B and Group C. Memis *et al.* (2004)[16] and Esmaoglu *et al.* (2005)[22] also found statistically significant and excellent quality of blockade in most patients receiving dexmedetomidine in IVRA block. Gupta *et al.* (2014)[17] also showed better quality of block in the two groups containing 0.5 μg/kg and 1 μg/kg of dexmedetomidine. Bhaumik *et al.*[19] in their study of bier's block for upper limb surgery, also reported improved quality of intraoperative anesthesia in patients who received dexmedetomidine as adjuvant to lignocaine in bier's block as compared to patients who received lignocaine only in bier's block. Our study results also correlate with that of Jewliker and Suryawanshi (2017)[20] who in their study also found improved quality of anesthesia in patients who received dexmedetomidine as an adjuvant to lignocaine as compared to patients who received lignocaine only in bier's block.

The baseline pulse rate was 81.70, 79.83 and 80.70 per minute in A, B, and C, respectively. Comparing the mean baseline pulse rate in the subjects of all the three groups during the surgery, there was no significant difference between the groups ($P > 0.05$). The baseline systolic blood pressure was 124.07 ± 9.262, 122.67 ± 9.345, and 124.33 ± 9.517 per mm of Hg in Groups A, B, and C, respectively. The mean baseline systolic blood pressure was comparable in all the three groups ($P > 0.05$). Similarly, no statistically significant results were found on comparing the mean systolic blood pressure, during both intraoperative and post-operative period at different time intervals between the three groups. The baseline diastolic blood pressure was 79.30 ± 6.566, 76.97 ± 8.036, and 79.23 ± 7.546 mm Hg in Groups A, B, and C, respectively. On comparing the mean diastolic blood pressure in subjects of all the three groups at baseline and during the procedure, we found no significant difference between the groups ($P > 0.05$). On comparing the mean respiratory rate in subjects of all the three groups at baseline and during the procedure, we found no significant difference between the groups ($P > 0.05$). On comparing the mean SpO_2 in subjects of all the three groups at baseline and during the procedure, we found no significant difference between the groups ($P > 0.05$).

Kavlas and Karande (2015)[23] also found that addition of dexmedetomidine to lignocaine did not cause any significant difference in the pulse rate between the groups. Furthermore, no baseline or intraoperative difference was found between the groups on the basis of systolic or diastolic blood pressure, respiratory rate, or SpO_2. Gupta *et al.* (2014)[17] in their study also found that changes in pulse rate, blood pressure, and respiratory rate were not significant between the groups in which 0.5 μg/kg and 1 μg/kg of dexmedetomidine were added as adjuvant. Abdalkader *et al.*[18] in their study also found that mean arterial pressure, heart rate, and SpO_2 values at any intraoperative and postoperative period were comparable, with no statistically significant difference between the group having dexmedetomidine as additive and the group which did not had any additive. Similar study results were

reported by Bhaumik *et al.*[19] who also found statistically insignificant differences in hemodynamic parameters between the groups.

There were only few incidence of side effects encountered in our study like, dryness of mouth which was observed in 2 (6.7%) cases in Group B and 3 (10%) cases in Group C ($P = 0.227$), bradycardia was noted in 1 (3.3%) in Group B and 2 (6.7%) in Group C ($P = 0.355$), and tinnitus in 1 (3.3%) ($P = 0.364$) and perioral numbness were noted in 1 (3.3%) ($P = 0.364$) cases only in Group C. All the results were statistically non-significant among the groups. Similar results were found in a study by Gupta *et al.* (2014)[17] while comparing 0.5 μg/kg of dexmedetomidine with 1 μg/kg of dexmedetomidine as an additive to lignocaine. Our study also correlate with the study of Abdelkadera *et al.*[18] who reported statistically insignificant adverse effects in patients received dexmedetomidine in IVRA as adjuvant. Bhaumik *et al.*[19] in their study also reported statistically insignificant rate of complications in the group receiving dexmedetomine as an adjuvant. Our study results also correlate with that of Jewliker and Suryawanshi[20] who also found similar results in their study.

CONCLUSION

The addition of dexmedetomidine to lidocaine for IVRA shortens the onset times for both sensory and motor blockade, improves the quality of the anesthesia, and extends post-operative analgesia time. This study also demonstrated that the addition of 1 μg/kg dexmedetomidine to lignocaine for IVRA showed significantly better improvement in the quality of anesthesia and post-operative analgesia in comparison to 0.5 μg/kg dexmedetomidine, without causing any significant side effects.

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Original Article

Association of Displaced Midshaft Clavicle Fractures Treated with Intramedullary Titanium Elastic Nail System and Its Outcome

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Abstract

Introduction: Fractures of the clavicle, which primarily occur in young males, constitute 2.6–4% of all fractures in adults. A male dominance of approximately 70% has been reported. The most frequent injury mechanism is a direct fall on the shoulder. Fractures are often sustained during sports activities or traffic accidents. The majority (69–82%) of fractures occur in the midshaft of the clavicle followed by 12–26% in the lateral part and 2–6% in the medial part. Advantages of TENS over plate fixation include shorter operative time and lesser chance of post-operative infection.

Materials and Methods: The study was conducted in the Bokaro General Hospital including inpatient and outpatient departments' COM and JNM Hospital, from 1½ years. Twenty-five patients were taken and divided in two groups, 20 patients in excellent outcome group, and five patients in good outcome group.

Results: In our study, 2 (10.0%) patients had FFH injury, 2 (10.0%) patients had FOOSH injury, and 16 (80.0%) patients had RTA injury. In good outcome, 3 (60.0%) patients had FOOSH injury and 2 (40.0%) patients had RTA-related injury. This was statistically significant (P = 0.0410).

Conclusion: Excellent outcome was more in male but good outcome was more in female which was statistically significant. Time for shoulder movements union in week was higher in excellent outcome patient compared to good outcome patient though it was not significantly associated with outcome. Abduction, external rotation, and internal rotation were significantly higher in excellent outcome patient compared to good outcome patient. We found that Constant score was higher in excellent outcome patient compared to good outcome patient. We concluded that functional outcome of displaced midshaft clavicle fractures was treated with intramedullary titanium elastic nail system.

Key words: Clavicle fracture, Intramedullary nailing, Midshaft fractures, Titanium elastic nail

INTRODUCTION

Fractures of the clavicle, which primarily occur in young males, constitute 2.6–4% of all fractures in adults. A male dominance of approximately 70% has been reported. The most frequent injury mechanism is a direct fall on the shoulder. Fractures are often sustained during sports activities or traffic accidents. The majority (69–82%) of fractures occur in the midshaft of the clavicle followed by 12–26% in the lateral part and 2–6% in the medial part.[1]

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The clavicle is easily fractured because of its subcutaneous, relatively anterior location, and frequent exposure to transmitted forces. The middle third, or midshaft, is the thinnest, least medullous area of the clavicle, and thus, the most easily fractured; the lack of muscular and ligamentous support makes it vulnerable to injury.[2] The muscle attachments often cause a dislocation of the major fragments in clavicle fractures and a shortening of the clavicle, particularly in midshaft fractures.[2] This can be anatomically explained by the fact that the medial and lateral parts of the clavicle are firmly secured by strong ligaments and muscles, whereas the middle part of the clavicle lacks any strong attachments and thus is more

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vulnerable to trauma. The muscle attachments often cause a dislocation of the major fragments in clavicle fractures and a shortening of the clavicle, particularly in midshaft fractures.[3]

Initially, the aim of treatment was union of fracture in whatsoever position fracture unites. Many methods of conservative treatment, namely, triangular sling, cuff and collar sling, three sling method, figure of eight bandage, figure of eight POP shoulder spica, clavicular brace, arm shoulder pouch, and many others have been described from time to time.[4] All these methods did not involve the reduction of fracture or unable to hold the fracture reduced hence the end results were malunion/nonunion in various cases. Malunion resulted in shortening, deformation, disfigurement, and poor cosmoses shortening (reduced distance between sternoclavicular joint to the shoulder joint) resulted in biomechanical disadvantage, persistence of pain, limitations of functions, and reduction of strength in upper limb in some of these cases.[4]

The majority of recent data suggests that operative treatment may be more appropriate as it improves functional outcome and reduces the risk of complications such as non-union and malunion. This is particularly evident in midshaft fractures. Displaced midshaft fractures were the most common type of clavicle fracture as well as the most frequently operated type of fracture.[1]

There are various surgical methods available for treating displaced midshaft clavicle fracture including TENS and PLATING. The study found that patients treated with TENS showed excellent outcome in 84% of cases while 60% in plating group for displaces midshaft clavicle fracture. Patients in TENS group better in terms of Constant and Murley score and DASH score than treated with plate.[5-7] The study also shows that intramedullary nailing and plate fixation have same long-term functional outcomes and treatment failure, but plate fixation leading to significant greater risks of adverse events not requiring surgery such as infection. Advantages of TENS over plate fixation include shorter operative time and lesser chance of post-operative infection.[8] Clavicle fractures are most common injuries in young and active individuals, especially those who participate in sports where high-speed falls (e.g., bicycling and motorcycles) or violent collisions (e.g., football and hockey) are frequent. In contrast, in children and elderly, they are related to falls, and they account for approximately 2.6% of all fractures. The most common site of fracture is a middle-third shaft; it accounts for 80% of all clavicle fractures. Older studies suggested that a fracture of the shaft of the clavicle, even when significantly displaced, was a mostly benign injury with an inherently good prognosis when treated nonoperatively.

- This study is aimed to assess the functional outcome of intramedullary titanium elastic nail system for displaced clavicle fracture.

MATERIALS AND METHODS

Study Population

The study was conducted in COM and JNM Hospital including inpatient and outpatient departments' COM and JNM Hospital.

Study Design

This was an analytical study.

Study Duration

The study duration was 1½ years.

Study Group

Twenty-five patients were taken and divided into two groups. Excellent outcome: 20 Patients. Good outcome: Five patients.

Inclusion Criteria

The following criteria were included in the study:

- All skeletally mature patients.
- All the displaced diaphyseal non commented/simple commination clavicle fractures (>2 cm displacement) – AO B1 and B2 fractures.
- Fractures with shortening of over 20 mm
- Fractures within 1 week

Exclusion Criteria

The following criteria were excluded from the study:

- Fractures with marked comminution.
- Brachial plexus injuries
- Paediatric fractures
- Pathological fractures
- Open fractures congenital anomaly or bone disease.
- Any medical contraindication for surgery.

RESULTS AND DISCUSSION

A total of 25 patients were present in this study.

In our study, 10 (40.0%) patients were 21–30 years old, 6 (24.0%) patients were 31–40 years old, 7 (28.0%) patients were 41–50 years old, and 2 (8.0%) patients were >51 years old. The mean age (mean ± SD.) of patients was 34.7600 ± 10.0635 years. In this study, male population [17 (68.0%)] was higher than the female population [8 (32.0%)].

We found that 2 (8.0%) patients had FFH injury, 5 (20.0%) patients had FOOSH injury, and 18 (72.0%) patients had

Table 1: Parameters

Outcome	Excellent	Good	Total	Chi-square value	*P*-value
Mode of injury					
FFH	2	0	2	6.3889	0.0410
Row %	100.0	0.0	100.0		
Col %	10.0	0.0	8.0		
FOOSH	2	3	5		
Row %	40.0	60.0	100.0		
Col %	10.0	60.0	20.0		
RTA	16	2	18		
Row %	88.9	11.1	100.0		
Col %	80.0	40.0	72.0		
Total	20	5	25		
Row %	80.0	20.0	100.0		
Col %	100.0	100.0	100.0		
Limb involved					
Left	8	2	10	0.0000	1.0000
Row %	80.0	20.0	100.0		
Col %	40.0	40.0	40.0		
Right	12	3	15		
Row %	80.0	20.0	100.0		
Col %	60.0	60.0	60.0		
Total	20	5	25		
Row %	80.0	20.0	100.0		
Col %	100.0	100.0	100.0		
AO classification					
B1	11	5	16	3.5156	0.0607
Row %	68.8	31.3	100.0		
Col %	55.0	100.0	64.0		
B2	9	0	9		
Row %	100.0	0.0	100.0		
Col %	45.0	0.0	36.0		
Total	20	5	25		
Row %	80.0	20.0	100.0		
Col %	100.0	100.0	100.0		
Associated injuries					
Bb Leg	1	0	1	8523	0.6530
Row %	100.0	0.0	100.0		
Col %	5.0	0.0	4.0		
I/L scapula spine	2	0	2		
Row %	100.0	0.0	100.0		
Col %	10.0	0.0	8.0		
No	17	5	22		
Row %	77.3	22.7	100.0		
Col %	85.0	100.0	88.0		
Total	20	5	25		
Row %	80.0	20.0	100.0		
Col %	100.0	100.0	100.0		

RTA injury. Ten (40.0%) patients had left limb involvement and 15 (60.0%) patients had right limb involvement. Sixteen (64.0%) patients had B1 and 9 (36.0%) patients had B2 in AO classification.

It was found that 1 (4.0%) patient had Bb leg injuries and 2 (8.0%) patients had I/L scapula spine in associated injuries. Twenty (80.0%) patients were excellent outcome and 5 (20.0%) patients were good outcome.

Our study showed that the mean days before surgery (mean ± SD) of patients were 3.5600 ± 1.3565 days. The mean follow-up in months (mean ± SD) of patients was 9.1200 ± 2.3861. The mean time for shoulder movements union in week (mean ± SD) of patients were 8.5200 ± 2.0841. The mean flexion (mean ± SD) of patients was 163.6000± 10.4602. The mean abduction (mean ± SD) of patients was 164.2000 ± 12.0485. The mean external rotation (mean ± SD) of patients was 71.2000 ± 6.5000. The mean internal rotation (mean ± SD) of patients was 73.0000± 5.4006 and the mean Constant score (mean ± SD) of patients was 88.9200 ± 4.1324.

It was found that in excellent outcome, 9 (45.0%) patients were 21–30 years old, 5 (25.0%) patients were 31–40 years old, 4 (20.0%) patients were 41–50 years old, and 2 (10.0%) patients were >51 years old. In good outcome, 1 (20.0%) patient was 21–30 years old, 1 (20.0%) patient was 31–40 years old, and 3 (60.0%) patients were 41–50 years old and this was not statistically significant ($P = 0.3270$).

We found that in excellent outcome, 4 (20.0%) patients were female and 16 (80.0%) patients were male. In good outcome, 4 (80.0%) patients were female and 1 (20.0%) patient was male. This was statistically significant ($P = 0.0100$).

We observed that in excellent outcome, 2 (10.0%) patients had FFH injury, 2 (10.0%) patients had FOOSH injury, and 16 (80.0%) patients had RTA injury. In good outcome, 3 (60.0%) patients had FOOSH injury and 2 (40.0%) patients had RTA-related injury. This was statistically significant ($P = 0.0410$).

It was found that in excellent outcome, 8 (40.0%) patients had left limb involvement and 12 (60.0%) patients had right limb involvement. In good outcome, 2 (40.0%) patients had left limb involvement and 3 (60.0%) patients had right limb involvement which was not statistically significant ($P = 1.0000$).

Our study showed that in excellent outcome, 11 (55.0%) patients had B1 and 9 (45.0%) patients had B2 in AO classification. In good outcome, all patients [5 (100.0%)] had B1 in AO classification. This was not statistically significant ($P = 0.0607$).

The present study showed that in excellent outcome, 1 (5.0%) patient had Bb leg injuries and 2 (10.0%) patients had I/L scapula spine in associated injuries which was not statistically significant ($P = 0.6530$).

In our study in excellent outcome, the mean age (mean ± SD) of patients was 33.9000 ± 10.2746 years and in good outcome, the mean age (mean ± SD) of patients was 38.2000 ± 9.3648 years which was not statistically significant ($P = 0.4043$).

Our study showed that in excellent outcome, the mean days before surgery (mean ± SD) of patients was 3.5000 ± 1.4690 days and in good outcome, the mean days before surgery (mean ± SD) of patients was 3.8000 ± 0.8367 which was not statistically significant ($P = 0.6678$).

Ferran *et al.*[7] (2010) found that mean follow-up was 12.4 months. There was no significant difference in either Constant scores ($P = 0.365$) or Oxford scores ($P = 0.773$).

We found that the mean follow-up in months (mean ± SD) of patients was higher in patients with excellent outcome [9.6000 ± 1.9841 Months] compared to patients with good outcome [7.2000 ± 3.1145 months] which was statistically significant ($P = 0.0415$).

Khalil *et al.*[8] (2009) found that two cases had intraoperative failure of fixation, nine complained of subcutaneous prominence of the screw head, five experienced decreased sensation over the site of incision, and three had symptoms of frozen shoulder.

In our study, in excellent outcome, the mean time for shoulder movements union in week (mean ± SD) of patients was 8.9000 ± 2.1250 weeks and in good outcome, the mean time for shoulder movements union in week (mean ± SD) of patients was 7.0000 ± 1.0000 weeks. It was not statistically significant ($P = 0.0669$).

McKee *et al.*[9] (2006) found that the range of motion was well maintained, with flexion averaging 170° ± 20° and abduction averaging 165° ± 25°. Compared with the strength of the uninjured shoulder, the strength of the injured shoulder was reduced to 81% for maximum flexion, 75% for endurance of flexion, 82% for maximum abduction, 67% for endurance of abduction, 81% for maximum external rotation, 82% for endurance of external rotation, 85% for maximum internal rotation, and 78% for endurance of internal rotation ($P < 0.05$ for all values). The mean Constant score was 71 points, and the mean DASH score was 24.6 points, indicating substantial residual disability.

The present study showed that the mean flexion (mean ± SD) of patients was higher in patients with excellent outcome [168.0000 ± 5.9383] compared to patients with good outcome [146.0000 ± 2.2361] which was statistically significant ($P < 0.0001$).

Our study showed that the mean abduction (mean ± SD) of patients was higher in patients with excellent outcome [169.0000 ± 7.5394] compared to patients with good outcome [145.0000 ± 5.0000] which was statistically significant ($P < 0.0001$).

We found that the mean external rotation (mean ± SD) of patients was higher in patients with excellent outcome [72.7500 ± 6.3815] compared to patients with good outcome [65.0000 ± 0.0000] and this was statistically significant ($P = 0.0136$).

In our study, the mean internal rotation (mean± SD) of patients was higher in patients with excellent outcome [74.5000 ± 4.8395] compared to patients with good outcome [67.0000 ± 2.7386] which was statistically significant ($P = 0.0031$).

Smekal *et al.*[10] (2009) found that Constant scores were significantly higher after 6 months and 2 years after intramedullary stabilization.

Bithrey *et al.*[11] (2017) found that the difference in Constant shoulder scores between the affected and unaffected shoulders for 14 patients was below 11 at 12 weeks' follow-up and all patients were satisfied with their scar after 12 weeks.

We also found that the mean Constant score (mean ± SD) of patients was higher in patients with excellent outcome [90.4500 ± 2.9465] compared to good outcome patients [82.8000 ± 1.6432] which was statistically significant ($P < 0.0001$) [Table 1].

CONCLUSION

Excellent outcome was more in male but good outcome was more in female which was statistically significant.

Associated injuries were not significantly related with outcome.

Days before surgery were not significantly associated with outcome but excellent outcome patients were higher follow-up in months.

Time for shoulder movements union in week was higher in excellent outcome patient compared to good outcome patient though it was not significantly associated with outcome.

Excellent outcome patients had higher flexion which was statistically significant.

Abduction, external rotation, and internal rotation were significantly higher in excellent outcome patient compared to good outcome patient.

We found that Constant score was higher in excellent outcome patient compared to good outcome patient.

We concluded that functional outcome of displaced midshaft clavicle fractures was treated with intramedullary titanium elastic nail system.

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Original Article

Comparative Evaluation of Efficacy of Antimicrobials Incorporated into Denture Adhesives: An *In Vitro* Study

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Abstract

Introduction: Denture adhesives are water-soluble and non-toxic substances placed between the denture and the tissues to enhance the normal physiological forces that hold dentures in place. They absorb water and swell to many times their original volume, and form anions that interact with the cations of the oral mucous membrane. They contain various flavoring agents such as oil of peppermint and wintergreen oil, which tend to facilitate microbial growth.

Purpose: This study aims to compare and evaluate the efficacy of four different antimicrobials incorporated into denture adhesives.

Materials and Methods: Two denture adhesive brands (FIXON and SECURE) in powder and cream formulations were used. The efficacy of four antimicrobials (nystatin, cephalexin, chlorhexidine, and silver nanoparticles) in denture adhesives was evaluated by assessing *Candida albicans* and *Streptococcus mutans* growth.

Results: Chlorhexidine digluconate and silver nanoparticles showed the highest antimicrobial effect when incorporated into denture adhesives.

Conclusion: Within this study's limitations, it can be concluded that chlorhexidine digluconate and silver nanoparticles can be viable antimicrobial therapies in denture adhesives.

Key words: Cephalexin, Chlorhexidine digluconate, Denture adhesives, Nystatin, Silver nanoparticles

INTRODUCTION

Fabricating a successful complete denture requires scientific knowledge and expertise. Even the most proficient clinicians sometimes may not be able to meet the patient's satisfaction. The psychological status of geriatric patients undergoing complete denture therapy is crucial in determining treatment success. Denture adhesives are water-soluble and non-toxic substances placed between the denture and the tissues to enhance the normal physiological forces that hold dentures in place. Denture adhesives have been used since the late 18th century and became popular in the early 19th century. The first reference by the American Dental Association to denture adhesives came from the Accepted Dental Remedies of 1935. The Council of Dental Materials, Instruments, and Equipment admitted that these products were nonmedical.[1] Denture adhesives are also known as fixatives and adherents and are supplied as powders, pastes, creams (soluble forms) and pads, and synthetic foams (insoluble forms). They absorb water and swell to many times their original volume and form anions that interact with the cations of the oral mucous membrane. They contain various flavoring agents such as oil of peppermint and wintergreen oil, which tend to facilitate microbial growth.[2-4] The purpose of this *in vitro* study is to compare and evaluate the efficacy of four antimicrobials incorporated into denture adhesives.

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MATERIALS AND METHODS

This study was conducted on two commercially available denture adhesives (FIXON and SECURE) in powder and cream formulations. Four antimicrobials were used: Cephalexin (bactericidal), nystatin (antifungal), silver nanoparticles, and 2% chlorhexidine digluconate. The culture media used were Sabouraud's dextrose agar media for *Candida albicans* and nutrient agar media for *Streptococcus mutans*. The total sample size taken was 320 and was divided into the following groups [Figure 1]:

The antimicrobials' efficacy was tested against two microorganisms' strains – *C. albicans* and *S. mutans*. Antimicrobials were added to the denture adhesives at an equal concentration of 1% (0.03 g of each of the antimicrobials in 3 g of denture adhesives). Denture adhesives without any antimicrobial incorporation were taken as controls. Vigorous spatulation was done to ensure uniform distribution. A digital weighing meter was used to measure the weights of the samples. Two methods were used to test the antimicrobial efficacy.

Lawn Culture Method

In this method, Sabouraud's dextrose agar medium was prepared. A measured quantity of Candidal strain (0.1ml) was inoculated into denture adhesive samples (controls, with nystatin, chlorhexidine digluconate, and silver nanoparticles). These inoculated samples were then streaked on the growth media with a sterile swab and were incubated for 24 h. The growth of *C. albicans* was then measured by counting the number of colony-forming units [Figure 2].

Kirby-Bauer Method

In this method, the nutrient agar medium was prepared and 24 h after the preparation, the *S. mutans* strain was streaked on the growth media. Then, bores were made in this media with an 8 mm sterile cork borer. Samples were placed in the prepared bores and the culture plates were incubated for 24 h. The antimicrobial susceptibility was tested by measuring the zones of inhibition around each sample. The zone of inhibition is the diameter of the area around each sample where there is no streptococcal growth and is measured with vernier calipers [Figure 3].

RESULTS

The growth of *C. albicans* was assessed by measuring the number of colony-forming units. The antibiotic susceptibility of *S. mutans* was estimated by measuring the zones of inhibition (in mm). The numbers were presented that were the mean and standard deviation of the number of colony-forming units and zones of inhibition (in mm) [Table 1]. Data analysis was done using Statistical Package for the Social Sciences (SPSS) version 15.0, the statistical analysis software. The data were analyzed by analysis of variance test.

The number of colony-forming units of *Candida* decreased from control groups (164.3, 29.5, 168.8, and 29.5) to nystatin groups (34.2, 20.1, 48.4, and 18.2), followed by chlorhexidine groups (14.7, 11.4, 23.2, and 11.4) and silver nanoparticles groups (5.2, 9.1, 1, and 7.1). There was high statistical significance ($P < 0.00001$) in the growth of *C. albicans* between the control groups and the groups incorporated with antimicrobials. The values of zones of inhibition increased

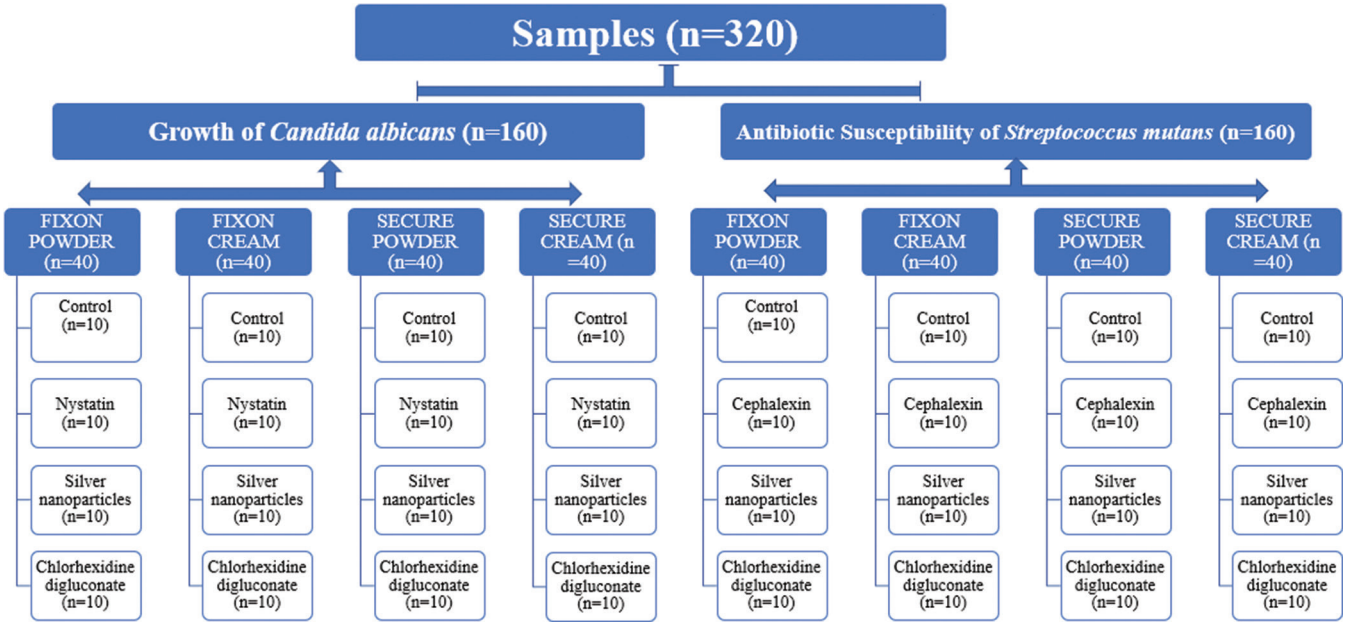

Figure 1: Schematic representation of distribution of samples

Table 1: Comparison of growth of *Candida albicans* (Colony Forming Units) and antibiotic susceptibility of *Streptococcus mutans* (Zones of Inhibition in mm) by one-way ANOVA analysis

Sample	Growth of *Candida albicans*					Antibiotic Susceptibility of *Streptococcus mutans*				
	Group	Mean	SD	f-ratio value	*P*-value	Group	Mean	SD	f-ratio value	*P*-value
Fixon powder	Control	164.3	45.988	99.365	1.00E-05	Control	5.3	4.922	13.209	5.70E-06
	Nystatin	34.2	4.661			Cephalexin	23.4	5.947		
	Chlorhexidine	14.7	5.922			Chlorhexidine	24.8	2.859		
	Silver nanoparticles	5.2	6.321			Silver nanoparticles	23.9	8.478		
Fixon cream	Control	29.5	9.095	15.257	1.44E-06	Control	12.3	2.945	23.621	1.26E-08
	Nystatin	20.1	6.196			Cephalexin	24.4	2.836		
	Chlorhexidine	11.4	7.933			Chlorhexidine	22.1	5.384		
	Silver nanoparticles	9.1	6.505			Silver nanoparticles	25.2	3.765		
Secure powder	Control	168.8	66.446	49.267	7.93E-13	Control	5.3	4.522	25.924	4.13E-09
	Nystatin	48.4	10.782			Cephalexin	23.4	5.947		
	Chlorhexidine	23.2	3.521			Chlorhexidine	24.8	2.859		
	Silver nanoparticles	1	2.16			Silver nanoparticles	23.9	8.478		
Secure cream	Control	29.5	9.095	17.859	2.88E-07	Control	9.5	2.838	42.492	6.45E-12
	Nystatin	18.2	7.099			Cephalexin	30.5	5.986		
	Chlorhexidine	11.4	7.933			Chlorhexidine	29	5.517		
	Silver nanoparticles	7.1	4.201			Silver nanoparticles	31.3	5.292		

from the control group (5.3, 12.3, 5.3, and 9.5) to the cephalexin group (23.4, 24.4, 23.4, and 30.5), silver nanoparticles group (23.9, 25.2, 23.9, and 31.3), and chlorhexidine group (24.8, 22.1, 24.8, and 29). There is a high statistical significance ($P < 0.00001$) in antibacterial susceptibility between the control groups and the groups incorporated with antimicrobials. Control groups showed the lowest zones of inhibition (more streptococcal growth), and silver nanoparticles showed the highest zones of inhibitions [Table 1].

There was decrease in *C. albicans* growth from powder to cream formulations in both the brands. Similarly, when powder formulations were compared with cream formulations, denture adhesive creams showed increased antimicrobial activity (higher zones of inhibition) than powders. This difference was statistically significant with SECURE powder and cream forms [Table 2]. The antimicrobial efficacy among the two denture adhesive brands (FIXON and SECURE) was heterogeneous [Table 2].

The efficacy of each antimicrobial is assessed by subjecting the values to the *post hoc* Turkey HSD test. There was a statistical significance ($P < 0.05$) between the nystatin and silver nanoparticles group. In contrast, no such significance was seen between nystatin and chlorhexidine groups and chlorhexidine and silver nanoparticles group. There was no statistical significance between cephalexin, 2% chlorhexidine digluconate, and silver nanoparticles in inhibiting the growth of *S. mutans* [Table 3].

DISCUSSION

The crucial role of denture adhesives in removable partial dentures has been documented in the literature. They are used in stabilizing trial denture bases during jaw relation and try-in procedures. They help in the patient's ability to adapt to new dentures and boost their confidence. They provide an extra sense of security to denture patients who are public speakers, teachers, business executives, and attorneys. They are also valuable adjuncts for administering drugs in prostheses designed as radiation carriers or radiation protection prostheses.[4-7] Despite the widespread use of adhesives, dentists continued to maintain a negative attitude toward these products. This was due to the misuse of adhesives and the general attitude that the dentist is incompetent or incapable of making a tight-fitting denture. The patients must be educated and instructed about the proper use of denture adhesives and should be cautioned against their misuse.

Another major drawback of these adhesives is that the flavoring and sweetening agents present in them often tend to harbor microbial growth and lead to denture candidiasis and sore mouth.[8,9] Studies conducted by Sampaio *et al.* showed that even the commercially available denture adhesives with antiseptics like p–hydroxybenzoic acid methyl ester and propylparaben showed no significant antimicrobial effect.[10] In the present study, various antimicrobials were incorporated into denture adhesives, and their efficacy against inhibiting candidal and streptococcal growth was studied.

In the present study, denture adhesive creams showed higher antimicrobial activity than powders. This difference was a statistically significant in the case of SECURE powder and cream. This may be because it was easier to obtain a homogeneous mass while mixing the antimicrobials to cream denture adhesives. This was in agreement with an earlier study which showed lower contamination among

Table 2: Comparison of growth of *Candida albicans* (Colony Forming Units) and antibiotic susceptibility of *Streptococcus mutans* (Zones of Inhibition in mm) among powder-cream, powder-powder, and cream-cream formulations of the two brands by paired "*t*" test

Treatment pairs/ samples	Fixon powder versus Fixon Cream		Secure powder versus secure cream		Fixon powder versus secure powder		Fixon cream versus secure cream	
	t-value	*P*-value	t-value	*P*-value	t-value	*P*-value	t-value	*P*-value
Paired "t" test for growth of *Candida albicans*								
Controls	9.09313	0.00000392	6.56828	0.00005149	-0.1761	Insignificant	0	Insignificant
Nystatin	5.70914	0.00014546	7.39746	0.00002057	-3.82251	0.00203714	0.67116	Insignificant
Chlorhexidine	1.05385	Insignificant	4.29921	0.00099648	-3.8966	0.00181910	0	Insignificant
Silver nanoparticles	−1.35964	Insignificant	4.08283	0.00137317	1.98826	0.03900748	0.81665	Insignificant
Paired "t" test for antibiotic susceptibility of *Streptococcus mutans*								
Controls	−1.72786	Insignificant	−2.48738	0.01728742	1.85996	0.04790975	2.16455	0.02931577
Cephalexin	1.13498	Insignificant	−2.66063	0.01301010	1.283	Insignificant	−2.91211	0.00862609
Chlorhexidine	0.38342	Insignificant	−2.13713	0.03065485	−1.26046	Insignificant	−2.83031	0.00985638
Silver nanoparticles	0.11505	Insignificant	−2.34139	0.02196332	0.40227	Insignificant	−2.96983	0.00785376

Table 3: *Post hoc* comparisons of growth of *Candida albicans* (Colony Forming Units) and antibiotic susceptibility of *Streptococcus mutans* (Zones of Inhibition in mm) among four antimicrobials

	Growth of *Candida albicans*				
Treatment Pair	Fixon Powder (*P*-value)	Fixon Cream (*P*-value)	Secure Powder (*P*-value)	Secure Cream (*P*-value)	Inference
Post hoc Turkey HSD Tests					
Control versus Nystatin	0.0010053	0.0318712	0.0010053	0.0074187	Significant
Control versus Chlorhexidine	0.0010053	0.0010053	0.0010053	0.0010053	Significant
Control versus Silver nano	0.0010053	0.0010053	0.0010053	0.0010053	Significant
Nystatin versus Chlorhexidine	0.265644	0.0527039	0.3539318	0.1789006	Insignificant
Nystatin versus Silver nanoparticles	0.0430956	0.0091941	0.0168274	0.0087321	Significant
Chlorhexidine versus Silver nanoparticles	0.7810394	0.8900618	0.465503	0.5535168	Insignificant
Antibiotic susceptibility of *Streptococcus mutans*					
Control versus Cephalexin	0.0010053	0.0010053	0.0010053	0.0010053	Significant
Control versus Chlorhexidine	0.0010053	0.0010053	0.0010053	0.0010053	Significant
Control versus Silver nanoparticles	0.0010053	0.0010053	0.0010053	0.0010053	Significant
Cephalexin versus Chlorhexidine	0.5067427	0.5459532	0.8999947	0.8999947	Insignificant
Cephalexin versus Silver nanoparticles	0.8999947	0.8999947	0.8999947	0.8999947	Insignificant
Chlorhexidine versus Silver nanoparticles	0.8159887	0.294143	0.8999947	0.7184465	Insignificant

denture adhesive creams.[1] When the two commercial denture adhesives were compared (FIXON and SECURE), the results were heterogeneous and not favoring one. This might be because of the variations in the composition of the adhesives.

Nystatin is a polyene antifungal agent produced by *Streptomyces noursei*. It has fungicidal activity against a broad spectrum of pathogenic fungi. It is also widely used as a topical formulation in treating oral candidiasis. It inhibits fungal growth through interaction with ergosterol, leading to loss of selective membrane permeability and eventually cell death.[11] Cephalexin is a beta-lactam antibiotic that belongs to first-generation cephalosporins. It is effective against Gram-positive and some Gram-negative bacteria. It disrupts the growth and inhibits the synthesis of the peptidoglycan layer of the bacterial cell wall.[12]

Schroeder Ju investigated chlorhexidine's ability to inhibit dental biofilm in 1969. It is available in three formulations: Acetate, digluconate, and hydrochloride, at different concentrations. Chlorhexidine digluconate (or chlorhexidine gluconate) is a cationic bis-biguanide with physiologic pH. It has a wide antibacterial spectrum and is active against Gram-positive and Gram-negative bacteria.[13,14] Mozayeni *et al.* compared the antifungal activity of 2% chlorhexidine digluconate with calcium hydroxide and nanosilver gels. They concluded that 2% CHX gels had significantly higher antifungal activity than nanosilver gels.[15] Shino *et al.* compared the antimicrobial effect of chlorhexidine and ketoconazole on *C. albicans* and found that chlorhexidine showed a significant antifungal activity which is comparable with ketoconazole.[16]

Silver nanoparticles constitute a very promising approach for the development of new antimicrobial systems.[17] Their antibacterial action is driven by the oxidative dissolution process. The positively charged silver ions (Ag^{+}) react with negatively charged ions of the bacterial cell wall and cause aggregation, thereby leading to bacterial dissolution and

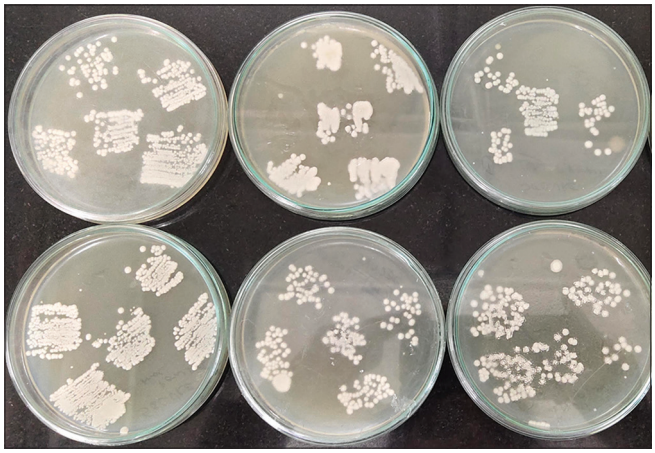

Figure 2: Growth of *Candida albicans* on Sabouraud's dextrose agar medium by Lawn culture method

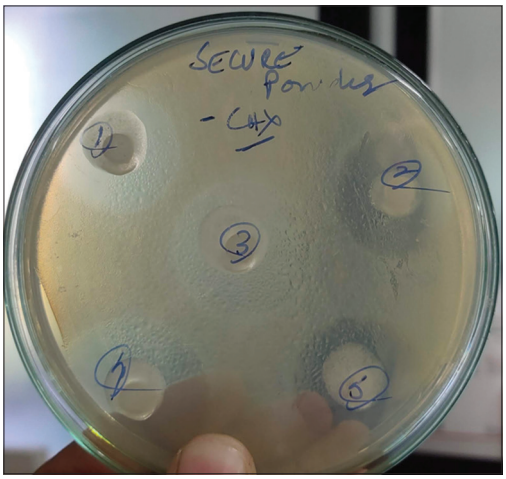

Figure 3: Antibiotic susceptibility of *Streptococcus mutans* on nutrient agar medium by Kirby-Bauer method

passivation. They are also known to have antifungal activity and act by permeating the fungal cell wall and damaging the cell wall and cellular contents.

