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Case Report

Aggressive Recurrent Basal Cell Carcinoma: A Case Report

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Abstract

Basal cell carcinoma (BCC) was first described in 1824 by Jacob who called it "ulcus rodens": Its current nomenclature was proposed by Krompecher in 1903. It is the most common type of nonmelanoma skin cancer and the most common malignancy in humans. BCC is typically slow-growing tumor, for which metastases are rare, it can be locally destructive and disfiguring. The current mainstay of BCC treatment involves surgical modalities such as excision, electrodessication and currettage, cryosurgery, and Mohs' micrographic surgery. The rates of recurrence are variable in the literature, between 10% and 40 %.

Key words: Basal cell carcinoma, Recurrence, Ulcus rodens

INTRODUCTION

Basal cell carcinoma (BCC) or rodent ulcer is a malignant skin tumor that causes significant morbidity by its local invasion and destruction of normal tissue. Most commonly, BCC occurs on the lower eyelid, followed by the medial canthus, upper eyelid, and lateral canthus.[1] If BCC on the head and neck is allowed to grow that it may invade the central nervous system and may lead to serious complications, including death. Its clinical appearance is variable, and diagnosis requires a high level of suspicion and careful observation.

The treatment is primarily aimed at the removal of the BCC in its entirety. An orbital exenteration refers to the surgical removal of the globe from the orbit, involving the separation of all connections between the globe and the surrounding tissues (including transection of the optic nerve). Recommending enucleation is one of the most difficult therapeutic decisions in ophthalmology, as the surgeon takes into account the patient's psychological makeup, the visual potential of the eye, the patient's cosmetic concerns, and the potential for complications. It is a major operation which is usually customarily undertaken to remove a malignant tumor involving the eyelids or structures around or behind the eye, and if not done, so then metastatic spread may occur through local extension or through the bloodstream. This surgery is planned to perform when all other options of retaining vision are ruled out. Other two most common indications for enucleation are intraocular trauma and a blind and painful eye.[2,3] Favorable therapeutic outcomes not only depend on the characteristics of the BCC but also depend on timely diagnosis and treatment.

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CASE REPORT

A 65-year-old female presented with a history of ulcerated lesion on the left upper eyelid, which was excised in June 2017. The histological diagnosis was BCC. The patient had no significant medical and family history. Clinical examination revealed a mass arising from the upper eyelid and involving orbital soft tissues. Magnetic resonance imaging showed 4.4 cm × 3.4 cm × 2.7 cm mass lesions involving entire left orbital content with the erosion of supraorbital rim and abutting left frontal sinus with no intracranial extension. Inferiorly lesion is infiltrating skin and subcutaneous plan anterior to the left maxillary sinus. Similar lesion anterolateral left parotid gland measuring 14 mm × 12 mm with few enhancing left cervical nodes [Figure 1]. Histological examination revealed recurrent basosaquamous carcinoma

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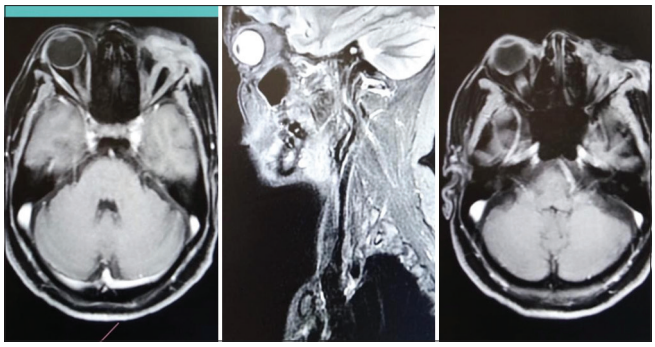

Figure 1: Magnetic resonance imaging revealed mass lesion involving entire left orbital content with no intracranial extension

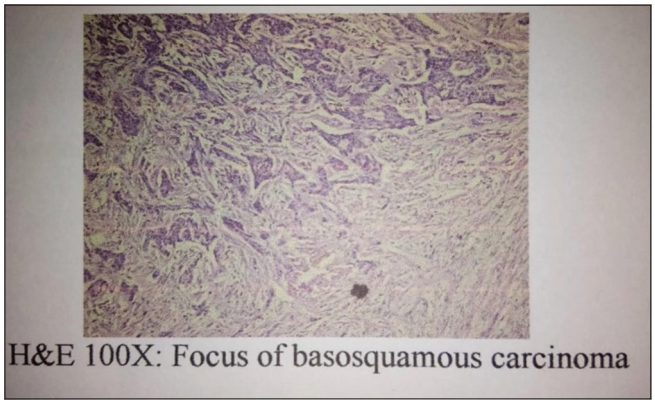

Figure 2: Microscopic examination revealed basosquamous carcinoma with small, uniform, and hypochromatic neoplastic cell with peripheral palisading noted with stromal collagen deposition, occasional basaloid cells have eosinophilic cytoplasm with variable keratinization. Keratin pearls noted. Foreign body giant cell reaction noted

Figure 3: Pre-operative basal cell carcinoma involving entire left orbit and post-operative picture of orbital exenteration and reconstruction with free anterolateral thigh flap

[Figure 2]. The plan was to do left orbital exenteration along with the excision of parotid node, followed by reconstruction with free anterolateral thigh flap [Figure 3].

DISCUSSION

BCC is the most common tumor affecting the eyelids and is responsible for considerable morbidity due to its locally invasive nature. BCC arises from the basal layer of the epidermis and accounts for 85–90% of lid malignancies, two-thirds of which are seen in the lower lid itself. Spread to surrounding skin is generally slow; failure to get appropriate treatment can lead to a considerable area of skin being destroyed.[4] A study done by Leibovitch *et al.*, in 2005, on invasive BCC found that the most common tumor site was the medial canthus, suggesting that medial canthus BCC possessed the highest risk of orbital invasion. Another study also showed the site incidence for BCC as the medial canthus (53.6%), followed by the lower eyelid (35.7%), the upper eyelid (7.1%), and the lateral canthus (3.6%), with a statistically significant difference between the disease sites.[5,6] In our present case, it was seen in the left upper eyelid which is not very common.

BCC is most commonly seen between 40 and 80 years of age, with a male preponderance.[7] Classically, the lesion of BCC appears as a slowly enlarging ulceration with raised and pearly border. Multiple clinical manifestations of this malignancy occur, which include nodular pigmented, morhpeaform or sclerosing cystic, superficial, basosquamous, and telebrating. The lesion may develop telangiectasia (a reddish hue caused by dilated capillaries).[8-11] In our present study, the lesion was basosquamous carcinoma with small, uniform, hyperchromatic, and basaloid cells.

The primary goal of treatment is the complete eradication of the BCC. The secondary goals are maintenance of lid function and cosmesis. The choice of treatment depends on a number of factors, including the size, location, and histologic type of BCC. The usual course of the disease is a gradual enlargement of the lesion with underlying tissue destruction necessitating treatment. Different modalities of treatment are cryotherapy, radiation therapy, chemotherapy, laser ablation, and electrodessication, but the most widely accepted choice is surgical excision.[10] The overall cure rate for BCC is between 95% and 100%. The recurrence rate ranges from 1% to 40%, depending on the type of treatment, size and histologic makeup, and location.[12,13]

While performing surgical excision, a wide safety margin is chosen around the clinically identified margins, as the true borders of the tumor, however, cannot be determined clinically. This "safety" margin reduces the probability of recurrence but with the side effect of larger wound, which requires more extensive reconstruction. A retrospective study done by Hamada *et al.* reported that there was zero recurrence of non-infiltrative BCC and 4.35% recurrence

with infiltrative BCC using a 4 mm margin.[14] Hsuan *et al.* reported an alternative approach using 2 mm margins and delayed repair for nodular BCC.[15] Luliano and associates in their study could achieve negative margins in only half (12 out of 24) of patients after orbital exenteration for periocular lesions.[16] In our present case, *en bloc* resection was done with clear margin and reconstructed with anterolateral thigh flap with microvascular anastomosis.

CONCLUSION

Basal cell carcinoma is most common non-melanoma skin cancer, which is locally aggressive and causes significant destruction by invasion in surrounding tissues. However it rarely metastasizes to distant tissues. Recurence rate varies from 10 % to 40 %. The mainstay of treatment of BCC is surgical excision.

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Case Report

Clinicoembryological Submission of Unusual Variation in Course and Branching Pattern of Lateral Cord of Brachial Plexus – A Case Report

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Abstract

Variations are commonly observed and being reported in the formation of lateral cord of brachial plexus and in the communication of branches of lateral cord of brachial plexus, but formation of median nerve by lateral root of median nerve from lateral cord and medial root of median nerve from medial cord at a substantially low level is quite unusual and the case reports regarding piercing of the coracobrachialis by lateral cord of brachial plexus are infrequent. The present case report describes an unusual unilateral course of lateral cord piercing the coracobrachialis and ensuing path followed by its various branches as well as unusually low-level formation of median nerve from lateral and medial roots coming from the lateral and medial cord of brachial plexus, respectively. This was witnessed in the infraclavicular part of the brachial plexus during the routine gross anatomy dissection of the left upper extremity in a 35-year-old Indian male cadaver. Since axilla and upper half of the arm are challenging areas for surgical procedures, so the unusual variations being reported in this case may help the surgeons of different specialties in exploration of neuronal tumor, shoulder reconstructive surgery shoulder arthroscopy, and using the coracobrachialis flap for different surgical purposes.

Key words: Brachial plexus, Coracobrachialis, Lateral cord, Low median nerve

INTRODUCTION

The brachial plexus is formed by the ventral primary rami of spinal nerves from C5 to T1. Invariably, the plexus may receive fibers from the ventral rami of C4 and T2 and is termed accordingly as prefixed or post-fixed, respectively. These rami unite, divide, and reunite to form lateral, medial, and posterior cord of brachial plexus. Eventually, these cords and their branches appear in the axilla around the axillary artery[1] lateral being lateral, medial being medial, and posterior being posterior to axillary artery in relation to pectoralis minor.

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Variations of the lateral cord of the brachial plexus with regard to composition of fiber bundle and absence or communication between its branches are common and have been reported by numerous authors.[1-7] The fibers from the median nerve may convoy the musculocutaneous as it transits that the coracobrachialis muscle is also being reported by various researchers such as Kaus and Wotowicz, 1995,[8] Williams *et al*., 1995,[9] Venieratos and Anagnostopoulou, 1998,[10] and Sevki *et al*., 2001,[11] but it is very rare to see coracobrachialis being pierced by lateral cord before its division into musculocutaneous and the lateral root of median nerve.[12,13]

In normal course as mentioned in the textbooks, the lateral cord gives its initial branch the lateral pectoral nerve to the pectoralis major muscle and then splits into musculocutaneous and lateral root of median nerve. The musculocutaneous nerve pierces the coracobrachialis and passes obliquely to the lateral side of the arm between

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the biceps brachii and brachialis muscle, supplying their musculature as well. Later, it pierces the deep fascia above elbow, lateral to the tendon of biceps brachii and then endures as the lateral cutaneous nerve of the forearm. Median nerve is formed anterior or anterolateral to axillary artery by the union of its two roots. The lateral root to the median nerve is the largest branch of the lateral cord of the brachial plexus while the median root arises from the medial cord of brachial plexus and crosses in front of axillary artery to join the lateral root. After union of both roots the median nerve, it descends anterior to the axillary artery and in the upper part of brachial artery to reach the medial aspect of brachial artery in the distal half of the arm.[9]

These anomalies must be kept in mind while performing surgical procedures either in trauma or any other pathological condition to avoid damage to these vital nerves.

CASE REPORT

During the routine dissection class on brachial plexus in the Department of Anatomy, All India Institute of Medical Sciences, Rishikesh, a 35-year-old Indian male cadaver, in the infraclavicular part of the brachial plexus on the left upper limb, we noticed that the lateral cord has pierced coracobrachialis muscles from its medial side. The first branch of the lateral cord, the lateral pectoral nerve was arising normally just below the outer border of first rib. It passed anterior to axillary artery and vein and supplied the deep surface of pectoralis major muscle. Then, the lateral cord comes to lie between the lateral border of coracobrachialis and medial border of biceps brachii. It then divides into lateral root of median nerve medially and musculocutaneous nerve laterally. The lateral root of median nerve was observed crossing from the lateral border of coracobrachialis downward, forward, and medially over the anterior surface of coracobrachialis to join its medial counterpart to form the median nerve approximately at the level of insertion of this muscle anterior to the brachial artery. In the normal course, the median nerve is formed in relation to the third part of axillary artery.

The other division the musculocutaneous nerve was seen passing between the two heads of biceps brachii and dividing into two branches, the upper one terminating in biceps brachii itself and the lower one was supplying the brachialis and thereafter continued as the lateral cutaneous nerve of forearm.

On exploring course of the lateral cord within the coracobrachialis muscles, it was observed to split into musculocutaneous and lateral root of median nerve. The branch to the coracobrachialis was seen to be arising from musculocutaneous nerve. The lateral root of median nerve did not give any branch within the muscle and no communication was observed between musculocutaneous and lateral root of median nerve within the coracobrachialis muscle or in the later part of their course and thereafter it followed the normal course till the hand as per the description given in the textbooks. The right upper limb of the cadaver did not show any such variation of lateral cord and was absolutely normal in relation, formation, and branching pattern of brachial plexus. No other arterial or muscular variations were observed in either of the limb.

DISCUSSION

Coracobrachialis is flexor of the arm and this muscle is vulnerable to the injury from the retractors placed beneath coracoid process during shoulder reconstructive surgery. In the recurrent dislocation of shoulder and shoulder arthroscopies, the operative management by coracoid graft transfers could be the source of the lesions to the structures piercing the muscle.[14,15] Coracobrachialis has been suggested for possible use as flap for coverage in infraclavicular defects of exposed axillary vessels, especially in post-mastectomy reconstructive surgery.[16]

The interpretation of atypical course of lateral cord requires consideration of the development and innervation of upper limb musculature. Muscles of the limbs are derived from somatic precursor muscle cells from the ventrolateral edges of the somites opposite the developing limbs, which lie lateral to the neural tube and cause bulge in the overlying ectoderm. Somites have a specific effect on the position of the developing spinal nerves, which preferentially grow through the cranial half of the sclerotome. Spinal nerves are derived from two sources, motor nerve from the neural tube and the sensory nerves from the neural crest.[9] The nerve cords from the spinal nerves that correspond to the early extent of limb buds grow distally to establish an intimate contact with the differentiating mesodermal condensations into intermuscular spaces and end in a premuscle mass. Sannes *et al.* in 2000[17] suggested that the developing axons is regulated by expression of chemoattractants and chemorepulsants in an extremely coordinated and site-specific fashion. Any alterations in signaling between mesenchymal cells and neural growth cones can lead to significant variations and probably in this case the alteration in signaling caused the lateral cord to pass through the coracobrachialis muscle. Once

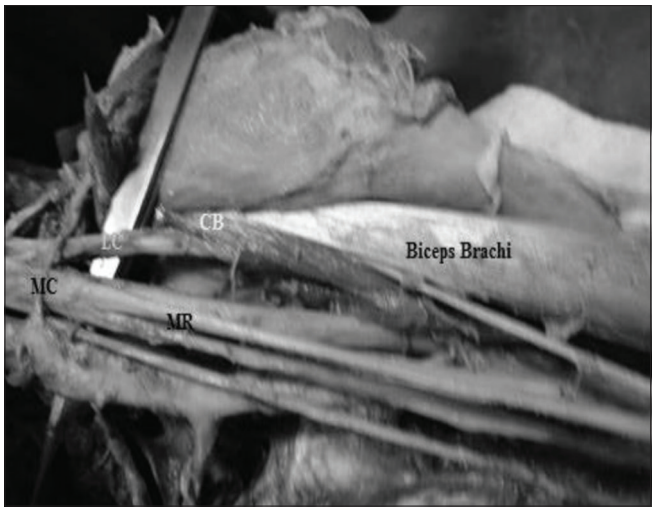

Figure 1: Left upper limb showing – MC – Medial cord, MR – Medial root of median nerve, LC – Lateral cord, CB – Coracobrachialis

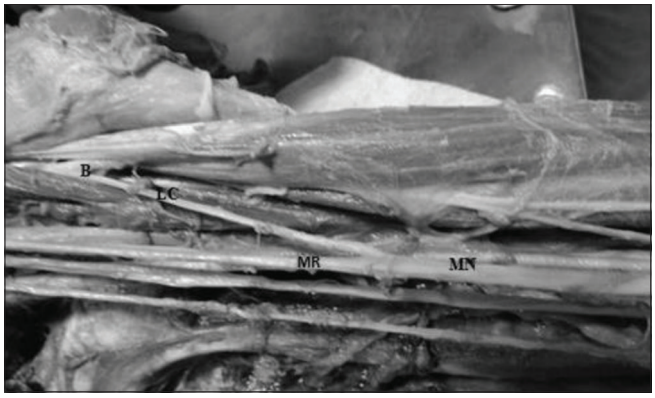

Figure 2: Left upper limb showing – MN – Median nerve, MR – Medial root of median nerve, LC – Lateral cord, B – brachialis

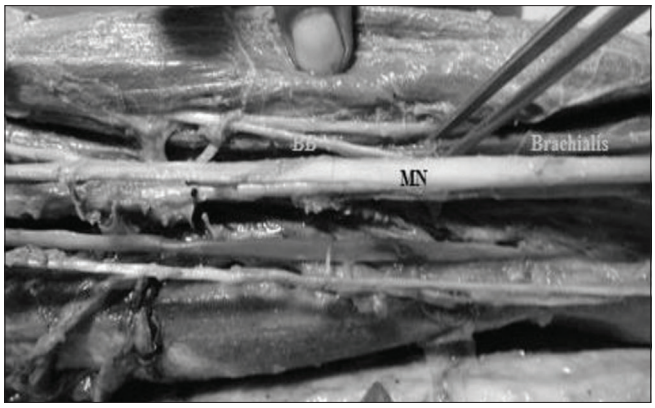

Figure 3: Left upper limb showing – MN – Median nerve, BB – Biceps brachii

formed any developmental differences would persist postnatally.[18,19]

In this case study, the site of the formation of median nerve is much lower as compared to the usual site of median nerve formation. Usually, the two roots (medial and lateral) are joining around the third part of axillary artery to form the median nerve.[20] In our case, the two roots are coming as low as the insertion of coracobrachialis and then they are joining in front of brachial artery instead of axillary artery to form the median nerve. This may be due to the lower divisions and branches of the lateral cord. This will give rise to the varied presentation in high and low median nerve lesions than in the normal case.

CONCLUSION

The knowledge of course and distribution of the lateral cord of the brachial plexus as well as the low formation of the median nerve are important during exploration of neuronal tumor, shoulder arthroscopy, shoulder reconstructive surgery, and using the coracobrachialis flap for different surgical purposes.

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Case Report

A Rare Case of VACTERL Association

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Abstract

Klippel-Feil syndrome (KFS) is a rare skeletal disorder primarily characterized by abnormal union or fusion of two or more cervical vertebrae. It also includes multiple system anomalies. Herewith, we report a case of 22 years old male who presented with multiple skeletal anomalies. On subsequent radiological investigations, patient was diagnosed to have Klippel-Feil syndrome with type IV club hand.

Key words: Cervical vertebra fusion, Club hand, Klippel-Feil syndrome

INTRODUCTION

Klippel-Feil Syndrome was originally described in 1912 by doctors Maurice Klippel and Andre Feil from France.[1,2] They described patients who had a short and webbed neck; decreased range of motion (ROM) in the cervical spine. These patients had a low hairline. Reports estimate that the condition occurs in approximately 1 in 40,000-42,000 live births and it affects females more frequently than males.[2]

Aim

This study aims to present a rare case report on VACTERL association with orthopedic manifestation.

CASE REPORT

A 22-year-old male patient presented with deformity of both hand and forearm since birth and swelling over the left knee for the past 1 week

H/O pain – insidious in onset, pricking in nature, intermittent, radiating to left leg, aggravated on doing work, relieved at rest

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H/O fever – low grade, no chills and rigors, no evening rise of temperature

No H/O loss of weight and appetite

He was the second child born to parents of Grade IV consanguinity

Natal history: Full term, forceps delivery, H/O delayed milestones, vaccinated up to date.

Past history: H/O bleeding per rectum on and off for past 5years and was diagnosed to havehemorrhoids and under irregular treatment.No H/O Diabetes,systemic hypertension bronchial asthma.

Prenatal history: He was the second child born to parents of Grade IV consanguinity.Mother conceived spontaneously, H/O drug consumption to terminate pregnancy by 3rd month of pregnancy.No H/O fever, diabetes mellitus, systemic hypertension during the course of pregnancy.

Personal history: He takes a mixed diet. Sleep is adequate. He is not a smoker and not an alcoholic.

Family history: Siblings and other family members do not have any congenital deformities.

Treatment History: Patient never had any treatment for the congenital deformity of the hand and forehand.

General Physical Examination: He is consious, cooperative, well oriented to time,place and person.

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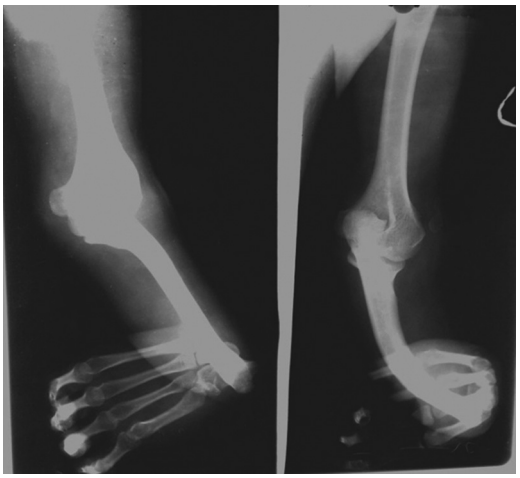
Not pale, not icteric, not cyanosed, no clubbing, no edema, no significant lymphadenopathy, no neuro-cutaneous markers.

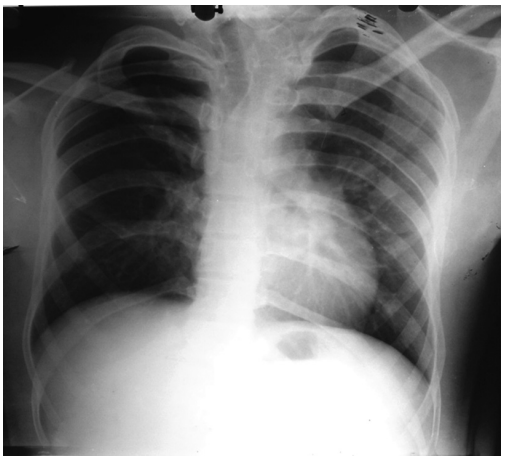
On Examination

Vitals: Stable

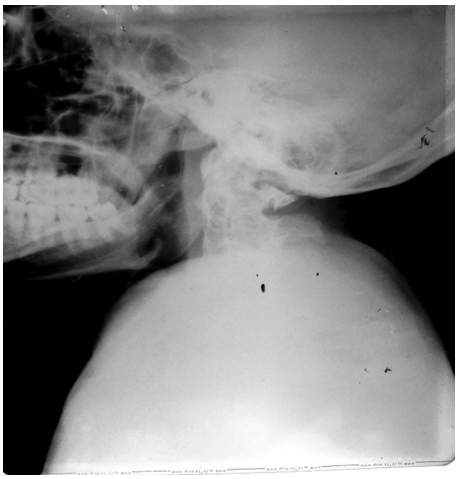
a. Radiograph right forearm with hand – AP and lateral view: Complete absence of radius with malrotated and superior angulated wrist with complete absence of thumb; fusion of the 2nd and 3rd MC and phalanx on the right hand with thinned out 2nd MC – Type IV club or mitten hand



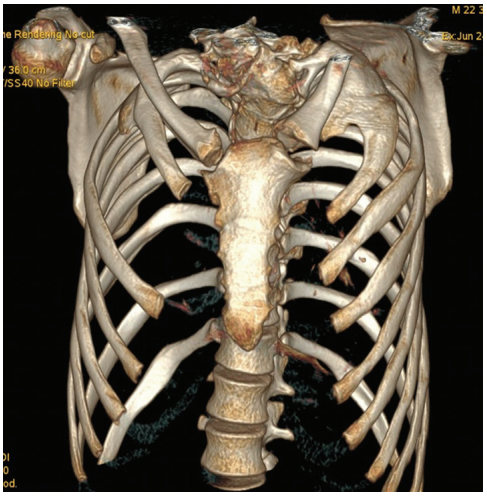
b. Radiograph left forearm with hand – AP and lateral view: Complete absence of radius with malrotated and superior angulated wrist with complete absence of thumb – Type IV club hand



c. Frontal chest radiograph – mild scoliosis of upper vertebra, widening of right intercostal space; left scapula higher in position when compared to right; bilateral 1st and 2nd ribs fused



d. Radiograph of cervical spine – lateral shows multiple cervical vertebra fusion with straightening of cervical spine with loss of cervical lordosis and short neck



e. 3D volume rendered image shows elevated left scapula – Sprengel deformity

f. 3D volume rendered image: Fusion of left 1st and 2nd ribs.

Other Investigations

- Blood investigations CRP – positive, rheumatoid factor – negative. Other blood reports under normal limits
- CT thorax – no significant abnormalities
- USG abdomen and pelvis – left pelvis ectopic kidney (left kidney is not visualized in the lumbar region and seen in the left hemipelvis posterior to the bladder assuring 9.8 × 3.9 cm)
- ECHO cardiogram: Mild MR and mild AR.

Management

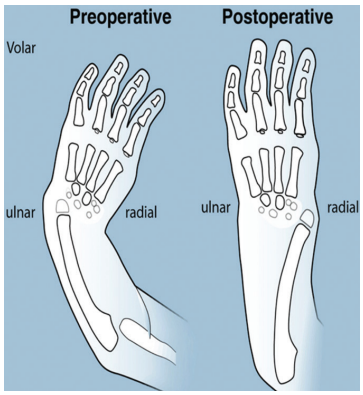
- Non-operative
  - Infants – splints are difficult to apply
  - Wrist and elbow physiotherapy
  - Serial casts to stretch tight structure.

- Operative
  - Centralization

  Indications:
  - Good elbow motion and biceps function
  - 6–12 months baby
  - Capable of tendon transfer.

- Radialization
  - Conversion of ulna into radius
  - Hand and carpal bones are translocated to ulnar side
  - Tendon repair
  - Low recurrence.

As our patient was adapted towards his various deformities and was symptom free, he was well managed conservatively.



Syndromic Association

HOLT ORAM (chromosome 12)	Thrombocytopenia – absent radius syndrome
Klippel–Feil syndrome	Fanconi anemia
VACTERL	
V – Vertebral defects	
A – Anal atresia	
C – Cardiac abnormalities	
T – Tracheoesophageal fistula	
E – Esophageal atresia	
R – Renal defects	
L – Limb anomalies	

CONCLUSION

- A high degree of suspicion and knowledge of various combinations of congenital anomalies must

be in kept in mind, in diagnosing of such complex cases

- These are rare congenital anomalies, which need team management
- Parental counseling also forms an integral part of this management.

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Case Report

A Rare Case of Oguchi Disease

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Abstract

Oguchi disease is a rare autosomal recessive disorder and the patients present with congenital stationary night blindness with slow dark adaptation. Two causative genes have been reported till date. The fundus shows typical golden sheen pattern which disappears when they remain in a darkened environment for few hours. We report a case of young girl who presented with non-progressive night blindness for 10 years and on examination typical fundus finding of Oguchi disease was revealed. The typical golden sheen fundus disappeared after 3 h of dark adaptation. This case is reported for its rarity as only <50 cases have been reported till date.

Key words: Dark adaptation, Mizuo-Nakamura, Oguchi

INTRODUCTION

Oguchi is an autosomal recessive disease characterized by congenital stationary night blindness and Mizuo-Nakamura phenomenon in which the fundus has a typical golden sheen pattern. It is a very rare condition and only 50 cases have been described in the literature till date.

CASE HISTORY

A 20-years-female presented to our OPD with complaints of defective night vision since 10 yrs. The patient was normal 10 years ago after which she noticed defective night vision which has not progressed since then. Day time vision is normal. There was no history of trauma, headache, field defects or any other significant positive complaints. No similar complaints in the family. She is single child to her parents. There was no history of consanguineous marriage.

On examination, anterior segment was normal in both the eyes. Vision in both eyes was 6/6 for distance and N6 for near vision. Color vision was normal. Fundus examination revealed normal optic disc and vessels with diffuse golden-yellow metallic sheen in the background retina [Figure 1a, 2a, 3a]. Oguchi was suspected and the patient was subjected to dark adaptation.

After prolonged dark adaptation of 3 h, the golden sheen disappeared with appearance of a normal reddish background retina [Figure 1b, 2b, 3b]. Field study was normal. Confirmation of Oguchi disease was made by electroretinogram (ERG) which showed absent A and b waves under light and increased wave in dark. The patient was explained about the condition and its prognosis. The patient was advised for regular follow-up.

DISCUSSION

Oguchi disease was first described by a Japanese Ophthalmologist Chuta Oguchi in the year 1907. Its characteristic fundus appearance was then described in the year 1913 by Mizuo. Oguchi disease is a rare autosomal recessive disorder which presents as non-progressive night blindness since childhood or birth with normal day vision. The typical fundus appearance is a diffuse or patchy, silver-gray, or golden-yellow metallic sheen with retinal vessels standing out in relief against the background. On prolonged exposure to dark adaptation for 3 h or more the unusual discoloration disappears with appearance of normal looking retina. This phenomenon is known as the Mizuo-Nakamura phenomena which is thought to be caused by the overstimulation of rod cells.[1]

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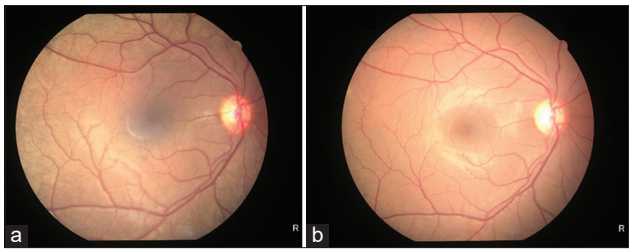

Figure 1: (a and b) Right eye fundus appearance before and after dark adaptation

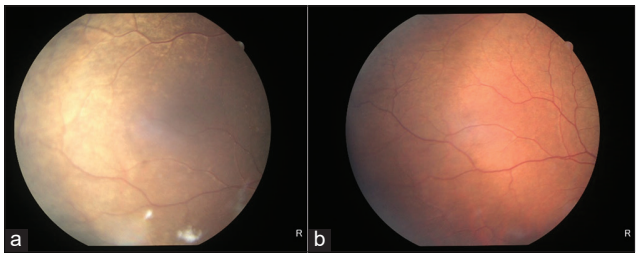

Figure 2: (a and b) Right eye fundus appearance before and after dark adaptation

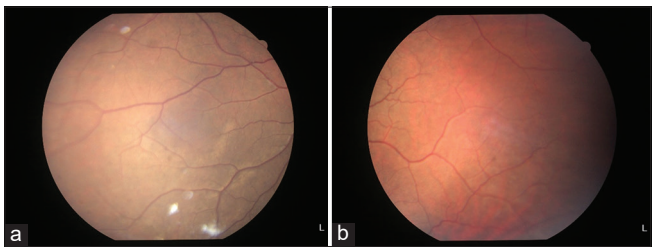

Figure 3: (a and b) Left eye fundus appearance before and after dark adaptation

Mutations in arrestin gene located on chromosome 2q37 or the rhodopsin kinase gene located on the chromosome 13q34 is found to be responsible for this disease. Rhodopsin kinase along with arrestin shuts off rhodopsin after it has been activated by a photon of light.

Yamamoto *et al.*[2] found that few cases of Oguchi are caused by defects in the GRK1 gene.

In ERG, the A- and b-waves on single flash are decreased or absent under lighted conditions and increased after prolonged dark adaptation. The b waves are nearly undetectable in the scotopic 0.01 ERG and nearly negative scotopic 3.0 ERGs.

Dark-adaptation studies have shown that rod thresholds are highly elevated decrease several hours later which results in recovery to the normal or nearly normal level.

Maw *et al.*[3] reported two Indian brothers with night blindness at an early age. 28-year-old brother presented with light-dependent golden fundus discoloration with 30-Hz flicker ERG responses. Under scotopic conditions, a white flash elicited a negative wave, whereas the response to a blue flash was extinguished. His 18-year-old brother had similar findings in his right eye. His fundus showed macular degeneration, mottled retinal pigment epithelium in the posterior pole and midperiphery, vitreous floaters, pale disk, and sheathed, attenuated vessels.

There is no specific treatment for the disease. Oguchi can lead to visual field defects at later stage. The patient should be on regular follow-up.

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Case Report

Obstructive Hydrocephalus Produced by Venous Ectasia of Dural AV Fistula

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Abstract

Dural arteriovenous fistula (Dural AVF) is an anomalous shunt between dural arterial and venous channels. About 10–15% of all intracranial vascular malformation are dural fistulas which represent anomalous shunts among arterial branches and dural venous sinuses, meningeal, or cortical veins. We are presenting a rare case of dural AVF treated by transarterial embolization and complicated by hydrocephalus.

Key words: Dural arteriovenous fistula, Hydrocephalus, Transarterial embolization

INTRODUCTION

A dural arteriovenous fistula is an abnormal direct connection between a meningeal artery, meningeal vein, or dural venous sinus. Dural AVF is approximately 10–15% of all cerebral vascular malformation which represent anomalous shunts among arterial branches and dural venous sinuses, meningeal or cortical veins.[1-4]

The common predisposing factor for dural AVF appears to be venous sinus thrombosis which causes the development of venous hypertension, lead to opening up of the microvascular connection within the dura. These channels become hypertrophied and result in direct shunting between arteries and veins.

CASE REPORT

A 52-year-old male admitted with chief complaints of headache, weakness of the left half of body, and slurring of speech. Computed tomography (CT) brain was suggestive of small to moderate size, enhancing vascular structure seen at ambient cistern on the right side [Figure 1].

Magnetic resonance imaging brain revealed a large lobulated lesion in the right side of midbrain extending into ambient cistern showing vascular flow voids [Figure 2].

On the day of the intervention, the patient had a Glasgow Coma Score of 15. Cerebral digital subtraction angiography (DSA) was done through the right femoral artery which showed dural AVF at the junction of the right transverse and sigmoid sinus. Arterial supply of dural AVF is from the right middle meningeal, right ascending pharyngeal artery, and right tentorial artery [Figure 3]. There was marked venous ectasia with cortical venous reflex (Cognard Type IIb). After 3 days, transarterial embolization was done with glue (NBCA) mixed with lipiodol. At the end of the intervention, the patient was awake, and no new neurological deficit was noted. CT angiography brain was performed, which showed a complete resolution of fistula. The patient was discharged with no neurological deficit.

After 1 month of embolization, the patient was again admitted with complaints of irrelevant talking, ataxia, and slurring of speech. The plain CT brain showed dilatation of bilateral lateral ventricles and third ventricles [Figure 4]. The right ventriculoperitoneal shunting was done and the patient was shifted to the intensive care unit. The patient improved neurologically and he was discharged [Figure 5].

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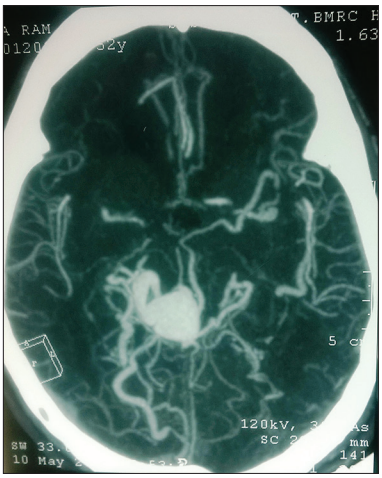

Figure 1: Computed tomography pre-surgrey showed enhancing vascular structure seen at ambient cistern on the right side

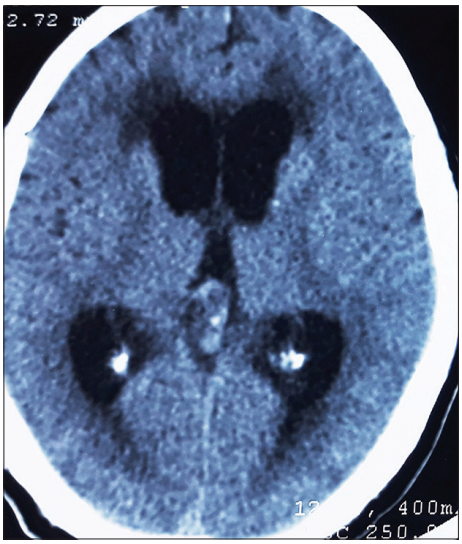

Figure 4: Post-embolization (1 month later) and non-contrast computed tomography brain show dilated ventricles

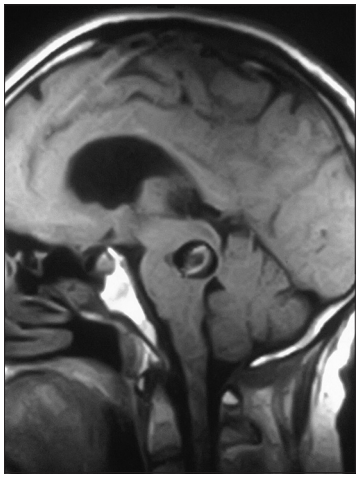

Figure 2: T1 sagittal show predominant hypointense lesion with laminated hyperintensities within due to flow signal

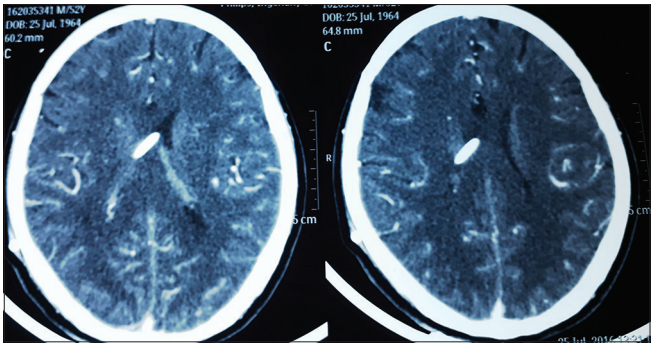

Figure 5: Contrast-enhanced computed tomography after shunt surgery, ventricles has returned to normal size

Figure 3: During pre-embolization digital subtraction angiography, RECA injection shows dural arteriovenous fistula filling through middle meningeal artery and ascending pharyngeal artery with marked venous ectasia

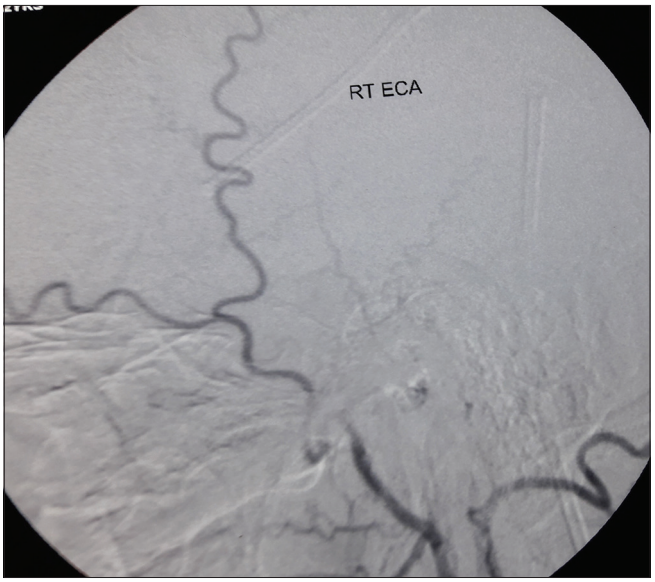

Figure 6: During post-embolization digital substraction angiography, the right external carotid artery injection shows no filling of dural arteriovenous fistula

After 6 months of embolization, the patient admitted for follow-up DSA. DSA showed no filling of AVF [Figure 6].

DISCUSSION

Hydrocephalus after the treatment of dural AVF is rare. No case of hydrocephalus after treatment of dural AVF by glue has been reported. Several reports have described the detection of hydrocephalus after coiling with hydrogel coil.[5-8]

Ozaki *et al.* reported two cases of delayed hydrocephalus after embolization of unruptured aneurysm using bare platinum coils. Chaves *et al.* reported a case of intraventricular hemorrhage after dural fistula embolization. Maimon *et al.* described morbidity of 6% (1/17 patients) related to a transient trochlear nerve palsy and in a retrospective study by Rangel-Castilla *et al.*, a complication rate of 9.7% (7 of 72 patients) was described, of which the only one corresponded to intraparenchymal hemorrhage.[9,10]

Dural embolization with ONYX (a non-adhesive embolic agent composed by ethylene vinyl alcohol dissolved in dimethyl sulfoxide) has grown to become one of the major approaches to dural AVF, which is linked to its remarkable cure rates and low morbidity. In fact, there are few complications noted after this technique.

After a systematic review of the international literature using the PubMed database, we were not able to find any article describing the occurrence of obstructive hydrocephalus after dural AVF embolization, which corroborate the relevance of this case report.

The phenomena behind the development of hydrocephalus remain unclear. Different hypotheses have been proposed to relate the phenomena and materials used for embolization. With bare platinum coils, mechanical obstruction of the CSF pathway due to the expansion of the embolized coil mass can be the cause of post-embolization hydrocephalus. Another theory of the obstructive hydrocephalus was due to IVH which was related to iatrogenic injury to a microperforator while retrieving the microcatheter used for arterial cannulation. Obstructive hydrocephalus, in this case, seems to be due to compression of aqueduct by venous ectasia of dural AVF.

In summary, we report a case of unusually delayed hydrocephalus after treatment of dural AVF with glue which has not been reported until now.

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Case Report

Cervical Vagal Schwannoma: A Diagnostic and Surgical Challenge

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Abstract

Cervical vagal schwannoma is a rare tumor. It presents a great difficulty in diagnosis and surgical treatment. We are presenting a case of 30-year-old female patient referred to us with the left side neck swelling. We investigated the patient and we faced difficulty in diagnosis. We carefully planned the surgical excision of the left side cervical schwannoma and successfully excised the tumor.

Key words: Cervical vagal schwanomma, Neurofibromatosis, Surgical excision

INTRODUCTION

Schwannoma and neurofibroma are the two common benign tumors of peripheral nerves. Neurofibromas are more frequently reported than schwannomas. Schwannoma is a rare benign tumor in the head and neck region which arises from Schwann cells.[1,2] Except olfactory and optic nerve, all cranial nerves, autonomous nerves, and spinal nerves are covered with Schwann cells. This raises the propensity of schwannomas to arise from these nerves.[3] As the latter are slow-growing tumors which present with rare symptoms, so their diagnosis becomes difficult. The main treatment option for a schwannoma is surgical excision. As each case can present differently, so surgical planning varies accordingly. We, hereby, present a unique case of the left-sided cervical vagal schwannoma which offered us a challenging diagnostic and surgical experience.

CASE REPORT

A 30-year-old female patient with a family history of neurofibromatosis presented with a painless left-sided swelling in the lower neck for 3 months. On examination, a 4 × 4 cm swelling was present on the left side of the neck medial to the sternocleidomastoid muscle (SCM). It was seen extending from the level of the cricoid cartilage to the medial end of the left clavicle. The swelling showed no movement on deglutition but was freely mobile in the vertical and horizontal direction. There was no restriction in the neck movements. Laryngeal examination appeared normal with normal bilateral vocal cord mobility. The patient was advised ultrasonography (USG) of the neck with fine-needle aspiration biopsy (FNAB) from the neck mass. USG neck revealed a 5x6 cm well-defined mass in the left parapharyngeal space. Repeated FNAB results were inconclusive. The patient was, therefore, advised contrast-enhanced computed tomography (CECT) scan. CECT scan showed a well-defined mass with peripheral vascularity in the left parapharyngeal space. The tumor mass was located between the common carotid artery (CCA) and internal jugular vein (IJV). It was seen separating both the vital vessels with an impression of compression or involvement of IJV which was visible on the CT scan [Figure 1].

Differential diagnoses of vagal nerve tumor, branchial cyst, and metastatic lymph node were made. Vagal schwannoma was the most preferred diagnosis relying on two the two key factors, a positive family history of neurofibromatosis and the other being a mass separating CCA from IJV. Excision biopsy was planned. Under general anesthesia a horizontal incision was made on the left side of the neck. The subplatysmal flap was elevated. SCM was mobilized and reflected over the mass. Yellowish-white mass was present compressing the IJV and arising from the vagus nerve [Figure 2]. Our concern was to preserve left IJV and vagus. The surgical mass was mobilized and removed by

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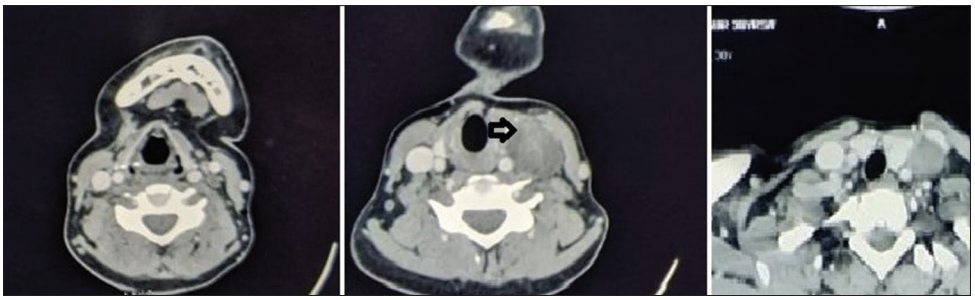

Figure 1: Contrast-enhanced computed tomography showing well-defined mass with peripheral vascularity in the left parapharyngeal space separating common carotid artery and internal jugular vein (IJV) with an impression of compression or involvement of IJV

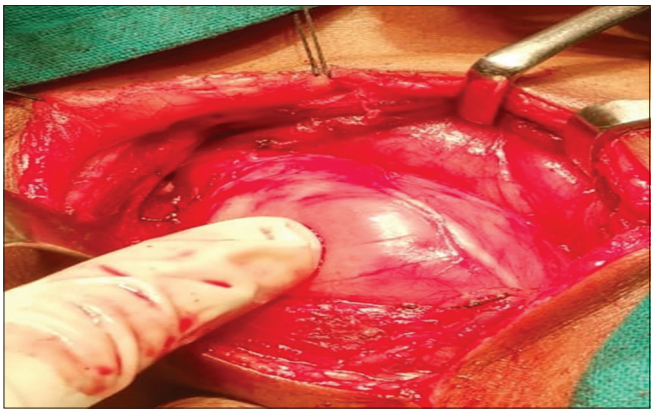

Figure 2: Intraoperative photograph showing smooth yellowish-white mass with vagus nerve

preserving the vagus nerve, but we ligated IJV for better access to the mass. She developed the left vocal cord palsy which recovered eventually 3 months postoperatively. Histopathology report of the excised mass revealed left-sided schwannoma.

