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Case Report

The Radix Entomolaris and Paramolaris: A Review and Case Reports with Clinical Implications

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Abstract

Normally, the permanent mandibular first molar has two roots, mesial and distal. However, mandibular molars may have an additional root located either buccally (radix paramolaris) or lingually (radix entomolaris [RE]). Understanding of the presence of an additional root and its root canal, anatomy is essential for successful treatment outcome. The aim of this paper is to review the prevalence and morphology of RE and to present two cases of permanent mandibular first molars with an additional third root (RE) in the Indian population. In this study, we did a clinical investigation of two cases; one case of successful endodontic management of permanent mandibular first molar characterized as RE, whereas the second one is a presentation of a case of severe bone loss around permanent first molar with an additional third root. The presence of an additional third root in permanent mandibular first molars may affect the prognosis of the tooth if it is misdiagnosed. Thus, an accurate diagnosis and thorough understanding of variation in root canal anatomy are essential for treatment success.

Key words: Additional third root, Permanent mandibular first molar, Radix entomolaris, Root canal anatomy

INTRODUCTION

The prevention or healing of endodontic pathology depends on a thorough chemomechanical cleansing and shaping of the root canals before a dense root canal filling with a hermetic seal. An awareness and understanding of the presence of unusual root canal morphology can thus contribute to the successful outcome of root canal treatment.[1] In a mandibular first molar, an additional third root, first mentioned in the literature by Carabelli is called the radix entomolaris (RE). This supernumerary root is located distolingually in mandibular molars, mainly first molars.[2] The presence of a separate RE in the first mandibular molar is associated with certain ethnic groups. Mandibular first molar which has three roots has a frequency of <5% in white Caucasian (UK, Dutch, Finnish, German), African (Bantu Bushmen), Eurasian, and Indian populations.[3] In those with Mongoloid traits, such as the Chinese, Eskimos, and Native American populations, it occurs with a frequency of five to more than 30%.[4,5] RE has an occurrence of <5% in the Indian population and such cases are not routinely observed during dental procedures.[6-12] Knowledge of such anatomic variation of root and root canals is essential during the treatment of the patients presenting with morphological diversities in their root canal anatomy. A case report on morphology, clinical approach to diagnosis and management of RE has been presented here.

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CASE REPORT

An 18-year-old female came for endodontic treatment of mandibular right first molar. On clinical examination, the tooth was deeply carious and was diagnosed with irreversible pulpitis. The radiograph of the mandibular right first molar was normal without any periapical changes. After anesthetizing the tooth, access preparation was done with an endo-access bur and canal orifices were located with DG 16 endodontic explorer. Initial negotiation of

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the root canals was conformed with K-file 10. The fourth distolingual canal orifice was present far from distal root canal orifices. The canal lengths were determined radiographically with K file ISO 15 size. They were cleaned with 2.5% sodium hypochlorite along with EDTA and shaped and the patient was recalled after 3 days. At the next appointment, obturation done [Figures 1-5 and Table 1].

Case 2

A 28-year-old female was referred for endodontic treatment of the mandibular right first molar with pain and swelling from past 2-month clinical presentation-patient is gone to root canal treatment 6 months back, on radiographic examination shows incomplete obturation with a missed canal in relation to 46 and periapical lesion in distal root and one missed canal treatment plan – retrieval of obturating material access cavity four distinct canal orifices were found and were coronally enlarged with gates glidden drills. Initial negotiation of the root canals was performed [Table 1 and Figures 1-5].

DISCUSSION

The etiology behind the formation of the RE is still unclear. In dysmorphic, supernumerary roots, its formation could be related to external factors during odontogenesis, or to the penetrance of an atavistic gene or polygenetic system (atavism is the reappearance of a trait after several generations of absence).

In eumorphic roots, racial genetic factors influence the more profound expression of a particular gene that results in the more pronounced phenotypic manifestation.[8] Curzon suggested that the "three rooted molar" trait has a high degree of genetic penetrance as its dominance was reflected in the fact that the prevalence of the trait was similar in both pure Eskimo and Eskimo/Caucasian mixes.[13,14]

The presence of a separate RE in the first mandibular molar is associated with certain ethnic groups. In African populations, a maximum frequency of 3% is found, while in Eurasian and Indian populations, the frequency is <5%. In populations with Mongoloid traits (such as the Chinese, Eskimo, and American Indians), reports have noted that the RE occurs with a frequency.

The RE is located distolingually, with its coronal third completely or partially fixed to the distal root. The dimensions of the RE can vary from a short conical extension to a "mature" root with normal length and root canal. In most cases, the pulpal extension is radiographically visible. In general, the RE is smaller than the distobuccal and mesial roots and can be separate from, or partially fused with, the other roots.[12]

A Classification by Carlsen and Alexandersen Describes Four Different Types of RE According to the Location of the Cervical Part of the RE

- Type A and B – Distally located cervical part of the RE with two normal and one normal distal root components, respectively
- Type C – Mesially located cervical part
- Type AC – Central location, between the distal and mesial root components.

This classification allows for the identification of separate and non-separate RE.

Table 1: Incidence of two canals in distal root of mandibular first molar

Author/year incidence (%) population group
Skidmore (1971) 28.9 Caucasians
Gulabivala *et al.* (2002) 33.4 Thai
Sen *et al.* (2004) 46 Turkish
Gulabivala *et al.* (2001) 10.1 Burmese

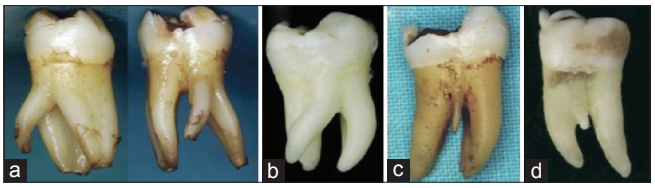

Figure 1: Clinical images of extracted mandibular molars with a radix entomolaris or paramolaris. (a) First molar with a radix entomolaris (distolingual view [left] and lingual view [right]). (b) Radix entomolaris on a third molar (lingual view). (c) First molar with a separate radix paramolaris (buccal view). (d) First molar with a fused radix paramolaris (buccal view). (Courtesy JOE [2007];33;59)

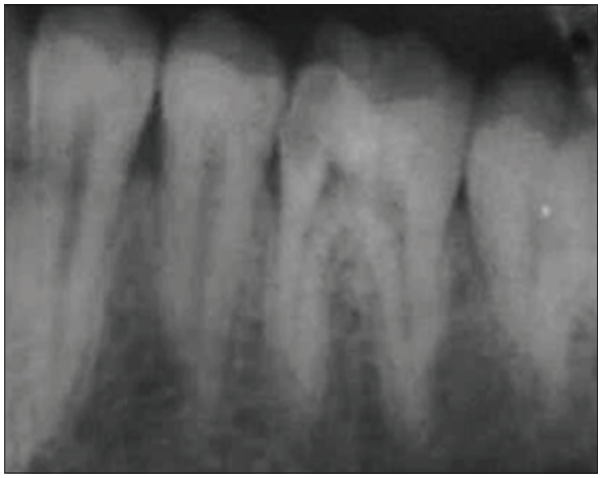

Figure 2: Pre-operative radiographic

Figure 3: Working length determination

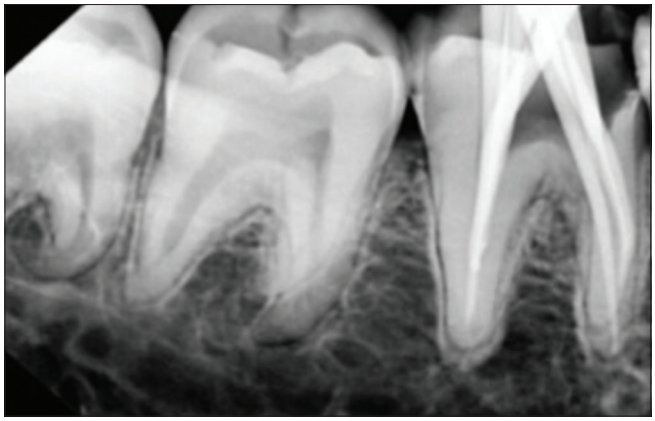

Figure 4: Master cone

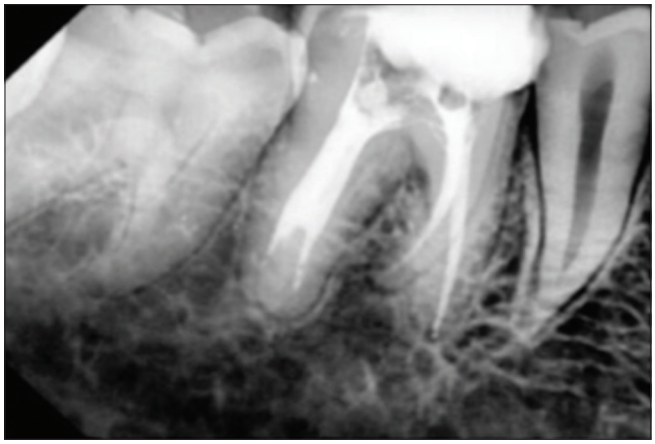

Figure 5: Obturation

De Moor *et al.* (2004) classified RE based on the curvature of the root or root canal.[7]

1. Type 1: A straight root or root canal[2]
2. Type 2: A curved coronal third which becomes straighter in the middle and apical third
3. Type 3: An initial curve in the coronal third with a second buccally oriented curve which begins in the middle or apical third.

Song *et al.* (2010) further added two more newly defined variants of RE.[8]

1. Small type: Length shorter than half of the length of the distobuccal root
2. Conical type: Smaller than the small type and having no root canal within it.

Radix Paramolaris (RP) (Additional Root Located Buccally)

Prevalence

Bolk reported the occurrence of RP.[12] RP is very rare and occurs less frequently than RE.[12] Visser reported the prevalence of RP to be 0% for mandibular first molars, 0.5% for second molars, and 2% for third molars.[15]

Classification

Carlsen and Alexandersen (1991) classified RP into two different types

1. Type A: Cervical part is located on the mesial root complex
2. Type B: Cervical part is located centrally between the mesial and distal root complexes.

Morphology

The RP is located mesiobuccally. The dimensions of RP may vary from short conical extension to a mature root which can be separate or fuse. Few observations can be made from various studies, that is, an increased number of cusps is not necessarily related to an increased number of roots; however, an additional root is always associated with an increased number of cusps and with an increased number of root canals.

Clinical Implications

Endodontic procedures

The presence of RE has clinical implications in root canal treatment. Accurate clinical and radiographic diagnosis can avoid failure of root canal treatment because of a missed canal in distolingual root. The most important basic principle for successful root canal treatment is the principle of "straight-line access."[13] Ultimate objective is to provide access to the apical foramen. As the orifice of RE is distolingually located, the shape of access cavity should be modified from classical triangular form to trapezoidal or rectangular form to better locate the orifice of distolingual root. The root canal orifices follow the laws of symmetry which help in locating the RE. Canal orifices are equidistant from a line drawn in a mesiodistal direction through the pulpal floor and lie perpendicular to this mesiodistal line across the center.[16-18] Straight-line access is essential as the majority of radices entomolaris are curved. Care must be taken to avoid excessive removal of dentin or gauging during access cavity preparation, as this may weaken the tooth structure. A thorough inspection of the pre-operative radiograph and interpretation of

particular marks or characteristics, such as an unclear view or outline of the distal root contour or the root canal, can indicate the presence of a "hidden" RE. To reveal the RE, a second radiograph should be taken from a more mesial or distal angle (300).[19,20]

Clinical inspection of the tooth crown and analysis of the cervical morphology of the roots by means of – periodontal probing can facilitate the identification of an additional root. Using various instruments such as endodontic explorer, pathfinder, DG 16 probe, and micro-opener champagne effect – bubbles produced by remaining pulp tissue in the canal, while using sodium hypochlorite in pulp chamber. An extra cusp (tuberculum paramolare) or more prominent occlusal distal or distolingual lobe, in combination with a cervical prominence or convexity.

An extension of the triangular opening cavity to the (disto) lingual results in a more rectangular or trapezoidal outline form. Visual aids such as a loupe, intraoral camera, or dental microscope can, in this respect, be useful. A dark line on the pulp chamber floor can indicate the precise location of the RE canal orifice. A severe root inclination or canal curvature, particularly in the apical third of the root (as in a Type III RE), can cause shaping aberrations such as straightening of the root canal or a ledge, with root canal transportation and loss of working length resulting. The use of flexible nickel-titanium rotary files allows a more centered preparation shape with restricted enlargement of the coronal canal third and orifice relocation. After relocation and enlargement of the orifice of the RE, initial root canal exploration with small files (size 10 or less) together with radiographical root canal length and curvature determination, and the creation of a glide path before preparation, is step-by-step actions that should be taken to avoid procedural errors.

CONCLUSION

The oral health-care professionals should be aware of this variation in the anatomy of permanent mandibular first molars. The initial diagnosis is of utmost importance to facilitate the endodontic procedure and to avoid treatment failures. Proper interpretation of radiographs taken at different horizontal angulations may help to identify a number of roots and their morphology. Once diagnosed, the conventional triangular cavity should be modified to a trapezoidal form distolingually to locate the orifice of the additional root.

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Case Report

Heterotopic Ossification at an Unusual Site: A Case Report

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Abstract

Heterotopic ossification (HO) is the formation of ectopic bone at non-physiological location, such as soft tissues around a joint. HO is a common complication seen after trauma and certain surgeries (e.g., total hip arthroplasty) involving specific regions such as hip. In neurogenic HO, ectopic bone develops in patients sustaining a spinal cord injury or traumatic brain injury (incidence 20–30%). Neurogenic HO characteristically involves major joints with hip joint being the most common, followed by elbow, shoulder, and knee joint. No reported case of HO in wrists, ankles, legs, and feet has been documented, making these highly rare locations. The ectopic bone may be asymptomatic or can cause significant functional impairment of the involved joint presenting as erythema, warmth, swelling with loss of range of motion; however, this case is a rare presentation involving ankle joint with no signs of inflammation. Plain X-rays and CT scans diagnose the new bone. Management involves primary prophylaxis with NSAIDs, bisphosphonates (not commonly used), and radiation therapy. Surgical excision is the definitive treatment. Neurogenic HO cases should undergo comprehensive and extended follow-up with attention to even rarely involved sites such as ankle, wrists, hands, and feet.

Key words: Ankle, Heterotopic ossification, Neurogenic heterotopic ossification, Traumatic brain injury

INTRODUCTION

As the name suggest, Heterotopic Ossification (HO) refers to bone formation at a non-destined or more specifically at a non-physiological location, particularly in soft tissues such as muscles and tendons around the major joints such as hip and elbow while joints of wrist, ankle, and feet are rarely involved.[1] HO has been widely recorded around elbow joint after soft-tissue trauma, elbow massage, or burn injuries, even without the direct involvement of the elbow.[2]

Traumatic brain injury (TBI) induced HO falls under a category called neurogenic HO or NHO. NHO is usually discussed more rather than its other two equivalents, namely, myositis ossificans progressiva (also known as fibrodysplasia ossificans progressiva) and traumatic myositis ossificans, the former being inherited as an autosomal dominant trait and the latter being localized pathological sequelae in the healing phase of a muscle injury by forming a bone rather than a muscle.[3]

NHO involves ossification in non-osseous tissues following neurogenic damage such as spinal cord injuries (most common), TBI, meningoencephalitis, and neurogenic syphilis (Tabes Dorsalis).

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CASE REPORT

A 30-year-old male presented with chief complaints of stiffness at left ankle joint with mild pain. He had difficulty in walking. He had a history of a roadside accident 2 years back in which he sustained a head injury leading to subdural hemorrhage along with Pott's fracture of the left ankle. He was operated for SDH with surgical decompression. Pott's fracture of the left ankle was treated with open reduction and internal fixation. He remained on mechanical ventilation for about 2 months in the post-operative period.

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Physical Examination

On inspection, there was no callosity, erythema, foci of infection (sinus/fistula), swelling, or bruising on the left ankle. Pulses were palpable bilaterally, and there was no increase in temperature. Mild tenderness was elicited. Hard bony prominence could be felt posteriorly and posterolaterally. There was a loss of dorsiflexion and plantar flexion at the ankle joint. Neurologic examination revealed intact sensory function, proprioception, and vibration sense in the affected lower extremity.

Imaging

Plain radiography (AP and lateral view) showed mature cortical bone around the ankle [Figure 1]. CT scan and 3D CT confirmed the X-ray findings showing mature bone all around the ankle joint but mainly antero-medially, medially, posteriorly, and posterolaterally [Figures 2-5].

Treatment

The patient was managed surgically where the heterotopic bone was excised through two approaches to the ankle joint, i.e., medial and posterolateral. A drain was inserted at the excision site to remove post-operative hematoma. The surgery was performed under spinal anesthesia. Post-operative X-ray was done, which confirmed the success of surgery [Figure 6]. Post-operative management included early mobilization of ankle and indomethacin 25 mg thrice a day was given for 6 weeks to prevent recurrence of HO.

DISCUSSION

HO occurs due to the interplay between genetic, hormonal, and local environmental influences. HLA B18 and HLA DRW7 have been implicated in affected patients.[4] HO and fracture healing processes are similar, and thus the local mediators and cytokines involved are also similar in these two processes. This is apparent not only from the lamellar bone strength and histological similarities between the callus and the heterotopic bone but also from the fact that the drugs that target the factors involved in the healing of fractures also prevent HO when given prophylactically after trauma. These factors include BMPs (especially BMP 2 and BMP 4), neuroinflammatory calcitonin gene-related protein, substance P, PGE2, and TGF-B1 and hence blunting these altered and overamplified HO inducing circuits form the basis of the preventive regimen.[5]

Chronology of HO involves osteoid deposition and definitive radiologic evidence of mineralization in a zonal pattern (CT) as early as 1-month, histological evidence around 1.5 months, and finally mature bone formation by the end of 1 year. This new bone develops at a higher rate than normal bone growth.[6]

Figure 1: Pre-operative plain radiograph of ankle (lateral view): There is a reduction of tibiotalar joint space with new bone formation in the posterior aspect of tibia extending up to the posterosuperior aspect of the calcaneum. There is evidence of metallic implant in the lower end of the tibia just above the articular surface

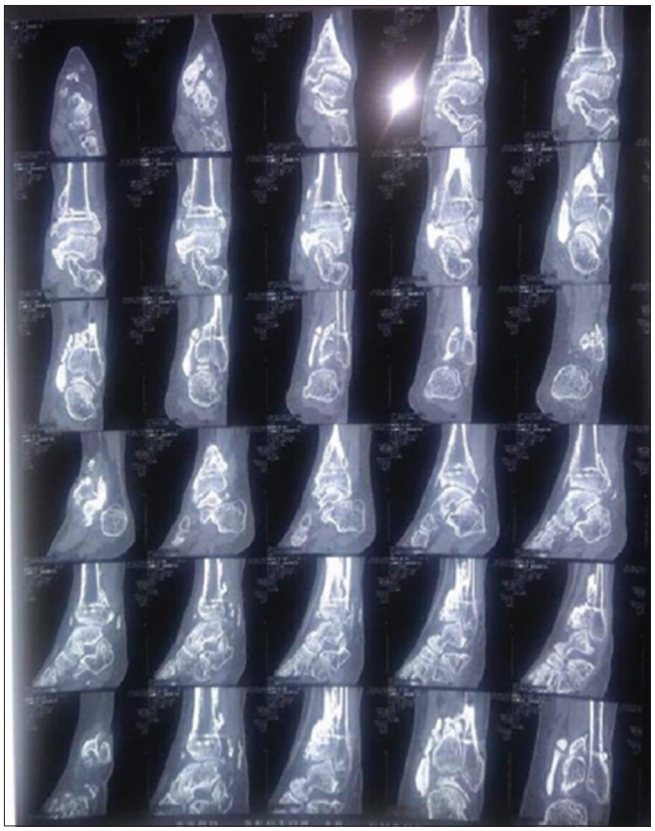

Figure 2: Pre-operative CT scan of the ankle joint with coronal and sagittal reconstruction: There is evidence of old fracture of the metaphysial portion of the tibia with a metallic implant in CT. There is reduction of the tibiotalar joint space with osteophytosis afflicting the tibiotalar joint. There is evidence of new bone formation in the posteromedial aspect of the tibia adjacent to the medial malleolus extending inferiorly up to the calcaneum. There is a slight irregularity of the articular surface of the talus

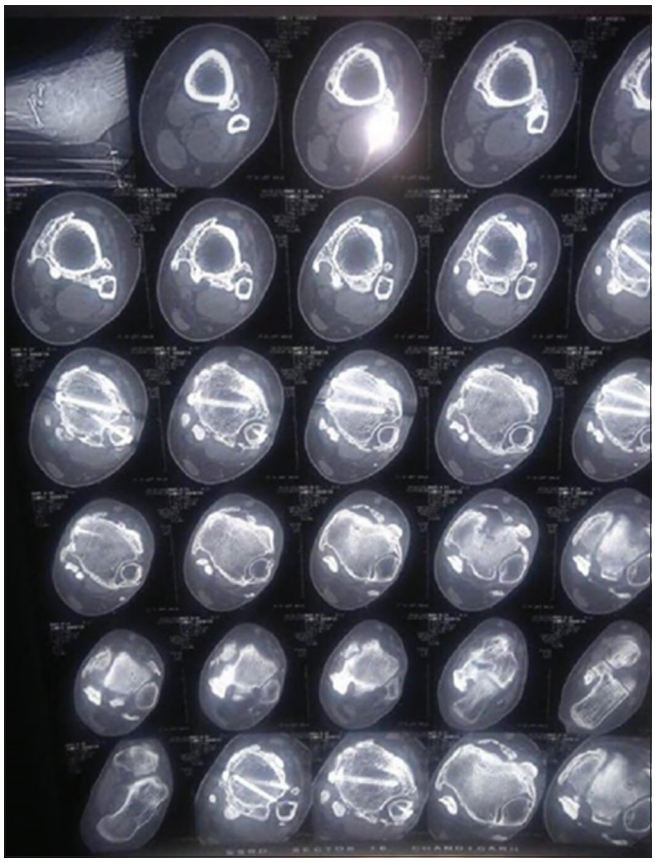

Figure 3: Pre-operative CT scan of left ankle with an axial view: There is evidence of new bone formation in the posteromedial aspect of the tibia and also adjacent to the anterolateral aspect of the metaphysial portion of the tibia

Figure 4: Pre-operative plain radiography of ankle (AP view)

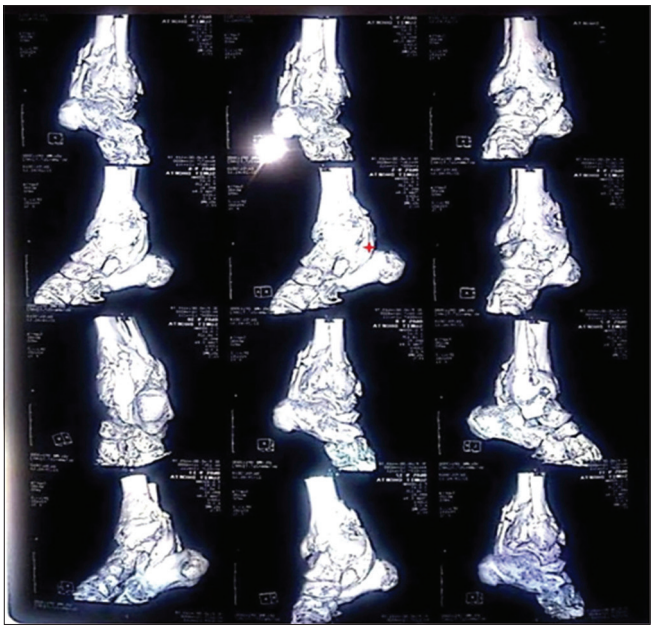

Figure 5: Pre-operative 3D CT reconstruction of the ankle joint. Is marked as the heterotopic bone

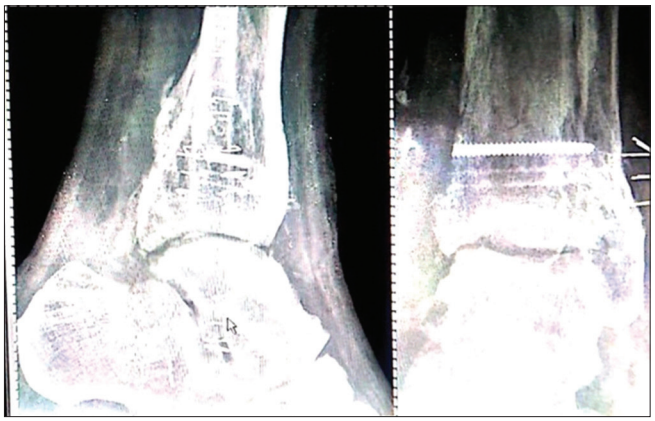

Figure 6: Post-operative X-ray: Lateral and AP view reveals successful excision of the heterotopic bone

HO has been mostly seen around the hip joint after surgeries like total hip replacement and also at the elbow joint following massage after elbow injury (also called myositis ossificans) or after any elbow surgery in non-head trauma patients. It has never been seen in the ankle. It has been reported in literature that HO rates in patients with elbow injury without concomitant head trauma are just 3–6%, whereas the rates have increased up to 90% in patients of head injury with elbow trauma.[7,8] Extrapolating this concept and keeping in mind rarity of the other joints like ankles being involved in HO (in both myositis ossificans or neurogenic HO), this case is an evidence of HO at an unusual site. Hence, we should be extra cautious while operating on an injured joint of a TBI case. All precautions should be taken to prevent the

occurrence of HO in such cases. These include meticulous handling of soft tissues during surgery, thorough washing or lavage of surgical debris and placement of a drain to prevent hematoma at the operated site; and post-operative indomethacin 25 mg 3 times a day for 6 weeks or combination with radiotherapy if required. This case like other cases of HO was managed by excision of the heterotopic bone, followed by indomethacin to prevent recurrence of HO. Excision of heterotopic bone is done once it matures (takes around a year). In this case, the heterotopic bone had matured and hence was excised successfully, and the patient regained ankle movements.

The HO could have been missed in this case because of high suspicion of ankle stiffness to be the result of ankle surgery or insufficient post-operative rehabilitation and also because ankle is, an extremely unusual site for HO.

Hence, we should be extremely cautious in follow-up of such cases, and such cases require prolonged follow-up.

CONCLUSION

This case draws a conclusion that HO can occur at rare sites like ankle if surgery is done at these sites following TBI. This case highlights the importance of considering HO as a differential when a patient with prior history of TBI presents with pain, restriction of range of movements, and stiffness in the previously operated joints with TBI. Therefore, in cases, where an ankle trauma patient with a concomitant head injury, has to undergo surgery of ankle joint, full preventive measures including post-operative indomethacin must be given to prevent the occurrence of HO, and these cases require a thorough, cautious and prolonged follow-up. Laboratory tests, like serum ALP, can be included in the first 4–6 months of follow-up. High ALP levels are helpful in diagnosing early HO.[2]

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Review Article

A Multidisciplinary Outlook in Prosthodontics

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Abstract

Prosthodontic research needs to cover all aspects that can contribute to the clinical outcomes. Without a strong interdisciplinary relationship between other disciplines of dentistry and prosthodontics, the esthetic, functional, and/or biological outcome may be compromised and necessitate extensive and expensive retreatment. Through this paper, we would like to review the outline of the areas that overlap between prosthodontics and other branches of modern dentistry that dictates the interdisciplinary treatment.

Key words: Multidisciplinary prosthodontics, Oral radiology, Oral surgery, Orthodontics, Pedodontics, Periodontics

INTRODUCTION

"Multidisciplinarity" signifies the juxtaposition of disciplines. Interdisciplinary research has been gaining prominence across all domains of science, engineering, and social sciences. In the contemporary advanced period of dentistry, there is a need for the multidisciplinary approach to achieve biologically acceptable, esthetic, functional, and patient satisfactory treatment outcomes. For a patient overall rehabilitation process, there is a need of involving various specialties either for removing the pathologically active tissues or modifying the anatomically defective sites before the start of the prosthetic part of treatment.[1]

Prosthodontics is a branch of modern dentistry that deals mainly to restore the lost form, function, and the esthetics of the patients. Rehabilitation of the orofacial defects in accordance with the surrounding anatomical, physiological, and biological tissues requires the intervention of various disciplines starting from the diagnosis to better treatment outcomes such as oral radiology, periodontics, endodontics, orthodontics, and pedodontics. This article aims to outline the areas of overlap between prosthodontics and other branches of modern dentistry that dictates the interdisciplinary treatment.

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WHAT'S MULTIDISCIPLINARY APPROACH?

Multidisciplinary dentistry refers to dental treatment that uses more than 1 type of dental strategy. This type of multilevel care occurs where there are various complex steps in treatment planning. The key is to build a team of likeminded, dedicated professionals who share a common goal of providing ideal oral health care to patients [Figure 1].

BENEFITS

For Clinician [Figure 2]

Improved patient care and outcome through the development of an agreed treatment plan, improved coordination of care, streamlined treatment pathways, and reduction in duplication of services.

For Patient

Gets the most appropriate treatment decision made by a team of experts and improved satisfaction with treatment and care.

ORAL RADIOLOGY

In the era of modern medicine and dentistry, the diagnostic pathway leads to the treatment planning phase

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Figure 1: Multidisciplinary prosthodontics

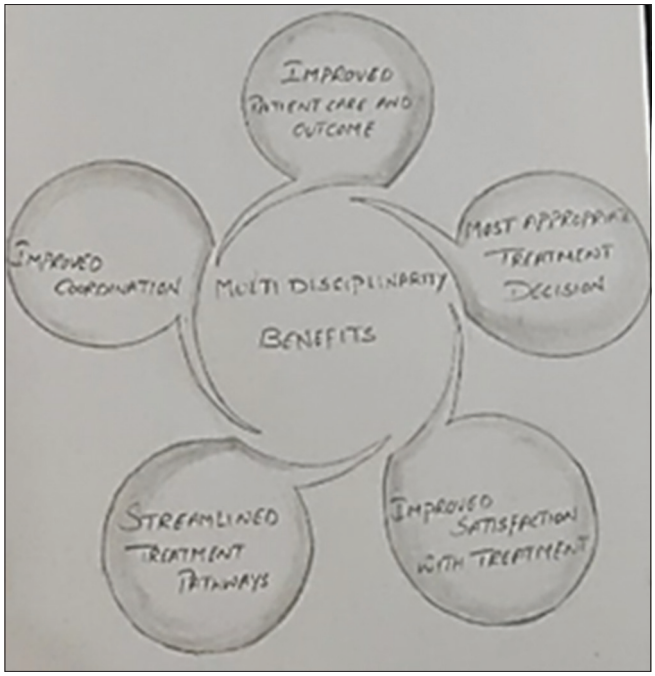

Figure 2: Multidisciplinary prosthodontics benefit

and successful outcomes. Oral radiology is vital for the assessment of structures such as jaws, jaw relationships, denture foundation, the position of anatomical landmarks, bone height-width, tooth condition, and their position in the arch. Radiology is of two types, intraoral radiography and extraoral radiography.

Intraoral Radiography

It includes periapical, bitewing, and occlusal projections.

The intraoral radiology has a limited role in defining:[1]

1. Abnormalities in the oral structures
2. Examining the tuberosities
3. Evaluating the submucosal conditions under denture bearing areas
4. Evaluating the periodontium and bone level at the abutment and pontic levels in fixed partial dentures (FPDs).
5. Pre-operative, operative, and post-operative imaging for implant therapy helps in the accurate positioning of the implants.
6. Post-operative imaging after 3–5 years and beyond can be used to assess the bone-implant interface and
7. Marginal peri-implant bone height.

Extraoral Radiography

These extraoral radiographs in complete denture can provide a survey of the patient's denture foundation and surrounding structures and evaluate the status of impacted teeth, trauma, and temporomandibular (TM) joint area.[2]

Panoramic Radiography

It is evaluated for the presence of retained root fragments, impacted teeth, radiolucency's, radiopacities and foreign bodies, location of mental foramina at or near the crest of the residual alveolar ridge, and maxillary sinus proximity to the crest of the residual alveolar ridge on a single film.[3]

Computed Tomography

It has become popular in implant and TM joint diagnosis at an acceptable radiation dose risk.[4] Cone-beam computed tomography provides cross-sectional images of the alveolar bone height, width, and angulations and accurately depicts vital structures such as the inferior alveolar dental nerve canal in the mandible or the sinus in the maxilla and also a reliable tool in ridge mapping technique.

Magnetic Resonance Imaging (MRI)

MRI techniques are currently being used in dentistry for diagnosis of TM joint diseases and inflammatory conditions of the facial skeleton.[5]

Specialized radiographic techniques arthrography of the TM joint is basically a method that will supply information on soft-tissue state of the TM joint.[2] In addition, radiotherapy protective devices/stents can be fabricated and used to shield/position tissues or to assist in the efficient administration of the radiation to a specific structure, thus reducing the post-operative morbidity of tissues.

Al Faleh *et al.* highlighted the necessity of routine radiographic examination of the jaws for all edentulous patients before constructing complete dentures.[1]

Jamil *et al.* reviewed on the different radiographic techniques used in the prosthodontics and concluded that there is crucial role of radiographs in prosthodontics and in their successful treatment outcomes.[5]

Thus, the different oral radiology techniques provide valuable information to the prosthodontist about the comprehensive oral scenario and play as a deciding factor in the treatment planning.

PERIODONTICS

The periodontium is a complex structure that consists of the periodontal ligament, gingiva, cementum, and alveolar bone.[6] Of all disciplines within modern dentistry, periodontics and prosthodontics have the strongest and the most intimate connections.[7]

The principal purpose of the periodontal aspect is to create a sound foundation where the final prosthesis is placed.

Its objectives are as follows:[8,9]

- Removal of local and environmental etiologic factors (preventive periodontal procedure like scaling)
- Plaque control and oral hygiene maintenance during the course of therapy
- Removal of pockets
- Restoring osseous and gingival contours (treatment of recession by grafting procedures)
- Removal of furcal invasions by combined periodontal, endodontic, and prosthetic procedures.
- Cosmetic gingival procedures (like gingivectomy/crown lengthening)
- Periodic recall and maintenance program.

The prostho-perio relation starts from the impression phase of the treatment:[10]

The use of retraction cord yields minimal gingival recession and also sulcular tissue preservation. If it is used with negligence in areas of insufficient attached gingiva or gingival fiber, injury occurs which leads to inaccurate impressions and impression material infuse into the gingival connective tissue and bone which, in turn, foreign body reaction.

The Provisional Restoration

In-accurate interim restorations with poor adaptation at the margins being under or over contoured with porous or rough surfaces result in inflammation, overgrowth, or recession of gingival tissues.

Marginal Fit

There should ideally be no gap at the interface for a restored tooth. Studies suggested that the 50 um gap is clinically acceptable.

The Contour of the Crown

Properly designed contours provide hygienic access, have the completeness to create the desired gingival shape and a pleasant visual tooth contour in esthetic areas.[10]

Smoothness of the Contacts and Contours

The fineness of the restorative margins and in the contacts and contours and on the gingival portion of the restoration is critical, porous or rough surface, over or under contoured restoration leads to gingival irritation, inflammation, and overgrowth, which progress toward bone loss and finally failure of the prosthesis.

Biologic Width and Margin Placement

Biological width (BW) has a tendency of self-restoration and adapts dynamically.[11] The conservation of periodontal health is dependent on the biologic width. The violation of BW has been widely discussed as a contributing factor that jeopardizes periodontal health.

The result of BW breach includes attachment loss, pain, gingival inflammation, localized gingival hyperplasia, pocket formation, and loss of periodontal structure finally early implant bone loss.[12]

BW and Implants

BW is very important in implant success. During the initial phase of implant healing, peri-implant bone remodeling is from the process of BW reformation to allow a stable soft-tissue barrier. In addition, the locations of microgaps and smooth/rough surface interfaces may be associated with the length of peri-implant BW. Platform switching is using abutments with a reduced diameter than the drilled implant diameter which limits the crestal resorption by maintaining the BW and preserving the interdental papilla.

According to Berglundh *et al.*, the strategies to prevent early implant-bone resorption were control of biologic width and microgap.[13]

As per Hsu *et al.*, robust supporting periodontal/peri-implant tissues, proper contacts, and occlusal scheme provide solid foundations for predictable prosthetic therapy.[7]

ORTHODONTICS

Orthodontics is a clinical branch of dentistry that will correct poor alignment, positioning of teeth, jaws, and face structure.[14] Pre-prosthetic orthodontics is necessary for some clinical scenarios mainly such as correction of anterior deep vertical overlap, orthodontics treatment with multiple missing teeth, tilted teeth, intrusion/extrusion of teeth, retainers/night guards, and space maintainers/regainers.[15]

Excessive Vertical Overbite

It can be treated either intrusion of anterior teeth, extrusion of posterior teeth, or a combination of both. A segmented intrusion of the anterior teeth is preferable in adult patients.[16]

Uprighting of Tilted Molars

Uprighting is necessary in directing the forces long axis to the tooth. A slight modification of tooth reduction will be sufficient when preparing the tooth for a FPD and use of a locked attachment or telescopic crown.[17]

Orthodontics Extrusion for Crown Lengthening Purpose

The advantages of orthodontic extrusion over surgical crown lengthening are – orthodontic extrusion provides a more favorable crown to root ratio, eliminates the risk of compromising the alveolar bone support of the adjacent teeth, and will not compromise the esthetic of the tooth that requires crown lengthening.[18]

Becker *et al.* stated that alignment of the tilted tooth through orthodontic treatment has the advantage of the elimination of the intrabony defect on the mesial side of the tilted tooth, simplify the preparation of the tilted abutment tooth to receive a FPD, aid in aligning the occlusal plane, and aid in the transmission of occlusal forces through the long axes of the tooth.[19] Alfallaz felt that the importance of diagnostic wax-up is a critical tool in nearly all situations to visualize and assess the treatment outcomes. Thus, orthodontics has a profound influence on the prosthodontic treatment planning.

ENDODONTICS

Endodontics is the branch of dentistry related to dental pulp and tissues surrounding the roots of a tooth. Endodontists has paid a great foundation for the creation and maintenance of successful prostheses.[20] The effect of endodontics is predominant on the overdenture and fixed type prostheses before the prosthesis fabrication on the teeth.[21]

In Fixed Prosthodontics

The amount of suprabony tooth structure is the most critical factor determining the restorative prognosis for a tooth and superstructure. Studies suggested that endodontically treated teeth are somehow more "brittle" than vital teeth.[22] The band of extracoronal material (usually metal or metal-ceramic) that encircles this tooth structure is termed as the ferrule and is usually provided by the crown, is very important in preventing the vertical fracture of the tooth.

In Tooth-supported Overdenture

Providing good apical seal and preserving the tooth are the key factors for the success.

Lakshmi *et al.*, from their study, concluded that for the endodontically treated tooth that requires a post, the minimum length of the solid tooth remaining would be the – biologic width (2.5 mm) + ferrule length (2 mm) + apical seal (4 mm) + post length (equal to crown length), (i.e., 8.5 mm + post length beyond crown margin). For those teeth not requiring a post, the requirements are for biologic width + ferrule length (i.e., 4.5 mm of the suprabony solid tooth; this assumes adequate bone support to provide a clinically acceptable level of mobility).[21] Barkhordar *et al.*[23] in 1989 compared restored teeth that were prepared with and without a ferrule and showed that the ferrule reduced vertical root fracture by one-third.

ORAL SURGERY

It is a branch of dentistry dealing with the surgical treatment or repair of any problematic or pathological condition of the mouth or jaws. The main aim of the pre-prosthetic surgeries is to provide an ideal denture bearing area or the foundation area on/in which the prosthesis gains retention, stability, and harmony with the surrounding structures. The pre-prosthetic surgeries are done under the reference/consultation of the prosthodontist.

There are two main categories of pre-prosthetic surgery procedure [Figure 3]:

1. Soft-tissue procedures
2. Hard tissue procedures.

Soft-tissue Procedures

It includes – excision of the hyperplastic ridge, prominent labial frenum, epulis fissuratum papillary hyperplasia, and mental nerve repositioning.

Hard Tissue Procedures

It includes – alveoplasty, maxillary tuberosity reduction, mylohyoid ridge reduction, excision of a maxillary or mandibular torus, reduction of genial tubercles, ridge extension procedures restoration of grossly deficient denture bearing areas (bone grafting).[24]

PEDODONTICS [FIGURE 4]

In the cases such as cleft lip and palate conditions, the multidisciplinary approach by a surgeon, orthodontist, speech therapist, pedodontist, and prosthodontist is very crucial. Providing of feeding bulb apparatus and the obturators that help in the suckling without gagging or struggling is the duty of the prosthodontist in many techniques including the pre-surgical nasoalveolar molding (PNAM). PNAM is an evolving technique which acts as a form of custom tissue expansion while correcting the

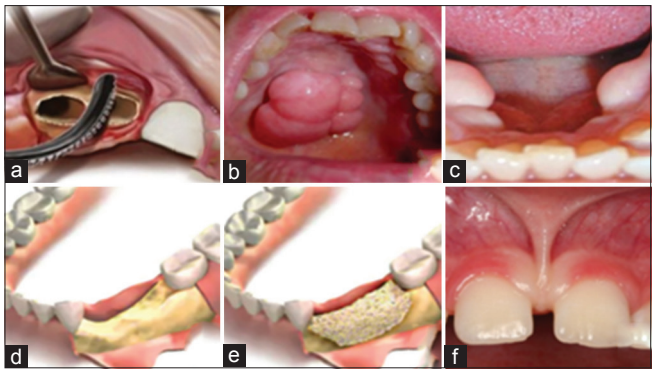

Figure 3: (a) Alveoplasty, (b) palatal exostosis, (c) mandibular tori, (d and e) ridge augmentation, (f) high frenal attachment

Figure 4: Prosthetic management of cleft conditions

nasal deformity non-surgically and addressing the shortness of columellar length deficiency and alveolar segment malposition with minimal surgery. Frequent surgical intervention to achieve the desired esthetic results can be avoided by PNAM.[25]

PUBLIC HEALTH DENTISTRY

Community dentistry helps in doing the survey among the population and analyzes the results and to draw the conclusion on the knowledge, awareness of the population toward prosthetic treatment, percentage of edentulism, and the prevalence of edentulous sites pertaining to the classification systems, and the age group commonly effected by edentulism, the percentage satisfaction of the patient's toward prosthetic treatment, etc.

ORAL PATHOLOGY

Pathology has an indirect relation to the prosthodontics in analyzing the quality of the saliva, determining the oral lesions, biopsies, and in obtaining the complete blood picture regarding the systemic condition of the patient.

CONCLUSION

- By working collaboratively, we can hope to answer questions never addressed before, including those with substantial influence on society. Clinical and research aspects of prosthodontics have become more multidisciplinary.
- Therefore, prosthodontists need to understand various technical procedures as well as the underlying physiological, anatomical, and biological principles.

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Original Article

Correlation Between Patterns of Bone Marrow Edema and Their Associated Soft-Tissue Injuries, as seen on Magnetic Resonance Imaging of Knee Joint in Patients with a Recent History of Trauma

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Abstract

Introduction: Bone bruise or bone marrow edema is a common innocuous finding in magnetic resonance imaging (MRI) knee of patients with trauma. The pattern of bone marrow edema provides insight into the mechanism of injury which, in turn, helps to evaluate the injuries with a more discerning eye. Five basic mechanisms of knee injury which are commonly seen in MRI scan of knee trauma patients are pivot shift, dashboard injury, hyperextension, clip injury, and lateral patellar dislocation. Each of these mechanisms causes characteristic bone marrow edema patterns and has associated soft-tissue injuries, following the musculoskeletal biomechanics.

Aim: The purpose of this study is to assess the correlation between bone marrow edema patterns and associated soft-tissue injuries.

Settings and Design: This is a cross-sectional study of 200 patients conducted at the Department of Radiodiagnosis and Imaging, MGM Medical College and Associated Hospitals, Indore.

Materials and Methods: MRI of 200 cases of recent knee injury was analyzed to determine bone marrow edema pattern. The pattern of edema and soft-tissue injuries was plotted and analyzed to see a significant correlation.

Statistical Analysis Used: Variables were expressed as percentages and comparison was done by Chi-square analysis. Two-tailed $P < 0.05$ was considered statistically significant.

Results: Significant correlation was seen between pivot shift injury and anterior cruciate ligament (ACL) tear, pivot shift injury and medial meniscus tear, dashboard injury and posterior cruciate ligament (PCL) tear, lateral patellar dislocation and medial patellofemoral ligament (MPFL) tear, and clip injury and medial collateral ligament (MCL) tear. Pivot shift was the most common bone marrow edema pattern, accounting for 55.5% of cases and hyperextension was the least common pattern, seen in only 3% of cases.

Conclusion: The pattern of bone marrow edema can provide a road map to associated soft-tissue injuries which assist in finer evaluation and can help in creating better patient management outcomes.

Key words: Bone bruise, Bone marrow edema, Magnetic resonance imaging knee, Musculoskeletal, Trauma

INTRODUCTION

Knee joint is a major weight-bearing joint of the human body with a wide range of dynamic mobility and is subjected to countless mechanical forces. Smooth functioning of the knee joint relies on many soft-tissue structures to maintain bone alignment and movement. When forces beyond the physiological range act on the joint, these result in bone and soft-tissue injuries.[1]

Bone marrow edema or "bone bruise" depicts the changes in bone secondary to trabecular injury. These are routinely seen in magnetic resonance imaging (MRI) scans of musculoskeletal trauma as areas of decreased signals on T1 images and increased signal on T2, STIR, PD, and fat-saturated images.[2]

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Five major mechanisms of knee injuries have been described, which are – pivot shift, clip, dashboard, lateral patellar dislocation, and hyperextension injuries. These mechanisms leave characteristic bone marrow edema patterns following the musculoskeletal biomechanics and hence cause specific associated soft-tissue injuries. This pattern of bone marrow edema is like a "footprint" of mechanism of injury and gives clues regarding the associated soft-tissue injuries.[3]

MATERIALS AND METHODS

This was a hospital-based cross-sectional study done at the Department of Radiodiagnosis and Imaging, Mahatma Gandhi Memorial Medical College and Associated Hospitals, Indore, from October 2019 to April 2020. A total of 200 cases of MRI knee with a recent history of trauma (<4 weeks) were included.

MRI of the affected knee joint was done as per imaging protocol and images were stored in a compact disc. Inclusion criteria were patients of age group 20–45 years with a recent knee injury (<4 weeks). Patients with compound or comminuted fractures, pathological fractures, orthopedic implants, neoplasm of knee joint, old injuries without marrow edema, and those having bone marrow diseases unrelated to trauma were excluded from the study.

MR studies were done by GE Signa Pioneer 3.0 T MR system with a dedicated knee coil. The patient was placed in supine position with the knee slightly externally rotated (10–20°) and sagittal (T1, T2, PD, and PDFS), coronal (STIR/merge), and axial (T2, PDFS) sequences were taken. Imaging was done using FOV: 150 mm, slice thickness of 3 mm on sagittal images; FOV: 150 mm, slice thickness of 3 mm on coronal images; and FOV: 150 mm, slice thickness of 3.5 mm on axial images with interslice gap of 1.5 mm. An axial acquisition through the patellofemoral joint was used as the initial localizer for subsequent coronal and sagittal images. The sagittal plane was primarily used to evaluate the bone marrow edema which was confirmed on coronal images.

MRI was analyzed by two observers to determine bone marrow edema pattern. The edema patterns were distributed into six categories, namely, pivot shift, dashboard, clip, hyperextension, lateral patellar dislocation, and complex or mixed pattern. The pattern of edema and soft-tissue injuries was plotted and analyzed to see any significant correlation.

Statistical Analysis

Data was analyzed using SPSS v 24.0. Variables were expressed as percentages and evaluation of dependence was done by Chi-square analysis. The strength of association was expressed by Phi coefficient (ø). Two-tailed $P < 0.05$ was considered statistically significant for all the tests.

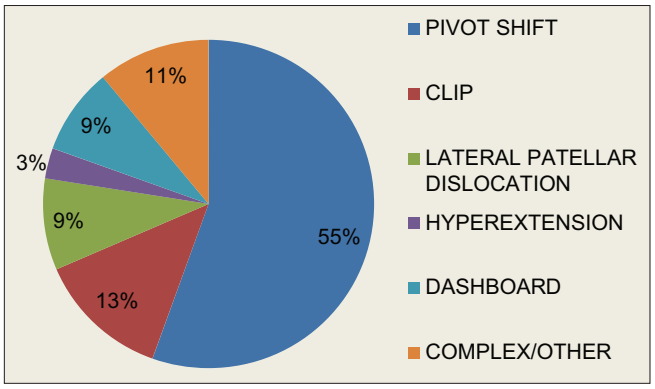
RESULTS

Knee Injury MRI Patterns

The most common pattern of knee injury observed in our study was pivot shift injury, which was seen in 55.5% of cases, followed by clip injury which was seen in 13% of cases. Lateral patellar dislocation and dashboard injuries were seen in 9% and 8.5% of cases, respectively. Hyperextension injury was the least common, accounting for 3% of cases. Nearly 11% of cases had complex bone marrow edema patterns not conforming to a single category and were classified as complex/mixed pattern [Graph 1, Table 1].

Pivot Shift Injury

Significant correlation was observed between pivot shift injury pattern and ACL injury, with ACL tear in 96.4% of cases. Chi-square test revealed $P < 0.001$ and Phi coefficient (ø) of 0.634. Posterior horn of medial meniscus was the second most common soft-tissue injury, seen in 45.9% of cases of pivot shift mechanism ($P < 0.05$) followed by MCL which was injured in 41.4% of cases. Other soft-tissue injuries observed were anterior horn of medial meniscus in 15.3% of cases, anterior horn of lateral meniscus in 6.3%,



Graph 1: Distribution of various types of knee injury patterns. Pivot shift injury was the most common mechanism observed accounting for 55.5% of cases. Hyperextension was the least common mechanism observed in this study, accounting for 3% of cases

Table 1: Distribution of various types of knee injury patterns

Type of injury	Cases	Percentage
Pivot shift	111	55.5
Clip	26	13
Lateral patellar dislocation	18	9
Hyperextension	6	3
Dashboard	17	8.5
Complex/other	22	11
Total	200	

posterior horn of lateral meniscus in 17.1%, and lateral collateral ligament in 12.6% of cases [Graph 2].

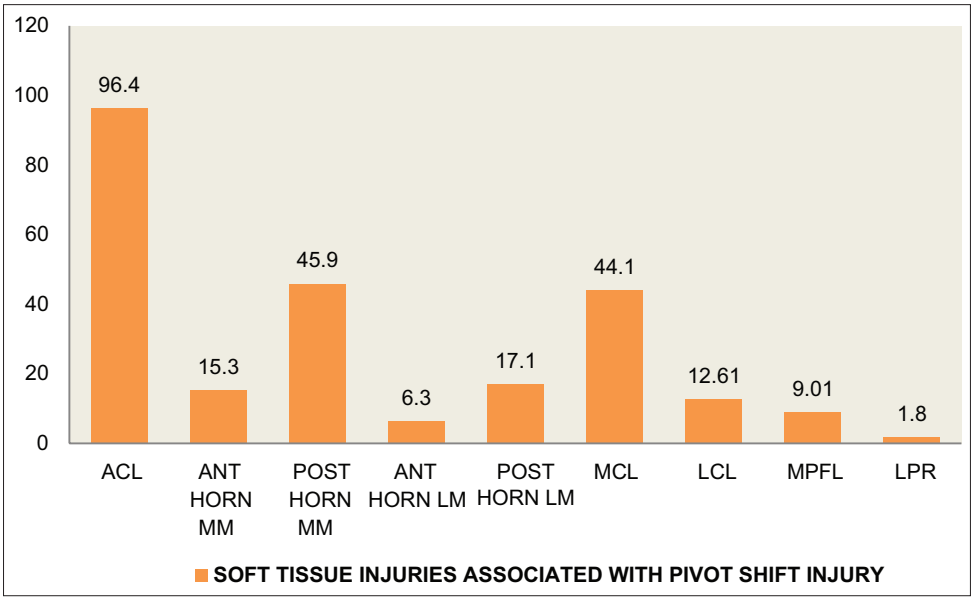
Dashboard Injury

Significant correlation was observed between PCL injury and dashboard pattern of bone marrow edema, with PCL injury in 88.23% of cases. Chi-square test showed $P < 0.001$ and Phi coefficient (ø) of 0.547. In dashboard pattern of bone marrow edema, PCL injury was far more common than ACL injury, which was seen in only 11.76% of cases. Other soft-tissue injuries observed were medial meniscus injury in 17.64% of cases, lateral meniscus injury in 17.64%, and MCL tear in 5.8% of cases [Graph 3].

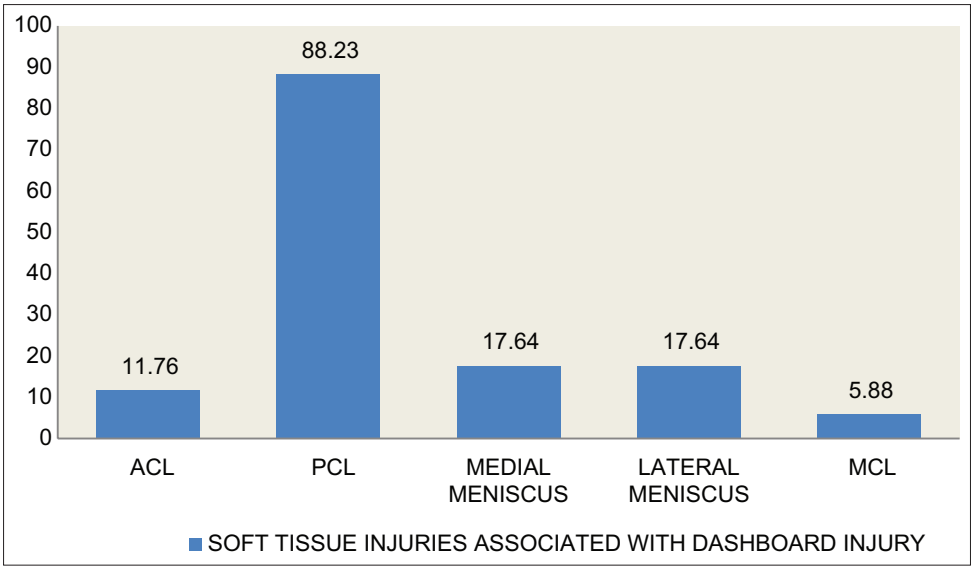
PCL avulsion fracture was more commonly seen in dashboard injury with 57.14% of all PCL avulsion fractures occurring in dashboard injury and 42.84% in other injuries [Graph 4].

Lateral Patellar Dislocation

Significant correlation was observed between medial patellofemoral ligament injury and lateral patellar dislocation pattern, with 94.45% of cases showing medial patellofemoral ligament injury. Chi-square test revealed $P < 0.001$ and Phi coefficient (ø) of 0.648. ACL was another commonly injured soft tissue, seen in 37.5% of cases [Graph 5].



Graph 2: Soft-tissue injuries associated with pivot shift injury. ACL was most common soft tissue to be injured followed by posterior horn of medial meniscus and medial collateral ligament. Pivot shift injury showed significant correlation with ACL injury ($P < 0.001$, ø coefficient of 0.634) and medial meniscus injury ($P < 0.05$)



Graph 3: Soft-tissue injuries associated with dashboard injury. PCL injury was the most common soft-tissue injury associated with dashboard injury ($P < 0.001$, ø coefficient of 0.547). PCL avulsion fracture was more commonly seen in dashboard injury (57.14%) than other types of injuries (42.84%)

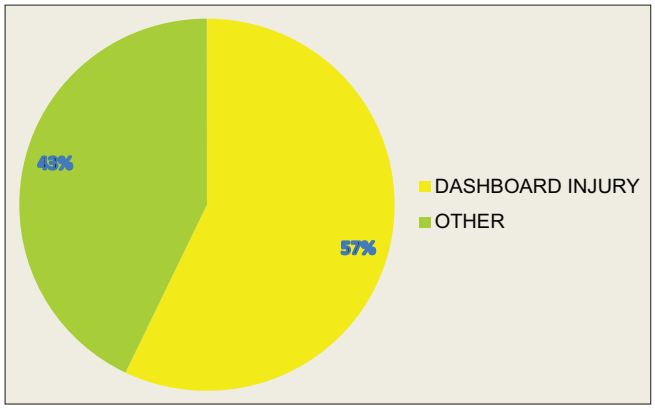
Clip Injury

Significant correlation was seen between MCL injury and clip injury pattern of bone marrow edema with 88.46% of cases having MCL injury. Chi-square test revealed $P < 0.001$ and Phi coefficient (ø) of 0.45. ACL was second most common soft-tissue injured, seen in 61.54% of cases, followed by posterior horn of medial meniscus, seen in 53.84% of cases [Graph 6].

O'Donoghue's triad of ACL, MCL, and medial meniscus injury was seen in 17 (15.3%) cases of pivot shift injury and 5 (19.23%) cases of clip injury.

Hyperextension Injury

In hyperextension injury, ACL and posterior horn of medial meniscus were most common soft-tissues injured, each seen in 50% of cases, followed by MCL injury (33.34%). LCL, PCL, and lateral meniscus injury were seen in 16.67% of cases each [Graph 7].