Bates *et al.* suggested that denture adhesives may inactivate innate immune mediators in the oral cavity, increasing the risk of *C. albicans* infections. They also reported that the inclusion of antifungal antibiotics (nystatin, amphotericin B, fluconazole, chlorhexidine gluconate, and chloride) to denture adhesives aids in a significant decrease of *Candida* infections and denture stomatitis.[18] Garaicoa *et al.* reported that *C. albicans* strains were susceptible to chlorhexidine dihydrochloride and fluconazole and may be candidates for inclusion in adhesive formulations compared to amphotericin B, chlorhexidine digluconate, and nystatin.[19] Chen *et al.* evaluated the pH and effects of streptococcal growth of denture adhesives. They reported that adhesives produce a pH below the critical pH of hydroxyapatite and may not be suitable for patients with natural teeth.[20] Almeida *et al.* reported that enriched fractions of *Equisetum giganteum* and *Punica granatum* combined with denture adhesives, played a collaborative role in biofilm control, and can be considered for temporary use in the treatment and prevention of denture stomatitis.[21] Rajaram *et al.* compared the influence of three different forms of a commercially available denture adhesive material on the growth of *Candida* species. They monitored the pH and number of colonies in the growth medium at different incubation periods and found that the strip form of adhesives showed a prolonged antifungal effect.[22]

In the present study, the antifungal effect of 2% chlorhexidine was significantly higher than nystatin, but there was no such significance with that of silver nanoparticles. There were no significant differences in antibacterial activity of 2% chlorhexidine, cephalexin, and silver nanoparticles. Hence, it can be inferred that both chlorhexidine and silver nanoparticles had significantly better antifungal and antibacterial activity.

Chlorhexidine digluconate is known to have the advantage of substantivity. That is the capacity of binding to soft and hard oral tissues, resulting in a long-lasting effect after administration. After a single mouthwash, about 30% of the active component remains in the oral mucosa, while negligible amounts are ingested. The cationic property reduces its absorption, either by skin or mucosae, including gastrointestinal tract mucosae.

While on the other hand, the systemic absorption and cytotoxicity of silver nanoparticles should be further studied. Furthermore, another demerit observed while using silver nanoparticles were that it has an inherent greyish black color that might hinder the patient's acceptance.

Limitations

1. As it is an *in vitro* study, the biologic environment of the oral mucosa could not be simulated
2. The retentive ability and viscosity of denture adhesives incorporated with antimicrobials should further be studied
3. Systemic influence and cytotoxicity of silver nanoparticles should be evaluated.

CONCLUSION

Within the study's limitations, 2% chlorhexidine digluconate and silver nanoparticles can be viable antimicrobial therapies in denture adhesives.

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Original Article

Role of Cross-sectional Imaging in Biliary Tract Malignancies in Therapeutic Decision-making

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Abstract

Introduction: Role of cross-sectional imaging in biliary tract malignancies in therapeutic decision-making plays an very important role.

Materials and Methods: Ethical committee clearance and informed consent were taken from 57 patients of suspected biliary tract malignancies who underwent Triphasic computed tomography (CT) and in whom these malignancies were histopathologically confirmed. Based on imaging findings and clinical parameters, the tumors were deemed operable and non-operable by experienced radiologists and operating oncosurgeons. In operable cases, the CT findings were compared with the intraoperative findings and the correlation was studied. Inoperable tumors were considered for palliative stenting with either endoscopic retrograde cholangiopancreatography (ERCP) or percutaneous transhepatic biliary drainage (PTBD). A prediction of feasibility or non-feasibility for successful ERCP was done based on imaging findings. A reasonable follow-up of the patients was done following surgery, ERCP, or PTBD to ascertain the effectiveness of these measures on the overall patient's outcome.

Results: We found that the CT findings were accurate in predicting operability in patients with biliary tract malignancies and CT findings correlated with intraoperative findings in majority of the operable cases. CT had sensitivity of 81.25%, specificity of 100%, positive predictive value (PPV) of 100%, negative predictive value (NPV) of 93.18%, and diagnostic accuracy of 94.74% in predicting operability. We also observed that the accuracy of CT in predicting feasibility or non-feasibility of successful ERCP-guided stenting was satisfactory in cases of non-operable tumors. CT had sensitivity of 71.43%, specificity of 84.62%, PPV of 90.91%, NPV of 57.89%, and diagnostic accuracy of 75.61% in predicting ERCP feasibility.

Conclusion: CT imaging findings were very helpful in deciding operability and non-operability in cases with hepatobiliary malignancies. CT imaging findings were further very useful in deciding feasibility of ERCP-guided stenting in non-operable tumors. Overall, cross-sectional imaging played a key role in imaging of patients with hepatobiliary malignancies in deciding the best therapeutic options for the patients.

Key words: Computed tomography, Gallbladder, Reduced dose, Standard dose, Ultrasonography

INTRODUCTION

Cancers of the biliary tract are one of most common malignancies of hepatobiliary system being second most common after hepatocellular carcinoma. Cancers of the biliary tract can be seen to occur in any part of biliary tree. Accurate pre-operative assessment of these tumors by the radiologist is of paramount importance, since the entire therapeutic management is dependent on it. Unnecessary major surgeries can be avoided if non-operability factors can be accurately identified and these patients can be diverted to other palliative therapeutic options which are more suitable in these advanced stages.

Our study also aims to assess suitability for endoscopic retrograde cholangiopancreatography (ERCP) or percutaneous transhepatic biliary drainage (PTBD) in non-operable tumors and assess, whether it is possible to predict non-feasibility of

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ERCP in certain situations. This can be helpful in avoiding unnecessary procedures and proceeding directly to the relevant therapeutic option, minimizing patient discomfort.

MATERIALS AND METHODS

- The ethical committee of VIMS and RC gave the ethical clearance and informed consent was obtained from all the patients
- The study population included 57 patients with obstructive jaundice with suspected biliary tract malignancies and in whom these malignancies were histopathologically confirmed
- Triphasic CT was performed on all the patients with Siemens Somatom Definition AS 128 slice multi-detector CT scanner with 5 mm collimation and a gantry speed of 0.05 s and pitch of 1.2 s, 120kvP, and 345 effective mAs [Figure 1]. First, a non-contrast axial cuts were obtained; thereafter, contrast was administered (Omnipaque (Iohexol) – 350 mg I/ml), typical doses of 1.5 mg/kg (60–90 ml) through pressure injector (Imaxeon, SW version – 1.5–0.12) using smart prep software (RCU manager) [Figures 2 and 3] and arterial, venous, and delayed phase were obtained. The typical scan parameters involved 5 mm and 1 mm slice thickness, coronal, axial, and sagittal reconstruction, with 120 MA and 60-80 Kvp
- The CT examinations were analyzed on dedicated work stations, this included Aquarius systems or Syngovia dedicated work station.

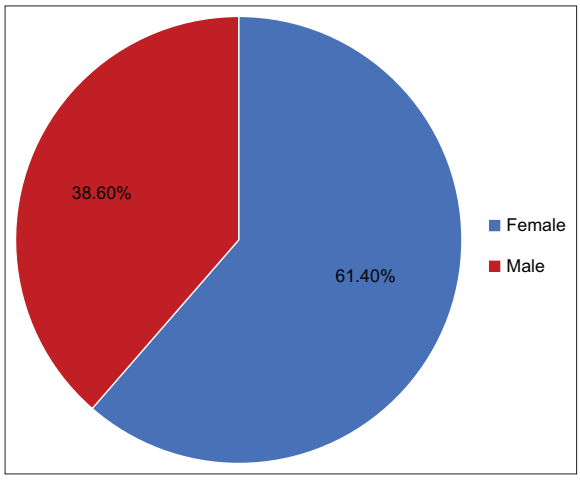

Figure 1: Siemens Somatom Definition AS 128 slice Multi-detector CT scanner – Pie diagram showing sex distribution of subjects

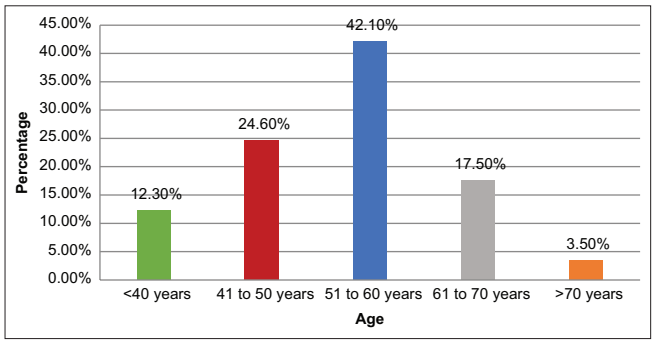

Figure 2: Smart prep software (RCU manager) – Bar diagram showing Age distribution of subjects

Inclusion Criteria

All patients with obstructive jaundice who present for CT imaging in department of radiology with suspected biliary tract malignancies and in whom these malignancies were ultimately confirmed.

Exclusion Criteria

The following criteria were excluded from the study:

- Cases in whom histopathological confirmation could not be done or in whom it is repeatedly negative
- Cases which were not ready for any further treatment following imaging diagnosis
- Patients without obstructive jaundice
- Patient allergic to contrast media
- Patients with high creatinine value secondary to renal failure.

The following details were analyzed:[1-4]

1. The size and location of the lesion
2. Level of biliary obstruction
3. Type of block: The block was classified according to Bismuth Corlette classification into type I, II, IIIa, IIIb, and IV
4. Extent of involvement of liver parenchyma
5. Involvement of adjacent structures or organs
6. Vessel encasement or abutment (to be mentioned in degrees)
7. Presence of locoregional or distant lymph nodal involvement

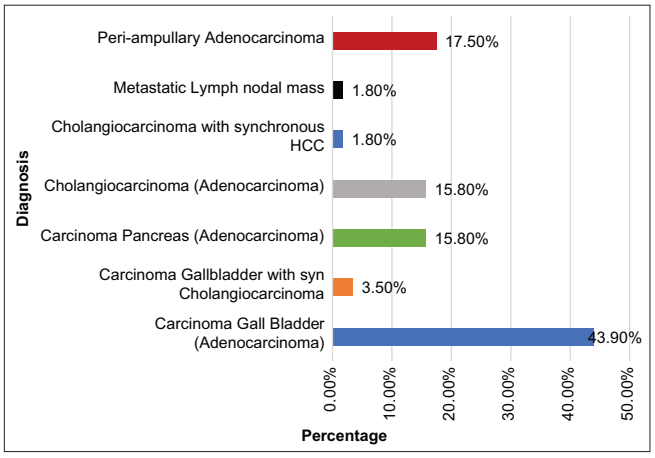

Figure 3: Pressure injector (Imaxeon, SW version – 1.5-0.12) – Bar diagram showing diagnosis distribution

8. Presence of peritoneal deposits
9. Presence of any distant metastases or metastatic lesions within the liver.

Histopathological confirmation of malignancy was obtained in all patients. Operability was assessed jointly by experienced radiologists and operating oncosurgeons in a multidisciplinary team meeting taking into the account the imaging findings and the other clinical parameters.[5-8]

In presence of following parameters, the tumor was deemed inoperable -

- Presence of metastatic lesions within or outside liver
- Presence of metastatic lymph nodes apart from locoregional lymph nodes in porta hepatis or Para duodenal region
- Type IV block with tumor extending into intrahepatic segmental ducts
- Encasement of hepatic artery: Minor degrees of abutment were considered equivocal and an operative exploration will be needed in such cases
- Encasement or obstruction of portal vein (minimal focal abutment is not a contraindication)
- Extensive contiguous infiltration of liver parenchyma with involvement of two or more segments precluding liver resection due to inadequate liver FLR
- An advanced block such as type IIIa or IIIb was considered inoperable in case of certain patient's factors such as – advanced age with poor performance status in presence of inadequate FLR precluding an extensive liver resection or in non-compliant patients who are unwilling for an extensive liver resection.

Based on above criteria, the lesions were classified as operable or inoperable. In operable cases, the findings on CT were compared with the intraoperative findings and the correlation was studied.[9,10]

Inoperable tumors were considered for palliative stenting with either ERCP or PTBD. A prediction of feasibility or non-feasibility for successful ERCP was done based on imaging findings. A non-feasibility or failure of ERCP was predicted based on following imaging findings:

- Type IV Block
- Large bulky tumor masses which will preclude endoscopic passage of guide wire through the lesions. This was based on size criteria and any bulky lesion greater than 2 cm in the region of the biliary tract was a contraindication
- Extensive duodenal stenosis or anatomical distortion of duodenal or ampullary region by lesions which will preclude passage of endoscope
- Irrespective of the predictivity of feasibility, all patients were first subjected to ERCP and the success and failure of ERCP was observed. Correlation was done of the predictivity from cross-sectional imaging and the outcome from ERCP.

A reasonable follow-up of the patients was done following surgery, ERCP, or PTBD to ascertain the effectiveness of these measures on the overall patient's outcome.

Statistical Analysis

Data were entered into Microsoft Excel data sheet and were analyzed using SPSS 22 version software. Categorical data were represented in the form of frequencies and proportions. Chi-square test was used as test of significance for qualitative data. Continuous data were represented as mean and standard deviation. *P*-value (Probability that the result is true) of <0.05 was considered as statistically significant after assuming all the rules of statistical tests. Statistical software: Microsoft Excel and SPSS version 22 (IBM SPSS Statistics, Somers NY, USA) were used to analyze data.[11-13]

RESULTS

A total of 57 patients who presented with obstructive jaundice and underwent triphasic CT scanning and in whom malignant causes of biliary obstruction were ultimately proved by histopathology were analyzed.

This included 22 males and 35 females [Figure 1]. The age range of the patients was from 30 to 79 years and mean age was 54. The age range in male patients was 30–79 and in female patients from 39 to 71 years and the mean age of male patients was 51 and of female patients was 54 [Figure 4]. The average duration of symptoms was of 2 months and ranged from 2 weeks to 1 year.

The chief complaints of the patients were pain abdomen, yellowish discoloration of sclera, loss of weight, and loss of appetite. The deranged LFTs were noted in all patients and the serum total bilirubin levels ranged from 1.5 to 26.5 and mean was 14. There was conjugated hyperbilirubinemia in all patients with raised direct bilirubin. There were associated liver enzyme derangements (AST/ALT/ALP) in all patients.

The size and location of the lesion are detailed in Figure 3. Liver parenchymal infiltration by the lesions was seen in eight patients, this was mainly by carcinoma of gallbladder in seven cases or mass forming cholangiocarcinoma in one case. A case of HCC was arising from the liver parenchyma itself and secondarily infiltrating the common bile duct (CBD). The segments involved by the tumors were mainly V and IV in seven cases with tumor extending into segment

VII as well in one case. With respect to involvement of adjacent structures or organs, there was additional infiltration of duodenum by carcinoma of head/uncinate process of pancreas in five cases and an infiltration from the adjacent duodenal bulb into the biliary system in three cases.

There was complete hepatic artery encasement in eight cases, partial hepatic artery encasement (< 180°) in three cases, superior mesenteric artery encasement in four cases, superior mesenteric vein encasement in three cases and significant portal vein encasement (more than 180°) in twelve cases. The vascular encasement was maximum in cases with carcinoma of head/uncinate process of while periampullary carcinomas had minimal vascular involvements.

The presence of locoregional lymph nodal involvement defined as enlarged nodes (more than 5 mm in short axis) in the porta hepatis, paraduodenal, or precaval region which were present in 22 cases. A distant nodal metastatic disease (defined as enlarged nodes, more than 5 mm in short axis in para-aortic regions or beyond) was noted in 25 cases. All these distant nodes were evaluated using CT-guided fine-needle aspiration cytology (FNAC) and proven to be containing metastatic deposits. There was presence of peritoneal deposits, noted as containing small enhancing nodules or frank omental thickening or caking in nine cases. There was presence of liver metastases in 11 cases and distant metastases (involving bones or lungs) in one case [Figure 5].

The type of block seen is detailed in Figure 4. The malignant etiology responsible for the lesions is highlighted in table. The details of histopathological confirmation obtained are enlisted in Figure 6. After detailed analysis of the imaging features and the histopathogical confirmation, the operability was discussed in a multidisciplinary team consisting of operating surgical oncologists specializing in liver resections and hepatobiliary surgeries. Based on the criteria listed above, 16 tumors were considered operable and 41 tumors were inoperable [Figure 7]. The details of factors which rendered the tumors inoperable either present alone or in combination are listed in Figures 7 and 8.

For the tumors considered operable, a comparison of intraoperative findings was done with the CT findings. The CT findings were accurate in predicting operability in 13 cases and correlated. There was non-correlation noted in three cases [Figure 9]. Overall, the predictive value of CT in predicting operative feasibility for hepatobiliary tumors was found to be as detailed in [Figure 10]. In the study, type of block, vascular involvement, and distant metastasis in imaging determined operability.

Parameter	Estimate (%)	Lower–Upper 95% CIs
Sensitivity	81.25	56.99, 93.41
Specificity	100	91.43, 100
Positive predictive value	100	77.19, 100
Negative predictive value	93.18	81.77, 97.65
Diagnostic accuracy	94.74	85.63, 98.19

CT had sensitivity of 81.25%, specificity of 100%, positive predictive value (PPV) of 100%, negative predictive value

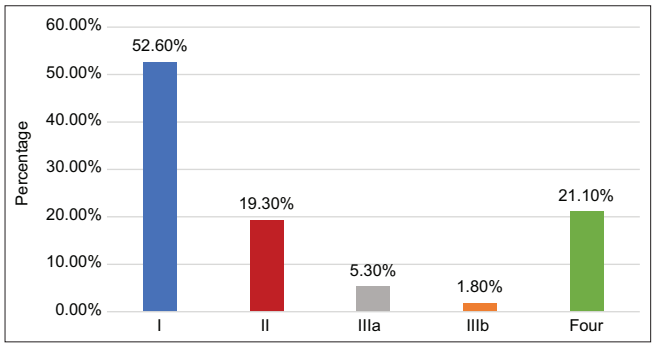

Figure 4: Bar diagram showing type of block

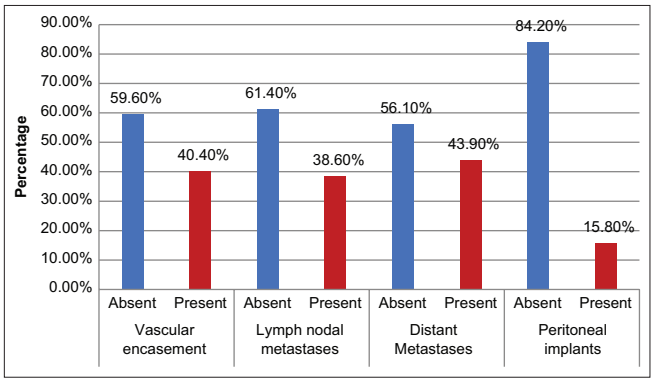

Figure 5: Bar diagram showing imaging findings

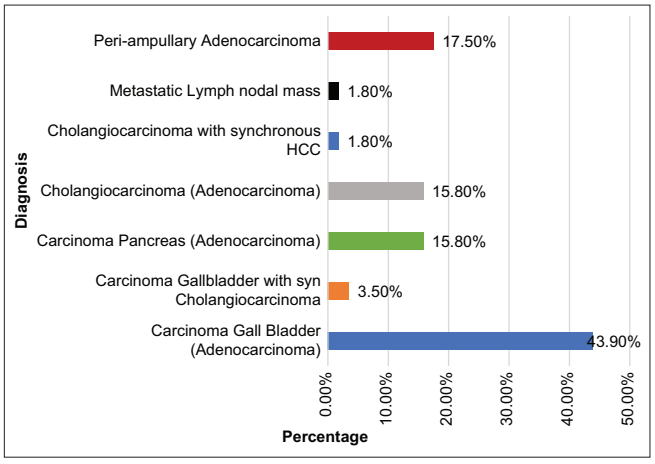

Figure 6: Bar diagram showing tissue diagnosis (HPE) distribution

(NPV) of 93.18%, and diagnostic accuracy of 94.74% in predicting operability. The major factors for non-operability were advanced level of block, presence of metastatic disease, or vascular encasements precluding resections.

Of the non-operable cases, 40 cases were considered for a palliative biliary stenting through either ERCP or PTBD. One case was not considered for any stenting as their performance status was too low to tolerate such procedures and a best supportive care plan was considered for them.

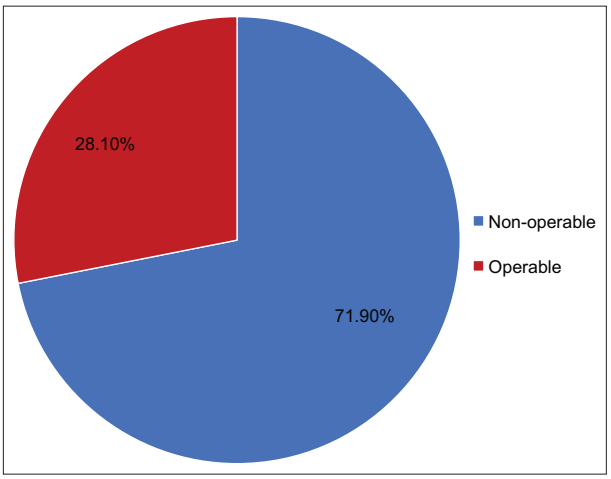

Figure 7: Pie diagram showing operability distribution

Based on the CT criteria listed above, a feasibility of ERCP was predicted in 22 cases, while ERCP was considered non-feasible in 19 cases. Of the cases, in which ERCP was considered feasible based on CT features, a successful ERCP could be performed in 20 cases, while ERCP was unsuccessful in two cases. In the cases, in which ERCP was considered not feasible based on CT criteria, the ERCP failed in 11 cases, while it was successful in eight cases [Figure 11].

Overall, the accuracy of CT in predicting successful ERCP-guided retrograde cannulation across stricture and a successful stenting is detailed in Figure 12. In cases of failed ERCP, the patients underwent PTBD and stenting and a PTBD was successful in all cases with successful negotiation of guide wire across the stricture, followed by balloon angioplasty and metallic stenting. CT had sensitivity of 71.43%, specificity of 84.62%, PPV of 90.91%, NPV of 57.89%, and diagnostic accuracy of 75.61% in predicting ERCP feasibility.

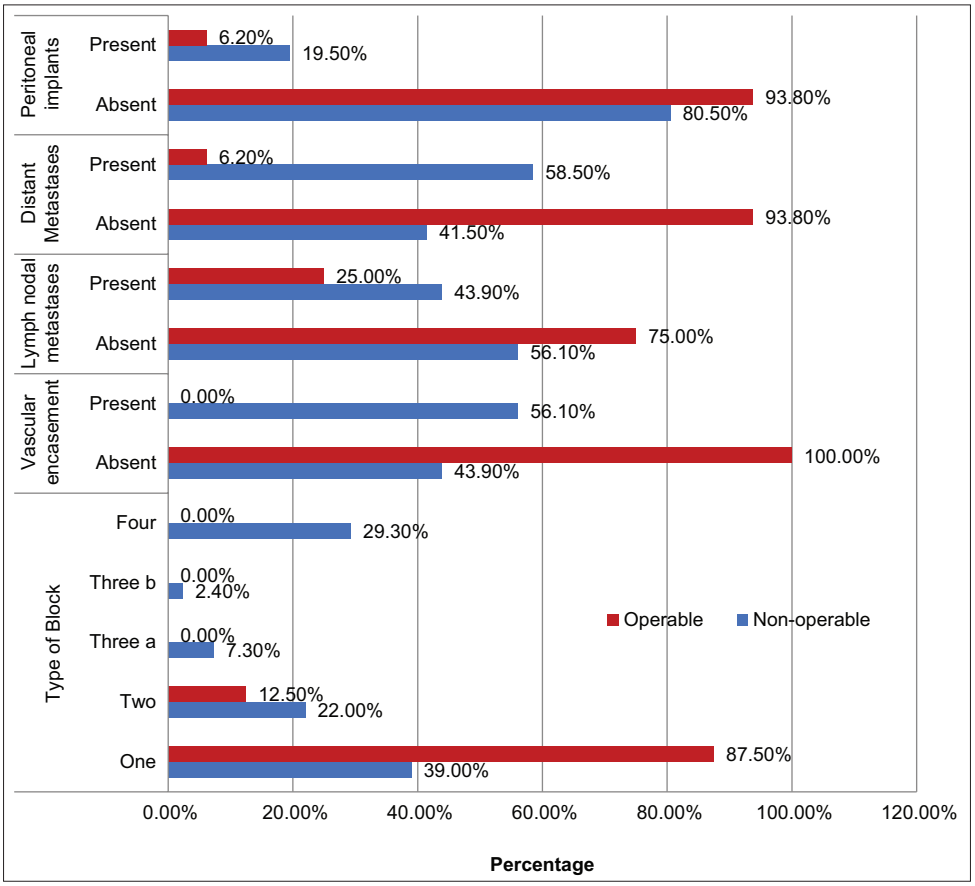

Figure 8: Bar diagram showing criteria's on cross-sectional imaging, which determine operability and non-operability of biliary tumors

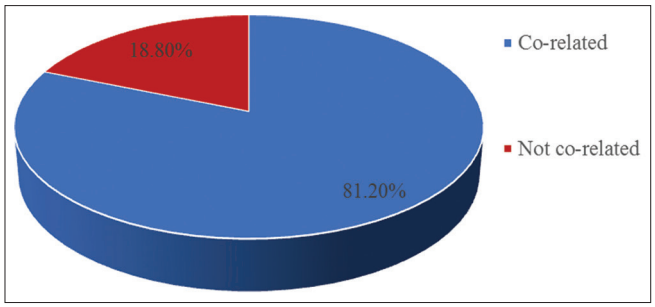

Figure 9: Bar diagram showing correlation of computed tomography findings with operability

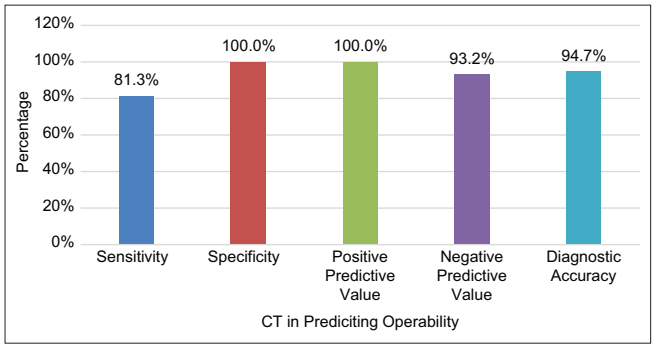

Figure 10: Bar diagram showing comparison of computed tomography findings with operability

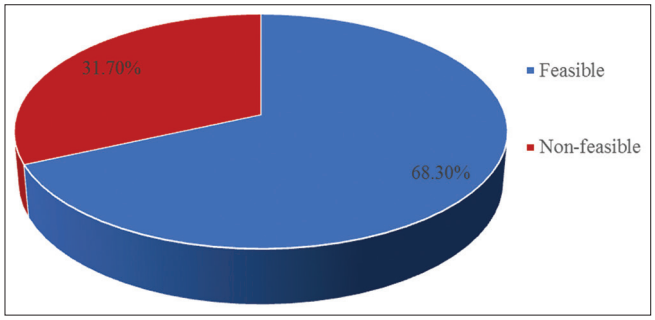

Figure 11: Pie diagram showing endoscopic retrograde cholangiopancreatography feasibility distribution among non-operable subjects

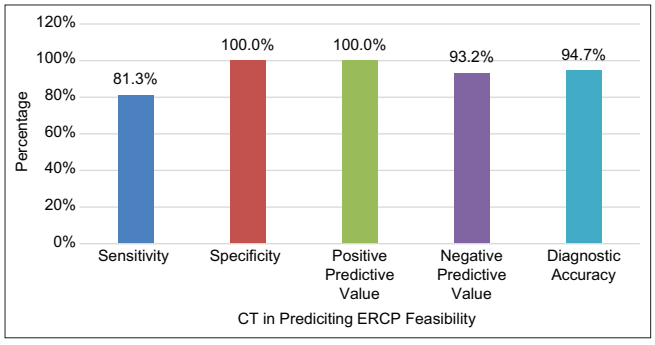

Figure 12: Bar diagram showing comparison of computed tomography findings with endoscopic retrograde cholangiopancreatography feasibility

ILLUSTRATIVE CASES

Case 1

Cholangiocarcinoma.

CT findings

There was obstruction at the biliary confluence with extension across the confluence into the right and left hepatic ducts suggestive of type IV block [Figures 13 and 14]. There was extensive obstruction on the right side with extension up to the third order biliary branches. The obstruction on the left was lesser with extension up to the secondary confluence. There was associated mild atrophy of the right lobe of liver.

MRCP findings

Suggests dilated IHBR and hepatic ducts with obstruction at the region of common duct- likely by soft-tissue stricture. Since the lesions were stricturous, but there was extensive type IV block; hence, a ultrasound (USG)-guided FNAC from the stricturous lesions causing ductal separation in the right lobe was done.

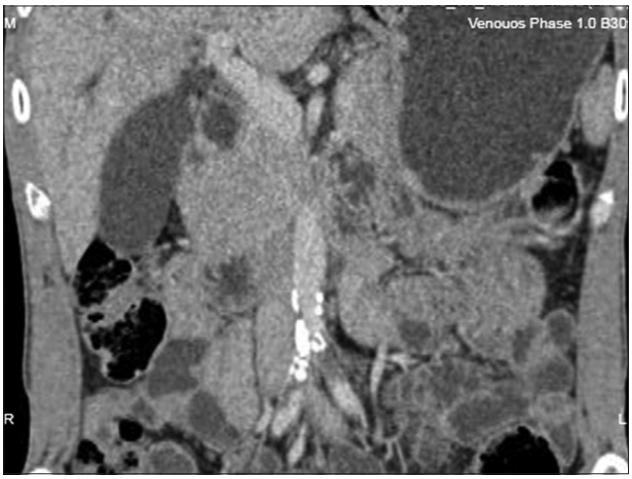

Figure 13: Type IV block

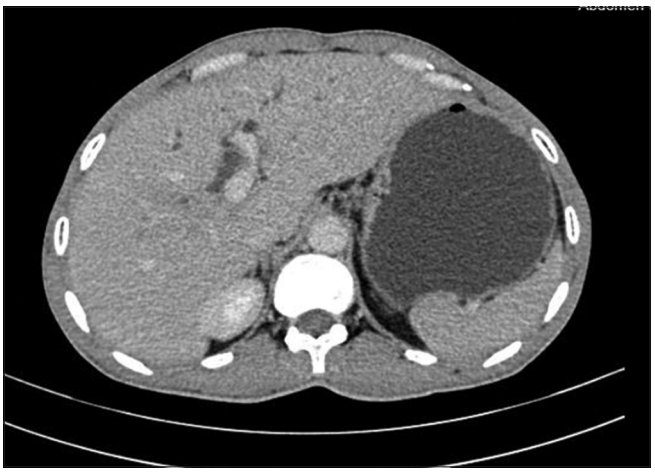

Figure 14: Type IV block

USG-guided FNAC (HPE report)
Adenocarcinoma and suggestive of cholangiocarcinoma.

Operability
The lesion was considered inoperable due to advanced type IV block. ERCP was considered not feasible due to type IV block. Plan was palliative stenting.

ERCP was not successful and failed and wire could not be negotiated across the stricture. The patient underwent PTBD and biliary stenting. The left PTBD was done and a metallic stent was placed across the stricture, since the right lobe was atrophic due to segmental blocks and most of the drainage was from the left lobe [Figure 15]. Post-stenting results were excellent with subsidence of jaundice and excellent results were noted up to a follow-up period of 6 months.

Case 2
Carcinoma Gallbladder.

CT findings
Necrotic mass arising from fundus of gallbladder with extension into subcapsular region and adjacent omental and pericolic fat stranding. The lesion shows indistinct fat planes with hepatic flexure and is causing Type I Block [Figures 16 and 17].

USG-guided biopsy (HPE)
Adenocarcinoma and carcinoma gallbladder.

Operability
Tumor was deemed operable.

Name of procedure
Radical Cholecystectomy.

Operative details
Tumor gallbladder involving segment IVb and V of liver.

Case 3

Carcinoma head of Pancreas.

CT findings
Multicystic well-defined lesion with enhancing internal septations within involving the head of pancreas with extensions, lesion is seen compressing 1st and 2nd part of duodenum, and focally abutting right kidney and gallbladder, superiorly lesion is abutting the left renal vein and causing mild compression of IVC type I block [Figures 18 and 19].

Intraoperative surgical specimen (HPE report)
Adenocarcinoma and carcinoma head of pancreas.

Operability
Operable.

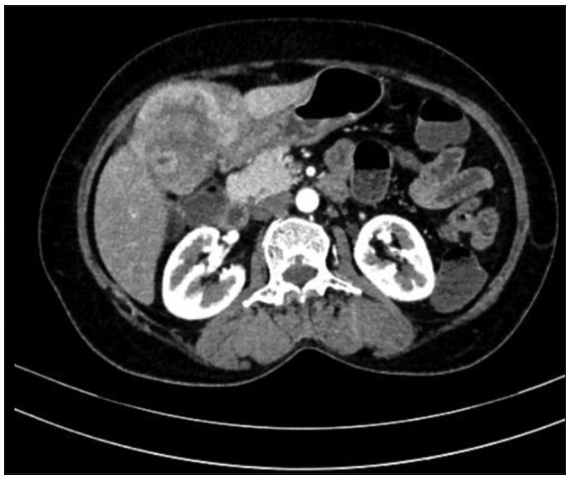

Figure 16: Hypervascular enhancing gallbladder mass

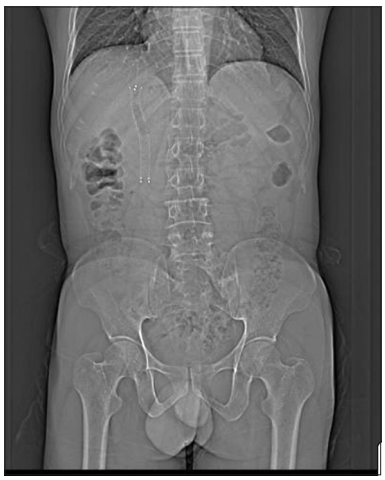

Figure 15: Stent in place

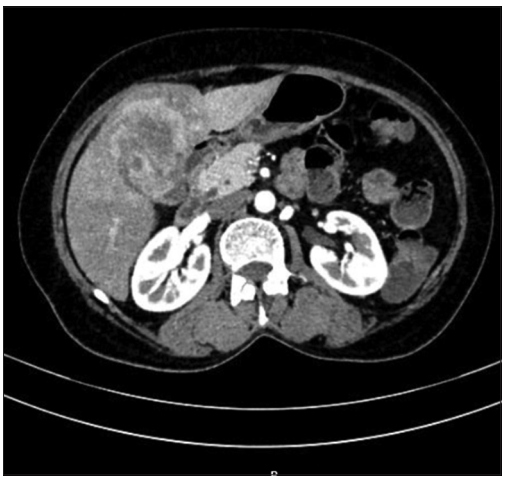

Figure 17: Infiltration in segment IV b and V of liver

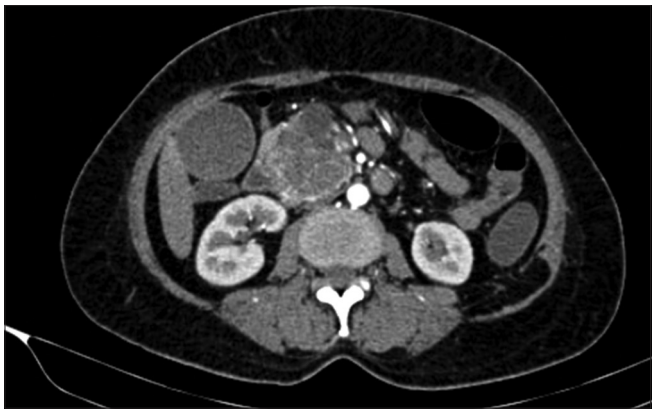

Figure 18: Enhancing lesion involving the head of pancreas

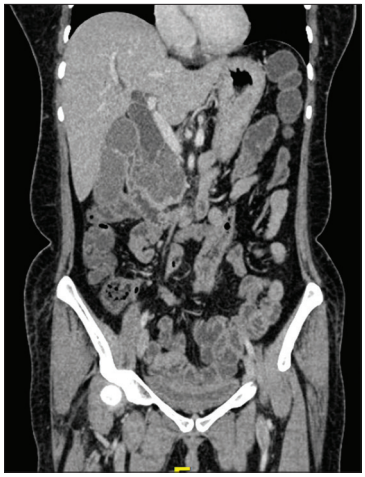

Figure 19: Type I block

Operative findings

Operative findings showed bulky nodular lesion in the head of pancreas with solid and cystic components causing type I block.Operative findings correlated with the CT findings.

DISCUSSION

Our study analyses the cross-sectional imaging findings in a large subset of patient population presenting with obstructive jaundice due to malignant causes. Obstructive jaundice due to malignant biliary obstruction is an important and common presentation in tertiary care referral cancer center such as ours and this study helped us to gain insights into different facets of this important clinical entity with regard to its imaging, which ultimately plays a crucial role in the entire subsequent patient management.