DISCUSSION

Schwannoma is a slow-growing benign tumor of peripheral nerves. Its occurrence is rare, though literature reports the head and neck region being its most preferred site. The lateral neck is the most usual site of schwannomas. These are frequently asymptomatic in the presentation. Few tumors present as slow-growing lumps in neck which usually go unnoticed by most patients. Occasionally, these cervical vagal schwannomas present with hoarseness of voice, paroxysmal cough during manipulation of mass, and Horner's syndrome.[4] Cervical schwannomas are freely mobile in both vertical and horizontal directions. The above features renders difficulty in the diagnosis of cervical schwannomas. The preferred investigations are USG of the neck, CECT scan, magnetic resonance imaging (MRI), and USG-guided FNAB and fine-needle aspiration cytology (FNAC). USG of schwannomas frequently illustrates well defined hypoechoic, homogenous mass with peripheral acoustic enhancement, and eccentric nerve trunk to mass.[2] USG-guided FNAB and FNAC are inconclusive in a wide number of cases which make their diagnosis even more difficult. CECT of vagal schwannoma shows a well-defined mass with peripheral enhancement in the parapharyngeal space. The most suggestive feature on a CT scan is the divergence of CCA from IJV by the tumor mass. In our case, CECT showed a well-defined mass that was separating CCA from IJV. The IJV seemed to be compressed or involved by the mass on CT scan which raised our suspicion of the occurrence of a metastatic lymph node or lymphoma. MRI of vagal schwannoma is also carried out in a few cases. MRI findings usually reveal a well-defined mass with the divergence of CCA and IJV.[1,2]

Treatment for vagal schwannoma is mostly surgical excision of the tumor. Excision can be done by extracapsular dissection or intracapsular method. The latter is the preferred technique as it attempts to save the nerve trunk from which the tumor arises.[3] Since vagal schwannomas can have varied clinical presentations, so the surgical scenarios vary accordingly and the treatment plan is case-customized. In our case, the tumor was seen compressing the IJV. Hence, we planned the ligation of IJV for an improved surgical exposure and to save the vagal main trunk. Histopathology of schwannoma shows spindle cells in Antoni A cell and Antoni B arrangement with interspersed verocay bodies.[1]

CONCLUSION

Cervical vagal schwannomas present with a diagnostic and surgical challenge. Each case can be distinctive. Consequently, the surgery is customized depending on the tumor size and the status of major vessels in relation to the tumor.

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Case Report

Management of Mandibular First Molar with Middle Mesial Canal: Two Case Report

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Abstract

Introduction: The outcome and long-term prognosis of the successful root canal therapy rely on the awareness and thorough understanding of variations in morphology that may exist in the root canals. The aim of the present study is to report a case of management of two mandibular first molar with the middle mesial canal.

Case Report: A 34-year-old male reported with pain for 3 months. He was diagnosed with irreversible pulpitis. The root canal treatment was initiated. The presence of an extra canal, which is not so common finding was found during the treatment. The treatment plan was modified accordingly and root canal was completed.

Discussion: The extra canal has been reviewed and discussed.

Conclusion: This mid-mesial canal can be visualized after obtaining access to the pulp chamber and removing hindrance covering the canal orifice with either burs or ultrasonic tips.

Key words: Extra canal, Mandibular molars, Mid Mesial Canal, Middle mesial canal

INTRODUCTION

The purpose of the root canal procedure aims at thorough cleaning and shaping of the canals and subsequently sealing the canal space so as to eliminate the pathology and prevent infection. Normal root canal anatomy is an exception rather than a rule and a wide variety of variations exist in the root canal system.[1] The outcome and long-term prognosis of the successful root canal therapy rely on the awareness and thorough understanding of variations in morphology that may exist in the root canals. Among the major obvious reasons for the failure of endodontic treatment is missed extra root with its root canal.[2] Every teeth in the dental arch may have extra root or a root canal, with more chance of variation existing in the posterior tooth.[3] Mandibular first molar being the most primitive tooth that erupts in the dentition and thus a the majority of times required endodontic intervention.[1] The variations in canals are far more common, and tooth with a simple root canal system is barely seen now. The variations seen in mandibular molars are – the third canal in the middle root on the mesial side, called as middle mesial (MM) canal, first mentioned by Vertucci, additional DL root c/a radix entomolaris and mesiobuccal (MB) root c/a paramolaris, C-shaped canals, a "ribbon-shaped communication" existing in the MB canal, and mesiolingual (ML) canal called as the isthmus.[4,5] The initial literature for the existence of extra and independent canal in the lower molar tooth was reported by Barker *et al.* and Vertucci and Williams. Canal was present in mesial root beneath the developmental groove joining the buccal and lingual canal on the mesial side.[6] Later, Martínez-Berná and Badanelli showed a middle canal along the distal root also.[7] Since then, several researchers have reported this type of configuration of the canal in lower molars. Middle canal is also referred by other names such as "Intermediate canal,

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mesiocentral canal, third mesial canal, accessory mesial canal, and middle mesial canal (MMC)."[8] Fabra-Campos (1985) in his study, out of 145 extracted human lower first molars, observed that "teeth with five canals had an incidence rate of 2.75%."[5] Martinez-Berna and Badanelli (1983) studied permanent mandibular molars and found out of 2362 molars, 1.5% teeth were with five root canals.[7] Jacobsen *et al.* (1994) stated that 12% of lower first molars had three canals on the mesial side.[9] Baugh and Wallace conducted a literature review and found out that the prevalence of middle canals in mesial root ranged from as low as 0.95% to as high as 15%.[10] Similarly, Kirci and Koç in 2019 in a literature review found the presence of the middle distal canal to be from 0.2% to 1.7%.[11] This series of cases documented the "endodontic management of 46 with the mid-mesial canal."

CASE REPORT

Case Report 1

A 34-year-old male with chief complaint of pain in the lower right back region of jaw for 3 months reported to dental OPD. The pain was intermittent, spontaneous, and got aggravated on the intake of cold and also during the night and relieved on the intake of medication. There was no history of pus discharge and fever. Medical history was not significant. When examined clinically, 46 revealed a distoproximal caries. Radiographic and neural sensibility investigations were carried out. On radiographic examination of tooth 46, caries was found to be close to distal pulp horn. Periodontal ligament space around the roots was found intact with initial apical widening [Figure 1].

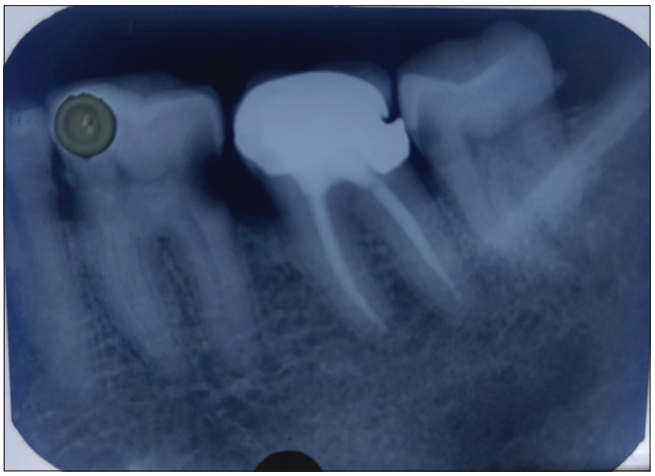

Figure 1: Pre-operative radiograph

Figure 2: Access cavity preparation showing five canals

Figure 3: Working length determination

On neural sensibility test, the affected tooth showed an exaggerated lingering response to pulp testing. The clinicoradiographic diagnosis was chronic irreversible pulpitis with 46, indicating the need of endodontic therapy. The treatment was then initiated, right IANB anesthesia was injected with 2% lignocaine with 1:100,000 adrenaline. Rubber dam was used to isolate single tooth. Caries excavation was done with 46 and pre-endodontic build-up was done using composite resin restoration. Access cavity preparation was made trapezoidal in shape following the dentinal map. Close inspection of the pulpal floor was done with endodontic explorer, a depression was felt in between two mesial canal. Troughing was done with round bur connecting the MB and ML canal to widen it. On widening, the pulpal floor showed three mesial orifices and two distal orifices [Figure 2].

The canal patency was obtained using a no. 10 K-file. Numerous angulated radiographs [Figure 3] were obtained to assure the independent existence of five discrete canals.

Individual canal preparation was carried out using Protaper NiTi instruments (Maillefer, Dentsply). Profuse irrigation

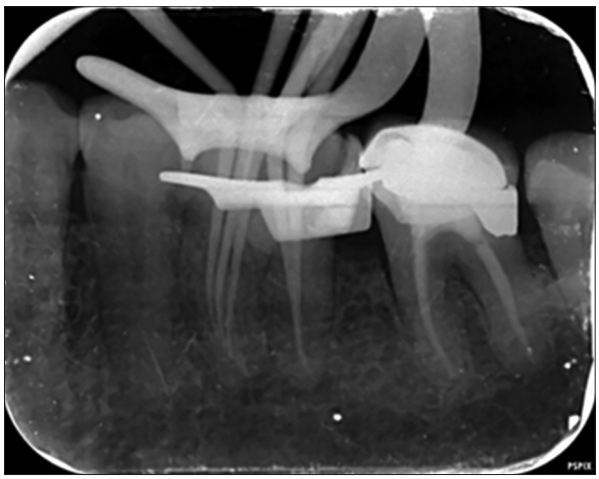

Figure 4: Master cone selection

Figure 5: Obturation

Figure 6: Post-endodontic restoration

was done with 5.25% NaoCl and EDTA alternatively with normal saline. Final flushing with chlorhexidine was done followed by drying of canals using absorbent points. Master cones were selected [Figure 4].

Figure 7: Prothesis with 3 months follow-up

Obturation was carried out with master cones (Maillefer, Dentsply, Tulsa, OK) and Sealapex sealer [Figure 5]. The post-endodontic restoration was done using composite resin restoration [Figure 6] followed by metal crown prosthesis with 46 [Figure 7].

Case Report 2

A 45-year-old male patient reported to dental OPD with spontaneous pain in lower right back tooth region suggestive of chronic irreversible pulpitis with 46. After proper anesthesia (using 2% lignocaine with 100,000), access to root canal orifices was established. Proper exploration of access cavity revealed total of four discrete orifices – three mesially (MB, mid mesial, and ML) and one distally. After obtaining canal patency, working length determination was done using an apex locator (Propex Pixi, Dentsply) and verified by angled radiograph [Figure 8].

The cleaning and shaping of canals were done using rotary Ni-Ti files (ProTaper, Dentsply-Maillefer) with 3% Naocl and EDTA alternatively with normal saline. Final irrigation was done with CHX and canals were dried using paper points followed by master cones selection [Figure 9].

Obturation was carried out with master cones and sealapex sealer [Figure 10]. The post-endodontic restoration was done using resin composite restoration and metal prosthesis [Figure 11].

DISCUSSION

The internal anatomy of tooth may vary from teeth to teeth. This case report considers mandibular first molar.[12] The certainty of success in endodontics depends on the following steps – preparation of access cavity, cleaning, shaping, and obturation of root canals.[13] Therefore, it

Figure 8: Working length determination

Figure 10: Obturation

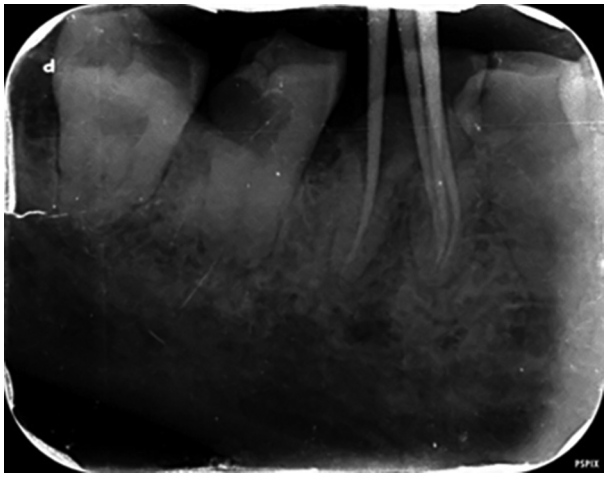

Figure 9: Master cone selection

Figure 11: Post-endodontic restoration

is imperative to identify, clean and shape, and obturate, all canals present in a tooth. Missed anatomy can be prevented by radiographic examination of the tooth before treatment, during access opening of tooth, with the aid of dental operating microscope, ultrasonics, and CBCT.[14] The radiographic examination should done before and even post-obturation in search of extra canal. The abrupt narrowing or disappearance of the canal indicates division of main canal. To detect extra canal in this 2D image angulated, radiographs are valuable.[15] Bedford *et al.* showed that routine radiographs were not sensitive in evaluating the number of canals, any canal obstructions, and existence of lateral and accessory canals.[16] The access opening of tooth should be modified following the dentinal map. Modification can be done using ultrasonic tips.[17] Various aids that can be used for the identification of extra canals include white line test, red line test, and dye test. MM canals have small orifices and may lie deep into the isthmus; hence, troughing to widen and deepen the isthmus and then exploring with DG16, the developmental groove increases the probability of canal detection.[18] Studies suggest the DOM enables to discover of 7.8% additional canals in mandibular molars. Under good illumination, DOM helps dentist to selectively remove dentin precisely.[19] Numerous studies have found that endodontists and oral and maxillofacial radiologists may recognize as low as 76% as many canals on traditional radiographs, but up to 100% of canals on CBCT radiographs. Missed canals have an impact on outcome of endodontic treatment. Bacteria surviving in these canals result in persistence of symptoms. In another study by Hoen and Pink, in 1100, endodontically treated teeth, failure in 42% cases was due to missed canals.[20] According to literature, in the mandibular first molars, the frequency of missed canal is more in distal (86%) than in mesial root (14%). A micro-CT study was done by Versiani *et al.*, they showed that middle canal is located under a dentinal projection in the groove connecting the two main canals.[21] In view of the fact that extra canals are formed linking two main canals, their diameter is less than the main canals. Therefore, overzealous preparation of middle canals may result in perforation.[22] Position of the middle canal with reference to the main canal was also

studied by Sherwani *et al*. They observed that 67% – the orifice of MM canal was in middle of the MB and ML orifice, 20% of cases – orifice was located nearer to the ML canal and 12% had the orifices to be situated closer to the MB canal.[23] In both cases, the canal was to be found in the middle of MB and ML canal orifices.

CONCLUSION

It is said that no two teeth are alike and the same applies to the root canal system. Variation is common finding and the root canals without any variation are rare. The above-documented case confirms this and states that an additional canal exists in the mesial side of the mandibular first molar. This mid-mesial canal can be visualized after obtaining access to the pulp chamber and removing hindrance covering the canal orifice with either burs or ultrasonic tips.

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Original Article

Comparative Study between Timed Intercourse and Intrauterine Insemination in Ovulation Stimulated Cycles in Unexplained Infertile Couples

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Abstract

Background and Objectives: It cannot be stressed enough that infertility is a problem of the couple and not an individual alone. IUI as a mode of artificial insemination is widely used in treating couples with unexplained infertility. The present study was done with the objective of comparing the effectiveness of TI and IUI with husband's sperm in couples with unexplained infertility undergoing superovulation with clomiphene.

Methodology: In this cross-over study, a total of 60 couples with unexplained infertility were subjected to controlled ovarian hyperstimulation with clomiphene and prospectively randomized to receive either TI (Group A) or IUI (Group B). The groups were interchanged when pregnancy was not achieved in either group after three cycles of each intervention.

Results: A positive pregnancy test was seen in both IUI and TI after cross-over. There were seven pregnancies (four in IUI and three in TI), out of which 6 (85.71%) were viable pregnancies, while one was non-viable (14.29%). Both IUI and TI had three viable pregnancies each. The one non-viable pregnancy was from the IUI group.

Interpretation and Conclusions: The findings of the present study showed that both TI and IUI are effective treatment modalities for women with unexplained infertility. Although the addition of IUI to ovulation induction does increase the cycle fecundability, it does not improve the fecundity.

Key words: Controlled ovarian hyperstimulation, Intrauterine insemination, Timed intercourse, Unexplained infertility

INTRODUCTION

Infertility is a failure of the woman to conceive within 1 or more years of regular unprotected intercourse. The highest possibility of conception appears to be with timed intercourse (TI) 1–2 days before ovulation.[1] Considerable controversy surrounds the simple form of infertility treatment called intrauterine insemination (IUI) and the conditions that respond to it.[2] Some prefer to use the term subfertility to describe women or couples who are not sterile, but exhibit decreased reproductive efficiency.[3] "Cycle *fecundability* is the probability that a cycle will result in pregnancy and fecundity is the probability that a cycle will result in a live birth."[3] The timing of sexual intercourse in relation to ovulation has a strong influence on the chance of conception.

Intrauterine insemination (IUI) as a mode of artificial insemination is widely used in treating couples with unexplained infertility for over 200 years. The rationale in all insemination techniques is to deposit motile sperm as close to the oocytes as possible. After the use of new sperm preparation methods and controlled ovarian hyperstimulation, IUI replaced other insemination techniques and became the most widely used method for semination.

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METHODOLOGY

In this cross-over study, a total of 60 couples from infertility outpatient department were enrolled and

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randomly categorized into Group A and Group B after being diagnosed as unexplained infertility. Both the groups (female partner) were given tablet clomiphene citrate (CC) 50 mg OD once a day for 5 days from day 2 to day 6 of the menstrual cycle followed by daily follicular monitoring by transvaginal ultrasound scanning (TVS) starting from day 10 till the day of ovulation. The day of ovulation was determined by TVS. The female partner in both groups received inj. human chorionic gonadotropin (HCG) 5000 IU IM when the Graafian follicular size was around 18–20 mm size.

Group A

The couples were advised to have timed intercourse (TI) for 2 days (once in 24 h) 36 h after the trigger with inj. HCG. The couples underwent three cycles of TI in Group A till conception. Couples with a failure of conception after three cycles underwent three cycles of IUI in Group B.

Group B

The couples were subjected to IUI 36 h after stimulating with inj. HCG. IUI was done using husband semen after preparing the semen sample by the swim-up technique. Three cycles were given for each couple until conception. Failure of conception after three cycles had to undergo three cycles of TI in Group A.

Therefore, this was a cross-over study design as both interventions were applied to both the groups.

Subjects in both groups were asked to follow-up on day 2 of menses or day 10 of missed periods.

Urine pregnancy test (UPT) and TVS for the visualization of the gestation sac were done on day 10 of missed period to confirm pregnancy. A positive UPT test was the determining factor for assessing the effectiveness of the two interventions, i.e., IUI and TI. The pregnancy outcome was analyzed as viable or unviable pregnancy or pregnancy wastage (P wastage). P wastage includes abortions and perinatal mortality as well. The quantitative data are represented as their mean ± SD. The Student's unpaired *t*-test was used for analyzing quantitative data. The significance threshold of *P*-value was set at < 0.05.

RESULTS

In the present study, a total of 60 patients were enrolled and categorized into Group A, where patients initially underwent three cycles of TI till conception, followed by three cycles of IUI until conception and Group B, where patients initially underwent three cycles of IUI until conception followed by three cycles of TI until conception.

In Group A, 4 (13.33%) cases reported positive UPT compared to 3 (10%) cases in Group B. Maximum cases, i.e., 27 (90%) reported negative UPT in Group B as compared to 26 (86.67%) cases in Group A. To test, whether this difference is statistically significant or not, Chi-square test was used as a test of significance. $P = 0.6876$ was statistically not significant.

Table 2 shows the outcome of TI and IUI cycles in Group A. In Group A, 30 patients underwent TI first, of which two got pregnant (6.67%). The remaining 28 went for IUI after cross-over, of which two got pregnant (71.4%). Therefore, out of 58 patients after crossing over, there were 4 (6.9%) pregnancies in Group A.

Table 3 shows the outcome of TI and IUI cycles in Group B. In Group B, 30 patients underwent IUI, of which two got pregnant (6.67%). The remaining 28 were subjected to TI, after cross-over, of which one got pregnant (3.57%). Therefore, out of 58 patients after crossing over, there were 3 (5.17%) pregnancies in Group B.

Table 4 gives the pregnancy outcome in both the study groups who underwent TI and IUI. There were seven pregnancies out of which six viable pregnancies (85.71%) which were in TI cycles and IUI cycles equally and one non-viable pregnancy (14.29%) from the IUI cycles.

Table 5 shows the outcome of TI and IUI cycles with respect to infertility. Out of 57 couples with primary

Table 1: Comparison of UPT in the study groups

UPT	Group A		Group B		Total		*P*-value*
	n	%	*n*	%	*N*	%	
Positive	4	13.33	3	10	7	11.67	0.6876
Negative	26	86.67	27	90	53	88.33	
Total	30	100	30	100	60	100	

*Calculated using the Chi-square test. $P<0.05$ considered statistically significant.
UPT: Urine pregnancy test

Table 2: Outcome of TI and IUI cycles in Group A

Group A	Number of patients	Number of pregnancies	Percentage of pregnancies
TI	30	2	6.67
IUI	28	2	7.14
Total	58	4	6.9

IUI: Intrauterine insemination, TI: Timed intercourse

Table 3: Outcome of TI and IUI cycles in Group B

Group B	Number of patients	Number of pregnancies	Percentage of pregnancies
IUI	30	2	6.67
TI	28	1	3.57
Total	58	3	5.17

IUI: Intrauterine insemination, TI: Timed intercourse

infertility, there were three pregnancies (1.84%) in patients who underwent 163 cycles of TI. These primary infertile couples underwent 160 cycles of IUI and 4 (2.5%) conceived with that. There were no pregnancies in couples with secondary infertility who underwent TI and IUI.

Table 6 shows the effect of the number of cycles of the treatment of TI and IUI on pregnancy in all patient categories.

TI

Of those patients who had three cycles of TI, there was one pregnancy, while those who had two cycles had two pregnancies. There were no pregnancies with just one cycle of TI.

IUI

Of those patients who had one cycle of IUI, there was one pregnancy, while those who underwent two cycles had three pregnancies. There were no pregnancies with three cycles of IUI.

DISCUSSION

Statistics regarding infertility is it primary or secondary; in general, population are not easy to analyze as a lot of couples do not seek medical help illustrating the potential for error in hospital-based statistics.

Including the cross-over groups, the conception outcome, i.e., positive UPT, was seen in four cases from Group A (13.33%), and three cases got pregnant from Group B (11.67%) [Table 1].

According to the study groups, after and before cross-over, there were in total four pregnancies, two with both IUI and TI, respectively, in Group A [Table 2]. While in Group B, there were three pregnancies, two pregnancies after IUI, and one after TI [Table 3].

Defining the pregnancy outcome, there were three viable pregnancies and one P wastage with IUI while three viable pregnancies with TI [Table 4].

TI: Out of the three, two were term live births, while one was preterm live birth at the 7th month.

IUI: Out of four pregnancies, three were viable with one twin gestation and one singleton live birth and one preterm breech delivery at 7½ months. There was one pregnancy wastage being missed abortion in the first trimester itself.

Table 4: Table of fecundity and fecundability in both study groups

Pregnancy outcome status	TI		IUI		Total	
	Number of pregnancies	Percentage of pregnancies	Number of pregnancies	Percentage of pregnancies	Number of pregnancies	Percentage of pregnancies
Viable pregnancy	3	100	3	75	6	85.71
Pregnancy wastage	0	0	1	25	1	14.29
Total	3	100	4	100	7	100

IUI: Intrauterine insemination, TI: Timed intercourse

Table 5: Outcome of TI and IUI cycles with respect to infertility category

Category	Number of couples	Timed intercourse			IUI			Total number of pregnancies
		Number of cycles	Number of pregnancies	Percentage of pregnancies	Number of cycles	Number of pregnancies	Percentage of pregnancies	
Primary infertility	57	163	3	1.84	160	4	2.5	7
Secondary infertility	3	9	0	0	9	0	0	0
Total	60	172	3	1.74	169	4	2.37	7

IUI: Intrauterine insemination, TI: Timed intercourse

Table 6: Outcome of the number of cycles of treatment in TI and IUI

Cycle number	Timed intercourse			IUI		
	Number of cycles	Number of pregnancies	Percentage of pregnancies	Number of cycles	Number of pregnancies	Percentage of pregnancies
1	0	0	0	1	1	100
2	4	2	50	6	3	50
3	168	1	0.6	162	0	0
Total	172	3	1.74	169	4	2.37

IUI: Intrauterine insemination, TI: Timed intercourse

Maximum patients were that of primary infertility as compared to secondary. All seven pregnancies were from couples who had primary infertility [Table 5]. Our study had a fixed number of cycles for each intervention. Of those patients who had three cycles of TI, there was one pregnancy, while those who had two cycles had two pregnancies. Of those patients who had one cycle of IUI, there was one pregnancy, while those who underwent two cycles had three pregnancies [Table 6].

Martinez *et al.*[4] reported the first randomized study on comparison of TI and IUI in gonadotropin-stimulated normal ovulatory cycles without any significant differences. Kirby *et al.*[5] compared IUI with LH-TI during spontaneous cycles and found no significant improvement in pregnancy rates except in couples with severe semen defect. However, based on meta-analyses of 980 cycles in randomized prospective studies, the addition of IUI to superovulation with gonadotropins in couples with unexplained infertility produced better results than superovulation alone.[6] Although five of the seven studies included in this meta-analysis failed to show significant benefit of IUI, the overall evaluation of all seven studies revealed a significant increase in the pregnancy rate with the addition of IUI. Our cross-over study showed that the addition of IUI over TI in ovulation stimulated cycles with CC in women with unexplained infertility improves the pregnancy rate, i.e., fecundability, but does not improve the chance of live birth, i.e., fecundity. Most studies have indicated that IUI is only useful if the cause is oligospermia and mild asthenozoospermia.[7,8] There was a cross-over trial conducted in 1990 by Deaton *et al.*[9] of CC/IUI versus TI, including 67 couples and 298 treatment cycles. The difference in fecundities was statistically significant, while the pregnancy outcome was not significantly different between the two groups. Another randomized prospective trial of IUI versus TI in superovulated cycles with clomiphene conducted by Agarwal and Mittal[10] showed that in women with unexplained infertility, the addition of IUI to ovulation induction does not improve conception rates.

There is a scope for further studies and large multicentric randomized controlled trials, including normal ovulatory and superovulated cycles in cases of unexplained infertility. Further, an in-depth study is essential to determine the benefit, cost-effectiveness, and potential side effects of IUI over TI for unexplained infertility. Furthermore, it can help to adjudge the subtle endocrine/ ovulatory defects which may influence favorable outcome. The mechanism by which IUI, either combined or not with ovarian stimulation, may enhance cycle fecundity in couples with unexplained infertility warrants further elucidation.

CONCLUSIONS

Positive pregnancy outcome was seen both with TI and IUI for ovulation stimulated cycles in unexplained infertile couples. Our cross-over study showed that the addition of IUI over TI in ovulation stimulated cycles with CC in women with unexplained infertility improves the pregnancy rate, i.e., but does not improve the chance of live birth.

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Original Article

Role of Cardiotocography and Amniotic Fluid Index Together in Predicting Perinatal Outcome in Low-risk Pregnancies

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Abstract

Introduction: The universal aim of maternity care provision is birth of a healthy baby to a healthy mother. Various invasive and non-invasive antepartum surveillance tests have been devised to access the fetal well-being. In developing countries like India, where workload is heavy with shortage of technical manpower and resource settings are poor, we need techniques which are adequate, simple, cost effective, easy to use, and less time consuming for better postpartum outcome.

Materials and Methods: This study was conducted over a period of 1½ years in 251 primigravidae with low-risk pregnancies at or near term who were observed with admission cardiotocography (CTG) and amniotic fluid index (AFI) and was followed during the course of labor to access mode of delivery, Apgar score at 0, 1, and 5 min of birth, and need for neonatal intensive care unit (NICU) admission.

Results: When both AFI and CTG together were correlated with mode of delivery, it was seen that in patients with cat 1 CTG irrespective of AFI, most of the patients were delivered by NVD and in cat 3 CTG patients irrespective of AFI, most of them were delivered by lower segment cesarean section (LSCS). In patients with cat 2 CTG, significant number of those was delivered by LSCS who had low AFI. When AFI and CTG together were studied for Apgar score at "1-min" of birth and NICU admission, it was seen that irrespective of AFI, low Apgar, and NICU admission was mostly seen in cat 3 CTG patients, but there was no neonatal mortality in our study.Data were entered into a Microsoft Excel Spreadsheet, relationship between categorical variables was analyzed using a Chi-square test and data were analyzed using STATA version 15.

Conclusion: Therefore, admission CTG along with AFI can effectively detect fetal distress if already present at admission and thereby avoid unnecessary delay in decision to deliver timely and improve fetal outcome. These simple, cost effective, non-invasive, and less time-consuming tests can identify those patients who need continuous fetal monitoring in low resource settings and fetal outcome can be improved.

Key words: Amniotic fluid index, Apgar, Cardiotocography, Neonatal intensive care unit

INTRODUCTION

Birth of a healthy baby to a healthy mother is the universal aim of maternity care provision. More care is being taken during labor to prevent an outcome such birth asphyxia and avoid its consequences. However, despite best efforts occurrence of birth asphyxia (2/1000 births in developed countries and up to 10 times higher in developing countries) continues to happen in obstetric practice.[1] According to a WHO estimate in 2014, about 4 million neonatal deaths occur yearly due to birth asphyxia, representing 35% of deaths of children under 5 years of age.[2] To prevent damage due to fetal asphyxia, several antepartum surveillance tests have been devised.

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Cardiotocography (CTG) ([NST]) is the most widely used primary non-invasive test for fetal well-being. The amniotic fluid index (AFI) as measured by the four-quadrant ultrasonic technique was added to antepartum testing to better identify fetuses at higher risk of poor perinatal outcome. The modified biophysical profile (MBPP) suggested by Devi

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and Swarnalatha combines NST as a short-term marker of fetal status and the AFI as a marker of long-term placental function. It is easier to perform and less time consuming than complete biophysical profile.[3] Thus, various antepartum surveillance techniques have been developed for prompt detection and management of obstetric complications. However, in developing countries like India, where workload is heavy with shortage of technical workforce and resource settings are poor, we need techniques which are adequate, simple, cost effective, easy to use, and less time consuming for better postpartum outcome.[1]

Aims and Objectives

The objectives of the study were as follows:

- To identify whether admission CTG and assessment of AFI together have a role in identifying the perinatal outcome
- To identify whether admission CTG and AFI assessment together can predict fetal morbidity and mortality.

MATERIALS AND METHODS

This prospective observational study was conducted in the Postgraduate Department of Gynecology and Obstetrics of GMC, Srinagar, associated Lalladed Hospital over a period of 1½ years. During this period, 50,410 patients were admitted in our hospital, 19,805 patients under went lower segment cesarean section (LSCS) and 14,488 patients were delivered by NVD. Two hundred and fifty-one women with low-risk pregnancies (primigravidae) at or near term (37 weeks–40 weeks) were observed with admission CTG and AFI; these women were admitted either in early labor or induction of labor which was done and these women were followed during the course of labor and were assessed for mode of delivery and perinatal outcome.

Inclusion Criteria

This included the following patients.

1. Term or near term patients (37 weeks–40 weeks)
2. Singleton pregnancy
3. Non-anomalous baby
4. Primigravidae
5. Intact membranes
6. Women in early labor or where induction of labor was done.

Exclusion Criteria

The following patients were excluded from the study:

1. Multiple pregnancy
2. Pre-term (<37 weeks)
3. Recurrent missed abortions
4. Premature rupture of membranes
5. Congenital anomalies
6. Previous bad obstetric history
7. Maternal age above 40 or <19
8. Previous LSCS
9. Intra uterine death
10. Non-cephalic presentation/malpresentation.

Parameters that were studied are

1. Age of the patients and gestational age at the time of admission
2. CTG changes (according to FIGO criteria for CTG interpretation)
3. AFI (By 4-quad technique)
4. Presence of meconium, cord around neck at the time of delivery
5. Mode of delivery (normal vaginal delivery, cesarean section)
6. Apgar score at 0, 1, and 5 min
7. Need for admission in neonatal intensive care unit (NICU).

CTG

CTG is electronic fetal monitoring which records fetal heart rate (FHR) and uterine activity on a graph.

CTG includes four parameters:

FHR (normal 110–160 bpm)

Baseline variability (normal 5–25bpm)

- Absent – undetectable
- Minimal – ≤5 bpm
- Moderate – 6–25 bpm
- Marked – >25 bpm.

Acceleration (normal, 2 or more accelerations that peak at 15 bpm above baseline within 20 min of beginning of test).

Deceleration (none); decelerations are periodic, transient decreases in FHR, usually associated with uterine contractions. They can be subdivided into four main types by their shape and timing in relation to uterine contractions.

There are four types of decelerations as defined by the National Institute of Child Health and Human Development nomenclature, all of which are visually assessed.

- Early deceleration
- Late deceleration
- Variable deceleration
- Prolonged deceleration.

CTG Interpretation

The cardiotocogram was interpreted as per FIGO guidelines.

AFI Measurement Technique

In 1987, Platt *et al*. discovered a four-quadrant method of assessing AFI. Using that technique, an AFI of 5 cm or less is defined as oligohydramnios.[4] Normal AFI values range from 5 cm to 25 cm. The AFI was interpreted in three categories (ranges).

AFI< 5 cm
AFI 5–15 cm
AFI >15 cm.

AFI estimation with CTG at admission, these two parameters altogether can be used as valuable screening test to detect fetal distress as early as possible and prevent fetal morbidity and mortality.

RESULTS

1. Majority of our patients (64.14%) in our study were in the age group of 25–30 years
2. Out of total 251 patients, 94 (37.45%) had cat 1 CTG, 78 (38.08%) had cat 2 CTG, and 79 (31.47%) had cat 3 CTG
3. Most of the patients 168 (66.93%) had adequate liquor (AFI 5–15 cm), 56 (22.31%) had oligohydramnios (AFI <5 cm), and 27 (10.76%) had AFI >15 cm.
4. When both AFI and CTG together were correlated with mode of delivery, it was seen that in patients with cat 1 CTG irrespective of AFI, most of the patients were delivered by NVD and in cat 3 CTG patients irrespective of AFI, most of them were delivered by LSCS. In patients with cat 2 CTG, significant number of those was delivered by LSCS who had low AFI.

The results show that when both CTG and AFI together are correlated with mode of delivery, cat 1 CTG patients in all AFI groups were delivered by NVD, whereas cat 3 CTG patients irrespective of AFI were delivered by LSCS. In cat 2 CTG patients, delivery by LSCS is seen significantly more in those with low AFI (<5 cm) than in those with AFI >5 cm.

1. When AFI and CTG together were studied for Apgar score at "1-min" of birth and NICU admission, it was seen that irrespective of AFI, low Apgar, and NICU admission was mostly seen in cat 3 CTG patients, but there was no neonatal mortality in our study.

When AFI and CTG together are compared with Apgar score at "0-min" of birth, newborns of cat 1 CTG group show good Apgar score in all AFI ranges, whereas cat 3 CTG patients irrespective of AFI show low Apgar score in significant number of newborns. In cat 2 CTG patients, low Apgar is seen mostly in those newborns who belong to low AFI group.

At "1-min" of birth, all newborns of cat 1 CTG group had a good Apgar score irrespective of the AFI whereas in cat 3 CTG group, low Apgar was seen in significant number of newborns in all AFI groups and in cat 2 CTG patients, low Apgar was seen in only one newborn belonging to low AFI group.

At "5-min" of birth, only six newborns had an Apgar score <6 and all of them belonged to cat 3 CTG patients with one of them in low AFI group and 5 in AFI 5–15 cm group, but no neonate in cat 1 or cat 2 CTG patients had a low Apgar at "5-min" of birth.

When AFI and CTG both together are compared with NICU admission, in Cat 1 group, no neonate was admitted in NICU at the time of birth irrespective of the AFI, whereas significant number of newborns in cat 3 CTG group required NICU admission in all of the AFI ranges. In cat 2 CTG patients, only one newborn belonging to low AFI group required NICU admission at the time of birth.

DISCUSSION

In our study [Table 1 of results], we also evaluated the role of CTG and AFI together in predicting the perinatal outcome and for determining the mode of delivery. The results of our study showed that patients with cat 3 CTG and low AFI <5 cm, all required LSCS, whereas patients with cat 1 CTG and AFI >5 cm are at lowest risk and can be induced to deliver vaginally. In our study, we also evaluated the role of admission CTG and AFI together in predicting the perinatal outcome by studying Apgar score at 0, 1, and 5 min [Tables 2-4 of results]. The results showed that in patients with cat 1 CTG and adequate liquor, all the newborns had an excellent Apgar score at the time of birth, whereas in patients with category 3 CTG irrespective of AFI, Apgar score <6 was seen in 16% of the newborns. In the group of patients with cat 3 CTG irrespective of AFI, a significant number of the newborns required NICU

Table 1: Comparison of AFI and CTG with mode of delivery

CTG	AFI (cm)	Mode of delivery	
		NVD	LSCS
Cat-1	<5	11	2
	5–15	65	4
	>15	12	0
Cat-2	<5	6	17
	5–15	24	26
	>15	3	2
Cat-3	<5	0	20
	5–15	2	47
	>15	0	10

Pearson Chi-square=148.99; *P*<0.001. CTG: Cardiotocography, AFI: Amniotic fluid index, LSCS: Lower segment cesarean section

Table 2: Comparison of AFI and CTG with Apgar-0

CTG	AFI (cm)	Apgar-0	
		<6	>6
Cat-1	<5	2	11
	5–15	0	69
	>15	1	11
Cat-2	<5	9	14
	5–15	2	48
	>15	1	4
Cat-3	<5	9	11
	5–15	16	33
	>15	4	6

Pearson Chi-square =50.87, *P*<0.001. CTG: Cardiotocography, AFI: Amniotic fluid index

Table 3: Comparison of CTG and AFI With Apgar-1

CTG	AFI (cm)	Apgar-1	
		<6	>6
Cat-1	<5	0	13
	5–15	0	69
	>15	0	12
Cat-2	<5	1	22
	5–15	0	60
	>15	0	5
Cat-3	<5	3	17
	5–15	9	40
	>15	1	9

Pearson Chi-square=29.46; *P*<0.001.CTG: Cardiotocography, AFI: Amniotic fluid index

Table 4: Comparison of CTG and AFI with Apgar-5

CTG	AFI (cm)	Apgar-5	
		<6	>6
Cat-1	<5	0	13
	5–15	0	69
	>15	0	12
Cat-2	<5	0	23
	5–15	0	50
	>15	0	5
Cat-3	<5	1	19
	5–15	5	44
	>15	0	10

Pearson Chi-square=17.86, *P*=0.022. CTG: Cardiotocography, AFI: Amniotic fluid index

Table 5: Comparison of CTG and AFI with NICU admission

CTG	AFI (cm)	NICU admission	
		Absent	Present
Cat-1	<5	13	0
	5–15	69	0
	>15	12	0
Cat-2	<5	22	1
	5–15	50	0
	>15	5	0
Cat-3	<5	17	3
	5–15	40	9
	>15	9	1

Pearson Chi-square=27.83; *P*<0.001. CTG: Cardiotocography, AFI: Amniotic fluid index, NICU: Neonatal intensive care unit

admission at birth [Table 5] of our results. Similar results were also observed in the study conducted by Eden *et al.*[5] in 1988, in which high-risk pregnancies were screened using a MBPP consisting of NST and ultrasound evaluation of amniotic fluid volume. Decreased amniotic fluid volume and spontaneous FHR decelerations were considered abnormal findings during antenatal testing and served as indications for delivery regardless of FHR reactivity. Despite interventions, decreased amniotic fluid volume and spontaneous decelerations were associated with an increased incidence of meconium staining, decelerations during labor, cesarean section for fetal distress, and small for gestational age infants. Similar results were also seen in the study by Anand *et al.*[1] in 2016 who concluded that AFI, NST, and color of liquor can effectively detect fetal distress already present at admission, thereby avoiding unnecessary delay and decrease in detection to delivery time and improve fetal outcome. Similar results were also observed in the study conducted by Sowmya *et al.*[6] in 2017, in which 70 patients with high-risk pregnancy were evaluated with the MBPP consisting of NST recording for 20 min, followed by ultrasound assessment of amniotic fluid volume, using four-quadrant technique. They concluded that when the MBPP is normal, it gives reassurance that the fetal status is good with good perinatal outcome. At the same time, when MBPP is abnormal, it indicates that the fetus may be compromised, thus MBPP can be used as primary antepartum fetal surveillance test to predict perinatal outcome and provide timely intervention in high-risk pregnancies.

CONCLUSIONS

From our study, the following conclusions were drawn;

- Pathological (cat 3) CTG at admission irrespective of the AFI is associated with more cesarean deliveries for fetal distress, meconium stained liquor intraoperatively and with poor perinatal outcome
- Cat 2 CTG is associated with more cesarean deliveries, especially in those patients who have low AFI
- Cat 1 CTG is associated with good perinatal outcome and most of the patients can be induced to deliver vaginally almost with any value of AFI
- In patients with cat 2 CTG and low AFI and those with cat 3 CTG, continuous fetal monitoring should be done till delivery, especially in a hospital like ours with heavy workload. Pediatrician should be kept available for the immediate and proper resuscitation and triaging of babies
- Therefore, admission CTG along with AFI can effectively detect fetal distress if already present at admission and thereby avoid unnecessary delay in decision to deliver timely and improve fetal outcome.

These simple, cost effective, non-invasive, and less time-consuming tests can identify those patients who need continuous fetal monitoring in low-resource settings and fetal outcome can be improved.

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Original Article

Diagnostic Dilemma of Inflammatory Bowel Disease: Study from a Tertiary Hospital in South India

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Abstract

Introduction: Diagnosis of inflammatory bowel disease (IBD) and other inflammatory conditions of the colon cannot be established when only one or few features are present as they share many pathological features. Hence, this study is undertaken to develop reproducible criteria which are valid in the diagnosis of IBD and to differentiate it further from ulcerative colitis (UC) and Crohn's disease (CD).

Purpose: The purpose of the study was (1) to study the histopathological patterns of the colonic biopsy specimen, (2) to develop the reproducible criteria which aid in the diagnosis of UC and CD, and (3) to evaluate the extent of interobserver variability over the final diagnosis.

Materials and Methods: Endoscopic punch biopsy procedure was done for 35 cases with suspected IBD which were sent to the Histopathology Department of Bengaluru Medical College. Tissue bits were fixed in 10% formalin and processed by the conventional method and embedded in paraffin blocks. Sections from these blocks were stained with hematoxylin and eosin according to standard procedures. After initial histomorphological reporting was done, the 35 slides were reported again by two pathologists. Cases with proven malignancy were excluded from the study.

Results: UC was diagnosed in 19 cases (53%) of 35 cases followed by indefinite for IBD in nine cases (25%). CD was seen in five cases (14%) followed by tuberculosis in two cases (5%). One case had evidence of dysplasia along with features of UC. The agreement between pathologists for the final diagnosis is 68.5%. Based on *P* value, the significant features which are most useful in the diagnosis of UC are: For activity – (1) cryptitis, (2) neutrophilic infiltration in lamina propria, and (3) crypt abscess; for chronicity – (1) crypt distortion, (2) crypt branching, (3) Mucin depletion, (4) crypt atrophy, and (5) crypt dilation.

Conclusion: UC was found to be more commonly reported among the IBD cases. Considerable disagreement can be seen between experienced pathologists reporting the same slides. Therefore, salient histological features based on better reproducibility along with adequate clinical and endoscopy findings can aid in distinguishing between UC and CD.

Key words: Agreement, Histopathology of ulcerative colitis and Crohn's disease, Inflammatory bowel disease, Reproducible criteria

INTRODUCTION

Ulcerative colitis (UC) and Crohn's disease (CD) are chronic inflammatory bowel diseases (IBD) of unknown cause. "Indefinite for inflammatory bowel disease (IBD)" is applied as a temporary classification to cases where a definite diagnosis cannot be made because of the absence of diagnostic features of CD and UC.[1]

The two diseases have similar histopathological features and the discriminating characteristics are often subtle and ill-defined.[2-6] Observer variation assessment may identify diagnostic problem areas and may have great therapeutic consequences in clinical practice.[7-10]

The diagnosis of IBD is established by a combination of medical history, clinical evaluation, laboratory data, which includes negative stool examinations for infectious

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agents, and typical endoscopic, histologic, and radiological findings.[11] Other non-infectious causes of diarrhea should be ruled out before a diagnosis is made.[12]

Colonoscopy with biopsies is the most accurate assessment method for the determination of disease extent and activity.[13,14] Pathologists should be aware of the frequency of various features in different settings and should also bear in mind the reproducibility of each feature.

There are rising incidence and prevalence of IBD in India topping the Southeast Asian (SEA) countries.[15] This topic is receiving emerging attention, as medical therapies, surgical approaches, and leading prognostic outcomes require more and more disease-specific strategies in IBD patients.[16]

Table 1: Disease-specific gender distribution

Sex	Impression				Total
	Crohn's	Indefinite for IBD	Tuberculosis	UC	
F					
Count	4	5	2	6	17
% within sex	23.5	29.4	11.8	35.3	100.0
M					
Count	1	8	0	9	18
% within sex	5.6	44.4	0.0	50.0	100.0

IBD: Inflammatory bowel disease, UC: Ulcerative colitis

MATERIALS AND METHODS

After obtaining approval and clearance from the institutional ethical committee, suspected cases of IBD were included in the study. Cases with proven malignancy were excluded from the study. A four-quadrant punch biopsy was obtained from the endoscopic procedure. The grossing of endoscopic biopsies sent to the histopathology department was done conventionally. Tissue bits so obtained were fixed in 10% formalin and processed by the conventional method and embedded in paraffin blocks. Sections from these blocks were stained with hematoxylin and eosin (H and E) according to standard procedures. A systematic histological assessment was made. The H and E stained slides were assessed for the histomorphological features. After initial reporting was done, the 35 slides were reported again by two pathologists.