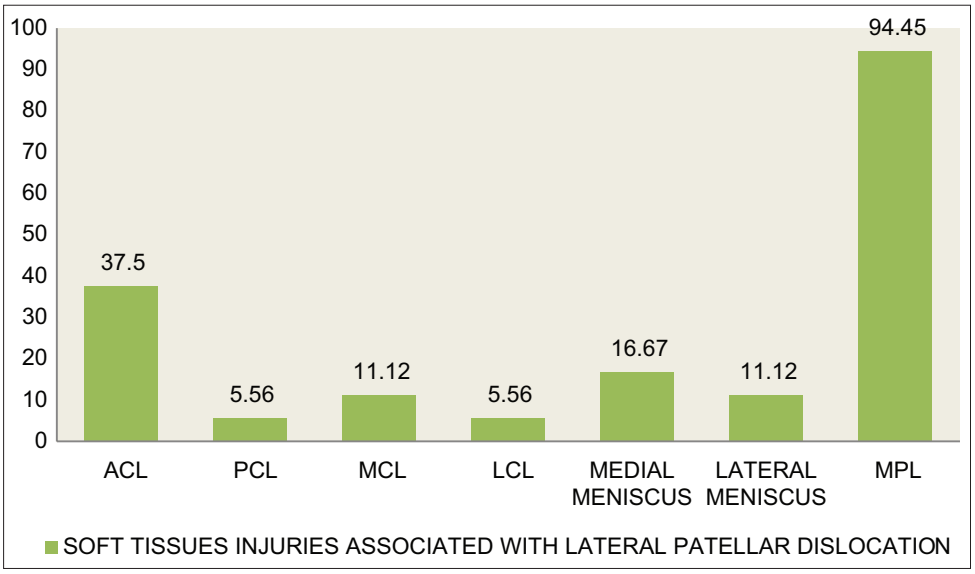
Graph 4: PCL avulsion fracture in dashboard injury compared to other injuries. PCL avulsion fracture was more commonly seen with dashboard injury as compared to other injuries

DISCUSSION

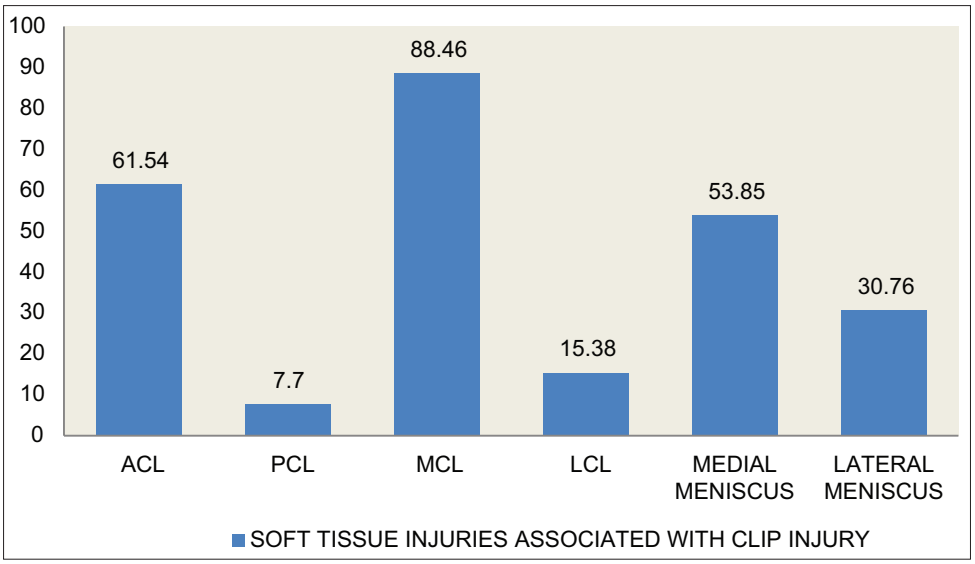
Knee joint is a major weight bearing joint of the human body, and hence prone to injuries, both by direct trauma and indirectly by compressive or tensile forces. While X-ray is the workhorse of musculoskeletal trauma, MRI provides far more extensive insight into the finer aspects of musculoskeletal injury with regard to soft-tissue damage.[4]

Two major types of forces can act on knee joint, compressive, or tensile. When compressive forces act on joint beyond the physiological range, it causes bone marrow contusion and damage to interposed soft tissues. On the contrary, tensile forces pull bones and soft-tissue apart, causing ligament and tendon injuries as well as avulsion fractures. Apart from the type of force involved, important facets determining type of injury are the direction of the force and state of flexion or extension of knee joint at time of injury. All these phenomenon give rise to bone marrow edema patterns which provide a clue to the type of injury.[5]

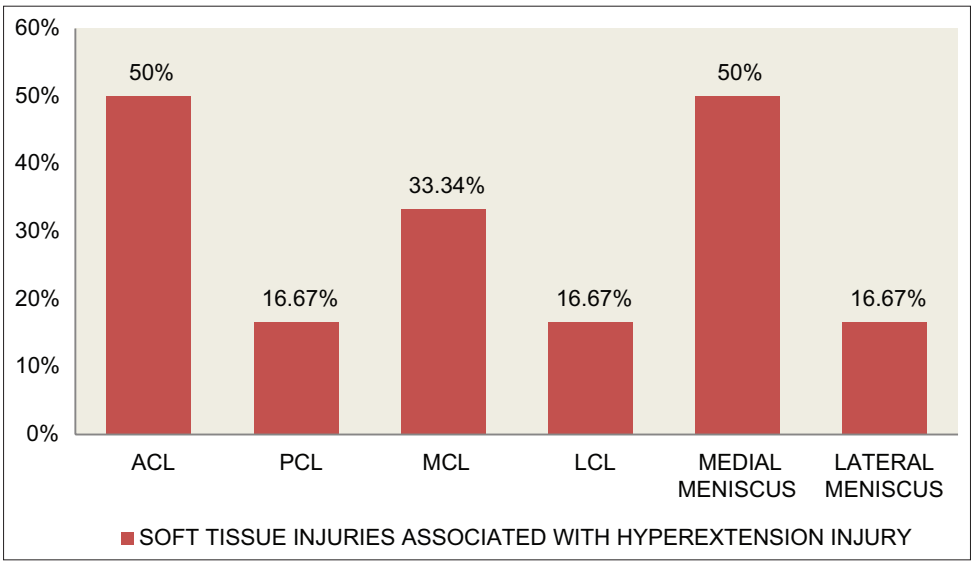
On MR images, trabecular contusion is seen as bone marrow edema. Although bone marrow edema is non-specific and can also be seen in inflammatory and neoplastic disorders, a traumatic cause is usually obvious based on clinical history.[6] Bone marrow contusion



Graph 5: Soft-tissue injuries associated with lateral patellar dislocation. Significant correlation was seen between medial patellofemoral ligament injury and lateral patellar dislocation ($P < 0.001$, ø coefficient of 0.648). ACL was another commonly injured soft tissue (37.5%)



Graph 6: Soft-tissue injuries associated with clip injury. Significant correlation was seen between MCL injury and clip injury pattern of bone marrow edema with 88.46% of cases having MCL injury (*P* < 0.001 and ø 0.45). ACL was the second most common structure injured, seen in 61.54% of cases, followed by posterior horn of medial meniscus, seen in 53.84% of cases



Graph 7: Soft-tissue injuries associated with hyperextension injury. In hyperextension injury, ACL and posterior horn of medial meniscus were most common soft-tissues injured, each seen in 50% of cases followed by MCL injury (33.34%). LCL, PCL, and lateral meniscus injury were seen in 16.67% of cases each

usually resolves in 6–8 weeks. In a study in 2007 by Boks *et al*. on the natural course of bone bruises in post-traumatic knees, they concluded that median healing time of bone bruises is 42.1 weeks.[7] In the present study, the patients having < 4 weeks history of trauma were included.

Many studies have been performed on a mechanism-based pattern to approach of knee injury, due to complex nature of the knee joint and multitude of forces acting on it. In their study on biomechanical approach to MR of acute knee injury in 2011, Macmohan *et al*. concluded that MR findings can reveal traumatic mechanism in many acute knee injuries and may predict subtle important but easily missed abnormalities.[8] In a study of clinical and diagnostic significance of bone marrow edema in 2007, Liu *et al*. concluded that MRI can accurately depict bone marrow edema and its adjunctive soft-tissue injuries.[9]

Hayes *et al*. published a mechanism-based pattern approach to classification of complex knee injuries in 2000, in which they proposed 10 patterns of bone marrow edema based

on direction of force and position of knee joint and their pattern specific soft-tissue injuries, which may help in better assessment of thorough extent of knee injury.[10]

In 2000, Sanders *et al.* described five major mechanisms of knee injury, which are – pivot shift injury, dashboard injury, hyperextension injury, clip injury, and lateral patellar dislocation.[3] By studying the distribution of the edema, one can understand the mechanism of injury that occurred and thereby predict with certain accuracy, certain associated soft-tissue injuries that may be present.

In the present study, pivot shift was the most common mechanism of injury and was seen in 55.5% of cases. This is similar to the study by Sahoo *et al.* (2016) on correlation between bone marrow edema and mechanism of injury, in which pivot shift was most common mechanism observed comprising 56.5% of cases.[11]

Pivot Shift Injury

Pivot shift injury is an indirect injury that occurs when a valgus load is applied to the knee in various states of flexion combined with external rotation of the tibia or internal rotation of the femur.[3] This type of injury usually occurs with maneuvers which involve rapid deceleration and simultaneous direction change and hence is commonly seen in sports injuries and two wheeler accidents.[11] These maneuvers cause tensile forces on anterior cruciate ligament (ACL) and can result in its rupture.[12] Once the ACL is disrupted, anterior subluxation of the tibia relative to the femur occurs, which results in impaction of the lateral femoral condyle against lateral tibial plateau. The resulting bone contusion pattern classically involves the posterolateral tibia and the lateral femoral condyle [Figure 1]. Rarely, medial tibial plateau can also be involved.[13] Following biomechanical pattern of injury, ACL is the most common soft-tissue injured. Other soft-tissues injured are menisci and MCL.[3,8-10]

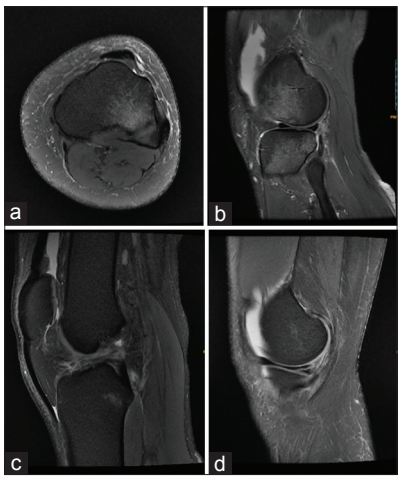


Figure 1: Axial and sagittal PDFS MRI knee images showing (a,b) classical pattern of pivot shift bone marrow edema, involving posterolateral tibia and lateral femoral condyle. (c,d) Complete ACL tear and Grade III tear of posterior horn of medial meniscus in same patient. Mild joint effusion is also present.

In the present study, ACL was the most common soft-tissue injured, which was seen in 96.4% of cases of pivot shift injury, followed by posterior horn of medial meniscus (45.9%) and medial collateral ligament (44.1%). A strong correlation was seen between pivot shift injury and ACL tear ($P < 0.001$, ø 0.634) in our study. Pivot shift injury was also associated with medial meniscus tear ($P < 0.05$).

These results are in keeping with the publication by Sanders *et al.* on bone marrow edema patterns in which they stated that soft-tissues injured in pivot shift include ACL, posterior horn of lateral or medial meniscus, and MCL.[3] A similar publication by Hayes *et al.* on mechanism-based approach to classification of knee injuries also supports these findings.[10] A study by Wei *et al.* on MR diagnosis and clinical significance of bone contusion of knee also showed that the most common soft-tissue injuries associated with pivot shift injury were ACL, medial meniscus, and MCL tears.[9]

Clip Injury

The clip injury is a contact injury which occurs after a pure valgus stress is applied to mildly flexed (<30°) knee.[3,12] It can be sustained during road traffic accidents (e.g., fall from two wheeler) and in sports.[11] The bone marrow edema is usually most prominent in the lateral femoral condyle and lateral tibial plateau as a result of direct blow, whereas a second smaller area of edema may be present in the medial femoral condyle due to tensile stress to the MCL [Figure 2]. Most common associated soft-tissue injury is varying degrees of sprain or disruption of the MCL, mostly near the femoral attachment site.[14] A Grade I sprain of the MCL is visualized on MRI as contour irregularity and edema superficial to the MCL with intact fibers. Grade II injury is a partial tear of the MCL and can be seen on MR images as a partial discontinuity of the fibers with adjacent areas of increased signal intensity on T2-weighted images. Grade III injury is complete disruption of fibers and can be seen as complete discontinuity of the MCL fibers with extensive surrounding high signal intensity on T2-weighted images.[15] Other soft-tissue injuries which can be seen are ACL and medial meniscus tears.[3,9,10]

In the present study, MCL tear was most common soft-tissue injury associated with clip injury and was seen in 88.46% of cases, followed by ACL tear in 61.54% and medial meniscus injury in 53.85% of cases. A strong correlation was seen between clip injury and ACL tear ($P<0.001$, ø 0.45) in our study. These results are in concordance with publications by Sanders *et al.* and Hayes

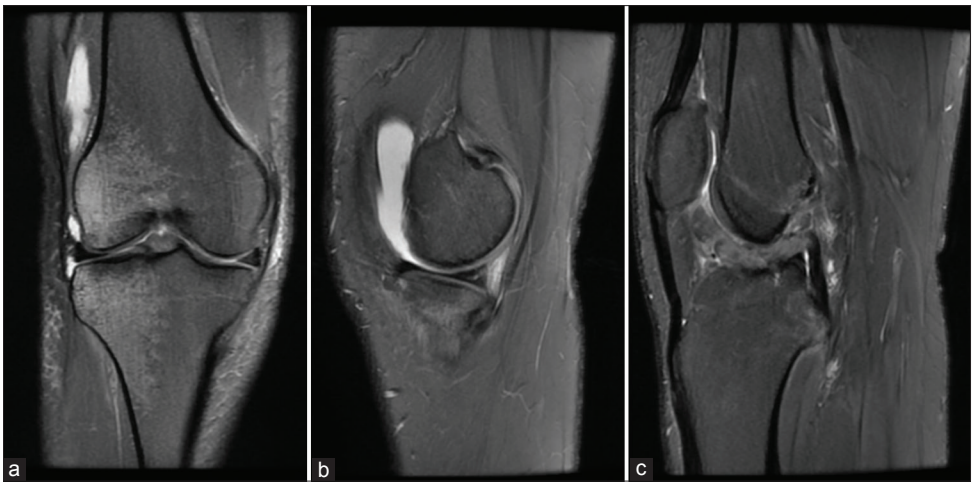


Figure 2: Coronal and sagittal PDFS MR images of knee joint showing (a) clip injury pattern of edema involving lateral femoral condyle and lateral tibial plateau. Grade I sprain of MCL is also seen. (b,c) Grade II tear in posterior horn of medial meniscus and ACL tear in same patient, together forming O'Donoghue's triad. Mild joint effusion is also present.

et al. on bone marrow edema patterns, which state that MCL, medial meniscus (specially posterior horn), and ACL are most common soft-tissues injured in clip injury.[3,10] Liu *et al.* reported MCL tear, ACL tear, and medial meniscus injury as the most common findings in clip injury in their study on clinical and diagnostic significance of bone marrow edema, which concurs with our findings.[9]

Dashboard Injury

Dashboard injury, as the name implies, can be sustained during car accidents where knee is pressed against the dashboard. It can also occur when flexed knee strikes ground during fall.[11] In this type of injury, an anteroposteriorly directed force is applied to a knee in 90° flexion.[12] In this position, PCL is more taut than ACL and hence more prone to injury. Furthermore, PCL is the primary resistance to posterior dislocation of tibia, making it the most commonly injured soft tissue in dashboard injury.[10] It is the only mechanism where PCL is injured more commonly than ACL. Bone marrow edema is classically observed in anterior proximal tibia and rarely on posterior surface of patella [Figure 3].[3]

In the present study, PCL was the most commonly injured soft tissue, seen in 88.23% of cases of dashboard injury. It was far more commonly injured than ACL in dashboard injury (11.76%). A strong correlation was seen between dashboard injury and PCL tear ($P < 0.001$, ø 0.547) in our study. Dashboard injury was also the most common mechanism causing avulsion fracture of PCL in the present study (57.14% of cases).

In publications by Hayes *et al.* and Sanders *et al.* on bone marrow edema patterns, they have stated PCL as the most common soft-tissue injured in dashboard injury, which supports our findings.[3,10] The result of the study by Liu *et al.* showed that PCL was the most commonly injured soft tissue in dashboard injury, which is in agreement with our findings.[9]

Lateral Patellar Dislocation Injury

Patella has a natural tendency to dislocate laterally. It can be further compounded by a shallow trochlear groove and patella alta.[16] Patellar dislocation is usually seen in young adults and athletes.[3] It is non-contact injury caused by twisting of knee. When internal rotation of femur occurs on fixed tibia, quadriceps contraction occurs causing dislocation of patella.[16-18] The classical bone marrow edema is seen on lateral femoral condyle and medial patella [Figure 4]. Distraction forces cause stretching and tear of medial patellofemoral ligament, which is the strongest lateral stabilizer of patella.[16-18]

In the present study, MPFL was the most commonly damaged soft tissue in lateral patellar dislocation, seen in 94.45% of cases. A strong correlation was seen between lateral patellar dislocation and MPFL tear ($P < 0.001$, ø 0.648) in our study. ACL was another commonly injured soft tissue, seen in 37.5% of cases.

In a publication on MR imaging of patellar instability, Diederichs *et al.* stated that MPFL is the most commonly injured soft tissue in lateral patellar dislocation, which supports our findings.[16] Sanders *et al.* have also stated in their publication on pattern of bone marrow edema that medial restraints of knee, especially MPFL is the most frequently injured soft tissues in lateral patellar dislocation.[3]

Hyperextension Injury

Hyperextension injury, as the name suggests, occurs due to hyperextension of knee joint, either directly by an anteriorly directed force on knee with planted foot or indirectly during

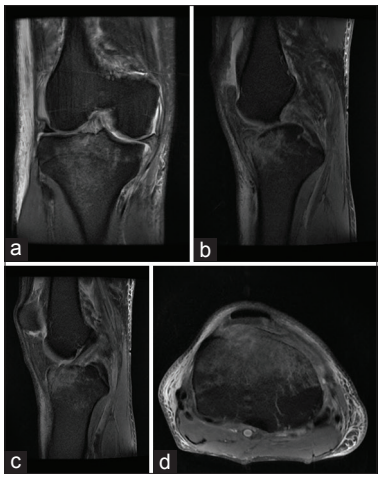


Figure 3: Axial, coronal, and sagittal PDFS MRI knee images showing (a,b,d) classical pattern of bone marrow edema in dashboard injury involving anterior tibia. (b,c) PCL tear is seen, with relatively intact ACL

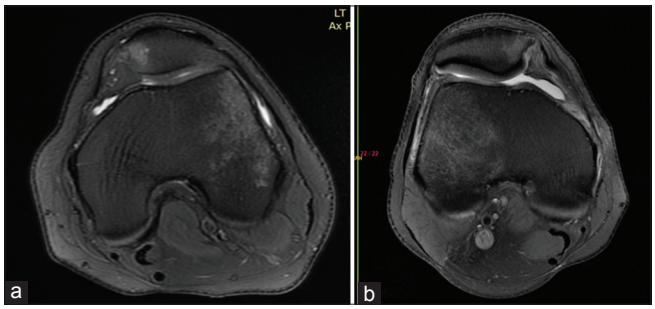


Figure 4: (a) Axial PDFS MR image of knee joint showing classical pattern of bone marrow edema involving medial patella and lateral femoral condyle with wavy medial patellar retinaculum. (b) Axial PDFS MRI knee image of another patient showing bone marrow edema in medial patella and lateral femoral condyle with medial patellar retinaculum and MPFL injury

forceful kicking.[12] The hyperextension of knee results in classical bone marrow edema on anterior tibia and anterior femur, known as "kissing contusions".[3] Rarely, if valgus force is also applied during hyperextension, the kissing contusions can be seen medially [Figure 5]. Associated soft-tissue injuries include tears of cruciate ligaments and menisci. Infrequently, with excessive force, injury to neurovascular bundle and popliteal fossa muscles may also be seen.[3]

In the present study, ACL (50%) and medial meniscus (50%) were most commonly injured structures in hyperextension injury followed by MCL (33.34%) and PCL (16.67%). These results are nearly comparable to the results of study by Liu *et al.,* in which ACL and PCL tears were common injuries in dashboard injury.[9] These findings are also in accordance with publication by Sanders *et al.* on bone marrow edema patterns, in which they have stated that ACL, PCL, and menisci are the most commonly injured soft tissues in hyperextension injury.[3]

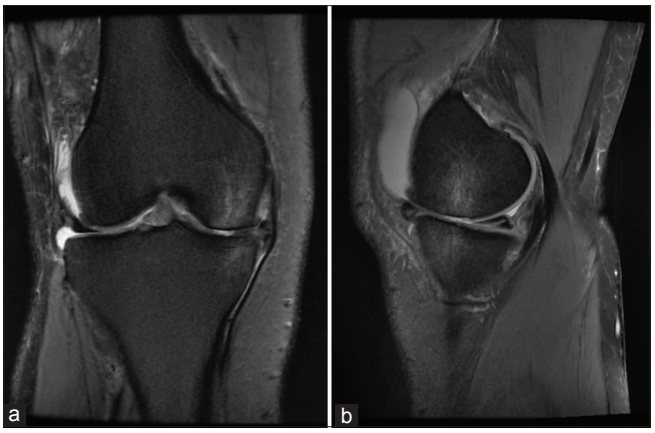


Figure 5: Coronal and sagittal PDFS MRI knee images showing "kissing contusions" on medial femoral condyle and medial tibial plateau in hyperextension injury. Grade II MCL sprain is also seen. (b) Medial meniscus extrusion and Grade II tear of posterior horn of medial meniscus in same patient. Joint effusion is also noted

CONCLUSION

Knee joint is a complex weight-bearing joint and is acted on by a multitude of forces. By studying the patterns of bone marrow edema, one can get an insight on mechanism of injury and predict the associated soft-tissue injuries. This systematic focused analysis can help in achieving a more accurate and rapid interpretation and furthermore create better patient management outcomes.

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Original Article

Clinical Spectrum of Otorhinolaryngological Manifestations in Leprosy: A Retrospective Analysis from Jammu and Kashmir

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Abstract

Introduction: Leprosy is a chronic infectious granulomatous disease caused by *Mycobacterium leprae*, also known as Hansen's disease. The disease affects the peripheral nervous system, skin, and mucous membrane. Dissemination and transmission of *M. leprae* are primarily from nasal mucosa of infected persons.

Materials and Methods: A record-based retrospective observational study was done in the Department of Dermatology and ENT, ASCOMS Hospital, Jammu, Jammu and Kashmir, to know the prevalence of otorhinolaryngological manifestations of leprosy using records of 49 leprosy patients retrieved for 5 years from 2013 to 2018.

Results: Forty-nine patients with 40 (82%) males and 9 (18%) females were included in the study having male–to-female ratio 4.5:1. A majority of the patients (47%) were in the age group of 20–40 years. Forty-seven (96%) patients had a multibacillary type of leprosy, while only 2 (4%) patients had paucibacillary leprosy. Seven (14%) patients showed reaction. Four (8%) showed type I and 3 (6%) showed type II reaction. Nasal manifestations were predominantly encountered among the otorhinolaryngeal manifestations. All the otorhinolaryngeal manifestations were in the multibacillary type of leprosy. The main nasal symptoms with which patients presented were nasal stuffiness (14%), crust formation (8%), and recurrent mild epistaxis (6%). On anterior rhinoscopy, mucosal changes (pale mucosa and edema) and nasal crusting were seen in 7 (14%) patients, atrophic concha was seen in 3 (6%) patients and ulceration of the septal perforation was seen in 2 (4%) patients. Saddle nose deformity was seen in 1 patient. Among the otological manifestations, two patients had erythematous nodules on pinna, while diffuse infiltration of ear lobules was noted in five patients. Labial edema was seen in two patients and nodular lesion on the lip in one patient.

Conclusion: Among the otorhinolaryngological manifestations, nasal involvement was the most commonly seen in leprosy patients. An otolaryngological examination should be routinely done in the diagnosed patients of leprosy.

Key words: Granulomatous disease, Leprosy, Pinnae, Rhinitis, Septal cartilage

INTRODUCTION

Leprosy is an infectious granulomatous disease caused by *Mycobacterium leprae*. It is also known as Hansen's disease. The disease affects the peripheral nervous system, skin, and mucous membrane.[1] It is one of the oldest known diseases and still continues to be a health hazard in many countries, including India.[2] It is mostly prevalent in tropical and subtropical regions.

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An annual new case detection rate of leprosy in India is estimated to be about 9.71/100,000 population.[3] India contributes about 60% of the new cases of leprosy globally as per the data on global leprosy figures.[4] Distribution of the disease in Indian states is not uniform. Jammu and Kashmir is a low endemic region and has controlled the prevalence, but its eradication is still a challenge. As per the NLEP figures, the annual new case detection rate in Jammu and Kashmir for the year 2015–2016 was 1.35.[3]

The disease manifests in its early form as loss of sensations on peripheral extremities such as hands and feet. It may also damage the skin, mucosa of the upper respiratory tract, reticuloendothelial system, and eyes if left untreated.[5] Otorhinolaryngological manifestations are more commonly seen in the lepromatous type of the

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disease. Nasal symptoms include nasal stuffiness, blood-stained discharge, and frank epistaxis. With the progression of the disease, patients may present with persistent nasal crusting, bleeding, atrophic rhinitis, septal perforation, and saddle nose deformity.[6] Pharyngeal globus, neck pain, and oral ulceration are oropharyngeal problems. Otological manifestation includes otitis externa, ear pain, hypoacusis, tinnitus, and vertigo.[7]

The present retrospective study was undertaken to study the clinical spectrum of otorhinolaryngological manifestations in the patients of leprosy presenting to an urban tertiary care hospital in Jammu and Kashmir.

MATERIALS AND METHODS

The present study is a record based retrospective observational study done in the Department of Dermatology and ENT of ASCOMS Hospital, Jammu and Kashmir. Records of all leprosy indoor and outdoor patients were retrieved for 5 years from 2013 to 2018 which included 49 patients reporting to the hospital. Data related to demography, detailed history and thorough clinical examination, smear result, and treatment given were collected for each patient. Patients were diagnosed clinically. The otorhinolaryngological examination included anterior rhinoscopy, otoscopy, oral examination, and indirect laryngoscopy, when indicated. Slit skin smear was performed in each case. Patients were classified as PB and MB according to WHO guidelines. The data collected were statistically computed using SPSS VERSION 17.0. Percentage and proportions were used for qualitative and nominal variables. Quantitative variables were expressed as mean ± standard deviation.

RESULTS

With a total of 49 patients, 40 (82%) were males and 9 (18%) were females [Figure 1]. Male-to-female ratio in the present study was 4.5:1. The mean age of the patients at presentation was 39.6 ± 4.2 years with age ranging from 18 to 72 years. A majority of the patients (47%) were in the age group of 20–40 years followed by the age group of 40–60 years (35%). Five patients (8%) were in the age group of >60 years while 10% of patients were below the age group of 20 years. The spectrum of diagnosis was as follows: 15 patients were classified as borderline lepromatous leprosy, 13 as lepromatous leprosy, 12 as borderline tuberculoid, 2 as histoid leprosy, 4 as pure neuritic, and 3 as borderline leprosy.

For clinical evaluation, the patients were divided into two groups of multibacillary (MB) and paucibacillary (PB). Forty-seven (96%) patients had a multibacillary type of leprosy, while only 2 (4%) patients had paucibacillary leprosy. Forty-two (86%) patients showed no reaction. Among the rest of the patients, 4 (8%) showed type I and 3 (6%) showed a type II reaction. None of the patients in the study had any history of contact with any known patient of leprosy.

All the otorhinolaryngeal manifestations [Tables 1] were in the multibacillary type of leprosy (lepromatous and borderline lepromatous type). Main ENT complaints with which patients presented were nasal stuffiness (7), crust formation (4), and recurrent mild epistaxis (4). On anterior rhinoscopy, mucosal changes (pale mucosa and edema) and nasal crusting were seen in all the seven patients, atrophic concha was seen in three patients, and ulceration of the septal mucosa without destruction of the septal cartilage was seen in two patients. Saddle nose deformity was seen in one patient. Labial edema was seen in two patients, while nodular lesion was seen on the lip in one patient. Nodules on pinna were seen in two patients, while diffuse thickening and infiltration of ear lobule were seen in five patients.

DISCUSSION

Diagnosis of leprosy is teamwork of dermatologists, otolaryngologists, pathologists, and bacteriologists. ENT examination of a suspicious dermal lesion should be routinely included as the nose is the most affected part of the leprosy patients. Once the nasal mucosa is affected, it can easily spread to the upper respiratory tract. Early diagnosis of the mucosal lesion can help in the early detection and treatment of this infectious disease. Suspicious dermal lesion supplemented with mucosal alteration of nose increase the degree of suspicion, thus helping an early diagnosis of leprosy.[7]

This is the first time such a study has been done in Jammu and Kashmir to observe the prevalence of otorhinolaryngological manifestation in leprosy patients.

In our study, the majority of the patients were males (82%). Males are more susceptible to contracting the disease due to more mobility and migration, thus coming in contact of an infected person. Most of the patients were young adults in the age group of 20–40 years (47%). A review of the clinical

Table 1: Prevalence of otorhinolaryngological manifestations in leprosy

Otologic manifestations	Diffuse infiltration of pinna (10%)
	Nodular lesions on earlobe (4%)
Rhinological manifestations	Pale mucosa and edema (14.2%)
	Nasal crusting (14.2%)
	Atrophic concha (6.1%)
	Ulceration of the septal perforation (4.2%)
	Saddle nose deformity (2%).
Oral cavity manifestations	Labial edema (4%)
	Nodular lesion on lips (2%)

spectrum of the disease showed that maximum patients, that is, 29 (59%) were in the borderline group (BB+BT+BL). This observation is comparable to the studies done by Thakker and Patel,[8] Sharma and Sharma,[9] and Moorthy *et al.*[10] In our study, 96% of the patients were in the multibacillary (MB) group, while only 4% were in paucibacillary (PB) group.

In our study, 8% of cases showed type 1 reaction and 4% showed type 2 reaction. Thaker and Patel[8] reported lepra reaction in 9.6% of the cases, of which 3.2% showed type 1 reaction and 6.4% showed type 2 reaction. Another study by Kalla and Salodkar[11] reported a lepra reaction in 11.1% of cases.

The earliest nasal mucosa changes are edema, submucosal granulomatous infiltration, and hypersecretion. On anterior rhinoscopy, nodular infiltration with crust formation and blood-=stained discharge is seen. The disease advances to ulceration of the nodules, scar formation, and septal perforation. The classical triad of saddle nose, septal perforation, and atrophic rhinitis is usually seen in the advanced disease.[12,13]

In our study, the main ENT symptoms with which patients presented were nasal, including nasal stuffiness, nasal discharge, and bleeding. None of the patients had any otological or laryngeal symptoms. One study reported nasal obstruction, crust formation, and recurrent epistaxis as common findings in their study.[7] In the present study, anterior rhinoscopy, mucosal changes (pale mucosa and edema), and nasal crusting were seen in all the 7 (14.2%) patients, atrophic concha was seen in 3 (6.1%) patients, and ulceration of the septal perforation was seen in 2 (4.2%) patients. Saddle nose deformity was seen in 1 (2%) patient. Silva *et al.*, in a study of 80 patients, reported septal perforation in ten patients, atrophy of nasal concha in 18 patients, and saddle nose deformity in three patients. Saddle nose deformity was reported most commonly associated to the leprosy by a study done by Farina in 1991.[14]

Other areas of upper respiratory tract are seldom involved nowadays due to early detection and availability of multidrug therapy. In our study, labial edema was seen in two patients, a nodular lesion on the lip in one patient , nodules on pinna in two patients, and infiltration of ear lobules in five patients. Therefore, although most patients present to the dermatologists, clinical alteration of upper respiratory tract supplements in making the diagnosis. Otolrhinoryngologist should be well aware of the specific clinical features associated with leprosy so that appropriate precautions (wearing gloves and masks) are taken while examining these patients.

CONCLUSION

Leprosy is a worldwide public health problem. Usually, the skin and peripheral nervous system are affected, but mucosal involvement is also seen with the progression of the disease. Nasal involvement is the most commonly seen ENT manifestation in the patients of leprosy. Nasal epithelium of untreated multibacillary leprosy patients contribute to the shedding of *M. leprae* into the environment and contacts of untreated MB cases are at risk for contact with *M. leprae*. An otolaryngological examination must be routinely done in all the diagnosed leprosy patients to identify the otolaryngological morbidities and prevent the sequelae. A high index of suspicion and needful investigation is required as a leprosy patient may first present to the otolaryngologist with complaints such as recurrent epistaxis.

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Original Article

Validity of Pneumonia Severity Score in Predicting Mortality of Pediatric Patients in a Tertiary Care Hospital

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Abstract

Background: Pneumonia is estimated to kill 410,000 children in India every year. In India, recent estimates in under-fives suggest that 13% of deaths and 24% of the National Burden of Disease is due to pneumonia. Very few studies have evaluated the predictors of mortality in children with pneumonia in developing countries. Hence, this study was planned to study predictors of mortality in children aged 1–59 months based on pneumonia severity score (PSS) in hospitalized patients with severe pneumonia.

Objective: The objective of this study is to assess the factors (clinical and investigational) contributing to the mortality in patients based on PSS in hospitalized patients diagnosed with severe pneumonia.

Materials and Methods: The present observational longitudinal study was carried out in a tertiary care PICU in a Govt. NSCB Medical College, Jabalpur for of 1 years (Ian 2019–December 2019). Children diagnosed as severe pneumonia of either sex between age group 1–59 months admitted in a hospital were enrolled in the study. Demographic data, clinical details, and laboratory parameters of the enrolled cases were recorded in a predesigned pretested pro forma. PSS was calculated and correlated with the outcome of the patients enrolled and followed up till discharge or death.

Results: Mortality was observed in 11 cases, and of them, 4 (36.4%) were males and 7 (63.6%) patients were females. This study showed that among clinical parameters pulse rate and SpO_2 were significantly raised (63.6%) and saturation was significantly <90 (72.7%) in children who succumbed to death ($P < 0.05$). This study observed a statistically highly significant association of PSS with the outcome of children ($P < 0.01$).

Key words: Modified PSI, Outcome, PICU, Pneumonia

INTRODUCTION

Pneumonia is estimated to kill 410,000 children in India every year. In India, recent estimates in under-fives suggest that 13% of deaths and 24% of the National Burden of Disease is due to pneumonia.[1] To reduce mortality, the World Health Organization (WHO) initiated the acute respiratory infection control program in 1983 which led to a decline in the infant mortality rate and under-fives mortality.[2] Case fatality rates in hospitalized children are reported to be between 8.7 and 47%.[2-4]

Although predictors of mortality were studied in developed countries, it cannot be used in developing countries due to differences in etiology and treatment resources available. Very few studies have evaluated the predictors of mortality in children with pneumonia in developing countries.[5-7] More studies are required to analyze the factors predicting mortality in hospitalized children.

There is a need for standardized pneumonia mortality predictive score easy to calculate and should be based on basic bedside parameters; therefore, this study was planned to study predictors of mortality based on pneumonia mortality predictive score (PMPS)in children aged 1–59 months hospitalized with severe pneumonia.

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OBJECTIVE

The objective of this study is to study the predictors of mortality based on pneumonia mortality predictive score (PMPS) in children aged 1–59 months hospitalized with severe pneumonia.

MATERIALS AND METHODS

The present observational longitudinal study was carried out in a tertiary care NICU un a Govt. NSCB Medical College, Jabalpur. The duration of the study was 1 year (Ian 2019 December 2019). Ethical clearance was sought for from the Institutional Ethical Committee before the start of the study. Children who were diagnosed as severe pneumonia 2 of either sex between age group 1 and 59 months admitted in a hospital were enrolled in the study.

For diagnosing the child as tachypneic or rapid respiration, the WHO guidelines followed, that is, for age <2 months is respiratory rate >60/min; age 2–12 months is respiratory rate >50/min, and age >1 year is respiratory rate >40/min. Children diagnosed and were followed up for outcome measurement until their discharge from the hospital or death.

A total of 75 children were enrolled and as per the WHO case definition was diagnosed as severe pneumonia. Demographic data, clinical details, and laboratory parameters of the enrolled cases were recorded in a predesigned pretested pro forma. Variables studied are age, sex, urban slum, any comorbidities present in the form of CNS, CVS, liver, kidney disease, and neoplasm were noted. At admission, altered mental status, pulse rate, temperature, SBP for sex and age, and SpO_2 were noted. The following investigations were noted ABGA pH, PaO_2, and hypoglycemia at admission (random blood sugar level <50 mg/dl), serum sodium, hematocrit, and chest X-ray. A score was calculated based on the following parameters:

1. Comorbities < 2 = 0, ≥ 2 =1.
2. Altered mental status yes = 1, No = 0,
3. SBP abnormal for age and sex = 1, normal = 0,
4. Temperature >100 F = 1,< 100 = 0,
5. PaO_2 < 60 = 1, > 60 = 0,
6. Pulse rate abnormal for age and sex = 1, normal = 0,
7. PaO_2 < 60 = 1, > 60 = 0,
8. ABG ph < 7.3 = 1, > 7.3 = 0,
9. SpO_2 < 90% = 1, > 90% = 0

Based on the above finding, patients were categorized into three groups mild (score <3), moderate (score between 3 and 6), and severe (Score >6). They were treated with appropriate therapy and the outcome recorded was discharge or death. Statistical analysis was conducted using STATA version 10.0. Categorical variables were compared between deaths and discharges by performing the Chi-square test. All tests were two-sided and $P < 0.05$ is considered significant.

RESULTS

Table 1 shows that total of 75 children aged 1–59 months were enrolled. Mortality was observed in 11 cases and of them, 4 (36.4%) were males and 7 (63.6%) patients were females However, the test of significance (Chi-square test) showed no significant association between outcome and gender ($P = 0.89$).

In the present study, <2 comorbidities were observed in 82.7% cases, whereas 17.3% cases had >2 comorbidities. The present study documented no statistically significant association between comorbidities and outcome ($P > 0.05$). Similarly, 12% cases presented with altered mental status; however, no statistically significant association between outcome and altered mental status was observed ($P > 0.05$), pulse rate was significantly raised (63.6%), whereas saturation was significantly <90 (72.7%) in children who succumbed to death ($P < 0.05$). However, no such association of outcome was observed for SBP and temperature ($P > 0.05$).

PaO_2 was < 60 in 100% cases in whom mortality was observed. Similarly, glucose levels were <50 in 36.4% cases. The present study observed statistically highly significant association of outcome with PaO_2 and glucose ($P < 0.01$).

Mild, moderate, and severe pneumonia severity score (PSS) were documented in 82.7%, 14.6%, and 2.7% cases, respectively. The present study documented a statistically highly significant association between PSS and outcome, that is, mortality was higher in cases with moderate and severe PSSs ($P<0.01$) [Tables 2-4].

DISCUSSION

Decreasing pneumonia deaths will significantly contribute to achieving the Millennium Development Goal of reducing under 5-year of mortality. This study was conducted to identify the clinical and laboratory variables

Table 1: Distribution according to outcome

Outcome	Frequency (*n*=75)	Percentage
Discharge	64	85.3
Death	11	14.7

Table 2: Association of clinical features with outcome

Clinical features		Discharge	Death	Total	*P* value
Co morbidities	<2	55 (85.9)	7 (63.6)	62 (82.7)	0.07
	>2	9 (14.1)	4 (36.4)	13 (17.3)	
Altered mental status	Present	8 (12.5)	1 (9.1)	9 (12)	0.75
	Absent	56 (87.5)	10 (90.9)	66 (88)	
SBP for age and sex	Normal	63 (98.4)	10 (90.9)	73 (97.3)	0.15
	Abnormal	1 (1.6)	1 (9.1)	2 (2.7)	
Temperature	<100 F	32 (50)	3 (27.3)	35 (46.7)	0.16
	>100 F	32 (50)	8 (72.7)	40 (53.3)	
Pulse rate	Normal	47 (73.4)	4 (36.4)	51 (68)	0.015
	Raised	17 (26.6)	7 (63.6)	24 (32)	
SpO_2	<90	2 (3.1)	8 (72.7)	10 (13.3)	0.001
	>90	62 (96.9)	3 (27.3)	65 (86.7)	

Table 3: Association between investigation findings and outcome

Investigations		Discharge	Death	Total	*P* value
PaO_2	>60	64 (100)	0 (0)	64 (85.3)	0.001
	<60	0 (0)	11 (100)	11 (14.7)	
ABG pH	<7.3	8 (12.5)	2 (18.2)	10 (13.3)	0.61
	>7.3	56 (87.5)	9 (81.8)	65 (86.7)	
Glucose	<50 mg%	2 (3.1)	4 (36.4)	6 (8.)	0.001
	>50 mg%	62 (96.9)	7 (63.6)	69 (92)	

Table 4: Association between pneumonia severity score and outcome

Pneumonia severity score	Discharge	Death	Total
Mild (<3)	61 (95.3)	1 (9.1)	62 (82.7)
Moderate (3–5)	3 (4.7)	8 (72.7)	11 (14.6)
Severe (≥6)	0 (0)	2 (18.2)	2 (2.7)

P=0.001

associated with deaths in hospitalized children aged 1–59 months with a diagnosis of severe pneumonia.

In the present study, about 33.3% of children had CNS disease, 12% of children presented with altered mental status, liver disease, and CHD was observed in 13.3% cases each. Renal disease and neoplasm was present in 2.7% and 1.3% cases, respectively. However, the present study documented no statistically significant association between outcome and comorbidities ($P > 0.05$).

Our study found that the pulse rate was significantly raised (63.6%), whereas saturation was significantly <90 (72.7%) in children who succumbed to death ($P < 0.05$). However, no such association of outcome was observed for SBP ($P > 0.05$).

PaO_2 was < 60 in 100% cases in whom mortality was observed. The present study observed a statistically highly significant association of outcome with PaO_2, SpO_2, and glucose ($P < 0.01$).

We found overall CFR of 14% compared to 3.9% for all-cause mortality in this age group. CFR of childhood pneumonia in various Indian studies ranges from 8.9% to 47%[3-6] and 3.4% to 12% in other developing countries.[8-10] This can be due to differences in etiology, immunization and treatment resources available.

Mild, moderate, and severe PSS were documented in 82.7%, 14.6%, and 2.7% cases, respectively. The present study documented a statistically highly significant association between modified PSI score and outcome, that is, mortality was higher in cases with moderate and severe PSI scores ($P < 0.01$).

The limitation of the study was that we could not find out the etiology of pneumonia. The study may have referral bias since many enrolled cases were referred from peripheral centers and findings cannot be generalized. The strength of the study was the study period of 1 year preventing the effect of an epidemic outbreak. There is a need to carry out extensive multi-centric studies involving both rural and urban areas to identify the severity of pneumonia based on this simple useful and easy to carry out PSS.

CONCLUSIONS

Mortality was observed in 11 cases, and of them, 4 (36.4%) were males and 7 (63.6%) patients were females. However, test of significance (Chi-square test) showed no significant association between outcome and gender ($P = 0.89$). Pulse rate was significantly raised (63.6%), whereas saturation was significantly <90 (72.7%) in children who succumbed to death ($P < 0.05$). The present study observed a statistically highly significant association of outcome with PaO_2 and glucose ($P < 0.01$).

Mild, moderate, and severe PSS were documented in 82.7%, 14.6%, and 2.7% cases. respectively. The present study documented a statistically highly significant association

between PSS and outcome, that is, mortality was higher in cases with moderate and severe PSI scores ($P < 0.01$).

Recommendation

PSS is a good predictor of mortality in children with severe pneumonia under low-cost settings.

PSS can help to select sick children for PICU admission and optimal utilization of limited PICU resources.

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Original Article

Functional Outcome of Unstable Distal Radius Fracture with Dorsally Displaced Radial Rim Treated with Volar Variable Angle Locking Compression Plate

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Abstract

Introduction: Distal radius is one of the common fracture sites of the human skeleton. Dorsally displaced distal radius fractures (DRFs) are the most common type of DRF.

Materials and Methods: Two matched cohorts of 20 matched patients, one with a displaced dorsal rim fracture >2 mm (Group 1), and the other without a dorsal rim fracture (Group 2) were analyzed in this study with volar variable angle locking compression plate fixation for dorsally unstable DRFs.

Results: No significant difference was found between the two groups in overall wrist function or wrist pain. The mean displacement of dorsal rims in Group 1 was 3.0 mm and the mean diameter of the retained articular portion of the dorsal articular wall was 2.0 mm. No significant difference was found between the two groups in terms of any radiographic parameters or the arthritic grading of radiocarpal joints.

Conclusion: These results suggest that a displaced dorsal rim fracture does not adversely affect the outcomes after the volar variable angle locking compression plate fixation of a dorsally displaced DRF, indicating that an additional dorsal approach is unnecessary for reducing a displaced dorsal rim fracture.

Key words: Displaced dorsal rim fracture, Distal radius fracture, Volar plate fixation

INTRODUCTION

The distal radius is the most common fracture site of the human skeleton, and dorsally displaced distal radius fractures (DRFs) are the most common type of DRF. This is because a fall with an outstretched hand is the usual injury mechanism and the dorsal cortex at the distal end of the radius is weaker than the volar cortex.[1-3] The traditional surgical rationale is that a dorsal approach should be used to treat dorsally displaced fractures and that a volar approach is best for volarly displaced fractures.[4-7]

Due to the recent introduction of the volar variable angle locking compression plate, dorsally displaced DRFs have been reported to be successfully managed using a volar approach.[8-10] However, when this approach is used for dorsally displaced DRFs, a displaced dorsal rim fracture, which sometimes contains a portion of the posterior articular surface of the distal radius, is often observed.[11,12]

Aim

The aim of the study was to evaluate whether an unreduced dorsal rim fracture affects outcomes after volar variable angle locking compression plate fixation of a dorsally displaced DRF.

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MATERIALS AND METHODS

This study was conducted on 200 consecutive patients who were treated by open reduction and internal fixation with a volar locking plate for dorsally displaced DRFs. The indication for open reduction and volar locking plate fixation after initial closed reduction were dorsal angulation of >108°, an articular gap or step off of >2 mm, a radial inclination of <108°, or radial shortening of >5 mm.

Inclusion Criteria

The following criteria were included in the study:

- A dorsally displaced intra-articular fracture amenable for open reduction and volar locking plate fixation within 2 weeks, after injury
- Physiologically active adults above 18 years of age.

Exclusion Criteria

The following criteria were excluded from the study:

- Pre-existing severe medical illness
- An ipsilateral upper-extremity fracture, dorsal Barton fracture with dorsal radiocarpal subluxation of 15° and a residual articular incongruity of the distal radius >2 mm after surgery.

Of 200 patients, only 120 patients met our criteria. The surgical procedures for DRFs were performed by the same surgeon. In all subjects, DRFs were reduced using a volar approach and fixed with a 3.5 mm volar variable angle locking compression plate fixation. Postoperatively, a short-arm splint was applied for 4 weeks, and subsequently, wrist motion was allowed with intermittent short-arm brace protection for another 2 weeks. Of the 120 patients, 96 (85%) patients completed 12 months of follow-up.

A case–control study design was used. Two groups of 20 patients were selected from the 79 patients with at least 12 months of follow-up: 20 with a displaced dorsal rim fracture >2 mm (Group 1) and 20 without a dorsal rim fracture (Group 2). These two groups were individually matched for (1) sex and (2) age and (3) fracture type according to the orthopedic trauma association fracture classification.

Clinical Evaluation

Patients were assessed for 3 months and final follow-up was done (mean 22 months, range 12–30 months). A physiotherapist, who was unaware of radiographic results and independent of the treating surgeon, examined all patients.

Radiographic Evaluation

Plain posteroanterior and lateral radiographs of injured wrists were obtained immediate postoperatively and at final follow-up visits. The amount of displacement of the dorsal rim fragment in Group 1 was measured using a millimeter ruler on lateral radiographs taken immediately postoperatively [Figure 1]. A computed tomography (CT) scan was performed preoperatively to determine the dimensions of the articular portion of the dorsal rim. The dimensions of articular portions of dorsal rims in Group 1 were measured using a millimeter ruler on sagittal views.

Radial inclination, volar tilt, and ulnar variance were measured on final follow-up radiographs, and arthritic changes of radiocarpal joints were graded using final follow-up radiographs, as previously described.

Statistical Analysis

The Mann–Whitney U-test was used to evaluate the significant differences between wrist functions, wrist pain, and radiographic parameters in the two groups, and the Fisher's exact test was used to evaluate significant inter-group differences in terms of wrist pain and arthritic grade. All analyses were performed using Statistical Package for the Social Sciences (SPSS1) ver. 14.0 software package (SPSS Inc., Chicago, IL, USA). Statistical significance was accepted for $P < 0.05$.

RESULTS

Clinical Outcomes

No significant difference was observed between Groups 1 and 2 in overall wrist functional outcomes (flexion, extension, supination, pronation, grip strength, MMWS, or DASH) at 3 months or final follow-up. Wrist pain at rest and with daily activity was not significantly different.

Radiographic Outcomes

Mean displacement of the dorsal rim in Group 1 was 3.0 mm (range, 2.0–4.5). CT showed that the dorsal

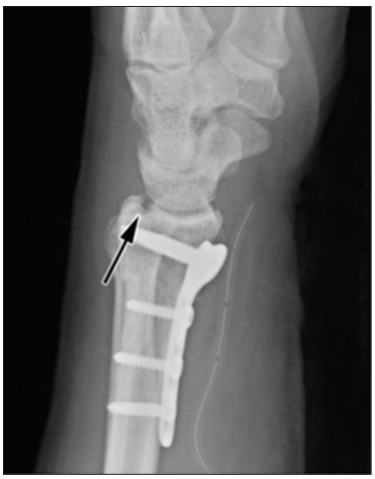

Figure 1: Lateral view plain radiograph showing a fractured dorsal rim fragment still displaced by 2.8 mm (arrow) after volar plate fixation

rim was composed of cortical bone with the small size of the articular surface and that the mean width of the retained articular portion of the fractured dorsal rim wall was 2.0 mm (range, 1.0–3.5) [Figure 2]. Inter-observer reliability for mean dorsal rim displacement was 0.66 (95% CI, 0.53–0.82; $P = 0.01$) and for mean width of the retained articular portion of dorsal rim was 0.64 (95% CI, 0.46–0.77; $P = 0.015$).

No significant inter-group difference was found for any radiographic parameter assessed.

Two patients in each group showed a Grade 1 arthritis change at the final follow-up, which was statistically insignificant. The inter-observer reliability for arthritic grading of the radiocarpal joint was 0.89 (95% CI, 0.80–0.97, $P < 0.001$).

DISCUSSION

In the present study, dorsally unstable DRF treated with volar variable angle locking compression plate fixation, there were no differences between the outcomes of patients with and without a displaced dorsal rim fracture. In addition, the CT scans showed that the dorsal rim fragments were composed mainly of cortical bone with a small size of retained articular portion of <3.5 mm (mean 2.0 mm).[13,14]

Since Knirk and Jupiter in 1986 concluded that accurate articular restoration is the most critical factor in a successful long-term result of intra-articular DRF, restoration of the articular surface has been arguably one of the most important areas for the management of intra-articular DRF. In addition, the deterioration of outcomes with the loss of reduction of the volar lunate facet fragment in an intra-articular DRF is well documented. However, the intra-articular fragments can be divided into some specific fragments, and there are no reports on the effect of a displaced dorsal rim fracture.

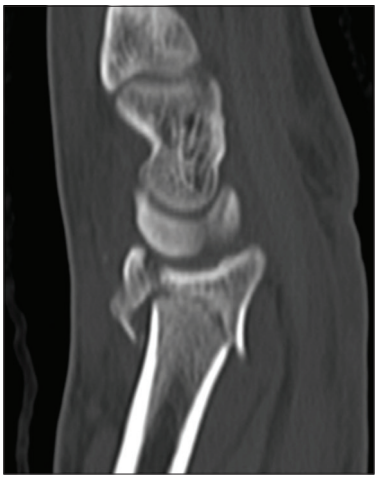

Figure 2: Pre-operative computed tomography scan (sagittal view) showing a fractured dorsal rim with small retained dorsal articular surface

Nevertheless, many articles generally concluded that dorsally displaced DRFs can be well managed through volar plate fixation alone, even though they did not consider the effect of a displaced dorsal rim fracture. The data in the present study indicating that a displaced dorsal rim fracture does not adversely affect the outcomes after volar variable angle locking compression plate fixation of a dorsally displaced DRF practically supports the results of those articles.

Patients with fractures of the dorsal articular margin of the DRF with dorsal radiocarpal subluxation (dorsal Barton fracture) were excluded from the study. These fractures are radiocarpal-fracture-dislocations rather than dorsally displaced DRFs. In general, it is very difficult to reduce the radiocarpal joint without dorsal exposure and fixation in these dorsal shearing fractures. In addition, volar-radiocarpal-ligament rupture or a volar-rim-avulsion fracture containing volar radiocarpal ligament is essential for dorsal subluxation of the radiocarpal joint. Therefore, the incidence of dorsal Barton fractures is quite low (0.5–1.6% of all DRFs). Dorsally displaced DRFs, which are the most common type of DRFs, occur by hyperextension force rather than shearing force. Radiocarpal subluxation does not occur in this type of injury because the volar radiocarpal ligament attaches to the large volar metaphyseal fragment and the carpus and the fractured distal part of the radius act as a single unit.

The strengths of this study are the well-controlled patients and control group, and the prospective collection of the functional and radiographic data. We also performed pre-operative CT scans in all recruited patients because all subjects in this study had an intra-articular DRF. Several studies reported that pre-operative CT scans influence the observer's management plans and result in increased inter-observer reliability in the proposed management of intra-articular DRFs. However, this study has several limitations that warrant consideration. First, plain radiography was used to determine the dorsal rim displacements after surgery. Substantial evidence indicates that the articular surface of the distal radius is better assessed by CT. Therefore, a future study will be needed to access the dorsal rim displacement with CT.

Although the above-mentioned specialized view might be superior to a view of the entire articular surface, there was no difficulty in measuring the dorsal rim displacement

on standard, lateral, and wrist radiographs because the dorsal rim was located at sites opposite to the volar plates or screws and the hardware did not interfere with the measurements of the dorsal rim displacement. Therefore, good inter-observer reliability was achieved for these parameters.[15-20]

CONCLUSION

A displaced dorsal rim fracture does not appear to affect the outcomes of volar variable angle locking compression plate fixation of dorsally displaced DRFs. This gives a clear idea that an additional dorsal approach is unnecessary for reducing a displaced dorsal rim fracture.

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Original Article

An Antimicrobial Activity Assessment of Three Endodontic Sealers on *Enterococcus faecalis*, *Candida albicans*, and Staphylococcus aureus by a Direct Contact Test: An *In Vitro* Study

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Abstract

Introduction: For a successful endodontic treatment, antimicrobial property of endodontic filing is mandatory. Hence, the aim of this *in vitro* study was to assess the antibacterial efficacy of three endodontic sealers on *Enterococcus faecalis*, *Candida albicans*, and *Staphylococcus aureus* by direct contact test (DCT).

Materials and Methods: The antimicrobial efficacy of three different sealers, AH Plus, mineral trioxide aggregate (MTA) Fillapex, and Endosequence BC was tested against *E. faecalis* ATCC 29212, *C. albicans* ATCC 10231 and *S. aureus* ATCC 25923 by DCT. Freshly mixed sealers were placed in flat bottom test tubes incubated at 37°C. Thereafter, 10 μL of suspension was drawn and spread over cultural plates to determine the colony count using a digital colony counter. Readings were taken at 1 h (fresh specimen), then at 24 h (after setting). The results were tabulated and statistical analysis was done using one way ANOVA and Tukey HSD test.

Results: DCT showed a significant decrease in microbial count in AH Plus, MTA Fillapex, and Endoseq BC at both the time intervals. Group 3 (Endosequence BC) showed minimum microbial count followed by Group 2 (MTA Fillapex) and maximum for Group 1 (AH Plus) for both the time intervals (1 h and 24 h).

Conclusion: Endosequence BC showed maximum antimicrobial efficacy against all the tested microorganisms for both the time intervals, followed by MTA Fillapex and AH Plus.

Key words: *Candida albicans*, Direct contact test, Endodontic sealers, *Enterococcus faecalis*, *Staphylococcus aureus*

INTRODUCTION

The exclusion of microorganisms from root canal is the priority of endodontic treatment. This is implemented by biomechanical preparation, irrigation with irrigants, and satisfactory filling of the three dimensional root canal.[1] The failure in the treatment is dominated by facultative and resistant microbial species. The persistent periradicular lesions after root canal treatment are because of the presence of *Enterococcus faecalis*.[2] Enterococci have the ability to grow in an environment of low-nutrient which can also survive as mono-infection. According to Sundqvist *et al*., 38% of failed root canal systems were commonly associated with *E. faecalis*. *Candida albicans*, dentinophilic microorganism, is associated with failed treatment.[3] The refractory periapical disease is associated with the biofilm of *Staphylococcus aureus* on tissues. Hence, these organisms were used as our study parameter. The application of sealers with antibacterial properties has further lowered the remaining microorganisms. One of the most commonly epoxy resin-based sealer is AH Plus (Dentsply International Inc., York, PA), which is eugenol-free, biocompatible, and radio-opaque. The Paste A of AH Plus has bisphenol-A

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epoxy resins majorly. It also contains zirconium oxide, silica, iron oxide pigments, and calcium tungstate. Paste B contains tricyclodecane-diamine, dibenzyldiamine, aminoadamantane, calcium tungstate, silica, zirconium oxide, and silicone oil.[4] Mineral trioxide aggregate (MTA) has been used as a sealer after modifications. MTA Fillapex has good biocompatibility and capacity in the formation of mineralized tissues. MTA Fillapex can also be used as perforation repair material in the root canal. It is also used as a retrograde filling material and used in cases of apexification.[5,6] In current times, bioceramic sealer is used for root repair material and also as a sealer because of its biocompatibility, alkaline pH (<12). It has other advantages like easily introducible in canal, non-shrinkable, and non-resorbable. The studies have shown bioceramic sealer to strengthen the root canal following obturation. One of the newer bioceramic endodontic sealers is Endosequence BC Sealer (Brasseler, Savannah, GA, USA), which majorly comprises of zirconium oxide and calcium phosphate. It also consists of calcium silicates and calcium hydroxide.[7,8] Agar diffusion test (ADT), a semi-quantitative technique, is the most frequent method used to study the *in vitro* antimicrobial activities. ADT cannot differentiate between bacteriostatic and bactericidal effects of materials. The outcome is influenced by the diffusibility and solubility of the biomaterials through the agar. Hence, it is not used for water-insoluble materials.[9] Therefore, the methodology adopted was direct contact test (DCT). DCT by Weiss *et al.* measures the effect between the tested microorganism and the material when they are in contact, on the basis of microbial viability. It measures the antimicrobial property of the biomaterial irrespective of the solubility and diffusibility of the tested materials. DCT is a quantitative test and reproducible assay which can also be used to study the insoluble biomaterials and can be used for standardized settings.[10] Therefore, the aim of this study was to compare the *in vitro* antimicrobial efficacy of three endodontic sealers against *E. faecalis*, *C. albicans*, and *S. aureus* using DCT. The null hypothesis tested was that there were no differences in the antimicrobial efficacy of Endosequence BC Sealer, MTA Fillapex, and AH Plus against *E. faecalis, S. aureus*, and *C. albicans*.