CONCLUSION

Our study aimed to evaluate the role of the role of cross-sectional imaging in biliary tract malignancies in therapeutic decision-making. With the study group of 57 patients with suspected, biliary tract malignancies undergoing triphasic CT scanning and the malignancies confirmed histopathologically. We observed that triphasic CT imaging was very accurate in deciding operability and non-operability in biliary tract malignancies and was also very useful in predicting feasibility or non-feasibility of successful ECRP-guided stenting in non-operable tumors.

Our goal of the study to assess the role of cross-sectional imaging in biliary tract malignancies was achieved. We found that triphasic CT imaging played a very key role in in deciding the best therapeutic management options for the patients.

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Original Article

Platelet-Rich Plasma versus Injectable Platelet-Rich Fibrin – A Randomized Control Trial

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Abstract

Introduction: Platelet-rich plasma (PRP) is a source of growth factors derived from a platelet concentrate obtained by centrifugation and is being used in hair regrowth in patients of androgenetic alopecia (AGA). Injectable-platelet-rich fibrin (iPRF) is advanced version of platelet-rich fibrin in liquid form which can be injected and contains stem cells with high regenerative potential.

Objectives: The objectives of this study were to study the effect of PRP and iPRF in patients suffering from AGA. A study was done between Group A (PRP) and Group B (iPRF) and effects on hair growth, hair loss, and the total duration, for which results remained was done.

Materials and Methods: Fifteen patients in each Group A (PRP) and Group B (iPRF) underwent monthly administration, for a total 3 months duration.

Results: Hair density increased by18% at 3 months after applying PRP. Hair density increased by 24% at 3 months after applying iPRF. It was maintained 6 months after receiving treatment (mean 185.53 ± 68.20 hairs/cm^2) in PRP group, and (mean 198.53 ± 68.20 hairs/cm^2) in iPRF group.

Conclusion: Both PRP and iPRF can be used in treatment of hair loss in men, but iPRF has better results. However, further studies are required to prove its correct efficacy.

Key words: Alopecia, Growth factors, Hair regrowth, Injectable-platelet-rich fibrin, Platelet-rich plasma, Regeneration, Stem cells

INTRODUCTION

Androgenetic alopecia (AGA) is characterized by progressive miniaturization of hair follicles in the scalp. In men, it is due mainly to androgens and genetic predisposition. Progressive hair loss, leading to bald patches on the scalp, occurs in 50–60% of men at the age of 70 years.[1,2] Oral finasteride and topical minoxidil are the currently approved therapeutic options, but both are associated with side effects, and there is a need for a newer treatment modality.

Platelet-rich plasma (PRP) is a 3 to 8 times platelet-enhanced product of plasma. Platelets contain a variety of growth factors including transforming growth factor-β, VEGF, platelet-derived growth factor, insulin-like growth factor, and epithelial growth factor.[3]

Platelet-rich fibrin (PRF) contains accumulated platelets and the released cytokines in a fibrin clot.[4] Advanced-PRF™ (A-PRF™) and injectable-PRF (i-PRF) are different from conventional PRF and are based on the concept that low speed of centrifugation yields maximum results and significantly higher number of leukocytes, platelets, and growth factor concentration-enhancing the regeneration process.

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MATERIALS AND METHODS

The study was done as a randomized control trial in patients attending outpatient department clinic at Shafia Skin Centre and Dr Rizvi's Multispeciality Clinic.

Thirty patients under 45 years of age were screened with diagnosis of AGA and no known history of malignant

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neoplasms, acquired immunodeficiency syndrome, hepatitis B, hepatitis C, or susceptibility to keloid scarring. Furthermore, none of the patients were receiving longstanding non-steroidal anti-inflammatory drugs or had active skin lesions in the areas affected by AGA. According to the Norwood–Hamilton classification, cases were divided as type I to type VII. Fifteen patients were treated with PRP and other 15 with iPRF. The baseline platelet count in patients had to be >140,000 platelets/μL. PRP and iPRF were done at 1 month interval and results were noted at the end of 3 months in both the group. Each patient was examined to locate the area with lowest hair density.

An area 1 cm^2 was marked and the hair in that area shaved. A metric tape measure graduated in centimeters was used to mark the square centimeter and the longitudinal distance from the corresponding end of the eyebrow or nasal root was measured. The image of the area was then amplified using a portable dermatoscope and a photograph was taken before each injection. This photograph was then magnified to permit manual counting.

PRP Preparation

PRP was prepared under sterile conditions, taking an 20 mL sample of peripheral blood through a scalp vein catheter and dividing it into 10 ml each and then transferred into a 10 ml tube that contained 1 mL of sodium citrate 3.8% and then centrifuged in a swing out rotor centrifuge (Remi Centrifuge) at 3000 rpm for 20 min.

PRF Preparation

iPRF was prepared under sterile conditions, taking a 20 mL sample of peripheral blood through a scalp vein catheter and dividing it into 10 ml each and then transferred into a 10 ml plain tube (without any anticoagulant) centrifuged in a swing out rotor centrifuge at 700 rpm for 4 min. iPRF is yellow-reddish fluid collected at the top and is separated by a dark layer at the bottom. Each 10 ml of whole blood gives 1 ml of iPRF.

Preparation of Scalp

Patients were advised to clean there scalp with shampoo at the day of PRP or iPRF therapy. The scalp is cleaned with betadine and a eutectic mixture of cream containing 2.5% of lignocane and prilocaine each was applied on the scalp for 40 min, to get the anesthetic effect. Thereafter, the scalp is cleaned with sterile gauze piece. PRP and iPRF are filled in insulin syringes and intradermal injections at a distance of 1 cm are given on scalp. A vibrator is inserted in a glove to keep the field sterile post procedure, patients were asked not to wash their head for 8 h, and to avoid exposure to sun or dust, and cover their head and restrict heavy weightlifting for 2 days. Paracetamol 650 mg was given if any patient complained of pain at injection site.

RESULTS

Thirty men with diagnosis of AGA were selected and enrolled in the study between September 2019 and March 2022. None were excluded from the study. Our study cohort comprised patients aged between 17 and 42 years (mean 26.7 ± 4.7 years). Stage 3 and 3 vertex, according to the Norwood scale, were the most frequent patterns (eight patients each, that is, 26.7%). Twenty-eight patients (93.3%) had a family history of AGA. Hair density increased by 18% at 3 months after applying PRP (165.0 ± 21 hairs/cm^2 before treatment to 194.0 ± 51 hairs/cm^2 after 3 months). This increase was significant and maintained 6 months after receiving treatment (mean 185.53 ± 68.20 hairs/cm^2, Friedman test, $P < 0.0001$) [Figures 1 and 2].

Hair density increased by 24.% at 3 months after applying iPRF (165.0 ± 21hairs/cm^2 before treatment to 204.0 ± 51 hairs/cm^2 after 3 months). This increase was also significant and maintained 6 months after receiving

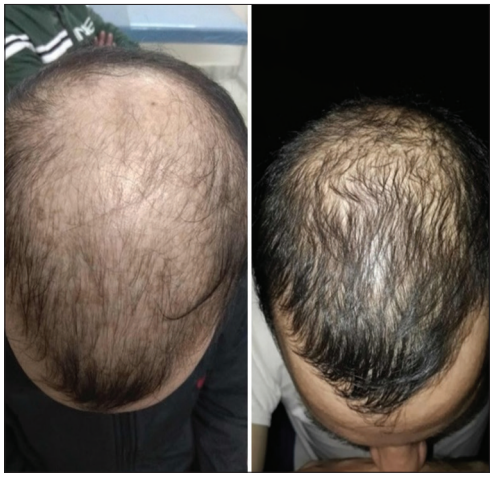

Figure 1: Before and after 6 months of treatment

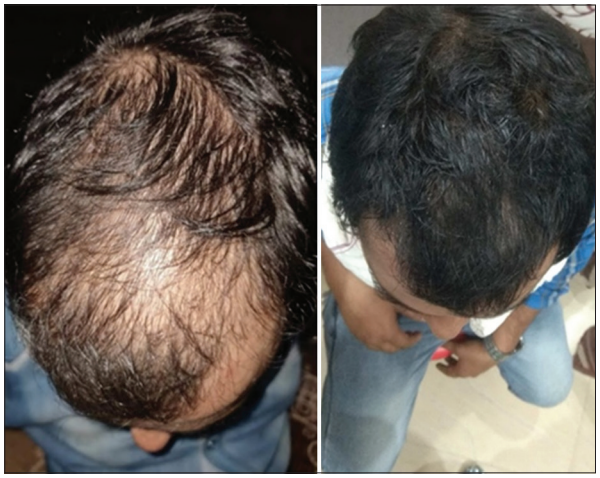

Figure 2: Before and after 6 months of treatment

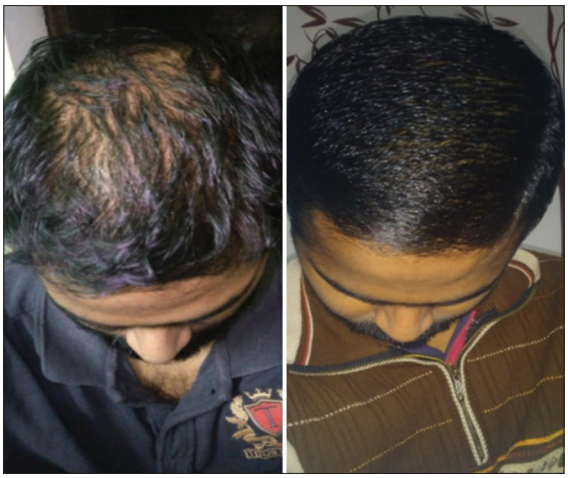

Figure 3: Before and after 6 months of treatment

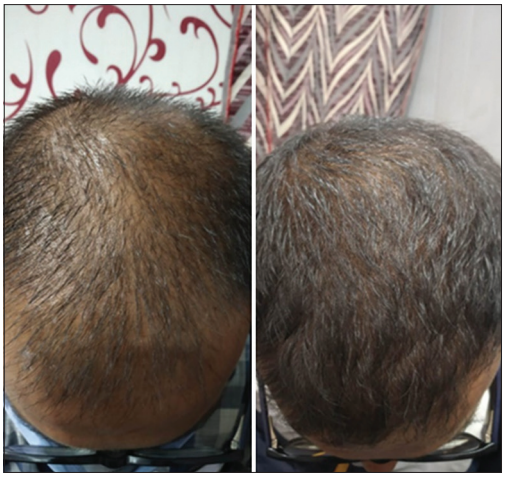

Figure 4: Before and after 6 months of treatment

treatment (mean 198.53 ± 68.20 hairs/cm^2, Friedman test, $P < 0.0001$) [Figures 3 and 4]. Side effects of both included tolerable injection site pain during each injection and minimal bleeding. There was no difference in pain or bleeding in both the groups. In our cohort, an increase in hair density by 10–20% was the outcome observed with greatest frequency (in 33% of patients [5/15]). In addition, in 6.7% of patients (2/30), an increase of more than 50% in hair density was observed [Figures 3 and 4]. However, at 6 months after performing the PRP injection, a decrease was demonstrated in hair density in 13.3% of patients (4/30) [Table 1]. In addition, we observed a correlation between efficacy of the application of PRP and type of AGA (Fisher exact test, $P = 0.04$). The pattern with least response was stage 3 vortex (only 37.5% of patients responded positively). However, the efficacy rate was 100% for stages 1, 3, and 4; 83.33% for stage 2; and 75% for stage 5. There was no correlation between a favorable response and patient age (Fisher exact test, $P = 0.5$) or duration of AGA (Fisher exact test, $P = 0.7$) [Table 2].

Table 1: Result in PRP group

Percentage Increase	Number of patients	Percentage
<10	2	13.3
10–20	6	39.6
20–50	4	26.4
>50	1	6.6
Decrease after 6 months	2	13.3

Table 2: Result in iPRF group

Percentage Increase	Number of patients	Percentage
<10	2	13.2
10–20	4	26.4
20–50	7	46.2
>50	1	6.7
Decrease	1	6.7

DISCUSSION

There are various treatment options available to treat AGA, such as, hair transplant, medications such as finasteride, and Minoxidil with low-level laser light therapy.[5] Most studies[6,7] using PRP for hair growth have shown good results, but the emerging iPRF uses as a treatment modality needed to be quantitated against the former. Masuki *et al*.[8] stated that A-PRF has a high concentration of white blood cells (WBCs) and platelets, whereas in PRP inflammatory cytokines were not present in high levels and there was no positive correlation between WBC counts and pro-inflammatory cytokine observed. Based on their study, authors concluded that i-PRF contains a higher amount of growth factors as compared to PRP, which not only functions as a scaffold but also a reservoir of growth factors.

Both PRP and PRF are platelet concentrates; however, double centrifugation processes, the addition of anticoagulants. PRF is one such platelet concentrate which requires one spin and does not use anticoagulants for its procurement.[1] Its three-dimensional fibrin network mimics the extracellular matrix in terms of its structure,[9] which creates the environment for cells to function optimally.

CONCLUSION

From the above study, it can be concluded, that both PRP and iPRF can be used for hair growth in patients with AGA. They both have a good result in, reducing hair fall, increasing hair density and have a good safety profile. Clearly, iPRF has better result than PRP in all the patients, and the results are also sustained for a long time. However, further studies are required to demonstrate its correct efficacy.

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Original Article

Assessment of Sociodemographic Profile, Severity, and Suicidality of Generalized Anxiety Disorder Patients Attending a Tertiary Care Hospital

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Abstract

Background: Generalized anxiety disorder (GAD) is characterized by an uncontrollable worry, for most days of a week, lasting more than 6 months, and causing significant impairment. It is usually associated with elements of apprehension, motor tension, and autonomic overactivity. Anxiety disorders have consistently been associated with an increase in suicidal behavior. It is often associated with lethal or near-lethal suicidal acts.

Purpose: The aim of the study was to assess the sociodemographic profile, severity, and suicidality of GAD patients attending a tertiary care hospital.

Materials and Methods: This was a hospital-based cross-sectional study. A total of 42 patients attending psychiatric services of a tertiary care hospital were taken up during the study period. Patients were diagnosed with GAD as per International Classification of Diseases, Revision-10, fulfilling inclusion and exclusion criteria. Sociodemographic parameters were assessed. The severity of GAD was assessed by Hamilton Anxiety Rating Scale (HAM-A). Suicidality was assessed by Mini International Neuropsychiatric Interview 5.0 (for suicidality). The statistical analysis of data was performed using Statistical Package for the Social Sciences for Windows (version 21.0. Chicago, SPSS Inc.) and Microsoft Excel 2010.

Results: The majority (38.10%) of the cases were of moderate severity. The mean HAM-A score was 23.07 ± 7.31. It was found that 11.90% of cases were not suicidal, the most of the cases (42.86%) were moderately suicidal and 14.29% cases were highly suicidal. High suicidal cases had the most elevated HAM-A score. The f-ratio value was 10.33835. By performing an Analysis of Variance test, these findings were statistically found to be significant (p-value <0.05).

Conclusion: Understanding the associations between the individual with anxiety disorder and suicidal behavior may help to reduce suicide rates.

Key words: Generalized anxiety disorder, Hamilton anxiety rating scale, Severity, Sociodemographic profile, Suicidality

INTRODUCTION

Generalized anxiety disorder (GAD) is characterized by an uncontrollable worry, more days than not, lasting >6 months, and causing significant impairment. There must be at least three of the following six symptoms: "Restlessness or feeling agitated or on edge; easily fatigued; difficulty concentrating or mind going blank; irritability; muscle tension; or disturbed sleep". All three symptoms need not be present simultaneously every day. Most of the time, GAD patients tend to exaggerate the likelihood and severity of the stressor to the point where catastrophe seems possible, likely, and imminent.[1] The anxiety should be generalized and persistent (i.e., free-floating). The sufferer must have primary symptoms for most days for at least several weeks at a time, usually for several months. It is usually associated with elements of apprehension, motor tension, and autonomic overactivity.[2]

GAD is a common condition; its 1-year prevalence range from 3% to 8%. The women to men ratio are

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2:1. A lifetime prevalence is close to 5% with the Epidemiological Catchment Area study suggesting a lifetime prevalence as high as 8%. About 25% of anxiety disorder patients have GAD with onset in late adolescence or early adulthood usually, also commonly seen in older adults. Often coexists with another mental disorders such as social phobia, specific phobia, panic disorder, or a depressive disorder, dysthymic disorder, and substance-related disorders.[3]

Suicide is defined as an act of self-inflicted self-intentioned cessation. It is a condition where a person under life stressors take himself into a cascade of noxious thoughts ultimately leading to a perception that the termination of one's life is the only solution for a seemingly intolerable life situation. In vulnerable individuals, this perceptual constriction gets translated into effective action.[4] According to the definition, suicidality includes completed suicide, suicide attempt, preparatory acts toward imminent suicidal behavior, and suicidal ideation.[5]

Anxiety disorders have frequently been associated with an increase in suicidal behavior in many studies.[6,7] A study shows that individuals who attempt suicide are more likely to be diagnosed with an anxiety disorder than those who do not attempt suicide, hence, concluding that anxiety is a correlate of suicidal behavior as well as a risk factor for suicidal behavior.[8] According to the Beck's cognitive model of suicide; anxiety (and agitation) can serve as an expression of attentional fixation on suicide, which interacts with hopelessness to increase suicide risk.[9] Joiner's interpersonal theory of suicide stated that the fearsome nature of suicidal behavior is consistent with symptoms showing anxious states (e.g., heightened arousal and agitation) and is often associated immediately before lethal or near-lethal suicidal acts.[10] Baumeister described that suicide results due to motivations to escape from unpleasant self-awareness as it generates negative affect, which often includes anxiety.[11] Disorders with anxiety/agitation as characteristic symptoms (i.e., GAD, social phobia, and PTSD) are often predictive of the transition from suicidal ideation to non-lethal suicide attempts.[12] Riskind and colleagues have theorized that a specific cognitive risk factor for anxiety (looming vulnerability), when coupled with hopelessness, enhances urges to escape psychological pain and increases the risk for suicide.[13-15] However, recent studies have provided strong support for elevated suicide risk in individuals with anxiety disorders independent of other psychiatric conditions.[13]

As there are limited studies on GAD and suicidality in our region, it has prompted us to take up this study. The primary purpose of this study was to assess the sociodemographic parameters, severity, and suicidality among GAD patients.

MATERIALS AND METHODS

Study Design and Sample

This was a hospital-based cross-sectional study. The sample for the study was drawn from the patients attending the psychiatry outpatient services in the Department of Psychiatry, at a tertiary care hospital during the study period. The study proposal was submitted to the Institutional Ethics Committee for review and appraisal and the study was undertaken after approval. Written consent was acquired from every participant and they were free to withdraw from the study at any point in time. All consecutive cases fulfilling the inclusion and exclusion criteria were taken for the study. The inclusion criteria were: (a) Patients of all ages, (b) patients of both sexes, and (c) patients diagnosed with GAD as per International Classification of Diseases, Revision-10 (ICD-10). The patients with the following conditions were excluded from the study: (a) Those with comorbid mental illness including mental subnormality, dementia, substance-related disorder, etc., (b) those with comorbid physical illness, (c) patients on cytotoxic chemotherapy, (d) pregnancy, and (e) patients on anxiety-producing drugs. A total of 42 participants/patients were taken up for the study in a duration of 1 year.

Assessment Tools

(a) Semi-structured Proforma for sociodemographic data. This contained the personal identification data of the patients such as the name, age, sex, marital status, religion, residential address, education, occupation, hospital number, and phone number. Records such as the total monthly income of the family and domicile were also obtained. (b) Modified Kuppuswamy's Socioeconomic Status Scale (2017) was used which is based on a composite score considering the education and occupation of the head of the family, also the monthly income of the family. The changes in the scale of income are proportional to the change in the consumer price index numbers for industrial workers (CPI-IW). The latest CPI-(IW) available for January 2017 has been calculated taking 2001 as the base year.[16] (c) The ICD-10 Classification of Mental and Behavioural Disorders. (d) Hamilton Anxiety Rating Scale (HAM-A) was used to assess the severity of anxiety. It is one of the first rating scales developed in the late 1950s to measure the severity of anxiety symptoms (both somatic and cognitive) which is still used in both clinical and research settings. There are 14 items and it takes 10–15 min to complete the interview. Each item is rated from 0 (not present) to 4 (severe) with the total score ranging from 0 to 56. The grading is as follows: (1) ≤17 = Mild Anxiety, (2) 18–24 = Moderate Anxiety, and (3) ≥25 = Severe Anxiety. This is also a clinician-rated scale. Reliability is fairly good and appears to be acceptable based on internal consistency, interrater, and test-retest studies. Validity appears good based on

correlation with other anxiety scales.[17] (e) Mini International Neuropsychiatric Interview (M.I.N.I) 5.0 (for Suicidality) is a short structured diagnostic interview for DSM-IV and ICD-10 psychiatric disorders (major Axis I), developed jointly by psychiatrists and clinicians in the United States and Europe. It was designed for short but accurate structured psychiatric interviews for multicentric clinical trials and epidemiological studies and also has been used as the first step in outcome tracking in non-research clinical settings. Validation and reliability studies have been done comparing the M.I.N.I. to the SCID-P and the CIDI. It has acceptably high validation and reliability scores and can be administered in a much shorter time (mean 18.7 ± 11.6 min and median 15 min) than the above-referenced assessment tools. It can be used by clinicians, after a brief training session. The M.I.N.I. is divided into modules identified by letters, each corresponding to a diagnostic category. For suicidality, there were six questions and the rating is done at the right of each question by circling either YES or NO, and grading is done as low, moderate, and high.[18,19]

Data Analysis

The statistical analysis of data was performed using the computer program, Statistical Package for the Social Sciences (SPSS for Windows, version 21.0. Chicago, SPSS Inc.) and Microsoft Excel 2010. The outcome of continuous measurements is presented as mean ± standard deviation. F-ratio value was calculated and the analysis of variance (ANOVA) test was done. Discrete data are expressed as numbers (%). For analyses, the statistical significance was fixed at a 5% level ($P < 0.05$). The F-ratio is the ratio of two mean square values. F-value is expected to be around 1.0, if the null hypothesis is true. Large F-ratio means that the variation among means is more than you did expect to see. ANOVA is an appropriate method to compare means of more than two groups instead of a t-test. The interest of ANOVA is on the locations of the distributions represented by means too. The relative location of the several group means can be more conveniently identified by variance among the group means than comparing many groups means directly when the number of means is large.[20]

RESULTS

During the study period of 1 year, 42 cases of GAD were taken up. The sociodemographic parameters were assessed and tabulated in Table 1. Among these cases, it was found that the most of the participants were Hindu (90.48%) by religion, whereas 7.14% were Islam and 2.38% were Christian by religion. About 78.57% of cases were from a rural background and 21.43% were from an urban background. The majority of cases of the study group were married (64.29% of cases), 33.33% of cases were unmarried, and 2.38% of cases were widow. The majority of the study groups were high school graduates (30.95% of cases). About 26.19% were educated up to middle school, 21.43% were graduates or post-graduates, 14.29% were intermediate or post-high school diploma, and 7.14% were illiterate. About 26.19% were skilled workers, 21.43% were clerical, shop owner or farmer, 16.67% were semi-skilled workers, 14.29% were professional workers, another 14.29% were unemployed, and 7.14% were semi-professional workers. In our study, it has been found that 35.71% were from the lower middle class (III), 28.57% were from the upper-middle class (II), another 28.57% were from the upper lower class (IV), and 7.14% were from upper class (I).

Table 1: Sociodemographic parameters of cases

Variables	Study Group	
	n=42	%
Religion		
Hindu	38	90.48
Islam	3	7.14
Christian	1	2.38
Others	0	0.00
Locality		
Rural	33	78.57
Urban	9	21.43
Marital Status		
Married	27	64.29
Unmarried	14	33.33
Widow	1	2.38
Separated/divorced	0	0.00
Education		
Professional degree or honors	0	0.00
Graduate or postgraduate	9	21.43
Intermediate or Post High School Diploma	6	14.29
High School Certificate	13	30.95
Middle School Certificate	11	26.19
Primary School Certificate	0	0.00
Illiterate	3	7.14
Occupation		
Profession	6	14.29
Semi-profession	3	7.14
Clerical, shop-owner, and farmer	9	21.43
Skilled worker	11	26.19
Semi-skilled worker	7	16.67
Unskilled worker	0	0.00
Unemployed	6	14.29
Socioeconomic Status		
Upper (I)	3	7.14
Upper Middle (II)	12	28.57
Lower Middle (III)	15	35.71
Upper lower (IV)	12	28.57
Lower	0	0.00

The distribution of GAD cases according to the severity is tabulated in Table 2. It was found that most (38.10%) of the cases were of moderate severity followed by 35.71% who were severe cases and 26.19% were mild cases. Here, the mean HAM-A score was 23.07 ± 7.31. The distribution of GAD cases according to the severity of is tabulated in Table 3. It

was found that 11.90% of cases were not suicidal, 30.95% of cases had low suicidality, 42.86% of cases were moderately suicidal, and 14.29% of cases were highly suicidal.

The relationship between severity of GAD cases and suicidality is tabulated in Table 4. In this study, cases having no suicidality had a mean HAM-A score of 19.00 ± 3.81, low suicidality had a mean HAM-A score of 17.08 ± 3.30, moderate suicidality had a mean HAM-A score of 26.50 ± 7.33, and high suicidality had a mean HAM-A score of 29.17 ± 4.54. Hence, high suicidal cases had the most elevated HAM-A score, followed by moderately suicidal cases. The f-ratio value is 10.33835. By performing an ANOVA test, these findings were statistically found to be significant ($P < 0.05$).

DISCUSSIONS

This study was a sincere attempt to assess sociodemographic parameters as well as to assess the relationship of severity and suicidality of GAD cases. At the end, data related to 42 GAD patients were interpreted. The majority of the participants were Hindu by religion due to the predominance of the Hindu population in the region. However, it was found in various studies that religion in general, along with spirituality, faith, and prayer, was associated with reduced anxiety/stress.[21] Shared practices and having meaning and purpose in life tend to be stronger predictors for mental well-being than the content and strength of one's beliefs. Many studies show lower levels of anxiety among more religious people; a large number of studies reported no association; several studies reported mixed or complex results, whereas ten studies suggest greater severity of anxiety among the more religious.[22]

Table 2: Distribution of generalized anxiety disorder cases according to the severity (as per HAM-A score)

Severity of GAD	HAM–A* Score	Study Group	
		Number (*n*)	Percentage
Mild	≤17	11	26.19
Moderate	18–24	16	38.10
Severe	≥25	15	35.71
Total		42	100.00
Mean±S.D. (HAM-A Score)		23.07±7.31	

*HAM-A: Hamilton anxiety rating scale (total score ranging from 0 to 56), GAD: Generalized anxiety disorder

Table 3: Distribution of generalized anxiety disorder cases according to the severity of suicidality (MINI 5.0)

Severity of suicidality (M.I.N.I. 5.0)**	Study Group	
	Number (*n*)	Percentage
No Suicidality	5	11.90
Low	13	30.95
Moderate	18	42.86
High	6	14.29
Total	42	100.00

**MINI 5.0: Mini-international neuropsychiatric interview

The majority of the cases were from rural backgrounds in our study which might be because the location of the hospital is in the vicinity of the rural population, contrary to a study where the urban communities had higher prevalence rates (35.7% vs. 13.9%; $P < 0.01$) than rural communities.[23] In a meta-analysis, by Ganguli in 2000, it was found that anxiety neurosis was reported to be marginally higher in prevalence in urban settings than in rural settings (106:100).[24] However, there are no specific study findings on GAD.

The most of the cases were married in our study, which indicates that marriage is not a protective factor against the development of GAD. Earlier studies have suggested that individuals with GAD report significantly higher levels of marital distress and are at a greater risk for divorce.[25] Studies also showed that relationship problems among GAD patients predict poor treatment response and long-term outcomes. In a study, it was found that GAD was significantly associated with the likelihood of entering into a marriage-like relationship. The results support the continued investigation into the association between couple functioning and the onset, course, and treatment of GAD, and suggest that couple therapy could be an untapped resource for the treatment.[26] The majority of the study group were high school graduates only. In a study by Remes *et al.*, it was found that GAD is more prevalent among the high education group which is contrary to our study.[27] Students with anxiety disorder lack interest in learning, poor performance in examinations, and on assignments.[28] Low educational levels were significantly associated with both anxiety and depression.[29]

Table 4: Relationship between severity of suicidality (MINI 5.0) and mean HAM-A scores

Severity of suicidality (M.I.N.I. 5.0)	HAM-A Scores (Mean±SD)	F-value***	*P*-value**** (<0.05)
No Suicidality	19.00±3.81	10.33835	0.000041
Low	17.08±3.30		
Moderate	26.50±7.33		
High	29.17±4.54		

***F-value: Ratio of two mean square values, expected to be around 1.0, if the null hypothesis is true, ****P<0.05, MINI: Mini-international neuropsychiatric interview, HAM-A: Hamilton anxiety rating scale

In this study, majority were skilled workers. In a study conducted by Mallik *et al.,* it was found that anxiety was most common among unskilled workers and businessmen.[30] According to the Kuppuswamy's socioeconomic status scale (modified), 35.71% were from a lower middle class (III), 28.57% were from an upper middle class (II), another 28.57% were from an upper lower class (IV), and 7.14% were from the upper class (I). In a study by Mallik *et al*, the most of the patients suffering from anxiety belonged to socioeconomic status IV, followed by socioeconomic V and VI, and 6% belonged to the upper class, according to the modified B.G Prasad Scale.[30]

In our study, it was found that the majority of GAD cases were moderate in severity, followed by severe cases and mild cases, which is consistent with the findings by Rollman *et al*, who found that 59% patients with GAD reported a moderate or greater level of anxiety symptoms on the Structured Interview Guide for the HAM-A.[31]

We have also found that the majority of GAD patients were moderately suicidal, followed by low suicidality, severe suicidality, and no suicidality, respectively, which is, however, a unique finding as no study has compared the severity of suicidality in patients of GAD. People with threshold or subthreshold GAD were significantly more likely to report suicidal ideation compared with people who did not have GAD.[32] In our study, high suicidal cases of GAD had the most elevated HAM-A score, which is consistent with the findings of Choi *et al*., who suggested that an increase of significant suicidal ideation was associated with more severe anxiety symptoms.[33] In another study, MINI interview was used to screen medical students, and a significant number have showed GAD (32.7%) and risk of suicide (30.2%).[34] In an Indian study, 20.2% participants were found to have anxiety disorders (moderate-to-severe) and 29.6% students were found to have a suicidal risk.[35]

CONCLUSION

The present study demonstrated that high suicidal cases of GAD had the most elevated HAM-A score, that is, increase in severity of GAD causes an increase in severity of suicidality. Understanding the associations between the individual with anxiety disorders and suicidal behaviors may help to reduce suicide rates. Hence, clinicians must carefully assess for suicidality among patients presenting with anxiety problems and treat timely.

LIMITATIONS OF THE STUDY

1. This was a one-time cross-sectional assessment study that lacked follow-up. It would be better if the GAD patients would have also been evaluated for the relationship between severity and suicidality before and after pharmacotherapy to establish whether severity can be used as an indicator of suicidality
2. The sample size of the study groups was relatively small and this study is hospital-based. Hence, the findings cannot be generalized to a larger community population
3. The study groups were not compared to age- and sex-matched control groups
4. Comorbidities were not taken into consideration.

STRENGTHS OF THE STUDY

This study has evaluated the severity and suicidality of GAD cases and the relationship between severity and suicidality was established. There is a limited research on this topic in our country. To the best of our knowledge, no study to date studied the relationship between severity of GAD and suicidality.

FUTURE IMPLICATIONS

The present study has revealed the relation between severity of GAD and suicidality. Hence, further research has to be carried out to use severity grading of GAD as an indicator of suicidality, which will be helpful in early detection and prevention of suicide in GAD patients.

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Original Article

Evaluation and Correlation of Different Patterns of Diabetic Macular Edema with Systemic Risk Factors

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Abstract

Introduction: Diabetic macular edema (DME) is the leading cause of vision loss in patients with diabetic retinopathy. Various morphological patterns of DME have been studied based on the images of optical coherence tomography (OCT) and their risk factors have been implicated.

Aim: This study was done to evaluate and correlate morphological pattern of DME with systemic risk factors on OCT.

Materials and Methods: Five hundred consecutive diabetic patients were screened. Four morphological patterns: Diffuse retinal thickness (DRT), cystoid macular edema (CME), posterior hyaloid traction (PHT), and serous retinal detachment (SRD) were evaluated with systemic risk factors.

Results: About 14.4% patients had DME. DRT was the most common pattern identified (43.1%) followed by CME (29.2%). Mean age of patients with SRD was significantly high. Insulin users, smokers, alcoholics, female gender, and patients with higher body mass index and dyslipidemia had higher prevalence of CME pattern. Patients with SRD had significantly higher HbA1c level and altered renal function. The central macular thickness and mean total macular volume were highest in patients with CME and least in DRT pattern. The visual acuity was least affected in DRT and was most affected in CME pattern.

Conclusion: DRT was the most common morphological pattern. It was predominantly seen in males, patients with shorter duration of diabetes, and lower HbA1c levels. Female gender, insulin use, alcohol consumption, smoking, and deranged lipid profile were significant risk factors for CME. Old age, longer duration of diabetes, higher HbA1c levels, and impaired renal function significantly predisposed to SRD. The study suggests a significant correlation between increased macular volume and deterioration of vision.

Key words: Cystoid macular edema, Diabetic macular edema, Diffuse retinal thickness, Optical coherence tomography, Posterior hyaloid traction, Serous retinal detachment

INTRODUCTION

Diabetic macular edema (DME) is the leading cause of vision loss in patients with diabetic retinopathy (DR).[1] It is estimated that about 15–25% of the diabetic population have DR and everyone has the potential to develop it over a period of time.[2] The exact pathogenesis of the DME is unclear. It is apparent that chronic hyperglycemia is the trigger for inflammatory process and the release of vasoactive substances due to retinal hypoxia.[3]

Among the vasoactive substances, vascular endothelial growth factor (VEGF) plays a pivot role in the pathogenesis of DME.[4] It increases vasopermeability of vessels as a result, of which there is disruption of inner and outer retinal barriers leading to abnormal inflow of fluid into neurosensory retina. Inflammation is also shown to be involved in pathogenesis. The inflammatory process causes complement activation which brings an inflow of

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neutrophils causing endothelial damage leading to more vessel disruption.[5]

According to the early treatment DR study, clinically significant macular edema, that is, CSME is defined as thickening of retina at or within 500 mm of the center of fovea or hard exudates at or within 500 mm of the center of fovea or a zone of thickness one disk large, within 1 disk diameter of macula.

Optical coherence tomography (OCT) is a non-invasive, non-contact transpupillary imaging technique that allows cross-sectional images of retina.[6] With the scanning speed of 53,000 A-scan/sec, OCT allows the evaluation of macular thickness and vitreomacular surface by taking cross-sectional images of retina.[6] Various morphological patterns of DME have been studied based on the images of OCT, namely, diffuse retinal thickness (DRT), cystoid macular edema (CME), posterior hyaloid traction (PHT), and serous retinal detachment (SRD).[7]

The DRT is characterized by a sponge like retinal swelling with reduced intra retinal reflectivity, CME pattern is characterized by intraretinal cystoid spaces of low reflectivity with highly reflective septa separating cystoid-like cavities in the macular area, and PHT is described as a highly reflective layer from the inner retinal surface. SRD as pattern is characterized by a dome like shallow elevation of the retina, with an optically clear space between the retina and the retina pigment epithelium. Some studies in the literature have shown that the response to anti VEGF injections may vary with morphological patterns of DME which, in turn, is influenced by various systemic risk factors.[8,9]

The risk factors influencing the development of DME include age, sex, type of DM, insulin use, duration of diabetes, body mass index (BMI), consumption of alcohol and smoking, Hypertension, urine albumin levels, Hb1Ac, lipid profile, serum creatinine, and blood urea levels. The aim of the present prospective observational study was to evaluate and correlate morphological pattern of macular edema with systemic risk factors.

MATERIALS AND METHODS

After taking permission from the Institutional Ethics Committee, the study was conducted on both eyes of 500 consecutive patients of diabetes mellitus of both sexes and above the age of 18 years visiting the outpatient of Regional Institute of Ophthalmology in Northern India. Patients with history of ocular trauma or surgery, hazy ocular media, or any other associated retinal or macular pathology were excluded from the study. After recording history, a detailed physical examination, including measurement of systolic and diastolic blood pressure and calculation BMI was done. Comprehensive ocular examination of both the eyes of each patient including best-corrected visual acuity evaluation using Snellens chart, intraocular pressure measurement by applanation tonometer, slit-lamp examination, and fundus examination by both direct and indirect ophthalmoscopy using 90 D lens after dilating the pupil with commercially available phenylephrine (5%) and tropicamide drops. Optical coherence tomography of each eye was done to measure the macular characteristics using RS 330 Nidek machine.

Patients with DME on OCT were recruited in the study after taking informed consent in vernacular language while adhering to the tenets of the Declaration of Helsinki. OCT identifies the layers of retina and determines macular thickness by measuring the distance between the inner limiting membrane and the retinal pigment epithelium (RPE). The Macular Cube scan, comprising 6 mm square grid, was used to record the macular data. Each scan comprised 200 A-scans. Macular thickness map on OCT revealed central macular thickness in the center 1 mm of area and mean macular volume in three concentric rings of diameters 1, 3, and 6 mm. One eye of each patient was included for analysis. If both eyes of the same patient had the same pattern, the eye with higher CMT on OCT was included and if one of the eyes had DRT and the fellow eye had CME, the eye with CME was considered, if one eye had DRT or CME and the fellow eye had PHT, the eye with PHT was included and if one eye had DRT, CME or PHT and the other eye had SRD, and the eye with SRD was evaluated.

Laboratory investigation of each patient included fasting blood sugar, HbA1c, lipid profile, blood urea, and serum creatinine and urine examination for glucose and 24 h urine for albumin levels. On the basis of amount of albumin excreted in urine in 24 h, patients were divided into three groups of normoalbuminuria (<30 g/dl), microalbuminuria (30–299 mg/dl), and macroalbuminuria (>300 mg/dl).