Table 2: Incidence of individual features in regard to histopathology diagnosis

Features	CD (%)	Indefinite for IBD (%)	TB (%)	UC (%)	*P*-value	Kappa value	Percentage agreement
Cryptitis	2 (10)	4 (20)	0 (0)	14 (70)	0.002*	0.533	77
Neutrophilic infiltration	2 (9.5)	5 (23.8)	0 (0.0)	14 (66.7)	0.013*	0.419	68
Epithelioid granuloma	5 (62.5)	0 (0)	2 (25)	1 (12.5)	0.008*	0.410	83
Langhans giant cell	0 (0)	0 (0)	2 (100)	0 (0)	0.002*	0.000	94
Neutrophils in lamina	3 (10)	11 (36.7)	1 (3.3)	15 (50)	0.070 (NS)	0.236	66
Crypt distortion	2 (14.3)	1 (7.1)	0 (0.0)	11 (78.6)	0.001*	0.578	80
Crypt abscess	3 (20)	0 (0.0)	0 (0.0)	12 (80)	0.005*	0.452	75
Loss of crypt architecture	2 (20)	0 (0.0)	0 (0.0)	8 (80)	0.016*	0.404	77
Ulceration	4 (14.8)	9 (33.3)	1 (3.7)	13 (8.1)	0.091 (NS)	0.269	70
Mucin depletion	1 (7.1)	2 (14.3)	0 (0.0)	11 (78.6)	0.006*	0.416	75
Lymphoid follicles in LP	1 (11.1)	3 (33.3)	0 (0.0)	5 (55.6)	0.067 (NS)	0.267	63
Mucosal inflammation	4 (14.8)	10 (37)	2 (7.4)	11 (40.7)	0.001*	0.576	86
Eosinophils	2 (8.3)	11 (45.8)	1 (4.2)	10 (41.7)	0.008*	0.442	77
Crypt abscess disruption	2 (22.2)	0 (0.0)	0 (0.0)	7 (77.8)	0.439 (NS)	−0.129	60
Submucosal lymphoid aggregate	1 (25)	1 (25)	0 (0.0)	2 (50)	0.064 (NS)	0.305	82
Crypt branching	1 (7.7)	0 (0.0)	0 (0.0)	12 (92.3)	0.009*	0.440	83
Paneth cell metaplasia	0 (0.0)	0 (0.0)	0 (0.0)	6 (100)	0.025*	0.545	77
Diffuse inflammation	4 (14.3)	9 (32.1)	2 (7.1)	13 (46.4)	0.159 (NS)	0.237	73
Plasma cells	5 (15.6)	10 (31.2)	2 (6.2)	15 (46.9)	0.324 (NS)	0.160	83
Villous configuration	0 (0.0)	0 (0.0)	0 (0.0)	3 (100)	0.324(NS)	0.160	83
Crypt atrophy	1 (10)	1 (10)	0 (0.0)	8 (80)	0.002*	0.524	80
Inflammatory polyp	1 (10)	0 (0.0)	0 (0.0)	9 (90)	0.002*	0.203	74
Submucosal fibrosis	3 (37.5)	0 (0.0)	0 (0.0)	5 (62.5)	0.049*	0.273	80
Crypt dilatation	2 (25)	0 (0.0)	0 (0.0)	6 (75)	0.674 (NS)	0.070	63
Thickened muscularis	3 (12)	9 (36)	0 (0.0)	13 (52)	0.005*	0.452	75
Regenerative change	1 (20)	1 (20)	0 (0.0)	3 (60)	0.049*	0.267	69
Crypt hyperplasia	2 (66.7)	0 (00.0)	0 (0.0)	1 (33.3)	0.000*	0.637	94
Edema lamina propria	4 (16)	8 (32)	1 (4)	12 (48)	0.319 (NS)	0.165	63
Ectatic blood vessels	2 (13.3)	9 (60.0)	2 (13.3)	2 (13.3)	0.002*	0.496	74
Neuronal hyperplasia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	-		93
Submucosal edema	1 (20)	0 (0.0)	0 (0.0)	4 (80)	0.007*	0.440	89

*P<0.05 – significant (Fischer's exact test). NS: Not significant. IBD: Inflammatory bowel disease, UC: Ulcerative colitis, CD: Crohn's disease

Statistical Analysis

The patient's details were recorded in a standardized format. Results were analyzed in the form of tables, graphs, and pie-charts. Histological parameters were evaluated. Values are expressed as $P < 0.05$ is considered statistically significant. SPSS 18.0 software is used for statistical analysis. Kappa values were calculated for interobserver variation.

RESULTS

The patients were in the age range of 7–65 years with a mean age of 40.1 years and standard deviation of 14.5. The peak incidence of IBD cases was found in the age group between 41 and 50 years, accounting to 31% of the cases followed by the age group of 31–40 years which constituted 20% of the cases.

There was a slight male preponderance in the cases of IBD which constituted 51.4% of all cases with females accounting to 48.6% of all IBD. The male to female sex ratio being 1.05:1. The mean age group of involvement among male patients was 44 years, whereas females it was 35.7.

UC was diagnosed in 19 cases (53%) of 35 cases followed by indefinite for IBD in nine cases (25%). CD was seen in five cases (14%) followed by tuberculosis in two cases (5%). One case had evidence of dysplasia along with features of UC.

Based on the *P*-value, the significant features which are most useful in diagnosis of UC are:

- For activity – (1) cryptitis, (2) neutrophilic infiltration in lamina propria, and (3) crypt abscess
- For chronicity – (1) crypt distortion, (2) crypt branching, (3) Mucin depletion, (4) crypt atrophy, and (5) crypt dilation.

The agreement between pathologists for the final diagnosis is 68.5% [Tables 1-4].

In our study, the strongest features based on the agreement were:

UC	CD
Cryptitis	Epithelioid granuloma
Neutrophilic infiltration in lamina propria	Thickened muscularis mucosa
Crypt distortion	Crypt hyperplasia
Crypt abscess	Basal plasmacytosis
Loss of crypt architecture	Neutrophilic infiltration in lamina propria
Mucin depletion	Mucosal inflammation
Crypt branching	Submucosal edema
Crypt atrophy	Eosinophils

UC: Ulcerative colitis, CD: Crohn's disease

DISCUSSION

Diagnosis of IBD based solely on histological features is challenging as no feature is absolute for diagnosis of IBD or type of IBD. Diagnostic accuracy is optimized if several features rather than a single feature are assessed along with the distribution of the disease with clinical and endoscopic picture. A stepwise approach is advisable so as not to miss any feature that might be contributing to the diagnosis.[17] Timing of biopsy is also important criteria where the cases are divided as – (a) early untreated IBD (<4 weeks), (b) established untreated IBD, and (c) long-standing IBD.[17]

In tropical countries like ours, differentiation of TB from CD is a difficult diagnostic dilemma as there has been a rise in the number of cases of CD.[18]

There has been a paucity of accurate epidemiologic data due to the diagnostic overlap of the IBD entities with conditions such as infectious colitis. Overall, both the incidence and prevalence of CD and UC are increasing with time. This can be attributed to a number of factors, including improved sanitation, diet, and medication exposures, increased IBD awareness among patients and clinicians, use of improved endoscopic and radiologic diagnostic modalities, and widened health-care access.[15]

The most common feature among these studies was crypt abscess followed by neutrophilic infiltration in lamina propria. However, these can be seen present in infectious etiology as well as in indefinite for IBD. Other features in our study such as cryptitis, mucin depletion, crypt branching, and crypt atrophy have been seen to strengthen the diagnosis of UC.

In the present study, features which showed poor agreement between the two observers were crypt abscess disruption, basal cell plasmacytosis, villous configuration, edema of lamina propria, and crypt dilatation. Features which are rarely observed usually have low kappa values. For example, crypt dilatation was present in 22% of the observations leading to a kappa of 0.07. Epithelioid granulomas were also observed in 22% cases, but the associated kappa value was considerably higher at 0.41, indicating that when seen, there was much closer agreement on their presence. By contrast, common features such as lymphoid aggregates may have poorer agreements.

Interobserver variability remains a major problem: In a study by Charles Bernstein, the range of agreement over the final diagnosis was only 65–76%. The greatest disagreement was seen in diagnosing CD, and it was most frequently diagnosed as UC. Even some normal cases were reported as CD or UC.[19] This study highlights that

Table 3: Frequency of detection of the reproducible features

Features	*P*-value A Theodossi *et al.*	*P*-value Le Berre	*P*-value Seldenrijk	*P*-value Ahmed	*P*-value current study
Cryptitis	<0.001	<0.0001	0.0000	<0.0001	0.002*
Neutrophilic infiltration	<0.001	<0.01	0.0000	<0.0001	0.013*
Epithelioid granuloma	<0.001	<0.01	0.0416	NS	0.008*
Langhans giant cell	<0.001	-	-	NS	0.002*
Neutrophils in lamina	<0.001	<0.0001	-	<0.0001	0.070 (NS)
Crypt distortion	<0.001	<0.0001	-	<0.0001	0.001*
Crypt abscess	<0.001	<0.0001	1.0000	<0.001	0.005*
Loss of crypt architecture	<0.001	<0.0001	0.0000	<0.0001	0.016*
Ulceration	<0.001	<0.05	0.0022	<0.001	0.091 (NS)
Mucin depletion	<0.001	<0.0001	-	<0.0001	0.006*
Lymphoid follicle in LP	<0.001	-	-	<0.0001	0.067 (NS)
Mucosal inflammation	<0.001	<0.05	-	NS	0.001*
Eosinophils	<0.001	-	-	<0.0001	0.008*
Crypt abscess disruption	<0.001	-	0.0111	<0.05	0.439 (NS)
Submucosal lymphoid aggregate	<0.001	-	-	NS	0.064 (NS)
Crypt branching	<0.001	-	0.0000	NS	0.009*
Paneth cell metaplasia	<0.001	-	-	NS	0.025*
Diffuse inflammation	<0.001	<0.05	0.0547	NS	0.159 (NS)
Plasma cells	<0.001	-	0.0000	NS	0.324 (NS)
Villous configuration	<0.001	-	0.0004	<0.01	0.324 (NS)
Crypt atrophy	<0.001	<0.01	-	<0.001	0.002*
Inflammatory polyp	<0.05	-	-	<0.05	0.002*
Submucosal fibrosis	<0.11	-	-	NS	0.049*
Crypt dilation	<0.001	-	0.1134	<0.001	0.674 (NS)
Thickened muscularis	<0.001	-	-	<0.0001	0.005*
Regenerative change	0.01	-	-	<0.05	0.049*
Crypt hyperplasia		-	-	NS	0.000*
Edema lamina propria	<0.001	-	-	NS	0.319 (NS)
Ectatic blood vessels	<0.001	<0.05	-	NS	0.002*
Neuronal hyperplasia	0.27	-	-	NS	-
Submucosal edema	0.19	-	-	NS	0.007*

personal interpretations play a major role even after criteria are set for experts. In our study, the agreement between the observers was around 70%, with disagreement found predominantly in distinguishing UC from indefinite for IBD due to overlapping features.

Hence, the clinician and pathologist must maintain an open dialog when it comes to reaching conclusions regarding the final diagnosis. The acceptable criterion for reliability of a particular microscopic feature was that it had been shown, in more than one valid study, to have a minimum value of 0.4 or a percentage observer agreement of at least 80%. For diagnosis of UC, crypt architectural distortion decreased crypt density, a villous mucosal surface, and transmucosal inflammation emerged as the most reliable. For a diagnosis of CD, the most reliable parameters were granulomas, discontinuous crypt distortion, and discontinuous mucosal inflammation. To diagnose infectious colitis, only normal crypt architecture and superficial mucosal inflammation satisfied the criteria.

Therefore, according to multiple studies, features which distinguish IBD from infective colitis with high reliability are basal plasmacytosis, crypt architecture abnormality such as crypt distortion, branching, and atrophy though some interobserver variability is encountered. The irregular or villous mucosal surface can also be taken as a high reliable diagnostic feature.[20-22]

Fairly reliable features are granuloma for CD, basal lymphoid aggregates, but it can be difficult to distinguish it from normal lymphoid aggregates. However, due to less sample size and limited observers, kappa value is lower and hence the features vary in the diagnosis of CD. Features such as lamina propria chronic inflammation and hypercellularity are considered to be less reliable as it has low reproducibility. Paneth cell metaplasia seen distal to splenic flexure has some interobserver variation and importance may be restricted to long-standing disease.[17,23,24]

These features were in accordance with the present study where the interobserver agreement determined by kappa value was 0.4 signifying fair agreement. Features helpful in identifying activity (active inflammation) of UC are crypt abscess and neutrophilic infiltration in lamina propria and cryptitis. For identifying chronicity, the features are crypt

Table 4: Comparative study of kappa value agreement

Features	Kappa value Theodossi *et al.*	Kappa value present study
Cryptitis	0.47	0.533
Neutrophilic infiltration	0.41	0.419
Epithelioid granuloma	0.41	0.410
Langhans giant cell	0.40	0.000
Neutrophils in lamina	0.40	0.236
Crypt distortion	0.38	0.578
Crypt abscess	0.37	0.452
Loss of crypt architecture	0.36	0.404
Ulceration	0.36	0.269
Mucin depletion	0.34	0.416
Lymphoid follicle in LP	0.33	0.267
Mucosal inflammation	0.33	0.576
Eosinophils	0.32	0.442
Crypt abscess disruption	0.31	-0.129
Submucosal lymphoid aggregate	0.31	0.305
Crypt branching	0.30	0.440
Paneth cell metaplasia	0.29	0.420
Diffuse inflammation	0.29	0.237
Plasma cells	0.27	0.160
Villous configuration	0.26	0.160
Crypt atrophy	0.24	0.524
Inflammatory polyp	0.22	0.203
Submucosal fibrosis	0.20	0.273
Crypt dilation	0.23	0.070
Thickened muscularis	0.17	0.452
Regenerative change	0.17	0.267
Crypt hyperplasia	0.15	0.637
Edema lamina propria	0.15	0.165
Ectatic blood vessels	0.10	0.496
Neuronal hyperplasia	0.14	0.000
Submucosal edema	0.10	0.440

distortion, loss of crypt architecture, crypt branching, crypt atrophy, and mucin depletion.

CONCLUSION

UC was found to be more commonly reported among the IBD cases. To reduce the interobserver variability, salient histological features based on better reproducibility can aid in distinguishing between UC and CD. Limitations faced in our study were inadequate samples which were sent unlabeled or from single numbers of observers and incomplete endoscopic findings.

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Original Article

Comparative Study of Intraperitoneal Instillation of Levobupivacaine (0.25%) Plus Dexmedetomidine Versus Ropivacaine (0.25%) Plus Dexmedetomidine for Post-operative Analgesia in Patients Undergoing Laparoscopic Cholecystectomy

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Abstract

Background: Instillation of intraperitoneal lignocaine, bupivacaine, levobupivacaine, and ropivacaine has been used following laparoscopic gynecological and general surgical procedures to reduce post-operative pain through randomized trials for many years. Hence, the present study was undertaken for assessing and comparing the efficacy of intraperitoneal instillation of levobupivacaine (0.25%) and ropivacaine (0.25%) for post-operative analgesia in patients undergoing laparoscopic cholecystectomy (LC).

Materials and Methods: Ninety patients were enrolled and were randomly divided into three groups of 30 each. Group L: Patients were given 20 ml of 0.5% levobupivacaine plus dexmedetomidine at 1 μg per kg body weight and making total volume 40 ml by adding normal saline (NS), intraperitoneally after gallbladder removal. Group R: Patients were given 20 ml of 0.5% ropivacaine plus dexmedetomidine at 1 μg per kg body weight and making total volume 40ml by adding NS, intraperitoneally after gallbladder removal. Group C: Patients were given 40 ml of NS. Postoperatively, the patients were assessed for pain utilizing visual analog scale (VAS). The results were statistically analyzed using latest software.

Results: The mean VAS score reading was lower in Group L and Group R in comparison to Group C at all the time intervals. The number of patients requiring rescue analgesia was significantly higher in Group C in comparison to other study groups. Among the L group and R group, the number of patients requiring rescue analgesia was lower in Group L in comparison to Group R.

Conclusion: Intraperitoneal instillation of local anesthetic solution in LC provided effective post-operative analgesia, but analgesia provided by levobupivacaine plus dexmedetomidine was significantly better than ropivacaine plus dexmedetomidine.

Key words: Dexmedetomidine, Intraperitoneal instillation, Laparoscopic cholecystectomy, Levobupivacaine, Ropivacaine

INTRODUCTION

Gallstones are hardened deposits of the digestive fluid bile that can form within the gallbladder. Laparoscopic removal is now the procedure of choice when cholecystectomy is indicated. Pain after laparoscopic surgery has a visceral component, as a result of surgical handling and diaphragmatic irritation by dissolved carbon dioxide and a somatic component due to the holes made in the abdominal wall for the trocars.[1-3]

Instillation of intraperitoneal local anesthetics has been used following laparoscopic surgical procedures to reduce postoperative pain through randomized trials for many years. The use of adjuvants with of local anesthetic has been found to reduce post-operative pain following laparoscopic

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cholecystectomy (LC) more effectively. Prolongation of time length of analgesia had been stated when dexmedetomidine was supplemented with local anesthetics in epidural blockades, caudal blocks, subarachnoid blocks, paravertebral blocks, brachial plexus blocks, ulnar nerve blocks, and greater palatine nerve blocks.[4-7] Hence, the present study was undertaken for assessing and comparing the efficacy of intraperitoneal instillation of levobupivacaine (0.25%) plus dexmedetomidine and ropivacaine (0.25%) plus dexmedetomidine for post-operative analgesia in patients undergoing LC.

MATERIALS AND METHODS

It was prospective, randomized, double-blind study comprising of 90 patients of American Society of Anesthesiologists (ASA) Grades I and II of age group 18–65 years of either sex, scheduled to undergo LC surgery under general anesthesia. All patients were randomly divided into three groups of 30 each. A double-blind study was done using sealed envelopes which were randomly selected and opened by an assistant, with instruction to instil the relevant drug. The syringe was labeled with the patient's name and was given to the investigator. An independent observer observed the onset of analgesia.

Group L: Patients were given 20 ml of 0.5% levobupivacaine plus dexmedetomidine at 1 μg/kg and making total volume 40 ml by adding normal saline (NS), intraperitoneally after gallbladder removal.

Group R: Patients were given 20 ml of 0.5% ropivacaine instead of levobupivacaine, keeping volume, concentration, and rest of the things similar.

Group C: Patients were given 40 ml of NS.

Pre-anesthetic check-up including detailed history and physical examination of the patient selected for study was carried out a day before surgery and was recorded as per pro forma. General physical examination along with examination of cardiovascular and respiratory system was done. Respiratory rate, pulse rate, and blood pressure were recorded preoperatively.

Patients were kept nil per orally for at least 6 h before operation. The patients were assured, the procedure was explained and a written informed consent was obtained in patient's vernacular language. Postoperatively, the patients were assessed for pain utilizing visual analog scale (VAS). The patients were enquired about nausea, vomiting, confusion, dizziness, number of times, and dose of rescue analgesia using a predesigned pro forma, which were assessed at 0, 0.5, 1, 2, 4, 6, 8, 12, and 24 h.

Rescue analgesics were inj. diclofenac 75 mg slow intravenously (in 100 ml NS) given when VAS was > 3 and injection dexmedetomidine 1 μg/kg intravenously (in 100 ml NS) for any patient who still demanded more analgesia. The data were systematically collected, compiled, and statistically analyzed using latest software (IBM SPSS 21 version). The results were compared to the previous studies.

RESULTS

With respect to the distribution of mean age, sex, difference in occupation, mean weight, ASA grading, and duration of surgery, the difference in the three groups was statistically non-significant ($P > 0.05$); hence, the three groups were comparable with respect to all these parameters [Table 1].

The mean pre-operative systolic blood pressure in Group L, Group R, and Group C was 112.72 ± 10.52 mmHg, 114.23 ± 7.22 mmHg, and 118.51 ± 9.56 mmHg, respectively. The mean systolic blood pressure at 1 h post-operative in Group L, Group R, and Group C was 121.19 ± 9.66 mmHg, 122.29 ± 9.71 mmHg, and 126.86 ± 7.85 mmHg, respectively. The mean pre-operative diastolic blood pressure in Group L, Group R, and Group C was 72.72 ± 5.78 mmHg, 70.12 ± 5.24 mmHg, and 68.56 ± 5.12 mmHg, respectively. The mean diastolic blood pressure at post-operative 1 hour in Group L, Group R, and Group C was 72.91 ± 10.56 mmHg, 73.21 ± 7.94 mmHg, and 80.88 ± 7.27 mmHg, respectively. The mean pre-operative heart rate was 78.42 ± 6.61 per minute in Group L, 76.56 ± 7.07 per minute in Group R, and 77.95 ± 7.45 per minute in Group C. The mean post-operative SpO_2 at baseline was 99.88 ± 0.09% in Group L, 99.71 ± 0.32 % in Group R, and 99.49 ± 0.15% in Group

Table 1: Demographic profile

Variables	Group L (Mean±SD)	Group R (Mean±SD)	Group C (Mean±SD)
Age group (years)	41.7±10.3	43.8±13.8	42.8±14.1
Weight (KG)	67.15±6.81	69.27±7.28	67.64±7.29
Mean duration of surgery (minutes)	60.44±5.61	61.05±4.55	61.67±5.28
Gender			
Male	5	4	7
Female	25	26	23

Table 2: Mean VAS score

Time (h)	Group L		Group R		Group C		Group L versus Group R	Group R versus Group C	Group L versus Group C
	Mean	SD	Mean	SD	Mean	SD			
0	1.53	0.51	1.73	0.45	2.19	0.65	0.18	0.02 (S)	0.01 (S)
0.5	1.87	0.57	2.07	0.69	2.32	0.79	0.19	0.03 (S)	0.00 (S)
1.0	2.23	0.68	2.13	0.78	4.46	1.01	0.75	0.01 (S)	0.02 (S)
2.0	2.60	0.77	2.83	0.65	2.91	1.02	0.19	0.00 (S)	0.01 (S)
4.0	2.47	0.78	4.37	0.78	2.75	1.12	0.02(S)	0.03 (S)	0.01 (S)
6.0	3.74	0.93	2.85	1.25	2.18	1.28	0.02(S)	0.02 (S)	0.01 (S)
8.0	2.57	0.93	2.68	0.87	3.92	1.50	0.92	0.01 (S)	0.00 (S)
12.0	1.94	0.76	2.87	0.87	2.03	0.91	0.42	0.02 (S)	0.01 (S)
24.0	1.10	0.71	1.23	0.77	1.26	0.68	0.77	0.81	0.44

VAS: Visual analog scale

Table 3: Number of patients requiring rescue analgesia

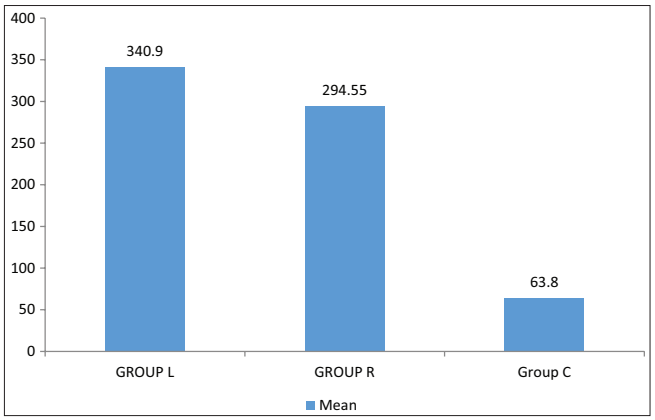
Time (h)	Group L		Group R		Group C	
	n	%	*n*	%	*n*	%
0	0	0	0	0	0	0
0.5	0	0	2	6.67	10	33.33
1.0	1	3.33	2	6.67	18	60
2.0	2	6.67	3	10	5	16.67
4.0	2	6.67	13	43.33	6	23.33
6.0	12	40	9	30	5	36.67
8.0	5	16.67	6	20	10	33.33
12.0	0	0	1	3.33	4	13.33
24.0	0	0	0	0	0	0

C, respectively. The mean post-operative readings of all the above-mentioned parameters were recorded in all the groups at 0, 0.5, 1, 2, 4, 6, 8, 12, and 24 h intervals. Zero time was the time of end of surgery.

The difference in the three groups was statistically non-significant ($P > 0.05$), with respect to mean pre-operative readings as well as intraoperative and post-operative readings of mean systolic blood pressure, diastolic blood pressure, heart rate, and SpO_2 at various intervals; hence, the three groups were comparable with respect to all these parameters.

The mean VAS scores readings in all the three groups were noted at 0, 0.5, 1, 2, 4, 6, 8, 12, and 24 h. Zero time was the time of end of surgery. The mean VAS score reading was lower in Group L and Group R in comparison to Group C at all the time intervals. The mean VAS score reading at 4 h in Group L and in Group R was 2.47 ± 0.78 and 4.37 ± 0.78, respectively. The mean VAS score for Group L was statistically significantly lower in comparison to the mean VAS score for Group R ($P < 0.05$) at 4 h postoperatively [Table 2].

The number of patients requiring rescue analgesia was significantly higher in Group C (58) in comparison to other study groups. Among Group L and Group R, the number of patients requiring rescue analgesia was lower



Graph 1: Mean time to first analgesic requirement

in Group L (22) in comparison to Group R (36) [Table 3]. While comparing between Group L and Group R, it was found that mean time to first analgesic requirement among Group L (340.90 ± 119.12 min) was significantly higher in comparison to Group R (294.55 ± 123.11 min.). However, mean time of first analgesic requirement among Group C (63.8 ± 135.4 min) patients was significantly lower in comparison to Group L and Group R [Table 4]. Complications were noted in <10% of the patients in both the groups. Nausea and vomiting were seen in two patients in Group L, three patients of Group R, and two patients in Group B. All the readings were comparable and the difference was found to be non-significant in the two groups ($P > 0.05$).

DISCUSSION

Reduced post-operative pain is one of the biggest advantages of laparoscopy compared with open surgery. Pain can increase morbidity and is the primary reason for prolonged hospitalization after LC. Patients frequently complain of back, shoulder region pains, and discomfort of port site incisions. Shoulder and sub-diaphragmatic pain occurs in about 12–60% of patients. Peak of pain intensity is during the first few post-operative hours and usually

Table 4: Mean time to first analgesic requirement

Time (min)	Group L	Group R	Group C	Group L versus Group R	Group R versus Group C	Group L versus Group C
Mean	340.90±119.12	294.55±123.11	63.8±135.4	0.00 (S)	0.000 (S)	0.001 (S)

declines after 2 or 3 days.[8] The etiology of pain after LC is multifactorial. One cause of pain after laparoscopy is the peritoneal insufflation with CO_2 and phrenic nerve irritation in the peritoneal cavity. In fact, the dissolution of CO_2 gas causes peritoneal irritation and phrenic nerve damage in LC. Additional contributing factors include sociocultural status and individual factors.[9-12]

Effective pain control is essential for optimum care of patients in the post-operative period. However, despite advances in the knowledge of pathophysiology of pain, the pharmacology of analgesics, and the development of more effective techniques, patients continue to experience considerable pain after surgery. If we can provide post-operative analgesia in a simple and inexpensive manner, it may go a long way in alleviation of pain and suffering.[9-12] The improved understanding of origin of abdominal and shoulder pain after laparoscopic procedures led to the use of intraperitoneal and port site instillation of local anesthetic to reduce post-operative pain. The ease of use and safety of local anesthetics are well recognized and collectively they serve as one of the most important classes of drugs in perioperative care. The main advantage of local anesthetic agents is that they do not have the adverse effects of systemically administered opioids, such as post-operative sedation, nausea, gastrointestinal paralysis, and respiratory suppression, and they act directly on the tissue that they are applied to. Local anesthetics are commonly administered in abdominal surgery by skin infiltration or epidural administration, blocking somatic afferents and providing significant benefits in reducing post-operative pain, and improving recovery.[9-12]

The present study was conducted to compare the post-operative analgesic effect of 0.25% levobupivacaine plus dexmedetomidine with 0.25% ropivacaine plus dexmedetomidine with NS (control group) following intraperitoneal instillation in LC.

The aim was accomplished by carrying out the study in 90 patients randomly divided into three groups of 30 each in the age group of 18–65 years, of either sex, of ASA Grades I and II selected for LC after proper pre-anesthetic check-up. Patients in Group L received 40 ml of 0.25% levobupivacaine plus dexmedetomidine (at 1 μg/kg) while patients in Group R received 40 ml of 0.25% ropivacaine plus dexmedetomidine (at 1 μg/Kg). Group C included patients that received 40 ml of NS. Three groups were compared with respect to hemodynamics, effectiveness, and duration of post-operative analgesia with the help of visual linear analog scale, side effects, and complications. Then, data were compiled, tabulated, and statistically analyzed.

With regard to mean age, sex ratio, occupation, weight, distribution as per ASA grading, duration of surgery, mean intraoperative and post-operative: Systolic B.P., diastolic B.P., heart rate, and SPO_2, the differences in all the three groups were statistically non-significant ($P > 0.05$). Hence, the three groups were comparable with respect to the above variables.

The mean VAS score reading was lower in Group L and Group R in comparison to Group C at all the time intervals. The mean VAS score reading at 4 h in Group L and in Group R was 2.47 ± 0.78 and 4.37 ± 0.78, respectively. At 4 h postoperatively, the mean VAS readings for Group L were statistically significantly lower in comparison to the mean VAS reading for Group R ($P < 0.05$).

The number of patients requiring rescue analgesia was significantly higher in the control group in comparison to other study groups. Among L group and R group, the number of patients requiring rescue analgesia was lower in Group L in comparison to Group R. While comparing between Group L and Group R, it was found that mean time to first analgesic requirement among Group L was significantly higher in comparison to Group R. However, mean time of first analgesic requirement among Group C patients was significantly lower in comparison to Group L and Group R.

Complications were noted in <10% of the patients in both the groups. Nausea and vomiting were seen in two patients in Group L, three patients of Group R, and two patients in Group B. All the readings were comparable and the difference was found to be non-significant in the two groups ($P > 0.05$).

In a study conducted by Beder *et al.*, they compared adding dexmedetomidine to intraperitoneal levobupivacaine in patients undergoing LC. Group C patients received intraperitoneal 40 ml NS as controlled group. Group L was given 40 ml 0.25% levobupivacaine. Group LD received 40 ml 0.25% levobupivacaine + dexmedetomidine 1 μg/kg. Post-operative VAS at different time intervals was significantly lower, time to the first demand of painkiller was longer (30.2 ± 14.4, 45.9 ± 20.1, and 56.5 ± 13.2 min),

and total painkiller consumption was lower (203.5 ± 42.9, 117.8 ± 63.7, and 46.3 ± 41.3 mg) in Group LD than Group L than Group C.[13]

In a study conducted by Bindra *et al.*, they assessed efficacy of pre-emptive analgesia with intraperitoneal instillation of ropivacaine in LC. In Group A, patients received 3 mg/kg of ropivacaine intraperitoneal instillation in 100 ml NS before creation of pneumoperitoneum and in Group B patients received 3 mg/kg of ropivacaine intraperitoneal instillation in 100 ml NS after completion of surgery. Significantly lower visual analog scores for pain were observed in Group A versus Group B. Group A reported significantly lower pain at 0 h ($P < 0.001$), 1 h ($P = 0.003$), 3 h ($P = 0.006$), 6 h ($P = 0.003$), and 12 h ($P = 0.001$) postoperatively, but the difference was not statistically significant after 12 h. The mean time of first rescue analgesic was 472.8 ± 26.32 min in Group A, as compared with 189 ± 11.87 min in Group B. A significantly lower analgesic requirement was observed in Group A versus Group B throughout the entire study period ($P < 0.05$).[14]

In a study conducted by Sharan *et al.*, they compared intraperitoneal instillation of bupivacaine and ropivacaine for post-operative analgesia in patients undergoing LC. Group A patients received 20 mL of 0.5% bupivacaine intraperitoneally after cholecystectomy and Group B patients received 20 mL of 0.5% ropivacaine intraperitoneally after cholecystectomy. The VAS score was significantly lower in Group B. Rescue analgesic requirement was also less in Group B. The instillation of bupivacaine and ropivacaine intraperitoneally was an effective method of post-operative pain relief in LC.[15]

In a study conducted by Karaman *et al.*, they assessed the effects of pre-incisional infiltration and intraperitoneal levobupivacaine 0.25% on pain control in patients undergoing LC. They reported that there were no intraoperative and post-operative complications related to levobupivacaine use.[16]

Our results were comparable to results obtained by above-mentioned studies.

CONCLUSION

Intraperitoneal instillation of local anesthetic solution in LC provides effective post-operative analgesia, and analgesia provided by levobupivacaine plus dexmedetomidine is significantly better than ropivacaine plus dexmedetomidine.

Limitation

The study population as calculated at the start of our project was based on the previous studies. We could have drawn that more positive results had the power of study been increased by inclusion of more number of patients but were avoided as it would have increased the inclusion of population at risk.

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Original Article

A Clinical Study of Blunt Trauma Abdomen in a Tertiary Care Hospital of Uttarakhand

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Abstract

Background: Blunt abdominal injuries are met more often nowadays due to increased industrialization and a greater number of vehicles, and is the third most common form of injury in road traffic accidents (RTAs) after orthopedic injuries and head injuries. Blunt injury to the abdomen can also occur as a result of fall from height, assault with blunt object and sports injuries, etc. Blunt trauma abdomen is seen in increasing number in the emergency department and therefore, the early diagnosis and treatment are very important and crucial for patients.

Methods: The study was carried out from January 2018 to December 2019. A total of 100 patients were studied. After detailed clinical history, physical examination various investigations such as complete blood count, X-rays, ultrasound of the abdomen, and computed tomography scan of the abdomen were done to complete the diagnosis. Then, data were statically analyzed.

Results: In our study, male patients were commonly affected (73%). The younger population between the age group of 18 and 40 years was predominantly affected (73%). The common mode of injury was RTAs (62%). The organ that was found to be most commonly injured in our study was the liver (27%) than spleen (22%). About 59% patients were managed conservatively while 41% were operated. The most common cause of death was cardiorespiratory failure followed by septicemia.

Conclusions: This research article shows that blunt injury abdomen is a major cause of morbidity and mortality in young age patients with RTA being the most common cause. Patients that are received in the emergency department should be given immediate attention and a quick and thorough evaluation of the patient must be done. Early diagnosis reduces the mortality rates and plays a major role in good outcome and lead to successful treatment in these patients.

Key words: Blunt trauma abdomen, Trauma, Liver, Spleen, Early diagnosis, Road traffic accidents

INTRODUCTION

Abdominal trauma continues to account for a large number of trauma-related injuries and deaths. Abdominal trauma due to a blunt force is a common presentation in the emergency room and is the leading cause of mortality and morbidity in children and adults.[1] Blunt injury to the abdomen can also occur as a result of fall from height, sports injuries, assault with blunt objects, industrial mishaps, fall from riding bicycle, and bomb blasts.[2] World over injury is the seventh cause of death rate and abdomen is the third most common injured organ and the injury can be either blunt or penetrating. Blunt abdominal trauma is one of the most common injuries among various injuries caused due to road traffic accidents (RTAs).[3] Rapid resuscitation is necessary to save the unstable but salvageable patient with abdominal trauma.[4] Due to the delay in diagnosis and inadequate treatment of the abdominal injuries, most of the cases are fatal. Hence, accurate diagnosis and avoidance of needless surgery are an important goal of evaluation.[5] Surgery is required in about 25% of the civilians who suffer abdominal injury.[6] Motor vehicle accidents account for 75% of cases of blunt abdominal trauma. Unrecognized intra-abdominal injury remains distressingly frequent cause for preventable death in a patient with blunt injury abdomen.[7] Blunt injuries are often missed as the clinical signs are less obvious. Blunt abdominal injuries can damage

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the liver, spleen, pancreas, bowel, and intestines and may result in bleeding or contusions. Some of the risk factors determining the mortality rates are sex, age, and the interval between the time of injury and management. In view of increasing number of vehicles and consequently RTAs, this research has been chosen to study the cases of blunt abdominal trauma with the aim, to evaluate the incidence of blunt injury abdomen, clinical presentation, morbidity, and mortality in tertiary care center in Uttarakhand.

MATERIALS AND METHODS

This study was conducted in the Department of Surgery, Doon Government Medical College, Dehradun, Uttarakhand. The duration of this study was from January 2018 to December 2019. This study was conducted on the 100 subjects who sustained abdominal injury. Patients who sustained blunt abdominal trauma were admitted and managed in hospital. After physical examination, detailed clinical history, X-rays, and laboratory tests, ultrasonography was done to arrive at the diagnosis. Demographic data collected including the age, sex, occupation, and nature and time of accident leading to the injury.

Inclusion Criteria

Patient age >18 years, admitted with the history of blunt abdominal trauma, RTA with suspected blunt abdominal injury, findings such as diagnostic peritoneal lavage or hemoperitoneum on Focussed Assessment with Sonography for Trauma (FAST), blunt trauma abdomen in sports injury, uncontrolled shock or hemorrhage, history of accidental fall from height, story of fall of the heavy object over the abdomen, undergoing surgical intervention, or treated by non-operative management were included in the study.

Exclusion Criteria

Patients with penetrating, gunshot injuries, stab, and patients of the pediatric age group were excluded from the study.

Statistical Analysis

The collected data were numerically coded and entered into Microsoft Excel 2010 and statistically analyzed. Socio-demographic pattern, mode of injury, and organs involved in patients who sustained blunt injury abdomen variables data were analyzed using descriptive statistics such as frequencies and percentages assessment.

RESULTS

In the current study, the total number of patients who had blunt injuries to abdominal organs was 100. Our study showed, maximum patients were male 73 (73%) and 27 (27%) were female. Male to female ratio was 3:1, and maximum of cases was in the 26–40 age group (54%), followed by 41–60 years group (23%), mean age was 39 years [Table 1].

From Table 2 in the study, author found the common cause of blunt trauma to the abdomen was RTA, i.e., 62 (62%) and the second common cause was fall from height (22%). Other causes were hit by blunt objects and assaults, i.e., 16 (16%).

The most common clinical presentation was pain abdomen (87%) followed by abdominal guarding and rigidity (80% cases) then distension (55%), shock (34%), and hematuria (4%) [Table 3].

Author found from Table 4, liver was the most common organ involved in 27 (27%) cases and spleen was the second most common organ injured in 22 (22%) cases. Small bowel and retro peritoneum were injured in 13%, 13% of cases. Injury to the kidney was in 10% cases, large bowel 6% cases, mesentery 4% cases, and diaphragm and bladder in each 2% cases, while pancreas was injured in 1% case only.

Out of 100 cases, 59 (59%) were managed conservatively and 41 (41%) were managed surgically [Table 5].

Table 1: Sex- and age-wise distribution

Sex	*n*=100	*n* %
Males	73	73
Females	27	27
Age group (years)		
18–25 years age group	19	19
26–40 years age group	54	54
41–60 years age group	23	23
>61 years age group	4	4

Table 2: Causes of blunt trauma abdomen

Causes	*n*=100	*n* %
Road traffi c accidents	62	62
Fall from height	22	22
Assault/injury with blunt objects	16	16
Total	100	100

Table 3: Clinical presentation

Presentation	No. of cases	Percentage
Abdominal pain	87	87
Abdominal distension	55	55
Hematuria	4	4
Abdominal guarding and rigidity	80	80
Shock	34	34

In this study, cardiorespiratory failure was the most common cause of death (5 cases). Three died of septicemia and another two died of shock and one from renal failure [Table 6].

DISCUSSION

Our study showed that maximum patients were male 73% in which the maximum number of cases was in the third and fourth decades of life (18–40 years). Most of the cases were in the first four decades of life. This indicates trauma is more common in young people. Maximum range was from 26 to 40 years. Average age was 34 years. Our study is comparable to study by Curie and Watne.[8] which showed maximum number of cases in the third decade (35%) ranging from 15 to 72 years with mean age of 39 years. Similar findings were made by Allen and Curry which showed 28% cases between 20 and 29 years of age.[9] In our study, male to female ratio was 3:1, was compared to other studies such as Tripathi *et al.*[10] reported a ratio of 4.4:1, the reason being the demographic profile of the Uttarakhand state.

Table 4: Organ involved in blunt trauma abdomen

Organs involved	*n*=100	*n* %
Liver	27	27
Spleen	22	22
Small intestine	13	19
Retroperitoneum	13	13
Kidney	10	10
Large intestine	6	6
Mesentery	4	4
Diaphragm	2	2
Bladder	2	2
Pancreas	1	1
Total	100	100

Table 5: Treatment opted

Organ	Total cases	Surgery	Conservative
Liver	27	2	25
Spleen	22	12	10
Kidney	10	0	10
Hollow viscera	19	19	0
Retro peritoneum	13	0	13
Mesentery	4	4	0
Diaphragm	2	2	0
Urinary bladder	2	2	0
Pancreas	1	0	1
Total	100	41	59

Table 6: Causes of mortality

Mortality	Total cases
Shock	2
Septicemia	3
Renal failure	1
Cardio/respiratory failure	5

The most common cause of blunt injury abdomen was RTAs (62%) which is comparable to most other studies. Mohapatra *et al.*[11] also reported that 62% cases of blunt abdominal injuries were due to RTA. Another study by Curie and Watne.[8] also reported that 58.6% cases of blunt trauma to abdomen were due to RTAs. As motor vehicle collisions and other RTAs are the common causes of abdominal trauma and can occur at any age.[6] Seat belts can reduce head and chest injuries but pose a threat to the internal organs such as pancreas and intestines. The second common cause was fall from height (22%) causing blunt trauma abdomen. Other causes were hit by blunt objects and assaults, i.e., 16 (16%) which comparable to most other studies by Mohapatra *et al.* and by Curie and Watne.[8,11] In present study, assault/injury with blunt object 11 cases (22.9%) and fall from height 1 cases (2.0%). Handle bar strikes while cycling or at play are another threat to children.[12] Sports injuries and fall from heights can injure the spleen and liver.

The location and severity of the blow and the position of the victim during injury, determine the combination of organs affected.[13] The reason why abdominal injuries are life-threatening, is that the organs in the retroperitoneal space can bleed profusely and some time resulting in hypovolemic shock before the patient got admission in the emergency department. The size and location of the liver make it more vulnerable and about 5% of the patients with abdominal trauma present with liver injury.[14] The risk of serious shock is more with the liver due to its profuse blood supply and capacity. Lacerations, contusions, and hematoma are common in the liver and it may even result in exsanguinations which necessitates an emergency surgery.[15] In the present study author found 34% cases of shock as clinical presentation in the patient reported to the emergency as case of blunt trauma abdomen. Author found in the study that liver was the most common organ involved in 27 (27%) cases and spleen was the second most common organ injured in 22 (22%) cases. Deaths are occurring every day, in many different settings, from injuries to the upper abdomen and lower rib cage that produce damage to the liver, spleen, and pancreas.[16] A study by Rutledge *et al.* found spleen to be most commonly injured than liver.[17,18] Small bowel and retro peritoneum were injured in 13%, 13% of cases in our study. In our study, injury to small intestine was less compared to a study done by Allen and Curry[6] which showed 35.3% cases.

The evaluation of any patient with trauma begins with A, B, and C (airway, breathing, and circulation).[19] If the patient is thermodynamically stable, then diagnostic investigations such as computed tomography (CT) scan

can be performed to assess abdominal and pelvic injuries. USG or extended FAST can be performed in unstable patients.[20] Once the primary survey (A, B, and C) is clear, hypovolemic patients require fluid resuscitation or blood transfusion. If the patient's clinical signs worsen immediate laparotomy is done. Out of 100 cases, 59% were managed conservatively, Davis *et al.* reported that 24.7% of cases had splenic injuries, out of which 10.7% were operated and 14% were managed conservatively.[21] In this study, liver injuries were present in 27% cases. In the contrary of this study, by Davis *et al.*, which showed 16.47% of liver injuries, of which 14% underwent laparotomy and suturing was done in all cases.[21] Another study by Curie and Watne. showed 20.6% of liver injuries.[8] The common surgeries performed in patients included splenectomy, primary closure of perforation and resection, and anastomosis. Similar surgeries were required in patients of blunt trauma abdomen as reported by Siddique *et al.*[22] and 41(41%) were managed surgically. Our study is comparable to study done by Davis *et al.* which reported 24.7% of cases had splenic injuries, out of which 10.7% were operated and 14% were managed conservatively.[5] Out of 100 cases in our study, 44% were managed surgically and 56% were managed conservatively. Our reports are comparable to Mohapatra *et al.*[11] who reported 39% laparotomy rates in their series. A study by Rutledge *et al.*[22] also reported that incidence of non-operative management in blunt abdominal trauma, who sustained both hepatic and splenic injuries was 48%. Conservative management depends on the extent of the injury and the hemodynamic stability of the patient. Hemorrhage control can be done by angiography assisted embolization and patients show a good prognosis.

If the abdominal injuries are not promptly treated on time or misdiagnosed, the prognosis can be worse. The associated complications can be sepsis, delayed splenic rupture, cardiorespiratory failure, shock, and death. In this study, cardiorespiratory failure was the most common cause of death. Three died of Sepicimia and another two died of shock and one from renal failure, which is comparable to a study by Jolly *et al.*[23] which showed wound infection in 14% of the cases. Another study by Davis *et al.* showed wound infection as a complication in 15% of the cases. [5] These results are again comparable to another study by Jolly *et al.*[23] which showed 10% mortality in their study with septicemic shock the most common cause of death. Another study by Davis *et al.*[5] showed 15% mortality with septicemia the most common cause of death.

CONCLUSION

Blunt injury abdomen forms significant load in our society. Increase in blunt trauma abdomen is due to excessive use of motor vehicles, in which most common age group is 21–40 years. Predominantly males are affected in large proportions. Most common mode of injury is RTAs. In this study the liver was found to be the most common organ affected in blunt trauma abdomen. It poses a diagnostic and therapeutic confusion for the attending surgeon due to widespread range of the clinical manifestations ranging from no early physical findings to progression to shock. Early diagnosis of the extent of injury by appropriate imaging (X-ray, ultrasound, or CT abdomen) and appropriate interventions, blood transfusion, and operative interventions is crucial in treatment and management. Blunt injury abdomen is usually less obvious. Clinical presentation is varied, something confusing. Hence, the trauma surgeon should rely on his physical findings in association with the use of these modalities. However, solid organ injuries are sometimes difficult to diagnose due to restricted use of modern amenities such as CT scan in India. Prompt and early diagnosis is mandatory to control the morbidity and mortality rates. Hemodynamically stable patients with solid organ injury, conservative management can be tried, and non-operative management is associated with less complication. The outcome is affected by associated injuries such as head injury, thoracic injuries, and fractures. From our study, we conclude that use of appropriate investigation in early diagnosis and clinical examination forms the key in the management of blunt abdominal trauma and in hemodynamically stable patients with solid organ injury, non-operative management or conservative management can be tried and it is associated with less complication and morbidity.

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Original Article

Comparative Study of Tamsulosin versus Placebo in the Management of Lower Ureteric Stone

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Abstract

Aim: This study aims to compare the effect of tamsulosin versus placebo in the management of lower ureteric stones.

Material and Methods: A total of 100 diagnosed patients of lower ureteric stone from the period of June 1, 2018, to May 31, 2019 (12 months), were taken for the study. The study group was divided into three groups, Group A taken tamsulosin 0.4 mg + steroids (deflozacort 6 mg), Group B taken tamsulosin 0.4 mg + dicyclomine 20 mg, and Group C dicyclomine 20 mg alone. The results of three group were compared by expulsion rate and expulsion time of stones. Chi-square test was used for calculating the effect.