MATERIALS AND METHODS

Grouping of Sample

This study was divided into three groups based on the following sealers.

1 = AH Plus, 2 = MTA Fillapex and 3 = Endosequence BC.

Depending on the microorganisms to be tested, these three groups were further subdivided into three groups of 18 each:

Sub Group A: *E. faecalis* (n = 18), sub Group B: *C. albicans* (n = 18), and sub Group C: *S. aureus* (n = 18).

Nine samples from each subgroup were analyzed at 1 h and the remaining nine samples were analyzed after 24 h. For this study, bacterial growth was measured by a microplate spectrophotometer. For DCT, 50 mg of sealer was mixed and settled in nine flat bottom tubes. The tubes for each sealer were prepared in triplicate. Following which 50 μL of 0.5 ml McFarland standard suspension (1.5×10^8 CFU/ml) of microorganisms was spread over the sealers. McFarland standards were used as a reference to evaluate the number of bacteria within a given range to standardize the microbial testing. It is based on the turbidity of bacterial suspensions. The samples were then incubated at 37°C to ensure the direct contact between bacteria and test sealers. The suspension of microorganisms and test sealers was in direct contact for 1 h and 24 h. The test tubes were incubated at 37°C, following which the test tubes were inspected for evaporation of suspension.

Ethics

Ethical clearance was taken from the I.T.S Institutional Ethics Committee (IIEC).

Statistics

The data were analyzed using SPSS 16.0. The intergroup comparison for normal data was tested by one-way ANOVA and Tukey HSD test. The intragroup comparison was tested by paired *t*-test (parametric test). The level of significance and confidence interval was 5% and 95 %, respectively.

RESULTS

The DCT showed a significant difference in microbial count among the groups (ANOVA $P = 0.0001$) at 1 h and 24 h. In paired *t*-test, Group 3 (Endosequence BC) showed a minimum microbial count of *E. faecalis* with a mean difference of 8.980, *C. albicans* with a mean difference of 7.889, and *S. aureus* with a mean difference of 6.540 for both time intervals, that is, 1 h and 24 h and it was significant [Table 1]. Group 2 (MTA Fillapex) showed the second-highest microbial count with a mean difference of 6.322 for *E. faecalis*, 7.222 for *C. albicans,* and 5.444 for *S. aureus*, for both the time intervals [Table 2]. In this study, Group 3 showed the highest microbial count of *E. faecalis* with a mean difference of 5.444 for *E. faecalis*, and 5.114 for *S. aureus* for both the time intervals, that is, 1 h and 24 h and it was significant [Table 3].

DISCUSSION

The predominant cause of failure of endodontic treatment is because of resistant microorganisms such as *E. faecalis*,

Table 1: Comparison of means of microbial count between two intervals in Endosequence BC by paired t-test

Parameter/Variable	Mean	Std. deviation	Std. error mean	95% confidence interval of the difference		*t*-test value	*P*-value
				Lower	Upper		
Enterococcus faecalis 1–24 h	8.980	2.345	0.782	7.803	4.197	7.675	<0.001**
Candida albicans 1–24 h	7.889	2.977	0.992	11.177	6.601	8.958	<0.001**
Staphylococcus aureus 1 h–24 h	6.540	2.345	0.782	7.803	4.197	7.675	<0.001**

*: Significant, **: Highly significant

Table 2: Comparison of means of microbial count between two intervals in mineral trioxide aggregate Fillapex by paired t-test

Parameter/Variable	Mean	Std. deviation	Std. Error mean	95% confidence interval of the difference		*t*-test value	*P*-value
				Lower	Upper		
Enterococcus faecalis 1–24 h	6.322	3.279	1.093	5.854	6.813	5.050	0.016*
Candida albicans 1–24 h	7.222	2.949	0.983	7.489	4.956	6.348	<0.001**
Staphylococcus aureus 1 h–24 h	5.444	3.167	1.056	5.179	1.010	5.263	0.011*

*: Significant, **: Highly significant

Table 3: Comparison of means of microbial count between two intervals in AH Plus by paired t-test

Parameter/Variable	Mean	Std. deviation	Std. error mean	95% confidence interval of the difference		*t*-test value	*P*-value
				Lower	Upper		
Enterococcus faecalis 1–24 h	5.444	5.503	1.834	3.674	5.215	□5.149	0.001**
Staphylococcus aureus 1 h–24 h	5.114	5.503	1.834	3.674	5.215	□5.149	0.001**

*: Significant, **: Highly significant

C. albicans, and *S. aureus*.[11] Bioceramic (Endosequence BC) sealers are known for its antimicrobial property during the setting and exhibit no shrinkage. The hydrophilic nature helps to form hydroxyapatite om setting and chemically bonds to dentin and gutta percha points.[12] MTA-based sealers (MTA Fillapex, Angelus, Brazil) are known for its properties such as remarkable biocompatibility, stimulating mineralization, and exhibiting higher push-out strengths than zinc oxide eugenol cements.[13] MTA consists of calcium oxide which has a similar mode of action to calcium hydroxide.[14] Epoxy resin-based sealers (AH Plus) have good antimicrobial, physical, and chemical properties.[15] Hence, these sealers are diminishes the survival of microorganisms during obturation. The result of the present study showed significant microbial count reduction with Endosequence BC than MTA Fillapex and AH Plus for both time intervals (1 h and 24 h). It showed maximum antimicrobial efficacy against *E. faecalis*, followed by *C. albicans* and least against *S. aureus* (Graph 1). This outcome resembled other studies where fresh Endoseq BC, MTA Fillapex, and AH Plus had antibacterial action against *E. faecalis* when tested by time-kill assay.[16] The results also were in accordance in the studies in which ADT, DCT, and modified DCT were implemented.[15,17,18,19] Endosequence BC showed the least microbial count against *E. faecalis* followed by *C. albicans* and least in *S. aureus*. The literature search does not have studies to support our result in relation to the highest reduction in *E. faecalis* followed by *C. albicans* and *S. aureus* using DCT. MTA Fillapex showed maximum antimicrobial efficacy against *C. albicans* followed by *E. faecalis* and least against *S. aureus*. AH Plus showed maximum antimicrobial efficacy against *E. faecalis* followed by *S. aureus* and showed no antimicrobial effect against *C. albicans*.

The antimicrobial property of the BC sealer is contributed by its alkaline pH that aids in the exclusion of microorganisms like *E. faecalis* which cease to survive at high pH, near to 11.5 or more. Furthermore, active calcium hydroxide diffusion over the period of time can be the reason for the antimicrobial efficacy.[20] On the contrary to our study, Hegde and Rathod (2017) stated that AH Plus sealer had better results than Bioceramic sealer against *E. faecalis*, in their study on *E. faecalis*. Such discrepancies can be due to the methodology used in the study which was ADT.[21]

MTA Fillapex showed second most statistically significant microbial count reduction for both the time intervals, that is, 1 h and 24 h against *C. albicans*, *E. faecalis*, and *S. aureus*. (Graph 2). This result was in accordance with Rahman *et al.* (2017), who found that MTA Fillapex and Real Seal SE both showed antifungal activity whereas only MTA Fillapex was effective against *E. faecalis*, rest of the materials did not depict any antimicrobial activity.[22] Another study by

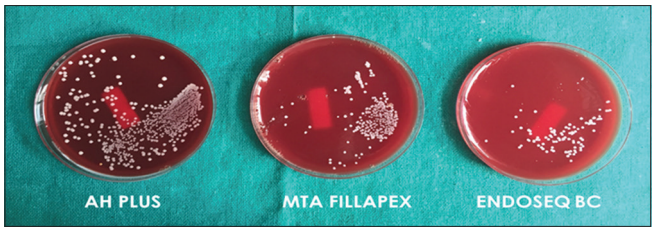
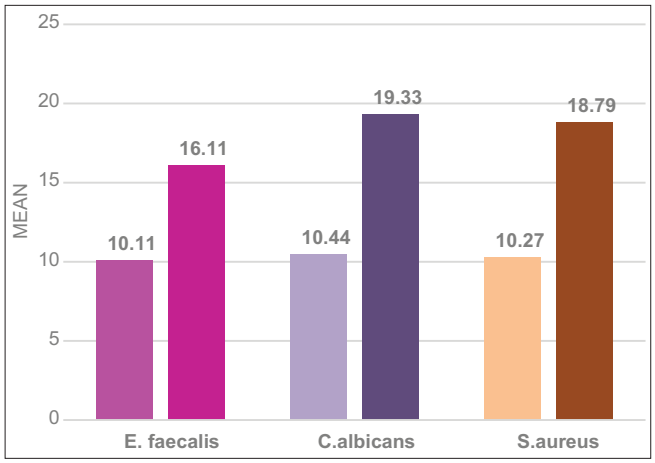
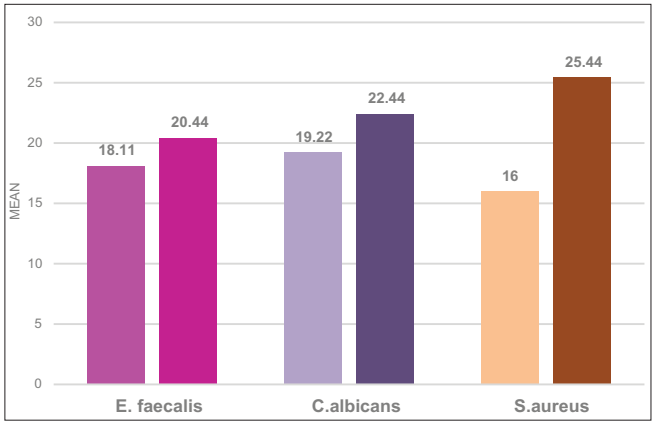


Figure 1: Microbial count for sealers for *Candida albicans* for 1 h

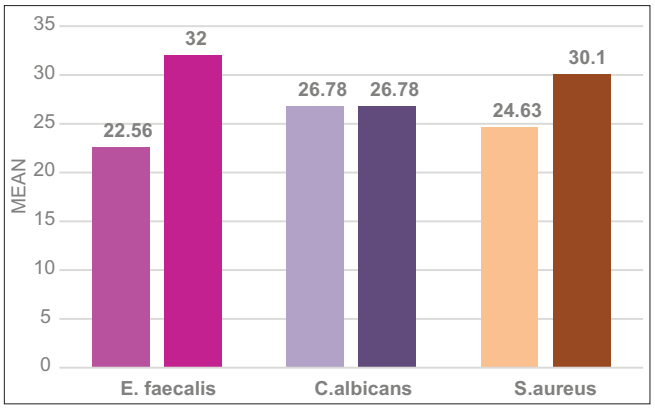


Graph 1: Comparison of mean microbial count for Endosequence BC in different time intervals



Graph 2: Comparison of mean microbial count for MTA Fillapex in different time intervals

Stowe *et al.* (2013) verified the antimicrobial properties of MTA which inhibited the growth of both *E. faecalis* and *Streptococcus sanguis*.[23] MTA Fillapex which contains calcium silicate which on contact with the moisture from dentin, begins the hydration of calcium silicates. The calcium silicate hydrogel and calcium hydroxide give a high pH which could be related to its antimicrobial property to MTA Fillapex.[24] On the contrary to this study, Ustun *et al.* (2013) in his study showed that MTA-based sealer has a least antibacterial effect at 20 min, whereas bioceramic sealer and epoxy resin sealer had maximum antibacterial



Graph 3: Comparison of mean microbial count for AH Plus in different time intervals

properties.[16] AH Plus, resin-based sealer, exhibited least antimicrobial efficacy against (Graph 3). Aravind *et al.* (2006) evaluated the antimicrobial property of five root canal sealers. The results showed that AH Plus has no antimicrobial action against *C. albicans* and Enterococci.[25] The result of Mickel *et al.* (2003) was in accordance with our study, who also verified AH Plus to be show minimum efficiency against *E. faecalis*.[26] The ineffective property of AH Plus is because of the elimination of formaldehyde. The presence of Bisphenol A diglycidyl ether in resin-based sealers induces its antimicrobial properties.[22]

Our study showed a significant difference in antimicrobial properties observed in MTA Fillapex, AH Plus, and Endosequence BC at 1 h (Figure 1). The antimicrobial activity of tested sealers decreased over time. This shows that resin-based and bioceramic root canal sealers are more efficient in a freshly mixed state and their antimicrobial properties decrease with time. However, the lowest long-time efficacy of AH Plus may be due to the paraformaldehyde released by this material only during the setting period. Similar studies were also reported by Heyder *et al.* (2013) discussing the antimicrobial properties for AH Plus owing formaldehyde, which is released in small quantities during the setting reaction.[22] According to the manufacturers, the processing time of AH Plus is 4 h and setting time at 37°C for another 8 h. Pizzo *et al.* (2006) suggested that the 24-h samples of AH Plus are ineffective in irradicating all *E. faecalis* in direct contact.[27]

CONCLUSION

Within the limitations of the study, it was concluded that:

Endosequence BC had the maximum antimicrobial efficacy against all the tested microorganisms for both the time intervals, followed by MTA Fillapex. The minimum efficacy was seen in AH Plus.

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Original Article

The Association between Serum Uric Acid Level and Dementia in Geriatric Population – A Case–Control Study

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Abstract

Importance: The increasing prevalence of dementia worldwide has reduced the quality of life in geriatric patients, thereby increasing the burden on the caregivers. As dementia evolves gradually, diagnosis of the disease is often delayed. Thus, the need for a sensitive biomarker for early diagnosis is instrumental.

Objective: The objective of the study was to study the association between serum uric acid levels and dementia in geriatric patients.

Design: This is a case–control study comparing the age-matched geriatric patients with and without dementia (cases – 50 and controls – 50).

Setting and Participants: A total of 100 geriatric patients from Government Villupuram Medical College and Hospital were included in this study for a study period of 4 months. Out of this, 50 were cases (with dementia) and 50 were controls (without dementia). Mini-mental state examination test was done to categorize the cases into mild, moderate, and severe subgroups (24–30 out of 30 as normal; 20–23 out of 30 as mild; 10–19 out of 30 as moderate; and score lesser than 10 out of 30 as severe). Serum uric acid levels were measured in the study population and compared between the cases and controls.

Results: The correlation of serum uric acid levels with cases and controls revealed 16% of the cases had hypouricemia, whereas none in the control group had hypouricemia. When serum uric acid levels were compared, it was found that 44% of the control group had normal serum uric acid levels and 82% of the cases had normal serum uric acid levels. Based on mini-mental state examination score, 10% of mild group and 21% of moderate group had hypouricemia and 4% of moderate group had hyperuricemia while the others had normal serum uric acid levels. All the data were statistically significant with "*P*" < 0.001.

Conclusion: The study identified the prevalence of hypouricemia in the study population. This study can pave the path for further multicentric research to delineate the role of uric acid level as potential biomarker for dementia.

Relevance: The information gained from this study will enable us to diagnose dementia in the early stages and improve the quality of life of the patients.

Key words: Dementia, Serum Uric acid level, Hypouricemia

INTRODUCTION

The World Health Organization (WHO) states that there is an increase in the dependence of geriatric population.[1] "Demographic Burden," as it is known, occurs due to the limited regenerative abilities, decreased immunity, and hiked susceptibility to non-communicable diseases and other comorbidities that this population faces. Dementia – a syndrome, in which there is deterioration in memory, thinking, behavior, and the ability to perform everyday activities, affects 50 million people across the world with an increase of 10 million cases/year.[2] The WHO estimates 4.1 million geriatric population with dementia in India and predicts the count would double every 20 years.[3,4] The vast majority of dementias is due to Alzheimer's disease

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(50–70%) with vascular dementia (25%), Lewy body dementia (15%), frontotemporal dementia, and alcohol-related dementia (10%) being the less common types.[1,5] The clinical spectrum ranges from mild memory deficit to major cognitive impairments imposing dependency for activities of daily living (ADL).[6] Dementia can lead to disability, reduced quality of life and also become a burden for the care takers.

The pathophysiology of dementia revolves around increased lipid content in neuronal tissues which is susceptible to free radical damage through lipid peroxidation compounded by reduced capacity of antioxidants.[1] Antioxidants such as uric acid, Vitamin A, Vitamin C, Vitamin E, and scavenging enzymes control the oxidative damage.[1]

Uric acid, an end product of purine nucleotides, is an endogenous aqueous antioxidant which traps free radicals and converts them into allantoin for urinary excretion.[7] Elevated lipid peroxidation and insufficient enzymatic and non-enzymatic antioxidants were shown in the peripheral tissues of patients with Alzheimer's disease.[8,9] After adjustment for several cardiovascular risk factors, higher serum uric acid levels were associated with a decreased risk of dementia and thereby a possible protective role.[10] Uric acid also exhibits pro-oxidant properties which compounds the final pathway of neuronal damage.[11] The contradicting effects of uric acid on dementia and cognitive function continue to perplex researchers in the field.[11] Our research study aimed to ascertain the association between serum uric acid and dementia in geriatric population. The objectives of the study were as follows:

1. To compare the serum uric acid level among elderly patients with or without dementia.
2. To determine whether serum uric acid levels correlate with severity of dementia based on mini-mental state examination (MMSE) score.

METHODOLOGY

This is a case–control study involving elderly South Indian population conducted in a public sector tertiary care hospital for a period of 1 year. Fifty cases and 50 age-matched controls were recruited using simple random sampling method. Eligible patients attending neurology outpatient clinic were screened for recruitment. The diagnosis of dementia was as per diagnostic and statistical manual of mental disorder (DSM-5), National Institute of Neurological and Communicative disorders and Stroke (NINCDS), and the Alzheimer's Disease and Related Disorders Association (ADRDA) recommendation. We employed the MMSE scoring system for patient enrolment. The inclusion and exclusion criteria are as per Table 1.

MMSE SCORING SYSTEM

The MMSE is a cognitive test which measures:

- Language abilities
- Visuospatial skills
- Attention and calculation
- Orientation to time and place
- Word recall

The MMSE is a tool that can be used to systematically and thoroughly assess mental status. It is an 11-question measure that tests five areas of cognitive function. The MMSE takes only 5–10 min to administer and is, therefore, practical to use repeatedly and routinely.

The National Institute for Health and Care Excellence (NICE) classifies

- 24–30 out of 30 are considered normal,
- 20–23 as mild cognitive impairment (MCI),
- 10–19 as moderate cognitive impairment, and
- <10 as severe cognitive impairment.

The enrolment process was based on self-interest of the participants and written informed consent was obtained from them or their legal guardian as the case may be. IEC approval was obtained. The recruited participants underwent the MMSE and their scores were recorded. Furthermore, 3 ml venous blood samples were collected, centrifuged and serum uric acid levels were analyzed by Beckman coulter fully auto-analyzer using uricase method. The collected data were analyzed statistically by SPSS version 25.

RESULTS

The sex distribution was 56% of males and 44% of females. The mean age of the cases was 69.68 ± 4.1 and that of controls 70.04 ± 4.3. The mean serum uric acid level of cases was observed to be 4.02 ± 0.01 and that of control group was 6.32 ± 0.01 [Table 2]. The mean values

Table 1: Criteria for the selection of the cases and controls

Inclusion criteria	Exclusion criteria
Geriatric patients with dementia based on MMSE score	People affected with dementia even before they reach the age of 65
	Patients with secondary causes for dementia like head injury, brain tumor, vitamin deficiency, and thyroid disorders.
	Patients with hyperuricemia such as gout, psoriasis, malignancies, and renal disorders.
	Patients consuming alcohol and drugs.

MMSE: Mini-mental state examination

of serum uric acid levels were subjected to two-tailed "*t*" test and very significant with $P < 0.0001$. Normal serum uric acid level is 3.4–7.0 mg/dl for males and 2.4–5.7 mg/dl for females. The variables were subjected to univariate and multivariate analyses to ascertain the association with cases and controls. Data revealed that 16% of the cases had hypouricemia, whereas none of the controls had hypouricemia. About 44% of the control group and 82% of the cases had normal serum uric acid levels which had statistical significance with $P < 0.001$. However, 2% of the cases had hyperuricemia when compared with 56% controls. The data showed statistical significance with $P < 0.001$ [Table 3].

In the cases based on MMSE score, 28% (14 cases), 66% (33 cases), and 6% (3 cases) of the patients belonged to the mild, moderate, and severe category, respectively [Table 4]. In this category, 7% ($n = 1$) mild and 21.2% (7 of 33 in moderate group had hypouricemia, whereas 2% of moderate group were hyperuricemic [Figure 2]. Correlation of MMSE score and serum uric acid level shows that 7% (1 out of 14) of mild group has hypouricemia and 85% (12 out of 14) has normal level of uric acid level. In the moderate group, 30% (10 out of 33)

Table 2: Mean serum uric acid level in cases and controls

	Cases	Control	"*P*" value
Mean serum uric acid level	4.02±0.01	6.32±0.01	<0.0001
Mean age of the study participants	69.68±4.1	70.04±4.3	

Table 3: Correlation of serum uric acid level with cases and controls

	Cases (%)	Control (%)	OR (95% CI)	"*P*" value
Below normal (hypouricemia)	16	0		
Normal range	82	44	0.36 (0.1619,0.8167)	<0.001
Above normal (hyperuricemia)	2	56	22 (4.094,458.8)	<0.001

Table 4: Cognitive function using mini-mental state examination score in cases and controls

Interpretation	Score	Cases	Controls	OR (95% CI)	*P* value
Normal	24–30	0 (0%)	50 (100%)	Reference	
Mild	20–23	14 (28%)	0 (0%)	4.2 (2.272, 8.617)	<0.001
Moderate	10–19	33 (66%)	0 (0%)	1.4 (0.9136, 2.24)	0.11
Severe	0–9	3 (6%)	0 (0%)	15.6 (5.467, 63.57)	<0.001

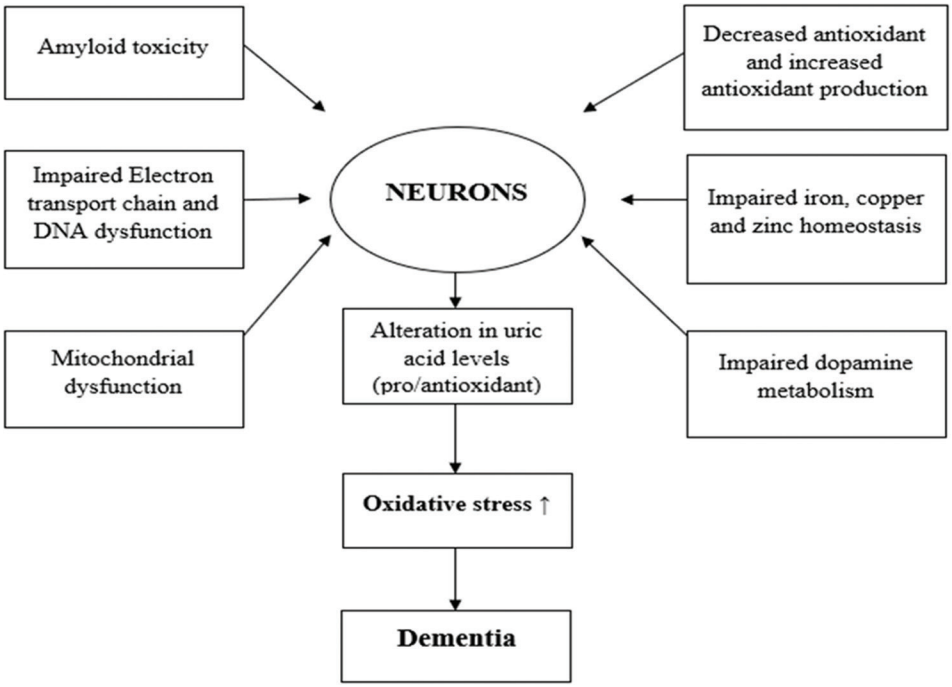

Figure 1: Pathophysiology of dementia

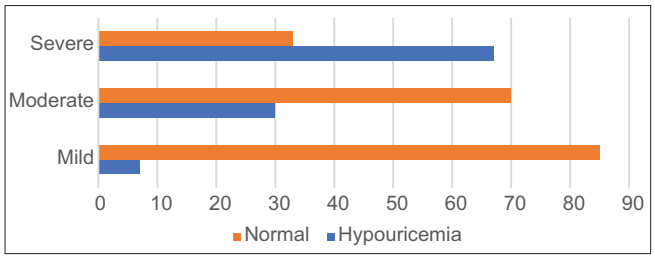

Figure 2: Correlation of mini-mental state examination score and serum uric acid levels

Table 5: Correlation between MMSE score and uric acid levels in cases

MMSE score	Hypouricemia	Normal	"*P*" value
Mild	1 (3.45) [1.74]	12 (9.55) [0.63]	<0.1
Moderate	10 (8.76) [0.18]	23 (24.24) [0.06]	<0.1
Severe	2 (0.80) [1.82]	1 (2.20) [0.66]	<0.1

MMSE: Mini-mental state examination

were hypouricemic and 70% has normal levels of serum uric acid levels. About 67% (2 out of 3) and 33% (1 out of 3) in the severe group had hypouricemia and normal uric acid levels, respectively. Correlation had statistical significance with "*P*" < 0.1 [Table 5].

DISCUSSION

The association between serum uric acid levels and dementia has been controversial for more than a decade. The MMSE is used to help diagnose dementia and rate its severity; however, it might not be an appropriate assessment tool if the patient has learning, linguistic/communication, or other disabilities.[12] Therefore, the need for a diagnostic biomarker is most felt for this disorder.

Most of the hypotheses explain that uric acid is a natural antioxidant, which might reduce oxidative stress and protect against the detrimental effects of free radicals in the brain. Historically, low serum uric acid level has been often reported in neurodegenerative diseases. We found in our study 16% (8 out of 50) of cases had hypouricemia, 82% (41 out of 50) had normal uric acid levels, and 2% (1 out of 50) had hyperuricemia. Comparatively, none of the control group subjects had hypouricemia, which was statistically significant ($P < 0.001$). Based on MMSE scores, the cases were divided into three categories such as mild (22%), moderate (66%), and severe (12%).

The correlation between uric acid levels and various stages of MMSE score in dementia patients showed that 7% [1 out of 14 patients] of subjects had hypouricemia in mild category. The data showed significant $P < 0.001$ and 21% had hypouricemia in moderate cases. At the same time, 4% hyperuricemia individuals were found in moderate group. However, most of the subjects had normal serum uric acid in both the groups.

A more recent meta-analysis by Tana *et al.*[13] included 46 papers ($n = 16,688$ participants) dealing with the causes of dementia and 22 papers dealing with Alzheimer's dementia (AD) diagnosis. They found lower serum uric acid levels in patients with a diagnosis of dementia with a stronger association between serum uric acid (SUA) and Alzheimer's dementia, as compared to Parkinson's dementia (PD) patients. These data could suggest a neuroprotective role of UA on cognitive function, showing its best influence on patients with the AD rather than other dementia types. However, there is no correlation that was found between the MMSE test score and SUA levels except for the subset of patients with Parkinson's disease.

The mechanisms of uric acid in neurodegenerative diseases of cognitive function are still controversial. One plausible model for neuronal damage is depicted in [Figure 1]. Uric acid is an antioxidant and also pro-oxidant, a double-edged weapon. Cervellati *et al.*[14] study says that oxidative stress seems to play a key role in the pathogenesis of the most of causes of dementia, in particular AD and PD. A meta-analysis by Schrag *et al.* found a significant reduction of total antioxidant capacity and sUA levels in AD patients than controls.[15] Only about 10% of persons affected with dementia are correctly diagnosed. Hence, it is of critical importance to carry out early identification and control methods in the diagnosis of dementia.

Zarry *et al.* analyzed the relationship between Alzheimer's dementia and serum uric acid based on disease progression. It was revealed that low plasma urate was associated with faster cognitive decline ($P = 0.008$).

Shen *et al.*[16] found that patients with Parkinson's dementia had lower serum levels of uric acid than healthy controls and this association was more significant in men than in women. Gregory *et al.*[17] did a French population-based cohort study that included 1598 adults >65 years of age, wherein low serum uric acid correlated with dementia. Chen *et al.*,[16] in a meta-analysis of case–control studies (n=2708 participants), found no significant difference between patients with AD and healthy controls in SUA level. Our study population had low serum uric acid levels among cases which was associated with severity of cognitive impairment.

CONCLUSION

The diagnosis of dementia is a clinical exercise. This study shows low serum uric acid levels more common in

dementia patients when compared with controls groups. SUA level could be a potential cost-effective agent to enable early diagnosis of dementia in geriatric population and plan timely intervention.

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Limitations

- Since it was a time bound study, the formula-based sample size could not be achieved.
- MMSE is a screening test even though it has high reliability and validity. MMSEs have subjective variability which may be very high in older age of the study population. This may be due to the potential survival bias.

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Original Article

Study of Urinary Tract Infection in Patients with Diabetes Mellitus

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Abstract

Introduction: Urinary tract infection is one of the most common types of bacterial infection in patients with diabetes mellitus.

Aim: The aim of the study was to assess the prevalence of urinary tract infection among hospitalized diabetic patients.

Materials and Methods: A hospital-based prospective study was carried out from June 2018 to May 2019. A total of 100 patients of diabetes mellitus with urinary tract infection were included in this study.

Results: Of 100 patients, 54 were male and 46 were female, the most common age group was 46–55 years. Most patients had a fever with rigor (48%) followed by dysuria (22%), suprapubic pain (20%), increased frequency of urine (18%), flank pain (10%), pyuria (6%), and hematuria (4%). Urine culture analysis revealed that *Escherichia coli* (29%) was the most common organism responsible of urinary tract infection. The majority of isolated organisms were sensitive to antimicrobial agents such as amikacin, nitrofurantoin, and levofloxacin.

Conclusion: Urinary tract infection is frequent in diabetic patient and the urine culture should be performed in all hospitalized patients with diabetes mellitus. Early diagnosis, knowledge of common predisposing factors, and appropriate clinical management are important to improve prognosis.

Key words: Diabetes mellitus, *Escherichia coli*, Urinary tract infection

INTRODUCTION

Diabetes mellitus has become a major health challenge worldwide. In India, the prevalence of diabetes is expected to increase from 31.7 million in the year 2000–79.4 million in 2030.[1] Diabetes mellitus has well-known risk factors such as age, heredity, obesity, hypertension, lack of exercise, smoking, alcoholism, dyslipidemia, and positive family history; few other possible risk factors are also under evaluation.[2]

Diabetes mellitus has a number of long-term effects on the genitourinary tract system. Urinary tract infection is one of the important causes of morbidity in diabetic patients.[3]

The mechanism of pathogenesis for the association between diabetes mellitus and urinary tract infection is not completely clear. However, it is suspected that high glucose concentration in the urine of these patients may favor the growth of uropathogens.[4] Human behavioral changes and lifestyle over the last century have resulted in a dramatic increase in the incidence of diabetes World Wide.[5]

The impairment in the immune system, poor metabolic control, as well as incomplete bladder emptying due to the autonomic neuropathy may all contribute to the increased risk of urinary tract infection in diabetic patients.[6]

Serious complications of urinary tract infection such as emphysematous cystitis, pyelonephritis, renal or perinephric

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abscess, bacteremia, and renal papillary necrosis occur more commonly in diabetic patients.[7]

Aim and Objective

The aim of the study is to assess the prevalence of urinary tract infections among hospitalized diabetic patients and identify the most frequent bacteria responsible for urinary tract infection.

MATERIALS AND METHODS

This prospective observational study was conducted at Indira Gandhi Institute of Medical Sciences, Patna, in the Department of General Medicine and the duration of the study was from June 2018 to May 2019. All one hundred cases in this study were examined according to clinical plan and investigated according to need. The study protocol was approved by the ethical committee of the institute and consent was obtained from each patient.

Inclusion Criteria

The following criteria were included in the study:

- Type I and Type II diabetes mellitus patients with signs and symptoms of urinary tract infection
- The patients more than 15 years of age
- Patients who will give the consent for the study.

Table 1: Gender distribution of patients in diabetes mellitus with urinary tract infection

Sex	Number of patients	Percentage
Female	54	54
Male	46	46
Total	100	100

Table 2: Distribution of patients by age

Age group	Number of patients	Percentage
15–25	08	8
26–35	12	12
36–45	22	22
46–55	35	35
56–65	15	15
66–75	5	5
>76	3	3
Total	100	100

Table 3: Sign and symptoms of urinary tract infection in diabetes mellitus patients (*n*=100)

Sign and symptoms	Number of patients	Percentage
Fever with rigor	48	48
Dysuria	22	22
Suprapubic pain	20	20
Increased frequency of urine	18	18
Flank pain	10	10
Pyuria	6	6
Hematuria	4	4

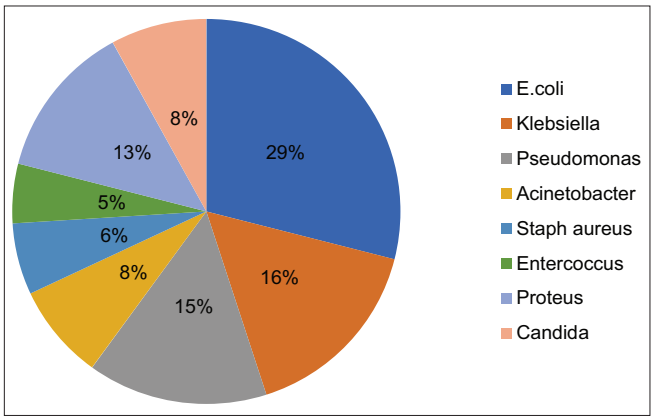
Exclusion Criteria

The following criteria were excluded from the study:

- The patients <15 years of age
- The patient who will not give consent for the study.

RESULTS

A total of 100 patients having diabetes mellitus with urinary tract infection were studied.



Pie chart showing uropathogens isolated in diabetes mellitus.

Most of the patients in the study were female (54%) as compared to male (46%) (Table 1). The most common age group was 46–55 years (Table 2). Most of the patient had a fever with rigor (48%) followed by dysuria (22%), suprapubic pain abdomen (20%), increase frequency of urine (18%), flank pain (10%) pyuria (6%), and hematuria (4%). Most of the patients were having more than one sign and symptoms (Table 3).

Escherichia coli (29%) was the most common organism isolated in urine culture followed by *Klebsiella* (16%), *Pseudomonas* (15%), *Proteus* (13%), *Acinetobacter* (8%), *Candida* (8%), *Staphylococcus aureus* (6%), and *Enterococcus faecalis* (5%).

E. coli isolated in this study had higher sensitive (86%) for amikacin and nitrofurantoin (23%) followed by colistin (20%), piperacillin plus tazobactam (18%), gentamicin (16%), levofloxacin (14%), ceftriaxone (9%), ciprofloxacin (4%), vancomycin (3%), and meropenem (2%). *Klebsiella* was more sensitive to levofloxacin (87.5%), nitrofurantoin (81%) and amikacin (75%), and least sensitive to ciprofloxacin (12.5%).

Pseudomonas aeruginosa was the third most common organism isolated in the urine of diabetic patients and they were sensitive to nitrofurantoin (86.6%), amikacin (66.6%), levofloxacin (40%), gentamicin (40%), piperacillin and

tazobactam (33.3%), colistin (26.6%), vancomycin (26.6%), ceftriaxone (20%), ciprofloxacin (13.3%), and meropenem (13.3%).

Acinetobacter was found to be sensitive most commonly with nitrofurantoin (75%) and amikacin (50%), whereas least sensitive to vancomycin (12.5%) and meropenem (12.5%). *S. aureus* was sensitive to amikacin (50%), nitrofurantoin (33.3%), ciprofloxacin (33.3%), ceftriaxone (33.3%), and gentamicin (33.3%) whereas levofloxacin, colistin, piperacillin plus tazobactam, vancomycin, and meropenem sensitive to *S. aureus* were 16.6%.

E. faecalis was sensitive to nitrofurantoin (60%), gentamicin (60%), amikacin (40%), piperacillin plus tazobactam (40%), ceftriaxone (40%), ciprofloxacin (40%), vancomycin (40%), meropenem (40%), levofloxacin (20%), and colistin (20%).

In this study, *Proteus* was commonly sensitive to nitrofurantoin (92.3%) and amikacin (84.6%) while least sensitive to meropenem (7.69%). In the 8% of the patient, Candida organism was isolated in urine culture and treated with antifungal.

DISCUSSION

In the present study, the prevalence of Urinary tract infection was slightly higher in female (54%) than male (46%). Females are vulnerable to UTIs due to their anatomy and reproductive physiology. The short urethra, urethra closer to the perirectal area where pathogen colonies easily, absence of bacteriostatic prostatic secretions, and sexual intercourse may force bacteria into the female bladder.[8] Chaudhary *et al.* found 62.5% prevalence of UTI among females and 37.5% among males.[9] Ijaz *et al.* showed more similar results to this study. They found 51.37% prevalence of UTI among females, while 48.63% in males.[10] Most frequently, patients were in the affected age group from 46 to 55 years (35%). This was similar to a study by Simkhada.[11]

In the present study, the most common clinical presentation was fever with rigor (48%) followed by dysuria (22%), suprapubic pain abdomen (20%), flank pain (10%), increase frequency of urine (18%), flank pain (10%), pyuria (6%), and hematuria (4%). A study done by Eshwarappa *et al.*[7] demonstrated that fever and dysuria were the most common clinical presentation. In this study, *E. coli* (29%) was the most common organism isolated in urine culture followed by *Klebsiella* (16%) and *P. aeruginosa* (15%). *E. coli* is a normal inhabitant of the gastrointestinal tract and thus may be a potential source for the development of UTI.[12] A study done by Ghadage *et al.*[13] reported that *E. coli* (41.3%) was the predominant uropathogen isolated followed by *Klebsiella* spp. (18.5%) and *Enterococcus* spp. (12%).

E. coli, the most prevalent pathogen in the present study, was more sensitive to amikacin, nitrofurantoin, levofloxacin, colistin and piperacillin, and tazobactam whereas other antibiotics sensitive to *E. coli* were ceftriaxone, gentamicin, ciprofloxacin, vancomycin, and meropenem.

Amikacin, which is easily available and cost-effective, remains a good choice for most of the uropathogens if renal status allows and there is a facility to follow renal function test regularly. *Klebsiella* was most commonly sensitive to levofloxacin, nitrofurantoin, and amikacin whereas *Pseudomonas* was most commonly sensitive to nitrofurantoin, amikacin, and levofloxacin. In this study, the most common antibiotics sensitive to *Acinetobacter* were nitrofurantoin amikacin, levofloxacin, and ceftriaxone, whereas most common antibiotics sensitive to *S. aureus* was amikacin, nitrofurantoin, and gentamicin. *E. faecalis* was commonly sensitive to nitrofurantoin, whereas *Proteus* was sensitive to nitrofurantoin, amikacin, and colistin.

CONCLUSION

Urinary tract infections are frequent in patients with diabetes mellitus. The present study showed fever with rigor as the most common feature in patients with urinary tract infections having diabetes mellitus and the most common uropathogen was *E. coli*. The proper management of urinary tract infection in diabetes is crucial as prompt diagnosis and correct use of antibiotics is vital for treatment.

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Original Article

FEAR Regarding Research among Health Professionals

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Abstract

Purpose: Evidence-based medicine practice is now inevitable and health professionals are bound to understand research concept thoroughly to practice based on evidence. When we are talking about research, usually health professionals avoid involving in researches for many reasons. This study was designed to assess the fear regarding health professionals based on a small scale designed focusing on scoring system and assess having some avoidance behavior.

Methods: It was a cross-sectional study design. Between July and September 2019, a self-administered questionnaire was distributed through online after getting data regarding contacts details of health professionals. We have approached 600 subjects in total, these participants were doctors, nurses, and allied health professionals. This health professional's works all over the country (e.g., Ministry of Health, ministry centers, university, and private sectors). The inclusion criteria were all health professionals work as registered health professionals. The Research Ethics Committee of the university approved the study.

Results: The results depict out of total, 26.2% of male and 26.4% of female have high FEAR scores, and 29% of male have low FEAR score in comparison to 18.4% of female. Health-care providers with bachelor show the highest FEAR score about 27.7%, while those with postgraduate degrees show the lowest fear with 22.2%. A bivariate logistic regression analysis done shows a statistically significant (P = 0.027) association seen with high fear score and age group, especially the youngest between 19 and 30 years and educational level (P = 0.024). Whereas, no statistically significant difference (P = 0.290) seen in the FEAR score with working experience. No statistically significant difference (P = 0.251) seen in the FEAR score with living.

Conclusion: Conclusively, the health professionals have fear about researches so need to assess its reasons for the rectification of the problem.

Key words: Fear, Health professionals, Publications, Research

INTRODUCTION

Rapidly growing health and applied health fields produce a huge amount of new information and becoming knowledge based on evidences discovered by researches. Thus, the new evidence-based knowledge needs to apply in the practice for an improvement of the health care system. Evidence-based medicine aims to change the current medical practice by application of scientific method.[1] To apply it, health professionals should understand science and art of research methodology. These all evidences are based on research, which motivates us for evidence-based practice. The meaning of research is ""an endeavor to discover facts by study or investigation."[2] Policy-makers utilize research for framing policies while administrators take decisions with the help of research outcomes. Either students, teachers, or practitioners all need a clear understanding of research or ultimate aim of conducting research is to improve health and patient care, thereby serving the humankind.[2] However, it is emphasizing that teachers should play a role in research or publications and there are enough evidences to prove that the quality of teaching improves if faculty is oriented toward research.[3] However, this is a responsibility of all health-care professionals to work for conducting ethical research.

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Nonetheless, when we talk about researches, usually the reactions of health professionals are not promising. Somehow, it reflects from their reactions that they might have some kind of fear about conducting researches. Normal fear is defined as a normal reaction to a real or imagined threat, is considered to be an integral and adaptive aspect of development.[4,5] As compared to other basic emotions,[6] the fear has been extensively researched.[7] Obviously, normal and adaptive fears have been differentiated from clinical fears or phobias based on several criteria, including whether or not the expressed fear is age or stage specific, persists over an extended period, and/or significantly interferes with everyday functioning.[8] This distinction is of particular relevance for the present discussion, given that a central focus of the extensive research into normal fear has been to determine its developmental patterns, intensity, and duration against which to identify pathological fear or phobia.[7] Therefore, the normal fear does not require having an extensive management. As regard to the research, fear is also considered as a normal fear and just need to handle through continuous exposure and proper understanding. We designed this study to assess the attitude of health professionals regarding researches among health professionals in Saudi Arabia.

METHODS

Study Design and Setting

It was a cross-sectional study design. Between July and September 2019, a self-administered questionnaire was distributed through online after getting data regarding contacts details of health professionals. We have approached 600 subjects in total, these participants were doctors, nurses, and allied health professionals. This health professional's works all over the country (e.g., Ministry of Health, ministry centers, university, and private sectors). The inclusion criteria were all health professionals work as registered health professionals. The Research Ethics Committee of the university approved the study.

Survey Instrument

Investigators prepared the questionnaire after applying a Delphi technique. A pilot study was conducted to assess the validity and reliability of the questionnaire. This questionnaire then applied to a group of health professionals randomly selected for assessing reliability coefficient that was 0.78.[8]

In addition to personal data and practice characteristics, the survey included that assessed participants' attitude toward research by measuring their perception through following 4 statements:

F= Fascinated with research "Extremely interested with research
E= Excited to do a research
A= Accepted to spare time for research
R= Regularly read research articles

These statements have been measured through a scale having options: Never, sometimes, usually, and always. Giving scores to each response from 1 to 4 made the score from 1 to 16. We have classified the measuring FEAR based on scores as high (1–8 scores) and low fear (9–16 scores).

Data Analysis

The data was collected and analysed by using SPSS-IBM version 22. All four statements based on Likert scale divided into two categories as high (1–8 scores) and low fear (9–16 scores) and cross tabulated these categories with demographic variables with the application of Chi-square. The $P < 0.05$ was considered as statistically significant level.

RESULTS

The demographic results yield that male participants 55% and 45% female. Almost half of them (50.6%) were doctors and only a few (9.1%) of them had diploma degrees. Most of them were living in the city about 91.9% and half of them (50.4%) having a work experience <5 years. Out of total, 26.2% of male and 26.4% of female have high FEAR scores, and 29% of male have low FEAR score in comparison to 18.4% of female (Figure 1). Besides, regarding health-care occupation (Figure 2), doctors exhibit the lowest fear score about 30.2% with 17.3 to the rest of health-care providers. Health-care providers with bachelor show the highest fear score about 27.7%, while those with postgraduate (PG) degrees show the lowest fear with 22.2% (Figure 3).

A bivariate logistic regression (Table 1) analysis done shows a statistically significant ($P = 0–027$) association seen with high fear score and age group, especially the youngest between 19 and 30 years with $P = 0.027$ and educational level with $P = 0.024$. Whereas, no statistically significant difference ($P = 0.290$) seen in the FEAR score with working experience. No statistically significant difference ($P = 0.251$) seen in the FEAR score with living.

Table 1: Bivariate logistic regression analysis

Variables	B	S.E.	Wald	df	Sig.	Exp(B)
Age group	0.188	0.183	1.062	1	0.303	1.207
Sex	□0.280	0.187	2.257	1	0.133	0.755
Occupation	□0.525	0.122	18.556	1	0.000	0.591
Education	□0.048	0.150	0.100	1	0.751	0.953
Living	0.388	0.329	1.392	1	0.238	1.473
Working experience	0.027	0.183	0.022	1	0.882	1.027
Constant	0.509	0.552	0.852	1	0.356	1.664

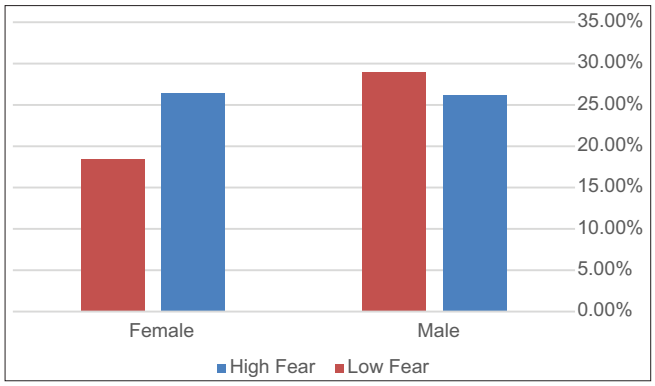

Figure 1: Comparison between gender and fear score (*P* = 0.009)

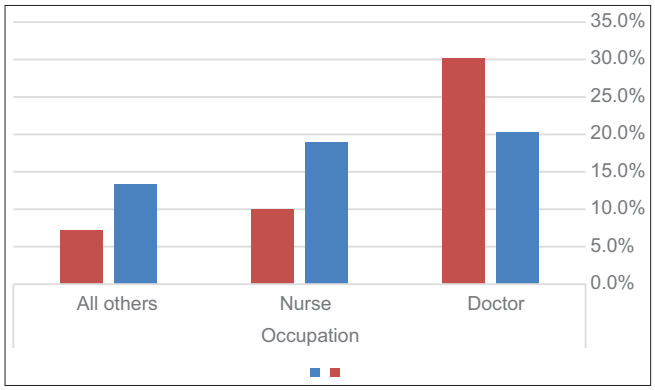

Figure 2: Comparison between health-care occupation and fear score (*P* = 0.000)score (*P* = 0.000)

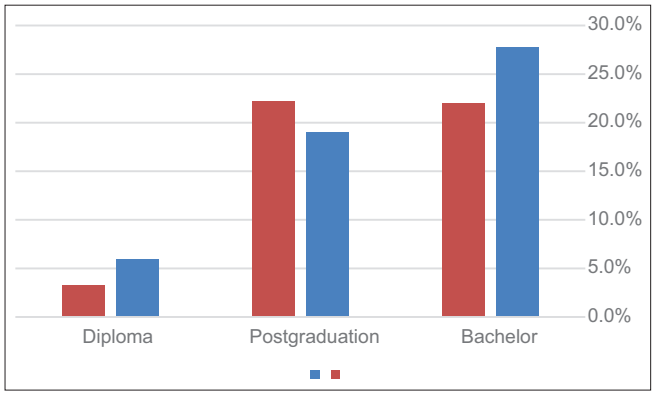

Figure 3: Comparison between educational level and fear score (*P* = 0.024)

DISCUSSION

This study depicted that health professionals have high fear scores about research, however, as compared to allied health professionals, doctors have less fear. There is no study so far published to measure the level of fear among health professionals as regard to this issue; therefore, it is difficult to have a direct comparison of our results with other studies.

Nonetheless, in the undergraduate curriculum, research methodology is covered under preventive and public health subjects and is not stressed upon. However, the scenario has been changed now, some of the universities provide conducive environment to the students, and it is one of important components of the CanMEDS competencies required from a physician.[9] If this gap is not filled at undergraduate level, then this lacuna is carried forward during the PG course where dissertation is a mandatory requirement. Therefore, as now, many universities or medical schools adopted the curriculum that is based on outcome based and competencies based,[9] should have scholar activities at undergraduate level. Henceforth, it is strongly recommended that students should involve in research activities from the beginning at their medical schools.

There is another issue needs attention that teachers, which are interested and qualify as guides for under as well as PG students. Majority teacher teaches because of the number of years of experience or publications, most of which being as gift authorship. Mediocrity in research continues unabated because many of the teachers and guides have shown little interest in being trained in research methodology.[2,10,11] Due to the casual attitude of teachers who are not oriented to research, the candidates are finding shortcuts to fill in a few pages in the name of thesis.

This scenario highlighted another subject that is preparation of researches through work on overnight like completing a ritual to get a degree.[10-12] The best example of it is preparation of the thesis overnight. Earlier, there were amendments to delete thesis for PG examinations in some countries, but this resulted in decrease in number of scientific publications, so, once again, thesis became a requirement for PG exams.[10] Hence, the PG thesis is one of the reasons cited by teachers for not involving in research. There are teachers mention many reasons for not teaching researches or involving in the researches[13] like are too busy, overwhelmed in academic load, have some extra administrative work, and so on that there so no time left for researches.

CONCLUSION

This study illustrated that health professionals have fear about researches and there is a need of development of a large-scale study and include other questions to measure real fear with reasons.

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Original Article

A Study to Assess the Clinicopathological Spectrum of Acute Complications of Diabetes Mellitus in Relation to Hypertension

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Abstract

Introduction: The prevalence of diabetes mellitus has been dramatically increasing worldwide, making it an extremely costly chronic disease, both in terms of patient morbidity and health-care expenditure. As many non-communicable diseases have similar pathophysiologic mechanisms, so the clinicopathological spectrum and incidences of complications may be expected to be different from that observed in the general population. However, not many studies are available in this regard. Therefore, this study was conducted to assess the clinicopathological spectrum of the acute complications of diabetes mellitus in relation to hypertension.

Materials and Methods: This cross-sectional, analytical study was conducted on patients admitted in the ICU with the acute complication of diabetes mellitus. One hundred patients aged more than 18 years were included in the study. Relevant medical history and investigations were recorded.

Results: The mean diastolic BP was significantly lower in hypertensive patients. More proportion of hypertensive patients had deranged creatinine.

Conclusion: From the present study, it can be effectively concluded that the epidemiological and clinic-pathological profile of the patients having acute complications of diabetes mellitus is significantly different in hypertensive patients than in the non-hypertensives. Further studies need to be done in this regard.

Key words: Complications, Creatinine, Diabetes mellitus, Diabetic ketoacidosis, Hypertension, Hypoglycemia

INTRODUCTION

Diabetes mellitus, a chronic metabolic non-communicable disease (NCD), has attained epidemic proportions worldwide. The prevalence of DM has been dramatically increasing worldwide, making it an extremely costly chronic disease, both in terms of patient morbidity and health-care expenditure. As of 2015, more than 415 million adults have diabetes mellitus, and this number is estimated to increase to 642 million by 2040. More than 95% of all adults with diabetes mellitus have type 2 diabetes mellitus (T2DM).[1] India is one of the epicenters of the global diabetes mellitus epidemic and has the second-highest number of people with the disease in the world (~69 million individuals as of 2015).[2]

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Acute complications include extreme levels of blood glucose, with accompanying symptoms and/or other laboratory abnormalities. The acute metabolic complications of diabetes consist of diabetic ketoacidosis (DKA), hyperosmolar non-ketotic coma (HNC), lactic acidosis (LA), and hypoglycemia.[3] In general, these states are reversible and but if not treated, can lead to death. Hospitalizations for acute metabolic decompensation are

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associated with significant morbidity and mortality, and they are considered preventable with adequate ambulatory care. Severe glucose disturbances are not the only acute DM related events that lead to hospitalization. It has been demonstrated that people with DM have a greater risk of developing infectious diseases.[4] Not only does DM confer a >2-fold risk of being hospitalized for infection, the risk ratio for death from infection is almost double for people with DM compared to people without DM.[5]

Coexisting diseases precipitate DKA and DKA precipitates coexisting disease. Most often, patients with DKA have an infectious disease and signs of infection should be vigorously sought for and treatment should be instituted as appropriate. Other prominent comorbidities include cardiovascular events (myocardial infarction, stroke, thrombophlebitis, and pulmonary embolism), acute gastrointestinal disorders, and a variety of intoxications.[6]

The inter-relationship of diabetes and various other NCDs has been the least studied. As many NCDs have similar pathophysiologic mechanisms, so the clinicopathological spectrum and incidences of complications may be expected to be different from that observed in the general population. However, not many studies are available in this regard.

Therefore, this study was conducted to assess the clinicopathological spectrum of the acute complications of diabetes mellitus in relation to hypertension.

MATERIALS AND METHODS

This cross-sectional, analytical, observational study was conducted after approval from the Institutional Ethics Committee. Patients more than 18 years of age, presenting with acute complications of diabetes mellitus Type II (DKA, HNC, LA, or hypoglycemia), admitted in the emergency department or ICU and who consented to participate were included in the study. Pregnant females and any patient not consenting to participate in the study were excluded from the study. A total of 100 patients were included in the study.

Written informed consent was obtained from all the patients. Detailed medical history, including additional comorbidities, was recorded. A physical examination was done. Routine hematological and biochemical investigations were carried out. The normal ranges considered for investigations are as follows:

1. Hemoglobin: More than 12 g/dL
2. Creatinine: 0.6–1.2 mg/dL
3. Fasting blood sugar: 100–125 mg/dL
4. Post Prandial blood sugar: <140 mg/dL.

Statistical Analysis

The descriptive and analytical statistics were done. All the data were analyzed using statistical software. For descriptive stats: Results were expressed as mean ± standard deviation and proportions. Comparisons between qualitative data were performed with the Chi-square test (Fisher's exact test when any cell value was <5). For quantitative data, Student's *t*-test was used. $P < 0.05$ was considered to be "Statistically Significant."

RESULTS

The prevalence of hypertensives amongst patients with acute complications of diabetes mellitus was 28%.

The acute complications of diabetes mellitus were more prevalent in the females in non-hypertensive patients and in males in hypertensive patients [Table 1]. The mean age was more in the hypertensives (63.82 years) compared to non-hypertensives (51.93 years).

The distribution of the clinical features is as per Table 2. No statistically significant differences were found.

On physical examination, the mean diastolic blood pressure was significantly lower in the non-hypertensive patients compared to hypertensives [Table 3].

Serum creatinine was deranged in 50% of the hypertensive patients compared to only 25% of the non-hypertensive patients and the difference was statistically significant [Table 4].

DISCUSSION

At present, there is a phase of epidemiologic transition, causing a shift in the disease epidemiology from the

Table 1: Demographics of the study group

Gender	Hypertensive		Non-hypertensive		*P*-value	Statistical significance
	n	%	*n*	%		
Males	15	53.6	35	48.6	0.656	Not significant
Females	13	46.4	37	51.4		
Mean age±SD (in years)	63.82±7.87		51.93±13.30		<0.0001	Significant

Table 2: Distribution of the study group as per clinical features

Clinical feature	Hypertensive		Non-hypertensive		*P*-value	Statistical significance
	n	%	*n*	%		
Giddiness						
Present	22	78.6	43	59.7	0.076	Not significant
Absent	6	21.4	29	40.3		
Sweating						
Present	16	57.1	40	55.6	0.889	Not significant
Absent	12	42.9	32	44.4		
Palpitation						
Present	4	14.3	20	27.8	0.080	Not significant
Absent	24	85.7	52	72.2		
Vomiting						
Present	6	21.4	26	36.1	0.159	Not significant
Absent	22	78.6	46	63.9		
Tachycardia						
Present	9	32.1	29	40.3	0.452	Not significant
Absent	19	67.9	43	59.7		
Breathlessness						
Present	2	7.1	10	13.9	0.193	Not significant
Absent	26	92.9	62	86.1		

Table 3: Distribution of the study group as per the findings of physical examination

Parameter	Hypertensive		Non-hypertensive		*P*-value	Statistical significance
	Mean	SD	Mean	SD		
Temperature	97.32	1.33	96.99	1.49	0.301	Not significant
Respiratory rate	22.21	5.29	22.57	5.28	0.763	Not significant
Pulse	86.96	10.94	89.96	13.10	0.287	Not significant
Systolic BP	120.21	14.85	118.17	13.65	0.513	Not significant
Diastolic BP	79.07	6.92	76.28	5.84	0.044	Significant

Table 4: Distribution of the study group as per hematological and biochemical investigations

Parameter	Hypertensive		Non-hypertensive		*P*-value	Statistical significance
	n	%	*n*	%		
Anemia						
Present	13	46.4	33	45.8	0.957	Not significant
Absent	15	53.6	39	54.2		
Deranged creatinine						
Present	14	50.0	18	25.0	0.016	Significant
Absent	14	50.0	54	75.0		
Deranged fasting blood glucose						
Present	24	85.7	61	84.7	0.901	Not significant
Absent	4	14.3	11	15.3		
Deranged post lunch blood glucose						
Present	18	64.3	48	66.7	0.821	Not significant
Absent	10	35.7	24	33.3		

communicable to the NCD.[7] Ever since we have successfully controlled the communicable diseases, NCDs have been on the rise. The most common of these are diabetes and hypertension.