Statistical Analysis

Statistical analysis was done using statistics software SPSS 21, IBM, USA. Pearson's Chi-squared test was used to determine whether there is a statistically significant difference between the expected frequencies and the observed frequencies in one or more categories. *t*-test and analysis of variance analysis were used to differentiate means among the two or more groups.

RESULTS

In the present prospective observational study out of 500 diabetic patients examined, 72 (14.4%) patients with DME

were recruited in the study. About 56.9% (41) patients were male and 43.1% (31) patients were female. Their mean age was 55.72 years and mean duration of diabetes was 9.93 years. On OCT, 31 (43.06%) patients had DRT, 21 (29.17%) CME, 13 (18.06%) PHT, and 7(9.72%) patients had SRD patterns.

Mean age of patients with SRD was significantly higher than patients with DRT, CME, or PHT. Predominant morphological pattern observed in males was DRT (34.7%), while in females was CME (20.8%). Insulin users, smokers, alcoholics, and patients with higher BMI and dyslipidemia showed significantly higher prevalence of CME pattern compared to DRT, PHT, or SRD, whereas patients with SRD had significantly higher HbA1c level and altered renal function. Association of hypertension with patterns of DME was not found to be significant [Tables 1 and 2] [Figure 1].

DISCUSSION

DME is the leading cause of blindness among patients with DR. This calls for the early diagnosis and follow-up of the patients to prevent or start early treatments. In DR, Muller cells are affected as a result of which interstitial fluid accumulates in the layers of the retina which is observed as DRT pattern on OCT [Figure 2a].[10] Subsequently, the long-standing fluid accumulation gives rise to liquefactive necrosis of Muller cells leading to cystic spaces formation and is observed as CME pattern on OCT [Figure 2b].[11] The pathophysiology of PHT is thought to be due to either vitreous changes in the premacular region or due to DR causing edema and traction [Figure 2c].[7] In advanced stage of diabetes, RPE function gets impaired causing accumulation of fluid between the neurosensory retina and RPE leading to retinal detachment which is seen as SRD on OCT [Figure 2d]. Since the main pathophysiology of DME is the presence of fluid between the layers of retina, OCT makes it easy to study DME and thus classify it into different morphological patterns.

Different morphological patterns of DME on OCT can predict the outcome and response to various treatment strategies which can lead to early start of treatment and can halt the progression of DME.[8,9] Studies in the literature have classified the DME patterns differently. Kim *et al.*[7] classified DME based on OCT as DRT, CME, PHT, SRD, and traction retinal detachment (TRD). Alkuraya *et al.*[12] classified DME as sponge-like retinal swellings as type 1, CME as type 2, SRD as type 3, and vitreofoveal traction as type 4, whereas Yassin *et al.*[13] and Otani *et al.*[14] classified DME into DRT, CME, and SRD subgroups. Out of 500 patients with DM, 72 patients (14.4%) presented with DME which was similar to results seen in a study done by Wong *et al.* (16.3%)[15] and Luxmi *et al.*,[16] whereas only 7.48% of patients were found with DME in a study done by Yau *et al.*[17] Mean CMT of the study group was 413.1528

Table 1: Showing clinicodemographic data of patients

Parameters	DRT	CME	PHT	SRD	*P*-value
Age (Mean±SD)	48.55±2.71	57.52±2.73	61.85±2.54	70.71±4.82	<0.001
Male (%)	25 (34.7)	6 (8.3)	6 (8.3)	4 (5.6)	<0.002
Female (%)	6 (8.3)	15 (20.8)	7 (9.7)	3 (4.2)	<0.002
Duration of Diabetes (Mean±SD)	4.52±2.77	11.76±1.97	14.00±3.19	20.86±3.58	<0.001
Insulin Use (Yes [%])	0 (0)	14 (19.4)	5 (6.9)	3 (4.2)	<0.001
Smoking (Yes [%])	4 (5.6)	12 (16.7)	-	-	<0.001
Alcohol Use (Yes [%])	1 (1.4)	12 (16.7)	-	-	<0.001
Hypertension (Yes [%])	22 (30.6)	11 (15.3)	10 (13.9)	6 (8.3)	>0.05
Mean BMI (Mean±SD)	22.22±1.87	27.96±2.55	23.38±2.23	23.45±2.89	<0.001
HbA1c (Mean±SD)	7.19±0.76	8.56±1.04	10.09±1.76	11.53±1.35	<0.001
Total Cholesterol (Mean±SD)	157.76±33.56	270.92±52.04	186.31±63.74	173.29±31.42	<0.001
Serum Triglyceride (Mean±SD)	138.75±40.22	256.59±83.44	176.85±48.03	168.14±36.41	<0.001
Serum LDL (Mean±SD)	95.01±18.50	125.20±39.93	110.71±40.12	106.86±28.91	<0.05
Serum Creatinine (Mean±SD)	0.78±0.27	1.32±0.58	1.06±0.38	1.36±0.50	<0.001
Blood Urea (Mean±SD)	38.21±3.26	55.28±23.71	45.70±19.86	59.86±31.38	<0.05
Albuminuria-Macro	0 (0)	0 (0)	1 (1.4)	5 (6.9)	<0.001
Albuminuria-Micro	2 (2.8)	12 (16.7)	4 (5.6)	1 (1.4)	<0.001

DRT: Diffuse retinal thickness, CME: Cystoid macular edema, PHT: Posterior hyaloid traction, SRD: Serous retinal detachment

Table 2 : Macular parameters and visual acuity and its correlation with different patterns of DME

Macular parameters	DRT	CME	PHT	SRD	*P*-value
Central Macular Thickness (Mean±SD)	323.06±18.32	533.14±65.01	414.46±55.05	449.71±49.83	<0.001
Macular Volume (Mean±SD)	9.43±0.69	13.12±2.13	10.62±1.73	10.36±1.13	<0.001
Visual Acuity (logMAR) (Mean±SD)	0.34±0.074	1.21±0.40	0.59±0.06	0.77±0.07	<0.001

DRT: Diffuse retinal thickness, CME: Cystoid macular edema, PHT: Posterior hyaloid traction, SRD: Serous retinal detachment

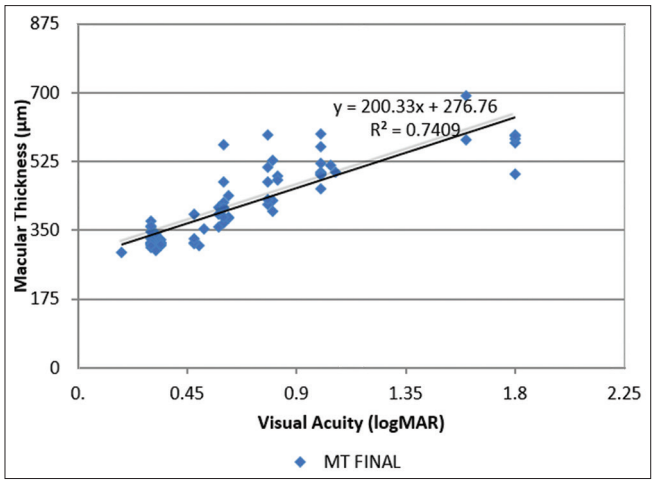

Figure 1: Showing correlation between macular thickness and visual acuity

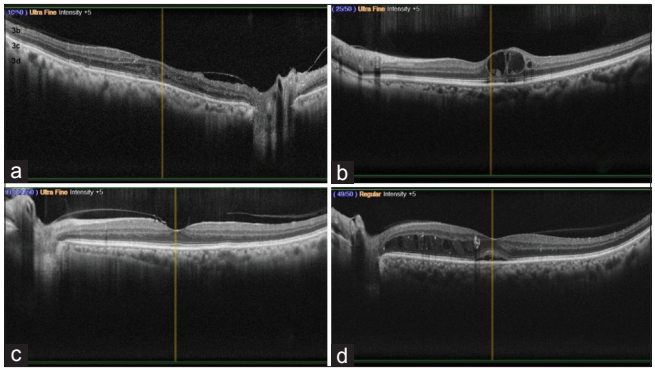

Figure 2: Optical coherence tomography scans showing (a) diffuse retinal thickness, (b) cystoid macular edema, (c) posterior hyaloid traction, and (d) serous retinal detachment

± 99.94106 and mean total macular volume of the study was 10.8113 ± 2.13107.

In this study, four morphological patterns of DME were observed on OCT, that is, DRT, CME, PHT, and SRD. In our study, 31 patients (43.1%) had DRT, 21 patients (29.2%) had CME, 13 (18.1%) patients had PHT, and 7 (9.7%) patients had SRD on OCT. The mean macular thickness was significantly high in patients with CME (33.14 ± 65.00) when compared with macular thickness in DRT (323.06 ± 18.31), PHT (414.46±55.05), and SRD (449.71±49.83). Similarly, Acan *et al.*[10] also observed the highest mean CMT in CME pattern (593.7 ± 165.3) and the lowest in DRT (313.6 ± 94.7). On the contrast, Kim *et al.*[7] showed highest mean CMT in patients with PHT and TRD. Mean total macular volume was highest in patients with cystoid pattern (13.12 ± 2.133) and least in DRT pattern (9.42 ± 0.69). The difference was highly significant ($P < 0.001$).

Similar to our observations, DRT was the predominant morphological pattern reported by Kim *et al.*[7] (39.5%), Acan *et al.*[10] (36.8%), and Luxmi *et al.*[16] (59.8%). It was followed by CME in 29.2% in our study, 21.8% by Luxmi *et al.*,[16] and 24.7% by Qureshi *et al.*,[18] whereas Otani *et al.*[14] reported DRT in 88%, CME in 47%, and SRD in 15% of all his patients. Figures were apparently higher as compared to our study as they had reported prevalence of morphology inclusive of all combination of patterns of maculopathy, whereas we considered only the worst grade of maculopathy.

Predominant morphological pattern observed in males was DRT (34.7%), while in females was CME (20.8%). Out of 31 patients of DRT, 25 (80.6%) were male and out of 21 patients with CME, 15 (71.4%) were female. Acan *et al.*[10] showed no significant difference between the DME patterns in respect of gender, whereas Luxmi *et al.*[16] reported that 42.3% of male patients had DRT pattern, while 100% female diabetics had CME.

The mean age of patients with SRD pattern was 70.71 ± 4.82 and that of DRT pattern was 48.55 ± 2.7. The difference was statistically significant ($P < 0.001$). No significant association of age was found by Luxmi *et al.*[16] and Acan *et al.*[10]

Mean duration of diabetes in patients with DME was longest (20.86±3.58 years) in SRD group and shortest (4.52±2.77 years) in DRT Group. In a study done by Luxmi *et al.*,[16] duration of diabetes in 47.4% of patients with CME and 31.3% of patients with SRD was as long as 20–40 years, whereas no significant association was observed by Acan *et al.*[10] Mean HbA1c in patients with SRD was 11.53 ± 1.35. It was significantly higher than in DRT (7.19 ± 0.76), CME (8.56 ± 1.04), and PHT (10.09 ± 1.76). This finding was consistent with the results recorded by Acan *et al.*[10] Both WESDR and DCCT have documented the affect of HbA1c level on the occurrence and progression of DME.[19] There are also studies in the literature that have postulated that with decrease of HbA1c, rate of DME, and subsequent micro vascular complications decrease.[20,21]

Total cholesterol level was significantly deranged in patients with CME (270.92 ± 52.04) compared to other morphological types of DME. Almost all patients had abnormal serum triglycerides levels with highest mean level of 256.58 ± 83.44 in patients with CME ($P = 0.000$). It was similar to the results by Luxmi *et al.*,[13] Zendar *et al.*,[22] and Gupta *et al.*[23] who concluded that majority of their patients with CME showed hypertriglyceridemia.

Similar to the results seen in studies by Zendar *et al.*[22] and Gupta *et al.*,[23] the mean serum LDL level in our study was within the normal range in patients with DRT and was deranged in non-DRT groups with significant high

levels in CME (P = 0.012). Studies in the literature have shown serum creatinine as an independent risk factor for maculopathy.[22,24] Aiello *et al.*[24] even confirmed reversal of macular edema after dialysis in some patients. We observed significant rise in serum creatinine (1.3 6 ± 0.49) and blood urea level (59.85 ± 31.37) in patients with SRD (P = 0.000). Likewise, Acan *et al.*[10] and Ghosh *et al.*[25] also found higher serum creatinine level in the SRD than in other patterns. Increased serum levels of urea and creatinine are significant markers for disruption of retinal photoreceptor external limiting membrane and inner segment ellipsoid zone in diabetics.[26] However, a study done by Ghosh *et al.*[25] did not show any correlation of blood urea with any type of DME.

About 34.7% of the patients in our study group showed albuminuria out of which 8.3% had macroalbuminura and 26.4% had microalbuminuria. Macroalbuminuria was significantly associated with SRD (83.3%), whereas microalbuminuria was significantly associated with CME (63.2%) P = 0.000. Study by Koo *et al.*[27] showed that serous type was more frequently seen in patients with albuminuria.

In our study, hypertension was not found to be significantly correlated with patterns of DME with (P = 0.265), while smokers, alcoholics, insulin users, and obese patients showed statistically higher prevalence of CME as compared to DRT, PHT, or SRD. Luxmi *et al.*[16] showed a positive correlation of insulin with CME (P = 0.003), whereas Acan *et al.*[10] showed no such correlation. In this study, only 22.2% patients were smokers and among them, the majority (75%) belonged to CME group P = 0.000. It was similar to the observations by Luxmi *et al.*,[16] (73.7%), but Romero *et al.*[28] showed no significant association between smoking and DME. Only 18% of the patients were alcoholic and majority (92.3%) of them showed CME pattern P = 0.000. None of the patient with PHT or SRD gave history of alcohol consumption. Acan *et al.*,[29] also in their study in Turkey, confirmed that DME was significantly associated with alcohol consumption.

Visual acuity was worst (1.21 ± 0.40 LogMAR) affected in CME pattern and least in DRT group (0.34 ± 0.074 LogMAR). The difference was statistically significant (P = 0.000) P = 0.000. Studies done by Yamamoto *et al.*,[30] Acan *et al.*,[10] and Ahmadpour-Baghdadabad *et al.*[31] also recorded visual acuity to be worse in CME as compared to other groups. In contrast to ours, studies done by Alkuraya *et al.*[12] and Yassin *et al.*[13] reported the worst visual acuity to be in vitreoretinal traction type and SRD, respectively.

CONCLUSION

Our study concludes that the most common pattern in 14.4% of patients with DME is DRT (43.1%) followed by CME (29.2%), PHT (18.1%), and SRD (9.7%). The mean age of patients with DRT pattern was minimum (48.55 ± 2.7) and maximum in SRD pattern (70.71 ± 4.82). Mean duration of diabetes was longest in SRD pattern (20.86 ± 3.58) and shortest in DRT pattern (4.52 ± 2.77). Male gender was correlated with higher prevalence of DRT and female gender with CME. CME is associated with use of insulin, smoking, alcohol consumption, and deranged lipid profile. Patients with deranged renal profiles and higher HbA1c level had significantly higher prevalence of SRD. Hypertension did not show any significant association with the study groups. A higher foveal thickness and increased total macular volume were associated with significant deterioration of visual acuity.

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Original Article

Music Therapy Session as Stress Buster among Diabetic: An Analysis by Heart Rate Variability

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Abstract

Introduction: Heart rate variability (HRV) is one of the important non-invasive measures to monitor the autonomic dysfunctions. Stressful experiences have been implicated in the modification of non-communicable diseases such as diabetes lifestyle modification and many adjunct modality such as music therapy contribute significantly apart from the pharmacological measures in the management of the diabetes. Music has been used with therapeutic purposes since ancient ages. In India, it is known as Raga Chikitsa. It is one of the effective nonpharmacological measures to combat the stress. There is paucity of data for use of raga-based Bollywood songs for music therapy; hence, we used collection of raga-based Bollywood songs for the session.

Materials and Methods: We evaluated 30 diabetics for the immediate effect of Music Therapy session by doing analysis of HRV using cardiac autonomic neuropathy analyzer. The data were subjected to Kubios analysis.

Result: It was found that there was fall in heart rate after (84.71 ± 9.13) MT session compared to before (93.9 ± 4.41) the session. The difference was statically significant (t = 6.31 and $P < 0.05$). The *t* test revealed statistically significant difference ($t = 2.77$ and $P < 0.05$) in the blood sugar level before (164 ± 39.8) and after (143 ± 23.3) music therapy session. The increase in the PNS index was statistically insignificant (t = 4.30 and $P > 0.05$). There was statistically significant decrease (t = 3.03 and $P < 0.05$) in the SNS index which is indicator of sympathetic activity of the body. Before session of therapy the overall stress index was 32.41 ± 5.1 it became 14.83 ± 5.46 after the session. The reduction in stress was statistically significant at 5% level (t = 2.91 and $P < 0.05$).

Conclusion: Hence, it can be concluded that music therapy using sessions of specific raga-based Bollywood songs can be stress buster among diabetics.

Key words: Diabetic, Heart rate variability, Music therapy

INTRODUCTION

Diabetes mellitus is one of the most common chronic disease all over the world. In 2020, according to the International Diabetes Federation, 463 million people have diabetes in the world and 77 million people belongs to India.[1] Stressful life, sedentary lifestyle, lack of exercise, eating habits, dietary factors, and environmental factors are some of the major reasons for rising trend of the diabetes worldwide. Stress management through lifestyle modification has become integral part of the diabetes treatment. Certain non-pharmacological measures such as music therapy restore the balance between sympathetic and parasympathetic and combat the stress. Music has been used worldwide for this purpose. Mozart,[2] in western, and Raga Chikitsa,[3] in Indian, subcontinent has been used widely for therapeutic purposes.

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Background of Music Therapy

Music therapy dates back to Pythagoras, who discovered that harmonic music is able to soothe people and cure ailments of the spirit, body, and soul. He believed that the mathematical nature of music influenced the mind and the body and termed it "musical medicine".[2]

Bruscia defined music therapy as systematic process of intervention, wherein the therapist helps the patient

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to achieve health, using musical experiences and the relationships that develop through them as dynamic forces of change.[4] Raga Chikitsa was written in the ancient times, which highlighted the usage of ragas for treatment of various ailments and the methodology to listen to such ragas for cures. Music deployed in a calibrated dosage which evokes a neural response. For the therapist, music as sound is – an instrument for creating the sensation of hearing, a transmission of controlled energy that is perceived by the ear, processed by the brain, and resonates in the energy centers of the body for restoring homeostasis.[5]

Practice of Music Therapy in View of Modern Medicine

Dr. Kinjalk founded the Kinjalk School of music therapy in 1996 to undertake clinical research in the field of music therapy. It focuses on the use of Indian musical forms as an adjunct to allopathic medicines. The technique invented by him KIMMA is used for identifying appropriate music for participants or patients as per their history, mood, suitability, and ailment. Patients are provided with an environment of medicine and music that have been reported to potentially help them in the management of stress-related disorders, hypertension, diabetes mellitus, depression, insomnia, anxiety state. KIMMA has been recognized as a landmark contribution in the field of music therapy.[6]

Apart from it, nowadays, many national organizations working in area of diabetes are also looking forward for the research in the field of adjunct modality in the management of diabetes. Dr. Sairam's Indian, music therapy association now started notion of music therapy in hospital set up. The local organizations in Chhattisgarh region such as Bilaspur Diabetes Society from Bilaspur CG, Yoga Research Unit from Govt CIMS Bilaspur, Department of Anatomy from AIIMS Raipur are taking special efforts for spreading awareness for prevention of diabetes and its management through lifestyle modifications and adjunct treatment modalities such as yoga, exercise, and music therapy. In diabetes, control of heart rate is affected. It is evident from various studies that heart rate responses are closely associated with brainstem regulation through the Autonomic Nervous System.[7] Evaluation of heart rate variability (HRV) can give bird's eye view to autonomic status of body. Hence, to evaluate autonomic functions, the present study was intended to evaluate effect of music therapy among diabetic by evaluation of HRV.

METHODOLOGY

The present study was carried out in the Department of Physiology attending Music Therapy Clinic. Recording for each participant was done in the morning hours between 9.00 A.M and 11.00 A.M. The participants were instructed to avoid tea, coffee intake, and strenuous physical exercise at least 2 h before the test. Each participant reported to the laboratory after a light breakfast. In the laboratory, after preliminary briefing, the participant was asked to lie down in the supine position and breathe in a relaxed manner, without going off to sleep. After a 10 min rest and confirmation of proper RR wave in the resting ECG the HRV recording in Kody's cardiac autonomic neuropathy (CAN) analyzer for 5 min started to have baseline HRV recording, the subjects were given 20 min session of music therapy using popular Indian Bollywood Songs of specific raga such as Hansdhwani, Yaman Puria Dhaneshree, Darbari, Bageshree, and Shudh Kalyan again after music therapy session a 5 min ECG recording for HRV analysis was done.

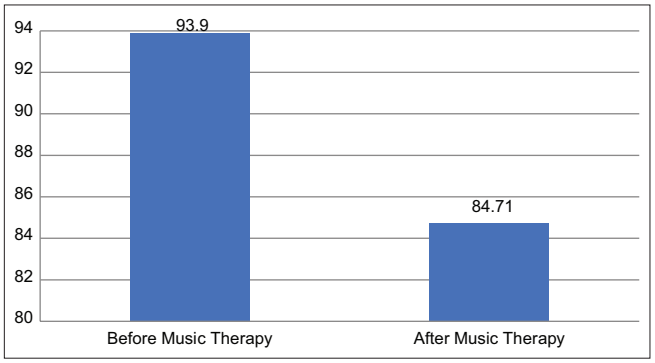
RESULTS AND ANALYSIS

The vital parameters such as temperature, pulse, respiration, oxygen saturation blood pressure, and blood sugar were noted before and after therapy session. The ECG was recorded before and after music therapy session for evaluation of HRV. The data collected from Kody's CAN analyzer were subjected to Kubios analysis.[8] Table 1 depicts the few of the important parameters.

The comparison for heart rate among diabetics before (93.9 ± 4.41) and after (84.71 ± 9.13) the music therapy session revealed that there was decrease in the heart rate after music therapy with the standard error of 2.55 (before) and 5.27 (after) music therapy session. When the difference was analyzed by *t*-test, it was significant with t-value 6.31 and $P < 0.05$. The details are depicted in Table 1 and Graph 1.

Table 1: Parameters before and after music therapy

Parameter	Before MT	After MT	t value	*P*-value
Heart rate	93.9±4.41	84.71±9.13	6.31	<0.05
Blood sugar	164±39.8	143±23.3	2.77	<0.05
PNS index	−2.22±0.13	−1.45±0.62	4.30	>0.05
SNS index	5.51±0.70	2.08±1.44	3.03	<0.05
Stress index	32.41±5.1	14.83±5.46	2.91	<0.05



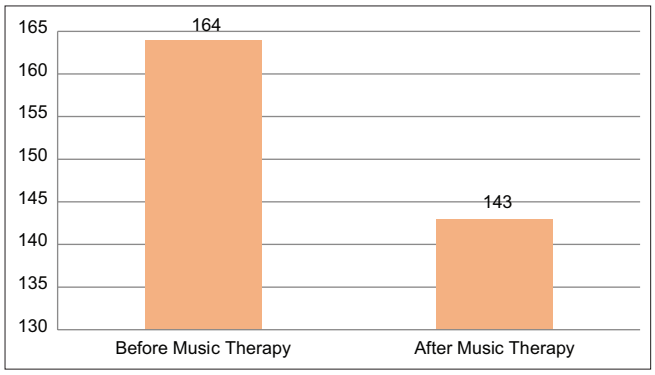
Graph 1: Changes in heart rate before and after session of music therapy

When blood sugar was compared among diabetics before (164 ± 39.8) and after (143 ± 23.3) the music therapy session, it revealed that there was decrease in the blood sugar after music therapy session with the standard error of 16.27 and 9.53 for before and after music therapy session, respectively. When the difference was analyzed by *t*-test, it was significant ($t = 2.77$ and $P < 0.05$). The details are depicted in Table 1 and Graph 2.

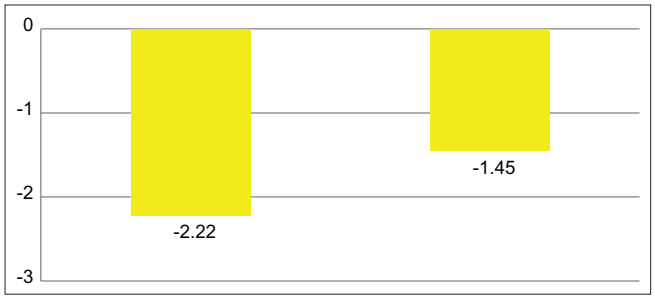
Regarding PNS index, although there was increase in the PNS index after the session of music therapy that the increase in the parasympathetic component was statistically insignificant when analyzed by *t*-test (t = 4.30). It was −2.22 ± 0.13 before which became −1.45 ± 0.62 after the session of music therapy. The details are depicted in Table 1 and Graph 3.

The Kubios analysis revealed fall in SNS index, it was 5.51 ± 0.70 before the session which became 2.08 ± 1.44. The fall in the SNS index which is sympathetic component was statistically significant when compared by *t*-test (t = 3.03) and $P < 0.05$. The details are depicted in Table 1 and Graph 4.

It was observed that the stress index, which is holistic indicator of HRV analysis for autonomic functions found to be significantly decreased after the session of music therapy. It was 32.41 ± 5.1 before which became 14.83 ± 5.46 after the session of music therapy that the details are depicted in Table 1 and Graph 5.



Graph 2: Changes in blood sugar before and after session of music therapy



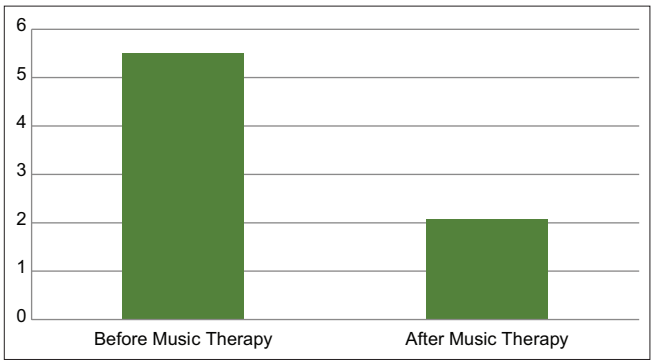
Graph 3: Changes in PNS index before and after session of music therapy

DISCUSSION

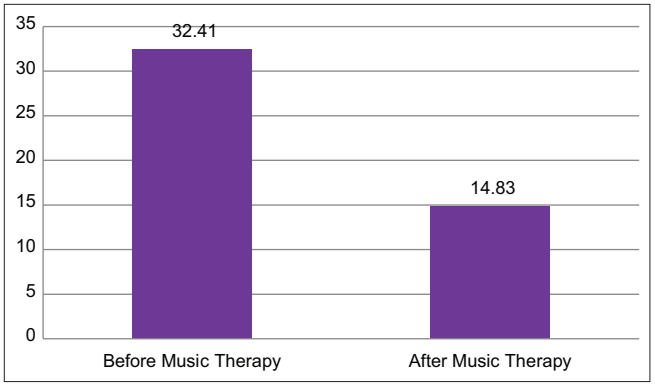
Raga is the sequence of selected notes (swaras) that lend appropriate "mood" or emotion in a selective combination. It is a yoga system through the medium of sonorous sounds. Depending on its nature, a raga could induce or intensify joy or sorrow, violence, or peace, and it is this quality which forms the basis for musical application.[9]

Music has been shown to be an efficient method of modulating emotions and autonomic nervous system activity and is potentially a low-cost and safe adjuvant for intervention and therapy. Sedative music induces both high relaxation and low tension subjectively in young adults. These relaxation effects of music are supported by a shift of the autonomic balance toward parasympathetic predominance in healthy adults. In addition, listening to pleasant music provokes parasympathetic activity compared with a resting condition. Thus, music may modify the autonomic nervous system.[10] Music is a powerful stimulus that evokes and modulates moods and emotions and can be used intentionally to regulate moods and emotions in daily life.[11]

As Ragas like Bageshree working as hypoglycemic,[12] hence, there was fall in blood sugar, the reduced heart rate can be



Graph 4: Changes in SNS index before and after session of music therapy



Graph 5: Changes in stress index before and after session of music therapy

attribute to anxiolytic Rag Hansdhwani, Yaman and Darbari as they ease tension. It also reflected as overall reduction in sympathetic component. Interestingly, in our study, we found reduction in sympathetic component significantly rather than the predominance of parasympathetic component after the music therapy session among the diabetic.

CONCLUSION

It can be concluded from the present study that there is significant effect on reduction of stress among diabetic after the music therapy session as we found that there was significant fall in heart rate, blood sugar after the session. The parasympathetic component the PNS index was increased after the session, but the change was statistically insignificant. There was statistically significant decrease in the SNS index which is indicator of sympathetic activity of the body. The overall stress index was also decreased to statistically significant level as reflected by Kubios analysis. Hence, it can be concluded that music therapy can be used as one of the nonpharmacological measures to combat the stress and sessions of specific raga-based Bollywood songs can be stress buster among diabetics.

Music therapy using raga-based Bollywood songs can be one of effective non-pharmacological measures in the armamentarium of adjunct modalities for battle against diabetes.

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Original Article

Comparative Study of Laparoscopic Preperitoneal versus Open Preperitoneal Repair of Inguinal Hernias

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Abstract

Objectives: To assess the outcomes of Open Preperitoneal and Laparoscopic Preperitoneal mesh repairs in Inguinal hernia. To compare both approaches in terms of Recurrence rate, duration of the surgery, duration of hospital stay, post operative pain, wound complications and chronic pain. **Materials and Methods:** This study is a Prospective observational study of 24 months duration from 01-11-2018 to 31-10-2020 evaluated in 30 patients(15 patients in each group), who are admitted with inguinal hernia in the Department of General Surgery, Gandhi Hospital, Secunderabad. Once the patient is admitted, demography is noted, formal informed consent is taken and then enrolled into the study. The relevant physical examination and investigations are done. Every alternate case is allotted into each group preoperatively. **Inclusion Criteria:** All Patients diagnosed with uncomplicated inguinal hernias with 20-40 years age. **Exclusion Criteria:** Patients with complicated inguinal hernias, patients with sliding hernia and complete hernia, patients who refused to give informed consent and patients age more than 40 years. **Conclusion:** The laparoscopic preperitoneal inguinal hernia repair is superior to open preperitoneal inguinal hernia repair in terms of post-operative pain, duration of hospital stay, and chronic pain. However, the risk of hernia recurrence remains same in both the groups when the mesh is placed preperitoneally, and moreover, operative time is reduced drastically in open group, when compared to the laparoscopic repair.

Key words: Laproscopic inguinal hernia repairs, Preperitoneal repairs of inguinal hernia, Inguinal hernia repairs

INTRODUCTION

A hernia is the protrusion of a viscus or part of a viscus lined by a sac through a normal or abnormal opening in the abdominal wall. Inguinal hernia is protrusion of abdominal contents through the inguinal canal. Approximately 75% of abdominal wall hernias occur in the groin. The lifetime risk of inguinal hernia is 27% in men and 3% in women.[1] Of inguinal hernia repairs, 90% are performed in men and 10% in women. The incidence of inguinal hernias in males has a bimodal distribution, with peaks before the 1st year of age and after age of 40. Abramson demonstrated the age dependence of inguinal hernias in 1978. Those aged 25–34 years had a lifetime prevalence rate of 15%, whereas those age 75 years and over had a rate of 47%.[2] Approximately 70% of femoral hernia repairs are performed in women; however, inguinal hernias are 5 times more common than femoral hernias. The most common subtype of groin hernia in men and women is the indirect inguinal hernia.[3] Repair can be done by Open or Laparoscopic method. Laparoscopic inguinal hernia repair has better results than open hernia repair. It has become a best alternative operation in the past 15 years.[4] Lap inguinal hernia repair is 2 types: Transabdominal Preperitoneal (TAPP) LIHR and Totally Extraperitoneal LIHR.[5] This study is to know whether laparoscopic preperitoneal placement of mesh has got any benefit on the recurrence rate as compared to open preperitoneal repair.

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MATERIALS AND METHODS

Open Preperitoneal Repair Pre-operative Preparation

Patients were kept NPO for about 6–8 h and were on liquid diet the before day. All patients received antibiotic prophylaxis half an hour before surgery. All patients were operated under spinal anesthesia.

Operative Technique

Transverse skin crease incision 5–6 cm long is given, deepened to the external oblique aponeurosis, and the cord is delivered. Indirect sac is dissected from the cord up to the extraperitoneal fat and inverted into the deep ring after

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Table 1: Postoperative pain

Study	Open preperitoneal	Laparoscopic preperitoneal	*P*-value
Abd-Elrahman Sarhana	3.39±1.1	1.1±1	<0.001*
Present study (h)			
6	6.53±1.02	3.13±0.61	0.00001*
12	4.53±1.02	2.27±0.44	0.003*
24	3.73±0.92	1.53±0.49	0.02*

Table 2: Duration of hospital stay

Study	Open	Laparoscopic	*P*-value
Abd-Elrahman Sarhan	1.7±0.53	1.4±0.57	0.00001
Present study	5.26±1.33	2.53±0.88	<0.0001

Table 3: Chronic pain

Study	Open	Lap	*P*-value
Abd-Elrahman Sarhana	7	1	0.03
Present study			
At 1 month	3	2	0.5
At 6 months	3	1	0.2
At 1 year	2	0	0.2
At 2 years	1	0	0.5

elevation of the inferior epigastric vessels anteromedial to create the preperitoneal space.[6] Gauze is inserted through the internal ring to keep the peritoneal sac inverted. The direct sac was isolated and the transversalis fascia around its neck is circumcised and the preperitoneal space reached directly. Dissection of the preperitoneal space can be done with Gauze swabs. Dissection is continued to the pubic tubercle medially, the iliac vessel laterally, and Cooper's ligament caudally. Monofilament knitted polypropylene mesh 7.0 × 15.0 cm in size is inserted into the preperitoneal space covering the entire groin area including indirect, direct, and femoral orifices.[7] Once the mesh was in place, its position is checked by inserting the index finger into the preperitoneal space between the inguinal ligament and mesh with boundaries of mesh covering Cooper's ligament caudally, iliac vessels laterally, and the rectus abdominis medially. Transversalis fascia is closed with vicryl suture and the mesh was fixed in place with abdominal pressure.[8] After closure of the external oblique and Scarpa's fascia with a running 3–0 vicryl suture, the skin incision was closed.

Laparoscopic Preperitoneal Repair Pre-operative Preparation

Patients were kept NPO for about 6–8 h and were on liquid diet the before day. All patients received antibiotic prophylaxis half an hour before surgery and were operated under general anesthesia. Nasogastric tube and Foleys catheter were placed.[9] The patient was placed in supine position with 10° head down with a tilt as per the side of hernia. In all cases, surgeon initially stands on the left side for pneumoperitoneum creation and trocar placement then moved toward patient head end opposite to side of hernia, camera assistant stands on head end of patient toward side of hernia, and scrub nurse stands on side of the patient. Instruments were used: 30° telescope, Veress needle, one 10 mm trocar, two 5 mm trocars, holding forceps, Maryland dissector, scissors, needle holder,10 mm to 5 mm reducing sleeve, electrosurgical apparatus – monopolar/bipolar, 15 × 12 cm 3D MAX Mesh knitted polypropylene pre-formed mesh, 2–0 vicryl suture material, 1-prolene in suture fixation cases, and non-metallic tackers in tacker fixation cases.

Operative Technique

Pneumoperitoneum creation and trocar placement

A small transverse periumblical/infraumblical incision made, through which Veress needle inserted perpendicular to abdomen with slight degree of tilt toward pelvis and pneumoperitoneum created. In patients with history of abdominal surgery, palmer's point used for Veress insertion. We place 10 mm camera port in the umbilicus, two working trocars just lateral to the rectus sheath each side, and few cms below the camera port.

Trocar position

Umbilical port, right pararectus, and left pararectus:

After reducing the contents, peritoneal flaps created by giving horizontal incision 2 cm above the defect extending from medial umbilical ligament to the level of anterior superior iliac spine. Incision curved down such as hockey stick on lateral aspect and dissection proceeded downward beyond the ileopubic tract by raising a flap of peritoneum.

Medial dissection

Using blunt dissection in the avascular plane (cob web like areolar tissue) peritoneum and preperitoneal fat separated from pseudo sac (in direct inguinal hernias), medially dissection extended up to pubic symphysis, inferiorly dissection extended up to obturator foramen.

Lateral dissection

Hernial sac dissected from cord structures using traction and short bursts of electrocautery. In cases of longer sac, the dissection continued close to the hernial sac distally into inguinal canal after creating a window between the sac and cord structures. In larger sacs, hernia sac is divided beyond the internal ring within the canal leaving the distal end of the sac *in situ*.

Parietalization

Peritoneum is separated from the vas and gonadal vessels as far as the mid psoas muscle. In all cases, preperitoneal dissection

is extended beyond midline on medial aspect, beyond anterior superior iliac spine exposing the psoas on lateral aspect, inferiorly up to symphysis pubis and obturator foramen and superiorly up to the level of working trocars. Medial dissection was done in direct hernia.[10] Lateral dissection was done in indirect hernia. The mesh is reverse loaded into 10–5 mm reducer. The laparoscope is withdrawn and mesh is taken into the preperitoneal space by blind insertion through the 10 mm trocar. Mesh was properly placed in the preperitoneal space. Mesh was fixed to cooper's ligament inferiorly, and rectus muscle on superomedial aspect, medial to inferior epigastric vessels using 1-prolene.[11] Peritoneal flaps are approximated with 2–0 vicryl in continuous manner without any gap. All port sites skin approximated with staplers after suturing rectus with 1–0 prolene. During post-operative period, all patients received same antibiotics, analgesic injections followed by oral treatment.

Post-operative Assessment of Pain

The pain experienced by the patients in post-operative period had been measured according to visual analog scale.[12] All the patients are ambulated within 12 h of surgery and are allowed oral feeds. Nasogastric tube and Foleys were removed after 12 h. Initially, the feeds were sips of liquids followed by normal diet in a gradual manner after resolution of post-operative ileus indicated by passing of flatus and normal bowel sounds on auscultation and return of appetite. The wounds were inspected for any seroma, hemotoma, and any infection. Patients were discharged after complete ambulation and tolerating normal diet.