Results: The mean age of Group A was 38.46 ± 10.68 years, Group B was 33.87 ± 9.62 years, and in Group C 32.94 ± 7.07 years. There was no significant relation between ages in stone expulsion. The mean calculus size in Group A was 5.93 ± 2.12 mm, Group B was 6.00 ± 2.03 mm, and Group C was 5.00 ± 2.01 mm. $P = 0.784$ was not statistically significant. In Group A, 40% of stones were on the left side and 29.7% on the right side, in Group B, 20% of stones were on the left side and 40% on the right side, and in Group C, 40% of stones were on the left side and 30.7% on the right side. $P = 0.126$ is not statistically significant. The mean time taken for stone expulsion in Group A was 5.39 ± 1.94 days, Group B was 4.75 ± 2.03 days, and Group C was 6.76 ± 1.90 days. $P = 0.006$ (<0.05) is highly statistically significant. Hence, in the present study, in Group A, 29 patients out of 33 patients, in Group B, 28 patients out of 33, and in Group C, 22 patients out of 34 patients, the stone was expelled out. $P = 0.040$ (<0.05) is highly statistically significant. There was no statistically significant difference which was found between the three groups in age, size, and side of stone.

Conclusion: The results of this study have shown a potentially important role of tamsulosin for conservative expulsive therapy of distal ureteral stones, broadening pharmacological indications rather than endoscopic treatments for the resolution of this disease. Obviously, further studies with larger number of cases are necessary to validate these promising and statistically significant results. The comparison with minimally invasive procedures in terms of cost and efficacy was useful, highlighting a predominant role of first-line pharmacological treatment, which can be easily be provided in an outpatient setting and not only at large, technologically advanced, centers. The drug tamsulosin proved to be safe and effective as demonstr ated by the low incidence of side effects and the increased stone expulsion rate and reduced expulsion time. Moreover, medical expulsive therapy with tamsulosin considerably decreased the analgesic use, thereby reducing additional need for pain relief and served as an effective bridge between watch-and-wait management and surgical intervention.

Key words: Patients, Therapy, Ureteric stone

INTRODUCTION

The incidence of nephrolithiasis in industrialized country is increasing. Ind eed, the number of ER admission for ureteral colic increased 55% from 1994 to 2000.[1] Most visit to the emergency room are secondary to distal ureteral stones smaller than 5 mm, which would be ideal candidates for the conservative management or stone expulsion therapy. The clinical management of distal ureter stone has benefited from an increased understanding of the molecular aspects of ureteral muscle. Identification of alpha-1a-adrenergic receptor as the specific subtype responsible for the muscular tone and contraction of the ureter directed the evaluation of a new line of pharmacological interventions aimed at promoting stone passage.[2]

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Pain is the main cause for hospital admissions and the site, size, and other renal factors are the key to determine further management. Smaller stones are liable to pass spontaneously with stones <5 mm having 68% chance of passing without treatment.[3]

The transport of stones from the kidney into the bladder and their movement through the ureter is accompanied by three basic factors;

1. Spasm of smooth muscles
2. Submucosal edema and
3. Associated pain.

Determining factors for spontaneous passage of stones are their size, their configuration, and the smooth muscle activity of the ureters. In the transport of stones, the greatest obstacle is usually the terminal part of the ureters in the intramural "detrusor tunnel." Usually, stones are 4 mm or smaller pass spontaneously, although with discomfort to the patient. Ureteral calculi of any size are often associated with renal obstruction, and care must be taken to prevent irreversible damage to the kidney whether choosing expectant or active management. In the past 20 years, the introduction of new, minimally invasive procedures such as percutaneous nephrolithotripsy, flexible ureteroscopy, extracorporeal shock wave lithotripsy, ureterorenoscopy, and laser for ureteral stones have considerably changed the historical therapy for this disease with a substantial decrease in morbidity. Pharmacologically, it is possible to treat the causes of ureteric stone retention such as edema, ureteral spasm, and infection, favoring its expulsion using drugs such as steroids, calcium antagonists, and glyceryl trinitrate. At present, alpha-1-adrenergic receptor antagonists represent the treatment of choice for lower urinary tract symptoms as shown in many randomized controlled clinical trials as well as in several case studies.[2] Studies have also revealed that alpha-1-adrenergic receptors in ureteral smooth muscle cells are significantly higher than other adrenergic receptors. Alpha-1-adrenergic antagonists have proved to inhibit basal tone of the ureters, their peristaltic frequency, and the ureteral contractions even in the intramural tract. The study is taken up to assess the possible role of the combined alpha-1a and alpha-1d selective antagonist tamsulosin for facilitating the spontaneous expulsion of distal ureteral stones.[2,4-11]

MATERIALS AND METHODS

The study was a prospective study and conducted in the Department of Surgery, Shyam Shah Medical College and Associated Sanjay Gandhi Memorial Hospital Rewa (Madhya Pradesh) from the period of June 1, 2018, to May 31, 2019 (12 months).

Inclusion Criteria

The following criteria were included in the study:

1. Acute ureteric colic patients of all age and gender groups
2. Suspected and diagnosed patients of lower ureteric stones
3. Ureteric stones size <10 mm in lower ureter.

Exclusion Criteria

The following criteria were excluded from the study:

1. Patients with ureteral stones associated with urinary tract infection (UTI), severe and refractory pain, severe hydronephrosis, and acute or chronic renal failure
2. Patients with ureteral stones associated with a history of ureteral surgery, ureteral procedure, or urinary tract anomalies
3. Patients with ureteral stones associated with renal calculus, vesical calculus, BPH, bladder outlet obstruction, urethral calculus, and ureteric calculi size more than 10 mm
4. All ureteral stones in upper and mid ureter
5. Pregnancy associated with ureteric calculi.

All patients were received and evaluated on outpatient basis and underwent a standard evaluation by abdominal renal ultrasonography.

RESULTS

The mean age of Group A was 38.46 ± 10.68 years, Group B was 33.87 ± 9.62 years, and in Group C 32.94 ± 7.07 years. There was no significant relation between ages in stone expulsion. The mean calculus size in Group A was 5.93 ± 2.12 mm, Group B was 6.00 ± 2.03 mm, and Group C was 5.00 ± 2.01 mm. $P = 0.784$ was not statistically significant. In Group A, 40% of stones were on the left side and 29.7% on the right side, in Group B, 20% of stones were on the left side and 40% on the right side, and in Group C, 40% of stones were on the left side and 30.7% on the right side. $P = 0.126$ is not statistically significant. The mean time taken for stone expulsion in Group A was 5.39 ± 1.94 days, Group B was 4.75 ± 2.03 days, and Group C was 6.76 ± 1.90 days. $P = 0.006$ (<0.05) is highly statistically significant. Hence, in the present study, in Group A, 29 patients out of 33 patients, in Group B, 28 patients out of 33, and in Group C, 22 patients out of 34 patients, the stone was expelled out. *P* value was 0.040 (<0.05) is highly statistically significant. There was no statistically significant difference which was found between the three groups in age, size, and side of stone [Tables 1-3].[12,13-16]

DISCUSSION

Ureteric stones are the third most common condition of urinary system exceeded only by the UTI and pathological

Table 1: Tamsulosin arms in randomized studies on treatment of ureteral stone

Study	Mean stone size (mm)	Expulsion rate (%)	Expulsion time	Pharmacologic regime: (tamsulosin 0.4 mg plus)	Follow-up	Side effect
Cervenakov *et al*.[14]	5.8	80.1	3.9 days	Tramadol (50 mg), diazepam (5 mg), veral (150 mg), yellow (120 mg)	1 week	Nil
Dellabella *et al*.[16]	7.2	90	4.4 days	Deflazacort (30 mg), cotrimoxazole (640 mg), diclofenac (75 mg on demand)	4 weeks	Nil
Autorino *et al*.[17]	6.1	88	4.8 days	Tamsulosin 0.4 mg versus control	2 weeks	Low
Porpiglia *et al*.[18]	5.4	60	7.7 days	Deflazacort (30 mg), diclofenac (75 mg on demand)	4 weeks	2
Yilmaz *et al*.[19]	6.0	79.3	6.3 days	Diclofenac (75 mg) on demand	4 weeks	Nil
Present study						
Group A	5.93	87.87	5.39 days	Tamsulosin (0.4 mg), deflazacort 6 mg), diclofenac (50 mg) on demand	3 weeks	2
Group B	6.0	84.84	4.75 days	Tamsulosin (0.4 mg), dicyclomine (20 mg), diclofenac (50 mg) on demand	3 weeks	3

Table 2: Expulsion rate

Expulsion	Group A (*n*=33)	Group B (*n*=33)	Group C (*n*=34)	*P*-value
Yes	29	28	22	0.040
No	4	5	12	
Total	33	33	34	
Rate	87.87	84.84	64%	

χ^2=6.435, *P*=0.040 (*P*<0.05), HS

Table 3: Expulsion time

Expulsion	Group	*n*	Mean time of stone expulsion (days)	Std. deviation	*P*-value
Yes	A	33	5.39	1.94	*P*=0.006
	B	33	4.75	2.03	
	C	34	6.76	1.90	
Total		100			

condition of the prostate. Ureteric stones have affected humans since the earliest record of civilization. The etiology of stones remains speculative. Even after extensive research on various aspect, no definite etiological factor is known. Recurrence and its management are still a great problem, although in the past 20 years due to the development of newer method of treatment for urinary stones, it has now become possible to treat urinary stones endoscopically. Medication is available that can help to prevent recurrence of calculi to some extent. The urine routine and microscopy examination and urine culture give the information regarding the urinary tract infection in causation of calculus formation.

In the present study, the incidence of radiologically confirmed cases of ureteric stones was 6.83% from the total patients reporting in surgical outpatient department. The incidence of ureteric stones observed by Singh *et al*.[17] was 11.4%; Shakya *et al*.[18] from Rewa was 2.26%, and Hughes[19] was 6–9%. Moreover, these results were similar to the present study.

Several authors have reported that 30–50 years of age period were maximum incidence of ureteric stones occur. In a study by Shakhssalim *et al*.,[5] the mean age of ureteric stone at presentation was 41.5 years ± 16.3 and peak incidence range was between 55 and 65 years. In the present study, the most common age group affected was between 30 and 40 years. Shakhssalim *et al*.[5] reported in his study that male-to-female ratio was 1.38 (male: 58% and female: 42%). In the present study, male-to-female ratio was 1.6:1.4.

In a study by Jeevaraman *et al*.,[10] the incidence of lower ureteric stones is more as compared to upper ureteric stones. Moreover, these results were similar to the present study.

The symptoms of ureteric stones are burning micturition and increased frequency of urination suggestive of urinary tract infection. Pain in abdomen has a typical, intermittent, and colicky in nature with specific radiation which is diagnostic of site of stone.[6] In the present study, most of the patient presented with flank pain (74.39%) and 33.33% presented with burning micturition (lower urinary tract symptoms).

Dellabella *et al*.[13] found greater efficacy with tamsulosin, which was compared with phloroglucinol, a spasmolytic drug very popular in Italy. Interestingly, these authors explained the positive effect of tamsulosin, it should induce an increase in the intraureteral pressure gradient around the stone as well as decrease the frequency of peristaltic contraction in the obstructed ureter and therefore a reduction of the allogeneic stimulus. Porpiglia *et al*.[15] compared the safety and effectiveness of nifedipine and deflazacort with those of tamsulosin and deflazacort for the treatment of distal ureteral stones. They concluded

that medical, particularly with tamsulosin, could reduce expulsion time. Yilmaz *et al*.[16] were the first to perform a randomized comparison of three alpha-1-blocker in the treatment of distal ureteral stones. They enrolled 114 patients who received nothing, tamsulosin, terazosin, or doxazosin for as long as 1 month. All three were equally efficacious.

In the present study, the expulsion rate in the tamsulosin group was 87.87% in Group A and 84.84% in Group B which was in concurrence with other studies. In Group C, the expulsion rate was 64%. In the present study, only five cases were complaining side effects in tamsulosin group which confirms the safety and tolerability of the drug and seven cases lost follow-up. The mean stone expulsion time in Group A was 5.39 ± 1.94 days, Group B was 4.75 ± 2.03 days, and in Group C, it was 6.76 ± 1.90 days.

Diclofenac sodium is nonsteroidal anti-inflammatory drug (NSAID) drug advocate for use in painful conditions. It possesses potent analgesic properties with a fast onset and longer duration. It has already been proposed that pain relief, together with spasmolysis of the ureter supporting stone passage, can be achieved by application of an NSAID such as diclofenac.

It is our belief from above study that a conservative approach to distal ureteral stones up to 10 mm should not be proposed for longer than 2 weeks to avoid renal impairment, urosepsis, and intractable pain.

CONCLUSION

Therefore, it is possible to suggest that the effect of tamsulosin on the obstructed ureter is to induce an increase in the intraureteral pressure gradient around the stone that is an increase in the urine bolus above the stone (and consequently an increase in intraureteral pressure above the stone) as well as decreased peristalsis below the ureter (and consequently a decrease in intraureteral pressure below the stone) in association with the decrease in basal and micturition pressures even at the bladder neck.[13] For these reasons, there would be a stronger urge to expel the stone. Furthermore, the decreased frequency of phasic peristaltic contractions in the obstructed ureteral tract induced by tamsulosin might determine a decrease in or the absence of the algogenic stimulus, as in our study.

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Original Article

Worth of Laparoscopy in Undiagnosed Chronic Abdominal Pain: A Tertiary Care Center Study

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Abstract

Introduction: Chronic abdominal pain which is difficult to diagnose initially not only encumbers the patient but it also affects their daily routine, leading to physical and psychological disability, here comes the role of diagnostic laparoscopy which proves to be beneficial aiding in diagnosing most of these cases. Hence, the aim was to evaluate the diagnostic value of laparoscopy in cases with chronic abdominal pain.

Materials and Methods: This study was done in the Department of General Surgery at Indira Gandhi Institute of Medical sciences, Patna, Bihar, from July 2019 to March 2020 in 40 patients. Prior Institutional Ethical Committee approval was also obtained for this study.

Results: Out of 40 patients included in this study, maximum number of patients were females. Male-to-female ratio was 1:1.4. The maximum number of patients were in the age group of 21–40 years (60%). Maximum patients 45% (n = 18) had complaint of pain in the right lower quadrant of abdomen. The most common finding during diagnostic laparoscopy was found to be pathology in the appendix accounting for 27.5% of cases (11/40).

Conclusion: Diagnostic laparoscopy is a safe and effective tool to establish the etiology of chronic abdominal pain and allows for appropriate interventions. It can serve as a time saving and cost-effective implement for these patients.

Key words: Abdominal pain, Appendicitis, Laparoscopy, Uncertain diagnosis

INTRODUCTION

Abdominal pain of chronic type is one of the most common disorders, which comes to the surgeon and physician in routine practice. The concern for patient is to have an etiology with chronic abdominal pain even after all the work up and diagnostic tests have been performed leading to their condition.[1] These patients are in good numbers with an estimate in the range of 30–40% as per various studies.[2] The pain in these people can be so engrossing and obsessive that it begins to impact the quality of life socially, physically, mentally, and economically becoming the main center of their life. These types of patients with pain in abdomen have been also referred to as undiagnosed chronic abdominal pain and their evaluation remains a daunting task.[3] These undiagnosed chronic abdominal pain imitate variety of abdominal conditions associated with pain and possess a conundrum to the operating surgeon for an intervention and possibility of diagnostic laparoscopy and proceed further. Since its emergence to the present days, laparoscopy has a comprehensive spectrum, it not only assists in diagnosis but also in contemporary surgical practice and the procedure has taken over for most of the interventions. It helps in avoiding unwarranted laparotomy and provides diagnosis to any planned surgery.[4,5] Although laparoscopy has gained popularity but has its own merits and demerits, so the role of laparoscopy is not free of controversies in patient with ill-defined abdominal pain. Most of the patients of pelvic pain have been treated with

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diagnostic laparoscopy followed by adhesiolysis which has gained acceptance in gynecological practice but not very well practiced in mainstream surgical literature and practice remains slow.[6,7] The burden of abdominal pain is shared by young females in reproductive age group who possess variety of conditions leading to lower abdominal and pelvic pain and inconsistent features of appendicitis where the worth of diagnostic laparoscopy comes into picture. Diagnosing with laparoscopy not only provides a better assessment for pain in these group of patients but also prevents negative appendicectomy.[8] Cases of abdominal tuberculosis (TB) present with very vague symptoms and are nightmare for the surgeon in clinical practice even after an extensive work-up with a series of tests. This results in starting most patients with empirical treatment even without proper evidence of the disease. Diagnostic laparoscopy in these cases can detect nodules in the peritoneal cavity and biopsy can be taken from various areas which would confirm the diagnosis. The result would avoid unnecessary overusage of anti-Koch's drugs and subsequent resistance and drug-related side effects faced by patients.[9] Variety of abdominal conditions can be diagnosed with laparoscopy as stated by other authors and therapeutic interventions can be planned accordingly.[10] Besides diagnosis, sometimes, the underlying etiology can itself be treated in the same sitting also known as therapeutic laparoscopy.[11] A simple dictum is that diagnosis should precede treatment whenever possible, so this way laparoscopic diagnosis will not only be time saving and cost effective but will serve as an important tool in avoiding unnecessary surgeries for most cases.

Aims and Objectives of the Study

The objectives of the study were as follows:

1. To evaluate whether diagnostic value of laparoscopy is worth in cases with new onset and chronic abdominal pain
2. Providing a much safe, time saving, and effectual accompaniment to non-surgical diagnostic modalities for establishing a conclusive diagnosis
3. As an adjunct in patients where conventional methods of investigations have failed to elicit a certain cause.

MATERIALS AND METHODS

This prospective observational study was carried out in the Department of General Surgery at Indira Gandhi Institute of Medical Sciences, Patna, from July 2019 to March 2020 in 40 patients. Approval from the Institute's Ethical Committee was duly obtained.

Inclusion Criteria

All patients of either sex or age, who will present with vague abdominal pain with new onset or chronic, admitted through emergency or outpatient department in whom history, clinical examination and routine diagnostic investigations fail to make a definite diagnosis, were included in the study.

Exclusion Criteria

The following criteria were excluded from the study:

1. Severe/decompensated cardiopulmonary failure
2. Acute myocardial infarction
3. Severe peritonitis
4. Infection of abdominal wall
5. Severe coagulopathy
6. Patient unfit for general anesthesia.

All patients in this study were subjected to complete preoperative evaluation in the form of medical history and clinical examination and investigations. The patients were be placed in supine position and operated under general anesthesia. In cases of previous upper midline incision or suspected massive intra-abdominal adhesions, the Veress needle was introduced through the abdominal wall in an area with no scars, most often in the left upper quadrant of the abdomen. After creating pneumoperitoneum, a standard three trocar techniques was used (10-mm through umbilical trocar and two 5 mm lateral trocars). A fourth 5 mm trocar was inserted in a few cases. The whole abdominal cavity was inspected carefully starting from the liver, gallbladder, anterior surface of the stomach, and spleen. Fine smooth graspers were used to safely touch the structures and elevating them for further inspection. The small bowel was examined by atraumatic graspers from the ligament of Treitz to the ileocecal valve. The colon including the appendix was inspected in same way as the small bowel. In females, the uterus, adnexa, and pouch of Douglas were inspected and the amount of fluid, color, and its site was noted. Specimen was sent for histopathological diagnosis and therapeutic intervention if needed was done. Post-operative hospital stay was recorded and the patient was followed postoperatively at regular intervals.

RESULTS

Out of 40 patients included in this study, maximum number of patients were female who accounted for 57.5% (23/40) of cases and the rest were male accounting for 27.5% (17/40) of cases. Male-to-female ratio was 1:1.4. The studied patients were in the age group ranging from 20 to 65 years, with a mean age of 32 years. The maximum number of patients were in the age group of 21–40 years (60%). The least number of patients were in the age group of 60 years and above with 12.5% of cases. Maximum patients 45% (n = 18) had complaint of pain in the right lower quadrant of abdomen followed by pain in the left lower quadrant

22.5% ($n = 9$). Other sites of pain were right upper quadrant, left upper quadrant, and periumbilical area. Some patients 5% ($n = 2$) had diffuse pain all over the abdomen [Table 1].

Seven patients in this study 17.5% (7/40) had a history of previous surgeries with three patients having a history of hysterectomy and two patients having a history of cholecystectomy and appendectomy each.

The most common finding during diagnostic laparoscopy was found to be pathology in the appendix 27.5% ($n = 11$), in which 10 patients had appendicitis while one patient had sealed appendicular perforation. The second most common finding was bands and adhesions in 20% of cases ($n = 8$). No diagnosis was established in 7.5% of cases ($n = 3$). Least common findings in present study were endometriosis and mesenteric lymphadenitis in 5% of cases [Table 2]. Some of the findings seen during laparoscopic procedure that could be depicted in the picture were omental node being taken for biopsy [Figure 1], ascitic fluid with peritoneal tubercles [Figure 2] and small bowel adhesions. [Figure 3].

DISCUSSION

Chronic abdominal pain is a frequent symptom and if not diagnosed after a series of investigations, possesses a challenge to the treating doctor, here comes the role of laparoscopy which can diagnose more than 90% of these patients in clinical practice.[12] In the present study also, diagnosis was done in 92.5% of cases (37/40). Early diagnosis is the key to any access toward the treatment of the disease, laparoscopy not only aims this but also reduces hospital stays, further readmissions providing mental and financial benefit to the patient.[13] Pathology

Table 1: Characteristics of studied patients

Characters	Value (%)
Age (years) mean (range)	32 (20–65)
Male	17 (42.5)
Female	23 (57.5)
Duration of pain (months) mean (range)	6 (3–10)
Site of pain	
Right lower quadrant	18 (45)
Right upper quadrant	2 (5)
Left lower quadrant	9 (22.5)
Left upper quadrant	5 (12.5)
Diffuse	2 (5)
Periumbilical	4 (10)

Table 2: Laparoscopic findings

Findings	Number of patients (n=40)	Percentage
Appendicular pathology	11	27.5
Bands/adhesions	8	20
Salpingitis with free fluid in pouch of Douglas	6	15
Koch's abdomen	5	12.5
Peritoneal omental deposits (disseminated carcinomatosis)	3	7.5
Inconclusive (no diagnosis)	3	7.5
Endometriosis	2	5
Mesenteric lymphadenitis (inflammatory)	2	5

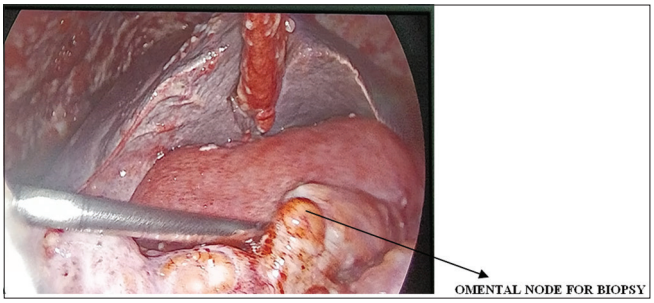

Figure 1: Omental node being taken for biopsy

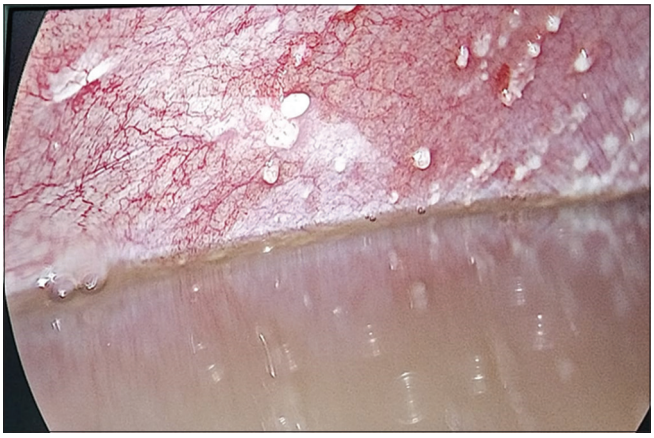

Figure 2: Laparoscopic image showing parietal peritoneum studded with tubercles and ascitic fluid

Figure 3: Laparoscopic image showing small bowel adhesions

of the appendix was one of the most common findings in our study. This is also in accordance with other studies where the sensitivity and specificity of laparoscopic appendectomy in patients who were posted for diagnosis were higher than of computed tomography scan (98% vs. 94%). This states the value of laparoscopy in achieving early and correct diagnosis of appendicitis and thus reducing the incidence of perforated appendicitis.[14] Abdominal TB is another condition which is known for its varied and confusing symptoms and can mimic between both inflammatory and carcinomatous pathology, and there is hardly any investigation that can be completely 100% correct for abdominal TB.[15,16] Laparoscopic examination of abdomen and examination of suspected nodules, deposits, and ascitic fluid for TB bacilli can be of great help in these cases. Although the cases of TB are high in a developing country like India, the incidence of abdominal TB is comparatively low in the present study. This may be due to the fact that many patients are treated empirically with antitubercular drug with no proper evidence of the disease. Laparoscopic diagnosis would avoid unnecessary overusage of anti-Koch's drugs and subsequent resistance and drug-related side effects regularly faced by patients. Many researchers in their studies done in the past have found out abdominal adhesions and appendicitis as the key diagnosis in laparoscopic procedures which is quite synonymous with the present study.[10] The pain in these adhesions may due to restricted mobility and distension of the organ particularly bowel.[17] Sometimes, conversion may be required to open procedures in these types of cases due to extensive bowel adhesions not amendable to laparoscopy. Diagnostic laparoscopy bears great significance in gynecological practice with main indications being infertility and chronic pelvic pain.[18] Cases of pelvic inflammatory diseases and endometriosis, relatively difficult to diagnose in ultrasound, were the main finding in some cases. Laparoscopy should be the main modality of diagnosing cases of chronic abdominal pain in females. The additional worth of doing laparoscopy can be in the fact that any therapeutic or definitive procedure can be done in the same sitting thus saving time.

CONCLUSION

Diagnostic laparoscopy can identify abnormal findings and improve the outcome in patients with chronic abdominal pain. However, it should be considered only after a complete diagnostic evaluation has been carried out. It allows the effective surgical treatment of many conditions encountered at the time of diagnostic laparoscopy.

Limitations

All the patients underwent anesthesia in this study, thus leading to unintentional associated risks. Of all the patients in this study, diagnosis with laparoscopy was not established in three patients. Various pathologies present in the retroperitoneum causing pain in abdomen are relatively difficult to diagnose with diagnostic laparoscopy.

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Original Article

To Know the Correlation of Prostate Size on Ultrasound with International Prostate Symptom Score and Uroflowmetry in Benign Prostatic Hyperplasia

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Abstract

Introduction: Benign prostatic hyperplasia (BPH) is an extremely common condition in elderly men and is a major cause of bladder outflow obstruction. An enlarged prostate may also be incidentally found on imaging of the pelvis or on rectal examination. Lower urinary tract symptoms (LUTSs) are one of the commonest presentations in urology clinics. Clinical diagnosis of BPH is made by the assessment of international prostate symptom score (IPSS), prostate size or volume, and reduced urinary flow rate. Uroflowmetry is one of the simplest and non-invasive urodynamic investigations used in the measurement of urinary flow rate using a flowmeter for the evaluation of obstructive LUTS. The IPSS is widely used to assess the severity of LUTS in men with bladder outlet obstruction and to evaluate the response to medical or surgical therapy for benign prostatic obstruction.

Materials and Methods: This prospective study was conducted on patients with LUTS to evaluate: (1) Prostate size on ultrasound, (2) correlate prostate size with IPSS, and (3) correlate prostate size with uroflowmetry. A total of 60 patients were included in the study attending the outpatient department of general surgery in Government Doon Medical College between June 2018 and September 2019.

Result: Our study states that maximum flow rate and prostate volume show a positive significant correlation having $P < 0.01$. Considering all the three grades of BPH, a positive correlation was found between prostate volume and maximum flow rate. A significant correlation was found between mean prostate volume and maximum flow rate signifying that the higher the prostate volume, the lower the maximum flow rates. The statistical analysis of prostate volume versus IPSS showed strongly significant correlation between the two parameters. Mean prostate volume was higher in patients with PSS of 18–35. It denotes that higher the prostate volume higher is severity index in patients with BPH.

Conclusion: On the basis of data, which were obtained after evaluation of 60 patients with BPH, it can be concluded that prostate volume and its relationship with peak flow of output can help predict the degree and cause of obstruction. The higher the prostate volume, the higher the possibility of the cause to be obstructive due to BPH. Uroflowmetry, IPSS, and ultrasound are non-invasive, easy, and cheap investigation in evaluation of LUTS, mainly due to BPH.

Key words: Hyperplasia, Prostate, Ultrasound

INTRODUCTION

Benign prostatic hyperplasia (BPH) is an extremely common condition in elderly men and is a major cause of bladder outflow obstruction. Although the term prostatomegaly is often used interchangeably with BPH, strictly speaking, prostatomegaly may refer to any cause of prostatic enlargement. By the age of 60, 50% of men have BPH, and by 90 years of age, the prevalence has increased to 90%. As such, it is often thought of essentially as a "normal" part of aging.

Although a degree of prostatomegaly may be completely asymptomatic, the most common presentation is lower urinary tract symptoms (LUTSs) including:

- Poor stream despite straining
- Hesitancy, frequency, and incomplete emptying of the bladder
- Nocturia

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Clinical diagnosis of BPH is made by the assessment of IPSS, prostate size or volume, and reduced urinary flow rate. Histopathologically, BPH is characterized by an increased number of epithelial and stromal cells in the periurethral transitional zones of the prostate. Ultrasound of the prostate is the investigation that enables us to visualize the prostate gland directly and is one of the most common diagnostic modalities performed nowadays. It can be done using the suprapubic abdominal approach as well as transrectal approach. Among several methods, the diameter method is the most commonly used method for the determination of prostate volume. It comprises measurement of height (H), width (W), length (L), and volume (V) and is calculated using the formula ½ (H × L × W).

Uroflowmetry is one of the simplest and non-invasive urodynamic investigations used in the measurement of urinary flow rate using a flowmeter for the evaluation of obstructive LUTSs. Urodynamic studies in patient with LUTSs are used for objective assessment of urinary bladder outlet behavior. However, to decide what is abnormal, it seems mandatory to agree on what can be considered normal. Although urodynamic studies are frequently used to evaluate voiding disorders in an elderly men with LUTS suggestive of BPH. The measuring instrument calculates the amount of urine, flow rate in milliliter per second, and length of time until completion of voiding. This information is plotted on a graph and interpreted by the treating doctor.

The international prostate symptom score (IPSS) is widely used to assess the severity of LUTSs in men with bladder outlet obstruction and to evaluate the response to medical or surgical therapy for benign prostatic obstruction. The IPSS is a written screening tool comprising seven symptom questions.

AIMS AND OBJECTIVES

The aim of this study is to evaluate:
1. Prostate size on ultrasound.
2. Correlate prostate size with IPSS.
3. Correlate prostate size with uroflowmetry.

MATERIALS AND METHODS

This study was conducted on patients with LUTS.

Study Design

This was a prospective study.

Duration of Study

The study duration was from June 2018 to December 2019.

Place of Study

The study was conducted at the Department of General Surgery, Government Doon Medical College, Dehradun, Uttarakhand.

Sample size: 60

Inclusion Criteria

The following criteria were included in the study:
1. Patients presenting with LUTS.
2. Age > 50 years.
3. Prostate size ≥ 20 g on Ultrasound

Exclusion Criteria

The following criteria were excluded from the study:
1. Patients who had undergone previous urinary tract or pelvic surgeries/trauma.
2. Patients who had a history of prostatic surgery, prostatic carcinoma, urethral stricture, vesical calculus, or neurogenic bladder.
3. Patients who had systemic disorders that could influence bladder function, such as neurological disorders (CVA and spinal abnormalities) and diabetes.
4. Patients whose pre-voided urine volume was <180 ml.
5. Patients unable to go for uroflowmetry

There were 60 individuals in the age group of 50–80 years with LUTSs. All these patients were subjected to a detailed history taking, physical examinations, international prostatic symptom score (IPSS) assessment, digital rectal examinations (DREs), ultrasound, and uroflowmetry. Written informed consent was obtained from all the patients who participated in the study after explaining the patient's diagnosis, the nature, and purpose of the study.

All included patients were evaluated using IPSS questionnaire and personnel interview with the patient, before treatment on the following symptoms, which they experienced over the past 1 month.
1. Incomplete emptying
2. Frequency
3. Intermittency
4. Urgency
5. Weak stream
6. Straining
7. Nocturia due to urinary symptoms.

The IPSS is the ideal instrument, which can be used to grade baseline symptoms severity. The IPSS is based on the answers to seven questions, which concern urinary symptoms. Each question is assigned points from 0 to 5, which indicate increasing severity of the particular symptom and a total score, which ranges from 0 to 35. Digital rectal examination was done and size of the prostate

was estimated along with its consistency and fixity of rectal mucosa with the gland. In addition, examination of external genitalia was done to exclude meatal stenosis or a palpable urethral mass. The patients with prostatic carcinoma and who have undergone previous prostatic surgery were excluded from the study.

All the patients underwent transabdominal sonography for the estimation of prostate volume, pre-void urine volume, and post-void assessment for the residual urine. The prostate gland was evaluated transabdominally after adequate bladder distension. The prostate gland assessed for volume, echo texture, morphology, focal lesions, and median lobe parenchymal calcification. The prostate volume was calculated using prostate ellipsoid formula: Anteroposterior × Transverse × Craniocaudal × 0.52. The grading of the prostate gland enlargement was done as follows:

- Grade I: 21–30 cc.
- Grade II: 31–50 cc
- Grade III: 51–80 cc
- Grade IV: 80 cc and above.

The urinary bladder was assessed for various abnormalities such as pre-void urine volume, wall thickness, mucosal regularity, calculi, diverticulitis, tumor, and post-void assessment for the residual urine. The patients were advised to come with empty bladder soon after the uroflowmetry. Post-void residual urine was determined using transabdominal ultrasound measurement using the formula for elliptical volume (transverse dimension × anteroposterior dimension × cephalocaudal dimension × 1/2).

Uroflowmetry was performed in all patients with full bladders and voiding volume, peak flow rate, average flow rate, hesitance time, and voiding time were recorded. Adequate privacy was provided and patients were asked to void when they felt a normal desire to void. The machine gave the result as peak flow rate, voiding time, voiding volume, and time to peak flow. The test involved normal urination and so patients did not experience any discomfort.

The data of the patients were analyzed and the patients were divided as per their symptom severities as was assessed by IPSS. The results of uroflowmetry, as were obtained from these patients, were compared using various statistical techniques. Pearson's correlation coefficient was used to assess correlation between various variables.

RESULTS

In the current study, the total number of patients taken for study was 60. In our study, patients age ranged between 50 and 79 years with a mean age of 62.18. Maximum number of patients were in the age group of 60–69 years [Table 1]. Lower socioeconomic patients showed maximum incidence of 36 (60%) [Table 2]. Maximum number of patients 25 (41.7%) in our study were having Grade 2 BPH [Table 3]. On USG, majority of our cases were Grade-2 (43.3%) and Grade 1 (40.0%) [Table 4]. As shown in Table 5, maximum

Table 1: Distribution of patients according to age group

Age group (years)	Number of patients	%
50–59	22	36.7
60–69	27	45.0
70–79	11	18.3
Total	60	100
Mean±SD	62.18±6.76	
Median	62	
Min-Max	50–78	

Table 2: Distribution of patients according to socioeconomic status

Socioeconomic status	Number of patients	%
High class	5	8.3
Middle class	19	31.7
Lower class	36	60
Total	60	100

Table 3: Distribution of patients according to prostate on DRE

Size	Number of patients	%
Grade 1	24	40.0
Grade 2	25	41.7
Grade 3	11	18.3
Total	60	100

Table 4: Distribution of patients according to prostate volume on ultrasound

Prostate volume	Number of patients	%
Grade 1 (21–30 cc)	24	40.0
Grade 2 (31–50 cc)	26	43.3
Grade 3 (51–80 cc)	10	16.7
Total	60	100
Mean	38.02±12.52	
Median	35 cc	
Min-Max	23–68 cc	

Table 5: Distribution of patients according to international prostate symptom score

IPSS score	Number of patients	%
−7	19	31.7
8−19	31	51.7
20−35	10	16.7
Total	60	100
Mean±SD	12.62±7.43	
Median	10	
Min-Max	3–30	

number of patients 31 (51.7%) were having IPSS score between 8 and 19.

In this study on uroflowmetry, the mean interval time was 8.83 s and ranged between 0 and 42 s, mean voided volume was 209.80 ml, and mean max. flow rate was 10.14 ml/s while mean voiding time was 66.92 s [Table 6]. In Q_{max} < 10 ml/s range 28 (46.67%) and in 10–15 ml/s 27 (45%) patients were there [Table 7]. In Grade 1, total patients were 24 and majority were in Q_{max} 10–15 ml/s range while in Grade 2, total patients were 26 and majority were in Q_{max} < 10 ml/s [Table 8]. In our study, Q_{max} < 10 ml/s group, the mean prostate volume was observed as 44.04 cc, in 10–15 ml/s group, it was 33.93 cc [Table 9].

In IPSS ≤ 7 group, patients were 19, out of which maximum were in Q_{max} 10–15 ml/s range while in IPSS 8–19 group, total patients were 31 and majority were in Q_{max} < 10 ml/s range [Table 10]. In the IPSS ≤ 7 group, the mean maximum flow rate was observed as 13.68 ml/s, in 8–19 group, it was 9.17 ml/s, and in 20–35 group, it was 6.40 ml/s [Table 11]. If we correlate IPSS score with prostate volume, majority 24 (77.4%) were in IPSS score 8–19 and they were having Grade 2 prostate volume [Table 12]. In the IPSS ≤ 7 group, the mean prostate volume was observed as 30.21 cc, in 8–19 group, it was 36.45 cc, and in 20–35 group, it was 57.70 cc in our study [Table 13].

Table 6: Distribution of mean uroflowmetry

Uroflowmetry	Mean±SD	Median	Min-Max
Interval time	8.83±8.41	7.50	0–42
Voided volume	209.80±82.61	180	105–518
Max. flow rate	10.14±3.93	10	3–20
Flow time	45.73±14.79	46	19–88
Voiding time	66.92±34.57	58.50	20–198

Table 7: Distribution of patients to maximum flow rate

Max. flow rate (ml/s)	Number of patients	%
<10	28	46.67
10–15	27	45
>15	5	8.33
Total	60	100
Mean±SD	10.14±14.79	
Median	10	
Min-Max	3–20	

DISCUSSION

The study which was done on 60 patients was designed to determine the relationship among parameters of uroflowmetry and ultrasound findings and IPSS. Patients were distributed according to age which ranged between 50 and 78 years. The mean of patients in this study was 2.18 ± 6.76 years. Most of the patients (45%) were in the group of 60–69 years. Mebust *et al.*, in their study, displayed almost similar results with patients who had an average age of 69 years, for benign prostatic hyperplasia.[1] Similarly, Iqbal *et al.* and Saleem *et al.* reported patients with mean ages of 63.4 and 65.6 years, respectively.

The patients of BPH who visited our hospital were studied. Socioeconomic status was categorized into three categories according to their monthly income. Lowest frequency of patients 5 (8.3%) was found in higher-class patients and highest frequency of 36 (60.0%) patients was found in the lower-class patients. In this study, 60 patients were distributed according to prostate size, categorizing 24 (40%) patients as Grade I, 26 (43.3%) patients as Grade II, and 10 (16.7%) patients as Grade III. The maximum being in Grade II. The mean prostatic size having a range of 23–68 cc was found out to be 38.02 cc which is almost equal to 40.l cc in 354 patients and 41 cc in 25 patients in the studies by Vesely *et al.* and Dicuio *et al.,* respectively.[2,3]

Depending on clinical suspicion of BPH, digital rectal examination serves an important role. It not only confirms our clinical diagnosis of BPH but also gives an idea of the clinical grade of the enlarged prostate. In this study, on DRE, 24 (40.0%) patients were diagnosed as Grade l BPH, while 25 (41.7%) were diagnosed as Grade II, and 11 (18.3%) patients were diagnosed as Grade III BPH. Almost all these findings of DRE were radiologically confirmed by ultrasonography. Therefore, it can be stated that DRE is a very efficient tool in the diagnosis as well as

Table 8: Correlation between prostate volume and maximum flow rate

Max. flow rate (ml/sec)	Prostate volume			*P* value
	Grade 1 (21–30cc)	Grade 2 (31–50 cc)	Grade 3 (51–80 cc)	
	Number of patients (%)	Number of patients (%)	Number of patients (%)	
<10	3 (12.5)	17 (65.4)	8 (80)	<0.001
10–15	16 (66.7)	9 (34.6)	2 (20)	
>15	5 (20.8)	0 (0)	0 (0)	
Total	24 (100)	26 (100)	10 (100)	

Table 9: Distribution of mean prostate volume according to maximum flow rate

Prostate volume	<10 ml/sec	10–15 ml/sec	>15 ml/s	*P* value
	Mean±SD	Mean±SD	Mean±SD	
	44.04±12.58 cc	33.93±10.38 cc	26.40±10.70 cc	0.001

Table 10: Correlation between maximum flow rate and IPSS

Max. flow rate (ml/s)	IPSS score			*P* value
	≤7	8–19	20–35	
	Number of patients (%)	Number of patients (%)	Number of patients (%)	
<10	2 (10.5)	17 (54.8)	9 (90)	
10–15	13 (68.4)	13 (41.9)	1 (10)	
>15	4 (21.1)	1 (3.2)	0 (0)	
Total	19 (100)	31 (100)	10 (100)	<0.001

IPSS: International prostate symptom score

Table 11: Distribution of mean flow rate according to IPSS

Max. flow rate (ml/sec)	IPSS score			*P* value
	≤7	8–19	20–35	
	Mean±SD	Mean±SD	Mean±SD	
	13.68±3.25 ml/s	9.17±2.82ml/s	6.40±2.88ml/s	<0.001

IPSS: International prostate symptom score

Table 12: Correlation between prostate volume and IPSS

Prostate volume	IPSS score			*P* value
	≤7	8–19	20–35	
	Number of patients (%)	Number of patients (%)	Number of patients (%)	
Grade 1	17 (89.5)	7 (22.6)	0 (0)	<0.001
Grade 2	0 (0.0)	24 (77.4)	2 (20)	
Grade 3	2 (10.5)	0 (0)	8 (80)	
Total	19 (100)	31 (100)	10 (100)	

IPSS: International prostate symptom score

Table 13: Distribution of mean prostate volume according to IPSS

Prostate volume	IPSS score			*P* value
	≤7	8–19	20–35	
	Mean±SD	Mean±SD	Mean±SD	
	30.21±11.11 cc	36.45±6.38 cc	57.70±8.78 cc	<0.001

grading of BPH. Basawaraj *et al.*[4] in his study had subjected patients to ultrasonography and graded in according to their prostate volume. Maximum number of patients had a prostate volume measuring 31–50 cc (35.7%) followed by patients having prostate volume more than 50 cc (19.8%). The largest prostate volume was 91 cc with mean being 36.98 cc ± 18.05 and median value of 33 cc. In our study, maximum number of patients were having prostate size measuring 31–50 cc (43.3%) followed by patients having prostate volume 21–30 cc (40.0%).

The lowest prostate volume is 23 cc and largest prostate volume is 68 cc, having a mean of 38.02□ 12.55 cc and median value of 35 cc. Therefore, both the studies have almost similar values, thereby focusing on the correlation between prostate volume and grading of the disease taking severity of symptoms into consideration.

IPSS score was brought into use by the American Urology Association and European.

Urology Association to evaluate the severity of BPH.[5] IPSS is used to evaluate therapeutic response in men with LUTSs. Basawaraj *et al.*[4] found that 21.4% of patients were having mild symptoms (IPSS score < 7), 37.3% of patients were having moderate symptoms (IPSS 8–9), and 41.3% of patients were having severe symptoms (IPSS 20–35). In the present study, it was found that 31.7% of patients were having mild symptoms (IPSS score ≤ 7), 51.7% of

patients were having moderate symptoms (IPSS 8–9), and 16.7% of patients were having severe symptoms (IPSS 20–35). The mean was found out to be 12.62 ± 7.43 with a median value of 10 and range being 3–30.

In our study, the mean voided volume was found out to be 209.80 ± 82.61 ml with a range 105–518 ml. The mean maximum flow rate is 10.14 ± 3.93 ml/s with a range 3–20 ml/s. The mean flow time is 45.73 ± 14.79 ml/s with a range 19–88 ml/s. The mean voiding time is 66.92 ± 34.57 s with a range 20–198 s. In our study, maximum numbers of patients (46.67%) were having maximum flow rate < 19 ml/s followed by 45% of patients having maximum flow rate between 10 and 15 ml/s. Only 8.33% were found to have a maximum flow rate >15 ml/s. Mean maximum flow rate was 10.14 ± 3.93 with a range 3–20. The findings are almost comparable to 9.67 ± 3.26 ml/s as the mean of maximum flow rate in the study by Malik *et al*.[6]. Range was 6.1–18.8 ml/s. In this study, maximum flow rate was correlated with prostate volume. *P* value was found out to be < 0.01, thereby showing a positive correlation between both parameters.

Correlation between prostate volume and maximum flow rate was studied taking into consideration all the three grades of BPH. *P* value came out to be < 0.001 which is suggestive of a significant correlation between maximum flow rate and prostate volume. Mohammed *et al*.[7] in their study also showed significance seen in the correlation between peak flow rate and prostate volume. Distribution of mean prostate volume according to maximum flow rate was studied statistically. Mean values of prostate volume were found to be higher in patients having maximum flow rate of <10 ml/s. *P* < 0.001 was suggestive of a significant correlation between mean prostate volume and maximum flow rate. This signifies that the higher the prostate volume, the lower the maximum flow rates. Relationship between maximum flow rate and IPSS was considered statistically. *P*<0.001 was significantly suggesting a positive correlation between maximum flow rate and IPSS. Singla *et al*.[8] and El Din *et al*.[9] in their studies had suggested a significant correlation between the above-mentioned parameters. However, Heynes *et al*.[10] in their study had stated a significant negative correlation between maximum flow rate and IPSS.

While studying the mean maximum flow rate according to IPSS, it was found that mean maximum flow rate was found to be highest in patients with IPSS ≤ 7 with *P* < 0.001, thereby indicating a positive correlation between the parameters. This suggests that higher the IPSS, lesser is the flow rate. El Din *et al*.[9] had, in their study, shown that there was no correlation between prostate volume and IPSS. Basawaraj *et al*.[4] in their study suggested a weakly significant correlation between the two parameters. However, the statistical analysis of prostate volume versus IPSS showed strongly significant correlation between the two parameters as *P* value was < 0.001. Mean prostate volume was higher in patients with IPSS 18–35. It denotes that higher the prostate volume higher is severity index in patient's BPH.

CONCLUSION

On the basis of data which were obtained after evaluation of 60 patients with benign prostatic hyperplasia, it can be concluded that prostate volume and its relationship with peak flow of output can help to predict the degree and cause of obstruction. Larger the size of gland lower the peak flow rate. It will help clinicians to determine the severity of the symptoms and line of management to be undertaken. The higher the prostate volume, the higher the possibility of the cause to be obstructive due to benign prostatic hyperplasia. Of all the parameters of uroflowmetry, maximum flow rate was the most representative of the symptoms severity of the patient. Uroflowmetry, IPSS, and ultrasound are non-invasive, easy, and cheap investigation in evaluation of LUTSs, mainly due to BPH.