Hypertension and diabetes have an overlapping spectrum of clinicopathological features. In a study by Emdin *et al.*,[8] it was concluded that a 20 mm Hg higher SBP was associated with a 58% higher risk of new-onset diabetes, whereas a 10 mm Hg higher DBP was associated with a 52% higher risk of developing diabetes.

Hypertension and diabetes when occur together with central obesity and dyslipidemia, it is called as metabolic syndrome. Metabolic syndrome refers to a cluster of various interrelated cardiometabolic risk factors that promote the development of atherosclerotic cardiovascular disease and T2DM. The prevalence of metabolic syndrome in India is 11–41%.[9]

Not many studies have been conducted on these diseases due to the recent shift of focus. While there has been some degree of insight into the pathophysiology and long-term complications[10] of these diseases, the short-term or acute complications and their inter-relationship remain understudied.

Therefore, this study was conducted to assess the clinic-pathological features of hypertension and acute complications of diabetes mellitus.

In the present study, it was found that of the patients suffering from acute complications of diabetes, 28% were hypertensives.

Demographics

In the present study, the mean age was significantly more in the hypertensives (63.82 ± 7.87 years) compared to non-hypertensives (51.93 ± 13.30 years). It was also observed that females were affected more than males.

The prevalence of diabetes is more in females.[11] In the study by Duarte *et al.*,[12] it was observed that women have poor glycemic control than men. Thus, the prevalence of complications would be more in women.

The prevalence of hypertension is more in males. This was concluded in the survey by Choi *et al.*[13] and in the study by Cutler *et al.*[14] These differences are hypothesized to be due to both biological and behavioral factors.[15]

Accordingly were the findings in the present study.

Clinical Features

In the present study, no statistically significant difference was found in the symptoms of acute complications of diabetes, between the hypertensive patients and non-hypertensive patients.

It is plausible since the pathophysiology of diabetes and hypertension are inter-related, as is evidenced by the overlapping spectrum of presenting symptoms.[16] The common symptoms of hypertensive crisis at presentation are headache, chest pain, palpitations shortness of breath, vertigo, sweating, and nausea and vomiting.[17] However, no increase in the prevalence of presenting symptoms was found in patients with controlled hypertension.

Physical Examination

In the present study, the mean diastolic blood pressure was more in patients with hypertension as compared to patients without hypertension.

In acute complications of diabetes, especially DKA, there is dehydration from fluid loss secondary to glycosuria.[18] The systolic blood pressure reflects the pumping capacity of the heart, while the diastolic blood pressure is an indicator of the volume of blood and elasticity and recoil of blood vessels.[19] Therefore, diastolic blood pressure would be a better indicator of dehydration/fluid loss. The findings in the present study indicate some unknown mechanisms at play, preventing diastolic hypotension from an acute complication of diabetes in hypertensive patients.

Investigations

In the present study, the prevalence of deranged creatinine, indicating possible renal damage, was more in the hypertensive patients compared to non-hypertensives.

Hypertension and diabetes, both damage kidney in the long term. Hyperglycemia induces renal damage directly or through hemodynamic modifications and may involve the interplay of multiple cytokines.[20] Hypertension causes renal damage by its direct deleterious effects on kidney vasculature.[21] Therefore, it is plausible that the prevalence of deranged creatinine will be more in hypertensive patients.

Limitations

The study was limited by the ICU admission of patients of acute complications of diabetes mellitus. Therefore, the results may not be generalized.

CONCLUSION

From the present study, it can be effectively concluded that the epidemiological and clinic-pathological profile of the patients having acute complications of diabetes mellitus is significantly different in hypertensive patients than in the non-hypertensives, in some aspects. Acute complications of diabetes mellitus carry a grave consequence as they increase mortality and morbidity. Therefore, further studies need to be conducted to assess the profile of the patients having acute complications and to explore the effects of other comorbidities.

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Original Article

Hangman's Fracture of the Cervical Spine: A Prospective Study

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Abstract

Introduction: Hangman's fracture is the second most common fracture of all the C2 vertebral fractures. It has been observed, which accounts for 55% of cervical fractures. They form 23–25% of (C2) axis fractures.

Materials and Methods: All Type II and IIa hangman's fractures operated were included in this study. Twelve patients (eight men and four women) between 20 and 60 years of age diagnosed with unstable hangman's fracture, treated, and followed up in our department were included in the study. Ten patients were injured in road traffic accidents, and two were injured due to falls from height.

Results: The total number of patients included in the study was 12, the age range from 20 to 60 years; male-to-female ratio is 8:4. All patients presented with neck pain. In Type II and IIa cases, the anterior approach was made in ten cases, where the reduction was achieved with traction. In anterior cases, the reduction was maintained after fixation.

Conclusion: The anterior approach with primary internal stabilization is the appropriate option for unstable Type II, Type IIa hangman's fracture in cases was preoperative reduction that could be achieved. Using the anterior approach with the primary internal fixation of these fractures, solid fusion was achieved in all cases.

Key words: Fixation, Fracture, Fusion, Unstable

INTRODUCTION

The first and second cervical vertebrae differ, anatomically and functionally, from the remainder of the cervical spine. Half the rotation in the cervical spine takes place in the atlantoaxial joint, and a large part of the movement in the sagittal and frontal plane in the joints between the occipital bone, atlas, and axis. Hangman's fracture is a term described for bilateral pars fracture of C2.[1] In 1965, Schneider *et al.*[2] coined the term "hangman's fracture." Hangman's fracture, the second most common fracture of the second cervical vertebra, has been observed, which accounts for 4–7% of cervical fractures, and they form 23–25% of (C2) axis fractures.[3] All these fractures are classified according to the various patterns of translation and angulation of the C2 over C3. Life-threatening sequel in hangman's fractures is rare because the vertebral canal is sufficiently wide at this level and the fragments tend to separate, thereby often decompressing the spinal canal. Management of the hangman's fractures is controversial. Most of the hangman's fractures are treated conservatively.[4] If surgery is indicated, an anterior approach using a C2/C3 graft and plate fusion is usually preferred.[5] Treatment is aimed at near-normal cervical alignment. In this study, the authors studied the surgical outcomes in ten cases of hangman's fractures treated by anterior approaches.

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MATERIALS AND METHODS

All Type II and IIa of hangman's fractures operated were included in this study. Twelve patients (eight men and four women) in a total of 20–60 years of age diagnosed with unstable hangman's fracture, treated and followed up in our department are included in the study. Ten patients were injured in accidents by vehicle, and two were

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injured due to falls from height. Clinical and radiological evaluation was done. X-ray parameters measured were the translation of C2 over C3 and C2–C3 angulation. CT cervical spine was done to look for other associated fractures; the MRI-C spine was done to see the cord compression, disc fragmentation, and ligaments injury. Hangman' fractures were classified according to the Levine-Edwards classification; preoperatively, all patients were put on cervical traction of 2 kg. A high cervical extra-pharyngeal approach in all 12 patients, cervical discectomy, and autologous bone fusion of C2–C3 with a titanium plate were performed.

RESULTS

The total number of patients included in the study was 12, the age range from 20 to 60 years; male-to-female ratio is 8:4. All patients presented with neck pain. The patient was classified according to Type 2–8 cases [Figure 1] and four cases of Type IIa [Figure 2]. C2–C3 average angle in Type II is 9.5°; the angle in Type IIa is 13°. All patients were treated with the anterior approach in Type II and IIa cases anterior approach in ten cases, where the reduction was achieved with traction, in anterior cases, reduction was maintained after fixation [Figure 3]. Type of fracture pre-operative angle translation distance surgery type 2 9.5° 4 mm anterior fusion (8) Type 2 A 13° 3 mm anterior fusion (4).

Type of fracture	Pre-operative angle	Translation distance	Surgery
Type II	9.5°	4 mm	Anterior fusion (8)
Type IIa	13°	3 mm	Anterior fusion (4)

All cases were followed for an average period of 1 year and noticed to have bony fusion and sagittal alignment. Neck pain subsided in all ten patients, which was present preoperatively. Patients recovered well after surgery, and no complications were noted.

No bone graft or plate screws complications were observed in any of the cases during the follow-up period.

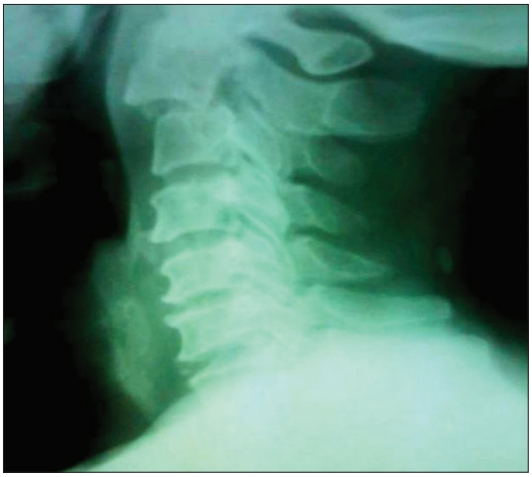

Figure 1: Type II hangman's fracture

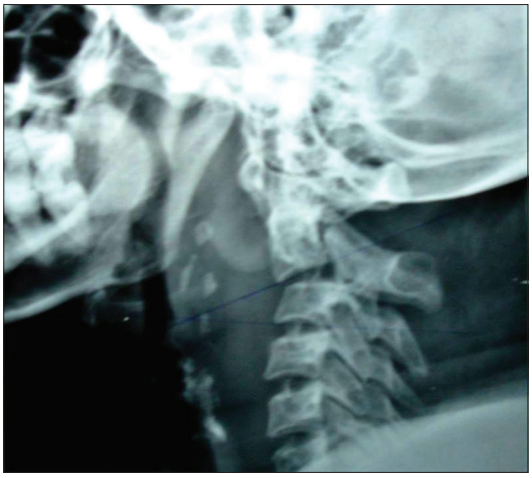

Figure 2: Type IIa hangman's fracture

DISCUSSION

Hangman's fracture also named as C2–C3 traumatic spondylolisthesis accounts for 4–7% of all cervical fractures and 25–30% of axis fractures. About 50–70% of the axis traumatic lesions are due to motor vehicle accidents, and 10–40% are due to falls from height.[6,7]

Management

Levine and Edward Type II and Type IIa hangman's fractures have been considered unstable due to translation and angulation of C2–C3.[8] The treatment for unstable hangman's fracture is still controversial.

Figure 3: C2–C3 anterior cervical discectomy and fusion

Most cases of hangman's fractures responded to conservative treatment comprised mild skeletal traction and external immobilization in a halo brace. Surgery is only necessary under certain conditions.[9]

Conservative

Patients were managed conservatively by various authors with halo immobilization; the literature revealed that the union rates of conservative treatments were nearly 100% in Type I, 60% in Type II, 45% in Type IIa, and 35% in Type III.[10]

Incomplete reduction of C2–C3 results in kyphosis, persisting neck pain in 60% of cases,[8] and decreased range of motion if angulation is more than 10.[6]

Indeed, accurate fracture reduction and realignment of C2–3 were seldom achieved with conservative treatment in unstable hangman's fractures.

Surgical Management

Failures and complications associated with conservative treatment can be addressed through surgical treatment.

Surgery is recommended if radiological controls demonstrate an increasing anterior displacement at the C2–3 level despite rigid immobilization. Further conditions necessitating surgical therapy include the dislocated Type IIa fractures (angulation >11° and anterior translation >3 mm); in exceptional cases of dislocated Type II fractures (anterior translation >3 mm), and Type III hangman's fractures.[8] Lesions combined with a traumatic C2–3 disc herniation compromising the spinal cord and established non-unions may also require surgery.[10,11]

Surgically treated patients with Type II and IIa require collar for 4 weeks postoperatively, however conservatively treated patient require Halo-vest for 3 months. Hence, the surgical treatment is beneficial over conservative therapy in terms of early ambulation.[1]

Surgery

Anterior, posterior, and combined approaches are employed to treat hangman's fractures.

Among the different posterior approaches, direct repair of the pars fracture has the advantage of preserving motion of the axis. Unfortunately, direct pars repair does not address instability at the disc and cord compression. Hence, when cord compression was noted, it is advised to make an anterior approach.[1,12,13]

CONCLUSION

The anterior approach with primary internal stabilization is an appropriate option for unstable Type II, Type IIa hangman's fracture in cases was preoperative reduction that could be achieved. Using the anterior approach with the primary internal fixation of these fractures, solid fusion was achieved in all cases.

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Original Article

Epidemiological Profile of Stroke in Central Kerala

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Abstract

Background: There is a rising trend in the incidence of stroke among Keralites, but proper data regarding the same are scarce. To date, no study has been published delineating the epidemiological profile of stroke in Central Kerala harboring a population of more than 5 million.

Objectives: The objectives of the study were to characterize the clinical profile, risk factors, type, and etiology of stroke in Central Kerala.

Methodology: A prospective cohort study was conducted in the Department of General Medicine in Amala Institute of Medical Sciences, Thrissur, Kerala, from January 2014 to January 2015 that evaluated 464 patients admitted with a diagnosis of stroke. Based on clinical examination and brain computed tomography/magnetic resonance image findings, patients were classified into ischemic and hemorrhagic stroke subtypes and enrolled.

Results: Of the total 464 patients, 44.6% were female and 55.4% were male. A maximum amount of cases were observed in the age group between 61 and 70 years. Among them, 63.6% of patients were hypertensive, 45.5% were diabetic, 12.7% had a cardiac disease, and 0.6% of patients had peripheral vascular disease. The incidence of hemorrhagic stroke was 27.8% and ischemic stroke was 72.2%. Most of the ischemic strokes were due to large artery atherosclerosis.

Conclusion: Our study has shown that systemic hypertension followed by diabetes mellitus was the prime risk factor contributing to stroke among Central Keralites. Tobacco use is widely prevalent among males in Central Kerala which could account for the increasing incidence of stroke among males. There is an urgent need to improve the lifestyle of people, especially in the age group between 61 and 70 years who were the most susceptible to stroke by implementing proper monitoring and control of modifiable risk factors.

Key words: Epidemiology, Hypertension, Kerala, Smoking, Stroke

BACKGROUND

Developing countries like India are having a huge burden of both communicable and non-communicable diseases. Among non-communicable diseases, stroke grabs a lion's share, in causing both mortality and morbidity among general population, especially the elderly. The poor are increasingly affected by stroke, because of both the changing population exposures to risk factors and, most tragically, not being able to afford the high cost for stroke care.

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The World Health Organization (WHO) defines stroke as "a clinical syndrome of rapidly developing focal or global disturbance of brain function lasting >24 h or leading to death with no obvious non-vascular cause."[1]

Kerala is a state in Southwest India spread over an area of 38,863 km^2 with a population of 33,387,677 as per 2011 census. The study center is located in Thrissur district and its catchment area includes Thrissur, Palakkad, and parts of Malappuram and Ernakulam districts together harboring a population of more than 5 million.

In the past one decade, stroke has emerged as a major public health problem in Kerala demanding robust interventions from the public sector health system to have well-designed protocols in place to improve patient safety, reduce mortality and morbidity due to stroke, and ensure good quality of life for stroke survivors.

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Stroke may be due to two major pathological subtypes including ischemic as well as hemorrhagic. Optimal patient management largely depends on whether the stroke is hemorrhagic or ischemic. Diagnosis and onset of treatment has to be immediate because the tolerance of the brain tissue to ischemia is lower than any other tissue.

Till date, no data have been published regarding epidemiological profile of stroke in Central Kerala. The analysis of the trend in stroke, its clinical profile, subtypes, etiology, and risk factors should provide valuable data that can further organize the health system structures and improve management protocol.

Objective

The objective of the study was to determine the demographics, risk factors, etiology, and clinical profile of acute stroke in Central Kerala.

METHODOLOGY

The study was conducted at the Amala Institute of Medical Sciences, Thrissur, a tertiary hospital in Central Kerala. Since January 2014, we have prospectively included patients with ischemic stroke and non-traumatic intracerebral hemorrhage within 72 h of admission. The study period was for 1 year till January 2015.

A detailed history was obtained from the patient and bystanders followed by a meticulous clinical examination. Furthermore, an informed consent was taken from the patient or bystanders for participating in the study. A plain computed tomography (CT) brain and magnetic resonance image brain were taken immediately. The study was conducted after acquiring consent from the scientific and ethics committee and by abiding the rules and regulations as per Helsinki Declaration.

Statistical Analysis

The data were consolidated and entered into Microsoft Excel and all analyses were performed using SPSS16 Software. Description of the sociodemographic characteristics and clinical features was done in terms of frequencies and percentages.

RESULTS

Epidemiology

Age and gender distribution

Of the total 464 patients, 207 were female and 257 were male [Figure 1].

The age range of 464 patients included in this study was 20–100 years. Maximum amount of cases were observed in the age group 61–70 years. While the most of the females belonged to the age group of 71–80 years, maximum males belonged to 61–70 years age group [Figure 2].

The presenting complaint among stroke patients included weakness, slurring of speech, altered consciousness, seizure, vomiting, headache, and sensory disturbances predominantly.

The usual comorbidities among these stroke patients were systemic hypertension, diabetes mellitus, cardiac disease, and peripheral vascular disease.

While 295 patients were hypertensive, 211 were diabetic and 59 had cardiac disease. Only three patients had peripheral vascular disease [Figure 3].

Of the 464 subjects studied, 129 were hemorrhagic stroke and 335 were ischemic strokes as confirmed by CT brain taken at the time of admission [Figure 4].

Ischemic stroke patients mostly presented with weakness and slurring of speech. Unlike ischemic stroke, hemorrhagic stroke patients most often presented with altered level of consciousness, seizure, vomiting, and headache [Table 1].

The most common etiology for ischemic stroke was large artery atherosclerosis followed by small vessel obstruction and cardioembolism [Figure 5].

Table 1: Distribution of symptoms among stroke subtypes (original)

Symptoms	Ischemic stroke (%)	Hemorrhagic stroke (%)
Weakness	69.60	52.70
Slurring of speech	53.40	41.90
Altered consciousness	31.60	67.40
Seizure	6.90	17.10
Vomiting	13.10	34.90
Headache	14.30	38.80
Sensory disturbances	6	4.70

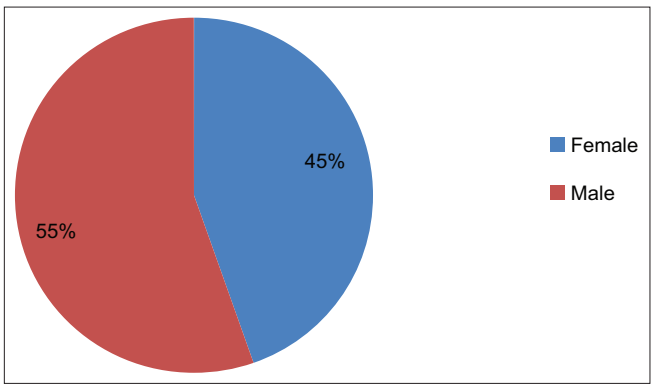

Figure 1: Gender distribution of stroke

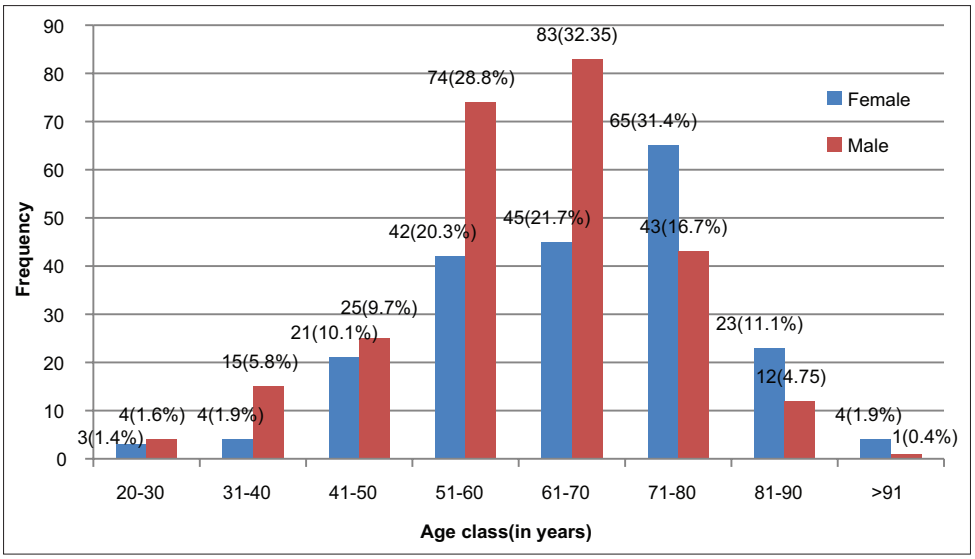

Figure 2: Age and gender distribution of stroke (original)

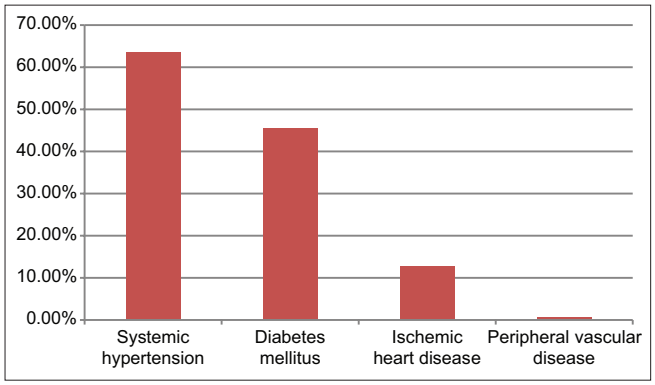

Figure 3: Distribution of comorbidities among stroke patients (original)

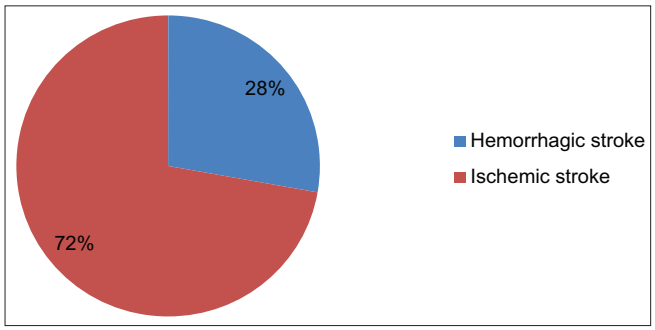

Figure 4: Distribution of stroke subtypes (original)

DISCUSSION

Age and Gender

Majority of these patients belonged to the age group of 61–70 years (n = 173). This is in comparison with the study done by Sridharan *et al.* in Kerala population where the mean age of stroke occurrence was 67 years.[2] The increasing incidence of stroke with increasing age has been demonstrated convincingly by the Framingham study.[3] While the maximum cases of females belonged to the age group of 71–80 years, maximum number of males belonged to 61–70 years age group. Out of the total study population, 55.4% (n = 257) were male and 44.6% (n = 207) were female making up the male-to-female ratio, 1.2:1 showing almost similar distribution between the two genders. This is again in tally with the findings of Framingham study.[3]

The main presenting complaint of stroke patients was weakness (n = 301, 64.9%) followed by slurring of speech (n = 233, 50.2%) and altered consciousness (n = 193, 41.6%). Headache, vomiting, seizure, and sensory disturbances were other complaints. Unlike ischemic stroke, hemorrhagic stroke patients presented predominantly with altered consciousness, headache, and vomiting. Their general condition was poor when compared to ischemic stroke at the time of admission.

Risk Factors

Hypertension (63.6%) and diabetes (45.5%) were frequent risk factors. Few had history of ischemic heart disease and rheumatic heart disease, and very few patients had peripheral vascular disease. Systemic hypertension alone or in combination with other risk factors can contribute significantly to stroke occurrence. Many studies have proven the role of these comorbidities in contributing to stroke. Lowering of blood pressure can significantly contribute to reduction of stroke incidence[4] and has been proven by many studies such as HOPE,[5] PROGRESS,[6] and LIFE study.[7] In the present study, 63.6% had systemic hypertension. This

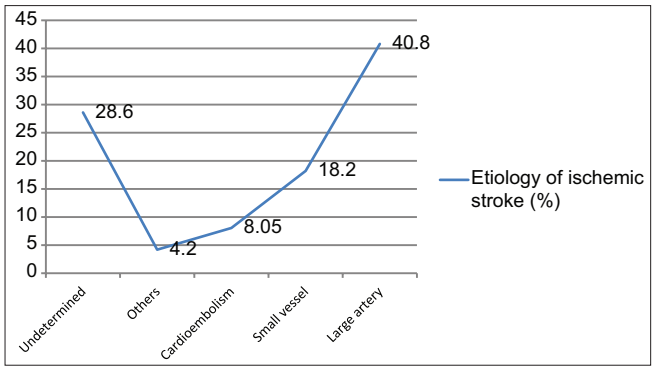

Figure 5: Etiology of ischemic stroke (original)

means almost two-third of the study population were hypertensive. The presence of hypertension could not be ruled out in the rest of the patients and hence the emphasis on periodic blood pressure measurements is highlighted. Ralph *et al.*[8] reported hypertension as the most powerful modifiable risk factor for stroke. Hypertension was more prevalent among hemorrhagic stroke (68.2%) when compared to ischemic stroke (61.8%). The SHEP study[9] was the first to show that treatment of isolated blood pressure specifically decreased the risk of hemorrhagic stroke. Thus far, the treatment of hypertension is the only proven preventive therapy for stroke.

Unlike hypertension, the incidence of diabetes mellitus in our study was only 45% reflecting that it is not a significant risk factor when compared to hypertension in the etiology of stroke. Tziomalos *et al.*[10] conducted a study which concluded that Type 2 diabetes is associated with a worse functional outcome of ischemic stroke. Furthermore, in the present study, the prevalence of diabetes is less among hemorrhagic strokes (39.5%) when compared to that of ischemic strokes (47.8%). Jørgensen *et al.*[11] had similar results and, in their study, intracerebral hemorrhages were 6 times less frequent in diabetic patients.

Smoking almost doubled the risk for stroke.[12] "Cigarette smoking is clearly identified as the chief preventable cause of death in our society and the most important public health issue of our time." This statement was first articulated in 1982 by the US Surgeon General C Everett Koop, and unfortunately, it remains accurate today. In the present study, more than two-third of the male stroke patients were smokers and none of the females smoked. Of the 257 males enrolled, 171 were smokers (66.55%). Among male hemorrhagic stroke patients, 75% were smokers and among ischemic stroke patients, 63% were smokers. The significantly higher frequency of smoking among males is probably related to the cultural background, as these habits are quite common among Indian males and are almost nil among females.

Epidemiology

Among the study population, 72.2% were ischemic strokes and rest 27.8% were hemorrhagic strokes as confirmed by CT brain. Reviewing the Indian stroke epidemiological data, the Mumbai registry has recorded 80.2% ischemic strokes and 17.7% hemorrhagic strokes.[13] Data from Kerala state were obtained from the Trivandrum Stroke Registry where 83.6% were ischemic strokes and 16.4% were hemorrhagic stroke.[2] While these data are from South Kerala, our study reflects the epidemiology of stroke in Central Kerala.

There were more strokes of undetermined type in patients enrolled from the rural communities because of a lack of neuroimaging information due to financial constraints. It was in Kolkata study where 32% of the patients had hemorrhagic stroke, which is the highest figure reported so far from India.[14]

Limitations

Our patients were mostly from the urban community and hence the results may not be applicable to rural population and this is a single hospital-based study.

CONCLUSION

- Age and gender distribution of patients with stroke in Central Kerala were consistent with the findings in similar studies done worldwide. The incidence of stroke was found to increase with age
- Among stroke subtypes, the incidence of ischemic stroke predominated over hemorrhagic stroke and this is comparable with other Indian studies
- While most of ischemic stroke patients presented with weakness as chief complaint, hemorrhagic stroke patients presented predominantly with altered sensorium, headache, and vomiting
- The general condition of hemorrhagic stroke patients was poor when compared to ischemic stroke patients at the time of admission
- Large artery atherosclerosis was the leading cause for ischemic strokes followed by small vessel occlusion and cardioembolism
- Systemic hypertension is the single largest risk factor for both ischemic and hemorrhagic stroke followed by diabetes and cardiac diseases
- Our study observed a high rate of tobacco use among males ending up in stroke which could be the reason for higher incidence of stroke among males than females. Henceforth, rehabilitation of tobacco users

and making them aware of the chaos tobacco can create to one's health is of prime importance.

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Original Article

An Observational Study of Placental Changes among Term and Preterm Babies Delivered in Tertiary Care Hospital

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Abstract

Background and Objective: Placental pathology has been implicated in the pathogenesis of preterm neonatal morbidity. However, the role of placental infection in the occurrence of neurological, lung, and infection morbidity among prematurely born infant remains controversial. Furthermore, there is disagreement regarding the association between sepsis in preterm neonate and *in utero* exposure to placental infection.

Objective: The present study was undertaken to investigate the association of placental pathology with the preterm and term delivery.

Materials and Methods: Design: This was a hospital-based observation study. The study included 100 placentas including 60 preterm placenta and 40 term placenta from singleton live birth delivered at Rajarajeshwari Medical College and Hospital from November 2018 to November 2019.

Results: As placental weight is one of the key indicators of fetal intrauterine status, among term placenta 26% weighed between 501 and 750 g and 14% weighed between 251 and 500 g. In the late preterm placenta, 6% were within 501–750 g and 38%were within 251–500 g. Among the early preterm placentas, 2% were found to be within 100–250 g and 14% were found to be within 251–500 g. Histopathological findings among term placenta in which 23% of the placentas were found to be with normal morphology, having two arteries and one vein embedded in myxoid matrix and unremarkable, maternal surfaces show mature vascularized villi and fetal parenchyma also shows mature villi and 5% showed features of chorioamnionitis, 8% of the placentas revealed occasional focal areas of calcification on the maternal as well fetal surfaces, 15% showed infarction, and 3% showed hemorrhagic changes. Histopathology findings among preterm placenta in which 14% normal morphology, 21% of chorioamnionitis, 10% shows focal and extensive areas of infarction with increased syncytial knots, 4% had hemorrhagic and perivasculitis changes with focal hyalinized villi, and 5% had villitis with mixed inflammatory infiltrate in the chorionic villi. Histopathology study among term and preterm comparison, it shows chorioamnionitis with Chi-square 19.604 with confidence interval of 35.66–77.04% with $P < 0.0001$, calcification with $P = 0.466$, placental infarction with confidence interval of 41.51–92.47% with $P = 0.0002$, placental hemorrhage with confidence interval of −31.33%–52.31% with $P = 0.613$, and villitis with confidence interval of 38.55–100% with $P = 0.002$. Relative risk with respect to histopathology among term and preterm placenta relative risk is 2.3 which means that preterm group has 2.3 times more risk of abnormal placental histopathology than term group.

Conclusion: Among histopathological study between term and preterm placenta, preterm placentas were most commonly associated with abnormal histopathological findings, among abnormal histopathological finding chorioamnionitis is the most common.

Key words: Gestational age, Placental pathology, Preterm infants;

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INTRODUCTION

A baby born before 37 completed weeks of gestation starting from the 1st day of last menstrual period is defined as a preterm baby. They are divided as late preterm, that is, babies born between 35 and 37 weeks of gestational age and early preterm, that is, babies born <35 weeks of

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gestational age. Preterm births are the second leading cause of death in children under 5 years of age. Of which, late preterm births (70%) being the most common.[1]

Placenta is the most accurate record of the infant's prenatal experience. It is a unique organ that arises *de novo* and is directly related to growth and development of the fetus. The placenta (Greek, *plakuos* = flat cake) is named on the basis of the gross anatomical appearance.[2]

Placenta provides a diary of gestational life. The placenta is often the most accessible and readily evaluable component of the triad of mother, infant, and placenta. It shows the cumulative effects of pregnancy-related events, reflects the intrauterine environment, and can be examined to a degree that the infant usually cannot.[3]

Placental examination has been self-explanatory in solving the litigation faced by the obstetricians during early times when the preterm babies arrived with neurological disabilities over a period of time.[4] Henceforth, placental examination serves as a key to recognize the underlying cause of preterm delivery Microscopic examination of the placenta helps to assess lesions such as chorioamnionitis, calcification, infarction, hemorrhage, villitis, and chorangiosis.

Chorioamnionitis is the inflammatory response to infections caused by microorganisms such as *Ureaplasma urealyticum*, *Gardnerella vaginalis*, *Mycoplasma*, *Fusobacterium*, *Chlamydia trachomatis, Streptococcus*, *Staphylococcus*, *Toxoplasma*, *Rubella*, *Cytomegalovirus*,[5] herpes virus, syphilis, malaria, and listeria. Placental tissues deposited with calcium are known as calcification which contributes to preterm delivery, especially in patients who are diagnosed with early preterm placental calcifications under ultrasonography.[6] Placental infarctions have found to be associated with late preterm with decreased fetoplacental blood supply subsequently causing preterm delivery.[7] Villitis is the inflammation of the chorionic villi; chronic villitis has association with preterm delivery.[5]

As the complications and the cost of management of the preterm babies are huge burden for the society as well as the family, identification of the cause for the preterm birth would throw a light to prevent preterm mortality and morbidity. This prospective study was conducted to determine the placental weight and pathological findings corresponding to the gestational age and lays down foundation for the pediatricians as well as the obstetricians by providing guidelines for the pathogenesis preterm delivery. Once the etiopathogenesis of the placental pathology is identified, further studies in this field help in providing interventions.

MATERIALS AND METHODS

Study Design

This was a hospital-based comparative study.

Type of Study

This was an observational study.

Study Site

This study was conducted at the Department of Paediatrics, Rajarajeshwari Medical College and Hospital.

Study Duration

Duration of the study will be conducted over a period of 12 months from November 2017 to November 2018.

Sample Size

n = 100 sample size is calculated based on previous years of incidence of preterm delivery in Rajarajeshwari Medical College in which 60 samples are of preterm placenta and 40 samples are of term placenta.

Selection Criteria

Inclusion criteria

The following criteria were included in the study:

1. All babies born with <37 completed weeks.
2. Patient willing to give an informed consent to participate in the study.

Exclusion criteria

The following criteria were excluded from the study:

1. Induced preterm deliveries secondary to:-
    - Scar tenderness
    - Diabetes mellitus
    - Pregnancy-induced hypertension.

After taking an informed written consent to participate in these study from participant and attenders, a detailed maternal history regarding any h/o fever and fowl smelling vaginal discharge was taken and look for any fetal tachycardia, maternal tachycardia, and uterine tenderness. As routine workup for preterm deliveries, maternal complete hemogram, C-reactive protein, and high vaginal swab were taken and were noted.

Collection, Storage, and Transport of Samples

Placental samples which include patients with gestational age <37 weeks and term deliveries after completing 37 and within 42 weeks of gestational age (which is considered as control group) were collected immediately after delivery and examined thoroughly after washing under running tap water and were stored in 10% neutral buffered formalin container after obtaining photographs and transported to the laboratory for further investigations.

Gross Examination

Placental weight (using weighing scale) was noted after trimming the membranes. After 48 h of fixation with 10% neutral buffered formalin, placental membranes were examined for rupture and cut from the ruptured site up to the placental margin and kept aside for blocking making a Swiss roll with ruptured site as the starting point and placental margin as the end point. Shape, size, completeness, and consistency are noted.

The umbilical cord is assessed for length, the color, knots, hematomas, and thrombosis, and the cut section of the cord is obtained for blocking. Both maternal and fetal surfaces are examined for the color change, appearance of vessels on fetal surface and number of cotyledons on the maternal surface is noted. Representative tissue bits were obtained from appropriate areas from both normal and abnormal areas, and the placental tissues were sent for processing.

Microscopic Examination

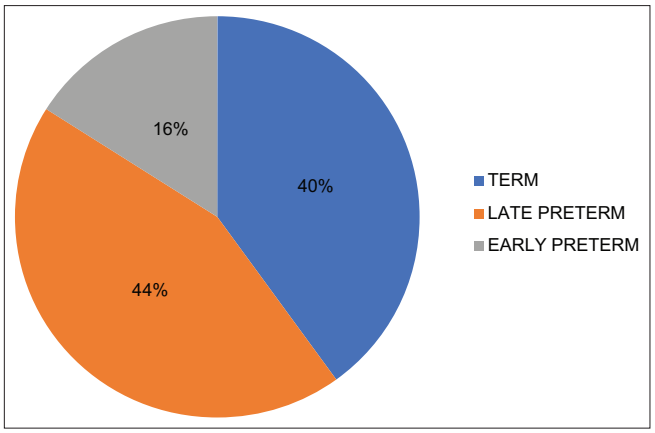
The stained placental slides were examined using compound microscope under ×10 and ×40. Changes such as chorioamnionitis, calcification, villitis, infarction, hemorrhage, chorangiosis, hyalinized villi, and perivasculitis were observed and the final observation were statistically analyzed and recorded accordingly.

DISCUSSION

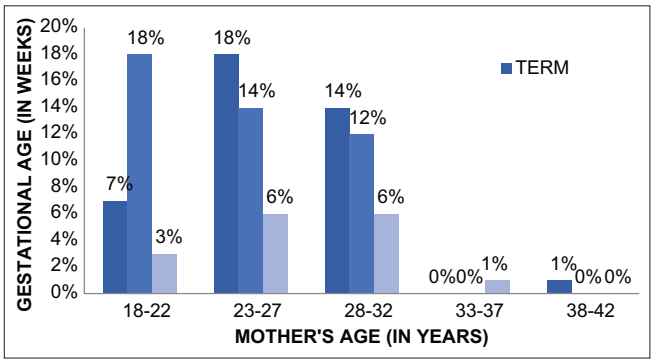
The placenta is a dynamic organ which plays a key role in maintaining fetal and maternal wellbeing. Fetal growth restriction and placental pathology go hand in hand. It is generally accepted that intrauterine events have an important effect on neonatal mortality and the development of long-term morbidity.[8] Therefore, placental examination may represent a means of investigating the intrauterine past to explain the present condition of the neonate. Timely examination of the placenta may even help in guiding therapies or surveillance of infants deemed at increased risk for mortality or significant morbidity.[9]

In our study, among 100 placental study, 40 cases (40%) were term and 60 cases (60%) were preterm placentas, in which early preterm were 16 (16%) and late preterm were 44 (44%) [Graphs 1-10].

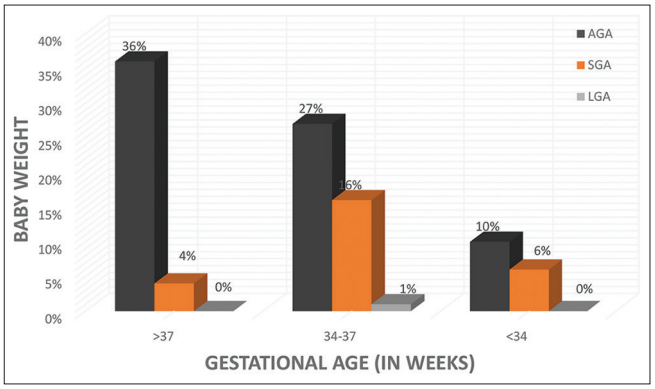
As placental weight is one of the key indicators of fetal intrauterine status, among term placenta, 26% weighed between 501 and 750 g and 14% weighed between 251 and 500 g. In the late preterm placenta, 6% were within 501–750 g and 38% were within 251–500 g. Among the early



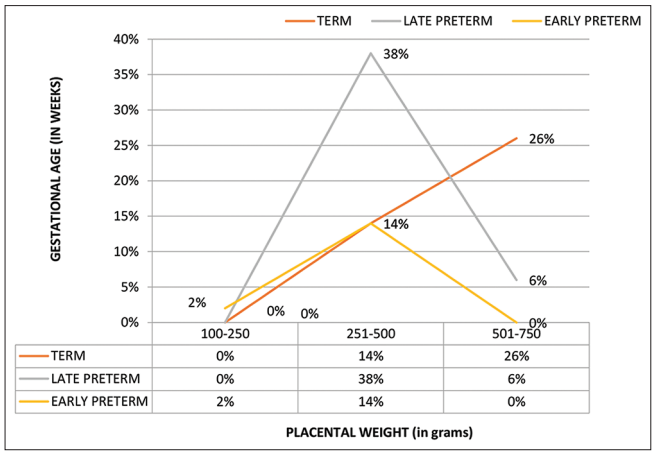
Graph 1: Percentage of gestational age. The study includes 100 cases out of which 40 (40%) cases were term and 60 cases (60%) were preterm including early and late preterm. Among which 44 (44%) were late preterm and 16 (16%) were early preterm



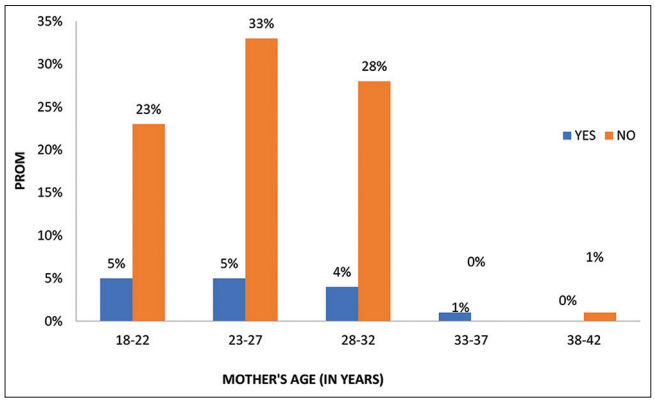
Graph 2: Graph explains the relationship between the age of mother with gestational age in weeks. Among the age group of 18–22 years, 23–27 years, 28–32 years; 7%, 18%, 14% are term deliveries respectively, about 18%, 14%, 12% are late preterm deliveries, respectively, and 3%, 6% and 6% were early preterm deliveries, respectively



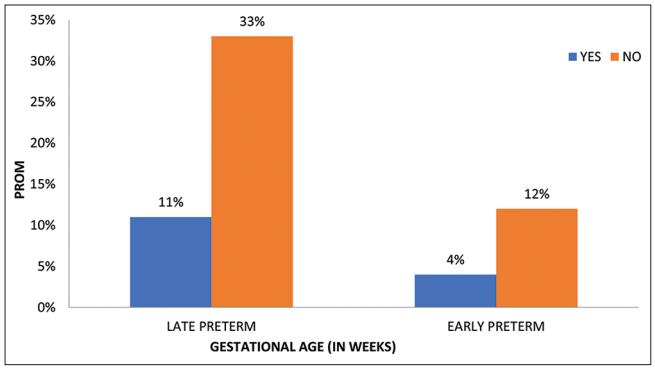
Graph 3: Comparison between gestational age and the weight of the baby. According to Fenton's centile chart, small for gestational age (SGA) ≤10th percentile. Appropriate for gestational age (AGA) = 10th–90th percentile. Large for gestational age (LGA) ≥90th percentile. Graph depicts the comparison of gestational age with the weight of the baby, among 40 term babies, 4 was found to be SGA and 36 were AGA. Among 16 early preterm babies, 10 were AGA and 6 were SGA. Out of 44 late preterm babies 16 were SGA, 27 were AGA, and 1 was LGA



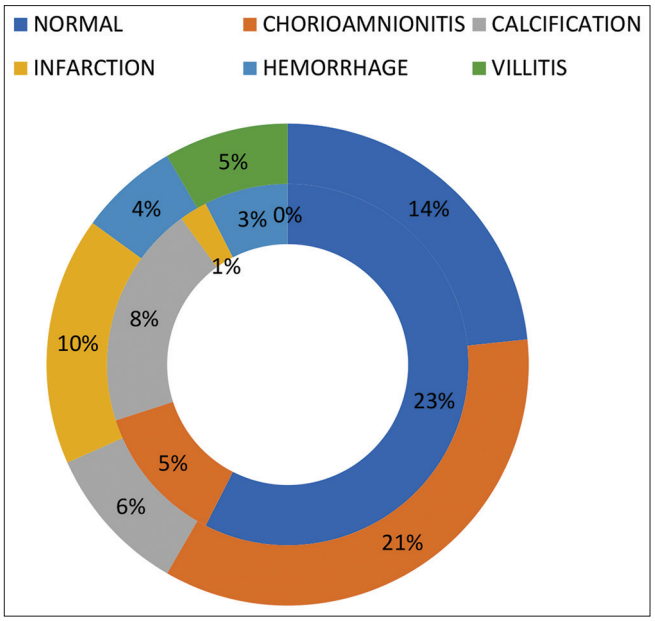
Graph 4: Comparison between gestational age and placental weight. Graph shows the comparison between gestational age and placental weight. Among the term placentas, 26% weighed 501–750 g and 14% weighed between 251 and 500 g. In the late preterm placentas, 6% were within 501–750 g and 38% were within 251–500 g. Among the early preterm placentas, 2% were found to be within 100–250 g and 14% were found to be within 251–500 g. There is increase in placental weight with gestational age of more than 37



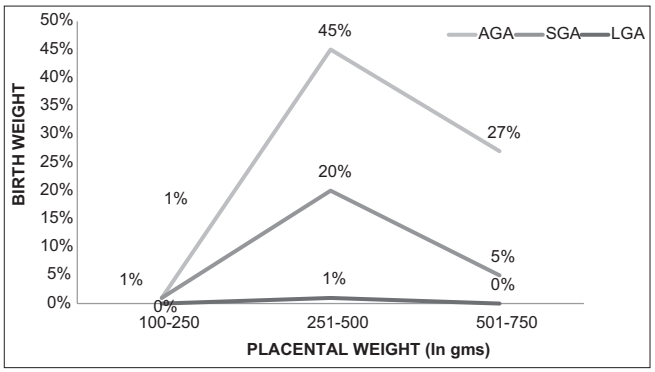
Graph 5: The role of mother's age with premature rupture of membrane (PROM). Mother's within the age group of 18–37 years presented with PROM. Higher at 18–27 years of age



Graph 6: Comparison between gestational age and premature rupture of membrane (PROM). Graph depicts the comparison between gestational age and PROM in early and late preterm delivery. About 11% of cases of late preterm presented with PROM and 4% cases of early preterm presented with PROM



Graph 7: Histopathological findings in term and preterm deliveries. Inner area of the doughnut shows the histopathological findings in term placentas in which 23% of the placentas were found to be with normal placental morphology; having two arteries and one vein embedded in the myxoid matrix and unremarkable, maternal surface shows mature vascularized villi lined by inner cytotrophoblast and outer syncytiotrophoblast with occasional syncytial knots, fetal parenchyma also shows mature terminal villi and 5% showed features of chorioamnionitis, 8% of the placentas revealed occasional focal areas of calcification on the maternal as well fetal surfaces. About 1% showed infarction and 3% showed hemorrhagic changes. Outer area of the doughnut shows the histopathological findings in preterm placentas in which the placental tissue reveals 14% of normal morphology, 21% of chorioamnionitis with inflammatory infiltrate and edema in the membrane with increased syncytial knots, 6% shows focal areas of calcification, 10% shows focal and extensive areas of infarction with increased syncytial knots, 4% had hemorrhagic and perivasculitic changes with focal hyalinized villi, and 5% had villitis with mixed inflammatory infiltrate in the chorionic villi

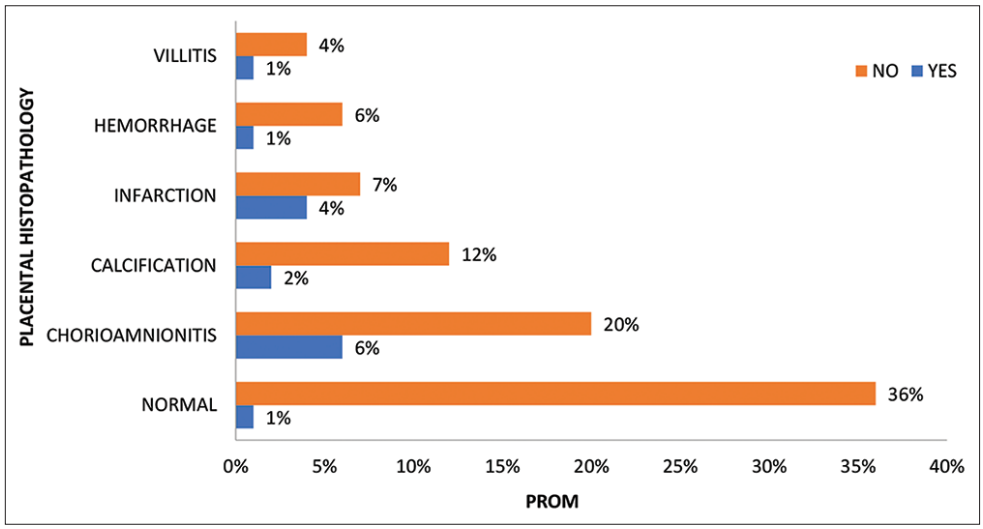


Graph 8: Correlates placental weight and birth weight of the baby. Within 100–250 g of placental weight 1%, 1%, and 0% were appropriate for gestational age (AGA), small for gestational age (SGA), and large for gestational age (LGA), respectively. Within 251–500 g of placental weight, 45%, 20%, and 1% were AGA, SGA, and LGA, respectively. Within 501–750 g, 27%, 5%, and 0% were AGA, SGA, and LGA, respectively. As the placental weight increases, baby's birth weight also increases

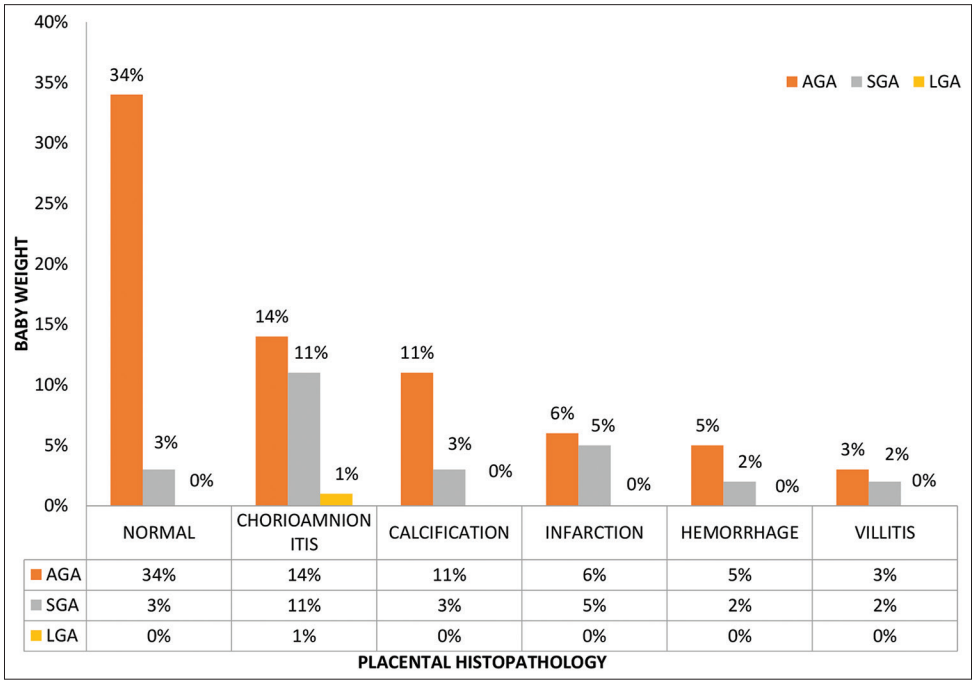
preterm placentas, 2% were found to be within 100–250 g and 14% were found to be within 251–500 g [Graph 4].

Histopathological findings among term placenta in which 23% of the placentas were found to be with normal morphology, having two arteries and one vein embedded in myxoid matrix and unremarkable, maternal surfaces show mature vascularized villi, and fetal parenchyma also shows mature villi and 5% showed features of chorioamnionitis, 8% of the placentas revealed occasional focal areas of calcification on the maternal as well fetal surfaces, 15% showed infarction, and 3% showed hemorrhagic changes [Graph 7].

Histopathology findings among preterm placenta in which 14% normal morphology, 21% of chorioamnionitis, 10% shows focal and extensive areas of infarction with increased syncytial knots, 4% had hemorrhagic and perivasculitis



Graph 9: Relationship between premature rupture of membrane (PROM) and histopathological findings in term and preterm deliveries. In the studies of 100 cases, 15 cases presented with PROM with consisted of 1% with normal placental histopathology, 6% with chorioamnionitis, 2% with calcification 4% with infarction, 1% with hemorrhage, and 1% with villitis



Graph 10: Relation between weight of the baby and histopathologiccal findings in term and preterm placentas. It is illustrated that the placentas of appropriate for gestational age baby accounted 34% of normal placental morphology, 11% of chorioamnionitis, 11% of calcification, 6% of infarction, 5% of hemorrhage and 3% of villitis. Small for gestational age babies accounted with 2% of normal placental morphology, 11% of chorioamnionitis, 3% of calcification, 5% of infarction, 2% of hemorrhage, and 2% of villitis. About 1% placentas of large for gestational age baby had chorioamnionitis

changes with focal hyalinized villi, and 5% had villitis with mixed inflammatory infiltrate in the chorionic villi [Graph 7].

Histopathology study among term and preterm comparison, it shows chorioamnionitis with Chi-square 19.604 with confidence interval of 35.66%–77.04% with $P < 0.0001$, calcification with $P = 0.466$, placental infarction with confidence interval of 41.51–92.47% with $P = 0.0002$, placental hemorrhage with confidence interval of −31.33–52.31% with $P = 0.613$, and villitis with confidence interval of 38.55%–100% with $P = 0.002$.

Histopathology among term and preterm placenta relative risk is 2.3 which means that preterm group has 2.3 times more risk of abnormal placental histopathology than term group.

CONCLUSION

Among histopathological study between term and preterm placenta, preterm placentas were most commonly associated with abnormal histopathological finding among which chorioamnionitis is most common abnormal pathology.

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Original Article

Comparison of Analgesic Effect of Fentanyl and Fentanyl with Midazolam as an Adjuvant to Intrathecal Bupivacaine in Lower Limb Surgeries

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Abstract

Introduction: Coadministration of drugs with synergistic effects considered one of the methods to increase the effectiveness of analgesia. The aim of this study is to evaluate the efficacy of midazolam to potentiate the analgesic effect of fentanyl as an adjuvant to bupivacaine.

Materials and Methods: This is a hospital based prospective, randomized, double-blind interventional control study conducted at SMS medical college and hospitals, Jaipur. A total of 90 patients were enrolled in the study. They were allocated into three groups, 30 in each. A total of 3.7 ml study drugs injected in each group. Intraoperative monitoring of hemodynamic parameters, duration of surgery, onset of sensory and motor block, duration of analgesia, sensory and motor block, and incidence of adverse effects was done and compared.

Results: There was no significant difference in mean pulse rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure ($P > 0.05$). The mean duration of surgery in Group A, B, and C was 101.3 ± 13.08, 92.93 ± 15.28, and 95.93 ± 16.03 min, respectively ($P > 0.05$). The mean onset time of sensory block in Group A was 7.29 ± 1.23, in B 4.92 ± 0.60, and in C 4.79 ± 0.91 min ($P < 0.05$). The mean onset time of motor block in Group A was 8.75 ± 0.55, in B 7.79 ± 0.42, and in C 7.57 ± 0.29 min. In Group A, mean time of sensory block was 194.4 ± 6.80, in B 236.60 ± 12.79, and in C 254.30 ± 7.32 min. In Group A, mean duration of motor block was 180.2 ± 5.22, in B 188.7 ± 4.04 and in C 199.6±6.69 min. In Group A, mean duration of analgesia was 215.7 ± 14.6, in B 445.8 ± 18.92, and in C 522.3 ± 16.33 min. The incidence of adverse effects was insignificant.

Conclusion: We conclude that midazolam potentiates the effect of fentanyl in terms of prolonged duration of analgesia and prolonged motor and sensory block when used as an adjuvant of bupivacaine without any significant hemodynamic compromise.

Key words: Adjuvant, Analgesia, Fentanyl, Intrathecal, Midazolam, Prolonged

INTRODUCTION

Perioperative pain management is a topic of concern as postsurgical pain is the most common complication of any surgery. A national survey conducted in the United States depicted, acute post-operative pain continues to be undermanaged with up to 60% of patients experiencing moderate to severe pain at hospital discharge.[1]

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Optimal perioperative pain management facilitates early post-operative ambulation, rehabilitation, and is considered a prerequisite to enhance recovery. The central neuraxial blockade is one of the most commonly used regional anesthesia for lower limb surgeries.

Anesthesiologists are at the heart of perioperative analgesic management, both as prescribers and administrators. During surgery, pain relief is their main aim.