After discharge, patients were followed up at 1 week, 1 month, and 6 months intervals. In the initial follow-up, the patients were evaluated for short term complications such as seroma, hemotoma, and wound infection. In the long-term follow-up, patients were evaluated for chronic pain and recurrence of hernia.

Statistics

Data entry was done by Microsoft Excel 2010 version and analysis using EPI INFO version 3.01. Data were presented in percentages and proportions. Numerical data were expressed as the mean ± standard deviation (SD) and range. Association between categorical variables was done using Chi-square test or Fisher exact test with p value less than 0.05 considered statistically significant.

RESULTS

A total number of 30 patients were included, 15 in each group, that is, laparoscopic preperitoneal repair group (TAPP) and open preperitoneal group, allocated randomly. All patients were evaluated by history and clinical examination. After informed consent, all patients were operated under general or spinal anesthesia. Type of operation (laparoscopy/open) was chosen randomly. Laparoscopic hernia repair is done under general anesthesia. Size of mesh used was 15 × 15 cm polypropylene mesh. Open hernioplasty (Tension-free Lichtenstein's hernioplasty) is done under spinal anesthesia. Size of mesh used was 7 × 15 cm.[13] Parameters assessed were pain (using visual analog scale [VAS]), post-operative complications (Seroma/hematoma formation, Mesh infection), Neuralgias, length of hospital stay, recurrence of hernia at the same site, assessed during their regular follow-up at intervals of 3 months, 6 months, 1 year, and 2 years. Age (mean±SD) $P = 0.9$, and duration of surgery $P = 0.00001$. Pain score at 6 hrs 6.53+/- 1.02 for open and 3.13+/-0.61 for lap with P value of 0.00001, at 12 hrs 4.53+/- 1.02 for open and 2.27+/- 0.44 for lap with P value of 0.003, at 24 hrs 3.73+/- 0.92 for open and 1.53+/- 0.49 for lap with P value of 0.02 which is statistically significant.

- Hematoma $P = 0.5$ *Chi-square test with Yate's correction
- Seroma $P = 0.3$ *Chi-square test with Yate's correction
- Pus collection $P = 0.5$ *Chi-square test with Yate's correction
- Hospital stay in days $P = 0.00001$
- Recurrence at 2 years $P = 0.5$* Chi-square test with Yate's correction
- Chronic pain (1 month) $P = 0.5$ *Chi-square test with Yate's correction
- Chronic pain (6 months) $P = 0.2$ *Chi-square test with Yate's correction
- Chronic pain (1 year) $P = 0.2$ Chi-square test with Yate's correction
- Chronic pain (2 years) $P = 0.5$ *Chi-square test with Yate's correction

DISCUSSION

The laparoscopic approach has become an excellent alternative to open repair for inguinal hernia for many patients and surgeons. There is abundant literature that emphasizes that laparoscopic inguinal hernia repair provides amazing results. Until a few decades ago, the standard method for inguinal hernia repair was suturing fascial structures around the hernia defect until Lichtenstein *et al.* introduced tension-free repair, which gained widespread recognition worldwide and surgeons mastered the technique rapidly.[14] There are advantages and disadvantages to laparoscopic repair. Clinically, silent contralateral hernia and other intra-abdominal pathologies are easier to detect with the TAPP approach. Despite excellent long-term outcome after TAPP repair, the use of laparoscopy in hernia repair is still limited due to disadvantages such as possible organ injury at the time

of trocar entry, port site hernia, and adhesions.[15] In this prospective study, two different techniques were used, both being tension-free (laparoscopic TAPP and open inguinal preperitoneal), with similar mesh location. The mesh was placed in the preperitoneal space between the peritoneum and the transversalis fascia, and secured over the myopectineal orifice using intra-abdominal pressure and treating the three most common types of groin hernia: Indirect, direct, and femoral hernia. Adequate dissection of the preperitoneal space with a large enough mesh avoids recurrence.[16] In this study, it is found that both open and laparoscopic approaches are effective and safe for preperitoneal repair of inguinal hernia, with low complication and recurrence rates. Recurrence was the main outcome measure in this study.[17] The results showed a low and similar recurrence rate in both approaches (1% in both), comparable to the results of Abd-Elrahman Sarhana study. The following was compared in both the groups: Duration of surgery, post-operative pain, seroma/hematoma formation, pus collection, length of hospital stay, recurrence of hernia, and chronic pain at intervals of 1 month, 6 months, 1 year, and 2 years.

The present prospective observational study has 30 cases. All of them were male, with mean age of 28.93 ± 5.68 (range: 20–39) in the open group. In the laparoscopic group, the mean age was 29.13 ± 5.52 (range: 20–38). The p value is 0.9, which is statistically insignificant

In Abd-Elrahman Sarhana study, the mean age was 41 ± 9.1 in the open group, and 38 ± 12.9 in laparoscopic group. The p value was 0.45.

In the present study, the mean duration of surgery in open group is 43.0±8.90 and in laparoscopic group, it is 82.33 ± 12.49, with $P = 0.00001$, which shows that it is statistically significant.

Post-operative pain was assessed at different time intervals, using VAS. The patients' pain was evaluated using Numeric Rating Scale, where 0 = no pain and 10 = extreme pain. The ranges then were divided into mild pain (1–3), moderate pain (4–6), and severe pain (7–10). In the present study, the VAS of pain at 6 h was 6.53 ± 1.02 and 3.13 ± 0.61 in open and laparoscopic groups, respectively, with $P = 0.0001$, which is statistically significant.[18]

The VAS of pain at 12 h was 4.53 ± 1.02 and 2.27 ± 0.44 in open and lap groups, respectively, with $P = 0.003$, which is statistically significant. The VAS of pain at 24 h was 3.73 ± 0.92 and 1.53 ± 0.49 in open and lap groups, respectively, with $P = 0.02$, which is statistically significant. This is comparable to Abd-Elrahman Sarhana study, where the VAS of pain is 3.39 ± 1.1 and 1.1 ± 1 in open and lap groups, respectively, with $P < 0.001$ which is statistically significant.

In the present study, there is one case in the open group with hematoma as a complication and none in the laparoscopic group. $P = 0.5$, which is statistically insignificant. In Abd-Elrahman Sarhana study, there is no case with hematoma occurrence.

In the present study, two cases in open group and one case in laparoscopic group developed seroma formation, which accounts to 13.3% and 6.7%, respectively, with $P = 0.3$, which is statistically significant. In Abd-Elrahman Sarhana study, six cases in open group and five cases developed seroma formation, which account to 6% and 5%, respectively.

In the present study, occurrence of wound infection is one case each in open and laparoscopic group, which accounts to 6.7% in each group, with $P = 0.5$, which is statistically insignificant. In Abd-Elrahman Sarhana study, two cases in each group had wound infection, accounting to 2% in each group, with $P = 1.0$, being statistically insignificant. Duration of hospital stay (in days).

In the present study, the mean of duration of hospital stay is 5.26 days with a SD of 1.33 days in the open group, whereas in the laparoscopic group, it is 2.53 days with a SD of 0.88 days.The p value is 0.00001, which is statistically significant.

In Abd-Elrahman Sarhana study, the mean duration of hospital stay is 1.7 ± 0.53 days in open group and 1.4 ± 0.57 days in laparoscopic group, with $P < 0.001$ which is statistically significant.

In the present study, the recurrence was seen in one case in each group, accounting to 6.7% in each group.[19] This has $P = 0.5$, which is statistically insignificant. In Abd-Elrahman Sarhana study, the recurrence was seen in one case in each group, accounting to 1% in each group. p value is statistically insignificant.

Chronic Pain at Different Intervals

In Abd-Elrahman Sarhana study, chronic pain is present in seven cases in open group, compared to one case in laparoscopic group, with p value being 0.03.[20] In the present study, chronic pain is seen in three cases in open group and two cases in laparoscopic group, three cases in open group and two cases in laparoscopic group, two cases in open group and 0 case in laparoscopic group, and one case in open group and 0 cases in laparoscopic group at the intervals of 1 month, 6 months, 1 year, and 2 years, respectively.[21]

CONCLUSION

The laparoscopic preperitoneal inguinal hernia repair is superior to open preperitoneal inguinal hernia repair in terms of post-operative pain, duration of hospital stay, and chronic pain. However, the risk of hernia recurrence remains same in both the groups when the mesh is placed preperitoneally, and moreover, operative time is reduced drastically in open group, when compared to the laparoscopic repair. Furthermore, the laparoscopic technique has a longer learning curve, whereas open repair can be done with a comparatively minimal skill and equipment and can be done at any primary centers. Even though short-term results are better with laparoscopic preperitoneal repair, both are comparable to each other in terms of recurrence. However, we need more evidence-based randomized clinical trials to compare the pros and cons of the two methods.

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Original Article

Clinical and Radiographic Evaluation of Bone Loss in Healing Extraction Socket of Single Rooted Teeth with and without Immediate Implant Placement Mitigating the Survival of Immediate Implant Placement

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Abstract

Background: This study was done to evaluate the bone loss in extraction socket healing with and without immediate implant placement in terms of hard-tissue changes clinically and radiographically.

Methodology: In this study, 20 patients were selected based on inclusion and were divided into two groups of 10 each whose single rooted teeth were indicated for extraction. Group A – Immediate implant placement following tooth extraction. Group B – No implant placement following tooth extraction. Clinically and radiologically mesial and distal crestal bone loss were recorded at baseline, 1st-, 3rd-, and 6th-month postoperatively. Clinical bone width was recorded at baseline, 1st-, 3rd-, and 6th- month postoperatively. Statistical analysis was done comparing all the records.

Results: There is a statistical significant difference in bone loss in extraction healing socket with immediate implant placement and without implant placement both in vertical and horizontal direction with more bone loss in extraction socket without implant placement. Around 1.5~2.0 mm of vertical and horizontal bone preservation can be achieved with immediate implant placement in freshly extracted tooth socket as compared to without implant placement. All the implants successfully survived after 6 months of healing period showing 100% survival rate.

Conclusion: Immediate implant placement into single rooted fresh extraction socket offers a predictable solution to tooth loss and also preserves noteworthy tissue dimensions as compared to without implant placement.

Key words: Bone loss, Extraction, Immediate implant, Implant, Osseointegration

INTRODUCTION

Humans have lost their natural teeth throughout the history for a variety of reasons mostly due to trauma, dental caries, and periodontal diseases. After tooth loss, underlying bone is not under normal function and it can slowly lose its mass and density, which can cause reduction of alveolar bone and vertical dimension of the face. Frequently, the physical appearance of the person is noticeably affected. Hence, the goal is to reinstate the patient's normal aesthetics, function, and speech by replacing single or several teeth. Today, the two most common treatment options for single tooth replacement are the fixed partial denture and the implant supported prosthesis.[1]

Implant therapy is an advanced treatment modality in today's field of dentistry, aiming to achieve an ideal esthetic and functional treatment outcome within the

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alveolar ridge or the edentulous spaces. The introduction of "osseointegration" and replacement of lost teeth by implants have revolutionized oral rehabilitation while significantly empowering restorative dentistry.[2] After tooth extraction, bone resorption occurs both buccolingually and apicocoronally. The first 6-month post-extractions are critical, carrying the highest rate of bone resorption in either direction.[3,4] A protocol has been developed in which implants are placed at the time of extraction of the teeth popularly known as immediate implant. Since the first report of the placement of a dental implant into a fresh extraction socket, there has been increasing interest in this technique for implant treatment.[5] As there has been a lack of comparative studies regarding evaluation of bone preservation with immediate implant placement, this study has aimed to evaluate the bone loss in immediate implant placement in fresh extraction socket as compared to normal healing extraction socket.

The aim of this prospective, randomized, and clinical study was to evaluate the bone loss in healing extraction socket with immediate implant placement as compare to without implant placement following tooth extraction under local anesthesia. The objectives of the study were to evaluate the mesial and distal marginal bone height with the help of UNC 15 periodontal probe and IOPA preoperatively and postoperatively clinically and radiographically and to evaluate the buccolingual bone width with the help of bone caliper preoperatively and postoperatively clinically.

METHODOLOGY

After getting approval from the Institutional Ethical Committee to conduct the study. (Ref. no. MGSDC/13 Dated on-16/12/2013), total of 20 patients were selected whose single rooted teeth were indicated for extraction who reported to OPD department of oral and maxillofacial surgery, MGS Dental College and Research Centre, Sri Ganganagar, Rajasthan, India. Patients selection was based on the inclusion criteria as stated below irrespective of sex, caste, and socioeconomical status. The study inclusion criteria were patients above age of 18 years, single rooted teeth indicated for extraction in upper and lower arch, and patients who were willing to undergo extraction for prosthetic rehabilitation and teeth which cannot be restored endodontically. Exclusion criteria were ankylosed tooth, patient with parafunctional habits like bruxism, patients with history of chronic or acute systemic disorders, and patients who has undergone radiotherapy and chemotherapy. Patients were informed about the procedure and a written informed consent was obtained.

Study Design

Patients were divided into two groups of 10 each.

- Group A – Patients who has undergone extraction followed by immediate implant placement. (Implant Group)
- Group B – Patients who have undergone extraction without immediate implant placement (Extraction alone group).

After detailed clinical examination, diagnostic cast and occlusal stent were fabricated [Figure 1]. Clinical and radiographical parameters were recorded by only one clinician in all the patients included in the study as mentioned:

- Mesial and distal marginal bone height from the incisal/occlusal surface of adjacent teeth by periodontal probe preoperatively and at the interval of 1st-, 3rd-, and 6th-month postoperatively
- Buccolingual bone width by bone caliper preoperatively and at the interval of 1st-, 3rd-, and 6th-month postoperatively
- Radiographic parameters with IOPA and IOPA Grid were recorded with occlusal stent wire as an occlusal reference point
- The mesial and distal marginal bone height preoperatively and at the interval of 1st-, 3rd-, and 6th-month postoperatively.

Clinical Procedure

All the patients were treated according to the strict surgical protocol under absolute aseptic conditions. Patients were advised to rinse with 0.12% chlorhexidine mouthwash preoperatively. Extraoral and intraoral betadine scrubbing and painting were done followed by draping of the patients. Under local anesthesia (2% Lignocaine hydrochloride with Adrenaline 1: 2,00,000.), atraumatic extraction was performed by using periotomes and tooth extraction forceps. Extreme care was exercised to avoid fracture of the socket walls especially the buccal cortex. The length and width of the extracted root were measured and recorded with the help of scale to determine the length and diameter of the implant to be placed. Apical curettage was done as when as needed. With standard sequential drills, the osteotomy site was prepared and extended ~ 2 mm beyond the apex of the extracted tooth for better primary stability using the socket walls as guide. Once the osteotomy site was prepared, the selected endoosseous threaded implant was placed 1–2 mm subcrestal as per the protocol. Primary stability was noted with torque ratchet wrench intraoperatively. Suturing with 3–0 black braided silk was done to enable maximum approximation and to ensure soft-tissue coverage to protect the implant site. Post-operative antibiotics (Cap. Amoxicillin 500 mg t.i.d) and

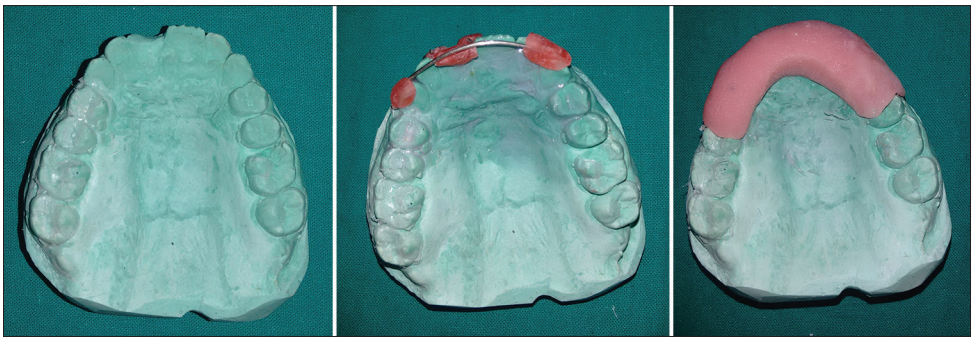

Figure 1: Pre-operative diagnostic cast and occlusal stent fabrication

analgesics (Tab. Combiflam t.i.d) drugs were prescribed for 3-day postoperatively. Patients were discharged with post-operative instructions and advised to maintain oral hygiene. Patients were recalled after 7 days for suture removal. Patients were reviewed after 1st-, 3rd-, and 6th-month postoperatively for clinical and radiographic assessment [Figures 2 and 3] Second stage surgery was performed after 4 months. Prosthesis was cement-retained type and luting glass ionomer cement was used for crown cementation [Figure 4]. For Group B, that is, extraction alone group atraumatic extraction is done and suturing done without immediate implant placement. Clinical and radiographical assessment was done in same manner.

Statistical Analysis

The recorded data were compiled and entered in a spreadsheet computer program (Microsoft Excel 2007) and then it was exported to data editor page of SPSS version 20 (SPSS Inc. Chicago, Illinois, USA). Descriptive statistics included were computation of means and standard deviations. The statistical test applied for the analysis was independent student paired *t*-test. Confidence interval and *P*-value were set at 95% and <0.05, respectively.

RESULTS

Comparison of healing of extraction sockets with or without immediate implant placement after 6 months of healing period has been done in the present study. The mean difference and standard deviation in bone loss level on mesial side between baseline and 6 months in Group A were 2.1 ± 0.39 and in Group B 4.15 ± 0.74. The mean difference and standard deviation in bone loss level on distal side between baseline and 6 months in Group A were 2.05 ± 0.43 and in Group B 4.8 ± 1.03. The mean difference and standard deviation in radiographic bone loss level on mesial side between baseline and 6th months in Group A were 2.15 ± 0.24 and in Group B 4.65 ± 0.66. The mean difference and standard deviation of radiographic bone loss level on distal side between baseline and 6 months in Group A were 2.15 ± 0.39 and in Group B 5.05 ± 0.75. The mean difference and standard deviation in clinical buccolingual bone width between baseline and 6 months in Group A were 2.15 ± 0.47 and in Group B 3.9 ± 0.39. Thus, the total amount of vertical bone preserved in Group A as compared to Group B both clinically and radiographically on mesial as well as distal side and total amount of horizontal bone (buccolingual width) preserved in Group A as compared to Group B was evaluated. The vertical mesial and distal crestal bone height in implant group (Group A) decreased around 2.15 mm and in extraction alone group around 4.5 mm with a difference of ~2.5 mm. The buccolingual width of the implant group after extraction of teeth decreased to 6.65 ± 1.15 mm from 8.8 ± 1.39 mm while the buccolingual width of the extraction alone group without implant placement decreased to 4.75 ± 0.35 mm from 8.65 ± 0.47 mm with a difference of ~1.75 mm [Figure 5]. Thus, both the groups showed lost in ridge width and height, although an improved significant result was obtained in the implant group.

DISCUSSION

The successful replacement of natural tooth by tissue-integrated tooth-root analog, that is, dental implant is a major advancement in the new era of dentistry. For success of implant treatment, direct structural and functional connection between ordered living bone and the surface of a load-carrying implant is important. Branemark *et al.* recommended 3–6 month stress free healing period to achieve optimum bone healing and osseointegration before loading.[2,6] However, with a disadvantage of undue waiting period was a source of inconvenience both for the patient and clinician, and many a times, the reason for avoiding implant treatment. To overcome this disadvantage of delayed implant placement, clinicians introduced immediate implantation into fresh extraction sockets which provide a reasonable solution to the treatment planning opportunities. This new immediate implant protocol combines the socket ossification period with the osseointegration period. It also reduces the treatment time by 6–8 months and

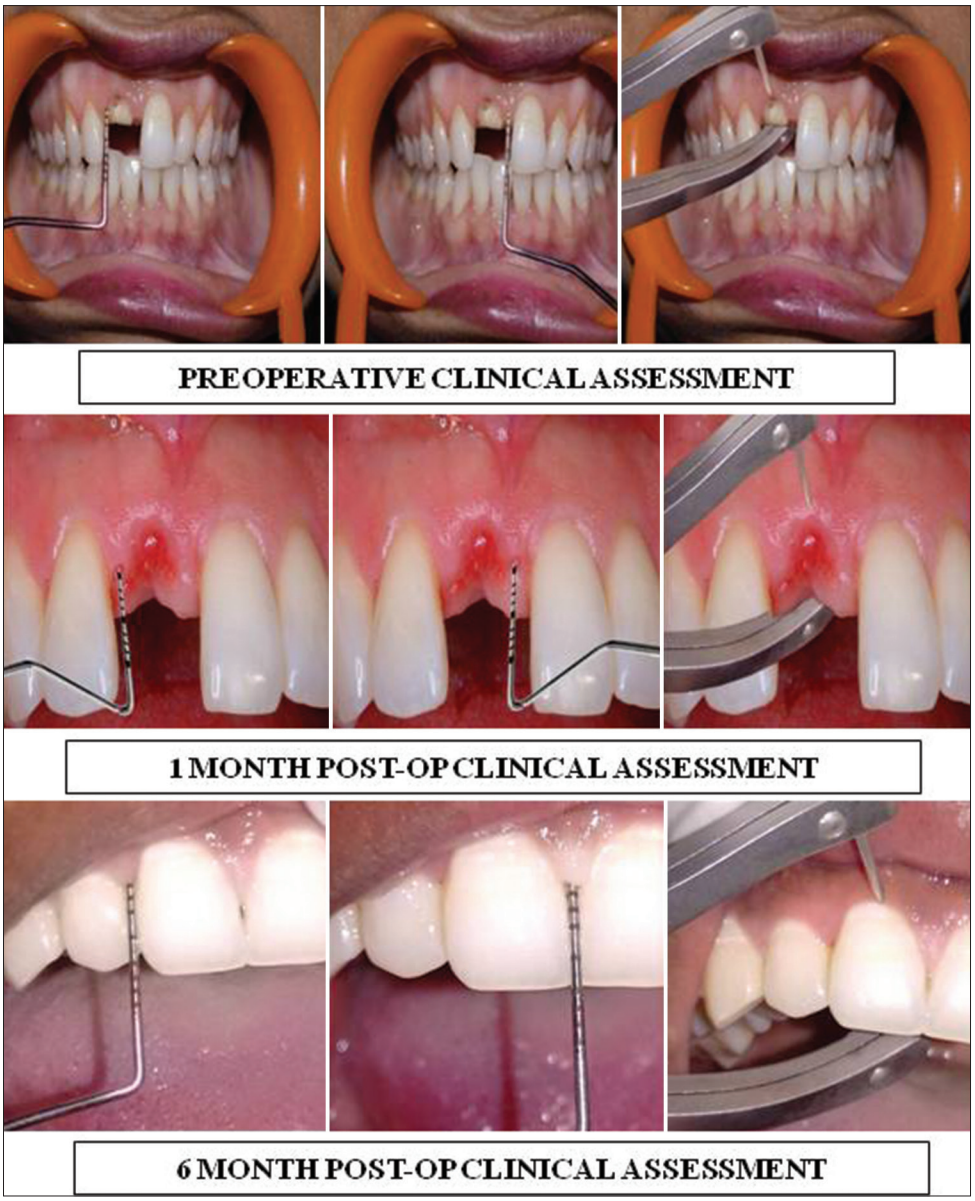

Figure 2: Intraoral clinical assessment

the associated bone resorption related to the extraction alone.[7] Bone loss after tooth extraction remains an inescapable phenomenon. Anatomically, bone resorption occurs both buccolingually and apicocoronally, being the first 6-month post-extraction more critical, carrying the highest rate of bone resorption in either direction. Few clinicians reported vertical socket height reduction of 3–4 mm, or approximately 50% of the initial socket height after 6 months of healing of extraction socket. In the present study, 4–5 mm of vertical bone loss occurred on mesial and distal aspect of the extraction socket without implant placement during 6 months of healing period which is similar to their findings. Studies by Chen and Van der Weigden *et al.* demonstrated that approximately 5–7 mm of horizontal or buccolingual ridge reduction, representing about 50% of the initial ridge width, occurs over a 6–12-month period.[8-11] In the present study, ~4 mm of horizontal bone loss occurred within 6 months of healing period which is concomitant with their findings. Few clinicians evaluated the vertical bone loss in freshly extraction sockets with immediate implant placement and it was around 1.2–2.5 mm at 6–9-month postoperatively. In the present study, results showed that there is a mean vertical bone loss of ~2.0 mm on mesial and distal side vertically in extraction sockets with immediate implant placement which is similar to the previous studies.[12-14]

Clinicians also noted 2.0–3.7 mm of buccolingual bone loss occurred during first 6 months of healing period. This is similar to our finding ~ 2.15 mm of buccolingual bone

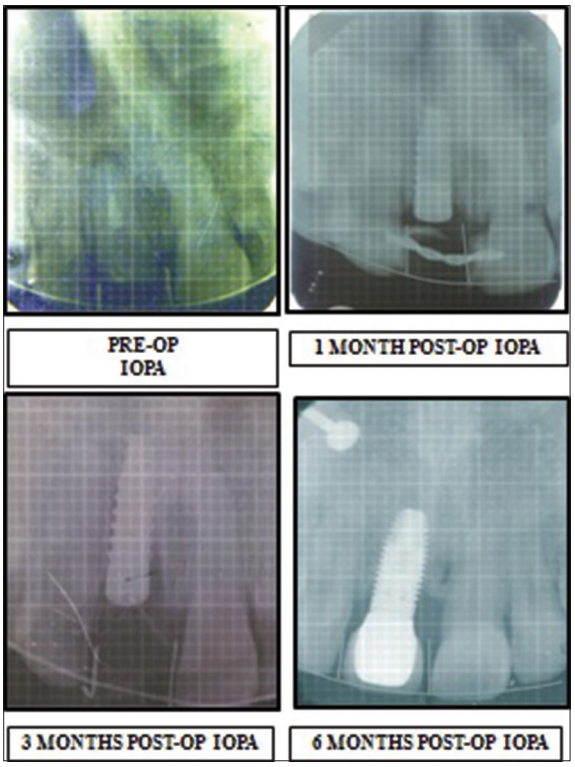

Figure 3: Radiographic assessment

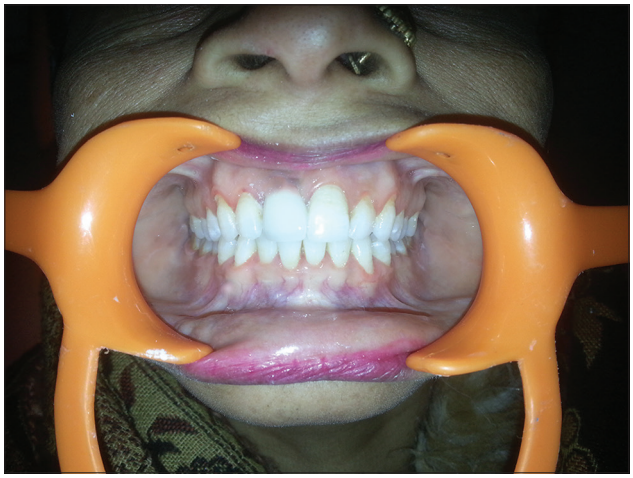

Figure 4: Final prosthesis in place

loss implying that the coronal bone remodeling around neck of immediate implant showed a healing pattern of new bone apposition with horizontal buccolingual width reduction of alveolar ridge.[12-17]

Few immediate biological and technical complications have been reported that includes fistula formations, periimplantitis, and soft-tissue dehiscence and exposure of metal margin, loosening of abutments and loosening or fractures of crowns. However, in most of the cases, abutments could be retightened and crowns could be recemented easily.[18,19]

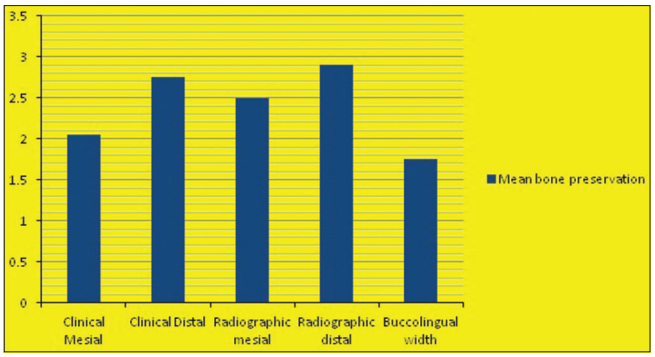

Figure 5: Graph showing total amount of vertical and horizontal bone preserved

Technically, in our study, one case had to be managed with 15 degree angulated abutment at the time of implant loading which is not considered as a complication as such. A natural looking restoration with the presence of harmonious gingival architecture was achieved in all cases including it. Thus, with regard to implant survival and success, there seems to be no reason to abstain from immediate placement of implants into fresh extraction sockets. Immediate placement of single tooth implants into fresh extraction sockets could be considered a valuable option to the delayed implant placement after complete ossification of the extraction socket with the advantages of restriction of additional bone loss, reduced treatment time, allow ideal implant position with favorable load distribution, improved function and esthetics, and better acceptance of the treatment plan by the patient.[20]

CONCLUSION

The results of the present study suggested that a different pattern of bone remodeling occurs around immediate dental implants. Immediate implant placement into fresh extraction socket offers a predictable solution to tooth loss and also preserves noteworthy bone and soft-tissue dimensions as compared to without implant placement. As in the present study, cases are not few sufficient to give any definitive conclusions for new guidelines for the modern rules of ideal timing of implant placement after tooth extraction, more extensive studies with larger sample sizes are recommended.

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Original Article

Prevalence and Predictors of Advanced Glaucoma at Presentation

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Abstract

Introduction: Despite advances in newer technologies and methods to diagnose and monitor patients of glaucoma, a meaningful proportion of patients present in an advanced phase of the disease. Our study aimed to assess the prevalence and evaluate the risk factors associated with advanced glaucoma in a hospital-based population.

Materials and Methods: In this case–control and observational study, randomly selected 760 eyes of 394 glaucoma patients were assessed. Patients having advanced glaucoma were grouped as cases and those having mild-to-moderate glaucoma as controls. Risk factors in each case were identified, tabulated, and statistically analyzed.

Results: Out of 760, advanced glaucoma was observed in 261 (34.3%) eyes. Multivariable logistic regression analysis revealed male gender, rural residency, unskilled occupation, diabetes mellitus or hypertension, no eye examination in the past 2 years, negative family history for glaucoma, and illiteracy as independent risk factors for advanced glaucoma at presentation.

Conclusion: High prevalence (34.3%) of advanced stage glaucoma at presentation in our study warrants the necessity to escalate consciousness among public on outcome of silently blinding disease, glaucoma especially in subjects who have identifiable risk factors. Public awareness would substantially halt their further visual deprivation and reduce the socioeconomic burden of the disease on the society.

Key words: Advanced stage, Glaucoma, Public awareness, Risk factors, Socioeconomic burden

INTRODUCTION

Glaucoma is the leading cause of irreversible blindness worldwide.[1] Unfortunately, the visual field loss in glaucoma is gradual, painless, and affects the peripheral field before encroaching on the central field of vision due to which a significant proportion of patients present when the disease has already progressed to advanced stage and are at imminent danger of lifetime blindness. Gessesse and Damji observed 38% of newly diagnosed glaucoma patients in advanced stage.[2] Gogate *et al.* also concluded that lack of education and awareness about glaucoma was major risk factors for late presentation.[3]

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MATERIALS AND METHODS

After taking permission from the Ethical Review Committee, the present study was conducted on 760 eyes of 394 consecutive patients of glaucoma visiting outpatient department on alternate days of Regional Institute of Ophthalmology in North India between January 2017 and December 2019. Eyes with absolute field loss within 5 degree of fixation, mean deviation >−12dB on visual field examination by Humphery field analyser and vertical cup disc ratio ≥0.8 on fundus examination were identified as having advanced glaucoma and grouped as cases. Eyes with VCDR>/=0.5 or difference of vertical cup disc ratio >0.2 between two eyes with typical glaucomatous field defects (mild-moderate glaucoma) were grouped as controls. Written informed consent was obtained from each patient before enrolment in accordance with declaration of Helsinki.

Detailed examination of all the patients including Snellen visual acuity, applanation tonometry, slit lamp

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Table 1: Risk factors for advanced glaucoma among glaucoma patients

Study Factor	Cases *n*=261 (%)	Controls *n*=499 (%)	*P*-value	Statistical Significance
Mean Age	68.27±8.135 years	60.25±10.534 years	<0.01	Highly Significant
Mean Intra Ocular Pressure	32.86±3.410mmHg	21.68±6.935 mmHg	<0.01	Highly significant
Mean Central Corneal Thickness	512.83±19.605 microns	518.47±17.636 microns	>0.05	Non-significant
Gender				
Males	207 (80.1)	281 (57.6)	<0.01	Highly Significant
Females	54 (19.9)	218 (42.4)		
Residency				
Rural	197 (75.5)	315 (63.1)	<0.05	Significant
Urban	64 (24.5)	184 (36.9)		
Education Level				
Illiterate	218 (83.5)	258 (51.7)	<0.01	Highly significant
Literate	43 (16.5)	241 (48.3)		
Occupation				
Skilled	64 (24.5)	228 (45.7)	<0.01	Highly Significant
Unskilled	197 (75.5)	271 (54.3)		
Family History of Glaucoma				
Negative	205 (78.5)	261 (52.3)	<0.01	Highly significant
Positive	56 (21.5)	238 (47.7)		
History of Systemic Disease				
Negative	65 (28.7)	331 (66.3)	<0.01	Highly Significant
Positive	186 (71.3)	168 (33.7)		
Eye examination in the past 2 years				
No	238 (91.2)	304 (60.9)	<0.01	Highly significant
Yes	23 (8.8)	195 (39.1)		
Economic dependence				
Economically independent	105 (40.2)	191 (38.3)	>0.05	Non significant
Economically dependent	156 (59.8)	308 (61.7)		

Table 2: Multivariate analysis of risk factors

Risk factor	Multivariate analysis	
	P-value	OR (95% CI)
Gender	0.000	0.226 (0.134–0.382)
Residency	0.000	0.414 (0.254–0.676)
Education	0.000	0.406 (0.248–0.663)
Negative Family history	0.000	0.364 (0.226–0.586)
Occupation	0.032	0.602 (0.378–0.957)
History of either diabetes mellitus or hypertension	0.000	4.350 (2.705–6.995)
Eye examination in the past 2 years	0.000	0.110 (0.059–0.207)

examination, gonioscopy with two mirror Goldman Gonio lens, fundus examination using direct and indirect ophthalmoscope, and visual field examination by Humphery field analyser was done. Patients with corneal opacity, secondary glaucoma, cataract, high myopia, or with history of ocular trauma or surgery were excluded from our study.

Data of all the patients including their age, IOP, central corneal thickness, residency-rural or urban background, education status, family history of glaucoma, skilled or unskilled occupation, history of diabetes mellitus or hypertension, history of ophthalmic examination in the past 2 years, economic dependence were recorded and compiled.

Statistic Analysis

Descriptive measures were expressed as percentages and/or means with standard deviations. Correlations were evaluated using univariate and multivariate tests. The statistical analysis was done using IBM SPSS for Windows, Version 19.0; Inc., Chicago, Illinios, USA. For univariate analysis, Pearson Chi-square and student *t*-test were used according to the nature of variables. For multivariate analysis, multivariate logistic regression analysis was used to adjust confounders. The level of statistical significance was set at $P < 0.05$. All variables with $P \leq 0.05$ in univariate logistic regression were considered candidates for multivariate logistic regression models. Odds ratios and 95% confidence intervals were calculated for the same.

RESULTS

Out of 394 patients recruited in the study, 249 (63%) were males and 145 (37%) were females. Two hundred and seventy-four (69.5%) patients were diagnosed as primary open angle glaucoma and 120 (30.5%) as primary angle closure glaucoma. Seven hundred and sixty eyes of 394 glaucoma patients were included in the study. Twenty-eight eyes were excluded due to either history of ocular trauma or surgery or due to hazy cornea, dense cataract, or some pathology in the posterior segment. On the basis of the given criteria, 261 (34.3%) eyes were diagnosed as

advanced glaucoma and grouped as cases and the remaining 499 (65.7%) of mild-to-moderate glaucoma patients as controls.

Univariate analysis of the risk factors associated with advanced glaucoma revealed that the mean age of cases (68.27 ± 8.135 years) was statistically higher than the mean age of controls (60.25 ± 10.534 years). Significant association was observed between male gender and advanced glaucoma ($P < 0.01$). The difference in mean IOP of cases (32.86 ± 3.416 mmHg) and of controls (21.68 ± 6.935 mmHg) was also statistically significant ($P < 0.001$) whereas CCT in both the groups (512.83 ± 19.605 microns of cases and 518.47 ± 17.636 microns of controls) was comparable ($P > 0.05$). The prevalence of advanced glaucoma was significantly more in patients from rural background ($P < 0.05$), with the lower level of education ($P < 0.001$) in unskilled workers ($P < 0.05$) in patients who had no family history of glaucoma ($P < 0.001$) and in those who gave history of no eye examination in the past 2 years ($P < 0.001$). There was also a significant association between diabetes mellitus and/or hypertension with advanced glaucoma ($P < 0.01$) whereas it was not found to be appreciably correlated with economic dependence of the patient ($P > 0.05$).

Multivariate analysis using multivariate logistic regression model revealed male gender ($P = 0.000$), rural residency ($P = 0.000$), illiteracy ($P = 0.001$), negative family history ($P = 0.000$), unskilled occupation ($P = 0.032$), history of either diabetes mellitus or hypertension ($P = 0.000$), and no eye examination in the past 2 years ($P = 0.000$) as notable risk factors for advanced glaucoma [Tables 1 and 2].

DISCUSSION

A small island of vision in the visual field during advanced stage of glaucoma is the major risk factor for lifetime blindness. It is not only agonizing for the patient but also reflects helplessness of the treating doctor. Asymptomatic nature of the disease, lack of awareness among public, and absence of persuasive screening programs in the developing countries contribute to late presentation of the disease. The present study attempts to identify the prevalence of advanced glaucoma at presentation and to elucidate the risk factors associated with it.