Our study states that maximum flow rate and prostate volume show a positive significant correlation having *P* < 0.01. Considering all the three grades of BPH, a positive correlation was found between prostate volume and maximum flow rate. *P* < 0.001 is suggestive of a significant correlation between maximum flow rate and prostate volume. It indicates that maximum flow rate decreases with increase in the prostate volume.

Distribution of mean prostate volume according to maximum flow rate was studied statistically. *P* <0.001 was suggestive of a significant correlation between mean prostate volume and maximum flow rate signifying that the higher the prostate volume, the lower the maximum flow rates.

Statistically, *P* <0.001 represents a positive correlation between maximum flow rate and IPSS, thereby stating the higher the IPSS lesser is the mean flow rate. While studying the mean maximum flow rate according to IPSS, it was found that mean maximum flow rate was found to be highest in patients with IPSS ≤7 with *P* <0.001, thereby indicating a positive correlation between the parameters. This suggests that higher the IPSS lesser is the flow rate. The statistical analysis of prostate volume versus IPSS showed strongly significant correlation between the two parameters as *P* value was <0.001. Mean prostate volume was higher in patients with IPSS of 18–35. It denotes

that higher the prostate volume higher is severity index in patients with BPH.

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Original Article

Study of Infant Feeding Practices in Rural Area in Goa

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Abstract

Background: Suboptimal feeding practices during the infancy increase the risk of death, illness, and malnutrition. Despite overwhelming evidence of the benefits of exclusive breastfeeding, only about 40% babies under 6 months are exclusively breastfed, due to the lack of understanding of optimal feeding practices and lack of support from health service providers, community members, and families; babies who are not exclusively breastfed in the early months have a higher risk of death, especially from infection. The Lancet's 2003 child survival series identified that exclusive breastfeeding could save up to 1.3 million children worldwide. This essential intervention involves the early initiation of breastfeeding and ensuring that the mother gives only breastmilk and no other food or fluids during the first 6 months of life. Undernutrition of children is an important contributor to the deaths of 10.5 million children globally each year.

Aims and Objectives: The present study seeks to estimate the proportion of mothers carrying out age-appropriate infant feeding practices. Besides, the present study was conducted to study factors associated with infant feeding practices and reasons preventing exclusive breastfeeding in infants.

Materials and Methods: A cross-sectional community-based study was conducted in the field practice area of Rural Health and Training Centre, Mandur, Goa, from February 2019 to August 2019. Recruitment of study population was done by a systematic random sampling method and study population comprised of mothers with infants between 9 months and 1 year. A structured questionnaire was used to collect data in a face to face interview with the mother.

Results: In the present study, 150 infants aged 9 months to 1 year were recruited. It was observed that exclusive breastfeeding up to 6 months was carried out in 94 infants (62.66%). Early initiation of breastfeeding was carried out in 37 infants (24.7%). Weaning of infants by 6 months was started in 72 infants (48.18%). Exclusive breastfeeding of infants was found to be statistically significantly associated with mother's occupation ($\geq^2 = 27.152$; $P = 0.00019$), religion ($\geq^2 = 12.19$; $P = 0.015$), and age ($\geq^2 = 25.4$; $P = 0.0002$).

Conclusions: Suboptimal feeding practices during the infancy increase the risk of death, illness, and malnutrition. It is imperative to educate mothers on infant and young child feeding practices and create awareness within communities to achieve optimal growth and development of infants.

Key words: Breastfeeding, Infant and young child feeding practices, Weaning

INTRODUCTION

Suboptimal feeding practices during the infancy increase the risk of death, illness, and malnutrition. Despite overwhelming evidence of the benefits of exclusive breastfeeding, only about 40% infants under 6 months are exclusively breastfed due to the lack of understanding of optimal feeding practices and lack of support from health service providers, community members, and families.[1] Infants who are not exclusively breastfed in the early months have a higher risk of death, especially from infection.[2] Undernutrition of infants is an important contributor to the deaths of 10.5 million children globally each year.

The Lancet's 2003 child survival series identified a package of proven nutrition interventions with the potential to avert up to 25% of child deaths if implemented. One of these

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interventions, exclusive breastfeeding, could save up to 1.3 million children worldwide. This essential intervention involves the early initiation of breastfeeding and ensuring that the mother gives only breast milk, and no other food or fluids, during the first 6 months of life.

The global strategy on infants and young child feeding[1-5] recommended that infants should be exclusively breastfed for the first 6 months of life to achieve optimal growth development and health.

Breastfeeding and other nutrition actions contribute to better health throughout the lifecycle. Routine health services offer opportunities to provide support for optimal feeding practices for infants. Throughout the postnatal/neonatal period, contact with new mothers provides an opportunity to counsel on-demand exclusive breastfeeding, observes the neonate for correct positioning and attachment, resolves problems, and discusses actions related to maternal nutrition during lactation. One of the strategies for addressing infant feeding practices at the health facility level is the Baby-Friendly Hospital Initiative. Besides, strengthening community-based activities to increase skilled and timely support for maternal nutrition and breastfeeding are essential. Community-based activities include education and support from skilled birth attendants and existing community groups, community mobilization, traditional and mass media, and home visits.

However, there are several challenges to optimal feeding practices for infants. Some studies have identified cultural and social factors which impact the feeding practices of newborns. There is a need to identify and address impediments to improve breastfeeding rates in particular. However, these factors vary among different communities.

Research is required to identify why suboptimal nutrition and infant feeding practices occur in various communities. Hence, there is a need to find factors which impede the establishment and maintenance of optimal breastfeeding practices.[6,7]

Infants and young children are at an increased risk of malnutrition from 6 months of age onward when breast milk alone is no longer sufficient to meet all their nutritional requirements. Complementary feeding should be started by the age of 6 months in infants. Introducing complementary feeds too late in the infancy period can lead to malnutrition.[2]

The present study was conducted with the following objectives: (1) To estimate the proportion of mothers carrying out feeding practices in infants from birth until 6 months of age, (2) to study factors associated with infant feeding practices, and (3) to study reasons hindering exclusive breastfeeding in infants.

MATERIALS AND METHODS

The present cross-sectional study was conducted in rural areas of Mandur, Goa, which is served by Rural Health and Training Centre Mandur under Goa Medical College, Goa, and has a population of 30,000 people. After taking necessary permissions and obtaining ethical clearance from the Institutional Ethics Committee, the study was conducted from February to August 2019. Using formula 4 pq/d^2, considering prevalence P = 60%[3] and error d = 8%, a minimum sample size of 150 participants were calculated. A systematic random sampling method was used to recruit 150 study participants from infants aged 9 months to 1 year of age in the study area. Informed consent of the mother was obtained before commencing the interview and questions were asked to the mother in the local language. A predesigned pretested questionnaire was used to collect data by face to face interview with the mother. Data were collected on the feeding practices of infants from birth to 6 months of age. Optimal feeding practices[6] as per the WHO and UNICEF recommendations include:

- Early initiation of breastfeeding within 1 h of birth
- Exclusive breastfeeding for the first 6 months of life defined as no other food or drink, not even water, except breast milk (including milk expressed or from a wet nurse) for 6 months of life, but allows the infant to receive ORS, drops, and syrups (vitamins, minerals, and medicines)
- Weaning of infant: Introduction of nutritionally-adequate and safe complementary (solid) foods at 6 months together with continued breastfeeding up to 2 years of age or beyond.

Statistical Analysis

The data were analyzed using SPSS software version 22. Data were expressed as frequencies and percentages in tabular form and Chi-square test was used in the analysis. A $P < 0.05$ was considered statistically significant.

RESULTS

In the present study, 150 infants aged 9 months to 1 year of age were recruited. It was observed that all infants in the study were breastfed, with exclusive breastfeeding carried out in 94 infants (62.66%), while the rest of the infants were partially breastfed. The proportion of male infants that were exclusively breastfed (72.7%) was higher than that of female infants (54.8%). Early initiation of breastfeeding was carried out in 37 infants (24.7%). It

was observed that 72 infants (48.18%) were weaned by 6 months of age while continuing breastfeeding, whereas weaning with complementary feeds was not started in 78 infants (51.82%) by 6 months. When asked about the type of weaning foods, 39 infants (54.2%) were given a liquid to semi-solid home-made foods, whereas 33 infants (48.8%) were given readymade weaning mixes.

In the present study, it was observed that the highest proportion of mothers (53.3%) was in the age group of 26–29 and the lowest proportion (2.7%) mothers were in the age group of 18–21. A higher proportion of the mothers (60%) was employed and 40% mothers were housewives. The highest proportion of mothers (66.7%) was Hindu by religion and only the lowest proportion of mothers (2.7%) was Muslims. The highest proportion of mothers (66.7%) had completed higher secondary education and only 1.3% of mothers were illiterate. The highest proportions of mothers (45.3%) belonged to Class 1 socioeconomic class and the lowest proportion of mothers (1.3%) belonged to Class 5 [Table 1].

It is observed in the present study that higher proportions of infants, 51.33% were males and only 48.67% were females. The highest proportion of infants (50.67%) were of birth order 1 and the lowest proportion of infants (18%) were of birth order of 3 or more. About 84% of infants were born with a birth weight of 2.5 kg and above, and 16% were low birth weight babies [Table 2].

Exclusive breastfeeding was found to be significantly associated with age, occupation, and religion [Table 3].

In the present study, mothers reported reasons for not exclusive breastfeeding as inadequate milk production (60.7%), maternal illness (7.3%), constraints faced by mother at work (24.7%), and due to poor sucking reflex of infant (7.3%).

Table 1: Sociodemographic profile of mothers

Variable	*n* (%)
Age	
18–21	04 (2.7)
22–25	20 (13.3)
26–29	80 (53.3)
30 and above	46 (30.7)
Total	150 (100)
Employment status	
Housewife	60 (40)
Service	90 (60)
Total	150 (100)
Religion	U
Hindu	100 (66.7)
Christian	46 (30.7)
Muslim	04 (2.7)
Total	150 (100)
Education	
Illiterate	02 (1.3)
Primary	06 (4.0)
Secondary	20 (13.3)
Higher secondary	100 (66.7)
≥Graduate	22 (14.7)
Total	150 (100)
Socioeconomic status	
Class 1	45.3
Class 2	37.3
Class 3	13.3
Class 4	2.7
Class 5	1.3
Total	150 (100)

Table 2: Profile of infants

Variable	*n* (%)
Gender of child	
Male	77 (51.33)
Female	73 (48.67)
Total	150 (100)
Birth order	
First	76 (50.67)
Second	47 (31.33)
Third or higher	27 (18)
Total	150 (100)
Birth weight	
<2.5 kg	24 (16)
≥2.5 kg	126 (84)
Total	150 (100)

Table 3: Sociodemographic factors of mothers and exclusive breastfeeding

Variable	Exclusive breastfeeding		Test of significance
	Yes	No	
	n=94	*n*=56	
Age			
18–21	2	2	χ^2=11.1776
22–25	10	10	Df=3
26–29	60	20	*P*=0.0108
30 and above	22	24	
Occupation			
Housewife	30	30	χ^2=7.655
Service	62	24	Df=2
Others	2	2	*P*=0.0217
Religion			
Hindu	70	30	χ^2=6.9033
Christian	22	24	Df=2
Muslim	2	2	*P*=0.0316
Education			χ^2=7.0047
Illiterate	1	1	Df=4
Primary	3	3	*P*=0.13564
Secondary	10	10	
Higher secondary	70	30	
Graduate and above	10	12	
Socioeconomic status			
Class 1	46	22	χ^2=1.7261
Class 2	34	22	Df=4
Class 3	11	9	*1*=0.7859
Class 4	2	2	
Class 5	1	1	

DISCUSSION

In the present study, 94 infants of 150 (62.67%) were found to have exclusively breastfed until 6 months of age. Whereas, it was observed to be 57.7% in a study by Benjamin and Zachariah (1993)[8] and 63.50% in a study conducted by Aggarwal *et al.*[9] However, it was observed that only 8.6% mothers practiced exclusive breastfeeding in a study conducted in Orissa.[5]

In the present study, 24.7%, i.e., 37 infants, were breastfed within 1 h after birth. Similar findings of early initiation of breastfeeding within 1 h (27.2%) were reported by Khan *et al.*,[10] Shwetal *et al.* (32.6%),[11] and Raval *et al.*[12] However, in a study conducted by Madhu *et al.*,[13] it was observed that 92% of infants had early initiation of breastfeeding, and Ekambaram *et al.*[14] reported that in their study, 97% of infants had early initiation of breastfeeding. This difference may be due to local cultural beliefs and practices which were more favorable in those particular regions.

In the present study, 48.18% of mothers started weaning at 6 months. In an interventional study of 35 parents in Delhi,[15] only 16.5% of mothers had started weaning at the recommended time, which is less than that observed in the present study.[15] A prospective interview study of 200 parents by Aggarwal *et al.*[16] showed that 17.5% of mothers had started complementary feeding at 6 months of age. A National Family Health Survey 3 for Karnataka State, India, reported that 72.5% of children aged 6–9 months were receiving complementary feeds and breast milk.[17]

In the present study, it was found that the most common reason for not exclusively breastfeeding was the inadequacy of breast milk secretion (60.7%). Similar findings of inadequate milk secretion in mothers (54.67%) were observed in a study conducted by Sriram *et al.*[18]

CONCLUSION

Suboptimal feeding practices during the infancy increase the risk of death, illness, and malnutrition. It is imperative to educate mothers on infant and young child feeding practices and create awareness within communities to achieve optimal growth and development of infants.

There is a need for community health education programs aimed at educating mothers on (1) initiation of breastfeeding within the first 1 h after birth, (2) exclusive breastfeeding until 6 months of age, and (3) continue breastfeeding until 2 years.

Furthermore, it would be effective to use mass media for educating people and encourage community support groups to promote breastfeeding and thereby prevent undernutrition in children. Breastfeeding has been repeatedly proven in various studies as a healthy and cost-effective method of feeding infants until 6 months of age.[19]

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Ethical Approval

Institutional Ethics Committee.

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Original Article

Transrectal Ultrasound Elastography – Evaluating Clinical Implications to Differentiate between Benign and Malignant Lesion of Prostate: A Prospective Observational Study

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Abstract

Introduction: Elastography is a non-invasive imaging to depict relative tissue stiffness or displacement (strain) in response to impacted force, carcinoma prostate (Ca-P) tissue is stiffer than normal tissue. Shear wave elastography (SWE) is a modified real-time imaging technique that represents a substantial advance in ultrasound elastography. There is no consensus regarding the cut off value of elastography to differentiate between benign and malignant lesions.

Methods: The present study aimed to determine cut off value to differentiate between benign and malignant lesions of prostate and to test sensitivity, specificity, and positive predictive value (PPV) of SWE. It is a prospective observational study, done over 6 months at a single tertiary care center. The study included 50 patients. All patients underwent 12 cores prostate biopsies. Elastography of the involved segment compared with histopathology of core biopsy from the same segment.

Results: Mean age was 69.12 years. Serum prostate specific antigen ranged from 3.8 to 698 ng/dl. Out of 50, 23 patients had Ca-P, 27 patients had benign histology. Elasticity in Ca-P group ranged from 76.5 to 161.7 kPa, with mean of 109.39 kPa. Elasticity in the benign group ranged from 19.7 to 134.1 kPa, with mean of 69.94 kPa. Based on these mean elasticity values, we concluded 90 kPa as cut off value as a mean between benign and malignant values to differentiate between benign and malignant lesions. Sensitivity calculated based on this cut off value is 82.6%, specificity – 55.6%, PPV – 61.3%, and negative predictive value (NPV) – 78.9%.

Conclusions: This study concludes that 90 kPa on SWE can be used as cut off between benign and malignant prostate lesions with high sensitivity (82.6%) and specificity (55.6%) and PPV of 61.3% and NPV of 78.9%.

Key words: Elastography, Prostate cancer, Transrectal ultrasound

BACKGROUND

Elastography is a non-invasive imaging to depict relative tissue stiffness or displacement (strain) in response to impacted force. Stiff tissues deform less and exhibit less strain than compliant tissues in response to the same applied force.[1]

Traditionally, grayscale transrectal ultrasonography (TRUS) is used in the diagnosis of prostate disorders and to guide biopsy.[2] Biopsy protocols should be optimized to accurately detect carcinoma prostate (Ca-P), while also reducing the number of prostate biopsy cores and biopsy-related complications. Ca-P tissue is stiffer than normal tissue, which is occasionally found during the digital rectal examination (DRE). It is one of the earliest organs, for

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which elastography was proposed, applied, and being used. Transrectal elastosonography has already been established to be feasible in guiding biopsies and for improving the detection of prostate lesions.

Shear wave elastography (SWE) is a modified real-time imaging technique that represents a substantial advance in ultrasound elastography.[3] When SWE is applied, the transducer generates an acoustic radiation force using a special "supersonic" speed that moves multiple focus points following the Mach cone principle.[4] Then, the tissue is mechanically excited by the Mach cone impulse to generate small, localized tissue displacements (1–10 mm). These tissue displacements have been tracked using a compression sonoelastography system to calculate the shear wave propagation speed and the quantitative tissue stiffness based on Young's modulus and kPa.[5,6] The previous studies have shown that the Young's modulus of Ca-P was significantly greater than that of benign prostatic tissue; the sensitivity ranged from 43% to 96.2%, and the specificity ranged from 69.1% to 96.2% in various studies.[7-13] There have been large differences among the results of these studies, and the cut off value for clinically adequate distinction between Ca-P and benign tissue remains undetermined.

The present study aimed to test overall accuracy, sensitivity, specificity, and positive predictive value (PPV) of SWE to differentiate between benign and malignant lesions of prostate and to determine cut off value to differentiate Ca-P and benign tissue.

METHODOLOGY

Prospective observational study conducted over period of 6 months in a single tertiary care center.

The study included 50 patients.

Patients were advised TRUS with elastosonography [Figures 1 and 2] and systemic prostate biopsies based on DREs and elevated serum prostate specific antigen (PSA) levels. All patients underwent 12 core systemic prostate biopsies. A single observer was involved throughout the study.

Post-procedural histopathology report followed [Figure 3].

Elastography of the involved segment compared with histopathology of core biopsy from the same segment.

Variables taken into consideration are age, serum PSA level, elasticity value of a segment, and histopathology of the same segment.

RESULTS

The mean age was 69.12 years, ranging from 56 years to 82 years. Serum PSA ranged from 3.8 ng/dl to 698 ng/dl. Out of 50 patients, 23 patients had Ca-P confirmed with histopathology examination. Rest 27 patients had benign histopathology ranging from

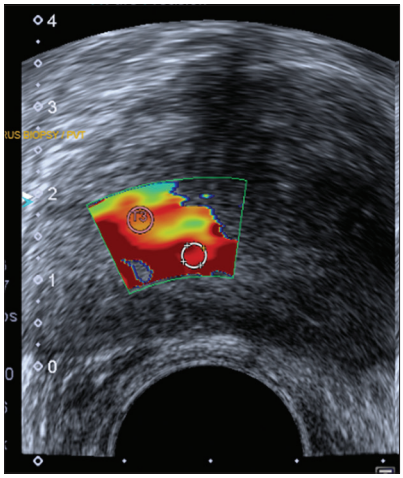

Figure 2: Elastography applied on same the suspected lesion and Elastography value measured (Red being highest value and blue being least)

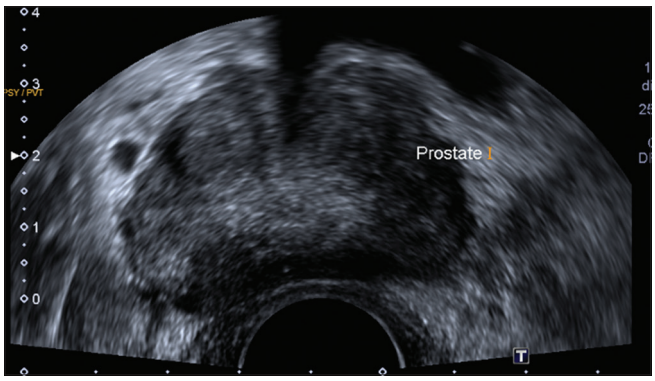

Figure 1: Normal TRUS image of prostate

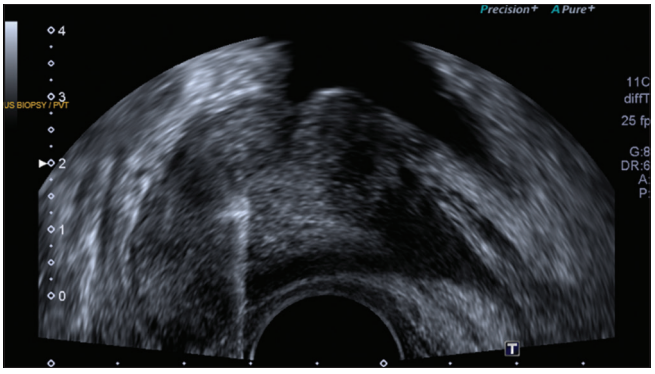

Figure 3: Biopsy taken from the same segment, which is later compared with Elastography value from the same segment

benign prostatic tissue, chronic prostatitis, and prostatic abscess to xanthogranulomatous prostatitis [Table 1]. The range of elasticity varied from 76.5 kPa to 161.7 kPa in the Ca-P group, with a mean of 109.39 kPa. The range of elasticity varied from 19.7 kPa to 134.1 kPa in benign prostate tissue group, with a mean of 69.94 kPaI [Table 2].

Thus, averaging both mean of benign and malignant elasticity values, 90 kPa was taken as cut off. Further, calculations were done based on that value.

Sensitivity of the study based on this cut off value is 73.91%, specificity is 76%, PPV 75.49%, and negative predictive value (NPV) 74.44% [Table 3]. All values are calculated using standard statistical formulas for sensitivity, specificity, PPV, and NPV.

DISCUSSION

SWE has been recently shown to be a useful technique for prostate examination, especially in diagnosing Ca-P. Previously, few studies have been conducted to measure its efficacy. Barr *et al.* reported that SWE showed a high sensitivity of 96.2%, specificity of 96.2%, PPV of 69.4%, and NPV of 99.6% for the detection of Ca-P when 37 kPa was used as a cut off value between benign and malignant lesions.[10] This study shows when low elasticity values are being taken as a cut off to differentiate between benign and malignant lesions, it provides high sensitivity and specificity. Ahmad *et al.* also showed that the sensitivity and specificity of SWE for Ca-P detection could each reach 90%.[7] No cut-off value was provided during this study. Woo *et al.* reported low sensitivity and variable specificity for the diagnostic value of SWE in the detection of Ca-P, even if the SWE parameters were significantly different between Ca-P and benign prostate tissues.[12] Porsch *et al.* showed that SWE was a poor predictor of malignancy for prostate lesions.[14] Considering these inconsistent results, we did plan our study to assess the diagnostic value of SWE for the detection of Ca-P based on elasticity. Based on mean elasticity values, we concluded 90 kPa as a cut off value. Taking this cut off into consideration, specificity and sensitivity were calculated. Values of sensitivity and specificity were quite high and acceptable for using 90 kPa as cut off value to differentiate between benign and malignant lesions. Thus, finding lesions more than 90 kPa elasticity on SWE can be considered malignant with 73.91% sensitivity and 76% specificity. Real-time quantitative SWE imaging is potential enough to change the clinical practice of Ca-P identification and screening by improving the localization of abnormal foci and allowing limited, targeted biopsies of suspicious areas, thereby reducing both complications and costs associated with the current practice of systemic prostate biopsies.

There are no specific cut off values as per the current literature available. Therefore, this study is interesting for future of TRUS guided biopsies, still, it is subjective for investigations. Based on the findings of this study and previous studies, we consider SWE to be a novel and non-invasive imaging technique that is superior to conventional TRUS for the assessment of tissue stiffness to provide information for the detection of Ca-P and biopsy guidance. There are no significant differences in intraobserver reproducibility among the measurements, practitioners should be trained in its application. Larger number of cases should be conducted to reveal the correlation between the Gleason score and the tissue stiffness of Ca-P. Multiparametric MRI (mpMRI) provides the best anatomical and functional imaging of the prostate compared with that of other imaging methods, and all related studies suggested that mpMRI could be used to trigger a targeted repeat biopsy for prostate cancer diagnosis.[15] Future research should be performed to evaluate the correlations between SWE and mpMRI with histopathology as the gold standard.

Table 1: Containing demographic profiles including patient's age, serum PSA levels, and histopathology reports

Age	69.12 years mean (56–82 years)
Serum PSA	60.83 ng/dl mean (3.8–698 ng/dl)
Histopathology	Number of patients
Adenocarcinoma prostate	23
Chronic prostatitis	8
Benign prostatic tissue	12
Prostatic abscess	6
Xanthogranulomatous prostatitis	1

PSA: Prostate specific antigen

Table 2: Range of elastography values of malignant and benign lesions with mean value

Elastography	Minimum (kPa)	Maximum (kPa)	Mean (kPa)
Malignant	76.5	161.7	109.39
Benign	19.7	134.1	69.94

kPa: Kilo pascle

Table 3: Calculating sensitivity, specificity, positive predictive value, and negative predictive value based on 90 kPa cut off for elastography

Parameters	Result (%)
Sensitivity	82.6
Specificity	55.6
Positive predictive value	61.3
Negative predictive value	78.9

CONCLUSION

To conclude, this study shows that 90 kPa on SWE can be used as cut off between benign and malignant prostate lesions with high sensitivity (82.6%) and specificity (55.6%) for the detection of Ca-P and is useful with PPV of 61.3% and NPV of 78.9%.

Limitations

Further studies with a multicenter design and larger number will be needed to assess the role of SWE in the detection of Ca-P. SWE can be combined with MRI for fusion biopsy to make the best use of both modalities.

Declarations

- Institutional Research Ethics Committee approval was obtained before the study (IEC Ref No: CSP-MED/19/NOV/57/198).
- The datasets used and/or analysed during the current study are available from the corresponding author on request.
- No conflicts of interest for any of the authors.

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Original Article

The Aftermath of Corona Pandemic on the Psychosocial Life of Coimbatore South Population: A Cross-sectional Study

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Abstract

Introduction: Coronavirus disease is an infectious disease caused by a newly discovered coronavirus. Since the new coronavirus can spread unnoticed so easily, many governments have felt the best way to ensure people having minimal contact with each other is to order total lockdowns. This study is performed a month after lockdown to evaluate the impact of corona pandemic on the psychosocial life of Coimbatore south population.

Materials and Methods: A cross-sectional randomized study was conducted at Coimbatore South, Tamil Nadu, India, between April 26, 2020, and April 30, 2020. The sample size was 600. Pre-tested structured and self-structured e-questionnaire was sent to the study population and the answers were viewed using separate email id.

Results: Of the 600 people, 59.5% were males and 40.5% were females. The majority (82.5%) of people felt that they were safe during the pandemic majority of people (61%) felt that the modern lifestyle was the cause for the pandemic and 66.9% of the people increased the usage of traditional and natural remedies during the lockdown.

Conclusion: We infer that the majority of the people (55%) enjoyed the break from their routine with an eye on their education and career.

Key words: Boredom, Coronavirus, Lockdown, World Health Organisation

INTRODUCTION

Coronavirus disease-2019 (COVID-19) is an infectious disease caused by a newly discovered coronavirus.[1] The World Health Organization (WHO) used the term 2019 novel coronavirus to refer to a coronavirus that affected the lower respiratory tract of patients with pneumonia in Wuhan, China, on December 29, 2019.[2,3] The WHO announced that the official name of the 2019 novel coronavirus is COVID-19, which has now been declared as a Public Health Emergency of International Concern by the WHO.[4] The COVID-19 virus spreads primarily through droplets of saliva or discharge from the nose when an infected person coughs or sneezes. Most of the infected people will develop mild to moderate symptoms and recover without requiring special treatment. People who have underlying medical conditions and those over 60 years old have a higher risk of developing severe disease and death.[5] People with mild respiratory symptoms who are otherwise healthy should self-isolate and contact their medical provider or a COVID-19 information line for advice on testing.[5] Globally, as of 2.00 AM CEST, April 27, 2020, there have been 213 countries, areas, or territories with cases 2,883,603 confirmed cases of COVID-19, including 198,843 deaths, reported to the WHO.[6,7] At this time, there are no specific vaccines or treatments for COVID-19. However, there are many ongoing clinical trials evaluating potential treatments.[1]

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In the absence of treatment or a vaccine, ceasing most human contact is really the only way to stop the spread of the virus. Essentially, the less the people have contact with each other, the less the virus can spread. Since the new coronavirus can spread unnoticed so easily, many governments have felt the best way to ensure people having minimal contact with each other is to order total lockdowns, with people only being allowed to leave to get food or medicine and to practice social distancing when they do leave their houses. To stay in houses with family and to work from home is quite unusual for people. At the time of our study, the first phase of lockdown was from March 25, 2020, and April 14, 2020. The second phase of lockdown continued from April 15, 2020, and is supposed to end on May 3, 2020. This study was performed a month after lockdown to understand the impact of corona pandemic on the psychosocial life of Coimbatore South population.

MATERIALS AND METHODS

Study Design and Setting

A cross-sectional randomized study was conducted at Coimbatore South, Tamil Nadu, India, between April 26, 2020, and April 30, 2020.

Study Population

Sample size: 600.

Inclusion Criteria

The following criteria were included in the study.

- Physiologically active males and females between 20 and 60 years old
- People residing in the same address for more than 6 months.

Exclusion Criteria

The following criteria were excluded from the study.

- People of age below 20 years old and above 80 years old
- Patients suffering from mental illness and bedridden patients were excluded from the study.

Data Collection

Since the Government has ordered complete lockdown all over the country, collecting data directly from a person using a questionnaire was practically not possible. Hence, data collection was done using Google form in the local language and English language. The study protocol was approved by the local ethical committee. The study population was determined by stratified random sampling. Pre-tested structured and self-structured e-questionnaire was sent to the study population and the answers were viewed using separate email id. Any user with average internet knowledge would be able to access the form and answers the questions. Only those who read and acknowledged the consent were able to participate in the study.

Questions related to psychosocial life during the specified time due to lockdown was structured. Each question had three responses, namely, yes, no, and unable to decide. Participants had to choose one option only. They are as follows…

RESULTS

The e-questionnaire was sent to 626 people. Of these, 26 people did not respond. Only 600 people responded. Hence, we accepted them as our study population.

Of the 600 people, 59.5% were males and 40.5% were females [Table 1].

This shows that males have better access to mobile phones and internet facilities.

About 69.2% of people fell under the age category of 20–30 years and 4.4% of people fell under the age category of 51–60 years [Table 2].

Table 1: Gender

Gender	Number of participants	Percentage
Male	357	59.5
Female	243	40.5
Others	0	0

Table 2: Age

Age groups	Number of participants	Percentage
20–30	415	69.2
31–40	90	15
41–50	55	9.2
51–60	26	4.4
61–70	13	2.2

Table 3: Residence

Residence	Number of participants	Percentage
Village	134	22.4
Semi urban	111	18.5
Urban	209	34.8
Metropolitan	146	24.3

Table 4: Educational qualification

Qualification educational	Number of participants	Percentage
10^{th}–12^{th}	38	6.3
Graduate	302	50.3
Postgraduate and above	226	37.7
Others	34	5.7

From this, we understood that the people between 20 and 30 years of age actively accessed the internet. This may be because they were students or worked from home.

About 34.8% of people are from the urban area, 24.3% of people are from the metropolitan area, 18.5% of people are from the semi-urban area [Table 3].

Hence, in total, the majority of the population (77.6%) had a good lifestyle. The literacy rate was about 94.3% in total [Table 4]. The majority of the people, namely, 56.7% were unmarried [Table 5].

A set of 20 questions were asked to assess the mental well-being of the study population [Table 6].

The majority of the people (50.5%) felt that their productivity was affected during lockdown and 36.3% of people felt that their productivity was unaffected [Table 6].

About 65.6% of people felt lonely during this lockdown and 30.4% of people did not feel anything abnormal [Table 6]. This could be because the majority of the study population were unmarried [Table 5].

About 59.5% of people felt that spending time on social media really helped them to kill time [Table 6]. This could be because the majority of the population were between 20 and 30 years of age [Table 2].

About 14% of people had negative thoughts about their health, whereas 81.8% did not have negative thoughts about their health [Table 6]. This could be because of the fact that they all remained indoors and avoided human contact.

One of the most astonishing facts from the study was that majority of the population (63.4%) did not bother about corona related WhatsApp images and stories, while 31.8% of them felt that it did affect [Table 6]. This is because of the adequate awareness taken by the Union and the State Governments.

The fear about gaining weight (44.8%) and vice versa (45.7%) among the study population was almost equal [Table 6].

Another astonishing fact about our study was that 79.7% of people engaged in more household work during the lockdown period. Only 18% of people did not involve [Table 6]. This shows that the basic oneness among the family has not lost even in this fast-paced world.

About 55% of people felt that it was good to have a break from their routine and 36.8% of people felt the other way [Table 6]. This may be because the majority of the population would not have taken an adequate break during the other days.

In another question, we found that 55% of people experienced boredom during the lockdown period and 38% of people did not experience any boredom [Table 6].

Table 5: Marital status

Marital status	Number of participants	Percentage
Married	258	43
Unmarried	334	55.7
Divorced	4	0.7
Separated	4	0.7

Table 6: Questions and responses

Questions	Yes (%)	No (%)	Unable to decide (%)
My productivity is affected since lockdown	303 (50.5)	218 (36.3)	79 (13.2)
I feel lonely during this lockdown	393 (65.6)	182 (30.4)	24 (4)
Spending time on social media help me to kill the time	357 (59.5)	191 (31.8)	52 (8.7)
I have any negative thoughts about my health	88 (14.7)	49 (181.8)	21 (3.5)
I feel that corona related WhatsApp images and stories affect my thoughts	380 (31.8)	191 (63.4)	29 (4.8)
I have gained weight during this lockdown	269 (44.8)	274 (45.7)	57 (9.5)
I am getting myself involved in more household work during this lockdown	478 (79.7)	108 (18)	14 (2.3)
I feel good because of a break from my daily routine?	330 (55)	221 (36.8)	49 (8.2)
I experience boredom due to ongoing lockdown	331 (55)	226 (38)	43 (7)
I am worried about my job	308 (51.3)	257 (42.8)	35 (5.8)
There are relationship conflicts during this lockdown	362 (60.3)	182 (30.3)	56 (9.3)
My personal life is affected	192 (32)	383 (63.8)	25 (4.2)
I feel that tele-counseling is effective during lockdown	221 (36.8)	236 (39.3)	143 (23.8)
Use of herbs and traditional remedies have increased in my house	401 (66.9)	169 (28.3)	29 (4.8)
My gut feeling says that I am safe during this pandemic	495 (82.5)	44 (7.3)	61 (10.2)
I feel our traditional lifestyle is the best	516 (86)	38 (6.3)	46 (7.7)
I do not enjoy things the way they were earlier	264 (44)	218 (36.3)	118 (19.7)
I am worried about self/children's education/career	368 (61.3)	186 (31)	46 (7.7)
My sleep, appetite, and daily life are disturbed	289 (48.2)	293 (48.8)	18 (3)
Modern lifestyle is responsible for spread of COVID-19	366 (61)	118 (19.7)	116 (19.3)

Table 7: Occupation

Occupation	Number of participants	Percentage
Self-employed	52	8.7
Government employee	43	7.2
Private employee	257	42.8
Homemaker	34	5.7
Not employed	17	2.8
Student	163	27.2
Retired	13	2.2
Other	21	3.5

This may be due to the fact that the majority (51.3%) of the study population were employed [Table 7].

As expected by us, 60.3% of people had relationship conflicts during this lockdown period and 30.3% of people did not have any relationship conflict [Table 6]. This could be due to the fact that the majority of the population were left unemployed due to lockdown and faced issues like boredom.

One of the interesting facts of our study was that only 32% of people felt that their personal life was affected and the majority of them, namely, 63.8% of people felt the opposite [Table 6].

About 36.8% of people felt that tele-counseling was effective during lockdown and 39.3% of people felt that tele-counseling would not be effective during lockdown and 23.8% of the study population were unable to decide [Table 6].

Another good thing during the lockdown was that about 66.9% of people increased the usage of traditional remedies in their houses. This could be due to the fact that people started to realize the importance of traditional and natural things in the day to day life and 86% of people felt that they were the best.

The majority (82.5%) of people felt that they were safe [Table 6] during the pandemic and 7.3% of people felt that they were not safe. This could be due to the effect of staying indoors.

As expected, 44% of people did not enjoy things the way they enjoyed them earlier and 36.3% of people said that they did not find any differences [Table 6].

As expected, about 61.3% of people worried their own/children's education/career and 31% of people had no worries about them [Table 6].

Interestingly, 48.2% of people felt that their sleep, appetite, and daily life were disturbed and 48.8% of people felt that their sleep, appetite, and daily life were not disturbed [Table 6].

About 61% of people felt that the modern lifestyle was responsible for the spread of COVID-19 and 19.7% of people felt that the modern lifestyle had nothing to do with COVID-19 [Table 6].

DISCUSSION

According to Seligman (2002), happiness was composed of 3 subjective facets: Positive emotion, engagement, and meaning. Happiness was, therefore, achievable by pursuing one or more of these facets. As a result, individuals low in one aspect could still be "happy" if they nurtured other components. In our study, we aimed to understand the impact of lockdown in the lives of people. We infer that the majority of the people (55%) enjoyed the break from their routine with an eye on their education and career. The majority of the people (79.7%) involved in household activities with their fellow family members. The majority of people (61%) felt that the modern lifestyle was the cause for the pandemic and 66.9% of the people increased the usage of traditional and natural remedies during the lockdown. Before the study, we expected the people to be stressed because of staying indoors for one continuous month. After analyzing the data, we were astonished that most of the people were positive and felt good. This could due to the awareness created by the Government and the role of media is commendable.

CONCLUSION

We infer that the majority of the people (55%) enjoyed the break from their routine with an eye on their education and career. This is the impact after 30 days only. However, the same study has to be repeated again after a month to know whether this lockdown still remains a blessing on the psychosocial life of the people or a catastrophe!!

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Original Article

Risk Factor Profile of Patients Infected with COVID-19: An Observational Study

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Abstract

Background: Coronavirus (CoV) infection has become a pandemic worldwide for February 2020. The infection rate has been increasing in India also which prompted the Government to implement countrywide lockdown.

Aims and Objectives: The main objective of our study is to evaluate risk factors predisposing the patients to COVID-19 infection.

Methods: This is a single center prospective observational study done during April and May 2020, where we have collected all demographic details of total 59 COVID-19 patients admitted to the intensive care unit or general ward in our institute. We have evaluated the detailed history of these patients for risk factors such as age, gender, smoking, alcohol exposure, diabetes mellitus, hypertension, and cardiovascular disease and studied their association with COVID-19.

Results: In our study, we have found the mean age of presentation to be 51 years and males with 64.4% are more infected than females. Diabetics with 32% is the most common risk factor followed by hypertension with 20.3%. Alcohol is next only to hypertension with 12% and smoking comprising 10% of the population studied.

Conclusion: Elderly male population, diabetes, and hypertension pose a greater risk for CoV severe acute respiratory syndrome coronavirus 2 infection in our population.

Key words: COVID-19, Diabetes, Old age, Pandemic, Risk factors

INTRODUCTION

A new zoonotic strain of coronavirus (CoV) has entered into human life from Wuhan city of China for December 2019.[1] It is one of the most fatal diseases with significant secondary infection rate, which the world has experienced in the past century. The disease caused by this new strain was named COVID-19 and declared a pandemic by the WHO on March 11, 2020.[2] COVID-19 has been affecting human beings all over the world, mostly affecting countries such as Italy, Spain, and the United States with maximum infectivity rate and fatality.

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In India, 1st COVID-19 case was detected on January 31, 2020, and incidence has been increasing then-on. As infection is quite new to the world, the pattern of infectivity and risk factors are yet to be proven. By the end of May, total number of COVID cases has reached 191,000 in India with a mortality rate of around 0.02% per lakh population, whereas worldwide, it is 4.1% per lakh population as per the WHO update on infection rate. Age and comorbid factors are considered as main risk factors for infection and deaths of COVID-19 patients. Several studies published till now have suggested a variety of risk factors for COVID-19. Our aim is to study and evaluate the prevalence of risk factors in patients with COVID-19 in our region.

RESEARCH DESIGN AND POPULATION

We have conducted a single centered, observational prospective study. Our hospital is a designated COVID-19 center and all the COVID-19 positive patients were

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admitted and given preliminary treatment. All the patients were diagnosed with COVID-19 using real-time (RT) PCR technique as per the WHO guidelines.

Inclusion Criteria

In our study, we enrolled all the patients who were tested positive with RT PCR for COVID-19.

Laboratory confirmation of COVID-19 is done by RT PCR technique using two genes, i.e., RDRP gene and E gene. All the patients who developed symptoms such as sore throat, fever, shortness of breath, and generalized weakness (malaise) are screened for COVID-19. Moreover, people who came in contact with COVID-19 positive patients were also screened. People who had international travel history before 14 days were also screened. We have enrolled all the patients who were tested positive for COVID-19 during the period from April 1, 2020, to May 15, 2020, in our study.

Data Collection

All the patients were admitted and the clinical history and demographic details were recorded. History includes information on smoking, alcohol intake, and comorbid conditions such as diabetes mellitus, hypertension, coronary artery disease, cerebrovascular disease, and chronic pulmonary disease. All the patients were evaluated and monitored for symptoms such as sore throat, fever, shortness of breath, and generalized weakness (malaise), vomiting, nausea, diarrhea, and headache. Laboratory investigations were sent for complete blood picture, liver function test, renal functions test, random blood sugar, HbA1c, lipid profile, BT, CT, PT, APTT, ECG, and chest X-ray which were also done, but our study is limited to risk factor evaluation. Data are analyzed using 2013 Microsoft Office Excel software.

RESULTS

Our study involved 59 patients with median age 51 years with minimum of 9 years and maximum of 59 years. Of them 38 were male and 21 were female accounting to 64.4% and 35.6%, respectively, as depicted in Table 1.

The common risk factors documented were diabetes with 32% accounting to 18 patients. The next most common risk factor was found to be hypertension in 12 patients, i.e., 20.3%. followed by alcohol intake in 12% of patients accounting for seven patients. Six patients nearly 10% had smoking as risk factor, cardiovascular disorders, and chronic respiratory diseases constituting <3% accounting to two patients in each category. All the above risk factors are depicted in Table 2 below.

Table 1: Sex distribution in COVID-19 patients

Sex	No. of patients	Percentage
Males	38	64.4
Females	21	35.6

DISCUSSION

CoV is a family of six strains with an envelope surrounding a non-segmented single-stranded RNA. A new seventh strain was identified in Wuhan in December 2019 causing pneumonia in most of the affected individuals and named that it as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). It is shown to be acting on ACE2 receptors in lung epithelium and causing respiratory epithelium damage and manifestations.[3] As it is a viral infection, it is postulated that infectivity rate is more in individuals, where immunity is compromised and a certain group of people who are highly exposed to it like health-care professionals.

In our study, we have illustrated that the risk of infection is more in the elderly population with the median age of 51 years. This study is similar to a recent study published in China by Yongli Yan *et al.*[4] The study also demonstrated that men are more affected than women with 64.4 % in male sex when compared with 35.6 % in the female sex. Yongli Yan *et al.* also published a similar trend in their study.

Huang *et al.* showed high prevalence of diabetes mellitus in their study with 20% in adults.[5] In our study, we have observed 32% of COVID-19 patients were diagnosed with diabetes, this suggests that patients with diabetes mellitus were more prone to develop COVID-19. The mechanism of increased susceptibility of diabetes should be studied. Next common risk factor associated with COVID-19 is hypertension with 20% which correlated to study published Shi *et al.*[6] Huang *et al.* showed that 15% of patients had hypertension in their study, whereas our study demonstrated prevalence of 20.32% in our study.[7]

Smokers in Huang *et al.*, comprised <1% but Shi *et al.*, quoted in their study that 8% of the patients were smokers.

Table 2: Various risk factors prevalent in COVID-19 patients

Risk factor	No. of patients	Percentage
Diabetes	18	32
Hypertension	12	20.3
Alcohol	7	12
Smoking	6	10
Respiratory disease	2	3
Cardiovascular disease	2	3

In our study, smokers were 10% which demonstrated smoking to be a significant risk factor in our population. Our study showed that 12% of patients had a history of alcohol intake. About 14.5% of cardiovascular disease are a risk factor in a study published by Wang *et al*., whereas our study had around 3% which shows that infection rates are not common in cardiac patients in our population. Our study had 3% of patients with a respiratory disease which is associated with COVID-19, whereas Wang *et al*., study had respiratory disease in 2% of population.[7]

CONCLUSION

SARS-CoV-2 is a new strain of virus from corona family is most common among diabetics and hypertensive population. Age alcohol and smoking emerged as the next common risk factors for COVID-19 in our study.

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Original Article

Supraorbital Keyhole Approach for Anterior Circulation Aneurysms: An Institutional Experience

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Abstract

Background: Pterional approach is most accepted and most common approach for clipping of intracranial anterior circulation aneurysms. This approach imparts good exposure of anterior and middle skull base. However the Pterional approach has potential adverse effects, such as long operative time, excessive blood loss, long hospital stay, and temporal muscle atrophy. Supraorbital keyhole via eyebrow incision is a minimal invasive approach for anterior circulation aneurysm surgery. This approach has advantages of less operative time, less blood loss, less brain retraction, short hospital stay and no temporal muscle atrophy.

Objective: Objective of this study to emphasize the advantages and limitations of supra orbital key hole approach for anterior circulation aneurysm surgery based on our institutional experience.

Material and Methods: Between September 2017 and February 2020, total 16 patients with anterior circulation aneurysms were operated by suprorbital keyhole craniotomy approach. All patients included were ≥18 years of age with Subarachnoid hemorrhage grade 1, grade 2, grade 3 on modified fischer scale. Intra operative and postoperative parameter noted and analyzed over a period of 3 months follow up.

Results: There were good cosmetic results with less approach related complications. We achieved good recovery (4/5) on Glasgow outcome scale score 4 or 5 were achieved in 87.5% of the patients in follow period of 3 months.

Conclusion: Supra orbital key hole approach is not a standard approach for all kind of anterior circulation aneurysms, it can be applied for small sized aneurysms with SAH grade up to 3 on modified fischer scale. An thorough pre-op work up, experience, skilled hand are prerequisites for supra orbital keyhole approach in aneurysm surgery. Selection of this approach should be based on aneurysms morphology, size of aneurysm, grade of SAH, brain edema, and the surgeon's experience.