Intrathecal administration of drugs in combination results in prolonged and better analgesic effect as compare to individual drug administration. In combination drug usage, doses of drugs also reduce which gives another advantage in avoiding their dose-related adverse effects.[2]

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0.5% hyperbaric bupivacaine is the most commonly used drug for spinal anesthesia; however, the most important disadvantage of the single injection is its limited duration.[3]

Opioids like fentanyl are the most common adjuvant drugs for prolongation of intraoperative and post-operative analgesia.[4,5] Midazolam produces a synergistic effect when administered with bupivacaine. Literatures have shown that administration of intrathecal midazolam with local anesthetics prolongs the duration of anesthesia and analgesia.[6-8]

This study was conducted to evaluate the efficacy of intrathecal midazolam to potentiate the analgesic effect of fentanyl as an adjuvant to bupivacaine in lower limb surgeries.

MATERIALS AND METHODS

After approval from the ethics and research review board of our institute, 90 eligible cases were randomly allocated into three groups using a computerized random number table. Thirty patients enrolled in each group.

1. Group A: Hyperbaric Bupivacaine + Normal Saline
2. Group B: Hyperbaric Bupivacaine + Fentanyl + Normal Saline
3. Group C: Hyperbaric Bupivacaine + Fentanyl + Midazolam.

A total of 3.7 ml drug injected in each group. Drugs were prepared and given by anesthetist other than the anesthetist who observed study variables. Thus, neither the patient nor the anesthetist (observer) was known to the drug used, that is, double-blinding was applied.

Inclusion Criteria

The following criteria were included in the study:

- Patients aged 20–65 years
- Weight – 40–60 kg
- ASA Grade I-II.
- Undergoing lower limb surgeries of duration <120 min.

Exclusion Criteria

The following criteria were excluded from the study:

- Not willing to give consent
- Any deformity or local sepsis in spinal lumbar region
- Severe hypovolemia increased intracranial pressure
- Any bleeding or coagulation abnormalities
- Hb <10 g%
- Pre-existing neurological, cardiovascular, metabolic, hepatic, respiratory, or renal disease
- Hypersensitivity to any of the study drugs
- Severe AS or MS
- In whom spinal anesthesia failed, the desired level of highest sensory block (T5-T6) not achieved and general anesthesia was required.

All patients underwent thorough pre-anesthetic check-up, including history, general physical and systemic examination, vital parameters, and ASA grading.

After written and informed consent, patients were allocated to one of the three groups. Pre-operative baseline readings of NIBP, PR, and saturation were noted. After securing an IV access, all patients irrespective of the group were preloaded with Ringer lactate 15 ml/kg over 10 min. Under all aseptic precautions, spinal anesthesia was performed at the L_3–L_4 interspace, with the patient in sitting position using a 25G Quincke spinal needle. Group A received intrathecal 0.5% hyperbaric bupivacaine 3.0 ml+0.7 ml 0.9% normal saline, Group B 0.5% hyperbaric bupivacaine 3.0 ml+0.5 ml fentanyl 25 μg+0.2 ml of 0.9% normal saline, and Group C 0.5% hyperbaric bupivacaine 3.0 ml+0.5 ml fentanyl 25 μg+0.2 ml midazolam 1 mg. The patient was placed in a supine position immediately after spinal injection. An indwelling urinary catheter was inserted. Intraoperative fluid management was done according to hemodynamic parameters. Vitals were recorded at 5 mins interval for the first 30 mins from the time of injection of the spinal solution and then after every 10 mins for the complete period of surgery.

Intraoperative monitoring of hemodynamic parameters, duration of surgery, onset of sensory and motor block, duration of analgesia, sensory and motor block, and incidence of adverse effects was done and compared.

The level of sensory block was assessed every 2 min after intrathecal injection of the drug by using 20G hypodermic needle (pinprick method) on midclavicular line on both sides until the level had stabilized for four consecutive tests. The onset of sensory block was defined as the time from the intrathecal injection of the drug to the time taken to achieve anesthesia to pinprick at T10 dermatomal level. The duration of sensory block was between the onset of sensory block to two-segment regression time.

The onset of motor block was defined as the time taken for the motor block to reach modified Bromage 3. The degree of motor block was assessed every 2 min until the highest modified Bromage score is achieved. The duration of motor block was the time between onset time and offset time.

The duration of analgesia was the time from the intrathecal injection to the first request of analgesia at VAS 3 was noted.

Post-operative Evaluation

Immediately after operation patients were shifted to recovery room.

1. Vitals – PR, NIBP, and saturation were recorded at a regular interval of 30 min for 8 h
2. Two segment regression time – Time of regression of sensory block by two segments from the highest level attained
3. Duration of analgesia – Analgesia duration was observed and recorded following pain scoring system – visual analog score (VAS). VAS consisted of a 10 cm horizontal paper strip with two endpoints labeled "No Pain" and "Worst pain ever." When patient complaints of pain in ward or recovery room, the patient was asked to mark the strip at a point that corresponds to the level of pain intensity, the patient presently felt. VAS score was serially assessed at half an hour interval starting from 60 min until the patient complains of pain (VAS >3).

The duration of effective analgesia was measured as time from the intrathecal drug administration to the patient's VAS score = 3 either in the recovery room or ward and was recorded in minutes. The patient's VAS = 3 and administration of rescue analgesia constituted the endpoint of the study. Intramuscular diclofenac was given as a rescue analgesic. The patient was kept under observation for a period of 24 h for routine post-operative monitoring.

Statistical analysis of the data was done with software – (Statistical Package for the Social Science) version 20.0.0 (SPSS Inc., Chicago, Illinois, USA). For a significant difference in the proportion of cases, a Chi-square test was applied. For significance, *P*-value was calculated. The continuous variables were analyzed by applying a one-way ANOVA test and *post hoc* test Tukey for intergroup comparison.

RESULTS

A total of 90 cases were enrolled in the study and divided into three groups. There was no drop-out.

Demographic Data

The mean age in Group A, B, and C was 43.13 ± 7.80 years, 44.23 ± 4.22 years, and 41.40 ± 5.28 years, respectively. Mean weight in Group A, B, and C was 61.33 ± 7.26 kg, 62.20 ± 6.72 kg, and 63.80 ± 7.37 kg, respectively. Mean height in Group A, B, and C was 163.70 ± 7.77 cm, 163.53 ± 7.52 cm, and 163.23 ± 7.90 cm, respectively. Among 90 patients, 67 were female and 23 were male.

Physical status of the patient was judged using ASA grading. Group A had 24 patients of ASA Grade I (80%) and 6 patients of Grade II (12.5%). Group B had 27 patients of ASA Grade I (90%) and 3 of Grade II (30%). Group C had 25 of ASA Grade I (83.33%) and 5 of Grade II (16.67%).

Hemodynamic Parameters

We observed pulse rate, systolic blood pressure (SBP), and diastolic blood pressure (DBP) at various time intervals. There was no statistically significant difference at different time intervals ($P > 0.05$). We also noted the intraoperative mean arterial pressure (MAP) which was statistically non-significant.

Duration of Surgery

The mean duration of surgery in Group A, B, and C was 101.3 ± 13.08 min, 92.93 ± 15.28 min, and 95.93 ± 16.03 min, respectively. There was no statistically significant difference ($P > 0.05$).

Onset of Sensory Block

The mean onset time of sensory block in Group A was 7.29 ± 1.23 min, in B 4.92 ± 0.60, and in C 4.79 ± 0.91 min. The difference was statistically significant ($P < 0.05$) [Figure 1].

The mean onset of sensory block was higher in Group A as compared to Group B and C. *Post hoc* Tukey test revealed that the mean onset of sensory block was statistically not significant between Group B and C ($P > 0.05$).

Onset of Motor Block

Mean onset time of motor block in Group A was 8.75 ± 0.55 min, in B 7.79 ± 0.42, and in C 7.57 ± 0.29 min. The mean onset of motor block was higher in Group A as compared to Group B and C [Figure 2]. This difference showed statistical significance ($P = 0.000$). *Post hoc* Tukey test revealed that mean onset of motor block was statistically non-significant between Group B and C.

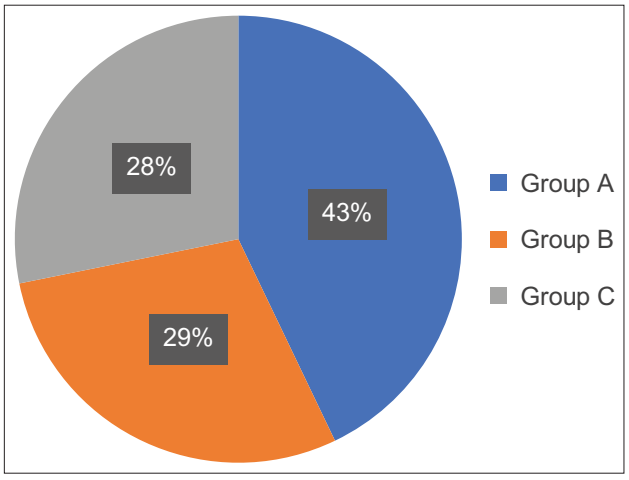

Figure 1: Comparison of onset of sensory block among study groups

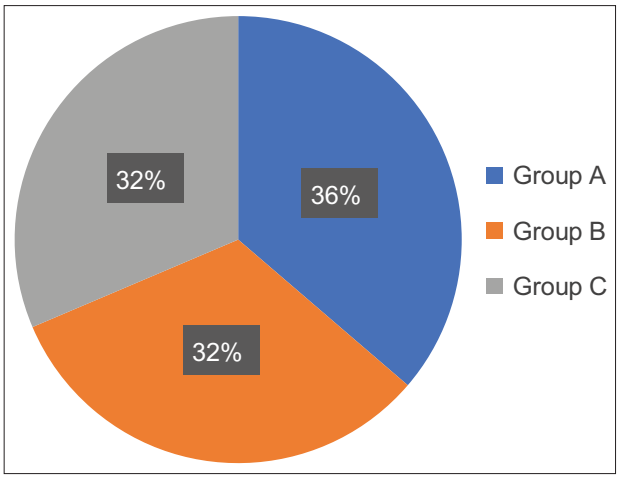

Figure 2: Comparison of onset of motor block among study groups

Duration of Sensory Block

In Group A, mean duration of sensory block by two-segment regression was 194.4 ± 6.80 min, in B 236.60 ± 12.79, and in C 254.30 ± 7.32 min. It was more in Group C as compared to Group A and B. Statistically significant difference was noted ($P = 0.000$). *Post hoc* Turkey test revealed that there was a statistically significant difference among the groups.

Duration of Motor Block

In Group A, mean duration of motor block was 180.2 ± 5.22 min, in B 188.7 ± 4.04, and in C 199.6 ± 6.69 min. There was a significant difference among the groups ($P < 0.05$). The mean duration of motor block was higher in Group C as compared to A and B. *Post hoc* Tukey test compared the *P*-value between the groups showed a statistically significant difference among all groups.

Duration of Analgesia

In Group A, mean duration of analgesia was 215.7 ± 14.6 min, in B 445.8 ± 18.92, and in C 522.3 ± 16.33 min. There was a statistically significant difference between Group A and B (P = 0.000), Group A and C (P = 0.000), and Group B and C (P = 0.000). This difference was statistically significant ($P < 0.001$). Group C had the longest duration of analgesia as compared to Group A and B.

Incidence of Side Effects

We observed various side effects intraoperatively and in the early post-operative period such as hypotension, bradycardia, nausea, and vomiting in all three groups. The incidence of hypotension was 20%, 13.33%, and 26.67% in Group A, B, and C, respectively. The incidence of bradycardia was 6.67%, 0%, and 10.0% in Group A, B, and C, respectively. The incidence of nausea and vomiting was 13.33%, 13.33%, and 13.33% in Group A, B, and C, respectively. There were no associated complications in 60.00%, 80.00%, and 50.00% cases of Group A, B, and C, respectively. We revealed that there was no statistical significance in their incidence.

Table 1 is showing a comparison of various study factors mentioned above among Group A, B, and C along with their P-values to describe their statistical significance.

DISCUSSION

The chore of medicine is to preserve and restore patient's health and to minimize their suffering. To achieve these goals, intellection about pain is a must because pain is universally understood as a distressing feeling, especially in post-operative period.

Spinal anesthesia is the most commonly used technique for lower limb surgeries. However, post-operative pain control is a major problem because spinal anesthesia using only local anesthetics is associated with relatively short duration of action, and thus early rescue analgesic is needed in the post-operative period. However, a combination of drugs with synergistic effects can enhance the anticipated impacts, and the patient may suffer from fewer side effects due to insignificant concentrations of each drug.

Intrathecal adjuvants are added to improve the quality of neuraxial blockade and prolong the duration of analgesia. Used intrathecally, fentanyl improves the quality of spinal blockade as compared to plain bupivacaine and confers a longer duration of post-operative analgesia. Intrathecal midazolam as an adjuvant can be used to improve post-operative analgesia.

Demographic Data

Regarding the age of patients, our study concurs with the study of Gupta *et al.*[9] where the mean age of patients was 40 ± 2.5, 39.1 ± 10.2, and 42.9 ± 12.6 years which is comparable with Group A, B, and C of our study, respectively. The mean weight of patients in the present study was comparable with the study of Gupta *et al.*[9] where it was 46.8 ± 8.7, 50.9 ± 8.0, and 58.7 ± 10.6 kg respective to our study groups.

Similarly, the mean height of the population of Group A, B, and C of our study was comparable with the study of Gupta *et al.*[9] where it was 161.1 ± 1.5, 161.0 ± 1.4, and 162.2 ± 1.1 cm respective with our study groups. To the best of our knowledge, no study described ASA physical status of the study population.

Hemodynamic Parameters

Our results concur with the study of Gupta *et al.*,[9] who observed that changes in PR, SBP, and DBP between

Table 1: *P*-value of comparison of various study factors among groups

Factors compared among groups	*P*-value		
	Group A versus B	Group A versus C	Group B versus C
Onset of sensory block	0.000	0.000	0.506
Onset of motor block	0.000	0.000	0.526
Duration of sensory block	0.000	0.000	0.000
Duration of motor block	0.000	0.000	0.000
Duration of analgesia	0.000	0.000	0.000

the groups and within the groups were not statistically significant with $P = 0.735$, $P = 0.148$, and 0.171, respectively. Shah *et al.*[10] observed no significant decrease in MAP when midazolam was used as an adjuvant with bupivacaine.

Onset of Sensory Block

Gupta *et al.*[9] observed that there was a statistically significant difference in time of onset of the sensory block between Groups B (bupivacaine) and BF (bupivacaine plus fentanyl) ($P = 0.000$) as well as between Groups B and BFM (bupivacaine + fentanyl + midazolam) ($P = 0.000$). There was no clinically or statistically significant difference in the time for onset of the sensory block between Groups BF and BFM ($P = 0.054$). Usmani *et al.*[11] observed a significant difference in time of onset of the sensory block when fentanyl was combined with bupivacaine. When midazolam was added to the bupivacaine, Agrawal *et al.*[12] observed no significant difference in onset of sensory blockade time.

Onset of Motor Block

Gupta *et al.*[9] concluded that there was a statistically significant difference in time of onset of the motor block between Groups B and BF ($P = 0.000$) as well as between Groups B and BFM ($P = 0.000$). There was no clinically or statistically significant difference in the time for onset of the motor block between Groups BF and BFM ($P = 0.054$). Usmani *et al.*[11] observed a significant difference in time of onset of motor block when fentanyl was combined with bupivacaine. When midazolam was added to the bupivacaine, Agrawal *et al.*[12] observed no significant difference in onset of motor blockade.

Duration of Surgery

A study almost similar to the present study done by Gupta *et al.*[9] and they observed duration of surgery was 128.8 ± 39.7, 125.6 ± 38.3, and 124.2 ± 35.8 min in their groups respective to our study groups.

Duration of Sensory Block

Gupta *et al.*[9] quoted that there was a statistically significant difference in duration of the sensory block between Groups B and BF, Groups B and BFM, and Groups BF and BFM. Bharti *et al.*[13] observed that the duration of sensory blockade was prolonged when midazolam is added to bupivacaine. Khanna and Singh[14] observed a significant increase in the duration of the sensory block with fentanyl when added to bupivacaine. Similarly, Tucker *et al.*[15] observed prolongation of the duration of the sensory block when midazolam added to fentanyl in labor analgesia.

However, some studies do not favor it. Roussel and Heindel[16] did not observe significant prolongation of the sensory block when fentanyl was added to bupivacaine. Bhattacharya *et al.*[17] also observed no significant prolongation of the sensory block when midazolam added to bupivacaine.

Duration of Motor Block

Our results concur with the study of Gupta *et al.*[9] where there was a statistically significant difference in duration of the motor block between Groups B and BF, Groups B and BFM, and Groups BF and BFM. Bharti *et al.*[13] observed that the duration of motor blockade was prolonged when midazolam is added to bupivacaine. Grewal *et al.*[18] also observed significant prolongation of the motor block by adding fentanyl to bupivacaine. Some study results are against to it. Roussel and Heindel[16] did not observe significant prolongation of the motor block when fentanyl added to bupivacaine.

Mean Duration of Analgesia

Gupta *et al.*[9] observed that mean duration of analgesia in Group B was 211.60 ± 16.12 min, in Group BF 420.80 ± 32.39 min, and in Group BFM 470.68 ± 37.51 min. There was a statistically significant difference in duration of analgesia between Groups B and BF ($P = 0.000$), between Groups B and BFM ($P = 0.000$), and between Groups BF and BFM ($P = 0.000$). Our study results favor these observations.

Various studies have observed the prolongation of analgesia with the addition of midazolam or fentanyl. Tucker *et al.*[15] observed prolongation of the duration of analgesia in labor when a combination of intrathecal midazolam and fentanyl was used for labor analgesia. Shah *et al.*[10] also observed prolongation of the duration of analgesia with the addition of 2 mg intrathecal midazolam to 15 mg bupivacaine and 0.15 mg buprenorphine. Most of the studies done so far have used intrathecal bupivacaine combined with either fentanyl[14,19,20] or midazolam.[6,12,21,22] All have shown a significant increase in the duration of analgesia.

Incidence of Side Effects

In a study conducted by Gupta *et al.*,[9] the incidence of side effects was 28% in Group BFM and 28% in Group BF, whereas it was 12% in Group B. The incidence of

bradycardia was maximum in Group BF while that of hypotension was same in Groups BF and BFM. In all three groups, the incidence of side effects was not found to be significant.

Martyr and Clark[23] found the incidence of hypotension as a common complication when intrathecal fentanyl was added to bupivacaine in elderly patients, but the incidence and severity of hypotension were not significant. Grewal *et al.*[18] and Ben-David *et al.*[20] found an increased incidence of hypotension by adding fentanyl to bupivacaine. Bhattacharya *et al.*[17] did not found any significant change in blood pressure when intrathecal midazolam was added to bupivacaine.

Rudra and Rudra[24] observed that when the two groups, one with a combination of intrathecal bupivacaine (0.5%) 10 mg with fentanyl 12.5 mcg and other with bupivacaine (0.5%) 10 mg and midazolam 2 mg were compared, the incidence of nausea and vomiting was found to be less in the group with a combination of bupivacaine with fentanyl than the group with bupivacaine and midazolam.

Shah *et al.*[10] also observed that when bupivacaine + buprenorphine was compared with intrathecal bupivacaine + buprenorphine + midazolam, incidences of nausea, vomiting, and bradycardia were the same in both the groups. These results were not found to be significant.

CONCLUSION

The present study concludes that midazolam potentiates the effect of fentanyl in terms of prolonged duration of analgesia and prolonged motor and sensory block when used as an adjuvant of bupivacaine without any significant hemodynamic compromise in lower limb surgeries.

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Original Article

Correlation between Hypothyroidism and Systemic Arterial Blood Pressure: A Case–Control Study

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Abstract

Background: Hypothyroidism has been known to be associated with changes in systemic arterial blood pressure. Diastolic blood pressure (DBP) is known to be elevated causing proportionate reduction in pulse pressure.

Aim: The aim of the study is to find out the correlation between systolic blood pressure (SBP), DBP, pulse pressure (PP), and mean arterial pressure of hypothyroid patients and normal individuals.

Materials and Methods: This case–control study was conducted in Government Rajaji Hospital attached to Madurai Medical College, Madurai. Twenty-five hypothyroid subjects were enrolled for the study (study group) from the department of endocrinology and metabolism. Twenty-five normal subjects who were age and sex matched with the study group were enrolled for the study (control group). Serum thyroid-stimulating hormone (TSH) levels were estimated in all the subjects. Arterial blood pressure was recorded in all the subjects in the sitting posture and the results obtained. The results are tabulated and analyzed by applying unpaired "*t*" test.

Results and Conclusion: Among the blood pressure parameters, only PP showed a positive correlation between the study group and control group. SBP, DBP, and mean arterial blood pressure showed no significance.

Key words: Diastolic blood pressure, Hypothyroidism, Mean arterial pressure, Pulse pressure, Serum thyroid-stimulating hormone level, Systolic blood pressure

INTRODUCTION

The prevalence of hypothyroidism is between 4% and 10% of the population.[1] Hypothyroidism is diagnosed when low levels of the thyroid hormones result in elevated levels of thyroid-stimulating hormone (TSH).[2] Arterial hypertension is known to be frequently associated with thyroid dysfunction, with a particularly high prevalence in chronic hypothyroidism.[3] Hypertension may be the initial clinical presentation for at least 15 endocrine disorders,[4] including overt and subclinical hyperthyroidism and hypothyroidism. Subclinical hypothyroidism has also been associated with arterial hypertension, mostly diastolic,[5-7] as well as with atherosclerosis[8,9] and coronary heart disease[10,11] in both sexes. Thyroid hormones play an important role in the normal function of heart and vascular physiology and hypothyroidism produces profound cardiovascular effects. It alters diastolic blood pressure (DBP) more than normal level and as a result of which pulse pressure (PP) is narrowed in an individual. This study tries to clarify this fact.

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Aims and Objectives

This aim of the study was to estimate serum TSH level and to measure the arterial blood pressure in the arm using mercurial sphygmomanometer in both the study and control population. Correlation was made between hypothyroid subjects and normal individuals in terms of systolic blood pressure (SBP), DBP, PP, and mean arterial pressure to find out statistical significance.

MATERIALS AND METHODS

This study was done in the Institute of Physiology, Madurai Medical College, Madurai, in association with the Department of Endocrinology and Metabolism,

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Government Rajaji Hospital attached to the Madurai Medical College.

The study group consists of 25 subjects who were newly diagnosed hypothyroid subjects in the age group of 20–40 years, of which 20 were female and 5 were male, who were free from any other diseases and disorders known to affect systemic arterial blood pressure. The control group consists of 25 subjects who were age- and sex-matched normal and euthyroid individuals. Written consent was obtained from the subjects before procedures.

Inclusion Criteria

Normal healthy adults in the age group of 20–40 years willing to participate in our study had been included in the study.

Newly diagnosed hypothyroidism patients based on clinical diagnosis and laboratory confirmation in the age group of 20–40 years willing to participate in our study had been enrolled.

Exclusion Criteria

Subjects with any history of thyroid illness or those were on treatment for thyroid illness had been excluded.

Any patient with chronic liver disease, chronic renal disease (CRD), pregnancy, or taking any drug altering serum TSH levels (octreotide, somatostatin, opiates, dopamine, glucocorticoids, growth hormone, L-dopa, bromocriptine, pimozide, phentolamine, thioridazine, methysergide, cyproheptadine, iodine, dopamine antagonists, and amiodarone) have been excluded.[5]

Patients having disorders known to affect blood pressure were excluded from the study.

Estimation of T3, T4, and TSH

Serum levels of TSH, total circulating T4, and total circulating T3 are measured by radioimmunoassay. Radioimmunoassay technique is a type of antibody-based competitive immunoassay.

Blood Pressure Measurement

Arterial blood pressure was recorded using mercurial sphygmomanometer and stethoscope. The individual was seated in a chair with back support and arm support. BP cuff was tied in the left arm and kept at the heart level and then recording was done. When the BP was taken, the cuff was inflated to a pressure approximately 30 mmHg greater than systolic, as estimated from the disappearance of the pulse in the brachial artery by palpation. Initial estimation of the systolic pressure by palpation avoids potential problems with an auscultatory gap. Korotkoff sounds transiently disappear as the cuff is deflated. Once the cuff is adequately inflated, the following steps were followed:

The stethoscope was placed lightly over the brachial artery, since the use of excessive pressure can increase turbulence and delay the disappearance of sound. The net effect may be that the diastolic pressure reading may be artifactually reduced by up to 10–15 mmHg.[12]

The BP was taken with patient's arm supported at the level of the heart. Allowing the arm to hang down when the patient is sitting or standing, will result in the brachial artery being 15 cm below the heart. As a result, the measured BP will be elevated by 10–15 mmHg due to the added hydrostatic pressure induced by gravity.[13]

The cuff was deflated slowly at the rate of 2–3 mmHg/heartbeat. The systolic pressure was equal to the pressure at which the brachial pulse can first be palpated as blood flow gets restored through the previously compressed vessel; the systolic pressure is also equal to the pressure at which the pulse is first heard by auscultation. Then, disappearance of sounds was taken as DBP value. The value was recorded close to the nearest 2 mmHg graduation in the manometer scale.

The BP was measured initially in both arms. If there was a disparity due to a unilateral arterial lesion, the arm with higher pressure was used for measurement.

The BP was taken at least twice, with the measurements separated by 1 or 2 min to allow the release of trapped blood. If the second value varied more than 5 mmHg from the first, continued measurements were made until a stable value was attained. The recorded value on patients chart was the average of the last two measurements.[14]

Calculation of PP: PP =SBP–DBP

Calculation of mean arterial pressure: Mean arterial pressure (MAP) = DBP + 1/3 PP

Observation

Statistical analysis was done by applying unpaired "*t*" test using SPSS software version 16.0.
The following are the results for SBP [Table 1].
The following are the results for DBP [Table 2].
The following are the results for PP [Table 3].
The following are the results for mean arterial pressure [Table 4].

DISCUSSION

Nitric oxide (NO) is an endothelium-derived relaxing factor, which is critical for cardiovascular homeostasis.[15-17] Various

hormones, including thyroid hormones,[18-22] regulate the activity of nitric oxide synthase and NO production, while altered NO level is associated with thyroid dysfunction.[23,24]

Ittermann *et al.*[25] did a study involving more than 10,000 children and adolescents found a positive correlation betw een elevated serum TSH levels and both systolic and DBP; however, this correlation was not established with hypertension as shown in Table 1. In our study, the mean value of SBP of the study group is 110.40, whereas the value of the control group is 112.00. Moreover, "*P*" value after applying unpaired "*t*" test and its results show that 0.4846 is more than 0.05. Hence, no statistical significance is present.

Table 1: Comparison of systolic blood pressure

Statistical parameters	Group 1 (study group)	Group 2 (control group)
Mean	110.40	112.00
SD	8.41	7.64
SEM	1.68	1.53
N	25	25

SD: Standard deviation, SEM: Standard error of mean, N: Numbers, Intermediate values used in calculations: t=0.7044, df=48. Standard error of difference = 2.272. 95% confidence interval of this difference in mean = from –6.17 to 2.97. "*P*" value = 0.4846

Table 2: Comparison of diastolic blood pressure

Statistical parameter	Group 1 (study group)	Group 2 (control group)
Mean	74.80	72.80
SD	6.53	4.58
SEM	1.31	0.92
N	25	25

95% confidence interval of this difference in Mean = from – 1.21 to 5.21. Intermediate values used in calculations: t=1.2533, df=48. Standard error of difference = 1.596. "*P*" value = 0.2162

Table 3: Comparison of pulse pressure

Statistical parameter	Group 1 (study group)	Group 2 (control group)
Mean	35.60	39.20
SD	7.12	4.93
SEM	1.42	0.99
N	25	25

95% confidence interval of this difference in mean = from –7.08 to –0.12. Intermediate values used in calculations: T=2.0785, df=48. Standard error of difference = 1.732. "*P*" value = 0.0430

Table 4: Comparison of mean arterial pressure

Statistical parameter	Group 1 (study group)	Group 2 (control group)
Mean	86.66	85.86
SD	6.38	5.29
SEM	1.27	1.05
N	25	25

95% confidence interval of this difference in mean = from –2.53 to 4.13. Intermediate values used in calculations: *t*=0.4829, df=48. Standard error of difference = 1.658. "*P*" value = 0.6314

Udovcic *et al.* showed that in hypothyroid state, DBP increases and PP narrows.[1]

A study by Berta *et al.* showed that elevated DBP is present in ~30% of patients with overt hypothyroidism. Cardiac contractility and output decrease leading to a narrowed PP as shown in Table 2.[26] In our study, the mean value of DBP of Group 1 (or) study group is 74.80, whereas the value of Group 2 (or) control group is 72.80. Moreover, "*P*" value after applying unpaired "*t*" test and its result shows that 0.2162 is more than 0.05 and hence no statistical significance is present.

As shown in Table 3 the mean value of PP of the study group is 35.60, whereas the value of the control group is 39.20. Moreover, "*P*" value after applying unpaired "*t*" test and its results show that 0.0430 is <0.05 and hence statistical significance is present. This is in accordance with the study done by Udovcic *et al.*[1]

As shown in Table 4 the mean value of mean arterial pressure of the study group is 86.66, whereas the value of the control group is 85.86. Moreover, "*P*" value after applying unpaired "*t*" test and its results show that 0.6314 is more than 0.05. Hence, statistical significance is not present.

CONCLUSION

In our study, we found out that there was no statistical significance between normal individuals and hypothyroid patients when comparing SBP, DBP, and mean blood pressure. However, PP was found to be narrowed in hypothyroid patients compared to normal individuals. However, the sample size is minimal, and hence, an elaborate study is needed to further strengthen our findings.

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Original Article

A Clinical Study of Anterior Sylvian Point and Use of Anterior Sylvian Point for Surface Mapping of Frontal Horn for Intraoperative Emergency Ventricular Tapping

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Abstract

Introduction: Anterior sylvian point (ASyP) had a constant relationship with a point in the skull just posterior to the "H"-shaped pterion over the squamous suture called the anterior squamous point (ASqP).

Objectives: The objectives of this study were as follows: (1) To confirm and establish the cisternal nature of ASyP and its relationship to other important neural and sulcal structures along the sylvian fissure. (2) To confirm the relationship of the AntSyP (ASyP) with the external cranial landmark ASqP for surface mapping of frontal horn for emergency ventricular tapping.

Materials and Methods: Forty adult human brains (20 – right side and 20 – left side), both male and female, were observed during surgery in Government Theni Medical College. Reliability of frontal horn tapping using the apex of Paine's triangle from ASyP as the entry point was analyzed using the following steps. Exposure of pterion by the standard FTP trauma flap incision. Standard FTP craniotomy opening of the skull and dura mater and observing for ASyP relation to ASqP. A catheter was introduced through the apex of the Paine's triangle identified using the surgical tapes to form a 2.5 cm isosceles triangle from the ASyP. A study of the relationship of ASyP to the external cranial surface, middle cerebral artery (MCA) bifurcation, and frontal horn of ventricles was done.

Conclusion: It could be safely concluded that ASqP is a reliable external cranial landmark for ASyP. ASyP can be the reference point for Paine's triangle and hence Paine's point. Hence, Paine's point could be used to tap the frontal horn in emergent situations. Furthermore, MCA bifurcation can be reached by ASyP cisternal dissection.

Key words: Anterior sylvian fissure, Anterior sylvian point, Paine's point, Ventricular tapping

INTRODUCTION

Historically Taylor and Haughton in their study of the topography of the convolutions and fissures of the brain published in 1900 were the first to use the term sylvian point, defining it as the point, where the main stem of the sylvian fissure (SyF) reaches the outer aspect of the hemisphere.[1]

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Yasargil *et al.* (1975) described in detail this point in his later publications, in agreement with few other authors, as the point in the fissure beneath the triangular part of the inferior frontal gyrus (IFG) dividing the proximal from the distal segment of the SyF. Furthermore, the horizontal and anterior ascending rami start from this point.[2,3]

In a recent publication by Rodrigues *et al.*, (2005), a detailed study of anterior sylvian point (ASyP) was made, and the cisternal nature was observed.[4] The constant location and cisternal nature make this one of the best initial sites to open the SyF.

Furthermore, in the same study, it was proposed that the ASyP had a constant relationship with a point in the skull just posterior to the "H"-shaped pterion over the squamous

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suture called the anterior squamous point (ASqP).[4] In the same study, the frontoparietal operculum was mentioned as a series of convolutions roughly arranged as a V-shaped convolution with the vertex as the ASyP, three U-shaped convolutions, and one C-shaped convolution. Based on these morphoanatomical features, it was proposed to be easier to avoid eloquent areas of the brain such as Broca's motor speech area and precentral motor cortex.[4]

Dr. Paine and Badjer *et al.* (1988) proposed a point (pt) at the apex of a 2.5 cm right-angled isosceles triangle based on the SyF for a ventricular puncture at the frontal horn.[5]

The present study intends to define ASyP and Paine's point and their relation to external cranial landmarks, frontal horn, and its surgical implications in the Indian population.

Objectives

The objectives of this study were as follows:

1. To confirm and establish the cisternal nature of ASyP and its relationship to other important neural and sulcal structures along the SyF
2. To confirm the relationship of the AntSyP (ASyP) with the external cranial landmark ASqP for surface mapping of frontal horn for emergency ventricular tapping.

MATERIALS AND METHODS

Forty adult human brains (20 – right side and 20 – left side), both male and female, were observed during surgery in Government Theni Medical College.

A study of the relationship of ASyP to external cranial surface and ventricles was carried out in the following method.

The following steps were followed.

Exposure of pterion by the standard FTP trauma flap incision.

The location of ASqP from key burr hole is measured using surgical tapes. A craniotomy is completed and the dura is opened with base toward the midline. ASyP is identified, and the distance from key burr hole is measured. An analysis is made as to whether the ASqP overlaps the ASyP.

Morphoanatomy of ASyP is measured. The relationship of ASyP to bifurcation of the middle cerebral artery (MCA) was observed.

Paine's point is identified at the apex of a 2.5 cm right-angled isosceles triangle based on the SyF from ASyP.

The frontal horn of the ventricle is tapped using a ventricular cannula at Paine's point. The free flow of clear cerebrospinal fluid (CSF) is considered as successful tapping.

RESULTS

ASyP

The ASyP was located inferior to the pars triangularis and anteroinferior to opercular IFG in the SyF.

It is frequently enlarged and has a cisternal nature. The mean diameter of ASyP was 3.84 mm with a range of 1.8–5.1 mm [Table 1].

ASyP to MCA Bifurcation

The MCA was observed to bifurcate deeper in the sylvian cistern underneath the ASyP in most of the cases. In the rest, it was seen bifurcating immediately anterior to this point within the sylvian cistern [Table 2].

ASqP Relationship with the ASyP

The ASqP is defined as the point just posterior to the central bar of the pterional "H" on the most anterior segment of the squamous suture. It usually overlies the ASyP. The position of ASqP in relation to ASyP as measured from key burr hole is observed. Although there was minimal variation, it was largely within 0.5 cm and can be easily corrected for with a larger burr hole.

The following observations were made.

This confirms the finding of Rodrigues *et al.* that the ASqP can be used to identify and approach ASyP.

Accuracy of Paine's Point in Ventricular Puncture

This is a point at the apex of a right-angled 2.5 cm isosceles triangle with its anterior limb abutting the sphenoid ridge dura and the hypotenuse over the SyF.

Through the apex of the triangle, the ventricular puncture of frontal horn was attempted and verified by the free flow of clear CSF.

On an average in 77.5% of the patients, the ventricular puncture can be done through the Paine's point. Even in

Table 1: Diameter of ant sylvian point

Diameter of ant sylvian point	R	L
Less than or equal to 2 mm	1	1
2–3 mm	2	3
3–4 mm	6	8
4–5 mm	9	5
>5 mm	2	3

Average size of ASyP is 4 mm

Table 2: Middle cerebral artery bifurcation in relation to ASyP

Middle cerebral artery bifurcation in relation to ASyP	R	L
Directly below ASyP	16	15
Below and just anterior to ASyP	4	5

Table 3: Ventricular puncture through Paine's point

Ventricular puncture through Paine's point	R	L
Yes	16	14
No	4	6

Table 4: Position of ASyP in relation to ASqP

Position of ASyP in relation to ASqP	Horizontal	
	R	L
At	13	14
Anterior	4	4
Posterior	3	2

Table 5: Position of AntSyP in relation to ASqP

Position of AntSyP in relation to ASqP	Vertical	
	R	L
At	16	14
Superior	1	2
Inferior	3	4

the rest, the ventricular puncture was successful within 2 cm anterior to the anterior limb of the triangle at the apex.[6]

DISCUSSION

ASyP

AsyP mean diameter in this study is on an average 4 mm in accordance with Rodrigues *et al.*[7] study, and it has a cisternal nature.

As emphasized by Yasargil, the opening of SyF at this point is easy and provides immediate access to MCA bifurcation as well as to the suprasellar cisterns and lateral aspect of insula.[3,8]

Various methods of opening the SyF have been proposed by various authors. The gold standard for SyF opening is that the arachnoid of SyF be opened on the frontal side of the veins distally so that the sacrifice of fronto-orbital venous tributaries that cross the SyF to the frontal lobes is not needed.[9,10] Few others open the SyF from the stem or by injecting water into the cisterns and then open up distally called water dissection technique of Toth *et al.* (1987).[7]

The opening of SyF also needs to be tailored to the lesion concerned. In this context, the opening of SyF from sylvian point has been proposed by few authors.

Paine's Point

The accuracy of Paine's point[12] in ventricular puncture is 77.5%, contrary to Hyun *et al.* [Table 3].[13] Even otherwise, the ventricles can be accessed as proposed by the above authors within 2 cm anteriorly from the anterior limb of the triangle in all specimens [Tables 4 and 5].

ASqP to ASyP Relation

The ASqP corresponds to ASyP horizontally in 67.5% and vertically in >75%. The consistently short distance between ASqP and ASyP indicates that ASyP is related to the center of a 1.5 cm burr hole on the anterior segment of the squamous suture just behind pterion that is the ASqP.

CONCLUSION

In Indian population, the ASyP corresponds to the ASqP in 67.5% horizontally and 75% vertically. Furthermore, in the rest of the cases observed, the ASyP lies underneath the ASqP within 0.5 cm both vertically and horizontally. Hence, it can be corrected with a 1.5 cm burr hole easily.

The mean diameter of ASyP is 4mm. The range of ASyP diameter in the Indian population is 1.0–5.5 mm. Hence, it is safer to open at this point.

The Paine's point also provides an approximate location for ventricular puncture in most of the cases. Even otherwise, the ventricle can be accessed within 2 cm from the anterior limb of the triangle in this study. Hence, ventricular puncture, by this way, may be used effectively to slacken the brain in the Indian population intraoperatively.

Since MCA bifurcation aneurysms are common during aneurysm clipping, ASyP offers a direct route to the underlying MCA bifurcation in most of the cases.

The knowledge of these basic anatomical features and relationship can help us in locating the ASyP through an initial burr hole centered on ASqP intraoperatively. Pre-operative planning can be done in advance with MR imaging. Intraoperatively, it helps us in avoiding complications altering the course of the surgery if necessary with the above knowledge.

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Original Article

Comparative Study on Body Mass Index between Hypothyroidism Patients and Healthy Volunteers

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Abstract

Background: Hypothyroidism is known to interfere with the metabolism of all the cells in the body, particularly fat metabolism in adipose tissue. This, in turn, leads to obesity. Body mass index (BMI) is widely used to assess obesity and metabolic syndrome. Obesity leads to a higher incidence of cardiovascular morbidity and mortality.

Materials and Methods: Twenty-five hypothyroid subjects were enrolled (study group) from the Department of Endocrinology and Metabolism, Govt. Rajaji Hospital attached to the Madurai Medical College, Madurai. Twenty-five normal subjects who were age- and sex-matched with the study group were enrolled to form the control group. Serum levels of thyroid-stimulating hormone (TSH), total circulating T4, and total circulating T3 were measured by radioimmunoassay to confirm hypothyroidism. Height and weight were measured using a stadiometer and weighing scale, BMI was calculated using Quetelet's index formula.

Results and Conclusion: The results were tabulated and analyzed by applying unpaired *t*-test and SPSS software version 16.0. BMI values of the study group and control group were compared, but there was no statistical significance. BMI values when compared with serum TSH levels within the same group, the Pearson correlation coefficient also showed no statistical significance.

Key words: Body mass index, Hypothyroidism, Quetelet index, Serum thyroid-stimulating hormone level

INTRODUCTION

Hypothyroidism is known to interfere with the metabolism of all the cells in the body, particularly fat metabolism in adipose tissue. This, in turn, leads to obesity. Body mass index (BMI) is widely used to assess obesity and metabolic syndrome. Obesity leads to a higher incidence of cardiovascular morbidity and mortality.

Obesity and hypothyroidism are two common clinical conditions that have been linked together closely. The link has become more relevant in the context of an unprecedented rise in the prevalence of obesity worldwide.[1]

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Various researchers have studied the effect of the thyroid hormones on BMI, and it has been demonstrated that overt thyroid dysfunction affects body weight. Clinical hypothyroidism causes an increase in body weight, while hyperthyroidism reduces it.[2]

Thyroid hormones regulate basal metabolism and thermogenesis and play an important role in lipid and glucose metabolism, food intake, and fat oxidation.[3]

Hypothyroidism is associated with decreased thermogenesis and decreased metabolic rate and has also been shown to correlate with a higher BMI and a higher prevalence of obesity.[4] There is clinical evidence suggesting that even mild thyroid dysfunction in the form of subclinical hypothyroidism is linked to significant changes in body weight and represents a risk factor for overweight and obesity.[4]

Aims and Objectives

The aim of the study is to measure height and weight and to calculate the BMI using Quetelet index formula both in the study group and control group and to compare the

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same between the two groups. BMI values of each group are compared with serum thyroid-stimulating hormone (TSH) levels within the group.

MATERIALS AND METHODS

This study was done in the Institute of Physiology, Madurai Medical College, Madurai, in association with the Department of Endocrinology and Metabolism, Govt. Rajaji Hospital attached to the Madurai Medical College. The study group consisted of 25 subjects who were newly diagnosed hypothyroid subjects in the age group of 20–40 years, of which 20 cases were female and five cases were male. The control group consisted of 25 subjects who were age- and sex-matched normal and euthyroid individuals, free from any other diseases. Written consent was obtained from the subjects before procedures.

Inclusion Criteria

Normal healthy adults in the age group of 20–40 years willing to participate in our study had been included in the study.

Newly diagnosed hypothyroidism patients based on clinical diagnosis and laboratory confirmation in the age group of 20–40 years willing to participate in our study had been enrolled.

Exclusion Criteria

Subjects with any history of thyroid illness or those were on treatment taken for thyroid illness had been excluded from the study.

Any patient with chronic liver disease, chronic renal disease, pregnancy, or taking any drug altering serum TSH levels (octreotide, somatostatin, opiates, dopamine, glucocorticoids, growth hormone, L-dopa, bromocriptine, pimozide, phentolamine, thioridazine, methysergide, cyproheptadine, iodine, dopamine antagonists, and amiodarone) have been excluded from the study.[5]

Estimation of T3, T4, and TSH

Laboratory evaluation: Serum levels of TSH, total circulating T4, and total circulating T3 were measured by radioimmunoassay. Radioimmunoassay technique is a type of antibody-based competitive immunoassay.

Measurement of height: Using stadiometer height was measured in all individuals in meters.

Measurement of weight: Using standard spring type weighing scale, weight was measured in all subjects in kilograms.

Calculation of BMI: BMI was done using Quetelet index formula,

Body mass index = Weight (kg)/Height (m^2)

OBSERVATION AND RESULTS

The results of unpaired *t*-test for BMI comparison are as follows.

95% confidence interval of the difference in mean = from –1.5215 to 1.8695

Intermediate values used in calculations:

$t = 0.2063$

df = 48

Standard error of difference = 0.843

P-value = 0.8374.

Statistical Comparison within Group

When the BMI values are compared with serum TSH levels within group, the following data were obtained as shown in Table 1.

i. In the study group
   Mean of BMI of hypothyroid subjects = 21.798
   Mean of serum TSH level of hypothyroid subjects = 74.6
   Pearson correlation coefficient t(R) = –0.0217
   Coefficient of determination (R^2) = 0.0005
   P-value = 0.9179
The result is not significant at $P < 0.05$.

ii. In the control group
   Mean of BMI of normal subjects = 21.624
   Mean of Serum TSH level of normal subjects = 2.344
   Pearson correlation coefficient(R) = 0.358
   Coefficient of determination (R^2) = 0.1282
P-value = 0.0788
The result was not statistically significant at $P < 0.05$.

Table 1: Comparison of BMI between the study group and control group

Statistical parameter	Group one (study group)	Group two (control group)
Mean	21.7984	21.6244
SD	4.0210	1.2679
SEM	0.8042	0.2536
N	25	25

SD: Standard deviation, SEM: Standard error of mean, *n*: Numbers

DISCUSSION

Thyroid hormones, including thyroxine and triiodothyronine, regulate the synthesis, mobilization, and breakdown of lipids. Therefore, thyroid hormones are closely related to obesity, and slight changes in serum thyroid hormone level can cause local fat accumulation and increased body mass.[6]

In a study done by Verma *et al*.,[7] it was found that in obesity patients, overt hypothyroidism was present in 33% of patients and subclinical hypothyroidism in 11% of patients. In our study, first, we have compared BMI scores of the study group with that of the control group. However, we have not found any statistically significant relationship ($P > 0.05$). The reason may be the recent onset of hypothyroidism in the study group population.

In a study done by Kare *et al*., in terms of the relationship between BMI and thyroid hormones, no significant relationship was found in Indian normal as well as obese adults groups.[8]

In a study by Solanki *et al*., they found a significant relationship between serum TSH and BMI and mean TSH increased as BMI increased.[9]

On comparison of serum TSH levels with BMI values within groups, no statistical significance was observed. This fact can be explained by the presence of BMI values >25 only in few numbers of persons in the study group population. Moreover, this might be linked with the prevalence of obesity and metabolic syndrome itself at the community level.

In a study done by Nyrnes *et al*.,[10] a positive and significant association between serum TSH within the normal range and BMI, both in a cross-sectional and a longitudinal study, was found. However, this does not necessarily imply a causal relationship between thyroid function and BMI within the normal serum TSH range.

CONCLUSION

Hypothyroidism and obesity go hand in hand. In our study, we found no statistical significance when we compared the BMI values of healthy individuals with hypothyroidism patients. On comparing, BMI values with serum TSH levels with each group also showed no statistical significance. Since our sample size was minimal, an elaborate study is needed to validate our findings.

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Original Article

An Observational Study of Fall Injuries among Infants in Special Reference to the Incidence and Risk Factors

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Abstract

Objective: The objective of the study was to assess the incidence and risk factors of fall injuries among infants admitted in our institution.

Design: Review of data from a large injury database.

Setting: The Emergency Department Injury Surveillance System.

Patients: A total of 2672 injured infants. Interventions Children's guardians were interviewed using a questionnaire. The results of an independent survey of 777 mothers of non-injured children younger than 2 years attending the same emergency departments were used to allow quantification of the role of specific nursery equipment in the causation of infant fall injuries. Main Outcome Measures: Annual rate of injury by falling in infants, overall and by cause.

Results: An annual incidence rate of 44 injuries per 1000 infants. The incidence of falls increases with increasing infant age. A high percentage of severe injuries was detected, most of them concussions (14.3%) and fractures (9.4%). Approximately 10% of infants with fall-related injuries required hospitalization. More than 36% of fall injuries involved nursery equipment. Infant walker use was associated with a higher incidence of falls (about 9/1000 infant-years), and these falls occasionally involved stairs and caused serious injuries.

Conclusions: Falls are a common cause of serious infant injuries, and nursery equipment is frequently involved in the injury-causing event.

Key words: Fall injuries, Infants, Nursery equipment, Risk factors

INTRODUCTION

Falls from different causes have been recognized as a major cause of death and disability worldwide and as a factor responsible for substantial morbidity among children of all ages.[1-3] A characteristic of injuries among very young children is that aspects of their normal behavior that is the natural curiosity or the physiologic development of motor skills could be associated with increased injury risk,[4-9] especially in an unknown environment or when inappropriate nursery equipment is used. Moreover, caretakers often show insufficient concern for the risks linked to the developmental milestones and sometimes forget that they should be prepared for unexpected behavior on the part of the infants.[10] Most fall-related injuries affect children during their early stages of development, and they usually occur at their home.[11] Falls are one of the most common causes of injuries among infants, and they have long been studied in relation to nursery equipment. Several studies have claimed the role of specific types of nursery equipment, such as infant walkers and bouncers, in the causation of fall-related injuries.[5,12-15] The present study aimed to assess the incidence of fall-related injuries among infants and assess the risk factors. The study was based on infant injury data collected from hospital records.

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MATERIALS AND METHODS

The focus of this investigation was on fall-related injuries among infants younger than 12 months who were brought for care in an emergency department during a 4-year period, from January 1, 2016, through December 31, 2019. The interviews

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took place in the emergency departments as well as in indoors of the hospital along with the child's medical examination by the attending surgeons. The questionnaire covers sociodemographic variables, the mechanism and the objects involved in the injury, type of injury and injured body part, supervision patterns, medical assessment of the injured child, and treatment provided. To assess the frequency of use of the various types of infant nursery equipment in the underlying population, and thus derive equipment-specific incidence rates of infant fall injuries, a special survey was conducted in the same hospitals In this survey, mothers of 777 non-injured very young children (1–2 years old) who consecutively, during a 3-month period, contacted the OPD services of the hospital for check-ups or very minor ailments were interviewed about the frequency of use of nursery equipment throughout the infancy of their children. It is worth noting that both studies were based on the same population. We performed this task with the use of pre-coded questionnaires covering the various types of nursery equipment. There were only 11 refusals among the 788 contacted women.

For the analysis, the injured infants were classified by age, sex, principal object involved in the event, and type of principal/primary injury. Subsequently, we calculated the incidence of infant fall injuries by equipment per 1000 infant-years, taking into account infant-years at risk in the underlying population and frequency of use of nursery equipment as estimated in the ad hoc survey. The number of infants at risk every year in the catchment areas (namely almost three districts Uttar and Dakshin Dinajpur and Malda district along with neighboring areas of Bihar state) was 12 075 (9250+ 2825). The study period was 4 years; therefore, the total infant-years at risk were 60 375. We multiplied this figure by the proportion of users of each specified type of nursery equipment. The incidence of falls by type of equipment (per 1000 infant-years) was calculated as the ratio of each nursery equipment–related number of fall injuries to the corresponding infant-years at risk. Due to overlapping person-time at risk during the 1 year of infant life and the joint contribution of more than one type of nursery equipment to an injury, the estimated figures per single equipment add to more than the total infant fall injuries from all nursery equipment. Throughout the analysis, SAS statistical software (SAS Institute Inc., Cary, NC) was used.

RESULTS

Table 1 shows the distribution of 2672 infants with fall injuries of a total of 4340 infants with injuries of any type recorded by demo-graphic variables, main objects involved in the event, and type of principal injury. It is estimated that about 4400 infant fall injuries occur annually in this area corresponding to an annual incidence rate of approximately 44 injuries/1000 infants. As far as infant age is concerned, the infant population at risk can be assumed to be equally distributed across the three 4-month age intervals. Thus, the substantial increase in the frequency of falls among all infants with increasing age was statistically highly significant (0–3 months, 12.7%; 4–7 months, 33.3%; and 8–11 months, 54.0%; $P < 0.001$ from a goodness-of-fit y^2 test with 2*df*). There was also evidence of a slight excess of male infants among those with fall injuries. Among the infant fall injuries, 269 (10.1%) were sufficiently serious to require hospitalization. As expected, most of the serious injuries were concussions (14.3%) and fractures (9.4%), which required hospitalization in 17.3% and 61.7% of instances, respectively. Among the 2672 infant fall injuries, 967 (36.2%) involved nursery equipment, mostly walkers (11.5%), strollers (8.8%), and bouncers (5.7%). Changing table-related infant falls required the highest hospitalization rate among the studied nursery items (17.1%). About half of the recorded infant fall injuries (54.7%) were related to home objects other than nursery equipment, mainly furniture (37.2%) or other immobile home structures (15.9%); of those, almost 1 in 10 required hospitalizations. In 244 instances (9.1%), the caregivers reported that infants slipped and fell from their arms; 1 in 5 infants who slipped and fell required hospitalization, and 36 of them had a fracture.

Table 2 shows the incidence of falls among infants by type of most frequently used nursery equipment, highlighting their involvement in the causality of these types of injuries. As indicated, in the catchment areas of the study hospitals, an average of 12,075 new deliveries are recorded every year. On the basis of this number and the fraction of users of specified nursery equipment, as ascertained from the mothers of 777 non-injured infants. The incidence of falls by equipment per 1000 infant-years can be estimated. Infant walker use was associated with the highest incidence of falls, and these falls frequently involved stairs and caused non-minor injuries (among these injuries, 8% were fractures, 20% were concussions, and 26% were open wounds). Infant bouncers, strollers, and changing tables were associated with a similar incidence of falls (about 4/1000 infant-years).

COMMENT

Falls among infants are responsible for a substantial fraction of infant morbidity and mortality, accounting for about six deaths annually/1 million infants in the United States.[16] The findings of our study indicate that almost two-thirds of all injuries recorded among infants were due to falls. More than one-third of these falls were associated with the use of nursery equipment. Another third of infant falls were related to home furniture and equipment, which implies either inappropriate use of these objects in infant care or

Table 1: Distribution of infants with fall injuries

Variable	Fall injuries, No. (%) (*n* = 2672)	No.	% of total hospitalized	% of all fall injuries in category
Age, mo				
0–3	340 (12.7)	57	21.2	16.8
4–7	891 (33.3)	89	33.1	10.0
8–11	1441 (54.0)	123	45.7	8.5
Sex				
Male	1465 (54.8)	149	55.4	10.2
Female	1207 (45.2)	120	44.6	9.9
Object involved in accident				
Nursery equipment	967 (36.2)	91	33.8	9.4
Walker	308 (11.5)	30	11.1	9.7
Stroller	234 (8.8)	11	4.1	4.7
Changing table	76 (2.8)	13	4.8	17.1
High chair	66 (2.5)	5	1.9	7.6
Crib	85 (3.2)	6	2.2	7.1
Bouncer	152 (5.7)	19	7.1	12.5
Other nursery equipment	46 (1.7)	7	2.6	15.2
Human arms	244 (9.1)	52	19.3	21.3
Home furniture	994 (37.2)	84	31.3	8.5
Immobile structures	425 (15.9)	38	14.1	8.9
Outside home objects	42 (1.6)	4	1.5	9.5
Type of principal injury				
Concussion	381 (14.3)	66	24.6	17.3
Fracture	251 (9.4)	155	57.6	61.7
Open wound	431 (16.1)	3	1.1	0.7
Strain/dislocation	22 (0.8)	0	0.0	0.0
Contusion/abrasion	884 (33.1)	31	11.5	3.5
No identifiable injury	686 (25.7)	8	3.0	1.2
Other injuries	17 (0.6)	6	2.2	35.3

Table 2: Estimation of incidence of infant injuries due to falls from nursery equipment by type of equipment

Nursery equipment	Users in population at risk			
	No. of falls (1996–2000)	(777 infants) No. (%)	Infant-years at risk by indicated equipment*	Incidence of falls by equipment per 1000 infant-years
Crib	85	705 (90.7)	54,760	1.6
Bouncer	152	482 (62.0)	37,433	4.1
Stroller	234	750 (96.5)	58,262	4.0
Walker	308	456 (58.7)	35,440	8.7
High chair	66	294 (37.8)	22,822	2.9
Changing table	76	243 (31.2)	18,837	4.0

lapses in parental supervision. As has been pointed out by other authors, use of nursery equipment carries a significant risk of falls during infancy.[5-8,12-18] In line with the literature, infant walkers tended to be associated with a relatively high risk of an infant fall injury.[6,8,19-21] Among the other objects in nursery equipment, infant bouncers, strollers, and changing tables were associated with a similar level of time-integrated risk [Table 2]. Infant falls led more frequently to an injury that required hospitalization. This may be attributed to the fact that the changing table may be furniture height or may be placed on a piece of furniture, which may result in an infant fall from a considerable height. Cribs appear to be less risky, even though they are used for longer periods. Obviously, there are variations in both times of exposure to and risk from nursery equipment so that our estimates are by necessity indications of average nursery equipment-related risk. In 251 instances, the reported fall injury led to a fracture. Several studies have suggested that fractures in very young children may involve an element of physical child abuse.[22,23] Whatever the true underlying reason, these ratios are comparable with those reported from other series of infant fall injuries.[24]

Our study pointed to the significant role of nursery equipment in fall-related injuries among infants. Parents should be aware of the potential hazards when purchasing such products and always use them according to the manufacturer's instructions.[25,26] The use of nursery items by infants should be under strict adult supervision. Leaving an infant on a changing table or other surface even for an instant without supervision may result in an injury since

infants who are left unsupervised can roll off and fall, especially if they are placed on an elevated surface.[25-27] If parents decide to purchase a walker for their child, notwithstanding current recommendations to the contrary, they should avoid its use on wheels, and they should restrict access to any stairs with a gate.[25] Infants should always be securely fastened with a safety belt when placed in a high chair, a changing table, or any other similar equipment.[25-28]

The advantages of this investigation are its general population coverage, large sample size, and use of a standard protocol. Moreover, the use of a comparison sample allowed the estimation of exposures in the population at risk, making it possible to calculate the nursing equipment-specific incidence rates.

As is common in injury research, we were unable to jointly examine predisposing conditions and triggering events in the causation of the infant falls. In the same context, we were unable to disentangle any hidden child abuse cases from that reported as unintentional falls. Compared with other parts of the country, a considerably higher proportion of injured infants were hospitalized, but this is a well-known phenomenon in this hospital, and it is frequently attributed to the inadequate development of primary health care in this country and the overprotective attitude of society toward children.[29,30]

In conclusion, we were able to calculate the overall incidence and estimate the nursery equipment-specific incidence of infant falls in the population. We found that among nursery equipment, use of infant walkers and, to a lesser extent, infant bouncers, strollers, and even changing tables are associated with a non-negligible risk of injury from infant falls. Diligent adult supervision informed product selection, and simple environmental modifications can contribute to the reduction of fall-related injuries in infancy.