In our study, 261 (34.3%) eyes were detected to be having advanced stage glaucoma at presentation. It was in accordance with observations in the literature.[2]

Abdull *et al.* in 2015, exhibiting the data of patients attending glaucoma clinic, revealed that 52% patients at presentation were blind in Northern Ghana (2005), 29% in Dar in Tanzania (2005), 41% in Ethiopia (2006), 25% in Benin (Nigeria) (2006), 21% in Nigeria (Kano) (2007), 34% in Yaounde (Cameroon) (2008), and 35% blind in Nigeria.[4] Criteria for blindness were presenting visual acuity <3/60 in better eye. The study emphasized on glaucoma blindness prevention strategies which promote early detection, and counseling of the patients to promote acceptance and adherence to treatment.[4]

The late presentation when the visual field defect progresses to involve central vision becomes a risk factor for glaucoma blindness.[5]

Older age (68.27 ± 8.135 years) was associated with advanced glaucoma at presentation as compared to controls (60.25 ± 10.534 years) in our study ($P < 0.05$). In agreement with our observations, Deva *et al.* found that older age (>63 years) was associated with visual field defects at presentation.[6] AW Francis *et al.* also confirmed that patients older than 65 years of age had significantly higher chances of progressing to advanced stage.[7] The probable exposition could be due to associated comorbidities in old age which impair optic nerve perfusion or to their late presentation in a relatively asymptomatic disease.

Similar to studies in the literature, we observed that men are more likely to present with advanced glaucoma ($P < 0.01$) than women.[4,8-11] The likely explanation is that women avail medical and health services earlier than men.[12]

Although patients with a first degree family history of glaucoma are 10 times more likely to have visual field defects at the time of glaucoma diagnosis but negative family history of glaucoma was found to be strongly associated with advanced glaucoma at presentation in our study ($P < 0.01$).[6] Patients with positive family history of glaucoma are more aware about the disease and attend ophthalmologist regularly whereas when there is no family history, people are less likely to know about the disease or its outcomes and they intend to present late when the disease has already progressed to advanced stage. Similar findings have also been reported in the literature.[4,11,13]

No statistical significance was observed between advanced glaucoma at presentation and central corneal thickness (CCT) in our study ($P > 0.05$). A study in 2012 also concluded that thinner CCT did not have more advanced visual field loss.[14]

Higher IOP (32.86 ± 3.410 mmHg) was significantly associated with advanced glaucoma at presentation in our study. Similar findings were confirmed in the literature.[4,9,11]

No eye examination in the past 2 years, lower education level, unskilled occupation, and history of systemic diseases such as diabetes mellitus and/or hypertension were significantly associated with advanced glaucoma at presentation. It was in accordance with other studies.[2,11-13,15-17]

A recent study on advanced glaucoma also identified asymptomatic high IOP, no family history, socially disadvantaged, and no recent sight testing as significant risk factors for glaucoma at diagnosis.[18]

The main limitation of our study was that it was a hospital-based study and sample size was small. Further prospective population-based studies for assessing these variables are required to evaluate more precisely the magnitude of the cause effect relationship more precisely.

CONCLUSION

Despite best of the treatment, patients with advanced glaucoma are at imminent danger of losing their vision. High prevalence (34.3%) of advanced stage glaucoma at presentation in our study warrants the necessity to escalate consciousness among public on outcome of silently blinding disease, glaucoma especially in subjects who have identifiable risk factors. Public awareness would substantially halt their further visual deprivation and thus reduce the socioeconomic burden of the disease on the society.

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Original Article

Comparative Evaluation of Bond Strength of Elastomeric Impression Materials with Different Tray Materials using Different Tray Adhesives: An *In Vitro* Study

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ABSTRACT

Introduction: Incomplete adhesion between the impression material and the tray can result in indelible deformity. Particularly, when the impression is removed with force, it can result in disengagement between the impression and the tray material. This can cause misshaping and warping of the final impression which ultimately leads to an inaccurate working model and poor fitting prosthesis.

Purpose: This study aims to compare and evaluate the bond strength between three different medium body elastomeric impressions with four different tray materials with the use of impression-specific, universal, and an unconventional adhesive.

Materials and Methods: Three medium body elastomeric impression materials (PVS, PE, and VXSE) and four custom tray materials (auto-polymerizing PMMA, Type II PMMA, Visible light-cure, and 3D printed Polylactic acid tray material) were used. For each impression material, three tray adhesives were used (impression-specific, universal, and unconventional adhesive). The trays were subjected to mechanical and chemical surface treatment by placing vertical and horizontal grooves with a bur and by applying tray adhesives. The tensile bond strength was tested using a Universal Testing Machine (INSTRON).

Results: Auto-polymerizing PMMA and 3D printed Polylactic acid trays showed significantly higher bond strength with all the impression materials and adhesives when compared to Type II PMMA and Visible light-cured trays. Impression-specific adhesives (Caulk, 3M ESPE and Identium) and Unconventional adhesive (Loctite, Cyanoacrylate) showed significantly higher bond strength with all the trays and impression materials when compared to Universal (Medicept) adhesive.

Conclusions: The use of either auto-polymerizing PMMA and 3D printed polylactic acid tray materials in combination with impression-specific adhesives and macroscopic roughening of the trays is suggested for better bonding between the tray and the impression materials.

Key words: Bond strength, Custom trays, Elastomers, Medium body, Tray adhesives

INTRODUCTION

Impressions play a crucial role in dentistry in general and in prosthodontics in particular. Successful indirect restoration requires distinct working casts or models which result from accurate impressions. The impression tray is a device used to carry, confine and control the impression material, while the impression is made. The choice of materials and techniques for fabricating custom trays is extensive, ranging from auto polymerizing, heat-activated acrylic resins, visible light-curable resins to thermoplastic resins. In the recent years, computer-aided design (CAD) and additive manufacturing technologies are also being used for custom tray fabrication. Fabricating a custom tray for final impressions is favored due to its merits. The

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key concept of using a custom tray is that it ensures a uniform thickness of impression material throughout the tray. Due to this, elastomeric impression materials undergo polymerization proportional to their thickness which is very beneficial. The custom tray's rigidity reduces the potential for distortion of impression compared to flexible stock trays.[1] In addition, the custom tray design minimizes the amount of material required for each impression, thereby reducing the cost per impression.[1] Hence, it is pivotal to properly bind the impression material to the rigid tray with the right adhesive. Bonding between conventional or 3D printed custom trays with impression material is an essential factor. For trays to be clinically effective, they must be rigid, firm. Dimensionally stable and should ensure adequate retention of the impression material. The impression material should remain attached to the tray in some way or the other. This retention can be acquired by either mechanical or chemical means. The mechanical means is usually by macroscopic roughening and the chemical means is by tray adhesive application. This study focuses on comparing and evaluating the bond strength of three different medium elastomeric impression materials (Polyvinyl siloxane, Polyether and Vinylsiloxane ether) to four different tray materials (auto-polymerizing PMMA, Type II PMMA, Visible light-cure, and 3D printed tray material) with the use of impression-specific (Caulk, 3M ESPE, Identium), universal (Medicept), unconventional (Loctite) adhesives.

MATERIALS AND METHODS

Three medium body elastomeric impression materials (PVS, PE, and VXSE) and four custom tray materials (auto-polymerizing PMMA, Type II PMMA, Visible light-cure, and 3D printed Polylactic acid tray material) were used. A total of 360 tray samples were fabricated, of which 120 were used for PVS, 120 were used for PE, and 120 were used for VXSE impression material. For each impression material, three tray adhesives were used (impression-specific, universal, and unconventional adhesive) [Figure 1].

Fabrication of Tray Samples

The tray samples were fabricated according to ADA specification no. 19 for elastomeric impression materials. One tray sample constituted of: (i) A tray of 30 mm × 4.5 mm thickness and 24 mm × 2 mm thickness hollow space for impression material and (ii) a solid disk of 30 mm × 2.5 thickness. A stainless-steel wire (gauge 19) was embedded on the opposite surface of both the tray specimens as a means of attachment to the universal testing machine [Figure 2]. Auto-polymerizing PMMA and Type II PMMA tray specimens were mixed in the ratio of 3:1 in a clean porcelain container, and were placed in the mold created from putty. For the fabrication of visible light-cured tray samples, vacuum-formed thermoplastic sheets were used instead of putty material to create the mold space. Light cure resin tray sheets were cut and placed into thermoplastic molds and were cured in a visible-light curing unit at 70–80 F for 2 min. For 3D printed trays, the polymethylmethacrylate trays and disks were scanned (Up3d UP300 3D Dental Laboratory Scanner). The looped SS wire was also scanned along with the trays and the disks. The scanned samples were designed using CAD software (OpenSCAD 2015.3-2, Windows) to obtain 3D data, and the samples were manufactured in a commercially available FFF 3D printer. With a margin width of 5 mm, a raft layer was formed to hold the tray samples. The raft layer had a thickness of 100 μm and the infill density was about 100%. After printing, the PLA tray samples were detached from the raft layer and were garnered. All the trays were fabricated 24 h before testing for tensile strength [Figure 3].

Surface Treatments

The surface of the tray was prepared by placing vertical and horizontal grooves with an inverted cone bur at a depth of 0.5 mm and even spaces of 10 mm. Later, the two strokes of tray adhesive were applied with a clean brush to the tray surfaces and were allowed to dry in the open air for 15 min. The, the trays were loaded with each impression material. All the samples were tested for tensile bond strength after 30 min of the setting of impression material using a Universal Testing Machine (INSTRON). Testing was performed in the tensile mode at a cross-head speed of 5 mm/min, set at full-scale load until separation failure was observed.

RESULTS

The maximum load (N) and the ultimate tensile strength (MPa) to separate the impression material from the tray were recorded. The numbers presented were mean of the samples' maximum load. The statistical analysis was performed using Statistical Package for the Social Sciences version 15.0, the statistical analysis software. The data were analyzed by analysis of variance test (ANOVA). The data were compared as a function of tray groups [Table 1] and as a function of adhesives [Table 2].

From the results obtained in the above study [Table 1], it can be deduced that the tensile bond strength achieved by both conventional auto-polymerizing PMMA trays and the new 3D printed Polylactic acid trays with all the three elastomeric impression materials and tray adhesives was similar. Among all the trays, auto-polymerizing PMMA and 3D printed Polylactic acid trays showed the highest tensile bond strength to medium-body elastomeric impression

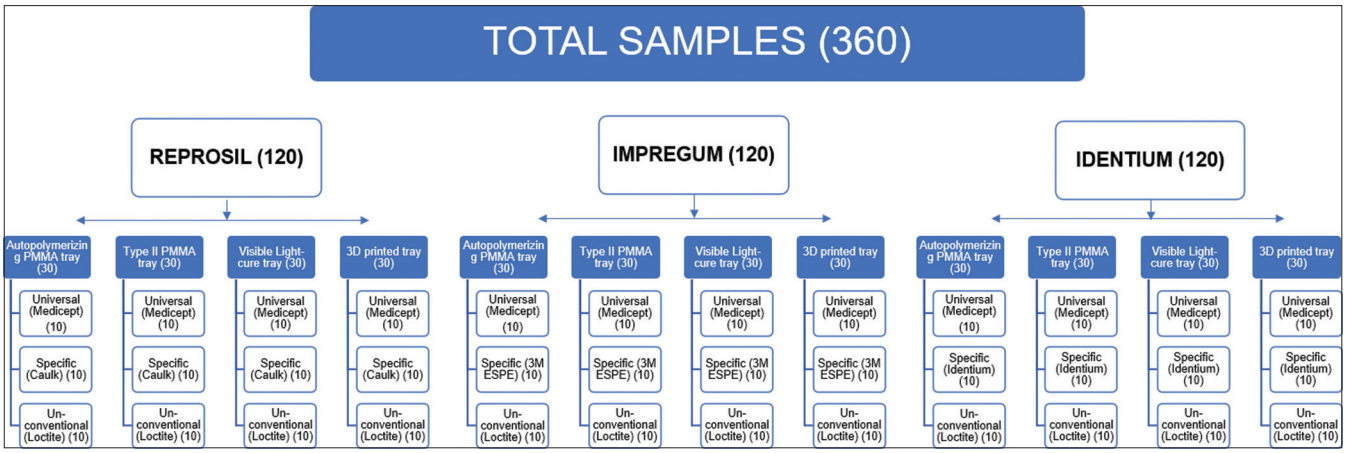

Figure 1: Schematic representation of distribution of the samples

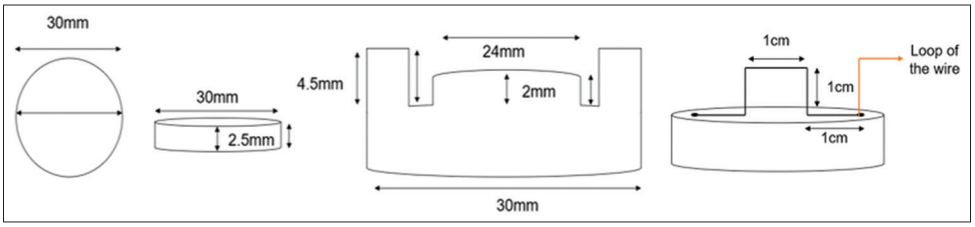

Figure 2: Schematic representation of the stainless-steel die and tray sample with embedded wire

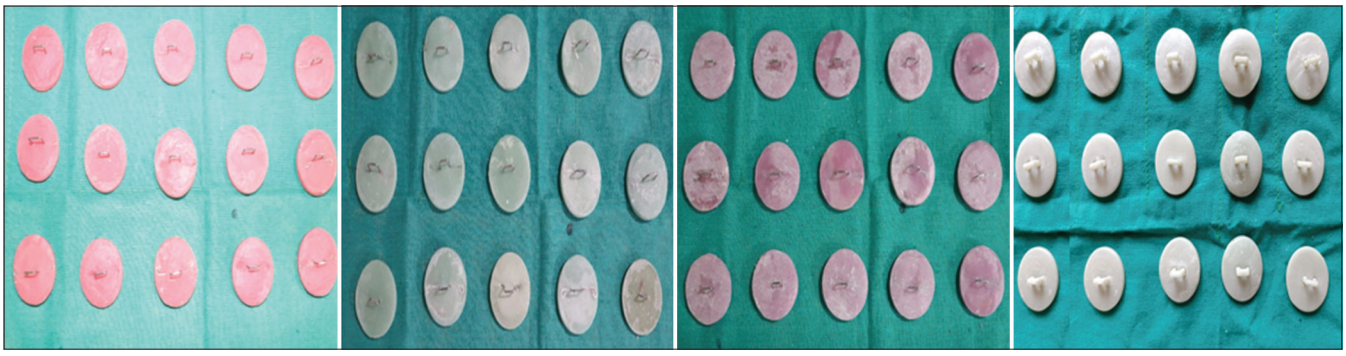

Figure 3: Tray samples: Auto-polymerizing PMMA, Type II PMMA, visible light-cure, and 3D printed PLA (from left to right)

materials with all the three adhesives. The *P*-values of the one-way ANOVA tests were <0.05, depicting a high statistically significant difference between the trays. The tensile bond strength achieved by visible light-cured trays was the least when compared to the other three tray materials with all the three impression materials and adhesives.

When the tensile bond strength achieved was compared as a function of adhesives [Table 2], the results obtained depicted that universal tray adhesive (Medicept) showed significantly lower bond strength than impression-specific adhesives (Caulk, 3M ESPE, and Identium) and unconventional (Loctite) adhesive. There was no such significant difference between specific and unconventional adhesives. In the case of polyether and vinylsiloxane ether impression materials, no statistical significance was observed among the three adhesives with visible light-cured trays.

DISCUSSION

Impressions are fundamental and play an essential role in dentistry. Accurate duplication of oral tissues and teeth is essential for a successful treatment outcome. Making an impression is the first step toward any treatment modality. Impression materials have also evolved from the most popular being irreversible hydrocolloid to the latest combination of elastomers (Vinylsiloxane ether). Elastomeric impression materials are available in the market in different consistency options, which include light body, medium body, heavy body, and putty consistency. Of these,

Table 1: Comparison of tensile bond strength of three impression materials as a function of tray groups with three adhesives by one-way ANOVA test

I. Comparison as a function of Tray Groups

IMP MATERIALS	TRAY GROUPS	ADHESIVES					
		Specific		Universal		Unconventional	
		Mean	f-value and significance	Mean	f-value and significance	Mean	f-value and significance
PVS (REPROSIL)	Auto -PMMA	112.651	47.6897 (*P*=127E-2)	64.86	17.4137 (*P*=3.75E-07)	114.695	47.1 (*P*=1.51E-12)
	Type II PMMA	90.01		44.905		89.293	
	VLC	41.62		28.537		44.252	
	3D PLA	115.79		62.73		115.81	
PE (IMPREGUM)	Auto -PMMA	115.13	61.8923 (*P*=2.78E-14)	62.22	14.3053 (*P*=2.69E-06)	118.43	45.0864 (*P*=2.81E-12)
	Type II PMMA	85.67		42.33		89.78	
	VLC	41.22		41.682		49.68	
	3D PLA	117.43		69.02		116.14	
VSXE (IDENTIUM)	Auto -PMMA	114.889	94.6739 (*P*=1.11E-16)	66.88	9.9206 (*P*=0.0000661)	114.23	63.5174 (*P*=1.88E-14)
	Type II PMMA	92.69		44.12		94.04	
	VLC	43.41		43.13		39.35	
	3D PLA	116.074		64.98		116.58	

p-values ≤ 0.05 depicted in green (statistically significant)

Table 2: Comparison of tensile bond strength of three impression materials with tray groups as a function of adhesives by one-way ANOVA test

II. Comparison as a function of Adhesives

IMP MATERIALS	ADHESIVES	TRAY GROUPS							
		Auto - PMMA		Type II PMMA		VLC		3D PLA	
		Mean	f-value and significance	Mean	f-value and significance	Mean	f-value and significance	Mean	f-value and significance
PVS	Specific	112.651	14.5159 (*P*=2.15E-12)	90.01	14.5159 (*P*=5.24E-05)	41.62	3.5979 (*P*=0.0412)	115.79	90.3241 (*P*=1.10E-12)
	Universal	64.86		44.905		28.537		62.73	
	Unconventional	114.695		89.293		44.252		115.81	
PE	Specific	115.13	53.566 (*P*=5.55E-16)	86.67	16.1246 (*P*=2.47E-05)	41.22	0.9372 (*P*=0.4041)	117.43	149.958 (*P*=5.33E-15)
	Universal	62.22		42.33		41.682		69.02	
	Unconventional	118.43		89.78		49.68		116.6778	
VSXE	Specific	114.889	127.0765 (*P*=1.83-14)	92.69	21.5517 (*P*=2.55E-06)	43.41	0.2855 (*P*=0.7539)	116.074	207.2751 (*P*=1.11E-16)
	Universal	66.88		44.12		43.13		64.98	
	Unconventional	114.23		94.04		39.35		116.58	

p-values ≤ 0.05 depicted in green (statistically significant), p-values ≥ 0.05 depicted in red (statistically insignificant)

the most commonly used consistencies are the medium and light body.

The medium body consistency is used primarily for making implant impressions as well as in fixed and removable treatments. Medium body elastomers or Monophase impression materials are suitable to be utilized as both the tray material and syringe material.[2] Its viscosity ensures that excess flow does not occur when it is loaded on an impression tray. However, when expressed through syringe tip, they can exhibit an apparent lowered viscosity that should be appropriate for intrasulcular impressions.[3] Hence, this study was conducted on three medium body elastomeric impression materials: Polyvinyl siloxane (Reprosil, Dentsply), Polyether (Impregum, 3M ESPE), and Vinylsiloxane ether (Identium, Kettenbach).

Beatriz *et al.*[4] studied the influence of trays on the accuracy of the impression made with elastomers and concluded that an ideal thickness of 2–3 mm of tray material is required to reduce distortion and avoid permanent deformation. About 2–3 mm of the thickness of tray material is ideal and will be sufficient to obtain a precise impression. Elastomeric impressions are found to be more accurate with a cross-sectional thickness of 2 mm.[5] Various authors have also reported that the ideal thickness of elastomeric impression material is between 2 and 4 mm.[1,4] Hence, in the present study, the trays were fabricated with a thickness of 2.5 mm, and a spacer was placed to make sure that a constant thickness of 2 mm of impression material.

It has been demonstrated that auto polymerizing acrylic resins should be made 24 h before the impression procedure.[6,7] All the custom tray materials were fabricated 24 h before the impression procedure, although it is required only for auto-polymerizing PMMA and Type II PMMA trays.[1] This is done for standardization. Visible-light cure tray materials were fabricated in a thermoplastic

mold so that it allows for the transmission of light from the light-curing unit.

With respect to surface treatments of the tray, the use of both the chemical and mechanical methods was suggested to increase the retention of the tray to the impression material.[2,8,9] Sankar[8] in their study concluded that alumina blasting produces an etched surface and adhesive being viscous may not wet the tray surface. They also concluded that large irregular spaces created by bur may be more conducive to wetting. Similar results were reported by Xu *et al.*,[10] who found that grit/sandblasting with aluminum oxide reduced the already present surface roughness of fusion deposited trays and weakened the bonding between impression and adhesive. Hence, in the present study, inverted cone tungsten carbide bur (FG35) at a depth of 0.5 mm was used. Evenly spaced vertical and horizontal grooves were placed at a width of 10 mm from each other. Perforating the tray was also not encouraged as studies have shown that perforations created high concentration stresses within limited material at perforation and also it decreased the overall strength and rigidity of the tray.[11]

The tray adhesives were applied as two strokes by same operator for standardization and were dried for about 15 min before loading the impression material onto the tray. Several authors have reported the tensile bond strength between the tray and the impression material as a function of tray adhesive drying time. Most of the studies suggested that 15 min of drying time was sufficient to acquire a significant increase in bond strength.[12-17]

In the present study, the trays were allowed to dry in the open air. The study conducted by Kothari *et al.*[17] showed that open-air drying the trays after the application of tray adhesives for 15 min allowed the solvent in the adhesive to completely evaporate. As a result of solvent evaporating entirely, the layer of the adhesive bonded to the impression material is exposed.

While the impression-specific adhesives (Caulk, 3M ESPE, and Identium) were specific for each impression materials (PVS, PE, and VSXE), the universal adhesive (Medicept) and unconventional adhesive (Loctite) were used for all three impression materials. A biocompatible and medically graded adhesive was also compared with impression-specific and universal adhesives. This unconventional adhesive: Loctite which is basically composed of cyanoacrylate and marketed by Henkel adhesives has also been used in a study conducted by Arshad *et al.*,[18] in their study, they concluded that with the use of this adhesive, there was a decrease in screw loosening and have obtained significantly higher detorque values. Hence, this adhesive was studied along with other routinely used tray adhesives. The Henkel adhesive portfolio provides a wide range of medical device adhesives that are compliant with ISO 10993 biocompatibility standards. These include: Henkel Loctite PRISM 4011, 4013, Loctite 349, and Loctite 180680.[19] In the current study, Henkel Loctite PRISM 4011 adhesive was used.

In the current study, the testing for tensile bond strength was done after 30 min from the setting of the impression material. Various other authors have conducted the tensile test after the set of impression material as per the manufacturer's instructions.[20-23] However, in the present study, the test was performed after 30 min of loading of impression material onto the tray surface. This was done considering the time lapse after making the impression in a clinical scenario.

The results of the present study depicted that the tensile bond strength achieved by both auto-polymerizing PMMA trays and the 3D printed Polylactic acid trays with all the three elastomeric impression materials and tray adhesives was higher than that of Type II PMMA and visible light-cured trays. This result was consistent with the study conducted by Xu *et al.*[24] who also reported greater bond strength with 3D printed PLA and conventional trays. This might be due to the difference in solubilities by the solvent in tray adhesive to the tray material.[25] Conventional acrylics (auto-polymerizing PMMA) have a heterogeneous structure of resinous matrix with varying sizes of filler particles.[11] 3D printed Polylactic acid trays also were reported to have an inherently present surface roughness.[24] This heterogeneous structure and surface roughness of auto-polymerizing PMMA trays and 3D printed PLA trays might have provided an increased surface area for the solvent of the tray adhesive to act on which resulted in their higher bond strength with the impression material. Type II PMMA trays are known to have less polymerization shrinkage and have less residual monomer and consequently less heterogeneous structure than the conventional PMMA trays[26] which explains decreased bond strength with the impression materials when compared to conventional PMMA and 3D printed PLA trays. Visible light-cured trays, on the other hand, show near-complete polymerization and almost no residual monomer,[1] hence showing fewer microporosities when compared to other trays. This might be the reason why visible light-cured trays showed the least bond strength with the impression materials when compared to other tray materials.

When the tensile bond strength achieved was compared as a function of adhesives, the results obtained depicted that universal tray adhesive (Medicept) showed significantly lower bond strength than impression-specific adhesives (Caulk, 3M ESPE, and Identium) and unconventional

(Loctite) adhesive, except in the case of polyether and vinylsiloxane ether impression materials, this result was not significant with visible light-cured trays.

Similar results were reported by other authors.[27] A custom tray's ability to retain the impression material is dependent on the potential of the adhesive solvent to dissolve the tray resin. This might be because impression-specific adhesives had specific reactive adhesives which contributed to higher adhesive capability with the impression material. Furthermore, these reactive adhesives contain a clear flammable liquid: methyl acetate. This liquid is often used as a solvent, which is a functional ingredient in dissolving the tray surfaces.[27] While impression-specific adhesives have high distinctiveness and affinity with the impression materials, this is often lacking with universal adhesives. Yi *et al.*,[28] also in their study, suggested the use of tray adhesives of the same company as that of impression material as they have shown highest bond strength than other combinations. Unconventional adhesive (Loctite) used in the study is primarily composed of 2-octyl cyanoacrylate monomer molecules. These monomers of 2-octyl cyanoacrylate quickly polymerizes in an exothermic reaction which helps in adhesion.[29]

As for polyether and vinylsiloxane ether, there was no statistical significance among three adhesives, when using visible light-cured trays. Possibly, this is because polyether and vinylsiloxane ether contain both polar (C=O) groups which are hydrophilic, and non-polar (CH3) groups which are hydrophobic. Hence providing a more wetting surface for the adhesives to act upon. This finding was in accordance with the study conducted by Oboudi SF *et al.*[30]

The results of the current study implied that auto-polymerizing PMMA and 3D printed Polylactic acid trays showed significantly higher bond strength with all the impression materials and adhesives. This was followed by Type II PMMA trays. Visible light-cured tray materials showed the least bond strength with all the impression materials. Impression-specific adhesives (Caulk, 3M ESPE, and Identium) and unconventional adhesive (Loctite, Cyanoacrylate) showed significantly higher bond strength with the trays and impression materials when compared to Universal (Medicept) adhesive.

Limitations

1. As it is an *in vitro* study, oral mucosal conditions could not be simulated.
2. The tray samples taken in the study had flat surfaces as opposed to multiplanar surfaces of the custom trays used in the oral cavity.
3. The samples constituted of tray surfaces opposing each other, while this is not the case *in vivo*, as the impression material is opposed by teeth or oral mucosa on one side.

CONCLUSIONS

Within the limitations of the study, it can be concluded that,

1. Auto-polymerizing PMMA and 3D printed Polylactic acid trays showed significantly higher bond strength with the impression materials and adhesives and are the best choice of custom tray materials when compared to Type II PMMA and visible light-cured trays.
2. Visible light-cured tray materials showed significantly lower bond strength with the impression materials and adhesive.
3. Impression-specific adhesives (Caulk, 3M ESPE, and Identium) showed significantly higher bond strength with the trays and impression materials when compared to Universal (Medicept) adhesive. Unconventional adhesive (Loctite, Cyanoacrylate) showed bond strength similar to that of impression-specific adhesives.

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Original Article

Operative Management versus Non-operative Management of Multiple Rib Fractures and Flail Chest after Blunt Trauma Chest: A Prospective Analysis

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Abstract

Introduction: Thoracic traumas are one of the most common causes of mortality due to trauma, multiple rib fractures, and flail chest being the most lethal among them.

Purpose: The purpose of this study was to find out the best treatment modality in patients with rib fractures.

Materials and Methods: This was a prospective study, in which out of 40 patients, 20 underwent operative, and 20 underwent conservative procedures.

Results: Through the cases performed in this study, we have tried to prove that patients, who were managed operatively for multiple rib fractures, especially flail chest, required a shorter duration of ventilatory support, were less likely to require tracheostomy and were less likely to develop septicaemia than patients managed conservatively. The other inferences made from this study were that males were affected with chest trauma more than females and the mean age was 45 years in both genders. The most common cause of chest trauma was road traffic accidents, followed by fall from height and assault.

Conclusion: This study demonstrates reduction in both intensity of pain and duration of disability through operative repair which has been established by other studies too.

Key words: Fixator plates, Flail chest, Rib fractures, Thoracic trauma, Thoracotomy

INTRODUCTION

Approximately 10–15% of all traumas are thoracic traumas and they cause death in 25% of all mortalities due to trauma. The wide range of thoracic trauma ranges from an undisplaced/minimally displaced rib fracture with minimal lung injury to multiple displaced rib fractures with severe lung contusion and hemorrhage. Patients with multiple rib fractures are predisposed to pulmonary insufficiency and compromised ventilation causing hypoxemia, hypercarbia, and pH disturbances. Furthermore, paradoxical chest wall motion noted in flail chest injuries and the rib fracture pain can cause significantly low tidal volumes, alveolar collapse, and hypoxemia.

Non-operative management includes extensive use of analgesics, intercostal drainage, and mechanical ventilation. Operative intervention involves reduction and internal stabilization of the fractured ribs using fixator plates, intramedullary nails or wires, and struts.

Operative versus non-operative management for rib fractures in 40 patients of thoracic trauma was compared in this study, out of which 20 were subjected for conservative management and 20 were operated. Conclusions were drawn on the basis of reduction of

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pain and days required to return to normal activity in both the groups.

MATERIALS AND MATHODS

In this randomized study, 40 patients with multiple rib fractures were studied; 20 were managed conservatively and 20 operatively. Comparisons between the cases and controls were made on the following basis:

- Duration of disability or return to work
- Intensity of pain.

Self-assessment of pain was done by patients at days 5, 10, 30, and 45 post-injury using Wong Baker Faces Pain Assessment Scale [Figure 1]. Patients with 2 or more rib fractures or with flail chest were included in the study.

Following patients were excluded from the study:

- Patients having fractures at non accessible sites
- Vitally unstable patients requiring mechanical ventilation or ones which are comatose
- Patients having fracture in floating ribs
- Patients who did not give consent to be a part of the study.
- Figure 2 is an example of a patient with left sided multiple rib fractures showing intraoperative image of rib fixation and Figure 3 is the postoperative Xray of the same patient.

Indications and Technique of Rib Repair

Indications

- Management of pain
- Chest wall defect and deformity
- Non-union of ribs
- Flail chest
- "On the way out" for thoracotomies.

Technique of rib repair[1-4]

1. Extramedullary fixation
    - Anterior plating with wire cerclage or bicortical screws.
    - Judet Strut
    - U-Plate
    - Absorbable plates.

2. Intramedullary fixation[5,6]
    - Kirschner wire fixation
    - Wire cut out
    - Rehbein intramedullary splint.

Complications

There are various complications reported such as superficial wound infections, wound drainage without infections, empyema, wound hematoma, and persistent pleural effusion. Fixation failure (due to plate loosening or wire migration) and chest wall stiffness and pain requiring plate removal have been reported in some patients. A few patients have also reported osteomyelitis, and the most common cause for that was infection from *Staphylococcus aureus* which was due to the contamination from a pre-operative chest tube.

RESULTS

The mean age of the patients in this study was 36 years and there was a male predominance.

Distribution according to age

Age	Number	Percentage
18–40 years	28	70.0
41–60 years	11	27.5
>60 years	1	2.5
Total	40	100.0

Twenty-eight (70%) patients were in the age group 18–40 years, 11 (27.5%) were in the age group 41–60 years, and 1 (2.5%) patient was of age more than 60 years. The mean age of the patients was 35.98 ± 8.95 years (range: 18–62 years). Majority of patients sustained thoracic injury due to road traffic accidents, followed by fall from height and assault.

Distribution according to mode of trauma

Mode of Trauma	Number	Percentage
Assault	4	10.0
Fall from height	6	15.0
Road traffic accident	30	75.0
Total	40	100.0

Four (10%) patients sustained injury due to assault, 6 (15%) patients sustained injury due to fall from height, and 30 (75%) patients sustained injury due to road traffic accident. The mean number of days of work lost was significantly higher in conservative group (57 days) compared to operative group (37 days).

Comparison of mean number of days of work lost in relation to type of management

Type of management	Number	Mean±SD	*t*-value	*P*-value
Conservative	20	57.15±11.60	6.603,	0.001*
Operative	20	36.90±7.31	df=38	
Total	40			

Unpaired "t" test applied. *P*=0.001, Significant

In conservative group, the mean number of days of work lost was 57.15 ± 11.60 days and in operative group, it was 36.90 ± 7.31 days. The mean number of days of work lost was significantly higher in conservative group compared to operative group ($P = 0.001$). The mean visual analog scale

Comparison of VAS between the types of management

VAS	Conservative (Mean±SD)	Operative (Mean±SD)	*t*-value	*P*-value
Day 0	5.30±1.56	6.80±1.06	−3.562, df=38	0.001*
Day 5	5.60±1.39	7.70±0.57	−6.243, df=38	0.001*
Day 15	6.05±1.28	8.35±0.49	−7.525, df=38	0.001*
Day 30	6.70±1.22	8.75±0.72	−6.487, df=38	0.001*
Day 45	7.30±1.22	9.25±0.64	−6.340, df=38	0.001*

Unpaired *t*-test applied. *P*<0.05 was taken as statistically significant, VAS: Visual analog scale

(VAS) score in conservative group was significantly lower than operative group at all-time intervals.

- At Day 0, the mean VAS in conservative group was 5.30 ± 1.56 and in operative group was 6.80 ± 1.06. The difference was found to be statistically significant (P = 0.001), showing a significantly higher VAS in operative group
- At Day 5, the mean VAS in conservative group was 5.60 ± 1.39 and in operative group was 7.70 ± 0.57. The difference was found to be statistically significant (P = 0.001), showing a significantly higher VAS in operative group
- At Day 15, the mean VAS in conservative group was 6.05 ± 1.28 and in operative group was 8.35 ± 0.49. The difference was found to be statistically significant (P = 0.001), showing a significantly higher VAS in operative group
- At Day 30, the mean VAS in conservative group was 6.70 ± 1.22 and in operative group was 8.75 ± 0.72. The difference was found to be statistically significant (P = 0.001), showing a significantly higher VAS in operative group
- At Day 45, the mean VAS in conservative group was 7.30 ± 1.22 and in operative group was 9.25 ± 0.64. The difference was found to be statistically significant (P = 0.001), showing a significantly higher VAS in operative group
- The mean VAS score in conservative group was significantly lower than operative group at all the time intervals (P < 0.05) [Figure 4]
- In patients with flail chest, VAS score showed a better value with operative management than conservatively managed patients. As the patients in operative group were able to regain their daily activities sooner, it was found that the use of analgesics was for lesser number of days in operative group than the conservative group. [Figures 1-4].

DISCUSSION

A number of case series and research articles have been published which support the trends observed in this study.[7] In general, all of the studies favored operative fixation

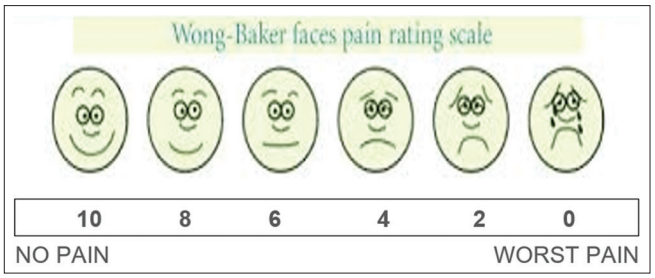

Figure 1: Wong-baker pain assessment scale

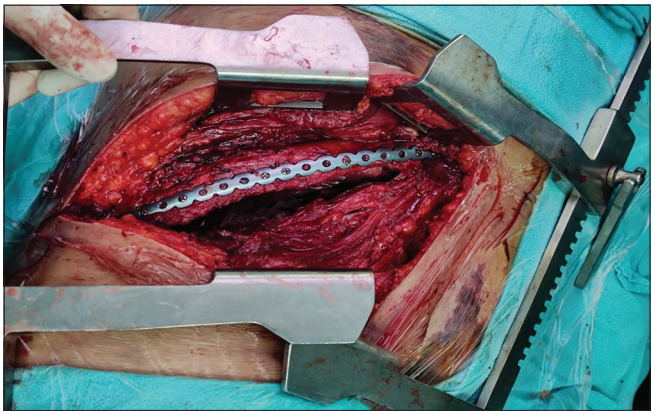

Figure 2: Intraoperative image of rib fixation

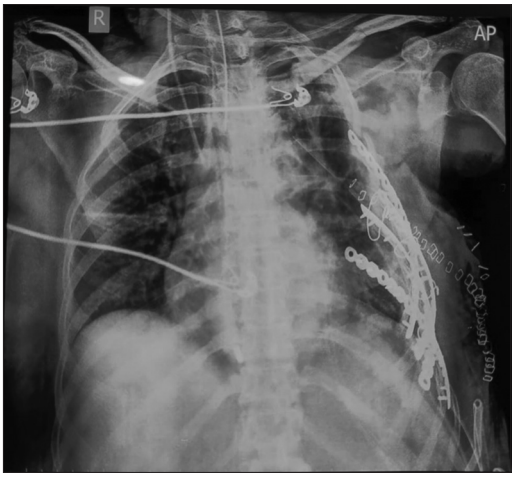

Figure 3: Post-operative X-ray

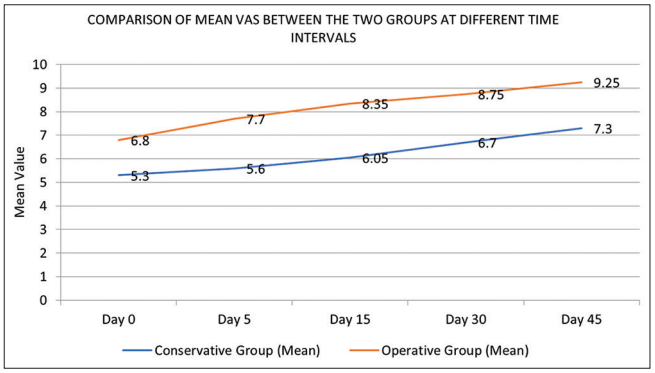

Figure 4: Mean visual analog scale between the two groups

of fractured ribs, there was a significant decrease in the number of days requiring mechanical ventilation, number of days in intensive care unit (ICU), and other pulmonary complications.[8]

Lardinois *et al.*[9] did a prospective evaluation of 66 patients who required surgery for flail chest out of a total of 732 patients. There were anterolateral flail segments in all of these patients. Reconstruction plates (made of stainless steel) were used for fixation. The mean ventilator time was significantly reduced to 2.1 days and immediate extubation was possible in 47% patients. Approximately 100% of the patients returned to their work within 2 months of surgery. Few patients required plate removal due to hardware related pain.