Key words: Anterior circulation aneurysm, Minimal invasive approach, Pterional craniotomy, Supraorbital keyhole surgery

INTRODUCTION

Various conventional approaches such as frontal and pterional approach are used to gain access anterior circulation aneurysms. These approaches impart excellent exposure to anterior and middle crania fossa. Major disadvantages of these approaches are such as long operative period, extensive brain retraction, more blood loss, long operative time, and poor cosmetic results. The evolution of these approaches from Dandy's frontotemporal "macrosurgical approach" to the supraorbital keyhole approach has served to provide satisfactory exposure to safely address different intracranial pathologies.[1] Keyhole approach for intracranial pathologies has shown how a evidently small incision can be sufficient for operating on tumors and aneurysms. The cosmetic results are considerably better in this approach.[2] The aim of "keyhole" surgery was not to achieve a small size incision and craniotomy for the purpose of a small opening. The goal of keyhole approach was to entitle adequate access to intracranial lesions while restricting trauma to adjacent tissue such as the skin, bone, dura, and brain.[3,4] Keyhole approach may not be suitable for all kind of lesions of the anterior skull base. There is a narrow viewing angle through this approach that may require frequent adjustment of the operating room table and microscope for adequate visualization of a given lesion. Illumination is often another problem as getting adequate light through

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such a small opening onto a deep-seated target areas.[2,5] In case of vascular lesions, a smaller opening in a blood-filled area can also make it burdensome to procure adequate vascular control without injury to neighboring structures.[6] Relative contraindications comprise the presence of a large frontal sinus, recent subarachnoid hemorrhage, and severe brain edema.[7,8] Almost all aneurysms of anterior circulation being amenable to clipping by supraorbital keyhole approach due to refinements in operative techniques. Supraorbital craniotomy approach has been shown to be efficacious and secure for anterior circulation aneurysms. This approach has many advantages such as less operative time, less retraction for brain, less blood loss, short hospital stay with good cosmetic outcome, and similar rate of complications related to the surgical treatment of anterior circulation aneurysms compared to conventional approaches.[5] Along with this rationale, we present our experience in clipping 16 anterior circulation aneurysms operated through supraorbital keyhole approach in a tertiary care hospital.

MATERIALS AND METHODS

Between September 2017 and February 2020, a total of 16 patients with anterior circulation aneurysms were operated by supraorbital keyhole craniotomy approach. All patients included were ≥18 years of age with subarachnoid hemorrhage Grade 1, Grade 2, and Grade 3 on modified Fisher scale computed tomography with anterior circulation aneurysm (anterior communicating, anterior cerebral artery aneurysm of A1, middle cerebral artery aneurysm M1 and M2 segment, and internal carotid artery bifurcation) on computed angiography brain [Figure 1]. In post-operative period, all patients underwent computed angiography.

Surgical Technique

The supraorbital keyhole approach executed in this study was delineated in detail by Perneczky *et al.*[4] The patient was placed in the supine position with head elevated 30° above the level of the heart and turned between 15° and 60° to the opposite side of intended site of incision. The degree of head rotation relies on the location of aneurysm. Extent of head rotation for the anterior communicating artery, middle cerebral artery, and internal cerebral artery was 40–60°, 15°, and 20–30°, respectively. The neck was slightly extended so that the zygomatic arch was the highest point. This position permits the gravity assisted self-retraction of the frontal lobe.

After sterilizing the surgical field, skin incision was made in the superior edge of the eyebrow or on the forehead crease just above the eyebrow, starting from the midpupillary line and extending laterally to just behind the frontal process of the zygomatic bone. The supraorbital nerve and artery, the frontal branches of the facial nerve, and the superficial temporal artery were always protected. Subcutaneous dissection was done from the supraorbital foramen to the frontozygomatic suture [Figure 1]. The temporalis fascia was incised close to its attachment at the anterior temporal line. Subperiosteal dissection of the temporalis muscle was done to expose the keyhole burr hole site. A burr hole was made on the superior temporal line, just above the frontal base. The craniotomy was performed using a high-speed drill. The medial-inferior edge of the craniotomy went around the level of the frontal base and the lateral edge to the sphenoid wing, at a width of 25–30 mm and a height of 15–25 mm [Figure 2]. A large frontal sinus is a relative contraindication to this approach. If the frontal sinus was entered inadvertently, it was exenterated by removing and cauterizing its mucosa and covered with a periosteal flap. The dura was opened in a semicircular fashion at frontal base. A traditional microsurgical technique was implemented with optimal illumination with an operative microscope. The arachnoid of the carotid cistern, the Sylvian fissure, and suprasellar cisterns were opened for cerebrospinal fluid (CSF) drainage, to create enough room for brain retraction and surgical manipulation. Lamina terminalis was sometimes opened to drain CSF. Water tight dural closure done at the end of surgery. Bone flap replaced and fixed with miniplates and screws. The

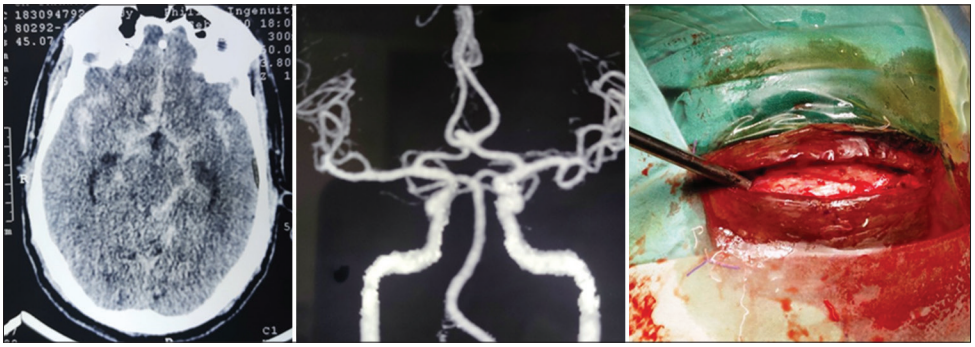

Figure 1: From left to right modified Fisher Grade 3 subarachnoid hemorrhage, second image shows Acom aneurysm, supraorbital skin incision, and dissection of subcutaneous tissue and frontalis muscle

Table 1: Pre-operative parameters

Age (years)	Sex	Hunt and Hess grade	Glasgow Coma Scale on admission	Modified Fisher grade of subarachnoid hemorrhage	Aneurysm location	Aneurysm size (mm)	Aneurysm shape
19	F	1	E4V5M6	1	Left ICA bifurcation	4.2 × 4.5	Saccular
55	M	2	E4V5M6	2	Acom	2.8 × 2.9	Saccular
43	F	2	E4V5M6	2	Acom	3.7 × 4.0	Saccular
45	M	2	E4V4M6	2	Acom and right ICA bifurcation	3.5 × 3.8 and 5.2 × 5.4	Saccular
55	F	2	E4V5M6	2	Acom	4.2 × 4.4	Bilobed
58	F	3	E4V2M5	2	Left ICA bifurcation	6.9 × 7.1	Saccular
45	F	2	E4V5M6	1	Acom and right MCA bifurcation	3.5 × 4.1 and 7.6 × 8.2	Saccular
46	M	3	E4V3M5	3	Acom	3.8 × 3.9	Saccular
57	F	2	E4V5M6	2	Acom	3.3 × 3.7	Multilobed
41	F	2	E4V5M6	1	Acom	4.1 × 4.3	Saccular
43	M	2	E4V5M6	1	Acom	4.0 × 4.2	Saccular
54	F	1	E4V5M6	2	Acom	3.6 × 3.7	Saccular
55	M	1	E4V5M5	1	Right ACA (A1 part)	5.7 × 5.9	Saccular
76	F	2	E4V5M6	2	Acom	3.5 × 3.8	Saccular
40	M	2	E4V5M6	1	Acom	3.3 × 3.6	Saccular
45	F	2	E4V5M6	2	Acom	4.4 × 4.5	Saccular

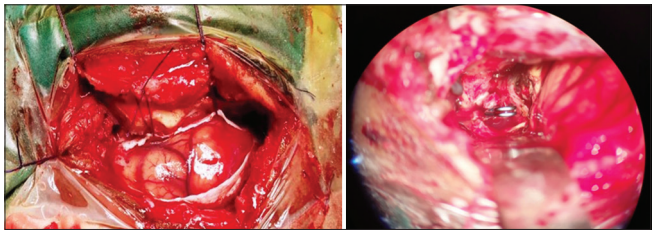

Figure 2: Left to right, brain edema after supraorbital keyhole craniotomy, microscopic view shows clipped Acom aneurysm

temporalis muscle and fascia were sutured back to the frontal pericranium. The surgical wound closed in layers. Skin incision closed with subcuticular sutures.

Data Collection

Pre-operative data collection included were age, sex, gender, clinical presentation, grading on Hunt and Hess scale, Glasgow Coma Scale on admission, subarachnoid hemorrhage grading on modified Fisher scale, and aneurysm morphology in form of size, shape, and direction.

Intraoperative data collection included were duration of surgery, violation of frontal sinus, and premature rupture of aneurysm before proximal control.

Post-operative data collection in follow-up period of 3 months included aneurysm clipping complete or incomplete, presence or absence of vasospasm, periorbital edema, surgical site infection, CSF leakage, numbness of supraorbital area, inability to raise eye brow, mucocele and depression of operated site, hospital stay, and outcome on Glasgow Outcome Scale.

DATA ANALYSIS AND RESULTS

Patients' age ranged from 19 to 76 years with a mean of 48.5 years. There were 10 (62.5%) females and 6 (37.5%) males. Sixteen patients were admitted after subarachnoid hemorrhage (SAH), 3 (18.7%) were in Grade 1, 11 (68.7%) in Grade 2, and 3 (18.7%) in Grade 3 on Hunt and Hiss scale. SAH grading on modified Fisher scale of patients was 6 (37.5%) in Grade 1, 9 (56.2%) in Grade 2, and 1 (6.25%) in Grade 3. There were total of 18 aneurysms in 16 patients at various locations (anterior communicating [72.2%], internal carotid bifurcation [16.6%], middle cerebral artery [5.5%], and proximal anterior cerebral artery [5.5]) and morphology. All aneurysms were ruptured. Size of aneurysm was ranged from 2.8 mm to 8.2 mm [Table 1]. All aneurysms clipped through supraorbital keyhole approach.

Duration of surgery (from skin incision to last skin suture) varied between 105 min (1 h 45 min) and 210 min (3 h 30 min). Average duration of surgery was 163 min (2 h 43 min). Inadvertent violation of frontal sinus was present only in two patients. Premature rupture of aneurysm before proximal control was present in two patients. Temporary clip used in 12 patients with average period of 4.8 min [Table 2].

Average drop in hematocrit was 4.14. Aneurysm occlusion was complete in all patients, Radiologically evident vasospasm was present in two patients. Transient periorbital edema was present in all patients. One patient developed subdural hygroma in post-operative period which treated with burr hole and suction evacuation. There was no surgical site infection. CSF leakage noted in two patients

which was managed conservatively. Transient numbness of supraorbital area was present in two patients and permanent numbness was present in one patient. Inability to raise eye brow transiently was present in two patients. Average hospital stay was 13 days. Post-operative Glasgow Coma Scale was 15/15 in 14 patients which was same as pre-operative period and E4VtM5 in two patients on discharge which was improved and gain consciousness. Good recovery was present in 87.5% on Glasgow Outcome Scale which was 5 in 12 patients and 4 in 2 patients. There were no mucocele formation and depression of operated site [Table 3].

Table 2: Intraoperative parameters

Violation of frontal sinus	Drop in hematocrit	Premature rupture of aneurysm	Duration of surgery (minutes)
No	2.52	No	178
No	5.58	No	155
No	4.08	No	168
No	2.45	No	125
No	3.98	No	136
No	4.10	Yes	210
No	4.25	No	131
No	6.21	Yes	206
No	4.41	No	178
Yes	4.33	No	128
No	4.23	No	170
No	5.10		200
Yes	2.98	No	105
No	3.70	No	188
No	4.24	No	148
No	4.15	No	185

DISCUSSION

The supraorbital keyhole craniotomy approach can be considered as a standard for clipping of different kinds of anterior circulation aneurysms. This approach has advantages such as small incision, small bone window compared to standard craniotomy with similar outcomes on Glasgow Outcome Scale, but requires prominent microneurosurgical techniques and instrumentation.[1] Good recovery GOS (4/5) achieved in 87.5% of patients on Glasgow Outcome Scale which was comparable to outcomes (76.6–82.6% in

Table 3: Post-operative parameters

GOS	Complete clipping of aneurysm	Surgical site infection	CSF leak	Hospital stay (days)	Numbness over supraorbital area	Inability to elevate eyebrow	Depression of surgical site
5	Yes	No	No	12	Absent	No	No
5	Yes	No	No	15	Absent	No	No
5	Yes	No	No	14	Absent	No	No
4	Yes	No	Yes	13	Transient	No	No
5	Yes	No	No	17	Absent	No	No
1	Yes	No	No	07	-	-	-
5	Yes	No	No	18	Absent	No	No
1	Yes	No	No	05	-	-	-
5	Yes	No	No	19	Absent	No	No
5	Yes	No	No	14	Transient	Transient	No
5	Yes	No	No	16	Absent	No	No
5	Yes	No	No	08	Absent	No	No
4	Yes	No	Yes	15	Transient	No	No
5	Yes	No	No	10	Permanent	No	No
5	Yes	No	No	11	Absent	No	No
5	Yes	No	No	17	Absent	No	No

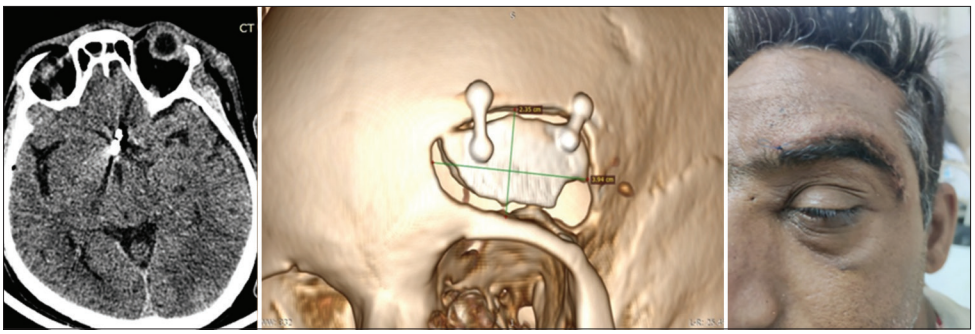

Figure 3: Left to right, NCCT head showing aneurysm clip *in situ*, 3D reconstruction shows post-supraorbital craniotomy defect with miniplates and screw, post-surgical scar mark in post-operative period

supraorbital craniotomy approach and 75–79.5 in pterional approach) in a study by Chalouhi *et al*.[9] One prevalent problem to this concept is the restricted access and scope for manipulation during aneurysm dissection which may lead to premature rupture of aneurysm. Premature ruptured rate was lower (12.5%) in our study as compared to Radonovic *et al*.[10] and Chalouhi *et al*.[9] (13.8%) in pterional craniotomy approach. The key to the problem is a thorough knowledge of microanatomy learned on cadavers. Average operative time was 163 min comparable to 150 min in a study of Won-Sang Cho *et al*.[11] Drop in hematocrit was 4.14 similar to Yuhee Kim *et al*.[12] Case selection is definitely important, as it is for one's ability to work in narrow, confined spaces. Evolution of tube shaft instruments has made this approach possible. Generous opening of arachnoid spaces, as well as Sylvian fissure, is imperative to achieve relaxation of the brain and corridor to the aneurysm location.[13] Dare *et al*. reported on the effective use of this approach in elective surgery of 10 aneurysms of the anterior circulation. The mean aneurysm size was 5.9 mm, with a range of 4–10 mm. They emphasized the advantage of this approach that incorporate minimal disruption and exposure of normal brain tissue, reduced frontal lobe retraction and an excellent post-operative cosmetic outcome.[6] In our study, we achieved similar outcome on Glasgow Outcome Score with good cosmetic results [Figure 3].

CONCLUSION

Supraorbital keyhole approach has many merits and also limitations compared to pterional approach. Supraorbital keyhole approach is not a standard approach for all kind of anterior circulation aneurysms, it can be safely applied for small-sized aneurysms with SAH grade up to 3 on modified Fisher scale with similar outcome on Glasgow Outcome Scale compared to pterional approach with good cosmetic results. A thorough pre-operative workup, experience, and skilled hand are prerequisites for supraorbital keyhole approach in aneurysm surgery. High-grade subarachnoid hemorrhage, brain edema, and giant aneurysm can limit the accessibility to aneurysm and may lead to premature rupture of aneurysm so selection of this approach should be based on aneurysms morphology, size of aneurysm, grade of SAH, brain edema, and the surgeon's experience.

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Original Article

Role of Magnetic Resonance Venogram as a Tool in Planning for Various Neurosurgical Operations

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Abstract

Objectives and methodology: Exact localization of superficial cortical veins is very important in planning for avoiding venous injuries. Cod liver oil capsules were placed on anterior and posterior ends of medial and lateral border of the tumor at scalp according to location of tumor and thus tumor boundaries were marked. Then 3DCEMRV and 2DTOF images were taken and then superficial cortical vein studied in marked area for comparison between both modalities of MRV and planning of surgery for avoiding venous injury.

Results: Most of the cases were in age group 16-60 years (89%). Most common clinical manifestation was headache (86.2%) and meningioma (58.2%) was found to be most common pathology. Clear depiction and morphology of superficial cortical vein was observed in 58 cases (100%) in 3DCEMRV as compared to 2DTOF 24 cases (41.3%) P <0.001S. Clear depiction and morphology of superior sagittal sinus was observed in 58 cases (100%) in 3DCEMRV as compared to 2DTOF 33 cases (60.3%) P <0.001S. In post operative CT Head, we found 6 (10.3%) cases of venous infarction. 7 patients (12%) developed motor weakness post operatively. In 3 cases, post operative MRV were done and found no venous injury.

Conclusion: This study showed that preoperative marking of tumor area and associated venous anatomy with the help of cod liver oil capsule and MRV was very helpful in planning the surgery and to avoid injury of the vein. 3DCEMRV was found to be better modality than 2DTOF for delineation of veins.

Key words: MR venogram, MR venogram in midline and paramedian mass brain, 2D TOF and 3D CE MR venogram

INTRODUCTION

Imaging of intracranial cortical venous system anatomy is important in planning neurosurgical operations of midline masses such as colloid cyst, distal anterior cerebral artery (DACA) aneurysm, corpus callosum gliomas, parasagittal and parafalcine masses, and other midline brain tumors. Parafalcine masses may not be as closely related to the superior sagittal sinus (SSS) as parasagittal tumors, but because of their close relation, their growth may also contribute to anatomical changes to the nearby cortical veins. During parasagittal tumors resection, saving the cortical veins is important as it offers normal venous drainage of the brain, as well as important collateral drainage. Disruption in venous outflow may result in venous infarction which leads to swelling, hemorrhage, and neuronal death and may have catastrophic result.[1,2] Magnetic resonance (MR) venography is very helpful to know the anatomic changes in the cortical veins and its relation with respect to tumor position before surgery so that it can be saved intraoperatively. Assessment of the patency of sagittal venous sinuses is very important to avoid major sinus injury, air embolism, and catastrophic bleeding intraoperatively. Moreover, cortical vessels, especially the veins, are important landmarks in craniotomy. With the help of 3DCEMRV, it has become possible to see the intracranial venous structures noninvasively. MR imaging technique with maximum intensity projection (MIP) method also presents more detailed information of brain surface structure by showing cortical veins.[3,4] The purpose of this study is to assess the usefulness of 3DCEMRV for the evaluation of intracranial venous system in pre-operative surgical planning of brain tumors. In this study, we have compared the visibility of the intracranial venous system on 3DCEMRV with respect to those of

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2DTOFMRV in surgical planning and compared it with intraoperative findings and also evaluated neurological outcomes postoperatively. In few cases, post-operative MRV was done to look for any venous injury.

MATERIALS AND METHODS

Patient population

From May 2017 to February 2020, 58 patients were included which admitted in the Department of Neurosurgery, Sawai Man Singh Medical College and Hospital, Jaipur. All patients underwent 3DCEMRV, as well as 2DTOFMRV in axial and sagittal planes.

Method

All the patients with midline supratentorial masses were selected on magnetic resonance imaging (MRI) brain images. After this cod liver oil, capsules were placed on anterior and posterior ends of medial and lateral border of the tumor at scalp according to the location of tumor on MRI images, and thus, the tumor boundaries were marked with the help of permanent marker. Then, MRV 2-DTOF image was taken in axial and sagittal view. After that, 0.4 ml/kg of gadolinium contrast agent was administered in cubital vein over 4 s and 3DCEMRV images were taken in axial and sagittal plane. All MR examinations were performed with 3-Tesla unit. All MR venographic source images were post-processed with a MIP algorithm to create projection venograms for both the 2DTOF MRV and the 3DCEMRV. All images were saved in DIACOM software. The marked area concerned, superficial cortical veins such as frontopolar vein, anterior frontal vein, middle frontal vein, posterior frontal vein, precentral vein, central vein, post-central vein, anterior parietal vein, posterior parietal vein and occipital vein and bridging veins joining the SSS were studied preoperatively. Sagittal sinus compression was also evaluated, which was defined as a narrowing and filling defect of the lumen. On the basis of these information and surgeons preference, the surgical corridor was decided. Intraoperative findings were compared with that of 3DCEMRV images and intraoperative photographs of cortical veins were taken. In few cases, post-operative MRV was done to look for any venous injury. All the patients were followed up and neurological status of the patients was monitored.

Inclusion Criteria

Conscious, cooperative, and stable patients with supratentorial midline brain tumors were included in the study.

Exclusion Criteria

The following criteria were excluded from the study:

- Unconscious, uncooperative, and unstable stable
- Allergic to gadolinium
- Ferromagnetic cardiac pacemakers, aneurismal clip, and defibrillators
- Claustrophobia

Image Analysis

Degree of visualization and patency of the intracranial venous system, superficial as well as SSS on 3DCEMRV were compared with those of 2DTOF [Figures 1 and 2]. In post-operative period, in few cases, MRV was done to look for any venous injury.

Ethical Consideration

The study protocol was approved by ethical committee. All patients gave written informed consent to participate after having received full written information about the study objective and conducts. Investigations were done using aseptic precautions. They had right to withdraw from study. Protection was given from any kind of harm. Full confidentiality of data was maintained. No religious issues involved. All religious customs were respected. The study was conducted under supervision.

Statistical Analyses

Statistical analyses were done using computer software (SPSS Trial version 23 and primer). The qualitative data were expressed in proportion and percentages and the quantitative data expressed as mean and standard deviations. The difference in proportion was analyzed using Chi-square test. Significance level for tests was determined as 95% ($P < 0.05$).

RESULTS

In our study, a total of 58 patients were included, in which 28 were male and 30 were female. All patients were conscious, oriented, and Glasgow Coma Scale was 15/15 at the time of admission. Most of the cases were in the age group of 16–60 years (89%) of age followed by elderly (>60 years) (11%). Chi-square = 0.008 with 2° of freedom; $P = 0.996$ NS. No significant difference was observed in age among the male and females ($P = 0.42$ NS). Among 58 midline masses, 28 were parafalcine and 30 were parasagittal. Majority of the masses were located in frontal lobe. Most common clinical manifestation were found to be headache (86.2%) followed by seizure (15.5%) and limb weakness (10.3%). We also found two patients with diminution of vision and two cases of bladder disturbances. Most common histological diagnosis was found to be meningioma (58.62%) followed by glioma (31.03%) and epidermoid cyst (6.89%) with one case of colloid cyst and one case of AVM.

Poor depiction and morphology of superficial cortical vein was observed in 34 cases (58.6%) in 2DTOF (n =

58) as compared to 3DCEMRV (n = 58) 0 (0%). Whereas clear depiction and morphology of superficial cortical vein were observed in 58 cases (100%) in 3DCEMRV (n = 58) as compared to 2DTOF (n = 58) 24 cases (41.3%) P < 0.001S (100%) showed in 3DCEMRV [Table 1]. In addition to this, we also found extra other small cortical vein drain the superior sagittal group in 7 (12%) cases in 3DCEMRV as compared to 2DTOF. Poor depiction and morphology of superficial sagittal sinus were observed 23 (39.65%) in 2DTOF (n = 58) as compared to 3DCEMRV (n = 58) 0 (0%). Whereas clear depiction and morphology of SSS were observed 58 (100%) in 3DCEMRV (n = 58) as compared to 2DTOF (n = 58) 33 (60.3%) P < 0.001S [Table 2]. 16 cases (27.5%) and 17 cases (29.3%) showed sagittal sinus compression in 2DTOF and 3DCEMRV, respectively, with P value 0.78NS. No new vein encountered during surgery. In post-operative CT head, we found 6 (10.3%) cases of infarction, 2 (3%) post-operative site hematoma, and 3 (5%) cases of pneumocephalus [Table 3]. No residual mass was present in any cases. In the present study, 7 patients (12%) developed neurological manifestations postoperatively in the form of newly developed motor weakness, 3 patients (8.3%) developed altered sensorium, and 2 patients died in post-operative period, no patient developed seizure. In three suspected cases of venous injury intraoperatively, post-operative MRV was done and these were analyzed with respective pre-operative images and no venous injury was identified.

DISCUSSION

Exact localization of superficial cortical venous system anatomy with respect to midline masses is very important in planning neurosurgical operations. On the basis of the cortical area that they drain, the superficial cortical veins are divided into four groups of bridging veins: (1) Superior sagittal group, which drains into the SSS; (2) sphenoidal group, which drains into the sphenoparietal and cavernous sinuses; (3) tentorial group, which converges on the sinuses in the tentorium; and (4) falcine group, which empties into the inferior sagittal sinus or straight sinus.[5] Surgery for midline masses such as colloid cyst, DACA aneurysm, corpus callosum gliomas, and parasagittal and parafalcine masses is synonymous with dissection of the veins surrounding the tumor, specifically the cortical parasagittal and bridging veins, SSS, and collateral venous channels.[6] These information on intracranial venous system anatomy can be obtained by TOF MRV and CE MRV which are non-invasive techniques. In general, MRV is performed without using contrast agent through 2D TOF MR venographic techniques.[7] 2D TOF MRV has been widely accepted for the imaging of intracranial venous system despite the well-known technique associated pitfalls. A major pitfall of TOF MRV is the artifactual intravascular signal loss that occurs at predictable points in the intracranial venous anatomy.[8] Images of higher spatial resolution are obtained in 3DCE MRV with less scanning time than

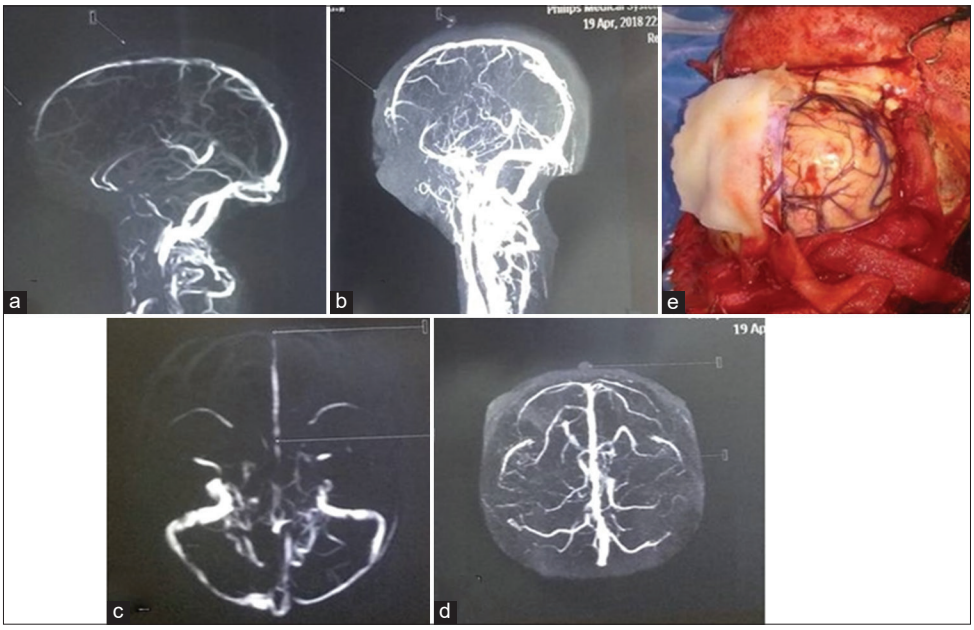

Figure 1: Comparison of 2D TOF and MR 3D CE MRV venography. Superficial cortical veins and superior sagittal sinus (SSS) can be seen in both of MR venographic techniques, but SSS and superficial cortical veins better depicted in 3D CE MRV. (a) Sagittal view and (c) axial view 2D TOF MRV showing poor visualization of superficial cortical vein in the marked area and entire SSS not clearly visualized. (b) Sagittal view and (d) axial view 3D CE MRV showing clear visualization of all superficial cortical veins and entire SSS. (e) Intraoperative photograph showing superficial cortical vein in defined marked area.

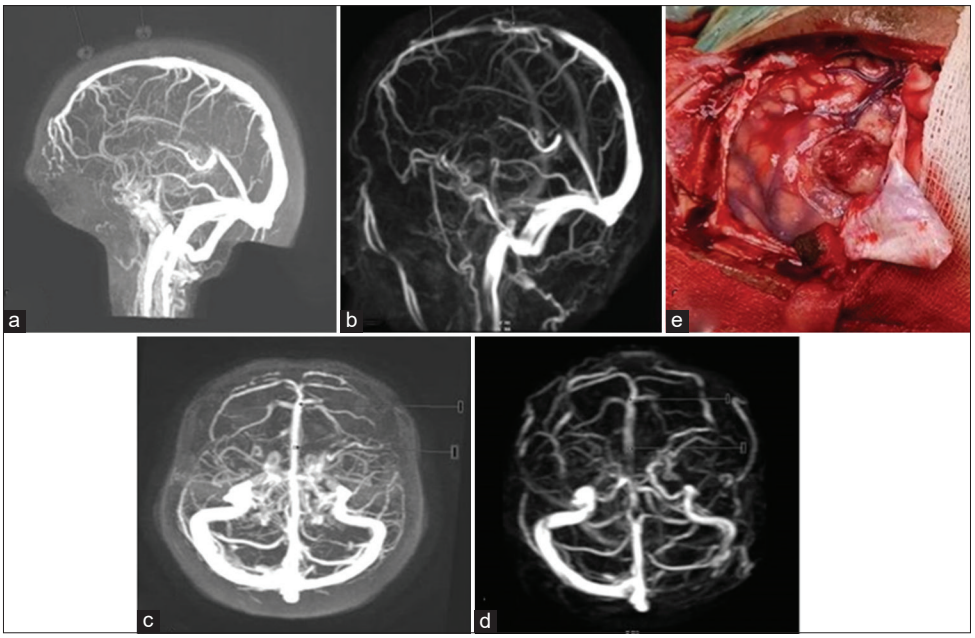

Figure 2: Comparison of pre-operative and post-operative superficial cortical vein on MR venography. (a,b) Sagittal view and (c,d) axial view showing pre-operative and post-operative MRV, respectively – no superficial cortical venous injury seen. (e) Intraoperative photograph showing superficial cortical vein in defined marked area

Table 1: Superficial cortical vein visualization (comparison of 2DTOF and 3DCEMRV)

Superficial cortical vein visualization	2DTOF (*n*=58) (%)	3DCEMRV (*n*=58)	*P* value LS
Poor	34 (58.6)	0 (0)	<0.001S
Clear	24 (41.3)	58 (100)	<0.001S
Other small cortical vein seen	-	7 (12)	0.019S

Table 2: Superior sagittal sinus visualization (comparison of 2DTOF and 3DCEMRV)

Superior sagittal sinus visualization	2DTOF (*n*=58) (%)	3DCEMRV (*n*=58) (%)	*P* value LS
Poor	23 (39.65)	0 (0.0)	<0.001S
Clear	35 (60.35)	58(100)	<0.001S
Sagittal sinus compression	16 (27.5)	17 (29.3)	0.78NS

Table 3: Post operative CT head finding

Post-operative computed tomography head	Number of patient (%)
Venous infarction	6 (10.3)
Post-operative site hematoma	2 (3)
Residual mass	0 (0.0)
Pneumocephalus	3 (5)

2D TOF MRV.[9] Common flow-related artifact seen on 2D TOF MRV can be avoided with the use of 3D CE MRV as it is flow insensitive.[8] False-negative results can also occur in 3D CE MRV in patients with enhancing intracranial lesions, such as neoplasms adjacent to dural sinus or veins.[10] However, various literatures have reported that administration of contrast agent helps to highlight these vessels, especially small veins, and also improve the vascular visualization.[7,11-13] In our study also, 58.6% and 41.3% of cases were having poor and clear depiction of superficial cortical vein, respectively, on 2DTOF, whereas all cases (100%) showed clear depiction and morphology of studied vein in 3DCEMRV. Furthermore, 60.3% and 100% of cases showed clear depiction of SSS in 2DTOF and 3DCEMRV, respectively. Thus, the results of the present study indicate better efficacy of 3DCEMRV over 2DTOFMRV. The study done by Leach *et al*.[14] also showed gadolinium-enhanced MRV to be superior than TOF MRV and also suggested the best evaluation using MRI. In the present study, the area over the tumor was marked by putting cod liver oil capsules, overlying veins were identified on 2DTOF MRV and 3DCEMRV image after that the surgical corridor was decided. Thus, pre-operative decision of surgical corridor allowed us to preserve the cortical veins maximally. The study done by Burtscher *et al*.[15] has shown that 3-D image technique revealed additional information compared with conventional 2-D images and had an influence on neurosurgical planning and strategy, improving neurosurgical performance and patient outcome. In the present study also, additional other small cortical veins were found in 3DCEMRV in 7 (12%) cases as compared to 2DTOF. Information about tumor and overlying superficial cortical veins and sagittal sinus in the marked area are obviating the need for the surgeon to mentally reconstruct the surgical anatomy from 2-D image. Thus, orientation would be faster and

more comprehensible.[5,16,17] With this information, the surgeon can plan the best approach for surgery. The study by Khu *et al*.[18] also concluded that knowing the exact location of cortical vein with respect to tumor helps in preserving them during surgery. In our study, 2DTOF and 3DCEMRV images were taken and found that 2DTOF images showed less depiction of superficial veins in the marked area as compared to 3DCEMRV, thus suggesting 3DCEMRV as preferred modality for locating veins. Abnormal radiological findings of intracranial venous structures were confirmed with intraoperative findings. The study done by Klingebiela *et al*.[19] observed that image quality was superior (4.3 ± 0.8; $P < 0.001$) for 3DCEMRV as compared with 2D TOF MRV (3.1 ± 0.7). The assessment of the evaluated sinus and veins was significantly improved using ec 3DCEMRV ($P < 0.05$) as compared with 2D TOF MRV. Superior depiction of the cerebral venous anatomy on maximum intensity projection images from 3DCEMRV.[19] Hence, 3DCEMRV is more informative than 2DTOF in delineation of superficial cortical and superior sagittal vein for surgical planning and to avoid the venous injury while operating. All the patients were followed up and 7 (12%) patients developed neurological manifestations postoperatively in the form of newly developed motor weakness, 3 (8.3%) patients developed altered sensorium, and 2 patients died in post-operative period. In three suspected cases of venous injury intraoperatively, post-operative MRV was done and these were compared with respective pre-operative images and no venous injury was identified. Evaluation of pre-operative and post-operative MRV can be useful in assessment of venous injury.

CONCLUSIONS

This study showed that pre-operative MRV of marked tumoral area and associated venous anatomy with the help of cod liver oil capsule was very helpful in planning the surgery and to avoid injury of the vein to the maximum extent. 3DCEMRV was found to be better modality than 2DTOF for delineation of veins.

It is also helpful in deciding the size of craniotomy.

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Original Article

Outcomes of Advanced Oncological Laparoscopic Procedures in a Tertiary Care Center

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Abstract

Introduction: Advanced laparoscopic procedures are performed in oncology for almost all visceral sites. We present the oncological and functional outcomes of series of patients who underwent advanced laparoscopic oncological procedures in our tertiary care center.

Materials and Methods: We analyzed 34 consecutive patients who underwent advanced laparoscopic oncological procedures by the same surgeon in the department of surgical oncology during the period of 2015–2019. Five patients underwent laparoscopic type C1 radical hysterectomy. Laparoscopic abdominoperineal resection was done for six patients, laparoscopic staging for carcinoma endometrium for seven patients, thoracoscopic esophagectomy for five patients, laparoscopic-assisted distal gastrectomy for two patients, and laparoscopic staging for ovarian cancer for four patients. Laparoscopic right radical nephrectomy and laparoscopic right hemicolectomy were done for one patient each.

Results: Out of the five patients who underwent laparoscopic Type C1 radical hysterectomy, one patient had residual IB1 disease. There was no bladder morbidity and all patients are alive without disease. Two patients who underwent laparoscopic abdominoperineal resection and one patient after thoracoscopic esophagectomy developed disease recurrence. None of the patients who underwent other procedures had major morbidity or disease recurrence.

Conclusion: Advanced laparoscopic procedures are feasible in oncology with minimal morbidity and good oncological outcome. The nodal yield and oncological outcome improve with increasing experience of the surgeon in minimally invasive surgical oncology.

Key words: Laparoscopic type C1 radical hysterectomy, Okabayashi space, Thoracoscopic esophagectomy

INTRODUCTION

Advanced laparoscopic procedures are performed in oncology for almost all visceral sites. Patients who undergo laparoscopic surgery have lower post-operative complication rates and shorter hospital stays compared to laparotomy.[1] Laparoscopic surgery has been found to be non-inferior to open surgery in terms of oncological clearance, recurrence rate, and long-time survivals in cancers of the rectum[2] and other sites like kidney.[3] Mixed results have been shown on the oncological outcomes of laparoscopic surgery for early disease in subsites like cervix.[4,5] Here, we present the oncological and functional outcomes of series of patients who underwent advanced laparoscopic oncological procedures in our tertiary care center.

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MATERIALS AND METHODS

We analyzed 34 consecutive patients who underwent advanced laparoscopic oncological procedures by the same surgeon in the department of surgical oncology during the period of 2015–2019, as shown in Table 1.

Out of the 34 patients, 5 patients underwent laparoscopic type C1 radical hysterectomy. Laparoscopic type C1 radical hysterectomy was done 6 weeks post-chemoradiation in

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the patients with advanced carcinoma cervix (4 patients with stage IIB and 1 patient with Stage IB2) on suspicion of clinical complete response. Five ports were used with patient in lithotomy position without the use of uterine manipulator to avoid tumor spill. Paravesical and pararectal spaces were created. Bilateral pelvic lymph node dissection was done. Latzko and Okabayashi Spaces defined. Ureters dissected till bladder base and uterine artery divided at origin from internal iliac vessels [Figure 1]. Rectal dissection done away from dorsal parametrium and vagina preserving the pelvic nerves meticulously along the mesoureter. Ventral and dorsal parametria divided with adequate vaginal clearance [Figure 2]. Laparoscopic abdominoperineal resection was done in six patients. Laparoscopic abdominoperineal resection was done 5 weeks post-neoadjuvant concurrent chemoradiation in patients with locally advanced carcinoma rectum. A 5-port technique was used for the abdominal phase [Figure 3]. Inferior mesenteric artery divided at origin just beyond the left colic artery [Figure 4]. Total mesorectal excision done till pelvic floor preserving the hypogastric plexus of nerves. Sigmoid colon was looped with a tape and brought out in the left iliac fossa port and divided extracorporeally. Subsequently, perineal phase was done as for an extralevator abdominoperineal excision. Laparoscopic staging including hysterectomy with bilateral salpingo-oophorectomy and bilateral pelvic lymph node dissection was done for seven patients with early endometrial carcinoma. The port placement and position were similar to type C1 radical hysterectomy. Total laparoscopic hysterectomy was done in five patients and two patients underwent laparoscopic-assisted vaginal hysterectomy [Figure 5]. Five patients underwent thoracoscopic esophagectomy post-neoadjuvant treatment. Thoracoscopic esophagectomy was done with the patient in prone position using four ports. Azygos vein was preserved in all cases. Infra-azygos dissection was done first starting inferiorly and then circumferentially dissecting away from the aorta [Figure 6]. Supra-azygos dissection

Table 1: The operative procedures and the number of patients

Name of the procedure	Number of patients
Laparoscopic type C1 radical hysterectomy	5
Laparoscopic abdominoperineal resection	6
Laparoscopic staging for carcinoma endometrium	7
Thoracoscopic esophagectomy	5
Laparoscopic-assisted distal gastrectomy	3
Laparoscopic adrenalectomy	2
Laparoscopic staging for ovarian cancer	4
Laparoscopic right radical nephrectomy	1
Laparoscopic right hemicolectomy	1

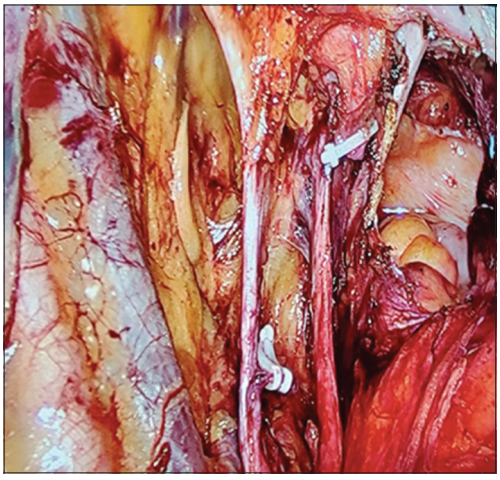

Figure 1: Laparoscopic view showing the left uterine artery clipped and divided at the origin and subsequent dissection over the left ureter

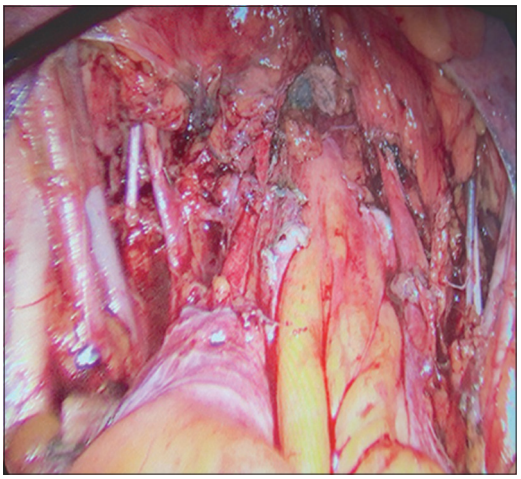

Figure 2: Completed radical hysterectomy showing bilateral ureters till bladder base, superior vesical vessels, obturator nerves, and external iliac vessels. Vagina opened and packed with pad to maintain pneumoperitoneum

Figure 3: Picture showing the port placement for laparoscopic abdominoperineal resection with head end on the right side. (Tape in the left iliac fossa port around sigmoid colon just before delivery and division)

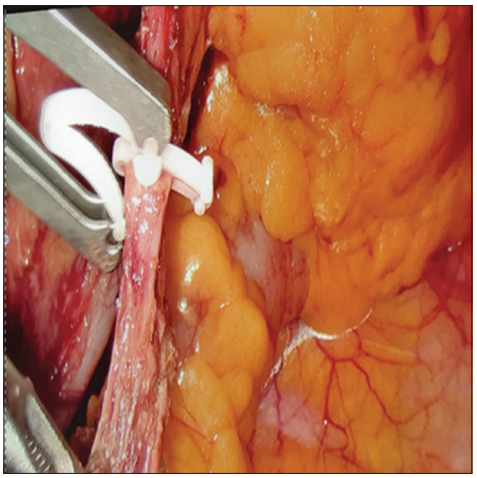

Figure 4: Laparoscopic view showing the clipping of the inferior mesenteric artery at the origin just beyond left colic vessels

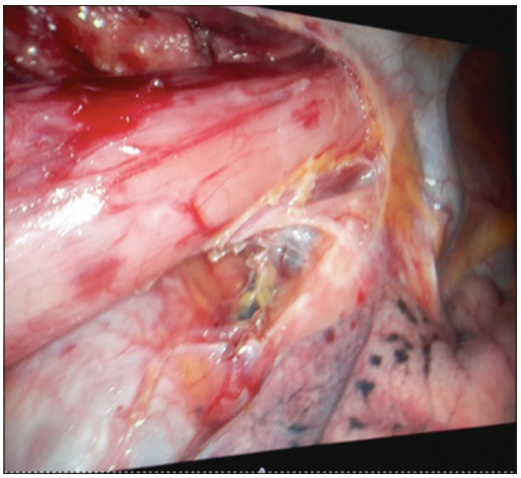

Figure 6: Thoracoscopic view showing the azygos vein, infra-azygos portion of mobilized esophagus, part of right lung and pericardium (patient in prone position)

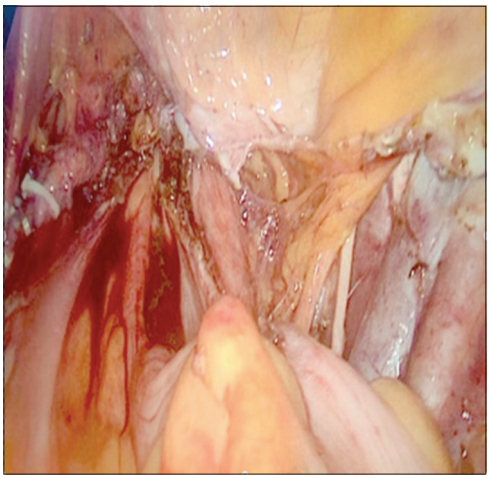

Figure 5: Completed staging for carcinoma endometrium showing right external iliac vessels, obturator nerve, cul-de-sac post-hysterectomy, and the clipped left uterine artery

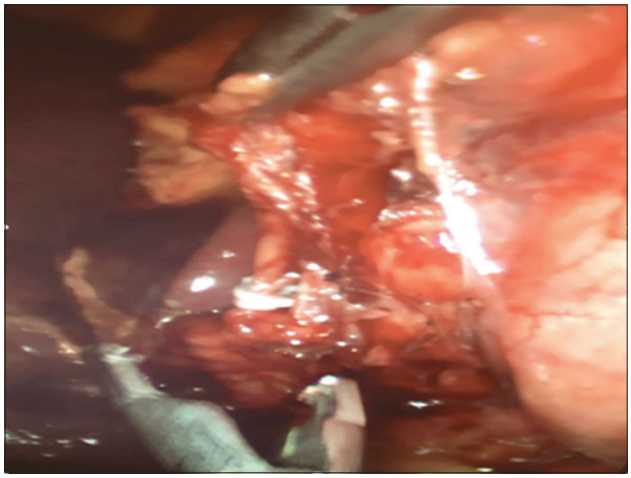

Figure 7: Laparoscopic view showing the clipped right gastric artery and level 5 nodal dissection. Part of suprapyloric portion of stomach and liver is seen

done preserving bilateral recurrent laryngeal nerves. After thoracoscopic mobilization of the esophagus, the patient was switched to supine position. The abdominal and neck phase were done simultaneously by two-team approach to reduce the operative time. Neck anastomosis was done by two stapler techniques creating a diamond-shaped anastomosis. Three patients underwent laparoscopic-assisted distal gastrectomy. Laparoscopic gastric mobilization and nodal dissection were done by five-port technique [Figure 7]. After mobilization with adequate nodal clearance, laparotomy was done for extracorporeal anastomosis including gastrojejunostomy and jejunojejunostomy. Four patients underwent laparoscopic staging for ovarian tumor. Two young patients had undergone ovarian cystectomy before and underwent fertility sparing laparoscopic staging. Two patients underwent laparoscopic staging post total abdominal hysterectomy and bilateral salpingo-oophorectomy. Laparoscopic pelvic lymph node dissection and infracolic omentectomy [Figure 8] were done as part of staging along with peritoneal biopsies. Laparoscopic right adrenalectomy was done for two patients in the left lateral position using four ports. Hepatic flexure was mobilized and duodenum kocherized till the right lateral border of inferior vena cava. Adrenal vessels were dissected, clipped, and divided. The adrenal gland along with mass excised in toto [Figure 9]. Both the patients had radiologically benign lesions on pre-operative evaluation. The right laparoscopic right radical nephrectomy and laparoscopic right hemicolectomy were done in one patient each. Laparoscopic right radical nephrectomy was done by transperitoneal approach using five ports in the left lateral position. Renal vessels dissected after colonic and duodenal mobilization. The patient had double renal artery, clipped and divided [Figure 10]. Subsequently, renal vein was clipped and divided. Ureter divided after clipping at pelvic

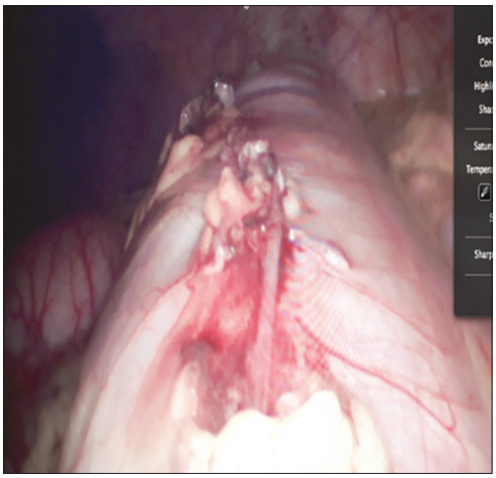

Figure 8: Completed infracolic omentectomy showing the transverse colon devoid of omentum

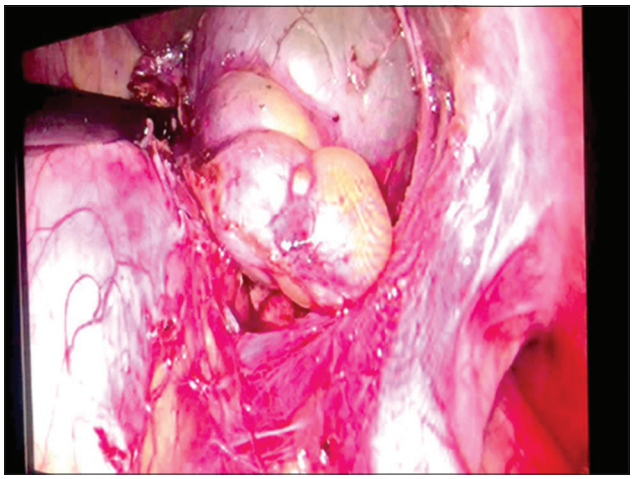

Figure 9: Laparoscopic view showing the resected right adrenal cyst over the upper pole of right kidney and right lateral border of inferior vena cava

brim. The kidney along with surrounding Gerota's fascia resected *en bloc* from the retroperitoneum. Laparoscopic right hemicolectomy was done in the 45° left lateral position using four ports. The ileocolic, right colic, and right branch of middle colic divided at origin after safeguarding the right ureter. The terminal 15 cm of ileum, right colon, and right one-third of transverse colon were resected through a 6 cm horizontal incision in right loin. Extracorporeal ileocolic anastomosis was done.