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Original Article

Assessment of the Success Rates of Stapled Hemorrhoidopexy Intervention for Grade III and IV Hemorrhoids among Adult Patients of North India: An Observational Hospital-based Study

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Abstract

Introduction: Hemorrhoid disease therapy is effectively been treated with conventional excisional hemorrhoidectomy. Stapled hemorrhoidopexy (SH) revolutionized the traditional surgical approach by the introduction of the theory of dealing with the rectal mucosal prolapse by resecting a mucosal cylinder above the dentate line by means of mechanical stapling. It is a non-excisional approach for the surgical treatment of hemorrhoid disease.

Materials and Methods: Ethical clearance was obtained from the institution. A total of 100 adult patients with Grade III/IV hemorrhoids indicated for surgery were recruited for the study purpose. Data collected were post-operative pain in the form of VAS scale, immediate complications, duration, or length of stay in the hospital along with the time to resume work again. SPSS 17.0 was used to carry out the analysis. All $P < 0.05$ were considered to be statistically significant.

Results: The mean age of the study group was 45 ± 14.93 years. The mean length of hospital stays, postoperatively for 21% subjects, was mere 1 day; however, it was 2 days for the rest of population studied. The only complication was with 2% of the study population having excessive intraoperative bleeding. The mean time to return to work was 8 days. About 77% of the patients resumed their work within 8 days of surgery.

Conclusion: Within the given limitations of the study, we can conclude that SH is a successful procedure for Grade-III/IV hemorrhoids in terms of immediate post-operative complications, pain as well as the duration of hospital stay.

Key words: Bleeding, Hemorrhoids, Pain, Stapled hemorrhoidectomy

INTRODUCTION

Hemorrhoid disease therapy is effectively been treated with conventional excisional hemorrhoidectomy. The Milligan-Morgan operation is the standard approach for hemorrhoid prolapse in Europe, while the Ferguson closed hemorrhoidectomy is the operation of choice in North America.[1] Excisional hemorrhoidectomy is associated with significant post-operative pain, leading to deferral of treatment. This pain also results in an increased hospital stay and late resumption of the daily chores or work. Stapled hemorrhoidectomy (SH) was introduced in 1998 as an alternative.[2] It revolutionized the traditional surgical approach by the introduction of the theory of dealing with the rectal mucosal prolapse by resecting a mucosal cylinder above the dentate line by means of mechanical stapling.[3] It is a non-excisional approach for the surgical treatment of hemorrhoid disease.[1] It aims at repositioning the prolapsed hemorrhoid tissue through a circular resection of the inner layers (mucosa,

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submucosa, and part of the muscularis propria).[2-4] SH was studied in several randomized controlled trials in which its safety and early-term efficacy have been demonstrated.[4-7] Systematic reviews have demonstrated that the short-term outcomes result favor SH when compared to the traditional excisional method.[8,9] SH is associated with shorter operative time, reduced inpatient stay, less pain, and earlier return to normal activities.[10] However, systematic analyses of literature evidence have shown that SH is associated with a high symptomatic recurrence rate.[8,11] This conflict resulted in Giordano *et al.* to conclude that patients should choose whether to accept a higher risk of recurrence and additional operation for the sake of the short-term benefits of SH compared with conventional hemorrhoidectomy.[12] There are important issues to be considered when reviewing the studies included in the systematic reviews concluding for higher recurrence associated with SH when compared to a conventional hemorrhoidectomy. One derives from the heterogeneity in the diagnosis of hemorrhoid disease grade. The second is that it must be noted that many of the randomized trials included in these reviews recruited very few patients. In these studies, the previous clinical experience (learning curve) with SH was not declared. On the other hand, participating surgeons entering these trials could possibly have reached an expert level by performing conventional techniques. In spite of this controversy, SH has been successfully used for the surgical management of hemorrhoids.[1-6] Considering conflict in reports, it is essential that to resolve this debate, evidence-based clinical studies should be carried out, and clinical evidence be recorded to settle the issue. Hence, the present study was carried out to evaluate the functional results among patients undergoing staple hemorrhoidectomy for Grade-III/IV hemorrhoids postoperatively.

MATERIALS AND METHODS

Ethical clearance was obtained at the start of the study from the Institutional Review Board. The SH technique is a regularly carried out procedure for indicated cases as a part of the treatment regime. The data of the same cases were used for the study purpose. The sample size has been calculated using the formula suggested by Snedecor and Cochran (1989) to prove the hypothesis: n = C2.

For this study, "*P*" was taken as 0.5, C a constant at a certain confidence level (its value at 95% confidence limit and 80% power is 1.96) while was the allowed error (taken as 10% or 0.10). Hence, $n = 96.04 \sim 96$. Thus, the calculated sample size is 96. After adding for a contingency of 4%, we had an assumed sample size of 100.

Inclusion Criteria

The following criteria were included in the study:

- Clinically diagnosed cases of Grade III and IV hemorrhoids (symptomatic).
- Patients of either sex
- Patients aged 18–70 years

Exclusion Criteria

The following criteria were excluded from the study:

- Patients with Grades I and II hemorrhoids
- Patients with a previous history of hemorrhoidectomy
- Patients with associated
- Fistula in ano, Fissure in ano
- Thrombosed piles
- Growth per rectum
- Anal stenosis
- Prolapse of single anal cushion
- Pregnant females
- Patients with portal hypertension

Operative Evaluations

One dose of ciprofloxacin and metronidazole was given at the time of anesthesia for surgery. All operations were performed in a lithotomy position, preferably under spinal anesthesia. In case of failure to achieve adequate anesthesia using spinal anesthesia, alternate anesthetic technique/general anesthesia were tried. Written informed consent was taken separately from the patients to include their details as a part of the study. The surgical procedure, as detailed by Altomare (Ellesmore and Windsor, 2002), was followed.

Post-operative Evaluation

Method of measurement of outcome of interest

Intraoperative complications, difficulty – intraoperative complications such as difficulty in accessing and locating anatomical structures, blood loss, and damage to adjoining vasculature, were noted in categorical terms. The pain was assessed using a visual analog scale (VAS), where a score of 0 represented no pain and a score of 10 represented the worst pain ever. The pain score was recorded every 6 h during the 1st post-operative day. Duration of hospital stay was recorded in the number of days and time to return to work was recorded in days. The data were collected on a semi-structured questionnaire. The data collected were coded into Microsoft Excel 2013. Descriptive statistics were performed with SPSS version 17.0 (IBM Analytics, New York, U.S.A). Pearson's Chi-square test was used to determine if there is a relationship between two categorical variables. $P < 0.05$ was considered statistically significant.

RESULTS

The mean age of the study group was 45 ± 14.93 years. The studied pathology was more prevalent (62%) in younger

(21–30 years) and middle age groups (31–50 years) than the older age group. Of the total 100 participants, 75 were male and 25 were female. In the study group, 73% subjects had Grade III and 27% had Grade IV hemorrhoids. Table 1 shows the overall mean length of hospital stay and the VAS score (pain assessment).

The mean length of hospital stays, postoperatively for 21% subjects, was mere 1 day; however, it was 2 days for the rest of the population studied. Table 2 shows the frequency distribution of the study population based on the VAS scale.

The only complication was with 2% of study population having excessive intraoperative bleeding. The mean time to return to work was 8 days. About 77% of the patients resumed their work within 8 days of surgery.

DISCUSSION

Ideally, the surgical intervention for hemorrhoids should be less invasive, painless, safe to perform, and effective in nature. The success rates of SH have been a point of discussion for long. SH was found to be associated with lesser pain in the immediate post-operative period.[1] SH is one among many new techniques that have appeared on the scene of hemorrhoid management at the turn of the 20th century that has yielded promising and good short-term results. It has gained popularity over the last decade for the management of Grade-III/IV hemorrhoidal disease,[1] as an alternative to open hemorrhoidectomy, long considered to be the gold standard. The technique has been standardized and the indications, contraindications, and operative technique have been defined. The results of SH have been weighed across multiple randomized trials.[13-23] In terms of age distribution, this study found that hemorrhoids affect the most active age group of 20–49 years, accounting for a total of 62% of those affected in this study. This is in accordance with other workers.[18,23] The present study showed that hemorrhoids affect mainly the productive members of society. There were more males than females comparable to previous studies,[18,23] the reason for male preponderance is not clear. Risk factors to females are similar to their male counterparts. If fact, pregnancy being the most common cause of abdominal distention in female should have exacerbated the hemorrhoids formation. One of possibility for a lesser prevalence of hemorrhoids among female could be the shielding effect of pregnancy against hemorrhoids development for an unclear reason and requires further studies for confirmation. In our study group, 73% subjects had Grade III and 27% had Grade IV hemorrhoids. Literature also showed that Grade III hemorrhoids are more common than Grade IV disease.[24,25] Intraoperative bleeding of 6–7 ml at the stapled line was identified in 2% patients only which was successfully controlled by hemostatic suture. The amount of bleeding was comparatively less than conventional hemorrhoidectomy in the previous study.[23] The mean length of hospital stay in our study was 1.79 days. Our study supports the earlier findings of shorter hospital stay post SH as reported by Bhandari *et al.* (2.9 days),[19] Voigtsberger *et al.* (3 days),[22] and Kishore *et al.* (3 days)[23] in their respective studies. The pain was assessed using the visual analog scale (VAS score). Our aim was to keep VAS score <5 using adequate analgesia classified using the world health organization (WHO). The mean VAS score of our study group was 4.42. Picchio *et al.*,[21] Sachin *et al.*,[26] and Watson *et al.*[27] in large multicenter trials have reported mild degree of post-operative pain with SH than open hemorrhoidectomy. We also found pain score was significantly less for SH. In our study group, mean time to return to work was found 8 days. About 79% of the study population returned to work in 8 or lesser days, similar to other studies.[28] It is estimated that the general complication rate for SH varies from 12% to 36.4% in comparison to 19–49% for open hemorrhoidectomy.[29-31] The intraoperative bleeding and discharge were witnessed in 2% of patients which was almost nil to exist, whereas Kishore *et al.* stated that it occurred in all the cases of open hemorrhoidectomy ranged from dressing soakage to about few drops during defecation in their study.[23] Persistence of pain after SH is considered chronic if it lasts one week after SH. The prevalence of persistent pain ranges from 1.6% to 31%.[23] Lelpo *et al.* reported that a prevalence rate of persistent pain after SH was 14.3%, while in our study, it was 5.2%, which is still within the reported range.[32] Although the cost of the stapler device is still relatively high, the length of hospital stay and the period of the patient's incapacity for work are undoubtedly reduced. The absence of local care and less post-operative pain is clear advantages to the patient. SH results in significantly lesser immediate post-operative pain than conventional

Table 1: The mean length of hospital stay and VAS score

	Mean±SD	Median	Min–Max
Length of hospital stay	1.79±0.41	2.00	1–2
VAS score	4.42±0.81	4.00	2–7

Table 2: Visual analog scale

VAS score	Frequency	Percentage
3	12	12.0
4	42	42.0
5	38	38.0
6	8	8.0
Total	100	100

excision techniques (by 2–3 levels on the visual analog scale) and offers more comfort to the patient.[18] In contrast, a study stated that SH caused more post-operative pain; those results remained controversial because they were seriously challenged by several letters to the editor and caused heated discussion with no consensus.[33] In this descriptive study of shorter duration, we found positive functional outcomes as shown in previous studies but needed further longer duration study for recurrence and longer duration outcomes. SH represents a simple and fast operation when compared to the procedure of transanal dearterialization. With the existing evidence, one cannot fail to appreciate that technical errors may play a pivotal role in the high recurrence rate (especially symptomatic) as compared to other conventional procedures.[34-36] There is always some difficulty in estimating the amount of mucosal prolapse that needs to be removed. It is, however, reasonable to assume that a higher degree of hemorrhoid prolapse requires a larger resection of rectal mucosa. As a result, there is increasing consensus among experts about the concept that fourth-degree hemorrhoid disease should not be a valid indication of SH. More in-depth analysis is therefore needed in overlapping cases with respect to the subjectivity of the technique being performed.

CONCLUSION

Within the given limitations of the study, we can conclude that SH is a successful procedure for Grade-III/IV hemorrhoids in terms of immediate post-operative complications, pain as well as the duration of hospital stay.

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Original Article

A Study on Orbital Cellulitis Due to Acute Sinusitis: A Multidisciplinary Approach

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Abstract

Introduction: Orbital infection has spread beyond the orbital septum leads to orbital cellulitis. The distinctive features of orbital cellulitis are proptosis and limitation of ocular movements. Additional useful signs are chemosis of bulbar conjunctiva, reduced visual acuity, afferent pupillary defect, and toxic systemic symptoms. Prompt diagnosis and treatment of orbital cellulitis is vital as it is associated with serious complications such as cavernous venous thrombosis, visual loss, meningitis, brain abscess, and sepsis.

Aims and Objectives: The purpose of this study is to evaluate clinical presentation, treatment outcomes, and post-surgical complications of diagnosed case of orbital cellulitis.

Materials and Methods: This is a cross-sectional study of patients with orbital cellulitis as a complication of acute sinusitis. All the patients were subjected to thorough clinical examination, ophthalmic and radiological evaluation. Computed tomography of paranasal sinuses done. All the patients in this study received appropriate medical and surgical management and follow-up evaluation done at the 1st month and 3 months.

Results: Orbital cellulitis due to fungal sinusitis is prevalent among uncontrolled type 2 diabetes mellitus patients in our study. Surgical management such as endoscopic sinus surgery with intravenous antibiotic therapy found to be more effective than conservative management alone.

Conclusion: Strict diabetic control, appropriate surgical and medical management, and a vigilant follow up resulted to a better outcome.

Key words: Acute sinusitis, Endoscopic sinus surgery, Fungal sinusitis, Orbital cellulitis

INTRODUCTION

Orbital cellulitis is defined as an inflammation of tissue behind the orbital septum. The orbital complications are more commonly seen in the pediatric aged group with the overall incidence of 3–4% in children affected by acute rhinosinusitis. In general, rhinosinusitis is responsible for 66–82% of cases of orbital infection and the acute ethmoiditis represents the most common.[1] Diabetes mellitus (DM) and immunosuppression increase the risk of infection. Orbital involvement can be easily suspected in case of ophthalmoplegia and proptosis. The diagnosis is usually achieved through the combination of clinical examination and radiological findings. Chandler classification still represents the most complete and popular to indicate the severity of the infection.[2] Orbital infection originating from paranasal sinuses can cause vision loss and death due to intracranial extension.[3] Aggressive antibiotic therapy and surgery can be considered to achieve optimal prognosis. The aim of this study was to report our experience about the prevalence of orbital cellulitis and its management due to a sinus infection.

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MATERIALS AND METHODS

This study was performed in the ENT Department in Chengalpattu Medical College and Hospital. A cross-

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sectional study was done from the period of February 2015 to February 2020.

Inclusion Criteria

The following criteria were included in the study:

1. Clinical diagnosis of orbital complication of acute rhinosinusitis.
2. Age of patients 5–65 years.
3. Clinical and endoscopic ground with imaging for the diagnosis of acute rhinosinusitis.
4. Patients with diabetes and non-invasive fungal sinusitis.

Exclusion Criteria

The following criteria were excluded from the study:

1. Age <5 years and >65 years.
2. Previous history of facial trauma.
3. Immunocompromised.
4. Invasive fungal sinusitis and with positive fungal cultures for mucormycosis.

All patients were undergone ophthalmologic evaluation with visual acuity, pupil reactivity testing of the affected eye, and ocular movement impairment. Diplopia could not be detected in the patients with complete eye closure. Diagnostic nasal endoscopy carried out for all patients. Computed tomography (CT) scan of paranasal sinuses with orbit was performed, culture-specific intravenous antibiotic therapy administered and surgical intervention done when necessitated.

RESULTS

Between February 2015 and February 2020, 30 patients were admitted to our institution with the diagnosis of orbital cellulitis as a complication of sinus infection. Their age varied from 5 years to 65 years. Most of the patients belong to the age group of 55 to 65 years [Figure 1]. Twenty-four were male and six were female [Table 1]. Out of 22 patients (73%) in the adult age group, 17 (78%) were diabetic and 5 (22%) were non-diabetic [Figure 2]. Among clinical features, periorbital swelling was common [Figure 3]. Blood cultures were done. The most commonly isolated bacterial species were *Staphylococcus aureus* (40%) and *Streptococcus* (20%) and fungal species *Aspergillus* (26%) [Figure 4]. The most commonly involved sinus in the pediatric age group is maxillary sinus (13%). On the contrary, ethmoid sinus (36.67%) is the most commonly involved in adult age group [Figure 5 and Table 2].

About 73.33% of the patients were given surgical clearance of the sinuses with intravenous antibiotic coverage as primary treatment. About 26.67% was treated conservatively with culture-specific intravenous antibiotics.

Table 1: Gender prevalence

Gender	No. of patients
Males (years)	
<15	6 (20)
>15	18 (60)
Females (years)	
<15	2 (7)
>15	4 (13)

Table 2: Sinus involvement

Sinus involvement	No. of patients (5)
Single sinus	18 (60)
Two sinuses	10 (33.3)
Multiple sinuses	2 (6.67)

Conservative management was carried out in children <9 years of age and those with uncontrolled type 2 DM. Only 2 young children (6.67%) who treated conservatively had recurrence of orbital cellulitis after 2 months of initial treatment. Three cases (10%) of orbital cellulitis, who were managed conservatively in the pediatric age group had turned into subperiosteal abscess during the course of treatment. Those who developed complications and those had recurrence were taken up for surgery. These patients had no recurrence during follow-up. Overall 90% of the patients in our study were given surgical management while only 10% of the patients had better outcome with conservative management alone.

DISCUSSION

Orbital cellulitis is the complication of sinusitis where the infectious process has extended beyond the orbital septum in which patient may present with pain, reduced visual acuity, compromised ocular motility, and significant proptosis. The most common predisposing factor for orbital cellulitis is sinus disease especially in children. Sinusitis is the leading cause for the development of orbital cellulitis and anatomic variations of the osteomeatal complex such as concha bullosa and paradoxical middle turbinate can predispose and exacerbate underlying sinusitis.[4] Chandler *et al.*[2] grouped complication of sinus inflammation into five classes. In Group 1, eyelids may be swollen along with the presence of orbital content edema (preseptal cellulitis). Group II reflects evidence of orbital cellulitis in which inflammatory cells diffusely infiltrate orbital tissues. In Group II, the eyelids may be swollen along with conjunctival chemosis as well as some degree of proptosis. Purulent material may be collecting as subperiosteal abscess between the periorbita and the bony walls of the orbit in Group III. Patients in Group IV (orbital abscess) may present with their abscess being inside

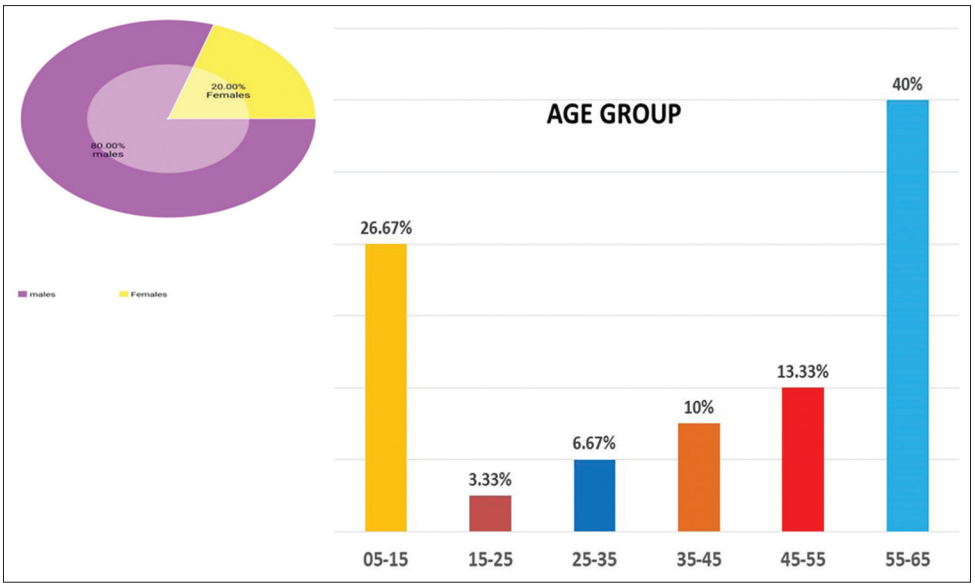

Figure 1: Age-wise distribution of orbital cellulitis

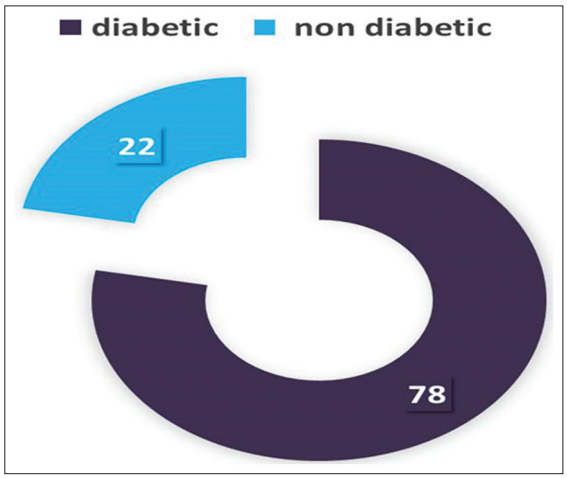

Figure 2: Orbital cellulitis in adult diabetic

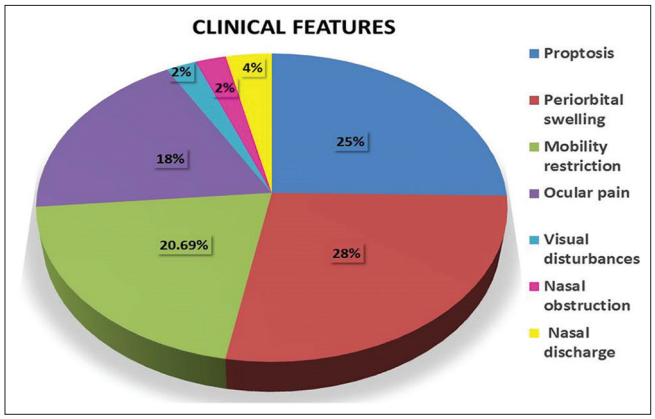

Figure 3: Clinical presentation of orbital cellulitis

or outside the muscle cone following untreated orbital cellulitis. Patients in Group V may present with bilateral eyelid edema along with involvement of the third, fifth,

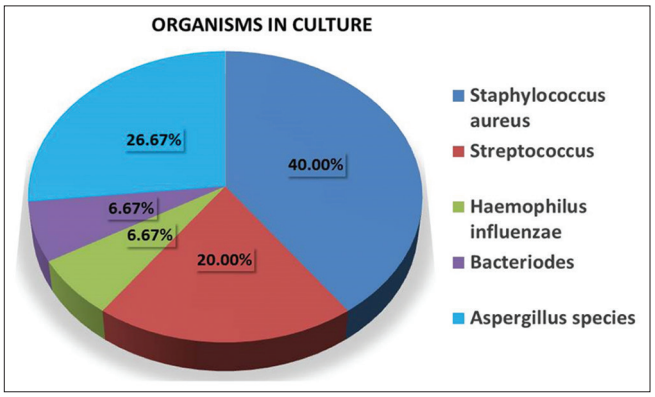

Figure 4: Microbiological profile of orbital cellulitis

and sixth cranial nerves which is thought to due to the extension of the infectious process into the cavernous sinus with formation of thrombosis. Radiographic imaging should be performed to confirm involvement of the orbit and degree of orbital involvement, evaluate for potential source of infection, and presence of abscess. Parenteral broad spectrum antibiotic such as a third-generation cephalosporin (cefotaxime or ceftriaxone) or a combined penicillin (ampicillin-sulbactam; amoxicillin/clavulanic acid) and surgical clearance of the sinuses remains main stay of treatment.

In our study, sinusitis-induced orbital cellulitis is found to be predominant among 55–65 years age group with mean age of 59.3 years. The second most commonly affected group in our study are younger children among 5–15 years age group with mean age of 9.7 years. Males are predominantly affected than females. This correlates with Choudhary *et al.*[5] a study of 218 patients of orbital cellulitis, found sinusitis as the most common predisposing

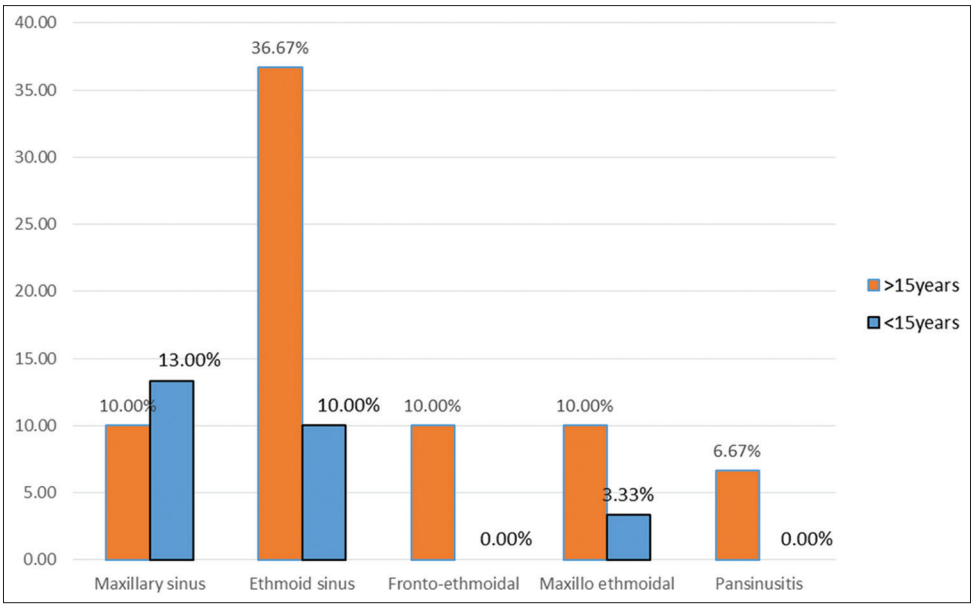

Figure 5: Comparison of sinus involvement in adult and children

factor in children. This correlates with Ferguson *et al.*[6], Meara *et al.*[7], and Bedwell *et al.*[8] studies where pediatric age group is predominantly affected.

Among adult population, 78% were found to be diabetic, which forms the major predisposing factor for fungal sinusitis. In our study, fungal sinusitis with orbital cellulitis due to *Aspergillus* species has alone taken into account though mucormycosis is predominant among diabetic individuals. Orbital cellulitis with proptosis (28%), periorbital edema (25%), extraocular movements restriction (20.69%), ocular pain (18%), visual disturbances (4%), and nasal symptoms (4%) has been reported in our study, correlates with Ferguson *et al.*[6] and Chaudhry *et al.*[9] studies where periorbital swelling, proptosis, mobility restriction, and ocular pain were the most commonly presented symptoms of orbital cellulitis in those patients they studied.

The involvement of single sinus (60%) and two sinuses (33%) was mostly encountered while 7% have multiple sinuses involvement. Among the reported cases of pediatric orbital cellulitis, ethmoid sinus (10%) and maxillary sinus (13%) were most commonly affected. Studies such as Ferguson *et al.*[6] and Chaudhry *et al.*[5] reported that maxillary sinus and ethmoid sinus were the most commonly involved sinuses in pediatric age group. Adult population have predominant involvement of ethmoid sinuses (36.67%), followed by maxillary sinus (10%), maxilloethmoidal (10%), frontoethmoidal (10%), and pan sinusitis (6.67%). In Morgan *et al.*[10], Fearon *et al.*[11], and Harris *et al.*[12] studies, frontal sinus disease has been frequently identified, especially in series in which a large number of adults and adolescents have been studied.

On imaging studies, there may be evidence of inflammatory/infective changes in the sinus areas as well as orbital structures, breach in lamina papyracea, lateral displacement of the medial rectus, and periosteum pushed away from the lamina papyracea and low-density mass effect without enhancement and air-fluid level in cases of abscess suspected. CT scan is indicated in all patients with periorbital inflammation in which proptosis, ophthalmoplegia, or decrease in visual acuity develop severe eyelid edema prevents an adequate examination and when surgery is contemplated.

Bacterial culture isolates were *S. aureus* (40%), *Streptococcus* (20%), *Haemophilus influenza* (6.67%), and *Bacteroides* (6.67%). *S. aureus* is most common isolated organism in our study. This correlates with Hornblass *et al.*[13] studies where *S. aureus* was reported as most common causative organisms for orbital cellulitis and formation of orbital abscess. Fergusson and Mcnab's study, *S. aureus* was the most commonly encountered organism and anaerobes were much less common which correlates with what we have been reported. Fungal cultures revealed *Aspergillus* species (26.67%) most commonly noted in diabetic individuals in our study.

Surgical clearance of the sinuses with perioperative and post-operative intravenous antibiotic therapy given in 63.33% of patients as initial treatment strategy. Children <9 years and those with uncontrolled type 2 diabetes were given intravenous culture-specific antibiotic therapy. About 10% of the patients developed complication such as sub periosteal abscess had taken up for surgical drainage of the abscess along with surgical clearance of the sinuses.

About 6.67% of the patients had recurrence after 1 month of initial treatment and these individuals were taken for surgery and had no recurrence during further visits. All diabetic individuals in our study were given good glycemic control as per physician opinion with oral hypoglycemic drugs and insulin therapy. Although conservative management had significant better outcomes, surgical indulgence had much more better results and speedy recovery and most importantly with no further progression to complications and no further troublesome episodes of orbital cellulitis during follow-up. This correlates with Setz *et al*.[14], Ferguson *et al*.[6], Chaudhry *et al*.[9], and Bedwell *et al*.[8] noted in majority of the cases, surgical intervention is indicated for significant underlying sinus disease, orbital or subperiosteal abscess, or both in the children and for older patients, sinus surgery remains the most common surgical intervention. Combined endoscopic sinus surgery with transnasal abscess drainage was carried out in patients with sinusitis.

CONCLUSION

Orbital complications of sinusitis tend to occur in children and aged individuals. DM becomes the main predisposing factor. Extraocular muscle limitation and proptosis predicted post-septal involvement and reduced visual acuity and the presence of RAPD indicates the likelihood of intra cranial complication which poses a risk of blindness and death. Imaging modalities and prompt consultation with otorhinolaryngologists and ophthalmologists and neurologists, intravenous antibiotic therapy, and prompt surgical drainage whenever indicated, results in better outcome.

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Original Article

Assessment of Post-operative Complications, Recurrence Rate, and Patient Satisfaction after Undergoing Stapled Hemorrhoidopexy Intervention for Grades III and IV Hemorrhoids among Adult Patients of North India

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Abstract:

Introduction: Hemorrhoids are one of the most frequent anorectal disorders encountered by clinicians in day-to-day practice and constitute about 50% of colorectal investigations. Stapled hemorrhoidopexy (SH) represents the first dramatic change in the treatment of hemorrhoids. Since its introduction, some researchers have raised concerns about the recurrence rate as well as patient satisfaction. Hence, the present study was carried out to evaluate recurrence rate and patient overall satisfaction with SH procedure at a tertiary care center in North India.

Materials and Methods: Ethical clearance was obtained at the start of the study from the Institutional Review Board. A total of 100 patients with Grade III/IV hemorrhoids were included. SH was performed as per the standard procedures. Data were collected on complications developed post operatively at different follow-ups and an overall patient satisfaction. The data were coded and entered into Microsoft Excel 2010.

Results: Post-operative complications we observed at the 1st week were bleeding and discharge in 5%, pain in 9%, and urinary retention in 11% of enrolled cohorts. At 1 month, hematoma formation was observed in 7.3% of total remaining patients (n = 96) and 5.2% still had post-operative pain. At 6 months, pruritus and stenosis were witnessed in 4.3% and 1.1%, respectively, of total remaining patients (n = 93). Recurrence rate was found 4.3% at the end of 6 months. The overall complication rates at 1 week, 1 month, and 6 months follow-up were 25%, 12.5%, and 9.7%, respectively.

Conclusion: The findings of our study confirm that SH is associated with a high patient satisfaction and with a lesser post-operative complications. We conclude that SH is safe with many short-term benefits.

Key words: Complications, Hemorrhoids, Stapled hemorrhoidopexy, Surgery

INTRODUCTION

Hemorrhoids are one of the most frequent anorectal disorders encountered by clinicians in day-to-day practice and constitute about 50% of colorectal investigations.[1] Hemorrhoids are characterized by pathological changes of anal cushions and include rupture of supportive connective tissues within the cushions, resulting in enlargement of venous plexus.[2] The exact incidence of this common condition is difficult to estimate as many people are reluctant to seek medical advice for various personal, cultural, and socioeconomic reasons. It has been estimated that 58% of people over 40 years have hemorrhoids in the United States. One million new cases are reported annually, at the rate of 47/1000 and this rate increases with age.[3-5] The

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etiological factors responsible for hemorrhoid development include constipation, prolonged straining, pregnancy, obesity, aging, hereditary, derangement of the internal anal sphincter, weak blood vessels, and absent valves in the portal vein.[5-8] Today, most patients with low-grade hemorrhoidal disease in whom medical treatment fails may be effectively treated with office-based procedures, such as banding, sclerotherapy, and infrared coagulation.[10-12] However, surgical hemorrhoidectomy is reserved for patients who are refractory to office procedures, who are unable to tolerate office procedures, who have large external hemorrhoids, or who have combined internal and external hemorrhoids with significant prolapse (Grades III to IV).[13] Excisional hemorrhoidectomy (EH) using Milligan-Morgan open hemorrhoidectomy and Ferguson closed hemorrhoidectomy are two most commonly used techniques for surgical correction, however, both the techniques have shown to be associated with severe pain postoperatively.[14-17] Stapled hemorrhoidopexy (SH) represents the first dramatic change in the treatment of hemorrhoids in many years introduced in 1997 by Longo.[18,19] If feasible, it is recommended as the first-choice procedure when post-operative pain is considered.[20] The results of SH have been assessed in some randomized controlled trials.[21,22] These studies have consistently shown a decrease in post-operative pain, analgesic requirement, length of surgical procedure, short recovery time, and early return to normal activities. However, despite these promising results, some recently published reviews showed data that there is no conclusive evidence for the long-term benefit of stapled procedure, despite patient acceptance being high.[23,24] Since its introduction, some researchers have raised concerns about the recurrence rate as well as patient satisfaction. Considering conflict in reports, it is essential that to resolve this debate, evidence-based clinical studies should be carried out and clinical evidence be recorded to settle the issue. Hence, the present study was carried out to evaluate recurrence rate and patient overall satisfaction with SH procedure at a tertiary care center in North India.

MATERIALS AND METHODS

Ethical clearance was obtained at the start of the study from the Institutional Review Board. The SH technique is a regularly carried out procedure for indicated cases as a part of the treatment regime. The data of the same cases were used for the study purpose. The sample size has been calculated as suggested by Snedecor and Cochran (1989), and the calculated sample size was 100. This observational study was undertaken in the Department of General Surgery at Asian Institute of Medical Science at Faridabad. A total of 100 subjects who were undergoing SH and fulfilled the inclusion and exclusion criteria were enrolled in the study. All subjects were followed up at 1 week, 1 month, and at 6 months periods. There were four patients lost to follow up at 1 month and 7 patients lost to follow up at 6 months; and remaining 93 patients successfully completed the study.

Inclusion Criteria

The following criteria were included in the study:

- Clinically diagnosed cases of Grades III and IV hemorrhoids (symptomatic).
- Patients of either sex
- Patients aged 18–70 years.

Exclusion Criteria

The following criteria were excluded from the study:

- Patients with Grades I and II hemorrhoids
- Patients with previous history of hemorrhoidectomy
- Patients with associated fistula in ano, fissure in ano, thrombosed piles, growth per rectum, anal stenosis, and prolapse of single anal cushion
- Pregnant females
- Patients with portal hypertension.

Operative evaluations: One dose of ciprofloxacin and metronidazole was given at the time of anesthesia for surgery. All operations were performed in lithotomy position preferably under spinal anesthesia. In case of failure to achieve adequate anesthesia using spinal anesthesia, alternate anesthetic technique/ general anesthesia was tried. A written informed consent was taken separately from the patients to include their details as a part of the study. The surgical procedure as detailed by Altomare (Ellesmore and Windsor, 2002) was followed.

Post-operative Evaluation

Method of measurement of outcome of interest: Post-operative pain, bleeding, discharge per rectum, and infection were recorded. Post-operative bleeding was recorded in terms of ml/number of dressings changed, discharge per rectum and/or infection were monitored as event and recorded whenever occurred. Patients were asked to confirm if they were satisfied with the overall procedure and its outcome at the end of the study as satisfied and not satisfied. The data collected was coded into Microsoft Excel 2013.

RESULTS

There were in all 100 participants in the study. Figure 1 shows the age distribution of the study population.

The studied group had male preponderance and male: female ratio was 3:1. Table 1 shows the sex distribution of the study population.

Table 1: Sex distribution of the study population

Gender	Frequency (%)
Female	25 (25)
Male	75 (75)
Total	100 (100)

In the study group, 73% of subjects had Grade III and 27% had Grade IV hemorrhoids. Out of 93 subjects, 5.4% had bleeding and discharge, 7.5% had hematoma formation, and 11.8% suffered urinary retention. Figure 2 shows the recurrence of the hemorrhoid with respect to time.

We successfully followed up all the enrolled patients at the 1st week; however, four patients at 1 month and total 7 patients at 6 months lost to follow up and remaining 93 patients successfully completed the study. Post-operative complications we observed at the 1st week were bleeding and discharge in 5%, pain in 9%, and urinary retention in 11% of enrolled cohorts (n = 100). About 75% of patients did not experience any complication post-SH. At 1 month, hematoma formation was observed in 7.3% of total remaining patients (n = 96) and 5.2% still had post-operative pain. At 6 months, we lost 7 patients to follow up. About 83.9% had no complication, on the other hand, pruritus and stenosis were witnessed in 4.3% and 1.1%, respectively, of total remaining patients (n = 93). Recurrence rate was found 4.3% at the end of 6 months. The overall complication rates at 1 week, 1 month, and 6 months follow-up were 25%, 12.5%, and 9.7%, respectively. Figure 3 shows distribution of the study participants as per the satisfaction rate.

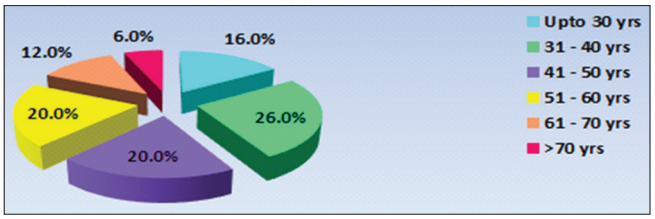

Figure 1: Age distribution of study population

Post op complications	1 week		1 month		6 month	
	Frequency	%	Frequency	%	Frequency	%
None	75	75.0%	84	87.5%	84	90.3%
Bleeding	5	5.0%				
Pain	9	9.0%	5	5.2%		
Urinary retention	11	11.0%				
Hematoma			7	7.3%		
Pruritis					4	4.3%
Recurrence					4	4.3%
Stenosis					1	1.1%
Total	100		96	100.0%	93	100.0%

Figure 2: Post-operative complications at different time of follow-up

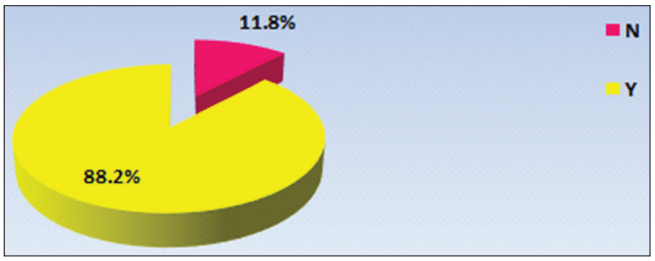

Figure 3: Patient's satisfaction rate. Y: Satisfied, N: Not satisfied

DISCUSSION

Hemorrhoidal disease is one of most frequent anorectal diseases encountered at Asian Institute of Medical Science at Faridabad and in general population at large. It is a significant cause of admissions and outpatient follow-up attendance at our hospital. SH, first introduced in 1997 by Longo, has gained popularity over the past decade for the management of Grade III/IV hemorrhoidal disease.[18] It has emerged as an alternative to open hemorrhoidectomy, long considered "gold standard." The technique has been standardized and the indications, contraindications, and operative technique have been defined. The results of SH have been weighed in many randomized trails.[21-26] Few Indian studies have also been documented.[27-31] In terms of age distribution, this study found that hemorrhoids affect most active age group of 20–49 years accounting for total of 62% of those affected in this study. This is in accordance with other workers.[30,32] Risk factors to females are similar to their male counterpart. If fact, pregnancy being the most common cause of abdominal distention in female should have exacerbated the hemorrhoids formation. One of possibility for lesser prevalence of hemorrhoids among female could be shielding effect of pregnancy against hemorrhoids development for unclear reason and requires further studies for confirmation. It is estimated that the general complication rate for SH varies from 12% to 36.4% in comparison to 19 to 49% for open hemorrhoidectomy.[33-35] Complications can be early (within 1 week after surgery) or late (1 week post-surgery). Early complications include bleeding, constipation, urgency defecation, pain, urinary retention, dehiscence of the suture, and rectal perforation with sepsis. Main late complications are anal stenosis, pruritus, urgency, and anal pain. In our study, the overall complication rates at 1 week, 1 month, and 6 months follow-up were 25%, 12.5%, and 9.7%, respectively. The early complications we observed were bleeding and discharge in 5%, pain in 9%, and urinary retention in 11% of the study group (n = 100). The post-operative bleeding and discharge was witnessed in 5% of patients (n = 100) which was almost nil to exist, whereas Kishore *et al.* stated that it occurred in all the cases of open hemorrhoidectomy ranged from dressing soakage to about few drops during defecation in their study.[30] As per randomized control trials

in different centers in the United Kingdom, significantly lowered post-operative bleeding was associated with SH group than open group.[23] Urinary retention is a common complication in anorectal surgery with an incidence of 1.5–32%. In our experience, urinary retention occurred in 11% of cases. The reasons for urinary retention are uncertain, but precipitating factors could be related to perioperative pain and perioperative fluid intake.[36] The overall recurrence rate in our study group was 4.3%. The recurrence rate for Grade III subjects was 1.4% as compared to 13% for Grade IV subjects. Giordano *et al.* in his meta-analysis of 15 studies reported incidences of recurrence in follow-up period of 12 months to 84 months.[25] Watson *et al.* in a multicenter, randomized controlled trial – eTHoS showed that 32% of patients in SH group at 12 months after randomization and 42% of patients in SH group at 24 months of randomization had recurrence of hemorrhoidal disease and incidence of recurrence was more in SH group than excision group.[26] The low recurrence rate in our study was probably because of short follow-up in our study. Pelvis sepsis has also been reported in literature but no such complication occurred in our study. The absence of local care and less post-operative pain is clear advantages to the patient. A study published in Lancet stated that SH caused more post-operative pain, those results remained controversial because they were seriously challenged by several letters to the editor and caused heated discussion with no consensus.[37] Minor complications following surgical procedures for hemorrhoidal disease are quite common and include pain, rectal bleeding, vasovagal reaction, micturition disturbances, anal fissures, and ulcers in the anal canal. Analgesics of the nonsteroidal anti-inflammatory drug group and others are used to treat mild pain. Observation and/or surgical hemostasis are relevant in case of minor rectal bleeding. Micturition disturbances should be monitored with bladder scans and catheterization if necessary. The pathophysiologic background of the treatment of hemorrhoidal disease by stapler is different than the pathophysiologic basis for excision hemorrhoidectomy and is being controversially discussed. The complete circular mucosa cranial to the hemorrhoidal plexus is resected, allowing reduction of mucosa prolapse by mucosa lifting and by fixing the prolapsed mucosa at the rectum wall. The reduction of arterial blood flow to the hemorrhoidal plexus is probably not the main point of the treatment. In this descriptive study of shorter duration, we found positive functional outcomes as shown in the previous studies but needed further longer duration study for recurrence and longer duration outcomes. Majority of the patients were satisfied with the outcome of the study. The hemorrhoids may prolapse and result in other symptoms of mucus seepage, pruritus, loss of discrimination and continence to flatus, and occasional fecal incontinence. The latter may cause social embarrassment. Patients with permanent prolapsed hemorrhoids may also face difficulty in maintaining local hygiene. These symptoms impact the quality of life of patients. A study by Garg *et al.* reported that SH improved the physical and the psychological domains of the quality of life of the patients.[38] The present study had certain limitations. We did not compare the outcome with the conventional surgical technique. Furthermore, the sample size was small and relatively equal number of men and women were not involved. Even though the study showed lesser complications, the long-term follow-up for Grades III and IV separately is required.

CONCLUSION

Overall recurrence rate in our study was 4.3% which was lower than previously published study probably because of shorter follow-up of our study. The findings of our study confirm that SH is associated with a high patient satisfaction and with a lesser post-operative complications. We conclude that SH is safe with many short-term benefits. It is a novel technique and has emerged as an alternative to open hemorrhoidectomy, long considered the "gold standard."

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Original Article

Study of Hematological Alterations in Malaria at a Tertiary Health Care Center of South Gujarat, India

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Abstract

Background: Malaria is a disease with a great global burden. It is one of the most prevalent parasitic infection common in tropical, subtropical countries, particularly Asia and Africa. Malaria causing plasmodia is parasites of blood and hence induces hematological alterations. The hematological changes that have been reported to accompany malaria include anemia, thrombocytopenia, leukocytosis as well as leukopenia, mild-to-moderate atypical lymphocytosis, monocytosis, eosinophilia, and neutrophilia. Hence, the present study is undertaken to evaluate the various hematological parameters affected in malaria and to observe the variations, if any, in *Plasmodium falciparum*, *Plasmodium vivax,* and mixed infections.

Materials and Methods: The present study was carried out in the Department of Pathology at Tertiary Health Care Center of South Gujarat from August 2018 to October 2018. A total of 480 smear-positive malaria cases were analyzed and various hematological parameters were studied.

Results: Out of 480 smear-positive cases, *P. vivax* was positive in 77% of cases, *P. falciparum* was positive in 22% of cases and mixed infection in 1% of cases. Most of the cases were seen in the age group of 21–40 years. Anemia was seen in 53.1% of cases. Normocytic normochromic blood picture was the most common type in anemic patients (46.6%). Thrombocytopenia was seen in 84.58% of the patients. Out of which, 75.86% were affected by *P. vivax*, 23.15% were affected by *P. falciparum*, and 0.98% were affected by the mixed infection. About 28.75% of cases showed hematological features of leukopenia, and 5.2% of cases were having leukocytosis.

Conclusions: Various hematological findings can help in early diagnosis of malaria which is essential for timely and appropriate treatment which can limit the morbidity and prevent further complications

Key words: Anemia, Hematological parameters, Malaria, Prevention, Thrombocytopenia

INTRODUCTION

"Malaria" received its name from Italian, as it was believed to arise due to foul air common near marshy areas. It is one of the most prevalent parasitic infection common in tropical, subtropical countries, particularly Asia and Africa.[1,2] It is a protozoan disease transmitted by the bite of infected Anopheles mosquito, and the incubation period varies from 8 to 30 days depending on species. Despite enormous control efforts, an increase in the drug resistance of the parasite, the insecticide resistance of its vectors, human travel, and migration has contributed to its resurgence and is a leading cause of mortality and morbidity in developing areas of the world.[3]

According to the WHO World Malaria Report 2018, an estimated 219 million cases of malaria occurred worldwide in 2017, compared with 216 million cases in 2016, 214 million cases in 2015. Most malaria cases in 2017 were in the WHO African Region (200 million or 92%), followed by the WHO Southeast Asia Region with 5% of the cases and the WHO Eastern Mediterranean Region with 2%. Fifteen countries in Sub-Saharan Africa and India carried almost 80% of the global malaria burden. Five countries accounted for nearly half of all malaria cases worldwide: Nigeria (25%), the Democratic Republic of the Congo (11%), Mozambique (5%), India (4%), and

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Uganda (4%).[1] In India, in the year 2017, a total of 8.76 million malaria cases had occurred, out of which about 48% of cases were *Plasmodium vivax* malaria.[1] The annual parasite index of India for the year 2015 was 0.9. Annual Blood Smear Examination (ABER) of India for the year 2015 was 9.6.

The incidence rate (i.e., the number of cases per 1000 population) of malaria globally reduced between 2010 and 2017; it fell from 72 in 2010 to 59 in 2017. India reported more than 3 million fewer cases (24%) from 2016 to 2017.[1]

Clinical presentations of malaria include – fever with chill and rigor, headache, diarrhea, vomiting, abdominal distension, cough, hepatomegaly, and splenomegaly.[2]

Malaria causing plasmodia is parasites of blood and hence induces hematological alterations. The hematological changes that have been reported to accompany malaria include anemia, thrombocytopenia, leukocytosis as well as leukopenia, mild-to-moderate atypical lymphocytosis, monocytosis, eosinophilia, and neutrophilia. Platelet abnormalities are both qualitative as well as quantitative.[4]

The high mortality rate in malaria infection is usually associated with heavy parasite load, anemia, low platelet count, jaundice, and delay in diagnosis.[2]

Hence, the present study is undertaken to evaluate the various hematological parameters affected in malaria and to observe the variations, if any, in *Plasmodium falciparum*, *P. vivax,* and mixed infections. The aim of the study is to find out changes in different hematological parameters in smear-positive malaria cases and to compare these changes in *P. vivax* and *P. falciparum* infection.

MATERIALS AND METHODS

Study Setting

The present study was carried out in the Department of Pathology at Tertiary Health Care Center of South Gujarat from August 2018 to October 2018. A total of 480 smear-positive malaria cases were analyzed.

Study Period

August 2018 to October 2018.

Study Design

This was a cross-sectional descriptive study.

Inclusion Criteria

The laboratory confirmed that smear-positive malaria cases from August 2018 to October 2018 were included in this study.

Exclusion Criteria

NIL.

Sample Size

The sample size was 480 cases.

Control(s)

Not required.

Methods of Collection of Data

All malaria positive cases were analyzed. Routine laboratory work, thin, and thick blood films were prepared and examined for defining the species involved. The thin and the thick smears were made on the same slide and stained with Giemsa stain. A minimum of 200 fields (oil immersion) were assessed to label a negative smear.

Hematological profile by a three-part cell counter was performed in all patients. Anemia and thrombocytopenia were labeled when hemoglobin was <11.0 g%, and platelet counts were <1.5 lakh/mm^3, respectively. Leukopenia and leukocytosis were labeled when the total WBC count was $<4.0 \times 10^3/mm^3$ and $>11.0 \times 10^3/mm^3$, respectively.

Blood film examination was also performed in all patients, and they were classified according to the morphologic type of anemia in the following category: Normocytic normochromic, normocytic hypochromic, microcytic hypochromic, and dimorphic (normocytic to macrocytic and microcytic to macrocytic).

Statistical Analysis

Qualitative data are presented as frequencies and percentages. All the data were analyzed using Microsoft Excel 2013.

RESULTS

The present study was carried out in the Department of Pathology at Tertiary Health Care Center of South Gujarat from August 2018 to October 2018. A total of 480 smear-positive malaria cases were analyzed, and hematological parameters were studied.

Out of 480 malaria positive cases, *P. vivax* was the most common observed species in our study accounting for 370 cases (77%) followed by *P. falciparum* accounting for 106 cases (22%) followed by 4 (1%) cases of mixed infection [Table 1].

Most of the cases were seen in the age group of 21–40 years (50%) with the highest prevalence between the age group of 21 and 30 years (32.5%). There were 28.2% of cases that were below the age of 20 years. Youngest case

was 6 months old, and the oldest case was 75 years old and both cases were having *P. vivax* infection [Table 2].

There were 312 cases of males (65%) and 168 cases of females (35%). In our study, male:female ratio was 1.8:1 [Table 3].

Anemia was seen in 255 (53.1%) cases. Out of which, 196 (76.9%) cases were of *P. vivax*, and 56 (21.9%) cases were of *P. falciparum* and 3 (1.2%) cases were of mixed infection [Table 4].

Blood picture was normocytic normochromic in 224 (46.6%) cases, which was the most common finding in the study followed by a microcytic hypochromic picture in 102 (21.2%) cases followed by normocytic hypochromic picture in 65 (13.5%) cases [Table 5].

Out of 480 cases, 138 (28.75%) cases showed hematological features of leukopenia and 25 (5.2%) cases were having leukocytosis. Out of 138 leukopenia cases, 90 cases (65.2%) were having *P. vivax* infection, and 48 cases (34.8%) were having *P. falciparum* infection. Out of 25 leukocytosis cases, 20 cases (80%) were having *P. vivax* infection, two cases (8%) were having *P. falciparum* infection, and three cases (12%) were having mixed infection [Table 6].

Out of total of 480 cases, the majority – 406 cases (84.58%) were having thrombocytopenia. Out of which, 308 cases (75.86%) were affected by *P. vivax*, 94 cases (23.15%) were affected by *P. falciparum*, and four cases (0.98%) were affected by mixed infection [Table 7].

DISCUSSION

Malaria is transmitted by the female anopheles mosquito, which causes clinical illness and pathological changes in various body organs with the parasites invading and multiplying in the circulating red blood cells. Malaria causes

Table 1: Total malaria positive cases

Total case	*Plasmodium vivax*		*Plasmodium falciparum*		Mixed infection	
	Number of cases	Percentage	Number of cases	Percentage	Number of cases	Percentage
480	370	77	106	22	4	1

Table 2: Age-wise distribution of malaria

Age group (years)	*Plasmodium vivax*		*Plasmodium falciparum*		Mixed infection		Total	
	Number of cases	Percentage	Number of cases	Percentage	Number of cases	Percentage	Number of cases	Percentage
0–10	61	16.4	09	8.5	00	00	70	14.6
11–20	53	14.4	12	11.3	00	00	65	13.6
21–30	126	34.0	28	26.4	2	50	156	32.5
31–40	62	16.7	22	20.8	00	00	84	17.5
41–50	33	8.9	20	18.9	00	00	53	11.0
51–60	26	7.1	13	12.3	2	50	41	8.5
61–70	8	2.1	02	1.8	00	00	10	2.1
71–80	1	0.4	00	00	00	00	01	0.2
Total	370	100	106	100	4	100	480	100

Table 3: Sex-wise distribution of malaria

Sex	*Plasmodium vivax*		*Plasmodium falciparum*		Mixed infection		Total	
	Number of cases	Percentage	Number of cases	Percentage	Number of cases	Percentage	Number of cases	Percentage
Male	233	63.0	78	73.6	1	25	312	65
Female	137	37.0	28	26.4	3	75	168	35
Total	370	100	106	100	4	100	480	100

Table 4: Anemia in malaria cases (hemoglobin <11 g%)

Total case	*Plasmodium vivax*		*Plasmodium falciparum*		Mixed infection	
	Number of cases	Percentage	Number of cases	Percentage	Number of cases	Percentage
255	196	76.9	56	21.9	03	1.2

numerous hematological alterations, of which anemia and thrombocytopenia are the most important.[4]

The results of the present study and its correlation with other studies are discussed as follows: [Table 8].

The most common species of malaria in the present study was *P. vivax* (77%) followed by *P. falciparum* (22%). Findings are compatible with studies done by Jadhav *et al*.[5] and Ca *et al*.[3] However, Bashawri *et al*.[6] reported higher falciparum prevalence and Jairajpuri *et al*.[7] reported a higher prevalence of mixed infection (47.1%).

P. falciparum is associated with serious complications such as severe anemia, malarial hepatitis, and renal failure; hence, *P. falciparum* infection on suspicion of complication should be further evaluated.

Mixed infections behave like falciparum malaria, but its incidence and severity are less than severe *P. falciparum* malaria. In mixed infection, *P. vivax* malaria has a protective role against the severity of falciparum malaria.

In the present study, 50% of cases were in the age group between 21 and 40 years and were found to be similar with the studies done by Agrawal *et al*.,[8] in which 75% of cases were in the age group between 21 and 40 years and Jairajpuri *et al*.,[7] in which 46% of cases were in the age group between 20 and 30 years.

Children aged under 5 years are the most vulnerable group affected by malaria. In 2017, they accounted for 61% of all malaria deaths worldwide.[1] Malaria can affect any age group. However, most studies show more adults as compared to children. The adult age group is more affected due to their greater mobility and greater risk of exposure due to more outdoor activity.[3]

The present study had 65% male patients as compared to 35% female patients. Other studies with comparable results include Surve *et al*.[4] with 57% males, Jadhav *et al*.[5] with 58.3% males, Erhart *et al*.[9] with 69% males, Bashawri *et al*.[6] with 75.9% males, Agrawal *et al*.[8] with 58.5% males, and Saha and Das[2] with 55.4% males.

Anemia was present in 53.1% of cases in our study. Other studies with comparable results include Igbeneghu and Odaibo[10] with 63.5% cases of anemia, Ca *et al*.[3] with 63% cases of anemia, Kashinkunti and Alevoor[11] with 69% cases of anemia, Sharma[12] with 86.7% cases of anemia, and Bhawna *et al*.[13] with 65.5% of cases of anemia.

There is a wide variation in anemia due to malaria infection depending on the geographical location of the study. Report of the year 2017 includes a section on malaria-related anemia, a condition that, left untreated, can result in death, especially among vulnerable populations such as pregnant women and children aged under 5 years. Recent years have seen a decline in awareness of the burden of malaria-associated anemia.[1]

Anemia was normocytic-normochromic in the majority (46.6%) of cases, which is concordant with other studies done by Bhawna *et al*.,[13] Bashawri *et al*.,[6] and Facer.[14] However, the microcytic hypochromic picture was seen in 21.2% cases, results are similar to other studies.[6,13,15] This is due to the geographical location of the study, where patients have Iron and Folate deficiency due to inadequate dietary intake, along with parasitic and bacterial infections which themselves cause a significant amount of anemia. Hence, practically it becomes difficult to determine the extent to which malaria alone contributes to the anemia.