Nirula *et al.*[10] did a retrospective study which compared flail chest patients, half of which underwent surgery and the other half managed conservatively. Adkins Struts were used for fixation of flail segments. The operative group showed a significantly lower number of ventilator days measured from the time of surgery to extubation. This study also determined the complication rates associated with surgical fixation. Various complications were noted such as superficial wound infections, draining wounds without infections, wound hematoma, empyema, persistent pleural effusion, and hardware failures and removal.

Tanaka *et al.*[11] randomized 37 flail chest patients which were managed conservatively or operatively and compared them on the basis of requirement of mechanical ventilation. The surgically repaired group exhibited fewer days in the ICU and on ventilator and showed lower pulmonary complications than non-operative group.

Ahmed and Mohyuddin[12] compared 38 patients that were treated non surgically using positive pressure ventilation with 26 patients, in which k-wire fixation of one rib of the flail segment was done. Other related complications such as hemothorax or a major air leak, and associated abdominal and orthopedic injuries were treated surgically. Groups were not matched or randomized and no statistical analysis was performed. They reported better outcomes in number of ventilator days, number of ICU days, number of patients requiring tracheostomy, chest infection rate, sepsis rate, and mortality rate, in patients that were managed operatively.

Granetzny *et al.*[13] reported a randomized trial of 40 patients, in which the operative group exhibited considerably less mechanical ventilation, ICU and admission days, and pneumonia compared to patients managed conservatively. In the operative group, forced vital capacity and total lung capacity were extensively higher, and chest wall deformity or persistent flail chest were significantly less.

This study was different than the other studies as the above-mentioned studies address mainly to flail chest. Most of the patients included in our study had multiple rib fractures, and these are the major portion of all thoracic trauma patients appearing in Outpatient department and emergency rather than flail chest.

Limitations

Several limitations of this study must be addressed:

- First, the sample size of this study was very small. This was due to limitations of admission of patients in COVID Pandemic and due to short duration of the study. Still, this study was unique in comparing on intensity of pain and duration of disability
- Second, very limited parameters of the patients were assessed. No comparison on ICU days or admission days of patients was made. There are various parameters which affect the healing of wound and recovery like socioeconomic factors or nutrition status, which were not evaluated in this study
- Third, there was no long-term follow-up of the patients and as a result pulmonary complications were not satisfactorily evaluated. Due to this, the effect of stabilization on functional outcome of the patients that were operated was not assessed with their counterparts
- Finally, there was no standardized protocol for pain management in the control group.

CONCLUSION

Out of the 40 patients with rib fractures, 20 underwent an operative procedure for rib fracture stabilization (cases) and 20 were managed conservatively (controls) and comparisons were made between the two. This study demonstrates reduction in both intensity of pain and duration of disability through operative repair which has been established by other studies too. Both the criteria were evaluated by patients themselves.

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Original Article

Comparative Study on Neonatal Outcome between Normal Weight Pregnancy and Obesity Complicated Pregnancy

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Abstract

Introduction: Maternal pre-pregnancy body mass index (BMI) >30 kg/m^2 is associated with increased rates of many complications during pregnancy for the mother, the fetus, and the neonate. Obese pregnant women are risk of delivering large babies and the neonates of such mothers have higher Neonatal Intensive Care Unit (NICU) admissions. Therefore, we aimed to compare the neonatal outcomes between normal weight pregnancy and obesity complicated pregnancy from a sample of population of Tamil Nadu.

Aims and Objectives: The aims of our study were to compare the neonatal outcomes between normal weight pregnancy and obesity complicated pregnancy.

Materials and Methods: This was a case–control study comprising 50 normal weight pregnant women (controls) and 50 obese pregnant women (cases). It was conducted in C.S.I Rainy Multispecialty Hospital, Chennai between April 2008 and March 2010. Mothers in first trimester who had BMI >30 kg/m^2 were chosen as cases and mothers in first trimester who had BMI between 18.5 kg/m^2 and 25 kg/m^2 were chosen as controls. The following neonatal outcomes were studied: Gestational age at birth, mean birth weight, APGAR score at 5 min, and Admissions in NICU.

Results: There was no statistically significant difference (P = 0.109) in terms of gestational age at birth between neonates of obese pregnancy and neonates of normal weight pregnancy. There was a statistically significant difference (P = 0.005) in the mean birth weight between neonates (3.20 kg) of obese pregnancy and neonates (2.94 kg) of normal weight pregnancy, APGAR at 5 min showed no statistical significance (P = 0.646) between case and controls. NICU admission was also found to be statistical insignificant (P = 0.296) between two groups.

Conclusion: Obesity is a risk factor that complicates pregnancy in more ways than one, affecting both the mother and the neonate. Maintenance of weight among pregnant women within the accepted limits of BMI would go a long way in ensuring better neonatal outcomes.

Key words: Neonatal outcome, Normal weight pregnancy, Obesity complicated pregnancy

INTRODUCTION

The World Health Organization (WHO) defines obesity as an abnormal or excessive fat accumulation that presents a risk to health, using the body mass index (BMI) ≥30 kg/m^2 as a crude estimate.[1] The global prevalence of obesity has increased considerably over the past two decades, and currently, about two billion people are either overweight or obese.[2] The WHO characterizes obesity as a pandemic issue, with a higher prevalence in females, especially those of child-bearing age, than in males.[3] Obesity is a rapidly emerging public health problem for women, with around 17.9% of pregnant women in first trimester presently classed with obesity.[4]

The health consequences of obesity come from excess adipose tissue, not the size of one's body. In spite of this limitation, BMI continues to be used today, because it is easily calculated and is the best tool available from a broad-

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based health policy perspective.[5] It is well known that obesity increases morbidity for both mother and fetus and is associated with a variety of adverse reproductive outcomes.[6-9]

Pregnancy complications in obese women were identified as early as 1945.[10] Complications of obesity seriously affect the obstetric outcome of such women, endangering both maternal and fetal health and well-being. Chinese researchers estimate that increasing BMI is associated with increased risks of adverse obstetric outcomes, such as pre-eclampsia, gestational diabetes, and preterm delivery.[11] Since then, a number of studies have reported a clear association between maternal obesity and adverse pregnancy and neonatal outcomes. In particular, obesity in pregnancy is associated with a high rate of pre-eclampsia, pregnancy-induced hypertension, gestational diabetes, abnormal labor, cesarean section, fetal macrosomia, lower respiratory tract infections, and infant birth defects.[12-16]

Maternal obesity is associated with abnormal fetal growth. Women who are heavier are less likely to have a pregnancy complicated by a small for gestational age infant or intrauterine growth restriction, but this protective effect appears to dissipate once the maternal BMI reaches the level of obesity (30 kg/m^2). The major concern in obese pregnant women is fetal macrosomia, which appears to be increased 2–3-fold in obese parturients.[17] Although a number of factors may explain this global increase in the prevalence of fetal macrosomia, the prevailing data suggest that maternal obesity is the main factor, followed by maternal diabetes status.[17]

Moreover, there appears to be a dose dependent relationship between maternal obesity and fetal macrosomia. In a recent meta-analysis, the prevalence rates of fetal macrosomia were 13.3% and 14.6% for obese and morbidly obese women, respectively, compared with 8.3% for the normal weight control group.[18]

Conventionally, the physical condition of the newborn is assessed using the APGAR scores at 1, 5, and 10 min after birth. Low APGAR scores indicate depressed vitality and are a useful tool for prediction of adverse neonatal and long-term outcomes.[19-22] Although there are a number of possible causes of low APGAR scores[23,24] among term infants without malformations, the vast majority of cases with APGAR scores between 0 and 3 at 5 min are due to perinatal asphyxia.[25] The previous studies on offspring of women with overweight and obesity found increased risks of APGAR <7 at 1 or 5 min.[26-28]

Aims and Objectives

The aims of the study were to compare the neonatal outcomes between normal weight pregnancy and obesity complicated pregnancy.

MATERIALS AND METHODS

This study was a case–control study comprising 50 normal weight pregnant women as controls and 50 obese pregnant women as cases. It was conducted in C.S.I Rainy Multispecialty Hospital, Chennai between April 2008 and 2010 after obtaining approval from the Institutional Ethics Committee and written informed consent from the participants. Obesity is defined by the presence of excessive total body fat. Since total body fat content is difficult to measure directly and since it correlates with total body mass divided by height^2 (BMI), overweight and obesity are commonly evaluated with simple measurement of height and weight and are defined as BMI between 25 and 29.9 kg/m^2, and BMI above 30 kg/m^2, respectively.

Mothers in first trimester who had BMI >30 kg/m^2 were chosen as cases and mothers who had BMI between 18.5 kg/m^2 and 25 kg/m^2 were chosen as controls.

Inclusion Criteria

The following subjects were included for our study:

- Pregnant women with first trimester BMI >30 kg/m^2
- Pregnant women with first trimester BMI between 18.5 kg/m^2 and 25 kg/m^2
- Pregnant women of all ages, all parity, and all socioeconomic status

Exclusion Criteria

The following subjects were excluded from our study:

- Mothers not booked at first trimester, miscarriage, mothers carrying anomalous baby, pregnant women with first trimester BMI between 25.1 kg/m^2 and 29.9 kg/m^2, pregnant women with first trimester BMI < 18.5 kg/m^2, and pregnant women who could not be followed up until delivery.
- Detailed history was taken and physical examination was carried out in pregnant mothers who were selected according to the criteria. They were followed up to delivery and postpartum and the neonatal outcome was studied until discharge. The following neonatal outcomes were studied: Gestational age at birth, mean birth weight, APGAR score at 5 min, and admission in Neonatal Intensive Care Unit (NICU).

Statistical Analysis

Differences between the case and control groups were evaluated using Chi-square and student "*t*" test. Statistical significance was deemed at $P < 0.05$.

RESULTS

In terms of gestational age at delivery, as given in Table 1, 90% of obese pregnant women and 94% of control women

delivered at term and 10% of obese women and 6% of control group delivered preterm. The difference between the cases and controls was not statistically significant. Chi-square = 0.577 and P = 0.749. The difference between two groups is not statistically significant.

As given in Table 2 below, 44% of the neonates of obese mothers were weighing between 3.00 and 3.49 kg, while 50% of the neonates of normal weight mothers were weighing between 2.50 and 2.99 kg. About 22% babies of obese women were between 3.50 and 3.99 kg, while 10% of the neonates of normal weight mothers were between 3.50 and 3.99 kg. Two babies (4%) were > 4.00 kg in obese mothers compared to no babies above 4.00 kg in normal weight mothers. Mean birth weight of the neonate in obese mothers was 3.20 kg and the same was 2.94 kg in normal weight mothers. Chi-square = 2.868, $P = 0.005$, it is statistically significant.

As shown in Table 3, among the neonates of obese women, APGAR score at 5 min of >7 was seen in 94% of neonates, while 6% neonates had APGAR score at 5 min of <7. Among the neonates of normal weight women, APGAR score at 5 min of >7 was seen in 96% of neonates, while 4% neonates had APGAR score at 5 min of <7. $P = 0.646$, it is statistically insignificant.

As shown in Table 4, 34% of babies born to obese women and 20% of babies born to control women were admitted in NICU. Major reasons for admission in babies of obese group were infant of diabetic mother, preterm, and macrosomia, while, in control group, the reasons were meconium aspiration and infant of diabetic mother. $P = 0.296$, it is statistically insignificant.

Table 1: Gestational age at delivery

Gestational age (wks)	Controls (Normal weight pregnancy)		Cases (Obese pregnancy)	
	Number	Percentage	Number	Percentage
>37 (Term)	47	94%	45	90%
35–36.6 (Preterm)	2	4%	3	6%
32–34.6 (Preterm)	1	2%	2	4%

DISCUSSION

Data regarding maternal obesity and preterm birth are conflicting. A study done by Baeten *et al.*[16] showed that there is an increased risk of preterm birth in obese pregnant women compared to normal weight pregnant women. A study done by Sebire *et al.*[29] showed that there is no increased risk of preterm birth in obese pregnant women compared to normal weight pregnant women. As shown in Figure 1, in our study, we found out that 90% of obese pregnant women and 94% of normal weight women delivered at term, while 10% of obese pregnant women and 6% of normal weight women delivered preterm. The difference was not found to be statistically significant which is in accordance with the study of Sebire *et al.*[29]

In our study, as shown in Figure 2, we found out that 26% of obese group mothers delivered babies of weight >3.5 kg, while only 10% of the control group mothers delivered babies of weight >3.5 kg. As shown in Figure 3, the mean birth weight of the neonates of obese group was 3.2 kg and that of the control group was 2.94 kg. This is statistically significant. This finding of ours is similar to the findings of studies done by Sebire *et al.*[29] and Ehrenberg *et al.*[30]

A study done by Persson *et al.*[31] clearly demonstrates that maternal overweight and obesity are associated with increased risks of low Apgar scores (0–3) at 5 and 10 min. However, a study done by Rode *et al.*[32] had opposite results. In our study, as shown in Figure 4, there was a difference of only 2% between cases and controls in APGAR score at 5 min. This is not statistically significant. This is in accordance with the studies done by Rode *et al.*[32]

Neonates of obese mothers had increased admissions, the major reasons for admissions being preterm, macrosomia, and gestational diabetes. According to a study by Suk *et al.*,[33] NICU admission rate was significantly associated with maternal obesity. Another study done by Minsart *et al.*[34] revealed that adjusted odds ratio for NICU admission was higher for obese mothers by 38% compared to non-obese mothers. However, in our study, we got contrary

Table 2: Mean birth weight of the neonate

Birth weight (Kg)	Controls (Normal weight pregnancy)			Cases (Obese pregnancy)		
	Number (%)	Mean Birth Weight (kg)	Standard Deviation	Number (%)	Mean Birth Weight (kg)	Standard Deviation
1.50–1.99	1 (2%)	2.94	0.416	1 (2%)	3.20	0.494
2.00–2.49	2 (4%)			1 (2%)		
2.50–2.99	25 (50%)			13 (26%)		
3.00–3.49	17 (34%)			22 (44%)		
3.50–3.99	5 (10%)			11 (22%)		
>4.00	0 (0%)			2 (4%)		

Table 3: APGAR at 5 min

APGAR at 5 min	Controls (Normal weight pregnancy)		Cases (Obese pregnancy)	
	Number	Percentage	Number	Percentage
< 7	2	4.0	3	6.0
> 7	48	96.0	47	94.0

Table 4: NICU admission and their indications

Indications	Controls (Normal Weight Pregnancy)		Cases (Obese Pregnancy)	
	Number	Percentage	Number	Percentage
Meconium aspiration	3	6.0	2	4.0
Respiratory distress	1	2.0	0	0.0
Infant – DM mothers	3	6.0	8	16.0
Preterm	3	6.0	5	10.0
IUGR	0	0.0	0	0.0
Abnormality	0	0.0	0	0.0
Macrosomia	0	0.0	2	4.0
Total	10	20.0	17	34.0

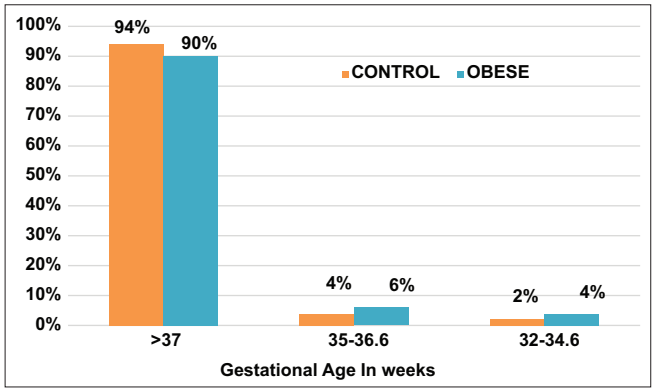

Figure 1: Gestational age at delivery

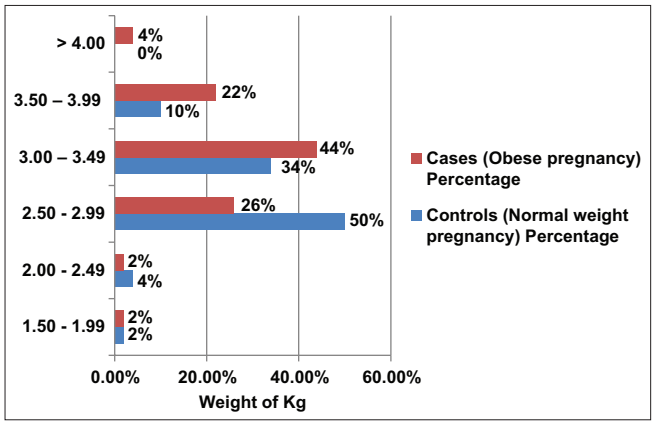

Figure 2: Birth weight of neonate

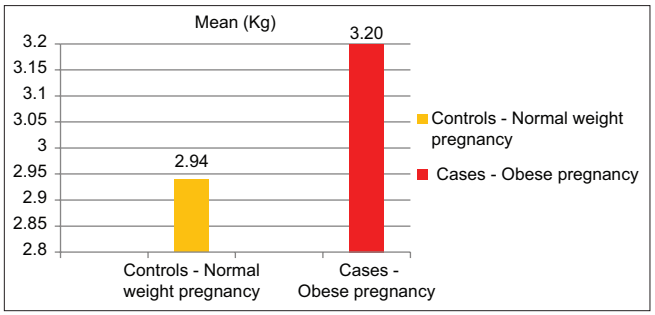

Figure 3: Mean birth weight of neonate

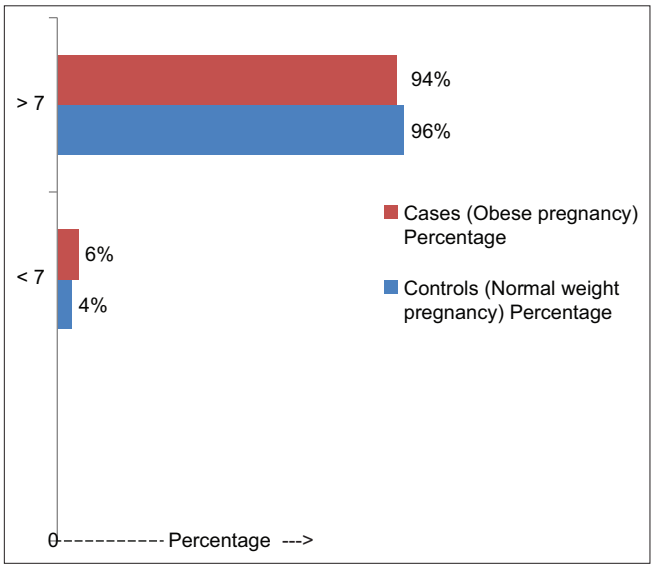

Figure 4: APGAR at 5 min

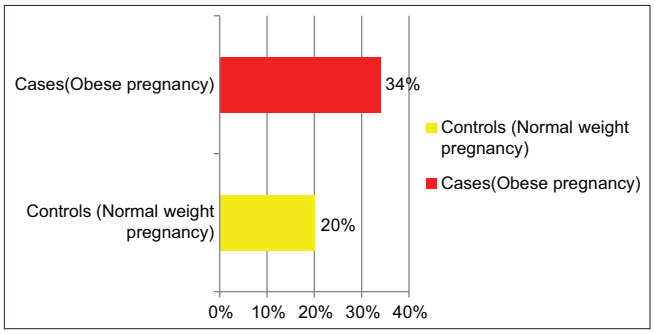

Figure 5: NICU admissions

results, as shown in Figure 5, about 34% of babies born to obese women and 20% babies born to control women were admitted in NICU. This is statistically insignificant. Major reason for admission in babies of obese group were infant of diabetic mother, preterm, and macrosomia, and in control group, the reasons were meconium aspiration and infant of diabetic mother.

CONCLUSION

Occurrence of maternal obesity continues to increase and poses major challenges not only to obstetricians but also to pediatricians, because maternal obesity affects both the mother and the neonate. The prevention of obesity

in women of reproductive age group would help us to improve neonatal health.

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Original Article

Comparative Evaluation of the Marginal Fit of Conventional and Direct Metal Laser Sintered Metal Crowns: An *In-vitro* Study

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Abstract

Introduction: The advent of computer aided designing/computer aided manufacturing and 3D printing has reduced human error and simplified the process of fabricating prosthesis by the conventional approach. However, the conventional technique of crown fabrication still remains in use due to the high cost of production of 3D printed crowns. Marginal integrity is an important factor that determines the longevity of the prosthesis. Hence, the aim of the present study was to compare the marginal gap formation in conventionally fabricated and 3D printed metal crowns.

Materials and Methods: Forty stone dies with standard dimensions were equally divided into two groups for fabrication of crowns using two different techniques. Group A consisted of crowns fabricated by the laser sintering technique and Group B consisted of crowns fabricated using the conventional lost wax technique. The fabricated crowns were seated onto the die and then dissected vertically in buccolingual direction followed by which the distance between the external marginal line and the most extended point of the crown was measured and noted as the marginal gap. Inter group comparison was done using the *t*-test.

Results: The marginal gap overserved in the conventionally fabricated crowns was significantly higher (105.95 μm) than the marginal gap observed in the laser metal sintered crowns (102.0 μm) ($P < 0.00$).

Conclusion: Within the limitations of the present study, it can be concluded that both the techniques give crowns with clinically acceptable marginal fit. However, crowns fabricated by metal laser sintering have a superior marginal adaptation than those fabricated using the conventional lost wax technique.

Key words: 3D printing, Direct metal laser sintering, Lost wax technique, Marginal gap

INTRODUCTION

It was Charles Hull, in 1986, who was the first to develop a 3D printer based on the technology of stereolithography.[1,2] Since then, 3D printers have gained significant popularity. Over a period of time, computer-aided-design (CAD)/computer-aided-manufacturing (CAM) systems and 3D printers have come to replace the traditional approach in prosthetic dentistry. The conventional approach of fabricating a metal substructure is the lost wax technique.

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With the advent of CAD/CAM, human errors decreased, processes were simplified, and production rates increased. The CAD/CAM approach is based on subtractive manufacturing technique which involves milling an object from a block or a disc based on the input design. However, the size of the milling tool and its applied angle limits the fabrication of more complex shapes. Further, the loss of material using the subtractive technique can reach up to 90%.[1,3] Every prosthesis is unique to that patient and its construction requires replication of convoluted geometry to a high level of precision. This is achieved by 3D printers which are based on additive technique where an object is formed by adding one layer at a time.[4] The object to be printed needs to be in an standard tessellation language file format. 3D printing requires either a virtually designed object on CAD software, volumetric data from cone beam computed tomography scans, or data from digital intraoral or laboratory surface scans.[4] In simple terms, the process

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can be described as follows: The dentist creates a digital dataset on the computer (CAD) and then designs a 3D object; the data of the 3D object are then transferred to the milling machine or a 3D printer, which creates a physical object from these data. In dentistry, 3D printing has been used for surgical planning, creating working models, fabrication of crowns, bridges, complete and partial dentures, manufacturing surgical implants, occlusal splints, surgical guides, and three-dimensional custom printed trays.[1,2] Fabricating dental prosthesis is a daily task for dentists. The key to a successful dental prosthesis is its dimensional accuracy and marginal fit as well as a smooth surface with good reproduction of the surface details. Due to the high cost of production of 3D printed dental prosthesis, the conventional technique still remains in use. Hence, the aim of the present study was to compare the marginal fit of conventional and direct metal laser sintered (DMLS) crowns.

MATERIALS AND METHODS

Standardization and Fabrication of Samples

To prepare the master model, a mandibular first right molar ivorine tooth was selected and it was mounted in acrylic resin cold cure. The tooth was prepared with an occlusal reduction of 1 mm and a chamfer finish line of 0.5 mm.

An impression of the prepared tooth was made using the one step elastomeric technique which was then poured using die stone. This procedure was repeated 40 times to obtain forty stone dies with standard dimensions which were then equally divided into two groups for fabrication of crowns using two different techniques. Group A consisted of crowns fabricated by the laser sintering technique and Group B consisted of crowns fabricated using the conventional lost wax technique. To standardize the wax patterns for Group B, first a digital impression of the stone die was obtained and a wax pattern of thickness 0.5 mm was designed using CAD software (ExoCad) on a separate stone die which was poured from the impression of the master model. This was 3D printed in pattern resin over which a putty index was made and this index was used as a guide to standardize the wax pattern of Group B which were fabricated using inlay wax. The patterns were immediately invested to avoid any distortion and were casted in Cobalt-Chromium (Co-Cr) alloy. The CAD-designed data were used to fabricate 20 laser sintered crowns for group A. A film of Co-Cr alloy powder was laid down by the machine and was then sintered at 1500°C to a thickness of 20 micrometer. This process was continued layer by layer till the entire crown structure was fabricated from the occlusal surface to the margins.

Sectioning of Samples and Measurement of Marginal Gap

The fabricated crowns were seated on the die and then mounted onto the platform of a water jet cutter which sectioned the prepared tooth and crown buccolingually in a vertical direction. A stereo microscope was used to observe the marginal gap. The distance between the external marginal line and the most extended point of the crown was measured which was noted as the marginal gap.

Statistical Analysis

Data obtained were compiled on a MS Office Excel Sheet (v 2019, Microsoft Redmond Campus, Redmond, Washington, United States) and subjected to statistical analysis using Statistical Package for the Social Sciences (SPSS v 26.0, IBM). Mean and standard deviation were obtained for numerical data. Normality of numerical data was checked using Shapiro–Wilk test and was found that the data followed a normal curve; hence, parametric test was used for comparison. Intergroup comparison was done using the t test. For all the statistical tests, $P < 0.05$ was considered to be statistically significant, keeping α error at 5% and β error at 20%, thus giving a power to the study as 80%.

RESULTS

The mean marginal gap observed in metal laser sintered crowns was 102.0 μm which was significantly lower than the mean marginal gap observed in conventionally fabricated crowns which was 105.95 μm. *P*-value of *t*-test was <0.01 which signifies a statistically highly significant difference [Table 1].

DISCUSSION

The traditional technique for fabricating the metal crowns and copings is the lost-wax technique using various metal alloys for casting.[5] It is technique sensitive and time consuming. This technique faces problems with making impressions in the oral cavity which may cause discomfort for patients and contraction of the material resulting in an inaccurate marginal fit or irregularities in the cast

Table 1: Intergroup comparison of the marginal gap observed in conventionally fabricated crowns and crowns fabricated by 3D printing

Group	*n*	Mean	Std. Deviation	Std. Error Mean	*P*-value of *t*-test
DMLS Technique	20	102.20	1.673	0.374	0.000**
Conventional Technique	20	105.95	2.305	0.515	

**A highly statistically significant difference between the groups (*P*>0.05)

metal.[6] The conventional lost wax technique is limited by the skills of the operator, the manual process of waxing, and use of spacer to obtain a 50 micrometer thickness as well as the thickness of the wax. These factors can lead to distortion.[7] In an effort to overcome these limitations, CAD/CAM systems and 3D printers have been introduced. The digitalization in dentistry has many advantages such as reduction of material wastage and fabrication time.[8] Since 2011, 3D printing has enjoyed a worldwide wave of popularity, especially selective laser melting metal printing technology. The newly developed DMLS system is an additive metal fabrication technology. Based on information received from three-dimensional (3D) CAD and using a data file, metal powder is shot selectively and fused with a laser to laminate approximately a 20–60 μm thick layer with each shooting to complete a metal structure.[7,9] With the rapid development and integration of software and hardware technologies, CAD/CAM design and 3D printing technology have been used to fabricate high-quality crowns with greater accuracy in addition to facilitating crown design by clinicians.

A precise marginal fit is an important factor that determines the longevity and function of the restored tooth. A crown with poor marginal fit will lead to micro leakage and eventually failure of the restoration. The clinically accepted marginal gap distance varies among different studies. A marginal gap is said to be clinically acceptable for longevity if its mean values are in the range of 50–120 microns.[10] According to Fransson *et al*., a marginal gap of <150 microns after cementation is clinically acceptable.[11]

The fit of the crowns prepared from both the techniques in the present study was in the clinically acceptable range. However, laser sintered crowns had a superior marginal fit compared to conventionally fabricated crowns. Previously, studies have compared the internal fit of copings and crowns fabricated using the conventional technique and 3D printed technique. Ucar *et al*. have previously reported an insignificant difference between the marginal gap of direct metal sintered systems and the conventional method.[12] In another study, Kim *et al*. observed the marginal fit of the DMLS system to be significantly inferior to that of the conventional lost-wax technique and slightly larger than the acceptable range.[13] Örtorp *et al*. have reported superior fit of the DMLS system compared to the conventional method.[7] However, the findings of the study should be interpreted in light of the possible study limitations. In the present study, the patterns were manufactured under ideal circumstances and controlled conditions which does not represent an actual clinical scenario.

CONCLUSION

Within the limitations of the present study, crowns fabricated by metal laser sintering have a superior marginal adaptation to those fabricated using the conventional lost wax technique. However, both the techniques gave crowns which had clinically acceptable marginal fit. Although 3D printing saves time and material, it is expensive and requires training. Thus, where 3D printing is not easily accessible and affordable, the conventional technique can continue to be the preferred choice of crown fabrication technique.

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Original Article

Effect of Duration of Exercise on Pulmonary Functions

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Abstract

Introduction: Several studies suggest a beneficial role of exercise in improving one's ability to sustain high levels of submaximal ventilation. Regular training improves the respiratory muscle strength as well as endurance.

Objectives: The objectives of the study are as follows: To assess the pulmonary functions using force vital capacity (FVC), force expiratory volume in 1 s (FEV1), FEV1/FVC, and forced expiratory flow (FEF) 25–75 in males who are involved in regular exercise in gymnasium for ≤1 year (Study group A), for 1–5 years (Study group B), and in sedentary healthy males (Study group C). To compare the pulmonary functions among Study group A, Study group B, and Study group C. To correlate effect of duration of exercise on pulmonary functions.

Materials and Methods: Estimation of FVC, FEV1, FEV1/FVC, and FEF 25–75 in 90 healthy males in the age group of 18–35 years is done by computerized portable spirotech spirometer as per ATS guidelines.

Results: In Group A 7% subjects, in Group B 100% subjects, and in Group C no subjects are having more than FEV1 median value. In Group A 53% subjects, in Group B 100% subjects and in Group C no subject are having more than FVC median value. In Group A 100% subjects, in Group B 33% subjects, and in Group C 63% are having more than FEV1/FVC median value. In all three groups, 57% subjects are having more than FEF 25–75 median value.

Conclusion: In this study, we found positive correlation between duration of exercise and improvement of pulmonary functions.

Key words: Exercise, Force expiratory volume in 1 s, Force expiratory volume in 1 s/Force vital capacity, Force vital capacity, Spirometry

INTRODUCTION

Regular exercise is associated with number of physical and mental health benefits. Each component of physical fitness (i.e., cardiorespiratory fitness, muscular strength, endurance, body composition, and flexibility) affects some aspect of health.[1] The body composition and abdominal obesity are associated with increased risk of adverse health outcomes, whereas greater fat-free mass is associated with a lower risk of mortality.[2] Higher levels of cardiorespiratory and muscular fitness are each associated with lower risks for diseases.[1,3] The minimum level of cardiorespiratory fitness required for health benefit may vary and depend on gender and age.[1]

Cardiorespiratory fitness includes cardiovascular fitness and respiratory fitness.[4,5] Increase in pulmonary ventilation and O_2 uptake is respiratory responses to exercise. Pulmonary ventilation increases in a linear fashion with increase in the intensity of exercise until an anaerobic threshold is reached.[5-7] The O_2 uptake by blood in the lungs increases from 250 ml/min at rest to about 4 l/min during heavy exercise. This is possible due to increased pulmonary perfusion, increased alveolar capillary PO_2 gradient, increased pulmonary diffusion capacity and Bohr's effect.[6-8]

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MATERIALS AND METHODS

Protocol for this study was designed and approved by the Institutional Ethical Committee. This was an analytical and observational study. Pulmonary functions of 90 healthy males recorded in accordance with the standardized methods which were divided into three groups.

Study group A includes 30 healthy males in the age group of 18–35 years, doing regular exercises in gymnasium (weight lifting exercises for the upper limbs, lower limbs, and torso along with cardio exercises in a well-equipped gymnasium having standard weights and machines) 30–45 min daily for at least 4–5 days/week (150 min/week) for ≤1 year.

Study group B includes 30 healthy males in the age group of 18–35 years, doing regular exercises in gymnasium (weight lifting exercises for the upper limbs, lower limbs, and torso along with cardio exercises in a well-equipped gymnasium having standard weights and machines) 30–45 min daily for at least 4–5 days/week (150 min/week) for 1–5 years.

Control Group, that is, Group C: For comparison, separate group of healthy subjects (only males) belonging to the same age group of 18–35 years, nearly same height and built were taken. They were from the same socioeconomic status and ethnic group as that of study group but they had sedentary lifestyle which means that they did not participate or were not involved in regular isotonic exercises, running, jogging, brisk walking (morning walks), swimming, aerobics, or any other sports activity.

History taking was followed by detailed clinical examination and based on the above findings, eligible subjects were finalized.

Collection of Data

Complete procedure was explained to the subject and a written informed consent was taken.

Spirometry[9]

For estimation of pulmonary functions, computerized portable spirotech spirometer was used as per ATS guidelines.

Procedure

The subject was asked to sit comfortably in the chair. The complete procedure was explained, any doubts would be addressed. Subject was instructed to take a deep breathe by deep inspiration with nostrils closed by applying nasal clip. The subject was asked to seal the lips around the sterile mouthpiece of spirometer and forcefully expire the air out, as fast as possible. Best of three recordings will be recorded and interpreted.

Following pulmonary function parameters have been recorded:

- Force expiratory volume in 1 s (FEV1)
- Force vital capacity (FVC)
- FEV1/FVC
- Forced expiratory flow 25–75% (FEF 25–75).

Statistical Analysis

Excel and R programming software were used for data analysis. Median and inter quartile range of continuous characteristics among 1-year exercise, 1–5 years of exercise groups, and no exercise group has been accessed using descriptive statistics. After the data were tested for normal distribution, pulmonary functions parameters were compared using Kruskal–Wallis test. Binary logistic regression was used to assess the association between exercise duration and pulmonary functions. Statistical significance was evaluated at 0.05 alpha level after using two-sided *P*-value.

RESULTS

Table 1 shows comparison between Study group A, Study group B and Study group C with respect to age, weight, height and body mass index.

Table 2 shows comparison between Study group A, Study group B and Study group C with respect to pulmonary functions.

Table 3 shows Logistic regression to assess the association between pulmonary functions and exercise duration.

In Group A 7% (2/30) subjects, in Group B 100% (30/30) subjects and in Group C no subject is having high FEV1 %P value. In Group A 53% (16/30) subjects, in Group B 100% (30/30) and in Group C no subject is having high FVC %P value. In Group A 100% (30/30) subjects, in Group B 33% (10/30) subjects and in Group C 63% (19/30) subjects are having high FEV1/FVC %P value. In all three groups the high FEF25-75 %P value is 57% (17/30).

DISCUSSION

We have compared pulmonary functions of Group A (≤1 year of exercise), Group B (1–5 years of exercise), and Group C (control). We found that there is statistically significant increase in FEV1, FVC, and FEV1/FVC in Group A compared to Group C and Group B compared to

Table 1: Comparison between Study group A, Study group B, and Control group C with respect to age, weight, height, and body mass index

Characteristics	No exercise (Group C) Median, IQR *n*=30	≤1 Year exercise (Group A) Median, IQR *n*=30	1-5 Years exercise (Group B) Median, IQR *n*=30	*P*-value
Age (years)	18 (18–19)	19 (18–21)	19 (18–22)	>0.05
Weight (kg)	62.79 (53.60–71.98)	62.53 (53.59–71.47)	61.21 (52.58–69.84)	>0.05
Height (m)	1.70 (1.65–1.75)	1.70 (1.66–1.74)	1.70 (1.65–1.75)	>0.05
BMI (kg/m^2)	22.4 (21.6–23.1)	22.7 (21.7–23.5)	22.7 (22.6–22.8)	>0.05

IQR: Inter Quartile Range, *n*: Number of subjects, m: meters, kg: kilograms, BMI: Body mass index, *P*>0.05 is statistically not significant, *P*≤0.05 was considered as significant at 95% confidence interval, *P*<0.0001 was considered as highly significant

Table 2: Comparison between Study group A, Study group B, and Control group C with respect to pulmonary functions

PFT Parameters	Group C	Group A	Group B	*P*-value
FEV1				
Median	98	110	119	0.0001*
IQ	(96–99)	(108–113)	(118–120)	
FVC				
Median	84	95	106	0.0001*
IQ	(82–87)	(93–97)	(103–108)	
FEV1/FVC				
Median	115	116	112	0.003**
IQ	(111–117)	(115–117)	(110–116)	
FEF 25–75				
Median	56	56	56	0.99***
IQ	(54–58)	(54–58)	(54–58)	

**P*<0.0001 was considered as highly significant. ***P*≤0.05 was considered as significant at 95% confidence interval. ****P*>0.05 is statistically not significant, FVC: Force vital capacity, FEV1: Force expiratory volume in 1 s, FEF: Forced expiratory flow

Table 3: Logistic regression to assess the association between pulmonary functions and exercise duration

PFT parameters	Group C	Group A	Group B
FEV1			
High FEV1%P	0	2 (7)	30 (100)
OR 95%C.I.	-	-	-
P-value	-	-	-
FVC			
High FVC%P	0	16 (53)	30 (100)
OR 95%C.I.	-	-	-
P-value	-	-	-
FEV1/FVC			
High FEV1/FVC%P	19 (63)	30 (100)	10 (30)
OR 95%C.I.	-	-	-
P-value	-	-	-
FEF 25–75			
High FEF 25–75%P	17 (57)	17 (57)	17 (57)
OR 95%C.I.	1	1	1
P-value	-	-	-

High FEV1% P: Defined as those who had FEV1% *P*≥115 (Median value of the overall FEV1% P), High FVC % P: Defined as those who had FVC % *P*≥95 (Median value of the overall FVC% P), High FEV1/FVC% P: Defined as those who had FEV1/FVC% *P*≥115 (Median value of the overall FEV1/FVC% P), High FEF 25–75%P: Defined as those who had FEF 25–75% *P*≥56 (Median value of the overall FEF 25–75% P), FVC: Force vital capacity, FEV1: Force expiratory volume in 1 s, FEF: Forced expiratory flow

Group A. We found that there is no statistical significance in the FEF 25–75 among Study group A, B, and Control group C.