RESULTS

Out of the five patients who underwent laparoscopic type C1 radical hysterectomy post- chemoradiation for carcinoma cervix, one patient had residual IB1 disease. There was no bladder morbidity in all the patients consequent to the nerve preservation. One patient had persistent vaginal discharge for 1 month which settled

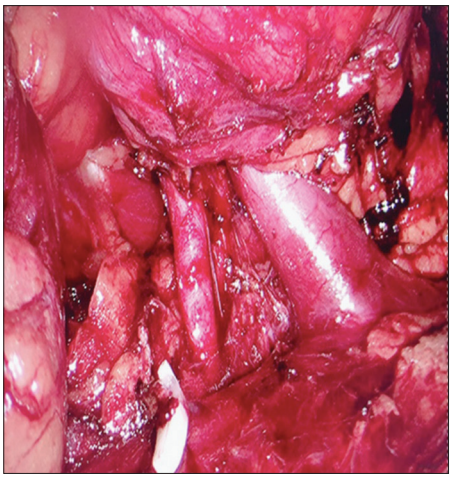

Figure 10: Laparoscopic view showing the right renal vein, one right renal artery, and clipped part of the other artery (double renal artery)

with conservative management. All the five patients are alive without disease. The mean blood loss was 50 ml. The residual urine was <50 ml in all cases. The operative time decreased from 6 h to 4 h in subsequent cases. The clinicopathological characteristics of the patients who underwent laparoscopic abdominoperineal resection are shown in Table 2. The mean blood loss was 100 ml. The operative time decreased from 7 h in the first case to 4 h in the last case. One patient had prolonged ileus postoperatively which settled with conservative management. The young patient with ypT4a disease developed non-salvageable local recurrence after 2 years and succumbed to the disease the subsequent year. The other patients with ypT4b disease were also a young patient and developed liver metastasis in 9 months. He succumbed to the disease in the next 6 months. The clinicopathological characteristics of patients who underwent laparoscopic staging for carcinoma endometrium are shown in Table 3. The operative time decreased from 5 h to 3 h in subsequent cases. The mean blood loss was 50 ml. None of the patients had major morbidity. The total nodal yield increased from 8 lymph nodes to 28 lymph nodes in the subsequent patients. All the patients are alive without disease after completion of adjuvant radiation. The clinicopathological characteristics of the patients who underwent thoracoscopic esophagectomy are mentioned in Table 4. The mean operative time was 4 h in view of two-team approach. Thoracoscopic phase lasted for 2 h. Mean blood loss was 100 ml. None of the patients had major morbidity. One patient had neck leak after thoracoscopic esophagectomy which settled with conservative management. One patient developed brain metastasis after 1 year and is on supportive treatment. All other patients are alive without disease. The T status of the patients who underwent laparoscopic-assisted gastrectomy was pT1b, pT2, and pT4a, respectively. Two patients had

Table 2: Clinicopathological parameters who have undergone laparoscopic abdominoperineal resection

Parameter	Number of patients
T status	
No residue	2
ypT2	2
ypT4a	1
ypT4b	1
Grade	
II	4
None	2
Morbidity	
Yes	0
No	6
Nodal positivity	
Yes	2
No	4
Disease status	
Alive without disease	4
Death due to disease	2

Table 3: The clinicopathological variables of patients with carcinoma endometrium

Parameter	Number of patients
Histology	
Carcinosarcoma	2
Endometrioid adenocarcinoma	4
Papillary serous	1
T status	
pT1a	6
pT1b	1
Nodal positivity	
Yes	0
No	7
Grade	
Grade I	1
Grade II	3
Grade III	3

Table 4: The clinicopathological characteristics of patients with carcinoma esophagus

Parameter	Number of patients
Pathology	
Squamous cell carcinoma	3
Adenocarcinoma	1
No residue	1
T status	
ypTo	1
pT1b	2
pT2	1
yPT3	1
Nodal positivity	
Yes	1
No	4
Grade	
Grade I	1
Grade II	2
Grade III	1

node-positive disease and the average nodal yield was 32 lymph nodes. All three patients had adenocarcinoma histology. One patient developed on table transverse colon necrosis following division of the mesentery during bursectomy. Resection of transverse colon and colocolic anastomosis was done. None of the patients had major post-operative morbidity. The operative time was 5 h. The average blood loss was 150 ml. All the patients are alive without disease. Both the patients post-laparoscopic adrenalectomy had benign disease. The operative time was 4 h in both the patients and blood loss was <50 ml. Both patients are free of the disease. Laparoscopic ovarian staging was done in four patients and none of them had residual ovarian disease, nodal disease, or omental disease. Upfront histology was epithelial ovarian tumor in three patients and granulosa cell tumor in one patient. Mean operative time was 2 h and mean blood loss was <40 ml. All the patients are alive without disease for the past 4 years. Laparoscopic right radical nephrectomy patient had clear cell carcinoma pT1b and Grade I disease. Blood loss was 100 ml and operative time was 5 h. The patient is alive without disease. Laparoscopic right hemicolectomy histopathology was suggestive of moderately differentiated adenocarcinoma pT3N2a. The blood loss was 100 ml and operative time was 5 h. The patient is alive without disease after adjuvant chemotherapy.

DISCUSSION

Laparoscopic procedure is encouraging for post-radiation hysterectomy because of lower blood loss and accelerated recovery. The significance of laparoscopic surgery in cancer related to gynecology has been accepted by many trials.[6] Laparoscopic radical hysterectomy (LRH) has equivalent survival results with open radical hysterectomy (ORH) and has no effect on the pattern of recurrence in early-stage adenocarcinoma of the uterine cervix.[7] Another study showed that LRH can be an appropriate therapeutic procedure for the control of FIGO Stage IB and IIA cervical cancer with tumor diameter of 3 cm or greater.[4] Oncologic and functional results of nerve sparing LRH are equivalent to those of conventional LRH.[8] Minimally invasive radical hysterectomy correlates with high disease recurrence and reduced overall survival than open abdominal radical hysterectomy among early-stage cervical cancer patients in a randomized trial by Ramirez *et al*. This study was done on patients with early cervical cancer who underwent upfront surgery; patients who underwent upfront radiation therapy were excluded from the study.[9] Total LRH is considered effective because of very low blood loss and post-operative morbidity. Patients enduring total LRH can be discharged after an overnight stay in the hospital.[5] Our study included five patients undergoing laparoscopic type C1 radical hysterectomy post-chemoradiation in Stage IIB and bulky Stage IB2 disease for suspicious residual disease. None of the patients

had major morbidity including bladder morbidity even in the post-radiation setting. All the five patients are alive without disease.

As in other laparoscopic procedures, laparoscopic abdominoperineal resection (LAPR) reduces post-operative complications and leads to faster post-operative recovery. LAPR has been shown to be non-inferior to open APR surgery in terms of oncological clearance, recurrence rate, and long-time survivals in a recent meta-analysis.[2] Short-term complications following APR are common and occur more frequently in patients who undergo open APR.[10] Another study by Odermat *et al.* showed that laparoscopic APR provided a shorter length of hospital stay while showing no intermediate-term differences in the survival or incidence of recurrence compared to open APR.[11] Laparoscopic abdominoperineal resection reduces the need for blood transfusions, antibiotics, and painkillers, allowing faster bowel transit resumption and better esthetic results.[12] Six of our patients underwent laparoscopic abdominoperineal resection without major morbidity. One elderly patient with multiple comorbid illnesses had prolonged paralytic ileus which settled with conservative management. The operative time decreased with increasing number of patients. Two patients succumbed to the disease – one patient due to non-salvageable local recurrence and the other patient due to distant metastasis. All other patients are alive without disease.

Api *et al.* found that there was no significant difference between open and laparoscopic staging for early stage carcinoma endometrium in terms of number of total resected lymph nodes. They also found that laparoscopic surgery provided adequate staging and similar survival rates compared to open surgery.[13] Our nodal yield increased with increasing number of patients. Akin to other malignancies, laparoscopic approach had lower postoperative complication rates and shorter hospital stay compared to laparotomy in carcinoma endometrium.[1] None of our patients who underwent laparoscopic staging for early endometrial carcinoma had intraoperative or post-operative complications. All the patients are alive without disease till date post-adjuvant radiation.

Palanivelu *et al.* reported their experience of thoracoscopic esophagectomy in the prone position introducing new interest in this approach.[14] Fabian *et al.* showed that performing thoracoscopic esophagectomy with the right approach in the prone position increased operative exposure, improved surgeon ergonomics, and shortened operative time compared with surgery from the left lateral decubitus position.[15] All our patients underwent thoracoscopic esophagectomy in the prone position. One patient developed neck leak and managed conservatively. There was no major morbidity in other patients. One patient developed brain metastasis and is on radiation therapy and supportive care. All other patients are free of the disease till date.

Experienced surgeons can safely perform laparoscopic gastrectomy with D2 lymphadenectomy for advanced gastric cancer as in a study by Hu *et al.*[16] The KLASS-01 trial revealed similar overall and cancer-specific survival rates between patients undergoing laparoscopic and open distal gastrectomy. It also showed that laparoscopic distal gastrectomy is an oncologically safe alternative to open surgery in Stage I gastric cancer.[17] Laparoscopic distal gastrectomy with D2 lymphadenectomy for locally advanced gastric cancer showed lower complication rate, faster recovery, and less pain compared with open surgery in the KLASS-02 trial.[18] Our series had both early and advanced gastric cancers dealt by laparoscopic-assisted gastrectomy. None of the patients had major post-operative morbidity. All the patients are alive without disease following adjuvant treatment.

Laparoscopic approach is safe and feasible for adrenal masses larger than 6 cm in the absence of local invasion or vascular infiltration.[19] One case had adrenal adenoma size of 6 cm and the other case adrenal cyst of size 8.5 cm. There was no post-operative morbidity in both the patients.

Laparoscopic surgical staging for apparent early stage ovarian cancer has similar surgical and oncological outcomes to laparotomy when performed by gynecologic oncologists.[20] In fact, a recent Taiwan study shows laparoscopic staging surgery performed for early stage ovarian cancer to have better long-term survival outcomes than the literature report. Laparoscopic treatment by a trained gynecologic oncologist is an ideal alternative for early stage ovarian cancer with the advantage of minimal invasiveness.[21] All our patients were operated by the trained surgical oncologist. None of them had post-operative morbidity. All the four patients are alive without disease.

Minimal invasive nephrectomy is a safe approach with similar oncologic outcomes to open nephrectomy for select patients with locally advanced RCC.[3] Our patient had pT1b disease and had the procedure without any morbidity. Post-procedure patient is disease free for the past 2 years.

Laparoscopic surgery can be used for safe and radical resection of cancer in the right, left, and sigmoid colon.[22] A recent meta-analysis observed that short-term outcomes following robotic right hemicolectomy and total laparoscopic right hemicolectomy (LRH) were superior to standard LRH and ORH. The adoption of more advanced minimally invasive techniques may ultimately improve

patient outcomes.[23] There was no morbidity in our patient and is disease free following adjuvant treatment for the past 2 years.

CONCLUSION

Advanced laparoscopic procedures are feasible in oncology with minimal morbidity and good oncological outcome. The nodal yield and oncological outcome improves with increasing experience of the surgeon in minimally invasive surgical oncology.

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Original Article

Histomorphological Spectrum of Ovarian Lesions in a Tertiary Care Institute in Gujarat with Special Emphasis on Ovarian Tumors

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Abstract

Introduction: Ovarian cancer is the third most common cancer among women of India. Microscopic examination is the gold standard for diagnosing ovarian tumors and plays an important role in determining prognosis.

Purpose: The aim of the study is to assess the frequency of non-neoplastic and neoplastic lesions in ovarian specimens and biopsies and to study the histomorphological spectrum, gross features, and age distribution of the ovarian tumors.

Materials and Methods: The present study was an observational retrospective study conducted over a period of 1 year (February 2019–January 2020) in the Department of Pathology in a Tertiary Care Hospital in South Gujarat. A total of cases (8 ovarian biopsies and 82 ovarian specimens) were analyzed. Tumors were classified according to the WHO classification 2014.

Results: Of 90 cases, eight were of non-neoplastic lesions, 13 were tumor-like lesions, and nine neoplastic lesions. Among neoplastic lesions, 43 cases (62.3%) were benign, 3 (4.4%) were borderline, while 23 (33.3%) cases were malignant. Histopathologically, surface epithelial tumors (76.7%) were the most common subtype followed by germ cell tumors (13.3%) and then sex cord tumors (10%). Malignant surface epithelial tumors constitute 78.2% of the total malignant ovarian tumors. The most common neoplastic lesion was serous cystadenoma. 30–39 years age group was the most common age group overall in ovarian tumors. Benign tumors were most common in the 30–39 years age group, while malignant tumors were most common in the 60–69 years age group. Bilaterality was seen in 10 (16.4%) of 61 gross specimens of ovarian tumors.

Conclusion: The frequency of malignant ovarian tumors was higher in our institute. Accurate histopathological diagnosis is essential for management and determining prognosis.

Key words: Germ cell tumor, Histopathology, Ovarian tumors, Serous carcinoma

INTRODUCTION

The ovaries are paired organs on either side of the uterus close to the lateral pelvic wall. A wide spectrum of pathological conditions – non-neoplastic and neoplastic can be seen in the ovary in routine surgical pathology.[1] Primary ovarian tumors can arise from any of the three cell types in the normal ovary: The multipotent surface (coelomic) epithelium, the totipotent germ cells, and the sex cord-stromal cells. Surface epithelial tumors constitute the large majority of ovarian neoplasms and, their malignant forms, account for almost 90% of ovarian cancers. Germ cell and sex cord-stromal cell tumors are comparatively less common; although they account for 20–30% of ovarian tumors, they are collectively responsible for <10% of ovarian malignancies.[2]

Ovarian cancer is the 7th most common cancer and 8th most common cause of death from cancer in women in the world.[3] National Cancer Registry Programme (NCRP) at Bengaluru, India states that Ovarian cancer is the third most common cancer among Indian women after breast and cervix cancer and constitutes about 6% of total cancer cases among the Indian women.[4]

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Ovarian cancers are called "silent killer" as the majority (70%) of women with ovarian cancers have already developed extra ovarian spread at the time of diagnosis. This is due to the fact that ovarian cancers are generally asymptomatic or have vague and nonspecific symptoms.[5] Histopathological examination remains the gold standard for diagnosing ovarian tumors, according to NCRP of India.[4] Most ovarian tumors cannot be differentiated from one another on the basis of clinical or gross characteristics alone. They, however, provide salient pointers which aid in diagnosis; hence, a clinician and pathologist have to work in collaboration to come to a final diagnosis.[6] Ovarian epithelial cancers must be differentiated from benign tumors, functional cysts, and other benign lesions such as endometriosis, pelvic inflammatory disease, or pedunculated uterine leiomyomata which mimic ovarian cancer.[7] Histological subtyping of ovarian epithelial cancers is important as they differ in their mean age of presentation, 5-year survival, molecular abnormalities, association with familial syndromes, and sensitivity to chemotherapy and other treatment modalities.[1]

According to NCRP of India on the status of ovarian cancers in India (2012–2014), the majority (50%) of the cases occurred between 45 and 65 years of age. Only 5% of the total cases were reported before the age of 25 years. Furthermore, more than 20% of the cases were reported beyond the age of 65 years. Hence, age is an extremely important clinical parameter relating to tumor behavior.[4] Most of the germ cell tumors are seen in children. Benign surface epithelial tumors occur mostly in young women between the ages of 20 and 45 years, while borderline tumors occur at slightly older ages. Malignant tumors are more common in older women between the ages of 45 and 65 years.[2]

Tumor stage and laterality may also give a clue to their nature. While sex cord-stromal tumors are predominantly unilateral, bilaterality is more commonly seen in tumors metastasized to the ovary and in serous carcinoma.[6] Important risk factors for ovarian cancer include nulliparity, family history, and germline mutations in certain tumor suppressor genes.[2]

The WHO classification of ovarian tumors is primarily morphologic and based on the cytologic features of the tumor cells. The findings of recent molecular studies, for the most part, support this morphology-based classification system and also demonstrate that it accurately reflects both histogenesis and the underlying molecular abnormalities of the different ovarian tumor subtypes.[1]

The aim of this study is to assess the frequency of non-neoplastic and neoplastic lesions in ovarian specimens and biopsies and to study the histomorphological spectrum, gross features, and age distribution of the ovarian tumors.

MATERIALS AND METHODS

- Study design – This study was an observational study (retrospective)
- Study location – The study was conducted in the department in a tertiary care hospital in South Gujarat
- Study duration – The study duration was 1 year (February 1, 2019–January 30, 2020)
- Sample size – The sample size was 90.

Inclusion Criteria

Ovarian biopsies and all ovarian specimens with histopathologically proven non-neoplastic and neoplastic lesion received as either as a solitary specimen or part of total abdominal hysterectomies or cystectomies.

Exclusion Criteria

The following criteria were excluded from the study:

1. Normal ovaries
2. Specimen of post-chemotherapy ovaries.

The present study was an observational retrospective study (February 2019–January 2020) conducted in the Department Of Pathology in a Tertiary Care Hospital in South Gujarat. A total of eight ovarian biopsies and 82 ovarian specimens with histopathologically proven non-neoplastic or neoplastic lesions received either as a solitary specimen or as part of total abdominal hysterectomy specimens or cystectomy specimens were studied. The normal ovaries and specimens of post-chemotherapy ovaries were excluded from the study.

A detailed patient history, clinical examination findings, radiological findings, and other relevant laboratory findings were noted from the histopathological requisition form sent alongside the specimen. The excised ovarian specimens and biopsies were fixed in 10% neutral buffered formalin. The tumors were weighed and measured. Thorough gross examination was done scrutinizing the outer surface and on-cut surface diligently looking for a cyst, its locularity, type of cystic fluid, any solid area, papillary projections, and hemorrhage and necrosis. From cysts, up to three sections of 3 mm were taken and from solid tumors, one section for each centimeter was taken, especially from areas of papillary appearance and any unusual area (hemorrhagic, calcified, or necrotic area). Associated tissue pieces were also examined and grossed.

Tissue processing was done as per standard procedure and paraffin-embedded blocks were made. Tissue sections of

5 μ thick were cut using a rotary microtome and stained by hematoxylin and eosin followed by microscopic examination. Special stains such as reticulin and Periodic Acid Schiff (PAS) and immunohistochemistry were performed whenever required. The tumor-like and neoplastic lesions were classified according to the 2014 WHO classification of ovarian tumors.

RESULTS

Our department received a total of 90 ovarian cases which included eight ovarian biopsies and 82 ovarian specimens either as solitary specimens or cystectomies or as part of hysterectomies with unilateral or bilateral salpingectomies over a period of 1 year (February 2019–January 2020), of which non-neoplastic and neoplastic lesions were identified. Of 90 cases (specimens and biopsies), eight were of non-neoplastic lesions, 13 were tumor-like lesions, and 69 were neoplastic lesions.

Among non-neoplastic lesions, five cases were of hemorrhagic cyst secondary to torsion and three cases were of endometriosis. All of them belonged to the 30–50 years age group.

Among 13 cases of tumor-like lesions, eight were luteal cysts and five were follicular cysts. They were seen within 20–59 years of age group and showed maximum incidence in 40–49 years age group.

Among neoplastic lesions, 43 cases (62.3%) cases were benign, three (4.4%) were borderline, while 23 (33.3%) cases were malignant [Figure 1].

Histopathologically, surface epithelial tumors (53 cases; 77%) were the most common subtype followed by germ cell tumors (9 cases; 13.04%) and then sex cord tumors (7 cases; 10.4%). The most common neoplastic lesion as well most common benign tumor was serous cystadenoma. Serous carcinoma was the most common malignant tumor. The most common germ cell tumor and the second most common benign tumor was mature cystic teratoma. The most common sex cord-stromal tumor was fibroma [Table 1].

Distribution of Surface Epithelial Tumors

Of 53 cases of surface epithelial tumors, 35 (66%) cases were serous tumors, 16 cases (30.2%) were of mucinous tumors, and two cases (3.8%) were of endometrioid histotype.

Alternatively, surface epithelial tumors can also be classified into benign (32 cases; 60.4%), borderline (3 cases; 5.6%), and

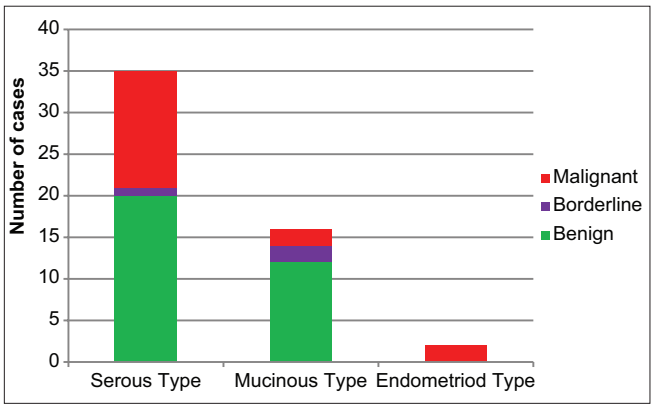


Figure 1: Distribution of surface epithelial tumors

Table 1: Histomorphological spectrum of ovarian tumors as per WHO classification 2016

	Nature	Cases	Percentage
Surface epithelial tumors		53	76.7%
A. Serous		35	
Serous cystadenoma	Benign	18	
Serous cystadenofibroma	Benign	2	
Serous borderline tumor	Borderline	1	
Serous carcinoma	Malignant	14	
B. Mucinous		16	
Mucinous cystadenoma	Benign	12	
Mucinous borderline tumor	Borderline	2	
Mucinous carcinoma	Malignant	2	
C. Endometrioid tumors			
Endometrioid carcinoma	Malignant	2	
Germ cell tumors		9	13.03 %
Benign mature cystic teratoma	Benign	7	
Dysgerminoma	Malignant	1	
Sex cord-stromal tumors		7	10%
Adult granulosa tumor	Malignant	3	
Fibroma	Benign	2	
Sex cord-stromal tumor with annular tubules along with foci of granulosa and Sertoli cell tumor	Malignant	1	
Sclerosing stromal tumor	Benign	1	

malignant (18 cases; 34%). Malignant surface epithelial tumors constitute 78.2% (17 of 22 cases) of the total ovarian cancers.

Among 35 cases of serous histology, 20 were benign, 1 case borderline, and 14 cases malignant. In the case of mucinous tumors, 12 were benign, two borderline, and two were malignant. Both cases of endometrioid type were malignant.

Distribution of Germ Cell Tumors

Among nine cases of germ cell tumors, most cases (eight cases; 88.9%) were mature cystic teratoma, while one case (11.1) was dysgerminoma [Figure 2].

Distribution of Sex Cord Tumors

Adult granulosa cell tumor [Figure 3] was the most common sex cord-stromal tumor followed by fibroma (2 cases) [Figure 4]. One case of the sclerosing stromal tumor and one case of sex cord-stromal tumor with annular tubules along with foci of granular and Sertoli cell tumors [Figure 5] were also seen.

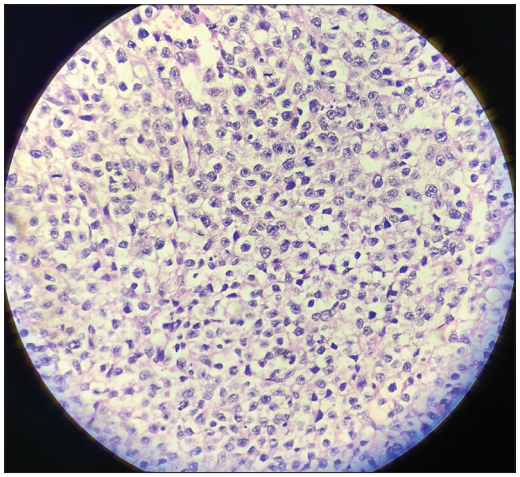


Figure 2: Photomicrograph of dysgerminosa(H&E Stain 400x)

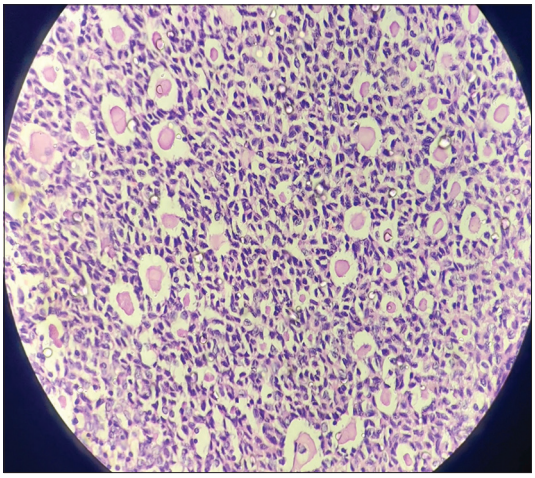


Figure 3: Photomicrograph of adult granulosa cell tumor (H&E stain 400×)

Figure 4: Gross specimen of fibroma

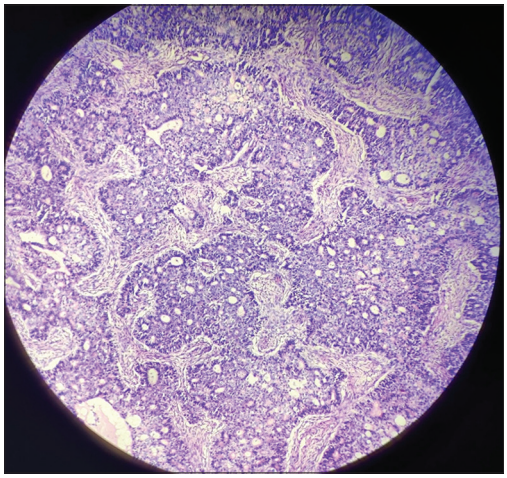


Figure 5: Photomicrograph of sex cord-stromal tumor with annular tubules along with foci of adult granulosa cell tumor and Sertoli cell tumor (H&E stain 100×)

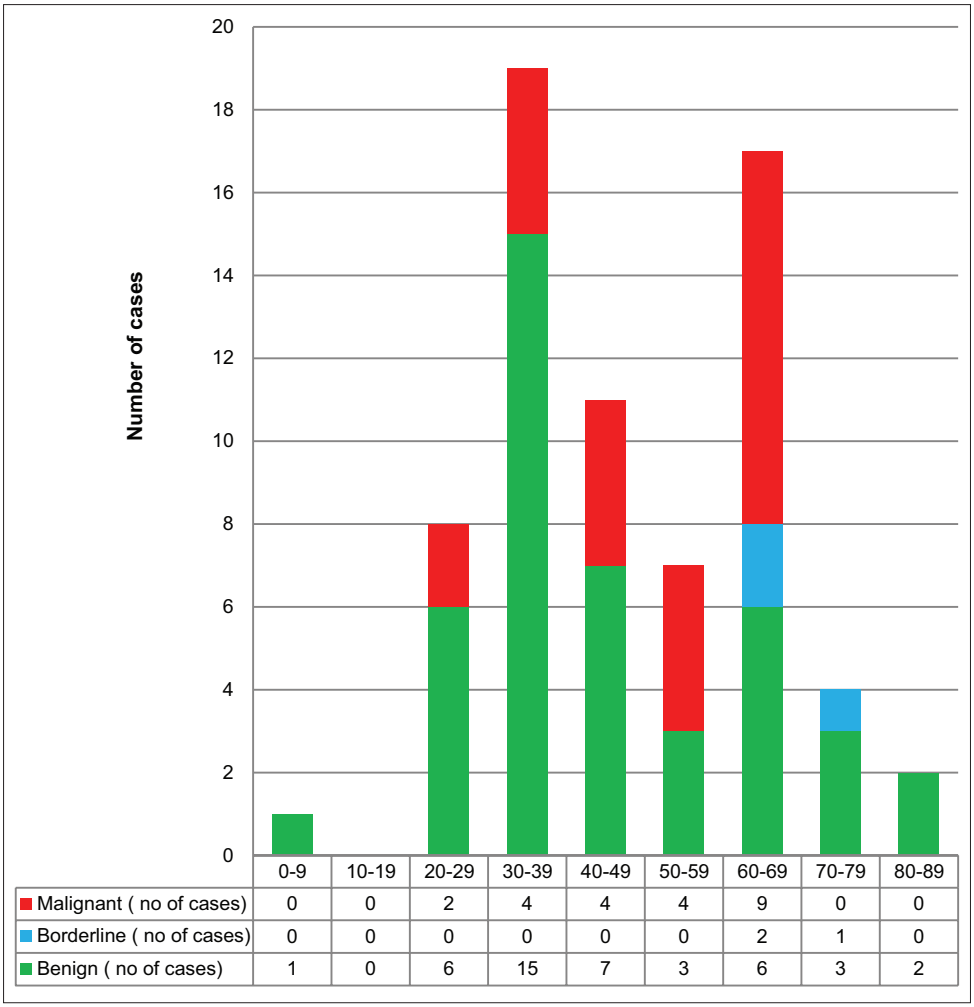
Age Distribution of Ovarian Tumors

The youngest patient was 5 years old and the oldest case belonged to an 82-year female.

Among 69 cases of ovarian tumors, most cases belonged to 30–39 years age group followed by 60–69 year age group benign tumors were most common in 30–39 years age group and gradually showed a decrease in later age groups. On the other hand, malignant tumors were most common in the 60–69 years age group [Figure 6].

Germ cell tumors were the only neoplastic lesions found below 20 years age group. Surface epithelial tumors were seen after 20 years of age and showed a bimodal peak at 30–39 years age group and 60–69 years age group due to the high incidence of benign and malignant tumors in these decades, respectively.

Sex cord-stromal tumors were mostly found in 20–59 years of age group and only one case was seen after 60 years of



	0-9	10-19	20-29	30-39	40-49	50-59	60-69	70-79	80-89
Malignant (no of cases)	0	0	2	4	4	4	9	0	0
Borderline (no of cases)	0	0	0	0	0	0	2	1	0
Benign (no of cases)	1	0	6	15	7	3	6	3	2

Figure 6: Age-wise distribution of ovarian tumors

age (most cases of sex cord-stromal tumors were seen in 40–59 years age group.

Gross Features of Ovarian Tumors

Of 61 gross specimens of ovarian tumors, the majority were cystic (40 cases; 65.6%), while 17 cases (27.8%) were solid mixed with cystic and four cases (6.6%) were pure solid. Among the 40 cystic specimens, most cases (37 cases; 92.5%) were benign, while two cases were malignant and one case was borderline.

Among epithelial tumors, 29 (90.6%) of 32 benign tumors were cystic, while only three cases (9.4%) were cystic mixed with solid. Among 11 cases of malignant tumors, nine cases (81.8%) were cystic mixed with solid and one case (9.1%) was pure solid while only one case (9.1%) of low-grade serous carcinoma was pure cystic. Among two cases of borderline epithelial tumors, one was pure cystic, while one case was cystic with solid.

Laterality

Ten cases (16%) (four benign and six malignant), of 61 ovarian specimens were bilateral. About 9% of benign tumors were bilateral, while 37.5% of malignant tumors were bilateral. Eight of 10 cases of bilateral tumors were surface epithelial type (three cases serous carcinoma [Figure 7], two cases benign serous tumors, and one case each of mucinous and endometrioid carcinoma) while only two cases were of germ cell origin (one case of dysgerminoma and mature cystic teratoma each). Bilaterality was not seen in any case of sex cord tumors.

Among unilateral ovarian tumors, the majority of tumors were right side (62%) in comparison to compared to the left side (37%).

Twelve of 16 specimens of ovarian malignant tumors had FIGO Stage 1, while two cases were Stage 2 and two cases were Stage 3.

Role of Special Stains and Immunohistochemistry

Special stains such as reticulin and PAS stain were utilized for the diagnosis of adult granulosa tumor and mucinous tumor. Immunohistochemistry played a key role in the final diagnosis of tumors. WT1 was used for diagnosing serous tumors [Figure 8] and tp53 was used for differentiating between low grade and high-grade serous carcinoma. Endometrioid carcinoma was diagnosed as well as distinguished from secondary tumors with the help of ER, PR, vimentin positivity, and CK20 and CDX2 negativity. Dysgerminoma was identified with the help of PLAP, CD-117 positivity, and EMA negativity. Non-Hodgkin's lymphoma was concluded after LCA and CD20 positivity and CK, vimentin, EMA, CEA, CD117 negativity. Sex cord-stromal tumor with annular tubules along with foci of adult granulosa tumor and Sertoli cell tumor showed CD99, CK positivity and S-100, chromogranin, EMA, PLAP, vimentin, and CK7 negativity.

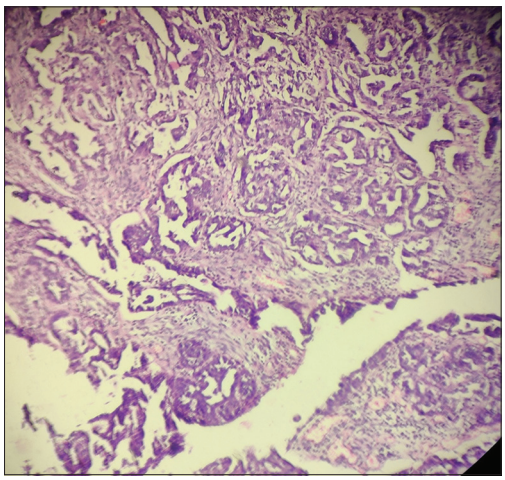


Figure 7: Photomicrograph of high-grade serous carcinoma (H&E stain 400×)

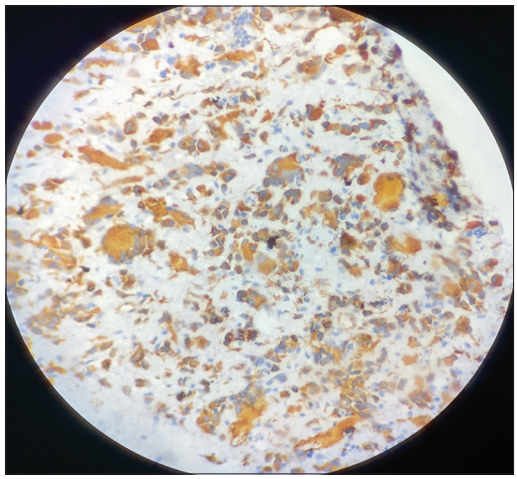


Figure 8: Photomicrograph of strongly WT1 positive high-grade serous carcinoma (400x)

DISCUSSION

In the current study, 82 ovarian specimens and eight ovarian biopsies were studied extensively. Ninety cases were classified into non-neoplastic lesions (8), tumor-like lesions (13), and neoplastic lesions (69 cases).

Non-neoplastic lesions (endometriosis and hemorrhagic cyst secondary to torsion) and tumor-like lesions were more common in the reproductive age group of 30–50 years in concordance with their functional nature. Luteal cysts were slightly more common than a follicular cyst.

Of 69 neoplastic lesions, 43 cases (62.3%) were benign, 3 (4.4%) were borderline, while 23 cases (33.3%) were malignant. Our findings are consistent with the study done by Panchonia *et al.*[8] The percentage of malignant tumors is much higher in the present study as compared to studies done by Phukan *et al.*,[9] Sawant *et al.*,[10] and Itha and Veeragandham,[11] as our institution being a tertiary care hospital receive a referral of a large number of malignant tumors from peripheral centers [Table 2].

Surface epithelial tumors (53 cases; 76.7%) were the most common subtype followed by germ cell tumors (9 cases; 13.03%) and then sex cord tumors (7 cases; 10%). Overall malignant surface epithelial tumors constitute 78.2% of the total malignant ovarian tumors [Table 3].

Table 2: Comparative analysis of ovarian tumors based on the nature of tumors

Name of study	Benign cases (%)	Borderline cases (%)	Malignant cases (%)
Present study	62.3	4.4	33.3
Panchonia *et al.*[8]	58	4	38
Phukan *et al.*[9]	75	3.6	21.4
Sawant and Mahajan[10]	75.7	6.1	18.2
Itha and Veeragandham[11]	76	10	14
Garg *et al.*[12]	81	1.2	17.6
Sharma and Bharadwaj[13]	86.6	3.6	9.8
Mohan *et al.*[14]	82.2	5.2	12.5
Patel *et al.*[15]	93	1.2	6.2

Table 3: Comparative studies of the histomorphological pattern of ovarian tumors

Name of study	Surface epithelial tumors (%)	Germ cell tumor (%)	Sex cord-stromal tumors (%)	Others
Present study	76.7	13.03	10	0
Patel *et al.*[15]	77.7	18.5	3.8	0
Garg *et al.*[12]	70.6	18.8	7	2.4% (metastatic)
Pilli *et al.*[16]	70.9	21.2	6.7	0.7
Phukan *et al.*[9]	66.7	23.8	7.2	2.4
Mohan *et al.*[14]	66.66	23.95	7.29 2.4	2.4

Table 4: Comparative analysis of the distribution of surface epithelial tumors

Name of study	Present study (%)	Garg *et al.* (%)[12]	Modi *et al.* (%)[17]	Dutta *et al.* (%)[18]	Patel *et al.* (%)[15]	Phukan *et al.* (%)[9]
Serous tumors	66	68.3	63	71	75.4	73.2
Mucinous Tumors	30.2	23.3	34	21	23.8	21.4
Endometrioid tumor	3.8	1.6%	1.9	-		1.7%
Others				Seromucinous – 8%	Transitional – 0.8%	Brenner – 3.5%

Table 5: Comparative analysis of the distribution of consistency of ovarian tumors

Name of study	Cystic (%)	Cystic and solid (%)	Solid (%)
Present study	65.6	27.8	6.6
Mohan *et al.*[14]	67.70	13.54	18.75
Patel *et al.*[15]	68.5	25.3	6.1
Itha and Veeragandham[11]	64	20	16
Phukan *et al.*[9]	59.5	27	13

Among 43 cases of surface epithelial tumors, serous tumors (66%) were the most subtype followed by mucinous type (30.2%). Endometrioid tumors (3.8%) were relatively infrequent. This is consistent with Garg *et al.*,[12] Itha and Veeragandham,[11] Phukan *et al.*,[9] Modi *et al.*,[17] and Dutta *et al.*[18] [Table 4].

Serous tumors were 57.1% benign 2.9% borderline and 40% malignant.[19] Mucinous tumors were 75% benign, 12.5% borderline, and 12.5% malignant. Both cases of endometrioid tumors were malignant.

Hence, while both serous and mucinous tumors were more commonly benign. In contrast, endometrioid tumors were predominantly malignant. This is consistent with studies done by Phukan *et al.*[9] and Modi *et al.*[17]

The most common neoplastic lesion was serous cystadenoma. This is consistent with studies done by Devi *et al.*,[20] Panchonia *et al.*[8] and Sharma and Bharadwaj.[13] Serous carcinoma was the most common malignant lesion in our study, consistent with studies done by Modi *et al.*[17]

Among 69 cases of ovarian tumors, most cases belonged to 31–40 years age group. This consistent with studies done by Patel *et al.*,[15] Devi *et al.*,[20] Garg *et al.*,[12] and Pilli *et al.*[16] However, 40–49 years of age group was more commonly affected followed by 30–39 years age group in Mohan *et al.*[14] and Srinivasan *et al.*[19]

Of 61 specimens of ovarian tumors, the majority are cystic (65.5%) followed by cystic with solid (27.8%) and pure solid (6.6%). Most benign tumors were cystic (86%), while the majority of malignant tumors were cystic mixed with solid (75%). This is concordant with studies done by Phukan *et al.*, Patel *et al.*, Itha and Veeragandham, and Mohan *et al.* [Table 5].

Ovarian tumors are known for their bilaterality. Bilaterality was seen in 10 (16.4%) of 61 gross specimens of ovarian tumors and more commonly seen in malignant tumors. This correlates with the higher pathological grading. Bilateral involvement often depends on the histological subtype of ovarian tumors. Bilaterality was most frequently seen in surface epithelial tumors and specifically in serous carcinomas (3 of 5 cases). Bilaterality in other studies was by 11% (Panchonia *et al.*[8]) and 22% (Itha and Veeragandham[11]).

Among unilateral lesions, neoplastic lesions were more common on the right side. This is consistent with studies done by Panchonia *et al.*[8] (52%).

CONCLUSION

Ovarian tumors are a heterogeneous group of tumors and this diversity creates challenges in timely diagnosis and management. An accurate diagnosis primarily relies on histomorphological examination which remains the gold standard with the support of ancillary studies such as special stains and immunohistochemistry. Clinical parameters such as age, laterality, and stage are additional factors which guide the overall management and prognosis of these neoplasms.

The ovarian neoplasms in our institute represented a wide histomorphological spectrum. The frequency of the distribution of neoplasms was similar to the reports in the literature. However, the incidence of malignant tumors was higher in our setup, as our institute is a tertiary care center. It is concluded from our study that the majority of ovarian tumors are benign. Surface epithelial tumors are the most common histological subtype of ovarian tumors.

The observations of our study and their assessment will provide valuable insight of distribution pattern of ovarian neoplasms in western India. Early diagnosis plays a critical role in decreasing morbidity as well as mortality among these patients.

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Original Article

A 3D-Computed Tomography Angiography Study to Help in Surgical Planning for Retrosigmoid Craniotomies

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Abstract

Aims and Objectives: It is impossible to precisely anticipate the course of the transverse and sigmoid sinuses and their individual relationship to superficial landmarks such as the asterion during retrosigmoid approaches. This study was done to determine the position of the asterion and the relationship between asterion and the transverse-sigmoid sinus junction (TSSJ) in making precise burr hole without damaging sinuses during retrosigmoid craniotomies.

Materials and Methods: Computed tomography (CT) angiography was performed in 50 patients to obtain 3D-CT volume rendering images of cranial bone and dural sinuses. After delineating the sinuses, by simple restructuring using software and opacity modulation, bone image is reinforced. Asterion type, distance from the tip of mastoid process to asterion and root of zygoma (ROZ) to asterion, and location of asterion in relation to TSSJ and distance between asterion and TSSJ were analyzed and measured.

Results: The incidence of type 1 (presence of sutural bones) in our study was 24% and type 2 (absence of sutural bones) was 76%. There was no statistically significance in the side and gender differences. The distance between the asterion and from the ROZ was 54.70 ± 3.68 on the right side and 54.32 ± 3.41 on the left side (*P*-0.612). The distance between asterion and tip of mastoid was 50.51 ± 2.67 on the right side and 50.12 ± 3.06 on the left side (*P*-0.716). The asterion was located on the T-S sinus complex in 36 (72%) cases. The asterion was below the T-S sinus complex in 13 (26%) cases, and above the T-S sinus complex in only 1 (2%) cases.

Conclusion: 3D-CT volume rendering imaging is capable of accurately visualizing the bony landmark and dural sinuses. An easy and simple restructured image provides precision and safety for the patient by ready and easy localization of asterion and TSSJ. This study was done to show that the previous cadaver-based anatomical studies can be done now in a more sophisticated and accurate manner with the latest technological advancements. This offers new options for anatomic research and morphometric investigations.