Table 5: Type of blood picture in malaria cases

Type of blood picture	Number of cases	Percentage
Normocytic normocromic	224	46.6
Normocytic hypochromic	65	13.5
Microcytic hypochromic	102	21.2
Dimorphic (normocytic to macrocytic)	42	8.8
Dimorphic (microcytic to macrocytic)	47	9.9

Table 6: Leukopenia and leukocytosis in malaria cases

TC	*Plasmodium vivax*		*Plasmodium falciparum*		Mixed infection		Total	
	Number of cases	Percentage	Number of cases	Percentage	Number of cases	Percentage	Number of cases	Percentage
Leukopenia	90	65.2	48	34.8	00	00	138	28.75
Leukocytosis	20	80	2	8	3	12	25	5.2

Table 7: Thrombocytopenia in malaria cases

Total case	*Plasmodium vivax*		*Plasmodium falciparum*		Mixed Infection	
	Number of cases	Percentage	Number of cases	Percentage	Number of cases	Percentage
406	308	75.86	94	23.15%	04	0.98

Table 8: Comparative analysis of different malarial species

Study	*Plasmodium vivax* (%)	*Plasmodium falciparum* (%)	Mixed (%)
Present study	77	22	1
Jadhav *et al*.[5]	62.17	37.69	0.04
Ca *et al*.[3]	60	30	10
Surve *et al*.[4]	55	45	-
Erhart *et al*.[9]	59	38	2
Jairajpuri *et al*.[7]	51.6	1.1	47.1
Bashawri *et al*.[6]	39	54.1	2.33

Table 9: Frequency of thrombocytopenia in different studies

Study	Incidence of thrombocytopenia (%)
Present study	84.58
Agrawal *et al*.[8]	85.5
Horstmann *et al*.[18]	85
Saha and Das[2]	82.43
Akhtar *et al*.[19]	71.06
Sharma[12]	70
Richards *et al*.[20]	67
Gill *et al*.[21]	63.33

We observed normal WBC count in 66.05% of the patients and leukopenia in 28.75% patients, leukocytosis (5.2%) was seen rarely in some cases. Leukopenia was present more frequently in *P. vivax* – infected patients (65.21%) than in *P. falciparum* – infected patients (34.78%) in our study.

Leukopenia was observed in a study done by Surve *et al*.[4] (18%), Bashawri *et al*.,[6] (13.3%), and Agrawal *et al*.[8] (26%).

Leukocytosis was observed in a study done by Kashinkunti and Alevoor[11] (11%), Agrawal *et al*.[8] (9%), Sharma[12] (13.3%), Biswas *et al*.[16] (12.2%), Surve *et al*.[4] (10%), and Bashawri *et al*.[6] (7.2%).

The results of leukopenia and leukocytosis in the present study were in concordance with other studies.

The reduction in circulating platelet count is consistently reported in the different types of malaria. In the present study, the percentage of patients showing thrombocytopenia was 75.86% in the case of vivax malaria and 23.15% in the case of falciparum malaria. The percentage of cases showing thrombocytopenia in falciparum infections and vivax infections varies in different studies. Studies conducted by Bashawri *et al*.[6] and Jadhav *et al*.[5] had thrombocytopenia more in vivax as in the present study, while in a study conducted by Erhart *et al*.,[9] thrombocytopenia is more in cases of falciparum malaria.

Thrombocytopenia is a common finding in cases of malaria, both vivax and falciparum, as shown by most of the studies conducted. In the present study, thrombocytopenia was seen in 84.58% of all malaria cases. Results are comparable with other studies, as shown in Table 9.

Patients who develop thrombocytopenia in malaria cases are seldom bleed whatever the grade of thrombocytopenia. The cause of thrombocytopenia in malaria cases is poorly understood; however, the researcher has proposed the following mechanisms as the cause of thrombocytopenia in malaria cases:[2]

- Decreased thrombopoiesis, however, bone marrow examination shows normal or increased number of megakaryocytes
- Peripheral destruction of platelets
- Sequestration of platelets in the spleen
- Some scientists have found disseminate intravascular coagulation (DIC) as a cause of thrombocytopenia; however, other scientists did not found DIC as a cause of thrombocytopenia.

According to Kumar *et al*.,[17] not only decreased platelet count occurs in malaria patients but also platelet dysfunction commonly encountered. According to them, two types of platelet dysfunction occur – platelet hyperactivity and platelet hypoactivity. Hyperactivity results from various aggravating agents such as immune complexes, platelet surface contact with infected RBCs, and damage to endothelial cells. Injured platelet undergoes intravascular hemolysis and releases cellular contents of the platelets that activate intrinsic coagulation cascade, as contributed to DIC. The hyperactive platelets may enhance hemostatic responses and, that is, why bleeding episodes are very rare in acute malarial infections, despite significant thrombocytopenia.

CONCLUSIONS

Malaria is one of the most common infections in the Indian subcontinent. Malaria affects mostly adults with male predominance. *P. vivax* is more common than *P. falciparum* and mixed infection. Complications associated with *P. falciparum* and mixed infection should be evaluated and the use of antibiotics along with antimalarial agents shows a better response.

The malarial infection causes various hematological and biochemical changes. Anemia and thrombocytopenia of varying severity are the most frequently observed hematological findings.

Depending on the geographical location of the study, discrimination of anemia, whether it is due to malaria or iron/FA deficiency, is difficult. However, severe anemia

is a poor prognostic factor, and malaria-related anemia, if left untreated, can cause a death, especially in women of reproductive age, pregnancy and children under 5 years.

Thrombocytopenia is another most commonly observed finding in malaria cases; however, bleeding manifestations are uncommon. In a patient with febrile illness, observation of thrombocytopenia warrants careful search for malaria parasite. The use of antimalarial agents, along with platelet transfusion in such patients, can lower the complications associated with it.

Various hematological findings can help in early diagnosis of malaria which is essential for timely and appropriate treatment which can limit the morbidity and prevent further complications.

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Original Article

A Study of Traumatic Small Intestinal Perforation: What Factors Determine Outcome?

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Abstract

Introduction: Small bowel injury is common after blunt and penetrating abdominal trauma resulting in significant mortality and morbidity in a generally active population. Delay in diagnosis and treatment results in a worse outcome. Our study aims to delineate the magnitude of the problem in a tertiary care teaching hospital and determine the factors resulting in a poor outcome.

Materials and Methods: This institution-based, observational descriptive study was conducted over a period of 15 months. The sample included patients with blunt or penetrating abdominal, trauma with small intestinal perforation. Patients with concurrent major CNS, cardiothoracic, and orthopedic trauma were excluded from the study. Various factors likely to affect final outcome were recorded. The appropriate surgical procedure was performed and post-operative recovery and any complications including mortality data were recorded and analyzed.

Results and Analysis: A total of 38 patients were included. Males outnumbered females. Mean age of presentation was 32.03 years signifying a younger population. Motor vehicle accidents and blunt trauma were more common. Mortality rate was 18.4%. The presence of shock at admission and death was significantly related. Delay in surgery significantly increased the length of hospital stay.

Conclusion: Small intestinal perforation resulting from abdominal trauma is a condition associated with a very high mortality and morbidity, especially in a young and active population. The efforts to reduce its incidence are beyond this discussion, but measures to reduce its resultant mortality and morbidity are definitely possible and feasible in a well-equipped, tertiary care setting. This requires sincere, well-concerted efforts from all strata of government including health caregivers.

Key words: Abdomen, Perforation, Small intestine, Trauma

INTRODUCTION

The small bowel distal to the ligament of Treitz is approximately 5–6 m in length in the adult, proximal 40% being the jejunum, and the remainder the ileum.

Protected anteriorly only by the abdominal wall musculature and occupying most of the true abdominal cavity, it is anatomically vulnerable to injury.

The jejunum and proximal ileum contain Gram-positive and Gram-negative organisms in 10^4–10^5 cfu/ml which rises to 10^5–10^8 cfu/ml in the ileum with a higher number of anaerobes too. This increase in bacterial load in the ileum is likely cause of an increased risk of infection with full-thickness injury in the distal small bowel versus the proximal small bowel.

Small intestinal injury is frequent after abdominal trauma with delay in the diagnosis being a major contributor to morbidity and mortality.

The incidence of small bowel injury (SBI) after penetrating abdominal trauma has been described 21%–60%. Mortality rates range from 10% to 25%, with most caused by associated vascular injuries.

SBI is less common in blunt trauma, being present in 2.7% of all blunt abdominal injuries, although these are associated with a significant mortality rate of 16.3%.

As no widely accepted diagnostic approach has been in use in the diagnosis of blunt SBI, quite a few stable

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blunt trauma abdomen cases are managed conservatively which results in significant delayed diagnosis of SBI and consequent morbidity and mortality.

This study not only describes the patterns of SBI after blunt and penetrating trauma but also describes the factors determining outcome in a tertiary care hospital.

AIMS

The aims of the study were as follows:
To describe the demographic and clinical profile of patients with traumatic small intestinal perforation in a tertiary care hospital.
To study the outcome of those patients.
To describe the factors affecting outcome in patients with traumatic small intestinal perforation.

REVIEW OF LITERATURE

Aristotle first recognized small bowel perforation from blunt trauma.[1]

Hippocrates was the first to report intestinal perforation from penetrating abdominal trauma.

In 1275, Guillaume de Salicet described the successful suture repair of a tangential intestinal wound.

Morbidity and mortality rates were very high over the ages until World War II, where prompt evacuation, improvements in anesthesia, and better understanding and treatment of shock reduced mortality rates to 13.9% for jejunal or ileal injuries and 36.3% if multiple injuries were present.[2]

Localized blows to the abdomen and motor vehicle accidents are the most important mechanisms of blunt SBI with falls and bicycle accidents adding up. Contusions, intramural hematomas, full-thickness perforations, and mesenteric avulsions of the small bowel have all been reported. Mechanisms postulated for injury to the intestine to occur include crushing of bowel against the spine, sudden deceleration shearing of the bowel from its mesentery and bursting of a "pseudo closed" loop of bowel owing to sudden increase in intraluminal pressure.[3]

Penetrating SBIs are caused by knives, gunshot wounds, and other piercing instruments. Of those with penetration of the peritoneum, only 30% of patients with knife wounds have significant injuries requiring operation, whereas over 80% of patients who suffer gunshot wounds have injuries requiring surgical repair.

Proper diagnosis of the severity of injury requires an accurate history of the traumatic event.

Patients with evisceration of abdominal contents after abdominal stab wound are associated with significant intra-abdominal organ injury in 75% even with no overt clinical signs that would mandate laparotomy[4] and require exploration.

A low threshold for laparotomy is appropriate in such situations with blunt injury as seat belt injuries, handle bar injuries, and blows to the abdomen such as being kicked by a horse or other large animal.

Sensitivity of clinical examination to identify patients for laparotomy exceeds 95% for stab wounds and gunshot wounds. Clinical examination of the abdomen has been unreliable in approximately 50% of blunt abdominal trauma patients.[5] Significant limitations include patients with head injury and altered level of consciousness, intoxication due to drugs or alcohol, and spinal cord injury. The variable effect of hemoperitoneum from associated solid organ injuries and the presence of distracting injuries (e.g., pelvic fracture) in the multi-injured patients may also limit the clinical reliability of the findings on physical examination. Clinical findings following penetrating SBI may be minimal initially as the luminal content of the small bowel has an almost neutral pH and is relatively sterile; the spill may also be relatively small, limiting the initial inflammatory response.

Diagnostic peritoneal lavage amylase and alkaline phosphatase levels may also be useful in identifying hollow viscus injuries, but the effectiveness of focused assessment with sonography for trauma in the same is unreliable.[6]

A CT scan showing unexplained intraperitoneal fluid, pneumoperitoneum, bowel wall thickening, mesenteric fat streaking, free intraperitoneal air mesenteric hematoma, and extravasation of either luminal or vascular contrast[7,8] is suspicious of bowel perforation.

Diagnostic laparoscopy is occasionally helpful in avoiding laparotomy in hemodynamically stable patients with penetrating abdominal trauma.[9] The major limitation cited with diagnostic laparoscopy is in the relative inability to detect hollow viscus perforations.[10] In patients found to have intestinal perforation, it is safest to convert to a laparotomy.

Surgical treatment requires careful inspection of the entire length of the gut.

Mesenteric hematomas adjacent to the bowel wall should be carefully opened and the mesenteric aspect

of the bowel inspected for injury. Obvious serosal tears should be closed with interrupted silk sutures. A Grade I intramural hematoma can be safely inverted with 3–0 or 4–0 silk seromuscular sutures. Full-thickness small bowel perforations including <50% of the circumference (Grade II) are repaired by careful debridement and primary closure. The preferred method is to use a two-layer closure with a continuous polyglactin suture for the inner layer and interrupted silk sutures for the outer layer. A transverse closure is preferable to prevent strictures. Injuries to more than 50% of the small bowel circumference should usually be resected because of the high likelihood of luminal narrowing with primary closure. Complete transection of the bowel (Grade IV) is treated by resection of the injured bowel and its adjacent blood supply followed by anastomosis. Grade V injuries require resection of the bowel with anastomosis.

An intra-abdominal septic complication most often presents as an intra-abdominal abscess. Anastomotic failure may present as a contained leak, diffuse fecal peritonitis, or as an enterocutaneous fistula.[11]

In general, jejunal resections are better tolerated than ileal resections. Ileal resection removes the "ileal breaking mechanism" which may cause decreased transit time throughout the gut. This may result in profuse diarrhea and significant fluid and electrolyte imbalances. Short bowel syndrome may occur in adults with <200 cm of residual small gut.[12]

MATERIALS AND METHODS

Study Design

It is an observational descriptive study carried out at a tertiary care hospital over a period of 15 months. Patients with blunt or penetrating trauma to the abdomen were screened and those with small bowel perforation were included in the sample. Patients with concurrent major CNS, cardiothoracic, and orthopedic trauma were excluded from the study. Parameters studied included age, gender of the patient, time since injury, type of injury (blunt or penetrating), other abdominal injuries with site, and grade of small bowel perforation. The appropriate surgical procedure was performed (primary closure of perforation, resection and anastomosis, and stoma formation), and post-operative recovery and any complications were recorded. Comorbidities were also included in the study parameters. A follow-up period of 6 months was carried out.

The collected data were analyzed using standard statistical methods with SPSS v25 statistical software including frequency analysis and descriptive statistics.

RESULTS AND ANALYSIS

A total number of 38 patients (n = 38) with traumatic SBI were included in the study. Males numbered 32 (84.2%) with 6 (15.8%) females. Ages ranged from 17 years to 48 years (mean = 32.03 years). Most of them suffered from blunt trauma (n = 31, 81.6%) and incidence of penetrating injuries was 7 (18.4%) [Table 1].

Mechanism of trauma was motor accidents (n = 16; 42.1%), pedestrian accident (n = 7; 18.4%), fall (n = 6; 15.8%), sports injury (n = 5; 13.2%), and physical assault (n = 4; 10.5%). [Table 1].

Time since injury ranged from 5 to 112 h with a mean of 34.49 h (SD 31.616).

An erect abdominal X-ray showed free gas under dome of diaphragm (n = 17; 44.7%) as opposed to no gas (n = 21; 55.3%) under diaphragm.

Shock at admission was present in 8 (44.7%) of patients, whereas 30 (55.3%) patients presented without shock.

Parts of the bowel injured were proximal jejunum (n = 17; 44.7%), distal jejunum (n = 6; 15.8%), proximal ileum (n = 4; 10.5%), distal ileum (n = 8; 21.1%), and a combination (n = 3; 7.9%).

Grade of SBI suffered was Grade II (n = 22: 57.9%), Grade III (n = 7; 18.4%), Grade IV (n = 3; 7.9%), and Grade V (n = 6; 15.8%).

Surgical treatments performed were primary repair (n = 12; 31.6%), resection and anastomosis (n = 10; 26.3%), feeding tube insertion through the perforation (n = 10; 26.3%), and ileostomy (n = 6; 15.8%).

Other visceral injuries noted were mesentery (n = 9), colon (n = 3), liver (n = 2), spleen (n = 1), and stomach (n = 1).

Post-operative morbidity included sepsis (n = 8; 21.1%), surgical site infection (n = 6; 15.8%), pneumonia (n = 3; 7.9%), diarrhea (n = 2; 5.3%), and wound dehiscence (n = 2; 5.3%) [Table 2].

Table 1: Mechanism of trauma

Mechanism of trauma	Frequency	Percentage
Motor accident	16	42.1
Pedestrian accident	7	18.4
Assault	4	10.5
Fall	6	15.8
Sports accident	5	13.2

Hospital stay ranged from 7 to 26 days with a mean of 16.29 days (SD 5.666).

Seven patients died postoperatively, six due to sepsis and one due to pneumonia (mortality rate of 18.4%).

Statistical analysis of the data shows up factors such as age, gender, time since injury, presence of shock on admission, free gas on AXR, grade of SBI, and associated visceral injury which may or may not affect outcomes such as mortality, post-operative complications (morbidity), and length of hospital stay.

No significant correlation could be found between these factors and outcomes ($P > 0.05$) except that the presence of shock at admission and death was significantly related ($P = 0.009$). Length of hospital stay was significantly affected by time elapsed from injury to surgical procedure ($P = 0.001$) and mildly by finding of free gas on AXR ($P = 0.049$) [Table 3].

DISCUSSION

The incidence of SBI associated with abdominal trauma ranges from 3 to 18%[13] and the frequency of SBI in blunt abdominal trauma is 18.1% in recent trauma literatures.[13] Males are significantly more affected compared to females.[13] In our study, we have seen that greater proportion of males was affected compared to females (M:F = 5.3:1). Most common age group affected in our study was 25–45 years (mean 32.03 years). In our study, various mechanisms of trauma were noted, among whose motor vehicle accident was the predominant cause of SBI (42%); this has also been supported by recent trauma literatures.[13,14]

Table 2: Post-operative complications

Complication	Frequency	Percentage
None	17	44.7
Sepsis	8	21.1
Surgical site infection	6	15.8
Pneumonia	3	7.9
Diarrhea	2	5.3
Wound dehiscence	2	5.3

Table 3: Correlation between factors and outcomes (*P*-values from two-tailed test)

Factors	Mortality	Complications	Length of stay
Age	0.870	0.491	0.144
Gender	0.907	0.479	0.802
Time since injury	0.238	0.714	0.001 (Sig)
Shock	0.009 (Sig)	0.816	0.664
Free gas on AXR	0.076	0.673	0.049 (Sig)
Grade of SBI	0.406	0.612	0.147
Associated injury	0.401	0.174	0.468

AXR: Abdominal X-ray, SBI: Small bowel injury; Sig: Significant ($P<0.05$)

It is seen that cases of blunt trauma were more than penetrating ones causing small bowel perforation.[12] In our study, the incidence of blunt and penetrating trauma responsible for SBI was 81.6% and 18.4%, respectively. We have noticed that most of our patients (52.6%) were operated within 24 h since injury; this was also reflected in the previous studies.[15]

We observed that the proximal jejunum (44.7%) and distal ileum (21%) were more prone to perforation. This is mainly due to their location and lack of redundancy in this part of the bowel. This has also been observed in earlier reports.[16] Some studies differ from this view.[17]

Dauterieve *et al.* in their study of 60 patients found that <½ of the perforations occurred in these zones (proximal jejunum and distal ileum).[17] However, they found that mesenteric injuries do occur more frequently than it was assumed earlier. We have seen mesenteric injury occurred in 23.7% of cases in our study. Associated colonic injury occurred frequently with small intestinal injuries but less in numbers (7.9%) compared to the mesenteric injury. This has also been reported in other studies.[17]

Isolated SBI was noted in 57.9% of cases in our study. Regarding the grade of injury in small bowel perforation, Grade II injuries were the most common (57.9%) as in other literature.[16]

In our study, the most commonly performed operative procedure was primary repair (31.6%). Simple closure is usually adequate for single perforation of the small intestine, but more extensive injuries such as multiple perforations and gangrene from mesenteric injuries usually require resection and anastomosis.[18] In our study, we have seen that 26.3% of injuries were managed by resection and anastomosis. Fang *et al.*[19] observed that a delay in surgery of more than 24 h after the injury in patients with perforated SBI did not significantly increase mortality, but was associated with a dramatic increase in the incidence of complications. Complications in our study were sepsis in 21.1%, surgical site infection in 15.8%, pneumonia in 7.9%, wound dehiscence in 5.3%, and diarrhea in 5.3% which is comparable to other studies.[19]

The mortality rate (18.4%) is within the range of previous studies (4–32%). Deaths mostly happened in cases associated with multiple injuries beside SBI.

SUMMARY AND CONCLUSION

We have tried to describe the clinicodemographic profile, the outcome, and also the factors determining outcome of the patients of traumatic small intestinal perforation in a tertiary care hospital.

Most of our patients were male (81.25%) and the age group, affected most was between 25 and 45 years of age (63.2%). The complete sentence should be In our study blunt trauma (81.6%) due to motor vehicle accident (42.1%) was the predominant cause of traumatic SBI.

Most patients (52.6%) presented to us in <24 h of injury. Most common part of small bowel affected was proximal (44.7%) and Grade II injury (55.26%) was predominant among them. Mesenteric injury was the most common associated injury noted (23.7%).

Isolated small bowel perforation was found in 57.9% of cases.

Most common operative procedure undergone was primary repair (31.6%) of the perforation. There were many complications noted, most commonly was sepsis (21%). Most of the patients were discharged in between 7 and 14 days (39.4%). Mortality rate is approximately 18.4% in our study. In our study, there are significant correlations between the presence of shock on admission and mortality and also time since injury and time spent in hospital stay. Overall, morbidity and mortality were associated with advanced age, delayed presentation, higher grade of injury, and associated injury.

Traumatic small bowel perforation is an entity which is seen mostly in outdoor working, young, male population due to road accidents. It has a significant morbidity and mortality in young and physically active population. Morbidity and mortality are mostly due to delayed presentation after injury, delay in diagnosis and associated injuries. Hence, early clinical suspicion and timely intervention may help to reduce its impact.

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Original Article

Gastric Carcinoma in the Young Adults: A Disturbing Trend in the Indian Population

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Abstract

Introduction: Gastric carcinoma is an aggressive malignancy with non-specific early symptoms. It is the second most common cause of cancer-related deaths in the world.

Materials and Methods: All cases of gastric carcinomas aged <40 years presented at Sri Ramachandra Institute of Higher Education and Research from January 2016 to December 2019 were included in this study. The presenting symptoms and outcome were collected from medical records. Pathology reports of the included cases were retrieved and associated factors were analyzed.

Results: Out of the 177 known cases of gastric carcinoma, 17 were under the age of 40 (9.6%), out of which, 10 (58.8%) were female and 7 (41.7%) were male. The number of males was higher in the patients >40 years. Fourteen cases (82.3%) were between 30 and 40 years. Three cases (17.6%) were between 20 and 30 years of age. *Helicobacter pylori* associated gastritis was seen in 6 cases (35.2%). Out of the 17 cases (41.1%), 7 were poorly differentiated. The distal stomach was the site of the tumor in 15 cases (88.2%), 2 cases were present in the gastroesophageal junction. The most common presenting complaints of these patients were abdominal pain, abdominal distension, vomiting associated with food intake, and constipation, with the duration of these symptoms being 1–6 months. Two patients (11.7%) had a positive family history. Three patients (17.6%) had a positive history of substance abuse. Five patients reported a history of loss of weight and appetite. One patient had metastasis to the liver, one to the liver, bone, and lungs, and one to the liver and esophagus. Ten patients (58.8%) were treated with gastrectomy (subtotal/distal/partial) and two patients with esophageal gastrectomy. Most of the patients were given chemotherapy and one was given palliative chemotherapy and radiotherapy.

Conclusion: Tumors rarely occur in the young, hence malignancy is not suspected and diagnosis is delayed. This leads to a higher mortality rate as patients present with advanced stage of the disease. This study highlighted the "shift in trend" of incidence of gastric carcinomas in younger age group. Screening and early diagnosis and treatment are essential for young patients.

Key words: Gastrectomy, Gastric carcinoma, Mortality rate

INTRODUCTION

Gastric carcinoma is an aggressive malignancy with non-specific early symptoms depending on the location of the tumor. It is the second most common cause of cancer-related deaths in the world. Effective screening programs for this disease exist only in three countries – Japan, Korea, and Chile.[1] Malignancy is not usually suspected in the young patients, thus postponing evaluation and treatment. Surgically curable early gastric cancers are usually asymptomatic and are infrequently detected outside screening programs. There are two distinct types of adenocarcinoma – intestinal and diffuse. Intestinal type tumors are commonly related to *H. pylori*.

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MATERIALS AND METHODS

Study Type

A hospital-based retrospective cohort study done on known cases of gastric carcinoma in a tertiary care hospital (SRIHER) using histopathology records.

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Sampling
Systematic random sampling.

Sample Size
All cases of gastric carcinomas aged <40 years presented from January 2016 to December 2019 were included in this study.

Inclusion Criteria
Known patients of gastric carcinoma under the age of 40 years were included in the study.

Exclusion Criteria
Age >40 years were excluded from the study.

Non-epithelial tumors and metastasis into stomach were not included in the study.

The presenting symptoms and outcome were collected from medical records. Pathology reports of the included cases were retrieved and associated factors were analyzed.

RESULTS

Out of the 177 known cases of gastric carcinoma, 17 were under the age of 40 (9.6%). Out of 17 cases, 14 cases (82.3%) were between 31 and 40 years. Three cases (17.6%) were between 21 and 30 years of age. Ten patients (58.8%) were female and 7 patients (41.7%) were male. The most common presenting symptoms of the patients were abdominal pain, abdominal distension, vomiting associated with food intake, and constipation. The duration of these symptoms is 1–6 months. Three patients (17.6%) had a positive history of substance abuse (alcohol and tobacco). Five patients (29.4%) reported a history of loss of weight and loss of appetite. Two patients (11.7%) had a positive family history.

H. pylori associated gastritis was seen in 6 patients (35.2%). The number of males was higher in the patients >40 years. The distal stomach was the site of the tumor in 15 cases (88.2%), 2 cases were present in the gastroesophageal junction. Seven (41.1%) of tumors were poorly differentiated.

Signet ring cells seen in 5 patients (29.4%), indicating diffuse type of carcinoma stomach. Two patients had metastasis to the liver, one patient had metastasis to the liver, bone, and lungs. Ten patients (58.8%) treated with gastrectomy and 2 patients with esophagogastrectomy. Five patients given palliative chemotherapy.

DISCUSSION

Carcinoma stomach is considered a disease of the middle aged and elderly. Indeed, its peak incidence is considered to occur in persons over 50 years of age.[2-4] However, the incidence of gastric carcinoma in the young, although not high, has been recorded in many studies. Approximately 3% of all cases of carcinoma of the stomach may occur in patients 35 years of age or younger patients.[4] A near universal finding in young patients has been observed that there is high frequency of advanced lesions and undifferentiated tumors at presentation in comparison with older patients; this has often been attributed to the delay in diagnosis.[5] Gastric cancer in the young patients spreads more rapidly and is biologically more aggressive.[6] Young patients less likely present as gastroesophageal junction growth as compared to antral growth.[7]

The incidence percentage of gastric carcinoma in patients <40 years of age in our study is 9.6%. The findings of my study were consistent with studies done by Katai *et al.*,[1] Matley *et al.*,[8] and Dhobi *et al.*[9] [Table 1]. The number of female patients (58.8%) was more than male patients consistent with the studies done by Matley *et al.* and Dhobi *et al.* A positive family history of gastric carcinoma was found in 11.7% of patients which was concurring with a study done by Dhobi *et al.* [Table 2].

Location of tumor occurs commonly in the distal stomach than GE junction [Table 3]. The location of tumor in our study concurs with the study done by Matley *et al.* Table 4 shows the percentage of poorly differentiated tumors having a poor prognosis among young gastric carcinoma patients which was around 41.1%, this percentage is slightly higher in comparing to a study by Katai *et al.* Signet ring

Table 1: The number of patients with gastric carcinoma under 40

Study	% gastric Ca under 40 years
My study	9.6
Katai *et al.*	7.1
Matlay *et al.*	7.2
Dhobi *et al.*	10

Table 2: Patients with family history of gastric carcinoma

Study	% family history
My study	11.7
Matlay *et al.*	5.4
Dhobi *et al.*	10

Table 3: Location of tumor occurs commonly in the distal stomach

Site	Distal stomach (%)	GE junction (%)
My study	88.2	1.6
Matlay *et al.*	89.1	5.4

Table 4: Percentage of poorly differentiated tumors: Show a poor prognosis among young gastric carcinoma patients

My study	41.1
Katai *et al.*	34.8

Table 5: Percentage of patients developing metastasis

My study	17.6%
Dhobi *et al.*	17.4%

Table 6: Mode of treatment

Management	Surgery (%)	Palliation (%)
My study	58.8	29.4
Matlay *et al.*	14	32
Katai *et al.*	79	14.6
Dhobi *et al.*	68	26

cells were seen in 29.4% of patients among the poorly differentiated carcinomas. About 17.6% of patients developed metastasis in the course of the disease which correlates with a study done by Dhobi *et al.* [Table 5].

In our study, 10 patients (58.8%) treated with gastrectomy and 2 patients with esophagogastrectomy. Five patients were given palliative chemotherapy. Table 6 gives the mode of treatment given to these patients and a comparison with other similar studies.

Gastric cancer is one of the leading causes of death. When we compared them with older patients, the differences we recorded were the high proportion of females, the frequency of the diffuses signet ring and infiltrating histological types and no associated gastritis. Average age of patients in Indian population is 55 years (according to Indian Council of Medical Research). Majority of tumors in the young are poorly differentiated.

CONCLUSION

Tumors rarely occur in the young, hence malignancy is not suspected and diagnosis is delayed. This leads to a higher mortality rate as patients present with advanced stage of the disease. This study highlighted the "shift in trend" of incidence of gastric carcinomas in younger age group. Screening and early diagnosis and treatment are essential for young patients.

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Original Article

Study of Correlation between Serum Sodium and Severity in Chronic Liver Disease

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Abstract

Introduction: The normal range of serum sodium is 135–145 mEq/L. Its homeostasis is vital to the functioning of the cell. An imbalance in the regulation of total body water can lead to abnormal sodium levels. Chronic liver disease (CLD) is associated with disturbance in water homeostasis leading to dysnatremias.

Aims and Objectives: This study aims to study the prevalence of hyponatremia in CLD patients and to correlate the serum sodium levels and severity in CLD patients assessed by Child-Pugh score and MELD score.

Materials and Methods: The study is conducted on consecutive patients admitted with CLD in medical wards (male and female) in Government General Hospital during the study period September 2018 to Febraury 2020.

Results: Alcohol is the most common etiology of CLD in this study followed by hepatitis B.

Conclusion: CLD is associated with abnormal serum sodium concentration. Hyponatremia is the most common abnormality in this study.

Key words: Ascites, Cirrhosis, Hyponatremia

INTRODUCTION

The normal range of serum sodium is 135–145 mEq/L. Its homeostasis is vital to the functioning of the cell. An imbalance in the regulation of total body water can lead to abnormal sodium levels. Chronic liver disease (CLD) is associated with disturbance in water homeostasis leading to dysnatremias.[1-5]

Hyponatremia is defined as concentration of sodium <135 mEq/L. It occurs when there is excess of water in relation to sodium. It is the most common electrolyte disorder in hospitalized patients and more so in CLD patients. A disturbance in total body water regulation leading to decreased clearance of solute free water and the consequent inability to match the urine output to the amount of water ingested leads to dilutional hyponatremia.

Hypernatremia is defined as concentration of sodium more than 145 mEq/L. It is associated with high mortality rate. Hypernatremia, though uncommon compared to hyponatremia in CLD patients, occurs due to use of osmotic cathartics and upper gastro intestinal bleeding. If present, it is associated with increased mortality.

Recent studies have reported that lower serum sodium levels were associated with increased complications and mortality leading to incorporation of sodium in the MELD score. Therefore, we undertook this study in our tertiary hospital to study serum sodium levels in patients admitted with CLD and to establish its significance.

Aims and Objectives

The aims of the study were as follows:

1. To study the prevalence of hyponatremia in CLD patients

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2. To correlate the serum sodium levels and severity in CLD patients assessed by Child-Pugh score and MELD score.

MATERIALS AND METHODS

The study is conducted on consecutive patients admitted with CLD in medical wards (male and female) in Government General Hospital, during September 2018 to Febraury 2020.

Study Design

This study is a cross-sectional observational study.

Method of Collection of Data

Ethical Committee clearance obtained from institution. Informed consent was obtained from the patients enrolled in the study. The data of the patients were collected using a pro forma. The pro forma contains patient's demographic profile with detailed history, clinical examination that will be carried out at the time of admission, investigations that were done to aid the diagnosis, and the serum sodium level. Patients were selected based on history, examination, laboratory investigations, and radioimaging suggestive of the diagnosis of CLD. The presence of various complications and the outcome of the patients were monitored. The severity of the disease was calculated using MELD score and Child Pugh score. Ascites was classified into three grades: Grade I – presence on examination not clear, but observed in imaging; Grade II – easily made out examination and palpation; and Grade III – severe abdominal distension requiring large-volume paracentesis. Hepatic encephalopathy was graded using West Haven criteria.

Inclusion Criteria

All patients with CLD diagnosed by examination, laboratory investigations, and radiological imaging were included in the study.

Exclusion Criteria

The following criteria were excluded from the study:

1. Patients with cardiac failure
2. Patients with chronic kidney disease
3. Patients on drugs such as diuretics, SSRIs, TCA inhibitors, MAO inhibitors, and cytotoxic drugs.

Statistics

The collected data were entered into a Microsoft Excel sheet. Graphs and tables were generated using Microsoft Word and Microsoft Excel. Statistical analysis was done using IBM, SPSS. Quantitative data were analyzed using mean, median, mode, and standard deviation. Qualitative data were analyzed using Chi-square test, one-way ANOVA, and Fisher's test. Difference between two variables is considered significant when $P < 0.05$ was obtained.

RESULTS

Data were collected from 100 patients admitted in our hospital [Table 1]. The mean age of the patients was 46.39 years with a range of 33–80 years [Table 2]. Out of the 100 patients, 85 were male and 15 were female [Table 3].

Alcoholic liver disease was the most common cause of CLD in this study accounting for 88% while chronic hepatitis B was found to be the causative factor in 6%, HBV and alcohol were seen in 5% of patients. One patient had HCV and alcohol as etiology for CLD. The mean concentration of sodium of all patients was 134.03 meq/L with a range of 118–144 meq/L.

Table 1: Clinical presentation of patients at time of admission

Clinical presentation	Number of patients	% of patients
Abdominal distension	100	100
Lower limb swelling	100	100
Altered sensorium	18	18
Gastrointestinal bleeding	19	19

Table 2: The demographic details and causes of CLD

Parameters	Number of patients	% of patients	Mean	Standard deviation
Age	100		46.39	10.227
Gender				
Male	85	85		
Female	15	15		
Cause of CLD				
Alcohol	88	88		
HBV	6	6		
HCV	0	0		
ALC and HBV	5	5		
ALC and HCV	1	1		
Meld score			16.39	6.998
Serum NA			134.03	5.321
≤130 meq/L	26	26		
131–135 meq/L	31	31		
≥136 meq/L	43	43		

Table 3: Frequency of complications

Complications	Number of patients	% of patients
Ascites	100	100
Hepatic encephalopathy	18	18
GI bleeding	19	19
Coagulopathy	12	12
HRS	11	11
SBP	12	12

Based on the serum sodium levels, 26% of patients had serum sodium levels ≤130 meq/L. About 31% of patients had serum sodium levels between 131 and 135 meq/L, while 43% of patients had serum sodium levels ≥136 meq/L. No patients presented with serum sodium >145. The mean MELD score was found to be 16.39 with a range of 7–34.

Patients were classified into three groups based on the serum sodium level to assess the association between serum sodium levels and patient characteristics, complications, and severity of disease as calculated by MELD score and CPS. Those with serum sodium levels ≤130 meq/L formed one group while those with serum sodium levels between 131 and 135 meq/L and those with ≥136 meq/L were the other two groups. Mean age of patients with sodium levels ≤130 meq/L was 47.23 ± 10.045 years while in those with serum sodium levels 131–135 meq/L and ≥136 meq/L were 46 ± 9.349 years and 46.16 ± 11.11 years, respectively. No statistical difference was found among the three groups ($P = 0.888$).

Serum sodium levels had a strong association with severity of disease as calculated by Child-Pugh class. Among those with serum sodium levels ≤130 meq/L, 13 belonged to Class B and 13 belonged to Class C. Among patients with serum sodium levels between 131 and 135 meq/L, 2 belonged to Class A, 23 belonged to Class B, and 6 belonged to Class C. Among patients with serum sodium levels ≥136 meq/L, 9 belonged to Class A, 30 belonged to Class B, and 4 belonged to Class C ($P = 0.0001$). Patients with serum sodium levels ≤130 meq/L had a mean MELD score of 25.12 ± 5.317, while those with levels between 131–135 meq/L and ≥136 meq/L had mean scores of 16.16 ± 4.390 and 11.28 ± 3.30, respectively. The difference in MELD scores among the three groups was statistically significant ($P = 0.001$). No statistical difference was found among the three groups with respect to age, gender, and causative factor.

All patients presented with abdominal distension and lower limb swelling at the time of admission. Around 19% of patients presented with GI bleeding while 18% of patients presented with a history of altered sensorium.

Among the 100 patients, ascites was present in all the patients present. Hepatic encephalopathy was present in 18% while GI bleeding was found in 19% of patients. Coagulopathy and SBP were found in 12% of patients, while hepatorenal syndrome was found in 11%.

Table 4, there was a significant difference in the occurrence of complications of CLD such as ascites ($P = 0.0001$), hepatic encephalopathy ($P = 0.001$), GI bleeding ($P = 0.005$), coagulopathy ($P = 0.025$), hepatorenal syndrome ($P = 0.0001$), and SBP ($P = 0.001$) among the three groups [Table 5].

Table 4: Frequencies of complications by serum sodium concentration

Complications	≤130 meq/L	131–135 meq/L	≥136 meq/L	*P*-value
Ascites	26	31	43	0.0001
HE	15	3	0	0.001
GI bleeding	10	6	3	0.005
Coagulopathy	7	2	3	0.025
HRS	11	0	0	0.0001
SBP	8	4	0	0.001

Table 5: Mortality according to serum sodium concentration

Mortality	≤130 meq/L	131–135 meq/L	≥136 meq/L	*P*-value
	8 (30.77%)	1 (3.34%)	0 (0%)	0.0001

Eight patients of the deaths have serum sodium concentration <130 meq/L, one death occurred in patients with serum sodium concentration between 131 and 135 meq/L, and no deaths in group with serum sodium concentration >136 meq/L. The difference in mortality among three groups is statistically significant ($P = 0.0001$).

DISCUSSION

A significant proportion of patients with CLD have abnormal serum sodium concentration. Hyponatremia is the most common occurrence in our study. No patients presented with serum sodium levels >145 meq/L. About 57% of patients had serum sodium levels <135 meq/L, while 26% of patients had serum sodium levels than 130 meq/L [Table 6].

Angeli *et al.* collected data of 997 cirrhosis patients from 28 hepatology departments across Europe, Asia, North America, and South America. Her study revealed that 50.6% of patients had normal serum sodium levels, 27.8% of patients had sodium levels between 131 and 135 mEq/L, and 21.6% of patients had serum sodium levels ≤130 mEq/L.

Kim *et al.* analyzed 188 patients admitted in Ilsan Paik Hospital, Korea, with complications of cirrhosis and found that 52.1% of patients had normal serum sodium levels, while 20.8% of patients had serum sodium levels between 131 and 135. About 27.1% of patients had serum sodium levels ≤130 [Table 7].

Raj *et al.* studied 100 patients with cirrhosis and found that 48% of patients had serum sodium levels more than 136 mEq/L, while 21% of patients had serum sodium

levels between 131 and 135 mEq/L. About 31% of patients had serum sodium levels ≤130 mEq/L.

Borroni *et al.* studied 156 patients admitted with cirrhosis and found that 29.8% of patients had serum sodium levels ≤130 mEq/L [Table 8].

The results of the present study extend the observations made by the above-mentioned studies that decompensated liver disease is associated with abnormal serum sodium concentration. It also shows that hyponatremia is the common abnormality with more than half of the patients having serum sodium levels <135 mEq/L.

Various studies have established that lower sodium levels were associated with ascites that is difficult to manage with diuretics and requiring frequent large-volume paracentesis. Arroyo *et al.* noted that patients having serum sodium less than mEq/L had a relatively low GFR and subsequently decreased free water clearance. These patients responded poorly to diuretics when compared with those who had sodium levels more than 130 mEq/L.

Table 6: Comparison of various studies showing distribution of patients according to serum sodium concentration

Studies	≤130 meq/L (%)	131–135 meq/L (%)	≥136 meq/L (%)
Present study	26	31	43
Angeli *et al.* (2006)	21.6	27.8	50.6
Kim *et al.* (2009)	27.1	20.8	52.1
Raja *et al.* (2016)	31	21	48

Table 7: Comparison of studies showing association between serum sodium concentration and hepatic encephalopathy

Studies	≤130 meq/L (%)	131–135 meq/L (%)	≥136 meq/L (%)
Present study	57.7	10.7	0
Angeli *et al.*	38	24	15
Kim *et al.*	43.1	35.8	24.4
Raja *et al.*	60.6	30.3	9

Table 8: Comparison of studies showing association between serum sodium concentration and hepato renal syndrome

Studies	≤130 meq/L (%)	131–135 meq/L (%)	≥136 meq/L (%)
Present study	42.3	0	0
Angeli *et al.*	17	10	6
Kim *et al.*	3.9	2.5	3
Raja *et al.*	77.7	22.2	0

Angeli *et al.* and Bernardi *et al.* also found that poorer response to diuretics was associated with lower serum sodium concentration compared to patients who showed response to diuretics.

The present study also found that patients with lower sodium levels had higher grade of ascites.

Angeli *et al.* found that 38% of patients who had serum sodium levels ≤130 mEq/L had hepatic encephalopathy compared to 24% with serum sodium levels between 131 and 135 mEq/L.

Kim *et al.* found that 43.1% of patients with serum sodium levels ≤130 mEq/L developed hepatic encephalopathy compared to 35.8% with serum sodium levels between 131 and 135 mEq/L.

Raja *et al.* found that 60.6% of patients had hepatic encephalopathy with serum sodium concentration ≤130 meq/L.

In the present study, patients with serum sodium levels ≤130 mEq/L had increased frequency of hepatic encephalopathy compared to the other two groups.

Angeli *et al.* found that 17% of patients with serum sodium levels ≤130 mEq/L had hepatorenal syndrome compared to 10% and 6% in patients with serum sodium levels 131–135 mEq/L and more than 135 mEq/L, respectively.

Kim *et al.* reported that 3.9% of patients with serum sodium levels ≤130 mEq/L had hepatorenal syndrome compared to 2.5% and 3% in patients with serum sodium levels 131–135 mEq/L and more than 135 mEq/L, respectively.

Raja *et al.* found that 77.7% of patients had HRS with serum sodium concentration ≤130 meq/L.

In the present study, patients with serum sodium levels ≤130 mEq/L had increased frequency of hepatorenal syndrome compared to other two groups.

Angeli *et al.* found that low sodium level was associated with increased frequency of spontaneous bacterial peritonitis.

Kim *et al.* reported that 33.3% of patients with serum sodium levels ≤130 mEq/L had SBP compared to 30.7% and 16.3% in patients with serum sodium levels 131–135 mEq/L and ≥136 mEq/L, respectively.

The present study also lends support to the above observations. About 30.77% of patients with serum sodium levels ≤130 mEq/L had SBP compared to 13% of patients

Table 9: Comparison of studies showing association between serum sodium concentration and SBP

Studies	≤130 meq/L (%)	131–135 meq/L (%)	≥136 meq/L (%)
Present study	30.77	13	0
Kim *et al*.	33.3	30.7	16.3

with serum sodium levels between 131 and 135 mEq/L [Table 9].

Angeli *et al*., Kim *et al*., and Shaikh *et al*. found no association between GI bleeding and sodium levels. The present study showed increased frequency of GI bleeding in patients with low sodium levels.

Warren *et al*. reported that 15 out of 25 patients with decompensated liver disease had hypernatremia in their study. The present study had no patients with serum sodium levels more than 145 mEq/L.

Kim *et al*. found that lower sodium levels were associated with increased MELD score and Child Pugh score. This indicates that lower serum sodium levels were associated with severe disease.

The present study also showed that patients with sodium levels ≤130 mEq/L had higher MELD score and Child Pugh score compared to other two groups.

Summary

The study was conducted on 100 patients admitted with CLD in medical wards in GOVERMENT HOSPITAL/ GOVERNMENT MEDICAL COLLEGE SURYPETA, Telangana. Alcohol is the most common etiology of CLD in this study followed by hepatitis B. Hyponatremia is the most common sodium abnormality (57%). No patients presented with hypernatremia.

Patients were divided into three groups based on serum sodium; those with serum sodium levels ≥136 mEq/L comprised one group while those with 131–135 mEq/L and ≤130 mEq/L formed the other two groups.

Serum sodium level was not associated with age, gender, and etiology of CLD.

Serum sodium ≤130 meq/L indicated the existence of ascites ($P = 0.0001$), hepatic encephalopathy ($P = 0.001$), hepatorenal syndrome ($P = 0.0001$), and spontaneous bacterial peritonitis ($P = 0.001$). Patients with serum sodium <130 mEq/L had increased frequency of complications than those with ≥136 mEq/L.

There was a significant difference in severity scores such as MELD and CPS among the three groups. Patient with serum sodium levels ≤130 meq/L had increased mortality (30.7%; $P = 0.0001$).

CONCLUSION

CLD is associated with abnormal serum sodium concentration. Hyponatremia is the most common abnormality in this study. Age, gender, and cause of CLD did not have any association with serum sodium levels.

Serum sodium levels <135 mEq/L are associated with increased frequency of complications such as ascites, hepatic encephalopathy, hepatorenal syndrome, spontaneous bacterial peritonitis, and GI bleeding when compared to patients with serum sodium levels ≥136 mEq/L.

Patients with serum sodium concentration <130 mEq/L are the most affected. Lower serum sodium levels are associated with increased MELD score, increased CPS score, and increased mortality indicating the inverse relationship between serum sodium levels and the severity of disease.

Thus, patients with decreased serum sodium levels should be considered a high-risk population because of the increased frequency of complications and mortality.

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Original Article

To Evaluate Subclinical Hypothyroidism in Type 2 Diabetes Mellitus

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Abstract

Introduction: Diabetes is the most common endocrinal disorder seen in clinical practice. The prevalence of diabetes in west is between 6 and 7.6%. Type 2 diabetes mellitus is the predominant form of diabetes accounts for 90% of cases globally.

Aims and Objectives: This study aims to know the prevalence of subclinical hypothyroidism in Type 2 diabetes mellitus during the study period of 1 year 6 months patients attending Government General Hospital/Government Medical College, Suryapet.

Materials and Methods: This study was done on patients attending Government General Hospital/Government Medical College, Suryapet. The total duration of study was 1 year 6 months. Patients attending Government General Hospital who were either previously or newly diagnosed Type 2 diabetes mellitus were included in the study.

Results: Fifty known or newly detected cases of Type 2 diabetes mellitus more than 30 years were selected randomly from the patients attending to the Diabetic Clinic Government General Hospital during the study period September 2018 to February 2020.

Conclusion: Subclinical hypothyroidism has been associated with a greater prevalence of cardiovascular disease and is relatively common in patients with Type 2 DM. Hence, it effects would be exaggerated in patient with Type 2 DM.

Key words: Diabetes mellitus, Sub clinical hypothyroidism, Type 2

INTRODUCTION

Diabetes is the most common endocrinal disorder seen in clinical practice. The prevalence of diabetes in west is between 6 and 7.6%. Type 2 diabetes mellitus is the predominant form of diabetes accounts for 90% of cases globally. An epidemic of type 2 DM is under way in both developed and developing countries although the brunt of the disorder is felt disproportionately in non-European populations.

India has already become the "diabetes capital" of the world. The number of people with diabetes in India currently around 40.9 million and is expected to rise 69.9 million by 2025.[1] Between 1995 and 2025, there is predicted to be 35% increase in the worldwide prevalence of diabetes. The rising number of people with diabetes will occur mainly in populations of developing countries, globally the number of people with DM is expected to rise from current estimates of 150 million s to 220 million in 2010 and 300 million in 2025.[2] The prevalence of Type 2 diabetes mellitus in South Indian states, Andhra Pradesh 16.6% (Hyderabad) 2001, Tamil Nadu 14.3% (Chennai) 2006, Kerala – Ernakulam – 19.5% 2006, Thiruvananthapuram 16.3% 1999, and Karnataka 12.4 (Bangalore) 2001.[1]

The disease has tremendous impact on the quality of life, and morbidity and mortality occur due to complications that affect the small vessels resulting in retinopathy, nephropathy, neuropathy, and large vessels resulting in ischemic heart disease and stroke.

Various studies done suggest that thyroid disorders are more common in diabetics (both Type I and Type II) than in the general population, highest in Type I diabetic females and lowest in Type II diabetic males; most common disorder being subclinical hypothyroidism. Thyroid dysfunction is also

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common in Type 2 DM because both of these illnesses tend to occur more frequently as people age. Several alterations in thyroid function are found in DM. Plasma T4 is normal, whereas plasma T3 is diminished, and plasma level of T3 is elevated in patients with severely uncontrolled diabetes.

Thyroid peroxidase (TPO) antibodies (also called as antimicrosomal antibodies, AMA) are found with elevated TSH levels and when positive in those with normal TSH levels, indicate future probability of the development of hypothyroidism in a diabetic. Both conditions are expressed with greater frequency after the altered immune states of pregnancy.

Subclinical hypothyroidism is defined by elevated TSH secretion in the presence of normal concentration of circulating thyroid hormones. This syndrome affects approximately 10 millions of people in the United States and is most prevalent in elderly women. Patients with subclinical hypothyroidism will be detected more frequently in the future as these patients have no or only minimal symptoms.

Subclinical hypothyroidism is a strong risk factor for atherosclerosis and MI, in elderly women. It was found to be a greater risk factor for MI, in postmenopausal women than hyperlipidemia, diabetes, previous smoking, and hypertension. Type 2 DM patients with subclinical hypothyroidism are associated with an increased risk of sight-threatening diabetic retinopathy and increased risk of nephropathy and cardiovascular events. Type 2 DM patients should be screened for subclinical hypothyroidism to prevent development of complications.

Aims and Objectives

This study aims to know the prevalence of subclinical hypothyroidism in Type 2 diabetes mellitus during the study period of 1 year 6 months patients attending Government General Hospital/Government Medical College, Suryapet.

MATERIALS AND METHODS

This study was done on patients attending Government General Hospital/Government Medical College, Suryapet. The total duration of study was 1 year 6 months.

Patients attending Government General Hospital who were either previously or newly diagnosed Type 2 diabetes mellitus were included in the study.

Inclusion Criteria

Patients of Type 2 diabetes mellitus either previously or newly diagnosed aged more than 30 years were included in the study.

Exclusion Criteria

The following criteria were excluded from the study:

1. All patients <30 years of age
2. Known hypothyroidism and hyperthyroid patients
3. Known patients of Type 1 diabetes mellitus.

Study Design

1. Randomly selected Type 2 diabetic patients were subjected to evaluation for thyroid function clinically and biochemically

Table 1: Age distribution

Age group (years)	No. of patients	Percentage
30–40	7	14
40–50	16	32
50–60	19	38
60–70	7	14
>70	1	2

Table 2: Sex distribution

Sex	No. of patients	Percentage
Male	15	30
Female	35	70

Table 3: Distribution of serum TSH among the study group

Serum TSH level	No. of patients	Percentage
<4.5 μU/ml	41	82
>4.5–10 μU/ml	9	18

Table 4: Sex distribution of subclinical hypothyroidism

Sex	Type 2 DM without S.C.H.	Type 2 DM with S.C.H.
Male	15	0
Female	26	9

Table 5: Age distribution of Type 2 DM without subclinical hypothyroidism versus with subclinical hypothyroidism

Age group (years)	Type 2 DM without SCH	Type 2 DM with S.C.H.
30–40	7	0
40–50	13	3
50–60	15	4
60–70	5	2
>70	1	0

Table 6: Mean duration of Type 2 DM

Type 2 DM without SCH	Type 2 DM with SCH	*P*-value
3.73±3.18	5.06±6.98	0.382

Table 7: Prevalence of the subclinical hypothyroidism in Type 2 DM and relation

Study	Subject groups	Parameters	Subject no.		Total
			Male	Female	
Celani *et al.*	Type 2 DM	Prevalence of abnormal TSH and anti-TPO	131	159	290
The Fremantle diabetic study	Women Type 2 DM	Prevalence anti-TPO	-	420	420
Radaideh *et al.*	Type 2 DM and normal population comparative study	Prevalence of thyroid dysfunction and anti- TPO	-	-	902 304
Ishay *et al.*	Women with type 2 DM with normal population – comparative study	Prevalence lipids, anti-TPO HBA1C	-	-	410 125
Perrous *et al.*	Diabetes mellitus	Prevalence of thyroid dysfunction	-	-	1310
Cordoso *et al.*	DM type	Prevalence	-	-	60
Ramaswamy *et al.*, Hyd.	Type 2 DM	Prevalence of thyroid dysfunction	-	-	120
Rajan *et al.*, Chennai	Type 2 DM	Prevalence of thyroid dysfunction	-	-	100
Present study	Type 2 DM	Prevalence BMI, lipid profile	15	35	50

Table 8: Prevalence of subclinical hypothyroidism in different study groups

Study	Prevalence
Celani *et al.*	15.16
The fremantle diabetic study	8.6
Radaideh *et al.*	6.6
Ishay *et al.*	5.4
Perrous *et al.*	4.8
Cordoso *et al.*	8.3
Ramaswamy *et al.*, Hyderabad	11
Rajan *et al.*, Chennai	10
Present study	18

2. Diagnosis of Type 2 diabetes mellitus was done as per the WHO guidelines.

RESULTS AND ANALYSIS

Fifty known or newly detected cases of Type 2 diabetes mellitus more than 30 years were selected randomly from the patients attending to the Diabetic Clinic Government General Hospital during the study period September 2018 to February 2020.

Among 50 subjects, 19 (38%) patients were in the age group of 50–60 years, 16 (32%) patients were in the age group of 40–50, 7 (14%) patients were in the age group of 30–40 years, and 1 (2%) patient was in the age group of >70 years. The age of the patient varied from a minimum of 35 years to max. 74 years. The mean age of the patient in the study was 53.06 ± 9.35 years [Table 1].

Among 50 subjects of Type 2 DM, 15 (30%) were male and 35(70%) were female [Table 2].

Type 2 DM patients with serum TSH levels below 4.5 μU/ml and above 4.5–10 μU/ml. Mean TSH in the study group 3.09 ± 1.95 [Table 3].

Among 50 subjects of type 2 DM, 9 (18%) are having subclinical hypothyroidism. All are female [Table 4].

About 78% of the Type 2 diabetics with subclinical hypothyroidism are in the age group of 40–60 years [Table 5].

Mean duration of diabetes mellitus in Type 2 diabetes with subclinical hypothyroidism 5.06 ± 6.98 [Table 6].

Mean duration of diabetes mellitus, without subclinical hypothyroidism 3.73 ± 3.18.

Mean duration of diabetes among two groups statistically not significant.

DISCUSSION

Few studies on the prevalence of the subclinical hypothyroidism in Type 2 DM and relation between them regarding various parameters have been done [Table 7].

Hence, the number of diabetic subjects included in various studies ranged from 60 Type 2 diabetics in a study by Cordoso *et al.* to 1310 diabetics in a study by Perrose *et al.*

Some studies included only Type 2 DM others both Type 1 and 2 DM.

The prevalence of subclinical hypothyroidism was 18% in the present study compared to 15.16% in a study by Selani *et al.*, the prevalence of subclinical hypothyroidism was more in females, aged, and associated with increased antithyroid peroxidase antibodies status in the present study like previous studies [Table 8].

CONCLUSION

Subclinical hypothyroidism has been associated with a greater prevalence of cardiovascular disease and is relatively common in patients with Type 2 DM. Hence, it effects would be exaggerated in patient with Type 2 DM.

Increased prevalence of subclinical hypothyroidism in females, aged, and associated with increased antithyroid peroxidase status in Type 2 DM.

All Type 2 DM patients should be screened for subclinical hypothyroidism to intervene early to prevent complications and progression of hypothyroidism.

Summary

1. Total number of subjects included in the present study was 50 Type 2 DM patients (males 15 and females 35)
2. The prevalence of subclinical hypothyroidism in Type 2 DM in the present study was 18%, all are female most of them are aged more than 50 years and associated with increased antithyroid peroxidase antibody status
3. Body mass index, total cholesterol, HDL cholesterol, LDL cholesterol, VLDL cholesterol, and fasting triglycerides levels were more in Type 2 DM with subclinical hypothyroidism compared to Type 2 diabetics without subclinical hypothyroidism, but statistically not significant.

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Original Article

An Analytical Study on Communication Abilities and Schooling in Children with Cochlear Implantation

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Abstract

Background: As per the World Health Organization 2018, the new estimate of disabling of hearing loss is 466 million people. The State Initiative on Disabilities Survey (2015), Kerala, India, indicates that 2.32% of populations in Kerala, India, are affected by some form of disabilities. Among them, 60,925 are hearing disabled based on the definition of hearing impairment in the Persons with Disabilities Act 1995. A cochlear implant (CI) is a surgically implanted electronic device that provides a sense of sound to a person with severe to profound sensorineural hearing loss in both ears.