West (1996) showed that exercise training is beneficial for improving one's ability to sustain high levels of submaximal ventilation.[10]

Cheng *et al.* (2003) showed that men who were engaged in exercise had higher FEV1 and FVC than the sedentary group.[11]

Farid *et al.* (2005) showed that the course of aerobic sport exercise causes an obvious increase in FEV1, FVC, and FEF 25–75 in asthmatic patients. Thus, the exercise training and regular short duration sports activity are involved in the improvement of pulmonary function.[12]

McArdle *et al.* (2010) showed that regular training improves the ventilator muscle strength as well as endurance. Twenty weeks of training improve ventilatory muscle endurance by approximately 16%. It also increases inspiratory muscle capacity to generate force and sustain a given level of inspiratory pressure.[4]

Pulmonary Functions

Physical training may have little effect on maximal static S and dynamic measures of pulmonary functions. However, it is beneficial for improving one's ability to sustain high levels of submaximal ventilation. Regular training improves the ventilator muscle strength as well as endurance.[4,13,14]

Mechanism

1. There is an increase in aerobic enzyme levels because of physical training[4,14-16]
2. Oxidative capacity of respiratory musculature increases after few weeks of exercise[4,14-16]
3. Furthermore, the capillary vascularization is increased in the pulmonary tissue as a result of physical training. There is an increase in number of functioning alveoli and their better inflation. Therefore, respiratory system becomes more efficient and capable of providing the better oxygenation.[4,14-16]

CONCLUSION

In the present study, we found that there is a statistically significant improvement in pulmonary function parameters – FEV1, FVC, and FEV1/FVC in ≤1 year exercise group compared to the no exercise group. Whereas there is profound improvement in pulmonary function parameters – FEV1, FVC, and FEV1/FVC in 1–5 years exercise group compared to 1 year exercise group. This shows a positive correlation between duration of exercise and improvement of pulmonary functions.

LIMITATIONS OF THE STUDY

In this longitudinal study, intermediate measures of other independent variables (different types of sports, diet and other medical conditions) were not performed; thus we cannot assess the influence of concurrent changes on results. Almost all of our control participants were from mid to upper socioeconomic strata, so generalization to other groups is not advised.

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Original Article

Comparative Evaluation of the Flexural Strength of Fiber-Reinforced Composite and Composite Containing Spheroidal Filler Particles: An *In Vitro* Study

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Abstract

Introduction: The mechanical properties of resin composites are largely influenced by their filler characteristics. Fillers come in various sizes and shapes which also govern their loading as well as the mechanism by which it strengthens the composite. Hence, the aim of the present study was to compare two composites with different file composition. Thus, in the present study, the flexural strength of composite containing fibrous fillers and composite containing spheroidal fillers was analyzed.

Methodology: Specimens were prepared based on ISO standardization and subjected to three point bending test to determine their flexural strength. Each group had a sample size of 20. Intergroup comparison was done using *t*-test and $P<0.05$ was considered to be statistically significant.

Results: It was observed that fiber-reinforced composite had higher flexural strength than composite containing spheroidal filler particles.

Conclusion: The filler morphology has an influence on the mechanical properties of resin composite. Fiber-reinforced composites have higher flexural strength than composites with spherical filler particles. However, both the composites meet the minimum requirement of flexural strength that is indicated for an occlusal restoration.

Key words: Fiber-reinforced composite, Flexural strength, Resin composite, Spheroidal filler

INTRODUCTION

Composite resins have gained popularity as the choice of restorative material both for anterior and posterior restorations due to their enhanced mechanical properties and demand for esthetics. Over the years, there has been significant development in the monomers used and the filler particles. The resin component forms the matrix which binds the filler particles together with the help of a coupling agent.[1] Of particular, importance is the characteristic of the filler particles which largely govern the mechanical properties of composites. The mechanical properties of composites, such as strength and elastic modulus, wear resistance and polymerization shrinkage is said to have been improved by improving its filler loading which is further influenced by filler morphology, whereas filler size influences the restoration's polish ability.[2] Composites with round filler particles have higher filler loading and thus higher strength.[2] Estelite Σ (Estelite) by Tokuyama Dental Corp is a new type of composite with fillers produced by the sol gel mechanism. The filler produced by the sol–gel method has a spherical shape and average particle size of 0.2 μm.

Earlier, silicate glass was the most commonly used filler particle. However, since they were not strong enough, cracks could propagate either through or around the glass particles.[3] This has been overcome with the development of newer fillers such as glass fibers, branched fibers, ceramic whiskers, and nanoporous fillers.[1] Glass fibers were the most commonly used fibers in dental composites. The properties of composites reinforced with fibers depend on

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the aspect ratio (l/d), volume fraction, and the orientation of fibers.[4] Favorably, oriented fibers allow fiber bridging which is a fiber toughening mechanism. Another factor that is important is the critical length of the fiber. If the length of the fiber exceeds the critical length by 2 times, then the fibers tend to break and the bridging energy declines. Longer fibers tend to align in a plane providing anisotropic reinforcement, whereas shorter fibers will be randomly distributed providing isotropic reinforcement.[4] Randomly, oriented fibers enhance the load bearing capacity by lowering the debonding. Since shape of the fiber is one of the factors that govern the mechanical properties of composite, the present study was conducted with the aim of analyzing and comparing the flexural strength of composite containing fibrous fillers (everX posterior by GC Corp., Tokyo, Japan) and composite containing spheroidal fillers (Estelite by Tokuyama Dental Corporation).

MATERIALS AND METHODS

The study consisted of two groups with 20 specimens in each group. Group A consisted of specimens made using Estelite by Tokuyama Dental Corporation and Group B consisted of specimens made using everX posterior by GC Corp., Tokyo, Japan.

To prepare standardized specimens for analysis, custom molds of dimension 25 × 2 × 2 mm were fabricated as per ISO standardization 4049:2009 and ISO 9917-1:2007 for polymer-based materials and powder/liquid acid-based cements, respectively. The test materials were packed into the molds using a teflon-coated composite filling instrument in increments of 2 mm thickness. To prevent the material from sticking to the walls, the molds were lined by petroleum jelly. Each increment was cured for 30 s by keeping the curing light of intensity 1200 mW/cm^2 at a distance of 2 mm from the increment. The final crement was cured by placing a mylar strip on top and the excess was removed using a polishing disk. The specimens were analyzed for voids and inaccuracies in dimension. To determine the flexural strength, the samples were mounted on a 3 point bending test device and loaded in the universal testing machine at a cross head speed of 1 mm/min. The flexural strength of each sample was calculated using the following formula:

$\sigma = 3Fl/2bh^2$
F – Maximum load (Newton)
l – Distance between the supports (millimeter)
b – Width of the specimen (millimeter)
h – Height of the specimen (millimeter).

Data obtained were compiled on a Microsoft Office Excel Sheet (v 2019, Microsoft Redmond Campus, Redmond, Washington, United States) and were subjected to statistical analysis using the Statistical package for the social sciences (SPSS v 26.0, IBM). The Mean and SD were obtained for numerical data. Normality of numerical data was checked using Shapiro–Wilk test and it was found that the data followed a normal curve; hence, parametric tests were used for comparisons. Inter group comparison (two groups) was done using t-test. For all the statistical tests, $P < 0.05$ was considered to be statistically significant, keeping α error at 5% and β error at 20%, thus giving a power to the study as 80%.

RESULTS

It was observed that the mean flexural strength of fibrous filled composite everX posterior (104.8655 MPa) was significantly higher than Estelite which contained spheroidal filler particles (87.3565 MPa) [Table 1]. *P*-value of *t*-test was <0.00 which signifies a highly significant difference.

DISCUSSION

Flexural strength of a material is defined as the maximum stress in a material just before it yields in a bending test. In a three point bending test, the inner and outer edges of a material are called its extreme fibers. At the inside, the material experiences maximum compressive stress, while at the opposite side, the stresses will be at the maximum tensile value. Most materials fail due to tensile stress. Composite resins are more susceptible to tensile stresses than compressive stresses.[5] Hence, higher the values of flexural strength, stronger is the material.

Based on the ISO classification 4049, polymer-based restorative material is classified as type I which is used for occlusal surface restoration and type II which include all other polymer-based restorative material.[6] The three-point bending test is based on the ISO specification number 4049/2000 for polymer-based restorative materials.[7] The minimum flexural strength requirement for Type I is 80 MPa and 50 MPa for Type II.[6] It was observed in the study that both the composites had flexural strength that met the minimum requirement to be used as a restorative material on an occlusal surface. However, everX posterior had higher flexural strength compared to Estelite which had spheroidal filler particles.

In a previous study, Estelite has shown comparable mechanical properties to nanocomposites and micro hybrid composites.[8] It has also been observed that Estelite maintains high gloss during wear due to its spherical sub-micron filler particles that help in keeping the surface smoother than irregular particles on exposure.[9] These fillers have been produced by sol–gel method. The

Table 1: The table depicts the standard deviation and mean values of flexural strength observed in each group

Variable / outcome	Group	*n*	Mean (MPa)	Std. Deviation	Std. Error Mean	*P*-value of t test
Flexural strength	Estelite (Group A)	20	87.3565	2.80875	0.62806	0.000**
	everX posterior (Group B)	20	104.8655	2.06015	0.46066	

***P*-value of *t*-test<0.00 is indicative of a highly significant difference

average particle size is 0.2 μm, with a narrow range from 0.1 to 0.3 μm; thus, the material is called a submicron composite.[8] Spherical fillers have smaller surface area and hence need less resin matrix to wet them. This allows a high filler loading in Estelite contributing to its mechanical properties.[8] An increase in fracture toughness is observed with increase in the filler loading. There are several mechanisms responsible for this. The crack bowing effect increases the line energy at the crack front and is a result of pinning by the filler particles. Another mechanism is crack branching which increases the crack surface area and resultant fracture energy.[2]

The reasons for the higher strength of fiber-reinforced composite in the present study is due to the action of fibers in resisting opening and crack propagation, their ability to stretch, to bridge, deflect crack, and the transfer of stress from matrix to fibers.[4,10] Mere insertion of fiber into composite is not enough to enhance the mechanical properties of the material. Of critical importance is the length and diameter of the fiber.[11] The length of the fiber must exceed the critical length which is calculated as the ultimate tensile strength of the fiber (f) multiplied by the fiber diameter (d), and divided by twice the shear strength of the matrix interface.[11] The minimum length at which the center of the fiber reaches its ultimate tensile strength when the matrix reaches its maximum shear strength is defined as the critical fiber length. In a study, the measured critical length of everX posterior was between 0.85 and 1.09 mm.[4] An optimum fiber length is required to maintain the bridging phenomenon which is 1.2 times the critical fiber length. It has been observed under scanning electron microscope that fractured parts of fiber-reinforced composite show fibers traversing the crack line and between fractured parts. This shows the ability of the material to resist displacement which will help in preventing food impaction and cavitation as well as imparting better potential for repair.[12] The results of the present study are in accordance with the previous studies which have also reported improved mechanical properties of short fiber-reinforced composites.[13,14] However, it must be noted that this study was performed under a controlled laboratory setting. Further, comparative studies are required which test the materials under clinical scenarios.

CONCLUSION

Within the limitations of the present study, it can be concluded that filler morphology has an influence on the mechanical properties of resin composite. Fiber-reinforced composites have higher flexural strength than composites with spherical filler particles. However, both the composites meet the minimum requirement of flexural strength that is indicated for an occlusal restoration.

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Original Article

Comparative Efficacy and Safety of Once-Daily Dosing and Twice-Daily Dosing of Deferasirox in Reducing Serum Ferritin Levels in Children with Thalassemia Major Patients

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Abstract

Objectives: The objectives of the study were to assess the efficacy and tolerability of two divided dosing of deferasirox in comparison to once-daily dosing.

Materials and Methods: Pediatric thalassemia patients more than 2 years of age who were receiving deferasirox as the only chelator over the past 6 months or more were included in the study group. Deferasirox administration schedule was switched from "once-daily" to "two divided daily" dosing schedule with the total dose per day remaining the same which the patient had been receiving earlier as once-daily dose. Serum ferritin levels that were done 6 months before "switch over" were taken as baseline. Serum ferritin levels were done at the time of "switch over" and subsequently at the end of 3rd and 6th month and were compared to the baseline serum ferritin levels. Duration for which patient had received single-dose deferasirox acted as control.

Results: The mean serum ferritin at baseline of the study group on "once-daily" dosing was 2501.52 ± 1392.03 ng/ml. At enrolment of patients (total 25) on "once-daily" dosing of deferasirox, 14 patients had decreasing serum ferritin levels, 10 patients had increasing trend of serum ferritin while in one patient, there was no change in serum ferritin when observed retrospectively for the past 6 months. After 6 months of "two divided daily dosing," serum ferritin decreased statistically in 4 (16%) subjects and increased significantly in 21 (84%) subjects. The mean ferritin of the four subjects with decreased serum ferritin at the baseline was 1800 ± 400 which subsequently decreased to 721.5 ± 301.96 ng/ml. Mean decrease in serum ferritin in four patients was 1078.5 ng/ml. No significant changes were observed in complete blood count, renal function test, liver function test, and blood sugar levels when compared to the baseline.

Conclusion: Two divided dosing of deferasirox was better tolerated with no adverse effects being reported.

Key words: Deferasirox, Iron chelators, Thalassemia

INTRODUCTION

Thalassemia is a group of inherited blood disorders caused by defects in one or more genes responsible for producing the globin chains in hemoglobin synthesis, characterized by a reduction in the synthesis of one or more of the globin chains, leading to imbalanced globin chain synthesis, defective hemoglobin production causing anemia.[1] Thalassemia is considered the most common genetic disorder worldwide.[2] The management of thalassemia is guided by the severity of anemia, suppression of excessive erythropoiesis, and prevention of excess iron overload. Patients who receive more than 100 units of packed red blood cells per annum usually develop iron overload.[3] To prevent iron overload and its complications, iron-chelating agents are started early when starting transfusion therapy. Commonly used chelating agents are deferoxamine, deferiprone, and deferasirox.[4]

Deferasirox has been developed in response to an overwhelming clinical need for a convenient effective and well-tolerated iron-chelating age. Studies have confirmed

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its ability to chelate cardiac iron, thus reducing cardiac iron overload.[5] It is currently administered as once-daily dose. Gastrointestinal symptoms such as nausea, vomiting, and abdominal pain are common and are reported in one-third of patient.[6] Skin rashes are the other common adverse effect. The most concerning effect is increase in serum creatinine that is reported in up to 1/3 of patients. Dividing deferasirox in twice-daily dosing will provide sustainable therapeutic levels of deferasirox throughout 24 h resulting in better clinical efficacy. Twice-daily dosing may lead to decreased dose-dependent side effect thus improved tolerability. Hence, this study was planned to assess the efficacy and tolerability of two divided dosing of deferasirox in comparison to once-daily dosing.[7]

MATERIALS AND METHODS

The study was conducted at the thalassemia day care center in the postgraduate department of pediatrics SMGS Hospital, Government Medical College, Jammu, Jammu and Kashmir, where 290 patients are registered. Forty patients were receiving deferasirox as iron chelator. In this study, all the pediatric thalassemia patients more than 2 years of age who were receiving deferasirox as the only chelator over the past 6 months or more were included in the study group. Deferasirox administration schedule was switched from "once-daily" to "two divided daily" dosing schedule with the total dose per day remaining the same which the patient had been receiving earlier as once-daily dose. Serum ferritin levels that were done 6 months before "switch over" were taken as baseline. Serum ferritin levels were done at the time of "switch over" and subsequently at the end of 3rd and 6th month and were compared to the baseline serum ferritin levels. Duration for which patient had received single-dose deferasirox acted as control.

Inclusion Criteria

- Thalassemia patients more than 2 years of age who have been receiving deferasirox as the only chelator for the past 6 months or more and whose serum ferritin levels have been documented in the past 6 months were included in the study.

Exclusion Criteria

The following criteria were excluded from the study:

- Thalassemia patients <2 years
- HbsAg positive and HBC positive
- Patients with deranged renal function tests (RFTs) (serum creatinine >2 times the age appropriate upper limit of normal before and during the study)
- Deranged liver function tests (LFTs) (transaminases more than 5-fold)
- Patients receiving more than 1 chelator.

Clinical examination of subjects was done monthly to monitor any organ or endocrine dysfunction. Complete blood counts (CBCs), RFTs, LFTS, and pancreatic enzyme assays were done monthly to monitor any adverse effect. At the end of 6 months of "two divided dosing," patients were evaluated for decrease in serum ferritin levels and were compared to the baseline serum ferritin levels. All the data from the patients of the study group were noted on the pro forma and were put in tabulated form and analyzed using appropriate statistical technique.

RESULTS

There were 16 males (64%) and 9 females (36%) in the study group with male-female ratio of 1.78:1.

- Mean age of the study group was 6 ± 2.09 years
- The mean dose of deferasirox in the study patients was 34.10 ± 3.62 mg/kg/day
- The mean serum ferritin at baseline of the study group on "once-daily" dosing was 2501.52 ± 1392.03 ng/ml. Subsequently after 6 months of two divided dosing, serum ferritin levels increased to 2873.96 ± 1434.60 ng/ml which was not significant
- At enrollment of patients (total 25) on "once-daily" dosing of deferasirox, 14 patients had decreasing serum ferritin levels, 10 patients had increasing trend of serum ferritin while in one patient, there was no change in serum ferritin when observed retrospectively for the past 6 months
- After 6 months of "two divided daily dosing," serum ferritin decreased statistically in 4 (16%) subjects and increased significantly in 21 (84%) subjects
- The mean ferritin of the four subjects with decreased serum ferritin at the baseline was 1800 ± 400 which subsequently decreased to 721.5 ± 301.96 ng/ml
- Mean decrease in serum ferritin in four patients was 1078.5 ng/ml
- The mean age of the above four patients was 6.5 years
- No significant changes were observed in CBC, RFT, LFTS, and blood sugar levels when compared to the baseline
- At the end of study, no significant change was observed in the number of blood transfusions when compared with the baseline
- Two divided dosing was better tolerated with no adverse effects being reported.

DISCUSSION

Thalassemia patients on chronic transfusion are susceptible for developing iron overload. Patients who receive more than 100 units of packed RBCs (annually) usually develop iron overload. Serum ferritin, liver biopsy, and

imaging modalities such as magnetic resonance imaging and superconducting quantum interference device can measure iron overload in the body. Complications arising from iron overload are cirrhosis, endocrine dysfunction, glucose intolerance, hypogonadism, hypothyroidism, hypoparathyroidism, and cardiomyopathy.[3] To prevent these complications, iron-chelating agents such as deferoxamine and deferasirox are used early when starting transfusion therapy.

Deferoxamine was the first iron chelator used for the treatment of chronic iron overload. It is administered parentally due to its poor oral bioavailability. Given its short half-life, it requires frequent administration, typically 57 times per week. It can be given by both intravenous and subcutaneous routes (Callender *et al.*, 1962). It requires prolong infusion time which affects the quality of life and increases the risk of noncompliance with therapy. Early and aggressive deferoxamine administration can adversely affect the skeletal maturation and results in growth retardation (De Virgillis, 1988). The cumbersome nature and complications associated with deferoxamine therapy pushed investigators to identify oral agents that would be suitable for long-term iron chelation in those with chronic iron overload.

Deferiprone was the first oral chelator to be used for the treatment of iron overload. Deferiprone results in more significant reduction in iron levels in those with higher burden. It may not be as helpful for those with less significant iron overload.[8] Deferiprone is associated with several adverse effects. Most concerning is agranulocytosis. In clinical trials, neutropenia is reported in up to 5% with agranulocytosis reported in <l%.[9] Gastrointestinal symptoms such as nausea, vomiting, and abdominal pain have been reported in up to 33% of patients**.** Elevation of liver transaminases has also been reported. Arthralgia and arthritis have been associated with deferiprone. Large joints such as knees are commonly affected. About 50% of cases develop within the 1st year of therapy.[8] Due to these side effects and non compliance of Deferipirone, investigators looks for oral iron chelators with more favorable attributes.

Deferasirox has been developed in response to an overwhelming clinical need for a convenient, effective, and well tolerated iron-chelating agent. It was approved by the US Food and Drug Administration in 2005.

Deferasirox is an orally active chelator that is highly selective for iron (III) and binds iron with high affinity in a 2:1 ratio. Deferasirox promotes excretion of iron, primarily in the feces. Deferasirox has very low affinity for zinc and copper and does not cause constant low serum levels of these metals.[10] Deferasirox is effective in lowering serum ferritin levels and decreasing overall iron burden. A dose-dependent effect on serum ferritin has been observed.[4,8] Studies have confirmed its ability to chelate cardiac iron, thus reducing cardiac iron overload.[5] In an iron balance metabolic study in iron overloaded adult thalassemia patients, deferasirox at daily doses of 10, 20, and 40 mg/kg induced the mean net excretion of 0.119, 0.329, and 0.445 mg Fe/kg body weight/day, respectively. Phase 2 and 3 trials involving deferasirox have shown that a dose between 20 and 30 mg/kg/day generally produces a net negative iron balance. The current maximum dose of deferasirox has been increased to 40 mg/kg/day. It is currently administered in single dose and is well tolerated. Adverse effects associated with its use are mild and self-limiting. Gastrointestinal symptoms such as nausea, vomiting, and abdominal pain are common and are reported in one-third of patient.[6] Skin rashes are the other common adverse effect. The most concerning effect is increase in serum creatinine that is reported in up to 1/3 of patients. In general, these are mild and transient and resolve on discontinuation of drug.[8]

Dividing deferasirox in twice-daily dosing will provide sustainable therapeutic levels of deferasirox throughout 24 h resulting in better clinical efficacy. Twice-daily deferasirox dosing may yield more homogenous suppression of non-transferrin bound plasma and lower peak levels. In addition, some adverse effects may be dose dependent and related to peak levels. Twice-daily dosing may lead to decreased dose-dependent side effect, thus improved tolerability.[7]

In our study, deferasirox in two divided dosing given at a median dose of 34.1 mg/kg/day for a duration of 6 months in 25 subjects with median age of 6 years showed statistically significant fall in serum ferritin in four subjects whose mean age was 6.1 years and baseline mean serum ferritin of 1800 ng/ml. Twenty-one subjects had significant rise in serum ferritin levels. However, deferasirox was better tolerated in "two divided" dosing as compared to "once-daily" dosing.

A longer study with a maximum dose of deferasirox, that is, 40 mg/kg/day started early at lower serum ferritin levels with an assessment of more reliable markers such as hepatic and cardiac iron are required for further evaluation of chelation efficacy of two divided dosing of deferasirox.

CONCLUSION

There is no significant difference in efficacy of once daily dosing versus twice daily dosing of Deferasirox in thalassemia. Although Two divided dosing of deferasirox

was better tolerated with no adverse effects being reported. Futher study with a higher dose of deferasirox, with an assessment of more reliable markers such as hepatic and cardiac iron are required for further evaluation of chelation efficacy of two divided dosing of deferasirox.

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Original Article

Comparison of Efficacy and Safety of Epidural 0.5% Bupivacaine and 0.5% Ropivacaine in Lower Extremities Surgery: A Prospective and Randomized Study

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Abstract

Introduction: Epidural anesthesia is the anesthesia of choice in various surgeries where in general or spinal anesthesia carries a risk. It is a type of regional anesthesia in which spinal nerves are blocked in the epidural space as they emerge from Dura. Epidural techniques are widely used for operative anesthesia, obstetric analgesia, post-operative pain control, and chronic pain management.

Aim: The aim of the study was to compare the efficacy and safety between epidural bupivacaine and ropivacaine for lower extremities surgery.

Materials and Methods: Patients were divided into two groups, Group R – 20 ml of 0.5% ropivacaine and Group B – 20 ml of 0.5% bupivacaine. Continuously SpO_2, respiratory rate, and heart rate were monitored. Hemodynamic variables such as systolic blood pressure, diastolic blood pressure, mean arterial pressure, and pulse rate were recorded for 120 min.

Results: Ropivacaine group shows lesser motor blockade with a mean of 217.419 min than bupivacaine. The ropivacaine group shows lesser sensory blockade with a mean of 240.968 min than bupivacaine. The comparison of both the groups showed that no major differences in regression of blockade though ropivacaine showed earlier regression than bupivacaine. The ropivacaine group had less similar episodes of hypotension and was managed adequately with fluids.

Conclusion: The efficacy of both drugs, ropivacaine, has shown promising results of shorter duration of action, lesser hemodynamic effects on the cardiovascular system, and no significant change in the quality of anesthesia than bupivacaine.

Key words: Bupivacaine, Epidural anaesthesia, Lower limb surgeries, Ropivacaine

INTRODUCTION

An epidural anesthetic and analgesic technique is central neuraxial anesthesia, which involves injecting drugs and the epidural space, causing a reversible block of sensory and motor functions.[1] The most of the abdominal and lower limb surgeries are based on regional anesthetic techniques. It provides a hemodynamically stable operative course with effective pain management and chronic pain relief.[2]

The epidural is advantageous over other regional techniques as it is a reliable form of anesthesia that provides excellent operating conditions. It renders the ability to administer additional local anesthetics with increasing duration of surgery, and also we can use the catheter for effective post-operative analgesia.[1]

This study uses the bupivacaine and ropivacaine in the same concentration to assess their efficacy and safety, as

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both are long-acting local anesthetics.[3] The use of both the drugs is preservative free and approved by FDA and can be safely used in epidural anesthesia and analgesia technique. No additives were added in this study, and since they are long-acting, we have chosen the proposed anesthesia of choice for the procedure.[4]

Aim

The aim of the study was to compare the efficacy and safety between epidural bupivacaine and ropivacaine for lower extremities surgery.

MATERIALS AND METHODS

This prospective and randomized clinical trial comprised 60 patients who were scheduled to have lower extremity surgery at Government Villupuram Medical College. Patients were enrolled between December 2019 and August 2020 after written informed permission. The study was carried out after the Institutional Ethics Committee had approved it.

Inclusion Criteria

Patients of either sex, age between 18 and 65 years, weight 50–70 kg, patients with American Society of Anesthesiologists Physical Status Class I and II were included in the study.

Exclusion Criteria

Patient refusal, patients with American Society of Anesthesiologists Physical Status Class III and Class IV, patient age <18 years, clinical conditions contraindicated to regional anesthesia such as coagulopathy, patients taking anticoagulants therapy, neurological and musculoskeletal disorder, skin infection in the lumbar area, allergy or intolerance to local anesthetic para-aminobenzoic acid, and atypical plasma cholinesterase were excluded from the study.

The sample size is calculated as 30 patients in each group, a total of 60 patients to ensure the power of 90% and 0.05 alpha error with a confidence interval of 95% for detecting a difference of at least 20% in the duration of the blockade, and a contingency of 10% is also considered.

Patients were divided into two groups, Group R – 20 ml of 0.5% ropivacaine and Group B – 20 ml of 0.5% bupivacaine.

Pre-aesthetic Evaluation

History was noted, including associated comorbidities, previous surgeries, medication, and drug allergies. General and systemic examinations were performed. Height, weight, pulse rate, blood pressure, and oxygen saturation were recorded. In addition, routine baseline investigations such as complete blood count, blood urea nitrogen and serum creatinine, random blood sugar, electrocardiogram, and chest X-ray were carried out.

Pre-operative Preparation

Patients were instructed overnight fast for 6 h. Pre-medicated with tablet ranitidine 150 mg and tablet alprazolam 0.5 mg. Informed consent was obtained from all patients in written format. The sensory and motor assessment methods were well explained to the patient.

During surgery, the patient's blood pressure, electrocardiogram, and pulse oximetry were recorded every 3 min for the first 15 min, then every 5 min till 30 min, and every 15 min for 120 min. Hypotension was treated with Ephedrine 3 mg IV injection in incremental doses if systolic blood pressure (SBP) falls >20% from the baseline value. Bradycardia was treated as heart rate <50 beats/min with Atropine 0.6 mg IV injection. The observer was instructed to assess the sensory and motor blockade for every 3 min during the initial 15 min period and after the surgical procedure. Therefore, the time of completion of epidural drug injection was considered zero time. The time to readiness for surgery was assessed as the time interval between local anesthetic injection and the onset of complete loss of pinprick sensation in the anterior axillary line bilaterally at the T10 level. Other sensory blockade parameters observed were maximum sensory block height, time to reach maximum block height, time taken for regression to L1, and time taken for complete regression of sensory block.

After data collection, it will be entered in MS Excel. As a result, it will contain both categorical and continuous data; for categorical variables, the Chi-square test or Fischer test and for continuous variables Independent *t*-test will be used. The analysis shall be done using SPSS statistical software. $P < 0.05$ is considered significant.

RESULTS

The majority of patients were between 30 and 50 years (43.3%). About 40% of patients were <30 years, and 16.7% of patients were >50 years. The mean and standard deviation of age in years is 36.4 ± 12.092. The median age in years is 36.5 and the range is 40 (19–59). The maximum numbers of patients were male 55% and 45% of patients were female. Out of 60 patients, the majority were in ropivacaine group 51.7% and 48.3% of patients were in the bupivacaine group [Table 1]. The mean age of Group B patients was 37.55 ± 12 years, and in Group R, 35.32 ± 12.28 years. There is no statistically significant difference in age between

groups $P = 0.480$. The mean height of Group B patients was 159.52 ± 7.36 cm and in Group R 160.65 ± 5.41 cm. There is no statistically significant difference in height between groups $P = 0.499$. The mean weight of Group B patients was 65.21 ± 7.35 kg and in Group R 64.61 ± 8.63 kg. There is no statistically significant difference in kgs between groups $P = 0.776$ [Table 2]. There is no significant difference in PR values between groups [Figure 1]. There is no significant difference in SBP values between groups [Figure 2]. There is no significant difference in diastolic blood pressure values between groups [Figure 3]. There is no significant difference in SPO_2 values between groups [Figure 4]. The hemodynamic parameters for both the groups interpreted are the variation in blood pressure significantly lowered in 10 min and 15 min which was effectively managed by vasopressors and fluids. This is seen more with the bupivacaine group than the ropivacaine group.

The mean duration of motor blockade concerning the group ($t = 2.194$, $P = 0.032$). The ropivacaine group shows lesser motor blockade with a mean of 217.419 min than bupivacaine. The mean duration of sensory blockade concerning the group ($t = 1.869$, $P = 0.067$). The ropivacaine group shows lesser sensory blockade with a mean of 240.968 min than bupivacaine. Mean of time for regression of blockade concerning the group ($t = 1.566$, $P = 0.123$). The comparison of both the groups showed that no major differences in regression of blockade though ropivacaine showed earlier regression than bupivacaine [Table 3]. Therefore, the requirement of rescue analgesia was not needed in both groups for the completion of the procedure. The intraoperative complication found is hypotension. That is more significant with the bupivacaine group, which is effectively managed by vasopressors. The ropivacaine group had less similar episodes of hypotension and was managed adequately with fluids.

Table 1: Distribution of patient characteristics

Patient characteristics	No. of Cases	Percentage
Age group		
<30	24	40
31–50	26	43.30
>51	10	16.70
Gender		
Male	33	55
Female	27	45
ASA		
I	30	50
II	30	50
Group		
Bupivacaine	29	48.30
Ropivacaine	31	51.70

Table 2: Comparison of patient characteristics

Patient characteristics	Bupivacaine		Ropivacaine		*P*-value
	Mean	SD	Mean	SD	
Age	37.55	12.00	35.32	12.28	0.480
Height	159.52	7.36	160.65	5.40	0.499
Weight	65.21	7.35	64.61	8.63	0.776

Table 3: Comparison of blockade between groups

Patient characteristics	Bupivacaine		Ropivacaine		*P*-value
	Mean	SD	Mean	SD	
Duration of Motor Blockade	234.66	32.68	217.42	28.13	0.032
Duration of Sensory Blockade	255.86	36.21	240.97	24.81	0.067
Regression of Blockade	206.72	29.53	194.52	30.75	0.123

DISCUSSION

Choosing epidural aims to have a wise knowledge about the technique and provide post-operative analgesia. This study was a prospective, randomized, controlled, and clinical study that evaluated the clinical efficacy and safety of 0.5% bupivacaine and 0.5% ropivacaine when given epidural anesthesia.

In our study, both the groups were comparable in age, sex, height, weight, ASA physical status, and type of surgery. In addition, there was no significant difference between the two groups.

This study uses both ropivacaine and bupivacaine at 0.5% of 20 ml to assess their efficacy in the epidural. Using both drugs in the same volume and concentration will produce effective results without affecting the statistical analysis. McGlade *et al.*[5] found that comparing both the drugs at the same concentration assessed their efficacy and safety.

The mean maximum sensory level reached in the present study was T8 in both groups, with the volume administered. Finucane *et al.*[6] found that the onset time for the sensory block to T12 was shorter when compared to the 0.5% bupivacaine group.

This study had a longer duration of sensory blockade with bupivacaine than with ropivacaine. Both groups showed sensory blockade with a mean of 240.968 min. The time of onset of the sensory block between the two groups was not statistically significant ($t = 2.194$, $P = 0.032$). Kerkkamp and Brown *et al.*[3,7] found a longer duration of the sensory block with bupivacaine.

This study showed a slower onset of ropivacaine than other groups. The motor block's onset time between the two

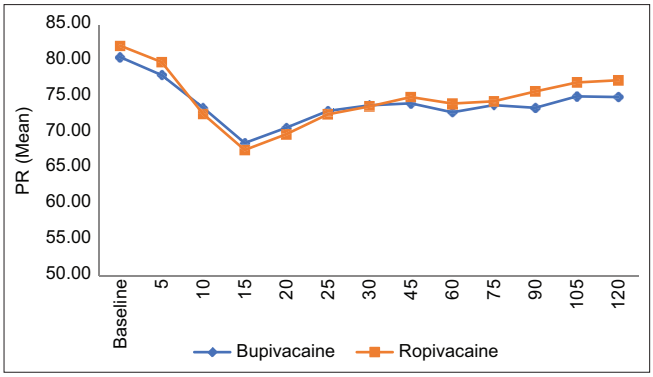

Figure 1: Comparison of PR between groups

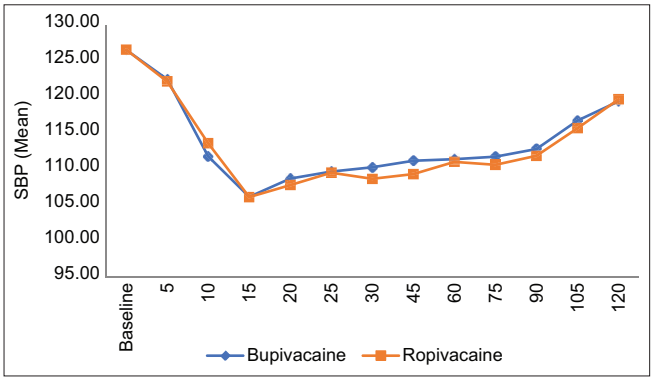

Figure 2: Comparison of systolic blood pressure between groups

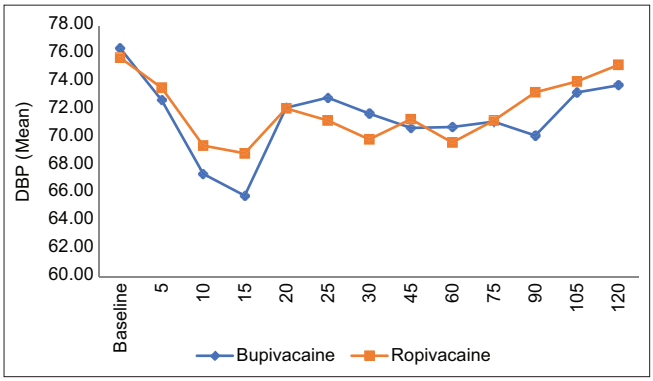

Figure 3: Comparison of diastolic blood pressure between groups

groups was statistically significant ($t = 2.194$, $P = 0.032$). The Ropivacaine group showed lesser motor blockade with a mean of 217.419 min than bupivacaine. Brockway *et al.*[8] showed that motor block produced by ropivacaine was slower in onset in the 0.75% ropivacaine group and also had a shorter duration of action.

This study showed no significant difference in the mean time for regression of blockade concerning the group ($t = 1.566$, $P = 0.123$). Although this study has no statistical

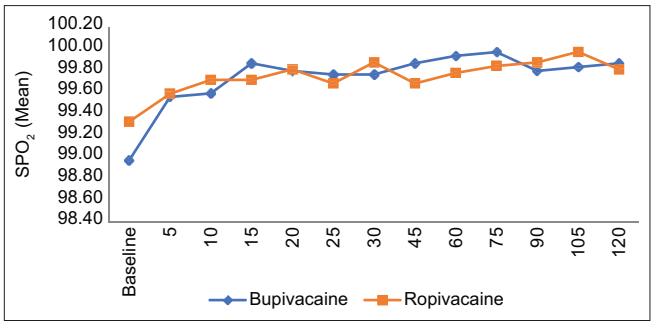

Figure 4: Comparison of SPO_2 between groups

difference, ropivacaine showed earlier regression than bupivacaine.

Our study concluded that both groups showed a fall in blood pressure at 10 min and it was lesser with the ropivacaine group, and there was no need for vasopressors in the bupivacaine group. Furthermore, the Chi-square test showed no significant difference between the groups ($P = 0.185$).

Zaric *et al.*[9] showed no significant changes in pulse rate, systolic and diastolic pressure, and mean arterial pressure between the two groups in the present study. In addition, there were no differences among groups in effective analgesia and patient satisfaction with analgesia in our study.

In our study, both groups showed no post-operative complications. Furthermore, Brockway *et al.*[8] showed no post-operative sequelae such as headache, backache, nausea, and vomiting for the next 24 h.

CONCLUSION

Our finding implies that comparing the efficacy of both drugs; ropivacaine has shown promising results of shorter duration of action, lesser hemodynamic effects on the cardiovascular system, and no significant change in the quality of anesthesia than bupivacaine.

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