Need for the Study: Even though the Sruthitharangam scheme was started by the Government of Kerala, India, in 2012, no study was carried out to estimate the outcomes in terms of usage of CI, education placement, and mode of communication after CI surgery.

Aims and Objectives: The aim of the study was to investigate the usage of CI, communication abilities, and schooling in CI children who have undergone surgery under Kerala Government free CI program. The current study was to report the usage of cochlear implantation, the education status, and mode of communication of the children who had undergone, free of cost CI surgery from June 2012 to December 2015 in Kerala, India.

Materials and Methods: The demographical data were collected from the register maintained at Government Medical College, Kozhikode, Kerala, India. The study was a cross-sectional study and the data were collected through the telephonic interview of 114 parents or caregivers among 132 parents who had undergone free CI surgery from June 2012 to December 2015 at Government Medical College Kozhikode. Eighteen parents or caregivers could not be contacted due to unavailability or change of contact number and data collection was possible only for 114 parents among the 132 parents. All the children had attended a minimum of 2 years of post-implantation Auditory-Verbal Habilitation (AVH) from Sruthitharangam empanelled centers. Each subject was asked questions to understand the current usage of the device, the mode of communication, type of schooling, and associated issues that affect the prognosis of CI is also considered. The obtained responses were scored accordingly and tabulated for further statistical analysis.

Observations and Results: The result reveals that among the 114 CI recipients, 93.8% (107 recipients) were using CI and 6.14% (seven recipients) were non-users. These data found that all children were enrolled in school and attending in variety of educational settings. In that, 82.45% (94 children) were attending mainstream education and 17.54% (20 children) were going to special schools. On further analysis of the communication, abilities showed that the majority of the children (75.43%) communicated orally, 21.05% of them communicated through total communication and 3.5% of them used sign language.

Conclusions: Kerala government Sruthitharangam CI program aid the majority of the children with severe to profound sensorineural hearing loss in acquiring oral communication skills and also benefiting integration in normal schools. Steps should be taken to reduce the number of non- users and also plan new strategies for better normal school integration for CI children under the government scheme

Key words: Cochlear implant usage, Cochlear implantation, Communication abilities, Educational status

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INTRODUCTION

As per the World Health Organization 2018 reports, the new estimate of disabling of hearing loss is 466 million people and 34 million of these are children. Disabling hearing loss refers to hearing loss >40 dB in the better hearing ear in adults and a hearing loss >30 dB in the better hearing ear

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in children.[1] The State Initiative on Disabilities Survey (2015) indicated that 2.32% of populations in Kerala, India, are affected by some form of disabilities. Among them, 60,925 are hearing disabled based on the definition of hearing impairment in Persons With Disabilities Act 1995.[2] According to the 2011 Census data, 7.01% of children in the age group of 0–6 years in India have a disability, inborn, or acquired.[3] Its incidence is estimated to be 4.8% in children aged 0–1 year and 6.4% in children aged 1–4 years.[4] Prevalence and severity of hearing loss vary with some factors, including socioeconomic status, exposure to infections, and consanguinity.[5] Lower-income and increasing age lead to increased incidence of hearing loss.[6] In this regard, early identification and intervention services can play a crucial role in prevention as well as remediation of the developmental delays that occur in young children. Early intervention broadly refers to the provision of services to infants, toddlers, and young children who are considered vulnerable for reasons of disability or risk of disability. Liberty (2000)[7] describes early intervention as, "…a philosophy of providing specialized services to children with special needs during their developmental years, with the aim of ameliorating the effects of biological and other factors that can affect the developmental outcome. Children with profound hearing loss who no longer benefit from hearing aids, cochlear implant (CI) may be the next best step. Cochlear implantation is a medical device that uses electricity to stimulate the spiral ganglion cells of the auditory nerve to restore sensorineural hearing loss. The purpose of this device is to convert sound to an electrical signal and deliver this to the hearing nerve, which by passes the damaged hearing apparatus.[8] It enhances good communication skills; auditory performance in these children. It is also benefiting the academic performance of the children. Modes of communication in CI children are classified into three: (1) Oral communication, (2) total communication, and (3) bilingual communication. Schooling consideration of CI children includes a public or private school with adequate facilities or inclusion in a public or private school adequate supports integrated within the school (special/normal). In Kerala, India, the government started first free cochlear implantation program in 2012 called "Sruthitharangam" which provides free cochlear implantation surgery and 2-year Auditory-Verbal Habilitation (AVH) for children with severe to profound hearing loss in the age group of 0–5 years. Two hundred and sixty-nine children under 5 years had undergone surgery under the scheme at Government Medical College, Kozhikode. Therefore, this study is significant as the first to report on the long-term outcomes of the Sruthitharangam CI programme at Government Medical College, Kozhikode. The outcomes measured were the relationship between implanted children's current status of CI usage, modes of communication, and their educational placement. Further this study also investigated the relationship of the variable age of implantation, additional disabilities, and the presence of abnormal radiological findings. In the present study consideration to the current status of CI usage, education status and mode of communication of the children who had undergone free of cost CI surgery from June 2012 to December 2015 in Kerala, India, were analyzed.

MATERIALS AND METHODS

This was a prospective, cross-sectional, and analytical study conducted from September 2012 to December 2015 at Government Medical College Kozhikode, Kerala, India. Children received the CI under the "Sruthitharangam" scheme and they had attended 2-year AVH at the same place. The demographical data were collected from the register maintained at Government Medical College Kozhikode, Kerala. The study was a cross-sectional study, and the data were collected through the telephonic interview from 114 parents or caregivers among 132 parents who had undergone free CI surgery from June 2012 to December 2015 at Government Medical College, Kozhikode, Kerala. Eighteen parents/caregivers could not be contacted due to non-availability or change of contact number, and the data collection was possible only for 114 parents among 132 parents. A questionnaire was used to collect the data from parents through a telephonic interview. The questionnaire contained queries about the current status of CI usage (user/non-user), current communication mode (oral, bilingual, and total communication), and educational placement (Regular/normal vs. special school), and associated medical issues. All the data were computerized and analyzed using Fisher's Exact test.

OBSERVATIONS AND RESULTS

The authors contacted 114 parents out of 133 parents through telephone. All the reported data is tabulated in Figure 1 which shows that the majority of the implantees, i.e., 107 children (93.8%) were using the device continuously. The remaining seven children were non-users. From the non-users group, four children have their processor repair issues and they could not afford the cost of repair. The patients then learned total communication. The other one non-user implantee lost his external implant. There were no radiological abnormalities, associated disabilities, intraoperative or post-operative complications in these two categories of patients who were non-users in the study.

Figure 2 shows that the majority of 86 (75.43%) of the implantees have acquired oral communication and

used it as their mode of communication. Other modes of communication used was: Total communication in 24 (21.05%) and bilingual communication in four (03.5%).

Figure 3 shows that out of 114 implantees 92 (82.45%) were in mainstream education. Those who were not in mainstream education were studying in special education schools; 20 (17.54%).

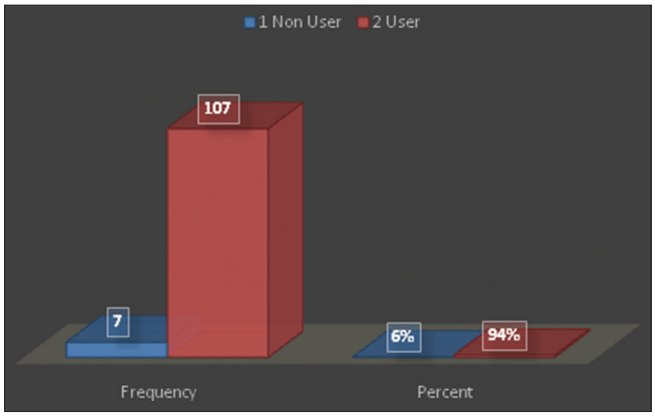

Figure 1: Showing the current status of CI Usage in children of the study (*n*-114)

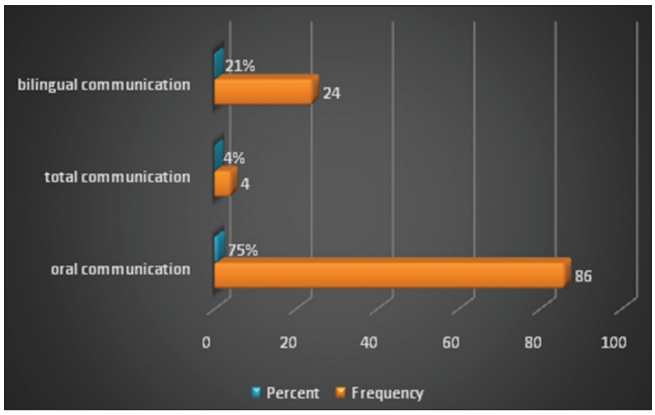

Figure 2: Shows the Modes of communication among the subjects in the study (*n*-114)

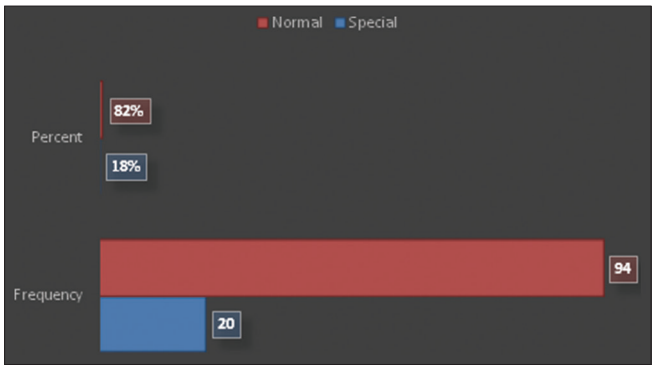

Figure 3: Showing the educational placement among the subjects in the study (*n*-114)

Fisher's exact test was performed to observe the significant relationships between the current status of CI users and types of education placement and modes of communication. The result of the Fisher's exact test between CI users and types of educational placement showed *P* value less than the significant level 5%, which implies that there was a significant relationship between these two variables. The result also showed that only 0.6% percentage of the CI non-users was attending the normal school. However, the results of the test between CI users and modes of communication were greater than the significant level, showing that the two variables were not related.

DISCUSSION

This study showed that the majority of cochlear recipients of the Sruthitharangam CI program were using the device, suggesting that they have gained benefits from cochlear implantation and thus using it continuously. A very small proportion of the implantees become non-users.

The result reveals that among the 114 CI recipients, 107 children (93.8%) were using CI and seven children (6.14%) were non-users. Further analysis of the data showed that all children were enrolled in schools and attending in variety of educational settings. Among them, 94 (82.45%) children were attending mainstream education and 20 children (17.54%) were going to special schools. Analysis of the communication abilities showed that 86 (75.43%) children communicated orally 24 (21.05%) of them communicated through bilingual communication, and 4 (03.5%) of them used sign language. There are many studies in the literature that were identical to the present study. A Korean study was done by Hoon *et al.*[9] in 2019, which investigated the educational status in bilateral deaf children with a cochlear implantation, found that among 64 implantees 46 (71.87%) were attending mainstream educational institutes. Eight (12.5%) of them were enrolled in integrated school set up and the remaining ten (15.62%) were attending special schools. The study by Goh *et al.*[10] in 2017 which investigated the long-term outcomes of cochlear implantation, in terms of device usage, modes of communication, educational placements, and functional auditory/oral performances found that among the implantees, the proportion of non-users of CI was low 02.4% and a large majority were full-time CI users 97.6%. These results were similar to the results observed in the present study. Contrera *et al.*[11] have conducted a study which determined the rates of long-term CIs use in children. They found that 93.2% of the implantees were using CIs regularly. "Sruthitharangam" free CI program was a successful program in Kerala wherein the number of CI users was of international standard. The hearing impaired children

joining the social mainstream in respects to educational placements and improving their modes of communication has given rise to a sense of confidence among the parents and children. To discuss few solutions to reduce the number of non-users, to improve oral communication and better educational placement, the stakeholders should concentrate on early hearing detection and intervention which should be the foremost step. The government should provide free amplification device/economic support after the warranty period was over, to reduce the number of nonusers.

CONCLUSIONS

Kerala government's "Sruthitharangam CI program" aided the majority of the children with severe to profound sensorineural hearing loss in acquiring oral communication skills and also benefiting integration in normal schools. Steps should also be taken to reduce the number of non-users and also plan new strategies for better normal school integration for CI children under government schemes.

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Original Article

Rectus Sheath Block and Subcutaneous Bupivacaine Infiltration for Post-operative Pain Relief in Midline Laparotomy

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Abstract

Background: The aim of the study was assessment of post-operative outcomes of rectus sheath block and comparison of outcomes between rectus sheath block and sub cutaneous bupivacaine.

Materials and Methods: This study enrolled 58 patients who were scheduled to undergo laparotomy. Group I – 30 patients received rectus sheath block using bupivacaine by placing catheters in between the muscle and posterior rectus sheath. Group II – 28 patients received bupivacaine infiltration by placing catheters in the subcutaneous plane. Visual analog scale (VAS) score, peak expiratory flow rate (PEFR), rescue analgesia, and complications were noted and follow-up of these patients was done.

Results: Both the groups were comparable, hemoglobin concentration and anesthesiologists grades (statistically insignificant). The majority of the patients from rectus sheath block group had VAS scores <5 comparing to subcutaneous infiltration group which was statistically very significant ($P \leq 0.001$). There was a statistically significant improvement of post-operative PEFR values in Group I as compared to Group II ($P < 0.001$). In Group I, 20 patients showed VAS score of 1 (no pain) at rest as compared only four patients in Group II. Rate of infection was more common in group receiving subcutaneous infiltration.

Conclusion: The patients from rectus sheath block group showed a statistically significant decrease in post-operative pain in terms of VAS scores compared to that of subcutaneous bupivacaine infiltration group. There was statistically significant decreased use of opioids as rescue analgesic in the rectus sheath group compared to that of the subcutaneous bupivacaine infiltration group.

Key words: Peak expiratory flow rate, Rectus sheath, Subcutaneous bupivacaine infiltration, Visual analog scale score

INTRODUCTION

Surgery is a major stress that induces secretion of various substances such as prostaglandins, serotonin, and histamines as a reaction to localized tissue damage. In laparotomies with larger incisions, in abdominal surgeries, incision site is the most significant cause of acute post-operative pain. Extended midline laparotomies have relatively long incisions and post-operative pain control of the incision site is important.[1,2]

Pain at the incision site if not effectively controlled interferes with breathing and causes atelectasis of lungs and also affects the cardiovascular, digestive, urinary, and musculoskeletal system and thus making the post-operative recovery difficult with poor surgical outcome.[1] The use of rectus sheath catheters for the administration of local anesthetic is based on the blockade of the anterior division of T6-T11 thoracoabdominal intercostal nerves. These nerves leave the spinal cord dividing into anterior and posterior divisions. The anterior division passes posterior to costal cartilages and then between transversus abdominis and internal oblique muscles,

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before passing medially to pierce and supply sensation to the rectus and the overlying skin. Therefore, a catheter placed anterior to the posterior sheath will block these nerves and reduce pain transmission from a midline laparotomy wound. Since 2007, the technique has further developed to include ultrasound-guided placement of rectus sheath catheter.[2,3]

The anterior rami of the thoracic nerve follow a curvilinear course forward in the intercostal spaces toward the midline of the body. The upper six thoracic nerve ends near the sternum as anterior cutaneous sensory branches. Thoracic nerves 7th–12th pass behind the costal cartilages and lower ribs to enter a plane between the internal oblique muscle and the transverses abdominis. The 7th and 8th nerves course slightly upward or horizontally to reach the epigastrium, whereas the lower nerves have an increasingly caudal trajectory.[3] As these nerves course medially, they provide motor branch to the abdominal wall musculature. Medially, they perforate the rectus sheath to provide sensory innervations to the anterior abdominal wall. The anterior ramus of the 10th thoracic nerve innervates the skin of the hypogastrium.[3,4]

Rectus sheath block will provide somatic pain relief from abdominal wall structures superficial to the peritoneum. For surgery deep to the peritoneum (such as bowel resection), there is usually a component of deeper visceral pain, for which systemic analgesia is routinely given immediately after surgery.[4] Major abdominal surgeries with upper abdominal incisions lead to severe abdominal pain, which if treated inadequately, causes shallow breathing, atelectasis, retention of secretion, and poor wound healing. This increases the incidence of post-operative morbidity and leads to delayed recovery with increased hospital stay.[5]

In this study, we will compare rectus sheath block and subcutaneous bupivacaine infiltration for post-operative pain relief in patients undergoing midline laparotomy. These pain reliefs will how much help in the post-operative recovery of patient will be assessed in terms of return of bowel sounds, passage of first flatus, nausea, vomiting, and improvement in peak expiratory flow rate (PEFR) and wound complications.

MATERIALS AND METHODS

- Study design: Prospective, observational
- Study period: From October 2013 to October 2014
- Study place: Department of Surgery, Netaji Subhash Chandra Bose Medical College, Jabalpur, M.P.

There will be two study groups:

- Group I – 30 patients will receive rectus sheath block using bupivacaine by placing catheters in between the muscle and posterior rectus sheath
- Group II – 28 patients will receive bupivacaine infiltration by placing catheters in the subcutaneous plane.

METHODS

Inclusion Criteria

- All patients undergoing midline laparotomy were included in the study.

Exclusion Criteria

The following criteria were excluded from the study:

- Previous midline surgery
- Simultaneous incision more than 1 cm (colostomy/ileostomy)
- Chronic liver and renal disease.

Ethical Approval: Taken

Informed concent was taken from the patient and study protocol as decided by institutional ethical committee was followed.

Evaluation of the Response to Intervention

In our study we have taken PEFR values of all patients undergoing midline laparotomy 3 readings in one hour preoperatively and compared with post op values in patients given either rectus sheath block or subcutaneous infiltration postoperatively, PEFR is used as an indirect measure to assess pain post operatively in patients after rectus sheath block or subcutaneous infiltration .post operatively we have measured PEFR after 2 hour and then other two readings 6 hourly.

Observations

This prospective, observational study was carried out in the department of anesthesiology. Fifty-eight selected cases were included under the study to determine the comparative study of outcome of midline laparotomy after rectus sheath block and subcutaneous bupivicaine following parameters:-

1. Demographic features: Age and sex.
2. Depending pre-operative factors such as hemoglobin, anesthesiologists (ASA) score, PEFR
3. Depending intraoperative factors such as incision length and duration of surrey
4. Depending post-operative factors such as visual analog scale (VAS) score, PEFR, assessment of patient, rescue analgesia, and wound complication.

Duration of surgery – in both groups, duration of surgery is divided in subgroups, comparatively statistically insignificant. $P = 0.45$, in both groups, in majority of the cases, the duration of surgery was <2 h; there was no statistically significant difference.

Follow-up of patients was satisfactory. Most of the patients came at the 4th week postoperatively. All of the patients done well at their follow-up with no post-operative wound complications.

RESULTS

The mean ±SD of age (in years) of patients receiving rectus sheath block was 38 ± 16.7 and that of patients receiving subcutaneous infiltration was 40.4 ± 13.7 which was statistically insignificant ($P = 0.54$). Both the groups were comparable in respect to the parameters such as age, sex, hemoglobin concentration, and ASA grades (statistically insignificant) [Table 1].

The incision length in majority of cases of both Groups I and II was between 15 cm and 18 cm. There was no statistically significant difference ($P = 0.43$) in length of incision in both the groups. The majority of the patients from rectus sheath block group had VAS scores <5 comparing to subcutaneous infiltration group which was statistically very significant ($P \leq 0.001$) [Tables 2 and 3].

Only 10 patients in Group I required tramadol as rescue analgesic as compared to 20 patients in Group II. The rescue analgesic requirement was very less in Group I as compared to Group II which was statistically very significant (P = 0.09) [Table 4].

In Group I, number of patients showing PEFR values >50% was 7 in the first reading, 21 in the second reading, and 16 in the third reading. While in Group II, no patients showed PEFR value >50% in the first reading. Only two patients in the second reading and four patients in the third reading showed PEFR >50% in Group II. There was a statistically significant improvement of post-operative PEFR values in Group I as compared to Group II ($P < 0.001$). In Group I, 20 patients showed VAS score of 1 (no pain) at rest as compared only four patients in Group II. Twenty patients in Group I showed VAS score of 1 with coughing as compared to five patients in Group II [Tables 5 and 6].

There were no statistically significant difference between the appearance of bowel sound postoperatively, time for passage of first flatus, and incidence of nausea and vomiting ($P > 0.05$). Rate of infection was more common in group receiving subcutaneous infiltration as compared to rectus sheath block group ($P < 0.05$). Incidence of hematoma and seroma formation was similar in both the groups [Table 7].

Statistical Analysis

After getting the required information, the collected data were coded, tabulated, and analyzed. The various statistical techniques, that is, the mean, standard deviation, and test of significance (t-test and Chi-square test) were used for drawing valid conclusions. Statistical analysis done using Student's *t*-test. SPSS 13.0 software was used to calculate *P* value. $P < 0.05$ was taken as statistically a descriptive analysis was done on all variables to obtain a frequency distribution. The mean + SD and ranges were calculated for quantitative variables. Continuous variables were compared by the Student's *t*-test. Proportions were analyzed with the Chi-square test.

DISCUSSION

In abdominal surgeries, incision site is the most significant cause of acute post-operative pain. Extended midline laparotomies have relatively long incisions and post-operative pain control of the incision site is particularly important. Pain at the incision site puts a lot of physical and mental burden on the patient, increases the duration of stay at the hospital leading to increased chances of hospital acquired infections. It interferes with the breathing process (decreased PEFR) and causes atelectasis of lungs. Uncontrolled pain also affects the cardiovascular, digestive, urinary, and musculoskeletal system and thereby making the post-operative recovery difficult with poor surgical outcome.[2-4,6]

Good post-operative pain control after laparotomy is a primary requisite to make patient comfortable, for early mobilization and for decreasing the complication rates. Post-operative pain is due to stretching of intra-abdominal cavity, peritoneal inflammation, and phrenic nerve irritation pains arising from the visceral and deeper peritoneal layer may be a greater contributor to overall pain than from subcutaneous and muscular layers of a wound incision.[5,7]

Rectus sheath block is a very good modality for relieving pain in patients of midline laparotomies. Local anesthetics administered through the catheter placed in rectus sheath binds with the intercostal nerves blocking the sodium channel responsible for pain transmission. It leads to interruption of pain transmission pathway. We chose bupivacaine as the local anesthetic for our study because of its prolonged duration of action and proposed antimicrobial, antifungal activity, and prevent ileus which is not present in other local anesthetics such as lidocaine and mepivacaine.

Bilateral intrafascial administration of bupivacaine for regional scalp block can decrease post-operative pain of diagnostic laparoscopy. Effective post-operative pain relief results in improve comfort, respiratory pattern, and rapidly recovery bupivacaine toxicity as excessive shivering, nausea, dizziness, confusion, seizure, and cardiac arrhythmias.[8,9]

The incision length in majority of cases of both Groups I and II was between 15 and 18 cm. There was no statistically significant difference ($P = 0.43$) in length of incision in both the groups. The majority of the patients from rectus sheath block group had VAS scores <5 comparing to subcutaneous infiltration group which was statistically very significant ($P \leq 0.001$). In a study by Gupta *et al.*, the time of first analgesic request was significantly delayed in patients who had fascial infiltration with bupivacaine after elective laparotomy than who do not. They also draw inference that bupivacaine wound infiltration improves pain score at rest within the first 6 h and pain score on coughing within the first 24 h postoperatively.[8,9]

Only 10 patients in Group I required tramadol as rescue analgesic as compared to 20 patients in Group II. The rescue analgesic requirement was very less in Group I as compared to Group II which was statistically very significant ($P = 0.09$). Rectus sheath block efficiently decreased the post-operative opioid requirement compared to subcutaneous infiltration of bupivacaine and it indirectly decreased the incidence of ileus. In Group I, number of patients showing PEFR values >50% was 7 in the first reading, 21 in the second reading, and 16 in the third reading. While in Group II, no patients showed PEFR value >50% in the first reading. Only two patients in the second reading and four patients in the third reading showed PEFR >50% in Group II. There was a statistically significant improvement of post-operative PEFR values in Group I as compared to Group II ($P < 0.001$) [Table 8]. Shah *et al.* found reduction in PEFR in first 48 hrs after surgery but no significant difference in reduction between control and study groups and therefore concluded that there was no significant benefit in either pain score or PEFR.[8-10]

In Group I, 20 patients showed VAS score of 1 (no pain) at rest as compared only four patients in Group II. Twenty patients in Group I showed VAS score of 1 with coughing as compared to five patients in Group II. Only nine patients of Group I had VAS score>5 (moderate to severe pain) at rest while 20 patients in Group II had the same score at rest. Six patients had VAS score >5 with coughing in Group I as compared to 20 patients in Group II. There was a statistically significant improvement of VAS score in Group I as compared to Group II ($P < 0.0001$).[10,11]

Among the pathways responsible for relaying pain after exploratory laparotomy, a significant contribution comes from visceral pain fibers arising from viscera and deep peritoneal layers which are not blocked by both of the above techniques, that is, the reason none of the study population was able achieve complete pain relief (VAS=0). There was no statistically significant difference between the appearance of bowel sound postoperatively, time for passage of first flatus, and incidence of nausea and vomiting ($P > 0.05$).

Rate of infection was more common in group receiving subcutaneous infiltration as compared to rectus sheath block group ($P < 0.05$). Incidence of hematoma and seroma formation was similar in both the groups. Choragi *et al.* (2013) enrolled 60 patients scheduled to undergo midline laparotomies into two groups of 30 patients each. Group I patients received suprafascial bupivacaine through a catheter while Group II patients received interfacial bupivacaine through a catheter placed between rectus sheath muscle and posterior rectus sheath. They found a significant reduction in median VAS scores ($P < 0.05$) in group of patients receiving interfacial bupivacaine as compared to suprafascial bupivacaine group. Opiate requirement was also significantly less in interfacial bupivacaine group as compared to suprafascial bupivacaine group (0.001). Our study was in unison with the study of Khorgami *et al.* in showing

Table 1: Anesthesiologists grading

Group	As a	Male (%)	Female (%)
Rectus sheath block	I	9 (15.5)	2 (3.4)
	II	12 (20.6)	1 (1.7)
	III	4 (6.8)	2 (3.4)
Subcutaneous infiltration	I	9 (15.5)	1 (1.7)
	II	12 (20.5)	2 (3.4)
	III	3 (5.1)	1 (1.7)

Table 2: Incision length

Group	Incision length	Cases (%)		Total
		Male	Female	
Rectus sheath block	12–14	8 (13.7)	3 (5.1)	11
	15–18	17 (29.3)	2 (3.4)	19
Subcutaneous infiltration	12–14	7 (12.1)	2 (3.4)	9
	15–18	17 (29.3)	2 (3.4)	19

Table 3: Duration of surgery

Group	Duration of surgery	Male (%)	Female (%)	Total (%)
Rectus sheath block	1:00–1:59 h	21 (36.2)	2 (3.4)	23 (39.6)
	2:00–2:59 h	4 (6.8)	2 (3.4)	6 (10.2)
	3:00–3:59 h	0	1 (1.7)	1 (1.7)
Subcutaneous infiltration	1:00–1:59 h	16 (27.0)	3 (5.1)	19 (32.1)
	2:00–2:59 h	7 (12.0)	1 (1.7)	8 (12.7)
	3:00–3:59 h	1 (1.7)	0	1 (1.7)

Table 4: Visual analog scale score

Group	Visual analog scale	Male (%)		Female (%)	
		At rest	On cough	At rest	On cough
Rectus sheath block	1 (no pain)	19 (32.7)	17 ((29.3)	1 (1.7)	3 (5.1)
	3 (mild pain)	1 (1.7)	4 (6.8)	0	0
	5 (moderate pain)	4 (6.8)	0	4 (6.8)	1 (1.7)
	>7 (severe pain)	1 (1.7)	4 (6.8)	0	1 (1.7)
Subcutaneous infiltration	1 (no pain)	3 (5.1)	4 (6.8)	(1.7)	1 (1.7)
	3 (mild pain)	4 (6.8)	3 (5.1)	0	0
	5 (moderate pain)	18 (11.9)	0	2 (3.4)	1 (1.7)
	>7 (severe pain)	6 (10.3)	17 (29.3)	1 (1.7)	2 (3.4)

Table 5: Rescue analgesia after visual analog scale scoring

Group			Rescue analgesia (%)					
			Tramadol 50 mg	Paracetamol				
				100 Ml	200 Ml	300 Ml	400 Ml	500 Ml
Rectus sheath block	Male	No. of patient	6 (10.3)	2 (3.4)	2 (3.4)	0	0	0
	Female	No. of patient	4 (6.8)	1 (1.7)	1 (1.7)	0	0	0
Subcutaneous infiltration	Male	No. of patient	17 (29.3)	5 (8.6)	5 (8.6)	3 (5.1)	2 (3.4)	0
	Female	No. of patient	3 (5.1)	1 (1.7)	2 (3.4)	0	0	0

Table 6: Pre-operative peak expiratory flow rate values

Group	Sex	Peak expiratory flow rate value	30–40	41–50	51–60	61–70	*P*
Rectus sheath block	Male	First reading	7 (12)	10 (17.2)	6 (10.3)	2 (3.4)	<0.001
		Second reading	6 (10.3)	8 (13.7)	9 (15.5)	2 (3.4)	
		Third reading	5 (8.6)	12 (20.6)	7 (12)	1 (1.7)	
	Female	First reading	3 (5.1)	2 (3.4)	0	0	
		Second reading	1 (1.7)	2 (3.4)	2 (3.4)	0	
		Third reading	0	5 (8.6)	0	0	
Subcutaneous infiltration	Male	First reading	3 (5.1)	9 (15.5)	10 (17.2)	2 (3.4)	<0.001
		Second reading	1 (1.7)	8 (13.7)	12 (20.6)	3 (5.1)	
		Third reading	3 (5.1)	9 (15.5)	9 (15.5)	3 (5.1)	
	Female	First reading	1 (1.7)	1 (1.7)	2 (3.4)	0	
		Second reading	-0	2 (3.4)	2 (3.4)	0	
		Third reading	1 (1.7)	2 (3.4)	1 (1.7)	0	

Table 7: Clinical signs

Group	Range (hours)	Appearance of bowel sound (%)		Passage of first flatus		Nausea/vomiting (%)	
		Male	Female	Male	Female	Male	Female
Rectus sheath block	12–24	9 (15.5)	2 (3.4)	3 (5.1)	0	8 (13.7)	0
	25–36	15 (25.8)	2 (3.4)	17 (29.3)	4 (6.8)	0	0
	37–48	2 (3.4)	0	4 (6.8)	1 (1.7)	1 (1.7)	0
	49–60	0	0	0	1 (1.7)	0	0
	61–72	0	0	2 (3.4)	1 (1.7)	2 (3.4)	0
Sub cutaneous infiltration	12–24	13 (22.4)	2 (3.4)	4 (6.8)	0	13 (22.4)	1 (1.7)
	25–36	10 (17.2)	2 (3.4)	18	2 (3.4)	1 (1.7)	0
	37–48	1 (1.7)	0	1 (1.7)	1 (1.7)	0	0
	49–60	0	0	(1.7)	1 (1.7)	0	0
	61–72	0	0	0	1 (1.7)	0	0

the superiority of rectus sheath block in comparison to subcutaneous infiltration. Rescue analgesic requirement was decreased postoperatively in our present study which was also in agreement with the study of Khorgami *et al.*[12] Crosbie *et al.* conducted a retrospective study comparing subcutaneous infiltration and rectus sheath block in alleviating post-operative pain 98 patients undergoing gynecological surgeries. With their observations, they

Table 8: Post-operative peak expiratory flow rate values

Group	Sex	Peak expiratory flow rate value	30–40 (%)	41–50 (%)	51–60 (%)	61–70 (%)	*P*
Rectus sheath block	Male	First reading	5 (8.6)	14 (24.1)	4 (6.8)	2 (3.4)	<0.001
		Second reading	2 (3.4)	6 (10.3)	14	3 (5.1)	
		Third reading	1 (1.7)	10 (17.2)	10 (17.2)	4 (6.8)	
	Female	First reading	0	4 (6.8)	1 (1.7)	-	
		Second reading	0	1 (1.7)	4 (6.8)	0	
		Third reading	0	3 (5.1)	1 (1.7)	1 (1.7)	<0.001
Subcutaneous infiltration	Male	First reading	4 (6.8)	20 (34.4)	0	0	
		Second reading	2 (3.4)	20 (34.4)	2 (3.4)	0	
		Third reading	1 (1.7)	18 (31.0)	4 (6.8)	0	
	Female	First reading	3 (5.1)	1 (1.7)	O	0	
		Second reading	-	4 (6.8)	O	0	
		Third reading	1 (1.7)	3 (5.1)	o	0	

concluded that rectus sheath block technique was efficient in relieving post-operative pain and decreasing post-operative opioid requirement ($P < 0.001$). Our study was in agreement to the study done by Crosbie *et al.*[13]

The present study was in agreement with studies done by Khorgami *et al.* and Crosbie *et al.* in terms of reduction in post-operative pain, rescue analgesic requirement, post-operative morbidity, and in improving lung function.[10-13]

CONCLUSION

The patients from rectus sheath block group showed a statistically significant decrease in post-operative pain in terms of VAS scores compared to that of subcutaneous bupivacaine infiltration group. There was statistically significant decreased use of opioids as rescue analgesic in the rectus sheath group compared to that of the subcutaneous bupivacaine infiltration group.

What this Study add to Existing Knowledge

Effective pain relief provided by that of the rectus sheath block group lead to significant improvement in PEFR values in the post-operative period compared to that of subcutaneous infiltration group. Implying that rectus sheath block was efficient in restoring post-operative pulmonary function compared to that of the subcutaneous infiltration group.

Limitation of our Study

1. Small sample size
2. Chances of bias
3. Single-center trial.

Contribution by Different Authors

First author: Dr. Sangeeta Chauhan, Assistant Professor, Dept. of Anaesthesiology, LNMC, Bhopal: Concept and data collection.

Second author and Corresponding Author: Dr. Chandra Shekhar, Assistant Professor, Department of Anaesthesiology, LNMC, Bhopal: Concept and data collection.

Third author: Dr. Kiran Bhatia, Associate Professor, Department of Anaesthesiology, SHKM GMC, Nalhar, Haryana: Discussion and guidance.

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Original Article

Effects of Intramuscular Dexmedetomidine Versus Clonidine on the Duration of Subarachnoid Block and Analgesia for Lower Limb Orthopedic Surgeries

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Abstract

Background: Alpha-2adrenergic agonists, when used simultaneously as systemic adjuvants to local anesthetics show synergistic action and improve the quality of spinal anesthesia and prolong the post-operative analgesia. We aimed to study the effects of intramuscular dexmedetomidine versus clonidine on the duration of bupivacaine sub-arachnoid block, post-operative analgesia, and sedation in patients undergoing lower limb orthopedic surgeries.

Materials and Methods: The study design was a prospective, randomized, and double-blind study. Eighty adult consented patients of ASA I or II, scheduled for orthopedic lower limb surgeries under spinal block were randomized to two groups of 40 patients per group. Group D received IM dexmedetomidine 1 μgkg^{-1}, Group C received IM clonidine 2 μgkg^{-1}, and 30 min before the bupivacaine subarachnoid block. The time of onset of sensory and motor block, the time required for complete sensory and motor recovery, time of the first request of rescue analgesia, and sedation levels were compared between the groups. Collected data were analyzed using the student "*t*" test, Chi-square test/Fisher exact test, and $P < 0.05$ was considered statistically significant.

Results: The mean onset time of sensory and motor block was reduced, the mean time required for complete sensory recovery was increased and the time of the first request of rescue analgesia was prolonged in the dexmedetomidine group compared to clonidine group with a significant $P < 0.05$. Ramsay sedation score was higher in the dexmedetomidine group compared to clonidine group ($P = 0.003$)

Conclusion: Premedication with a single dose of intramuscular dexmedetomidine before bupivacaine spinal anesthesia acts as an effective adjuvant and potentiates the quality of block and prolongs post-operative analgesia more than intramuscular clonidine.

Key words: Clonidine, Dexmedetomidine, Intramuscular, Post-operative analgesia, Premedication

INTRODUCTION

Orthopedic lower limb surgeries are lengthy procedures associated with significant post-operative pain. Although sub-arachnoid block is the most commonly used regional anesthetic technique, it has the disadvantage of a short duration of anesthesia and post-operative analgesia. When compared to general anesthesia, it is associated with less blood loss, surgical stress, useful in difficult airway cases, decreased incidence of thromboembolic events along with a decreased length of stay, cost, aids in early ambulation, and lowers 30-day mortality.[1] Various techniques and adjuvants were tried intrathecally and systemically along with local anesthetics to improve the quality of block, prolong the postoperative analgesia, and to eliminate the anxiety related to surgery during regional anesthesia.[2-3] Alpha-2 adrenergic agonists clonidine and dexmedetomidine have both sedative and analgesic properties[4,5] and potentiate the effect of local anesthetics when used as adjuvants in regional anesthesia. They prolong the duration of sensory and motor block and also post-operative analgesia.[6-8]

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Clonidine and dexmedetomidine can be administered by intramuscular, oral, intranasal, intravenous, intrathecal, and epidural routes.[9-11] They act by a central and a peripheral mechanism which enables them to give these drugs through different routes with the same effect. Dexmedetomidine a selective α-2-adrenoreceptor agonist is more effective than clonidine as analgesic and sedative with an α_2/α_1 selectivity ratio which is 8–10 times greater than that of clonidine.[12] However, the dose of clonidine 1.5–2 times higher than dexmedetomidine.[13,14]

There are very few studies comparing the effects of intramuscular clonidine and dexmedetomidine on the quality of the sub-arachnoid block. Hence, our objective is to evaluate and compare the effect of intramuscular dexmedetomidine versus clonidine on the onset and duration of sensory and motor block, time for request of the first analgesic, sedation level, and adverse effects if any after sub-arachnoid block in te lower limb orthopedic surgeries.

MATERIALS AND METHODS

After approval of study protocol by the Institutional Ethics Committee, we conducted this prospective randomized double-blind study on 80 consented adult ASA Grades I and II patients of either sex, aged 20–60 years, weighing 50–70 kg, height measuring 150–170 cm, and posted for elective lower limb orthopedic surgeries under spinal anesthesia in the Orthopedic operation theater, Government General Hospital affiliated to Rangaraya Medical College, Kakinada.

Exclusion Criteria

1. Unwilling by Patient,
2. Patients allergic to the amide group of local anesthetics
3. Patients with a history of cardiac disease, diabetes mellitus, hypertension, chronic obstructive respiratory disease, hepatic, renal, neurologic disease, and psychological disease.
4. Patients on Alpha-2 agonists, beta-blockers, alcohol, and drug abuse
5. Patients with bleeding diathesis, pre-existing neurological, spinal deformities, infection at the site of the block (contraindications for the sub-arachnoid block)
6. Pregnancy
7. Emergency surgeries

Written informed consent was obtained from all the 80 patients after completing a thorough pre-anesthetic checkup with all necessary/relevant investigations and every patient was explained about visual analog scale (VAS) 0–10 for pain scoring and was kept on nil by mouth for 8 h before surgery.

Patients subjected to the study were randomized into two groups of 40 subjects each by computer-generated random numbers using sealed envelopes. The premedicant study drugs were premixed by an anesthetist who is unaware of the study. The study drugs were administered intramuscularly to all the patients as a single dose 30 min before giving sub-arachnoid block.

- Group D: n = 40 received intramuscular dexmedetomidine 1 $\mu g/kg^{-1}$ diluted up to 2 ml with normal saline as a single dose.
- Group C: n = 40 received intramuscular clonidine 2 $\mu g/kg^{-1}$ diluted up to 2 ml with normal saline as a single dose.

Standard monitors were attached and vitals such as heart rate (HR), non-invasive blood pressure (NIBP), electrocardiography (ECG), Pulse oximetry (SpO_2), and respiratory rate (RR) were recorded baseline, before injection and post-injection. An 18-G venous cannula was secured and Ringer's lactate solution was infused at the rate of 10 ml/kg before spinal anesthesia. After 30 min, under strict aseptic conditions, the subarachnoid block was performed at L_3–L_4 interspace using a 25 Gauge Quincke–Babcock's needle. After the free flow of CSF, 0.5% hyperbaric bupivacaine 3 ml (15 mg) was injected intrathecally. The time of injection was noted as 0 (time). The observer anesthesiologist who records data was blinded to group allocation. Oxygen was supplied at a rate of 6 L/min using a face mask. The onset and duration of sensory and motor block were tested using the pinprick method. The motor blockage was graded using modified Bromage scale[15] (Grade 0: No paralysis, Grade 1: Unable to raise the extended leg, Grade 2: Unable to flex the knee, and Grade 3: Unable to flex ankle). Sensory and motor block were tested every minute during the first 10 min, every 15 min intraoperative and postoperatively. The time of onset and duration of sensory and motor block were recorded. The time of injection was noted as time 0. The time taken to attain the highest dermatomal level was noted.

The time of recovery of sensory block was considered as two-dermatome regression from the highest sensory level. The time of recovery of motor block was the time to return to Grade 1 on the modified Bromage scale.

VAS

VAS[16] was used to test post-operative pain (Scale 0: No pain and 10: Worst possible pain) at 4, 6, 12, and 24 h. The duration of analgesia was considered as the time since the administration of the sub-arachnoid block until the first request of rescue analgesia. Injection diclofenac sodium 75-mg intramuscular is given for patients with a VAS score of three or more.

Sedation Score

Sedation score was assessed using Ramsay's Sedation Scale[15] (RSS) (Score 1: Anxious or agitated, Score 2: Co-operative and tranquil, Score 3: Drowsy but responsive to command, Score 4: Asleep but responsive to glabellar tap, Score 5: Asleep with sluggish response to tactile stimulation, and Score 6: Asleep and no response). The sedation score was recorded every 10 min after administration of the drug and then 10 min after giving sub-arachnoid block and thereafter postoperatively.

Vital parameters such as non-invasive blood pressure, heart rate, respiratory rate, and SpO_2 were noted baseline, after premedication, 3 min after sub-arachnoid block, every 5 min for the first 15 min, and, after that, every 15 min up to 1 h, after that every 30 min till the end of surgery. The duration of surgery was noted. A drop in MAP from 20% of the baseline is defined as hypotension and managed with intravenous fluid bolus and mephentermine 3 mg increments. Heart rate <50 beats/min is defined as bradycardia and managed with intravenous Atropine 0.5 mg. Respiratory rate <12 breaths/min is defined as respiratory depression and managed with oxygen supplementation. Side effects if any such as hypotension, bradycardia, nausea, and vomiting, respiratory depression, and shivering noted.

The sample size was calculated based on the pilot study observations conducted with a sample of 20 patients, ten patients in each group. To get a difference of >20% increase in the mean time for request of the first analgesic in between the groups with an α-error of 0.05 and power of 85%, we needed a sample size of 37 patients in each group (using power analysis and sample size software.com). Hence, 40 patients were enrolled in each group to account for dropouts. The patients involved in the pilot study were excluded from the original study.

Statistical Analysis

The collected data were finally analyzed using Microsoft Excel and GraphPad.com software. Data were disclosed as mean, standard deviation, ratio or percentage (%) or absolute numbers, and compared using student's *t*-test, Fisher's exact test, and Chi-square test to detect the significance of study parameters between the two groups. $P < 0.05$ was considered statistically significant.

RESULTS

All the 80 patients completed the study successfully under spinal anesthesia. The demographic data of the patients in terms of age, sex, weight, height, ASA I/II, and mean duration of surgery were comparable without any statistically significant difference between the groups [Table 1].

Premedication with intramuscular dexmedetomidine before sub-arachnoid block with bupivacaine resulted in earlier onset of sensory (3.58 ± 1.16 min) and motor block (4.56 ± 1.32 min) in Group D when compared to clonidine (Group C) which has a mean onset time of 4.51 ± 1.32 min and 5.46 ± 1.04 min for sensory and motor block, respectively, with a statistically significant difference between the groups ($P = 0.001$) [Table 2, Figure 1].

The mean time required for complete sensory recovery was 218.31 ± 24.82 min in Group D which was higher than Group C (199.05 ± 26.84 min), which was statistically significant ($P = 0.001$), [Table 2, Figure 2].

The mean time for complete motor recovery was similar in both groups. It was 223.42 ± 16.58 min in Group D and 216.31 ± 18.06 min in Group C, respectively, with no statistically significant difference among the groups ($P = 0.070$) [Table 2, Figure 2].

The mean time of the first request of analgesia was increased in Group D (339.04 ± 22.73 min) as compared to Group C (228.38 ± 26.20 min) with a statistically

Table 1: Demographic data of the patients

Parameters	Mean±Standard Deviation (*n*=40)		*P* value
	Group D	Group C	
Age in years	38.81±10.16	40.02±9.92	0.591
Weight in kg	55.43±5.8	56.20±5.49	0.539
Height in cm	159.65±6.92	159.83±6.70	0.906
Gender (%): Male/ Female	32/08	35/5	0.545*
ASA I/II	30/10	32/8	0.789*
Duration of surgery(Min)	106.35 ± 25.01	104.72± 26.21	0.776

Data expressed as mean (SD) or ratio or absolute numbers, Student *t*-test, *Chi-square test/Fisher exact test

Table 2: Comparison of outcome parameters

Parameters	Mean±Standard Deviation (*n*=40)		*P* value
	Group D	Group C	
Onset of Sensory blockade (Min)	3.58±1.16	4.51±1.32	0.001*
Onset of motor block (Min)	4.56±1.32	5.46±1.04	0.001*
Time of sensory recovery (Min)	218.31±24.82	199.05±26.84	0.001*
Time of motor recovery (Min)	223.42±16.58	216.31±18.06	0.070
Time of first request of analgesic(Min)	339.04±22.73	228.38±26.20	0.001*

Data expressed as mean (SD) or ratio or absolute numbers, Student *t*-test, **P*<0.05 Statistically significant

significant difference between the groups (P = 0.001), [Table 2, Figure 3].

Regarding the distribution of vital data, lower heart rates were observed in Group D than that of Group C but without any statistically significant difference except 5 min after the sub-arachnoid block where there was a significantly lower mean heart rate (P = 0.024) in Group D. The mean heart rates (HR) were maintained hemodynamically stable above 70/min in both the groups [Figure 4].

There was no significant difference in MAP in both the groups after pre-medication and the MAP was maintained hemodynamically stable above 75 mm of Hg throughout the perioperative period among the groups [Figure 5].

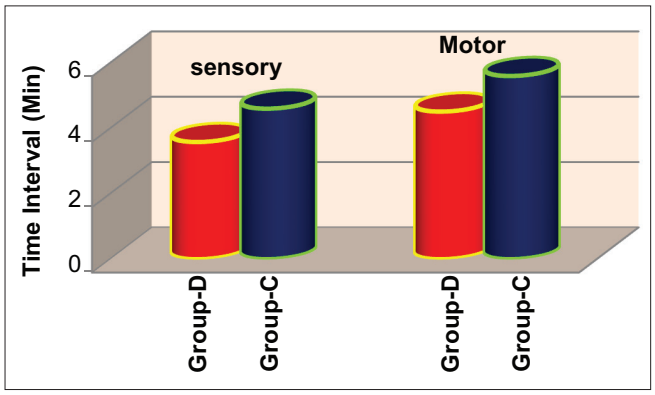

Figure 1: Onset of sensory and motor block

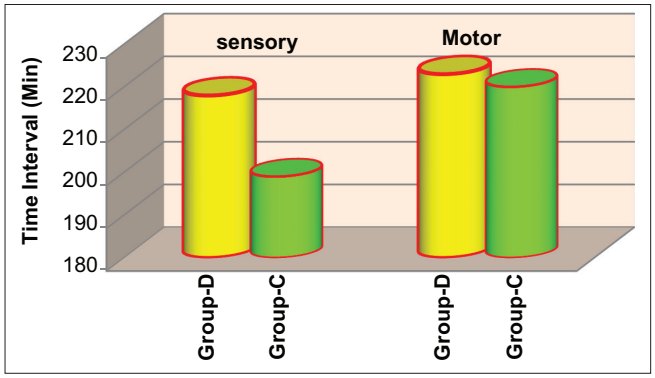

Figure 2: Time of sensory and motor recovery

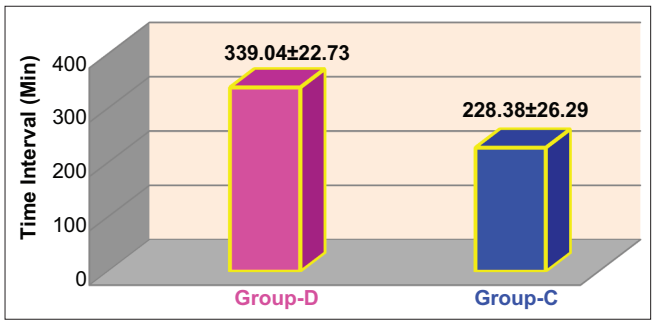

Figure 3: Time of first request of analgesic (min)

The mean sedation scores were higher in Group D than Group C (P = 0.003). In Group D, patients with sedation score >3 were 26 (65 %) and Group C was 12 (30 %) [Table 3].

There were no statistically significant side effects such as hypotension, bradycardia, nausea and vomiting, and respiratory depression, among the groups [Table 4].

DISCUSSION

Various adjuvants to local anesthetics have been tried in spinal anesthesia by intrathecal or by systemic routes to extend the duration and to improve the quality of spinal block and to produce post-operative analgesia and anxiolysis.

Alpha-2-adrenergic agonists such as dexmedetomidine and clonidine act by different mechanisms to produce analgesia, of which the central mechanism is attributed to their action at the spinal level where they act on laminae VII, VIII of the ventral horns of the spinal cord and action at the locus coeruleus and dorsal raphe nucleus is attributed to their action at the supraspinal level. They also act by peripheral mechanism and vasoconstricting effect on blood vessels.[17] These actions aid us to administer these drugs through various routes but produce similar effects irrespective of routes of administration.

The α2-adrenoreceptor agonists, namely, dexmedetomidine and clonidine as adjuvants to local anesthetics can be administered by epidural, intrathecal, caudal routes, and by peripheral nerve blocks. They have also been used as systemic adjuvants to local anesthetics and as premedicants by different routes to extend anesthesia and provide analgesia. There are studies about the use of intravenous dexmedetomidine and clonidine as systemic

Table 3: Ramsay sedation score

Score	Group D (n=40)	Group C (n=40)	P value
Sedation score (>3)	26 (65%)	12 (30%)	P=0.003*

Data expressed as mean (SD) or ratio or absolute numbers, *P<0.05 statistically significant

Table 4: Adverse events

Parameters	Data expressed as percentage or absolute numbers	
	Group D (n=40)	Group C (n=40)
Bradycardia	6 (15%)	4 (10%)
Hypotension	2 (5%)	2 (5%)
Nausea and Vomiting	1 (2.5%)	2 (5%)
Respiratory depression	0	0
Shivering	0	0

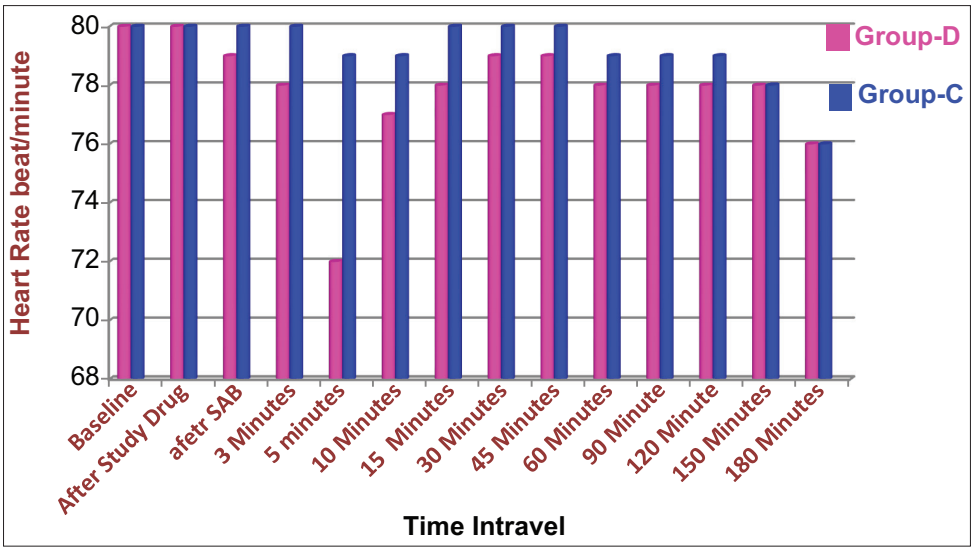

Figure 4: Comparison of heart rates

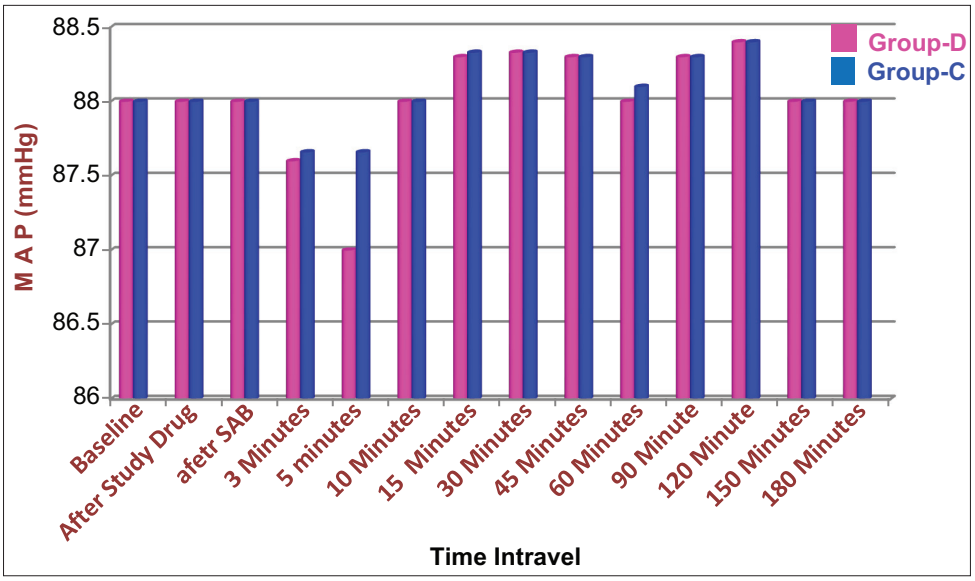

Figure 5: Comparison of mean arterial pressure (mmHg)

adjuvants for prolongation of spinal anesthesia. Rapid administration or infusion of these drugs might produce hypertension,[18] tachycardia, and bradycardia resulting in significant hemodynamic variability. To avoid these effects, we selected the intramuscular route for the administration of these drugs in our study.

In a study conducted by Aho *et al.*,[19] on the effect of intramuscular dexmedetomidine and clonidine on the attenuation of hemodynamic and stress response to gynecologic laparoscopy, the dose of IM clonidine used was 4.5 μg/kg^{-1} and doses of IM dexmedetomidine used were 0.6 μg/kg^{-1}, 1.2 μg/kg^{-1}, and 2.4 μg/kg^{-1}. The higher doses were associated with significant hypotension and bradycardia and the lower doses were found ineffective. That is why we have taken dexmedetomidine 1 μg/kg^{-1} and clonidine 2 μg/kg^{-1} by the intramuscular route in our study.

Scheinin *et al.*,[20] in their study on pharmacological actions of intramuscular dexmedetomidine concluded that dexmedetomidine takes 60–150 min for its maximum effect after IM injection and according to Singh *et al.*,[21] intramuscular clonidine takes 30–60 min for its maximum effect after injection. Furthermore, hyperbaric bupivacaine gets fixed to the neural structures of the spine 30 min after injection. Because of the above effects, the IM injections were given 30 min before giving spinal anesthesia in our study.

In our study, intramuscular dexmedetomidine versus clonidine prolonged the duration of bupivacaine spinal

anesthesia and analgesia. The time of the first request for rescue analgesia was significantly prolonged in the dexmedetomidine group compared to the clonidine group that could be explained by the highly selective nature of dexmedetomidine for α-2-adrenoreceptors particularly α_{2A} and α_{2C} when compared to clonidine. The results of our study correlated with the study of Reddy *et al.*,[22] except that we used the intramuscular route in our study instead of the intravenous route, and also the dosages used in our study are double the doses used in their study.

Our study demonstrated the earlier onset times of sensory and motor block and prolonged duration of sensory block. However, the duration of the motor blockade was not effected, might be explained by direct suppression of impulse conduction in the large, myelinated A-alpha fibers. Our results are similar to the study conducted by Kaya *et al.*,[23] where there is no effect on the duration of the motor block with a single dose of 0.5 $\mu g/kg^{-1}$ of dexmedetomidine.

Dexmedetomidine is a highly selective α_2 agonist with α_2:α_1 binding ratio of 1620:1 whereas clonidine has a binding ratio of 220:1.[24] This property of dexmedetomidine accounts for its sedative and analgesic properties compared to clonidine. In our study, there is effective sedation with a score >3 noted by Ramsay's Sedation Scale in the dexmedetomidine group as the patients remained cooperative and easily arousable exempting the need for intra-operative sedation. These findings correlate with the findings of the study of Ustun *et al.*[25]

Hemodynamic stability was maintained throughout. Less than 20% fall from baseline in heart rate and MAP was observed among the groups. There is no excessive sedation, respiratory depression, or shivering noted in our study.

CONCLUSION

We conclude from our present study that, a single dose of dexmedetomidine 1 $\mu g/kg^{-1}$ given by intramuscular route preceding spinal anesthesia resulted in the rapid onset of sensory and motor block, extended the time of sensory recovery with prolonged post-operative analgesia, provided satisfactory sedation levels, with stable cardiovascular parameters, and without any adverse effects making it an effective adjuvant and remarkable alternative to intramuscular clonidine 2 $\mu g/kg^{-1}$ for lower limb orthopedic surgeries under Bupivacaine spinal anesthesia.

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