Key words: 3D-computed tomography angiography, Asterion, Mastoid process, Retrosigmoid craniotomy, Root of zygoma, Transverse-sigmoid sinus junction

INTRODUCTION

The asterion serves as the junction of the lambdoid, parietomastoid, and occipitomastoid sutures and has been used in retrosigmoid craniotomy to locate the transverse-sigmoid sinus junction. The initial burr hole is important in obtaining optimal exposure for retrosigmoid craniotomies to give access to the lesions in the cerebellopontine angle (CPA) region.[1]

Transverse and sigmoid sinuses are the natural limits of the exposure and precise planning of the initial burr hole prevents any sinus injury catastrophe and saves time in quick exposure. Relationship of the asterion to the underlying venous structures in cadaveric studies has shown variability and is not patient-specific.[2]

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With recent advances in the 3D-computed tomography (CT) volume rendering technique, it is possible to visualize minute bone sutures and venous structures of the posterior fossa.[3]

As cadaveric studies have shown considerable variability in the relationship of the asterion to the underlying venous structures and its population-specific variability, its validity as a surgical landmark has been questioned.[4]

This study aims to determine the anatomic position of the asterion and using the root of the zygoma and the tip of the mastoid process as palpable points. We also tried to clarify the relationship between the asterion and the transverse-sigmoid sinus junction and distance between asterion and transverse-sigmoid sinus junction (TSSJ) using a 3D-CT procedure *in vivo*.

Aim of the Study

The following parameters were analyzed and measured.

- Asterion type
- Distance from the tip of mastoid process to asterion and
- Distance from the root of zygoma (ROZ) to asterion
- Location of asterion in relation to (TSSJ).

MATERIALS AND METHODS

A retrospective, open-label, single-centered study was conducted among 50 subjects attending Neurosurgery OPD, Government Rajaji Hospital, Madurai, meeting the inclusion and exclusion criteria over 24 months (June 2017–May 2019) after obtaining a written informed consent of all study subjects.

Patients who underwent CT angiogram brain or for any reason were included in the study. Patients who had craniofacial fractures, disrupting the skull base and altering the anatomy, previously operated for head trauma, or another brain surgery were excluded from the study group.

CT-angiography performed using 64 slices Toshiba scanner. Scans were transferred to the work station and reconstructed images and measurements obtained using inbuilt special software.

It is a retrospective study, frequency distribution tables were developed according to various factors such as age described in terms of mean and standard deviation (SD).

RESULTS

The incidence of type 1(presence of sutural bones) in our study was 24% and type 2 (absence of sutural bones) was 76% (Table 1).

Type 2 with absence of sutural bones seen in Figure 1.

There was no statistically significant difference in side difference. The below table shows the mean and SD of the two measurements of the asterion in different genders and on different sides [Tables 2 and 3]. The distance between the asterion and the ROZ was 54.70 ± 3.68 on the right side and 54.32 ± 3.41 on the left side (*P*-0.612). The distance between asterion and tip of mastoid was 50.51 ± 2.67 on the right side and 50.12 ± 3.06 on the left side (*P*-0.716) [Figure 2].

There is a male preponderance with a higher asterion level than females. The asterion was located on the T-S sinus complex in 36 (72%) cases. The asterion was below the T-S sinus complex in 13 (26%) cases and above the T-S sinus

Table 1: Incidence of asterion types

Gender	Type 1 (presence of sutural bones) (%)	Type 2 (absence of sutural bones) (%)
Male (*n*=32)	8 (25)	24 (75)
Female (*n*=18)	4 (2.22)	14 (77.78)

Table 2: Position of the asterion from the ROZ and the TMP – gender preponderance

Morphometric parameter	Male	Female	*P*-value
ROZ (mm)	55.80±2.33	51.29±2.62	0.002
TMP (mm)	51.34±3.12	48.65±3.45	0.005

ROZ: Root of the zygoma, TMP: Tip of mastoid

Table 3: Position of the asterion from the ROZ and the TMP – side preponderance

Morphometric parameter	Right	Left	*P*-value
ROZ (mm)	54.70±3.68	54.32±3.41	0.612
TMP (mm)	50.51±2.67	50.12±3.06	0.716

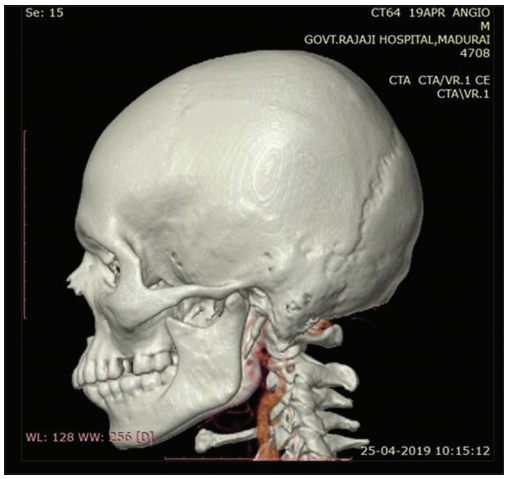

Figure 1: Volume rendered image with bony reconstruction to identify the type of asterion.In this image Type 2 (absence of sutural bones) noted.

complex in only 1 (2%) cases. The inferior aspect of TSSJ was located anterior to the asterion [Table 4].

DISCUSSION

CP angle is commonly gained access through retrosigmoid craniotomy. The correct location of the burr hole, especially the initial burr hole, is crucial to avoid venous injury and obtain optimal exposure. In this study, we used the root of the zygoma and the tip of the mastoid as the palpable landmarks to locate the asterion.

The current advances in image-rendering have made it possible to generate 3D models by reconstructing image data and perform a precise morphometric investigation *in vivo*.[5]

Berry and Berry,[6] showed 12% of Type 1 asteroin groups as compared to 88% Type 2 groups. Kellock and Parsons[7] showed 19.8 Type 1 cases as compared to 80.2 Type 2. Saheb *et al.*[8] showed 23.15 Type 1 cases as compared to 76.85 Type 2 groups. Singh[9] showed 16.36 Type 1 as compared to 83.64 Type 2 asteroin groups. Sudha *et al.*[10] showed eight Type 1 as compared to 92 Type 2 asteroin groups. Leon *et al.*[11] showed 25.6 Type 1 as compared to 74.4 Type 2 study groups. The incidence of type 1 (presence of sutural bones) in our study was 24% and type 2 (absence of sutural bones) was 76%.

Using 64 bilateral measurements obtained in 32 Chinese patients, a morphometric study was performed on the location of the asterion. The results showed that in Chinese, the distance from the asterion to the ROZ was 54.6 ± 5.50 mm on the right and 54.1 ± 5.42 mm on the left side, and the distance from the asterion to the tip of the mastoid process was 49.10 ± 3.56 mm on the right side and 48.70 ± 2.23 mm on the left side. Day and Tschabitscher,[12] showed that distance from asterion to ROZ was 53.88 ± 5.09 and distance from asterion to tip of mastoid was 49.20 ± 4.68. Martinez *et al.*[13] showed that distance from asterion to ROZ was 55.42 ± 4.92 and distance from asterion to tip of mastoid was 49.7 ± 4.80 as compared to our study which showed that distance from asterion to ROZ was 54.70 ± 3.68 on the right side and 54.32 ± 3.41 on the left side ($P = 0.612$) and distance from asteroin to the tip of mastoid was 50.51 ± 2.67 on the right side and 50.12 ± 3.06 on the left side ($P = 0.716$).

Table 4: Relationship between the asterion and TSSJ

Asterion location	Male (%)	Female (%)
At TSSJ	22 (44)	14 (28)
Below TSSJ	9 (18)	4 (2.24)
Above TSSJ	1 (2)	0

TSSJ: Transverse-sigmoid sinus junction

Day and Tschabitscher[12] reported asteroin over the transverse sinus in 61% of cases. Uz *et al.*[14] reported 54% of

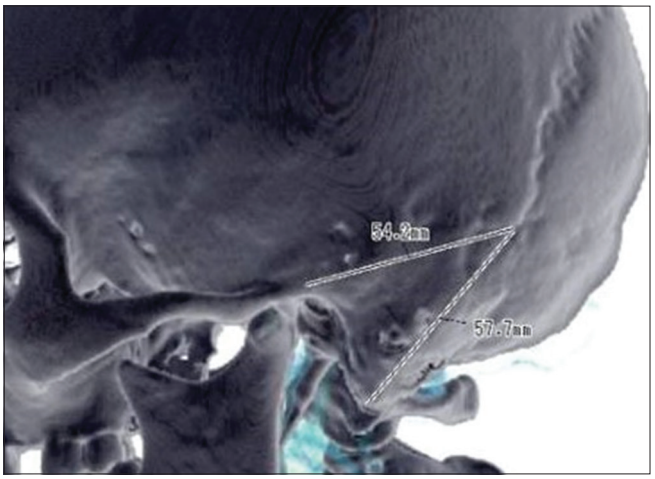

Figure 2: Negative reconstructed images measuring distance from the tip of mastoid process and root of zygoma to the asterion

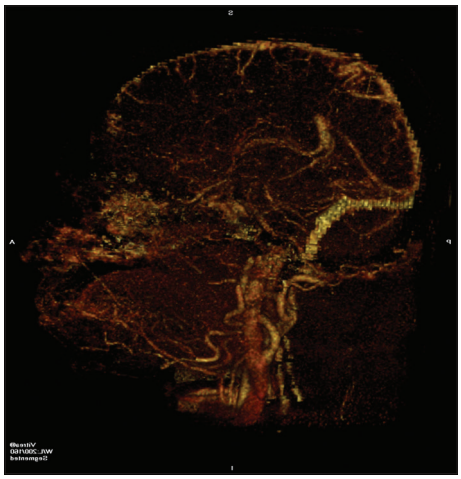

Figure 3: Initial vascular imaging showing all of arterial and venous structures

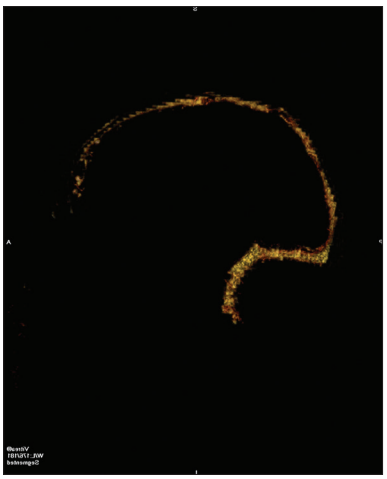

Figure 4: Delineated images showing only the dural sinuses

Figure 5: Dural sinus image reinforced over the bony reconstructed images

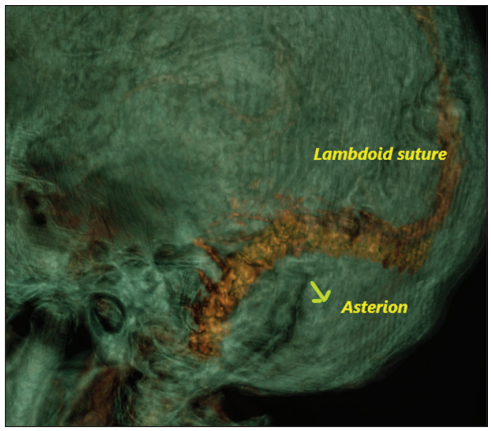

Figure 6: Close look of the reinforced images. Lambdoid suture and the asterion seen. The relationship of asterion with the transverse-sigmoid sinus junction (TSSJ) is identified. In this patient, the asterion is little below the TSSJ erion

asterion over the transverse sinus. Martinez *et al*.[13] reported that the asterion was over the transverse sinus in 76.2% of their cases. Leon *et al*.[11] showed that 82.4% of asteroin were over the transverse sinus complex, as compared to our study which showed the asterion located on the T-S sinus complex in 36(72%) cases. The asterion was below the T-S sinus complex in 13 (26%) cases and above the T-S sinus complex in only 1(2%) case [Figures 3-5].

The TSSJ is the point of the posterior and inferior aspect of the knee (upper genu) between the sigmoid and transverse sinuses, which is paramount in obtaining optimal exposure in CPA.[15] The inferior aspect of TSSJ was located anterior to the asterion. Once it is known where the junction is, the initial drilling is carried out approximately 1 cm lower and medial to this point.

In our study, TSSJ was located 1.9 cm anterior to the asterion [Figure 6].[16]

CONCLUSION

3D-CT volume rendering imaging is capable of accurately visualizing the bony landmark and dural sinuses. An easy and simple restructured image provides precision and safety for the patient by ready and easy localization of asterion and TSSJ. This helps in making precise burr hole without damaging sinuses during retrosigmoid craniotomies. This study was done to show that previous cadaver based anatomical studies can be done now in a more sophisticated and accurate manner with the latest technological advancements. This offers new options for anatomic research and morphometric investigations.

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Original Article

Level of C-reactive Protein in Obese and Overweight Individuals at Indira Gandhi Institute of Medical Sciences: A Tertiary Care Center of Bihar

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Abstract

Introduction: Human adipose tissue releases interleukin-6 which is a pro-inflammatory cytokine that causes low-grade systemic inflammation. Acute-phase C-reactive protein (CRP) is a sensitive marker for systemic inflammation. Low-grade systemic inflammation in overweight and obese can be measured by serum CRP level.

Objective: The objective of this study was to find out the prevalence of raised serum CRP level among the obese and overweight person.

Materials and Methods: Overweight and obese persons were screened for raised CRP (≥3.0 mg/L) after excluding comorbidity.

Results: The prevalence of raised CRP among obese and overweight is 23%, the female has higher prevalence of 25.45% as compared to male 20%. The prevalence among overweight and obese participants is 18.88% and 60%, respectively.

Conclusions: The finding suggest a higher prevalence of low-grade systemic inflammation in obese as compared to an overweight person.

Key words: Body mass index, C-reactive protein, Low-grade systemic inflammation, Obesity, Overweight, Prevalence

INTRODUCTION

C-reactive protein (CRP) is an annular, pentameric protein found in plasma, whose level rise in response to inflammation. CRP was discovered by Tillett and Francis in 1930. Its physiological role is to bind to lysophosphatidylcholine expressed on the surface of dead or dying cells (and some types of bacteria) to activate the complement system promoting phagocytosis by macrophages, which clears necrotic and apoptotic cells and bacteria. Thus, CRP is thought to act as a surveillance molecule for altered self and certain pathogens. This recognition provides early defense and leads to a pro-inflammatory signal and activation of the humoral, adaptive immune system. It is an acute-phase protein of hepatic origin that increases following interleukin-6 (IL-6) secretion by macrophages and T cells. The CRP is a sensitive marker of inflammation.[1] Plasma CRP levels are low in healthy individuals without any illness.

The fundamental cause of obesity and overweight is an energy imbalance between calories consumed and calories expended. For adults, the World Health Organization (WHO) defines that overweight is body mass index (BMI) between 25 and <30 kg/m^2, and obesity is a BMI 30 kg/m^2 or higher. Worldwide, obesity has nearly tripled for 1975. In 2016, more than 1.9 billion adults were overweight. Of these, over 650 million were obese. About 39% of adults aged 18 years and over were overweight in 2016, and 13% were obese.[2]

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Adipose tissue has always been considered a passive storage depot for fat, but it is also known to play an active role in metabolism by producing the pro-inflammatory cytokines and IL6.[3-5] As IL6 has inflammatory properties as well as stimulation of acute-phase protein production in the liver, the release of IL6 from adipose tissue may induce low-grade systemic inflammation in person with excess body fat.[6-8] Moreover, the accumulation of free fatty acids in obesity activates pro-inflammatory serine kinase cascades, which, in turn, promotes adipose tissue to release IL6 that triggers hepatocytes to synthesize and secret CRP.[9,10]

Since inflammation is believed to have a role in the pathogenesis of cardiovascular events, elevated concentrations of CRP are found in patients with acute coronary syndromes. The acute phase reaction is associated with elevated levels of fibrinogen, a strong risk factor for coronary heart disease (CHD), with autocrine and paracrine activation of monocytes by IL-6 in the vessel wall contributing to the deposition of fibrinogen. The acute-phase response is associated with increased blood viscosity, platelet number, and activity. Thus, there is the role of CRP and IL6 in the pathogenesis of CHD.[11] Measurement of CRP has been proposed as a method to improve the prediction of the risk of these events.[12]

Obesity is commonly cited as a risk factor for the development of CHD. Epidemiologic studies tend to support this contention, particularly those focusing on patients with central obesity.[13]

Objective of Study

The objective of this was to know the prevalence of raised serum CRP level in an overweight and obese person.

MATERIALS AND METHODS

After approval of the study protocol from the ethical committee of the institute Indira Gandhi Institute of Medical Sciences (IGIMS), this cross-sectional and observational study (prevalence study) included 100 obese and overweight participants of more than 18 years of age from outpatients department of general medicine IGIMS. Those obese or overweight having associated inflammatory condition, infectious disease, and other comorbidities which are known to influence CRP were excluded from the study. Height and body weight were measured using standardized procedures. BMI was calculated as weight in kilogram divided by the square of height in meter. The WHO definition was used to define overweight (BMI, 25–29.9 kg/m^2) and obesity (BMI ≥30 kg/m^2), and serum CRP was measured in all participants. Level ≥3.0 mg/L was labeled as raised. Interpretation of raised CRP was done depending on serum level. Level between 3.0 and 10.0 mg/L is minor elevation, >10–100.0 mg/L is moderate elevation, and more than 100.0 mg/L is marked elevation. Finally, data were statistically analyzed to determine the prevalence of raised serum CRP among obese and overweight.

RESULTS

Among 100 participants 45 were male, and 55 were female. Among males 41 were overweight and four were obese, female group 49 were overweight, and six were obese. Sixteen participants were in the age group 18–40 years, 56 were in the age group 41–60, and the number of participants ≥61 years of age is 28 [Table 1].

Elevated CRP level was present in 20% of men, and 25.45% of women and overall prevalence of raised CRP in study participants is 23%. The prevalence of moderately raised CRP level (≥10–100 mg/L) in men and women is 4.44% and 5.45%, respectively, whereas minor elevation of CRP (3–10 mg/L) is present in 15.55% of men and 20% of women. None of the participants have marked elevation (>100 mg/L) of CRP. Overall 18% of participants have minor elevation and 5% have a moderate elevation of CRP.

The prevalence of raised CRP among overweight (BMI-25–29.9 kg/m^2) men and women is 17.07% and 20.4%, respectively, whereas the prevalence of raised CRP among obese (BMI- ≥30 kg/m^2) men and women is 50% and 66.66%, respectively. The prevalence among overweight and obese participants is 18.88% and 60%, respectively [Table 2].

The prevalence of raised CRP among 18–40 years of age group is 3%, and among 41–60 years is 16%. Older participants (≥61 years) have a prevalence of 4% [Table 3].

DISCUSSION

Earlier studies have reported a high prevalence of raised CRP in obese and overweight, but in these studies, the high prevalence may have been confounded by inflammatory or infectious disease. We carefully excluded infectious or inflammatory disease and other factors in study participant which is known to influence serum CRP level. In our study, the prevalence of raised CRP in obese

Table 1: Characteristics of the study participants

Variables	Number (men)	Number (women)
Sample size number (*n*-100)	45	55
Age group in years		
18–40	7	9
41–60	26	30
≥61	12	16
Body mass index (kg/m^2)		
25–29.9 (over weight)	41	49
≥30 (obese)	4	6

Table 2: Prevalence of elevated C-reactive protein by BMI category

BMI level of CRP	Overweight men (*n*-41) (%)	Obese men (*n*-4) (%)	Overweight women (*n*-49) (%)	Obese women (*n*-6) (%)
Minor elevation (*n*-18)	(*n*-6) 14.63	(*n*-1) 25	(*n*-8) 16.32	(*n*-3) 50
Moderate elevation (*n*-5)	(*n*-1) 2.43	(*n*-1) 25	(*n*-2) 4.08	(*n*-1) 16.66
Marked elevation (*n*-0)	(*n*-0)	(*n*-0)	(*n*-0)	(*n*-0)

Table 3: Prevalence of elevated C-reactive protein by age and sex category

BMI level of CRP	18–40 (men) (*n*-7)	18–40 (women) (*n*-9)	41–60 (men) (*n*-26)	41–60 (women) (*n*-30)	≥61 (men) (*n*-12)	≥61 (women) (*n*-16)
Minor elevation (*n*-18)	(*n*-2) 28.57%	(*n*-1) 11.11%	(*n*-5) 19.23%	(*n*-8) 26.66%	(*n*-0)	(*n*-2) 12.5%
Moderate elevation (*n*-5)	(*n*-0)	(*n*-0)	(*n*-1) 3.84%	(*n*-2) 6.66%	(*n*-1) 8.33%	(*n*-1) 6.25%
Marked (*n*-0)	(*n*-0)	(*n*-0)	(*n*-0)	(*n*-0)	(*n*-0)	(*n*-0)

and overweight is 23%, which is comparable to a study done by Visser *et al*.[14]

Our data showing a high prevalence of raised CRP in women compared with men (20% vs. 25.45%), it could be due to the fact that at a similar BMI, women have more body fat than men.[15]

The prevalence of raised CRP among obese is more than 3 times higher (60%) than overweight participants (18.88%). A similar observation was found in a study by Visser *et al*.[14] Again, this could be due to difference in the amount of body fat in overweight and obese.

Raised CRP among obese and overweight was also investigated after stratification by age group (young = 18–40 and middle-aged = 41–60; old = ≥61) and of the level of CRP (minor elevation, moderate elevation, and marked elevation), in our study, the prevalence of minor elevation is common in young and middle-age participant as compared to older people, whereas moderate elevation was more common in the older participant. None of the participants have marked the elevation of CRP.

Our result, along with the evidence of earlier studies, has important implication for the cardiovascular risk in an overweight and obese person.

CONCLUSIONS

Higher BMI is associated with a high prevalence of raised CRP which suggests that a high prevalence of a state of low-grade systemic inflammation is present in an overweight and obese person.

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Original Article

Intrathecal Chloroprocaine Plus Fentanyl and Levobupivacaine Plus Fentanyl in Infraumbilical Surgeries in Adults

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Abstract

Background: The changing trend from an inpatient to outpatient has urged us to use short-acting local anesthetic with adjuvants such as opioids to intensify sensory block without affecting sympathetic blockade in spinal anesthesia. This study was designed to compare the safety and efficacy of 25 μg fentanyl as an adjuvant to either 10 mg levobupivacaine or 40 mg chloroprocaine intrathecally.

Materials and Methods: In this prospective, randomized, clinical trial, 60 patients of 18–60 years were randomly divided into two groups of 30 each, to receive either 4 ml of 1% chloroprocaine (40 mg) plus 25 μg fentanyl (Group C) or 2 ml of 0.5% isobaric levobupivacaine (10 mg) plus 25 μg fentanyl (Group L) intrathecally. Patients were monitored for 24 h for sensory and motor block characteristics as a primary outcome and post-operative analgesia, hemodynamics, and side effects as a secondary outcome.

Results: Onset of sensory block and time to maximum sensory block were rapid in Group C (2.53 ± 1.20 min and 4.40 ± 1.45 min) as compared to Group L (4.43 ± 1.12 min and 8.10 ± 0.83 min) ($P < 0.001$). The maximum sensory block was T4 in Group C and T6 in Group L. Maximum Bromage score was 2 in both groups but achieved earlier in Group C as compared to Group L ($P < 0.001$). Duration of sensory and motor block was significantly prolonged in Group L (264.47 ± 29.97 min and 173.80 ± 31.47 min) as compared to Group C (101.50 ± 10.30 min and 75.93 ± 10.41 min). The total duration of analgesia was also prolonged in Group L (259.83 ± 29.60 min) as compared to Group C (96.50 ± 9.84 min). Patients remained hemodynamically stable and no significant side effects and complications were noted.

Conclusion: Chloroprocaine provides adequate duration and depth of surgical anesthesia for short procedures with the advantages of faster block resolution.

Key words: Chloroprocaine, Fentanyl, Infraumbilical surgeries, Spinal anesthesia

INTRODUCTION

The trend of ambulatory surgery is rapidly growing worldwide. The primary goal of ambulatory surgery is a rapid onset and offset of anesthesia, fast patient recovery, and rapid patient discharge.[1] Spinal anesthesia is a suitable option for infraumbilical surgeries and as the shift toward ambulatory surgery continues, search for short-acting local anesthetics with rapid onset, adequate potency, predictable duration of action with decreased toxicity profile continues.

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Levobupivacaine, a pure S-enantiomer of bupivacaine, is an amide local anesthetic[2] which provides differential sensory and motor block, that is, rapid onset and longer duration of sensory block with short duration of motor block and less cardiac toxicity.[3,4] Chloroprocaine is an amino-ester local anesthetic with a very short half-life which has been successfully used for spinal anesthesia for short surgical procedures. Recently, the preservative-free formulation of 2-chloroprocaine has been extensively evaluated with a favorable profile in terms of both safety and efficacy.[5] It provides faster offset times and quicker patient discharge from the hospital. To prolong the effect of low dose local

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anesthetics, adjuvants such as opioids are added, which produce a synergistic effect by acting directly on opioid receptors in the spinal cord. Fentanyl, a short-acting lipophilic opioid which stimulates μ1 and μ2 receptors, potentiates the sensory blockade without intensifying the motor block, thus providing good quality of intraoperative and post-operative analgesia, hemodynamic stability with minimal side effects.[6]

Until date, scant literature is available where low doses of chloroprocaine and levobupivacaine, with fentanyl as an adjuvant, were compared for block characteristics in short surgical procedures. Hence, the present study was designed to compare the safety and efficacy of 25 μg fentanyl as an adjuvant to either 10 mg levobupivacaine or 40 mg chloroprocaine intrathecally in patients undergoing infraumbilical surgeries, in terms of onset and duration of sensory and motor blockade as a primary outcome and post-operative analgesia, hemodynamic parameters, side effects, and complications as a secondary outcome.

MATERIALS AND METHODS

In this perspective, randomized, clinical trial, 60 patients of American Society of Anesthesiologists grades I and II of either sex, in the age group of 18–60 years scheduled for elective infraumbilical surgeries under spinal anesthesia were included after approval from the Institutional Ethics Committee and CTRI registration (CTRI/2018/05/013565). Patients with unwillingness for the procedure, coagulation or neurological disorders, deformity, or previous surgery of spine, pregnancy, and allergy to the study drug were excluded from the study. A day before surgery, a detailed pre-anesthetic check-up was done. A general physical examination along with systemic examination, assessment of airway, and local examination of the lumbar spine was done. Relevant investigations were reviewed. Visual analog scale (VAS) was explained to the patients to determine the level of analgesia in the post-operative period. It was carried out with a 0–10 cm line. The first end mark "0" means "no pain" and the end marked "10" means "severe pain." Informed consent was taken from all the patients.

Patients were randomly divided into two groups of 30 each, using a computer generated table of random numbers. Group C (n = 30) received 4 ml of 1% 2-chloroprocaine (40 mg) plus 0.5 ml fentanyl (25 μg) and Group L (n = 30) received 2 ml of 0.5% isobaric levobupivacaine (10 mg) plus 0.5 ml fentanyl (25 μg). The volume of drugs was different in both groups to meet the requirement of equipotent doses. To prevent bias, one anesthesiologist performed the subarachnoid block and another anesthesiologist blinded to the study drug was assigned to monitor the block characteristics, hemodynamics, and side effects.

All patients were given tablets alprazolam 0.25 mg and tablet ranitidine 150 mg orally a night before surgery and at 6:00 am on the day of surgery. Patients were asked to orally restrict solids for 6 h and clear fluids for 2 h before surgery. After shifting to the operation theatre, multipara monitor was attached and baseline respiratory rate (RR), heart rate (HR), noninvasive systolic blood pressure (SBP) and diastolic blood pressure (DBP), peripheral oxygen saturation (SpO_2), and electrocardiography (ECG) were recorded and continuous monitoring was started. An intravenous line was secured and injection midazolam 1 mg and injection butorphanol 1 mg was given intravenously 3–6 min before the start of the surgery.

Patients were preloaded with 10 ml/kg body weight of ringer lactate solution. Under all aseptic precautions, spinal anesthesia was given in L3-L4 space with 25 gauge or 26 gauge Quincke spinal needle through the midline approach in lateral decubitus position. On the free flow of cerebrospinal fluid, the study drug was injected intrathecally. Patients were immediately turned to a supine position and oxygen was started at the rate of 6 L/min. All parameters were noted by taking the time of giving the study drug intrathecally as time 0. Continuous monitoring of RR, HR, noninvasive SBP and DBP, SpO_2, and ECG was done intra-operatively every 2 min for the first 10 min, thereafter every 5 min until 30 min and then every 15 min until the end of surgery in both the groups. Postoperatively readings were recorded every 30 min until 180 minutes of surgery, then one hourly until 12 h and then every three hourly until 24 h of study. Bradycardia (HR below 60 beats per minute) was treated with injection atropine sulfate 0.6 mg IV. Hypotension (defined as fall in blood pressure more than 20% below the baseline) was treated with IV fluids and injection ephedrine 5 mg boluses titrated according to blood pressure.

Sensory blockade was assessed by loss of sensation to pinprick in the midline using a 22 gauge blunt hypodermic needle every 3 min for the first 15 min, then every 5 min for the next 15 min, then every 15 min until 180 min of surgery thereafter, postoperatively sensory blockade was checked one hourly for the next 12 h and then three hourly until 24 h of the study period. The onset of sensory block (when patient does not feel pinprick at T10 level), the highest level of sensory block achieved, time to maximum sensory block, regression of sensory block to L5, and total duration of sensory block (regression to S1 dermatome) were noted. Post-operative pain was monitored using VAS score every 15 min until 180 min, then one hourly until 12 h and every three hourly until 24 h and rescue analgesia was given when the VAS was >3 in both the groups. Inj. diclofenac 75 mg

intramuscularly was given as rescue analgesia and if needed, inj. tramadol 50 mg intramuscularly was given. Time to first rescue analgesia (total duration of analgesia) and total number of doses of rescue analgesia was also noted.

Motor blockade was checked every 3 min for the first 15 min, then every 5 min for the next 15 min, then every 15 min until 180 min of surgery Thereafter, postoperatively motor blockade was checked one hourly for the next 12 h and then three hourly until 24 h of study period according to modified Bromage scale:- Grade 0: No motor block, Grade 1: Inability to raise extended leg; able to move knees and feet, Grade 2: Inability to raise the extended leg and move knee; able to move feet, and Grade 3: Complete block of lower limb. Maximum motor block achieved, time to the maximum motor block, and total duration of motor block (motor recovery to Bromage 0) were noted. When the motor block was totally resolved, patients were allowed to ambulate. Surgery was allowed to start when sensory block to T10 dermatome was achieved. The quality of surgical analgesia was assessed and graded as excellent – no supplementary drugs required, good – analgesic required, fair – more than one analgesic required, and poor – general anesthesia required. Patients were monitored for any side effects or complications such as hypotension, bradycardia, nausea, vomiting, sedation, urinary retention, pruritus, headache, backache, and neurological changes for 24 h.

Statistical Analysis

Power analysis was done. Effective size/power of the study was determined by taking in to account the mean onset of sensory block, mean duration of sensory block, and total duration of analgesia. The power was well above 90% by taking α error 0.05. The sample size was calculated as per formula with a conventional multiplier for alpha = 0.05

Conventional multiplier for power (b) = 0.8

$$n = 2[(a+b)^2\sigma^2]/(\mu1-\mu2)^2$$

where n = Sample size in each of the group
$\mu1$ = Population mean in treatment Group I
$\mu2$ = Population mean in treatment Group II.

Hence, 30 patients were included in each group for power analysis of 80% and were divided in open-label fashion, according to computer-generated randomization.

The data from the present study were systematically collected, compiled, and statistically analyzed using software IBM SPSS 22 to draw relevant conclusions. Data were expressed as means, standard deviation, number, and percentages. The patient characteristics (nonparametric data) were analyzed using the "Chi-Square tests" and the inter-group comparison of the parametric data was done using the "Unpaired *t*-test." *P*-value was determined to finally evaluate the levels of significance. $P < 0.05$ was considered as statistically significant.

RESULTS

In the present study, both groups were comparable with respect to demographic characteristics and duration of surgery [Table 1]. The mean time taken for onset of sensory block and the time to maximum sensory block was significantly more in Group L ($P = 0.000$). The median maximum sensory level reached was higher in Group C (T4 in Group C and T6 in Group L). The median maximum motor block achieved in both the groups was Bromage 2, but the meantime taken for achieving it was significantly more in Group L ($P = 0.000$). Regression of sensory block to L5 dermatome was significantly prolonged in Group L ($P = 0.000$). The total duration of sensory and motor block was also significantly more in Group L as compared to Group C ($P = 0.000$). The time taken for unassisted ambulation was significantly more in Group L as compared to Group C ($P = 0.00$). Time for micturition was also significantly delayed in Group L as compared to Group C ($P = 0.00$). Motor and sensory block parameters are shown in Table 2.

VAS was 0 at 75 min of the study period, then it started increasing in both the groups. VAS was on higher side in Group C as compared to Group L until 180 min. ($P = 0.000$) and patients demanded the first dose of rescue analgesia at 105 min. After this interval, VAS was on the significantly higher side in Group L ($P = 0.000$) and the

Table 1: Demographic profile of patients in Group L and Group LF

Parameter	Group C (*n*=30)	Group L (*n*=30)	*P*-value
Mean age in years	37.80±13.05	38.59±11.84	0.370
Sex ratio (%)			
Male	23 (76.67)	20 (66.67)	0.390
Female	7 (23.33)	10 (33.33)	
Mean weight in kilograms	64.40±8.03	67.80±7.34	0.060
ASA grade %			
Grade I	26 (86.67%)	27 (90%)	0.688
Grade II	4 (13.33%)	3(10%)	
Mean duration of surgery in minutes	40.13±6.18	41.83±8.71	0.521

patient demanded the first dose of rescue analgesia at 4th h of the study period, as shown in Figure 1. Hence, the duration of analgesia was significantly prolonged in Group L (259.83 ± 29.60 min) as compared to Group C (96.50 ± 9.84 min) ($P = 0.000$). The total number of doses of rescue analgesia required in 24 h was also significantly less in Group L as compared to Group C ($P = 0.03$) [Table 2]. The quality of surgical analgesia was excellent in both groups as none of the patient required supplementary analgesia intraoperatively.

Hemodynamic parameters remained stable and comparable throughout the study period, as shown in Figures 2-4. Four (13.33%) patients in Group C and three (10%) patients in Group L had bradycardia, which was corrected with Injection atropine sulfate and was comparable in both the groups ($P > 0.05$). Six (20%) patients in Group C and four (13.33%) patients in Group L had a fall in blood pressure intraoperatively, which was managed with IV fluids and intermittent boluses of injection ephedrine. The incidence of hypotension was comparable in both groups ($P > 0.05$). RR and SpO_2 remained stable and comparable at all measured intervals. Patients were monitored for side effects and complications for 24 h [Table 3]. The incidence of pruritis was comparable, that is, four (13.33%) patients in both groups. None

Table 2: Sensory and motor block characteristics in Group C and Group L

Parameters in minutes	Group C (*n*=30)	Group L (*n*=30)	*P*-value
Onset of sensory block to T10 dermatome	2.53±1.20	4.43±1.12	0.00
Median maximum sensory level	T4	T6	0.00
Time to maximum sensory level	4.40±1.45	8.10±0.83	0.00
Time for regression to L5 dermatome	90.10±10.53	212.70±29.05	0.00
Total duration of sensory block	101.50±10.32	264.47±29.97	0.00
Duration of analgesia	96.50±9.84	259.83±29.60	0.00
Total number of doses of rescue analgesia	4.47±0.51	3.33±0.70	0.03
Maximum motor block	2	2	-
Time for maximum motor block	6.40±1.45	9.73±1.77	0.00
Total duration of motor block	75.13±10.41	173.80±31.47	0.00
Time to unassisted ambulation	99.33±7.3	195.10±20.4	0.00
Time to micturition	102.45±5.6	214.12±22.44	0.00

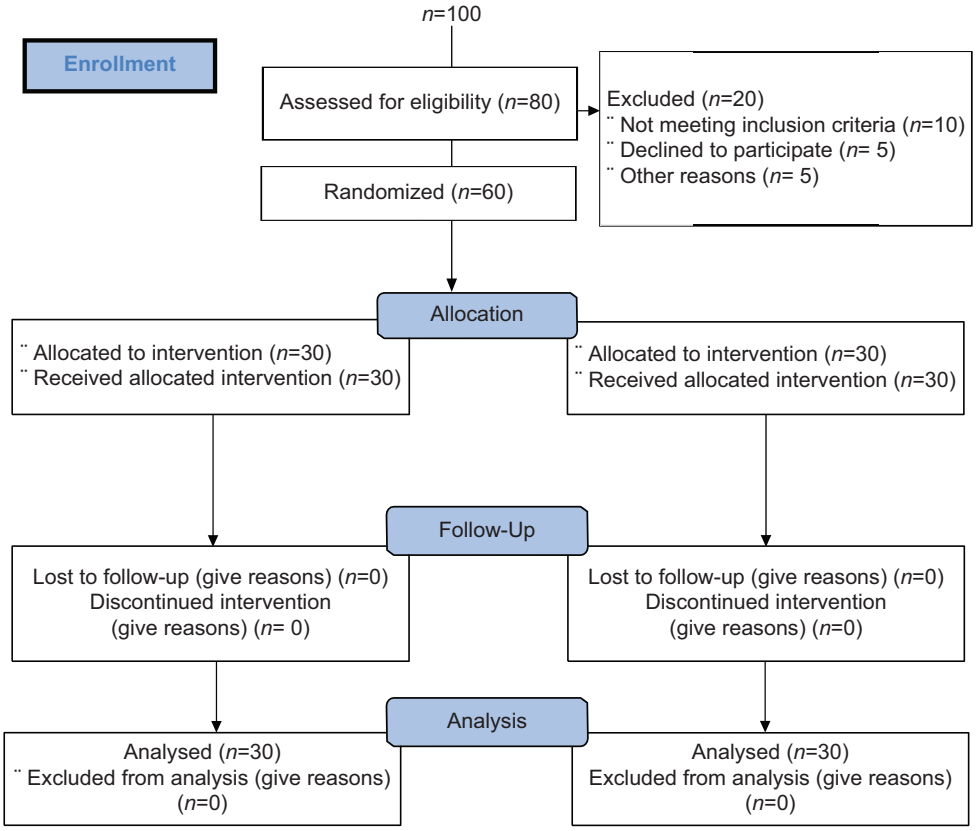

Figure 1: Consort flow diagram

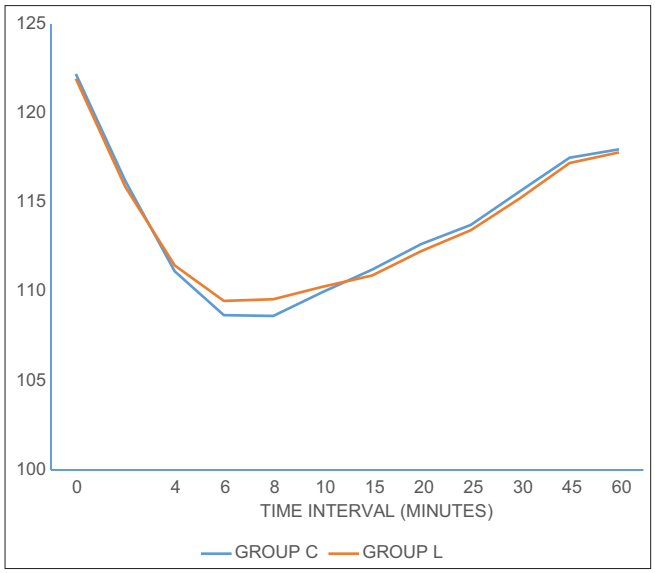

Figure 2: Systolic blood pressure in two groups at different time intervals during the intraoperative period

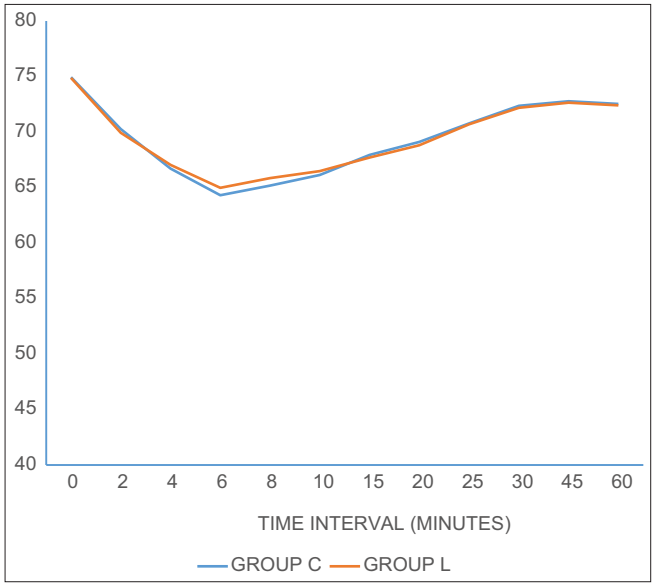

Figure 3: Diastolic blood pressure in two groups at different time intervals during the intraoperative period

of the patient had nausea, vomiting, urinary retention, shivering, headache, backache, local anesthetic toxicity, and respiratory depression throughout the study period in both the groups.

DISCUSSION

Spinal anesthesia remains a preferred technique for infraumbilical surgeries due to its rapid onset and offset, easy administration, minimal expenses, and negligible side effects. With a trend toward ambulatory surgery, lower doses of local anesthetics are being used, but sometimes inadequate anesthesia occurs.

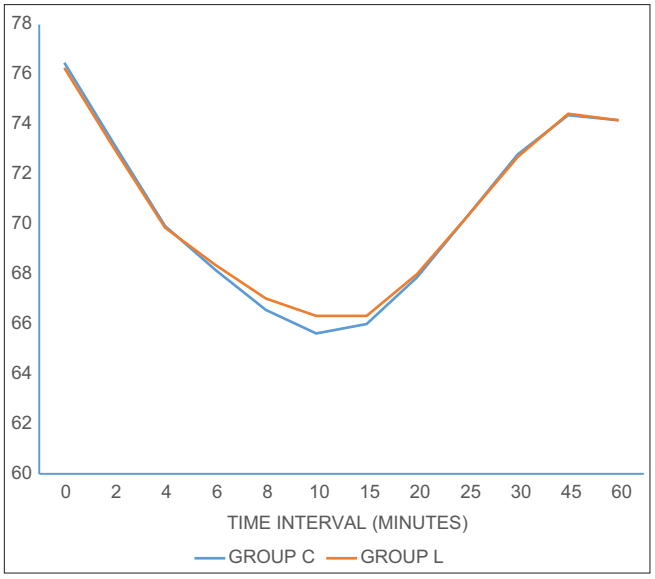

Figure 4: Mean heart rate in two groups at different time intervals during the intraoperative period

Table 3: Side effects and complications in Group C and Group L

Side effects and complications	Group C (*n*=30) (%)	Group L (*n*=30) (%)	*P*-value
Bradycardia	4 (13.33)	3 (10)	0.6433
Hypotension	6 (20)	4 (13.33)	0.2923
Pruritis	4 (13.33)	4 (13.33)	0.118
Respiratory depression	0	0	1
Nausea	0	0	1
Vomiting	0	0	1
Local anesthetic toxicity	0	0	1
Headache	0	0	1
Body ache	0	0	1
Urinary retention	0	0	1

As the duration of anesthetic action of local anesthetics is dose-dependent, a study was done to find the minimum effective dose of chloroprocaine for intrathecal use, where three different doses 30, 40, and 50 mg were compared for block characteristics. It was found that 40 mg is the effective dose, as reducing the dose to 30 mg resulted in an insufficient block.[7] Similarly, for levobupivacaine, 10 mg intrathecal dose was found to be the minimum effective dose for sensory and motor block.[8] In the present study, fentanyl 25 μg was added to above local anesthetics, that is, 10 mg levobupivacaine (Group L) and 40 mg chloroprocaine (Group C) with an aim to enhance the duration of sensory analgesia without intensifying the motor block with hemodynamic stability. In the present study, it was found that the addition of 25 μg fentanyl to equipotent doses of chloroprocaine and levobupivacaine results ins different sensory and motor block characteristics. In the chloroprocaine group, there was a faster onset and early regression of sensory and motor block as compared to

the levobupivacaine group. The maximum level of sensory block achieved was T4 in Group C and T6 in Group L and it was achieved earlier in Group C as compared to Group L. However, the duration of analgesia was shorter in Group C as patient demanded more doses of rescue analgesia in the post-operative period as compared to Group L. However, due to early block resolution, patients were able to ambulate and micturate early in Group C. There was no significant difference in hemodynamic parameters, side effects and complications in both groups.

A study was done using 30 mg chloroprocaine + 12.5 μg fentanyl intrathecally and observed that onset of sensory block was achieved in 4.7 ± 0.79 min, maximum sensory level achieved was T8 (6.2 ± 0.76 min), regression of sensory block to S1 in 94.72 ± 5.32 min, and duration of analgesia was 105 min.[9] Similarly, the onset and duration of motor block are 5.36 minutes and 81.46 min, respectively.[9] In the present study, the maximum sensory level achieved was T4 and was earlier, and regression was also delayed. This difference can be due to the higher doses of chloroprocaine and fentanyl used in the present study. In a study done by Vath and Kopacz[10] studied the block characteristics of 40 mg chloroprocaine with 20 μg fentanyl as an adjuvant observed that the maximum sensory level achieved was T5 (T4 in the present study) and regression to L1 was in 78 min and duration of sensory block was 104 min (101.50 ± 10.32 min in Group C). Hence, the sensory block characteristics of the present study are almost comparable to the above study. To test the hypothesis that addition of dextrose increases the baricity of chloroprocaine and how it affects block pattern, Warren and Kopacz[11] used 10% dextrose as an adjuvant to 40 mg 2-chloroprocaine and observed that maximum sensory level achieved was T3 which is almost consistent with the present study (T4) but time to achieve this level was more 14 ± 9 min as compared to the present study (4.40 ± 1.45 min). Duration of sensory and motor block was 95 ± 8 min and 80 ± 14 min, respectively (101.50 and 75.13 min, respectively, in Group C of the present study), and time to ambulate was 96 ± 7 min (99.33 min in Group C) and time to void was 101 ± 7 min (102.45 min in Group C of the present study). Although we have used the same dose of chloroprocaine as the above study with fentanyl as an adjuvant in place of dextrose, the duration of sensory and motor block, time to ambulate, and time to void is still consistent with the results of above study.

In Group L, the onset of sensory block to T10 occurred in 4.43 ± 1.12 min, maximum sensory block achieved was T6 in 8.10 ± 0.83 min. Similar findings were observed in previous studies also, using 10 mg levobupivacaine and 25 μg fentanyl. Attri *et al.*[12] used the same dose and observed that the maximum sensory level achieved was T6 and the time taken to achieve was 8.46 ± 1.87 min. Girgin *et al.*[3] used 5 mg levobupivacaine and 25 μg fentanyl, the maximum sensory level achieved was T7 as compared to T6 in the present study difference may be due to less dose of levobupivacaine used in the above study. Akan *et al.*[13] using 7.5 mg 0.5% levobupivacaine combined with 25 μg fentanyl found that the meantime to onset to T10 was 6.9 ± 1.7 min and it is more prolonged as compared to Group L because a lesser dose of levobupivacaine and fentanyl was used. In the present study, maximum motor block achieved was Bromage 2 and the time taken to achieve maximum motor block (9.73 ± 1.77 min) was almost similar to the results of the previous studies done by Attri *et al.*[12] (8.38 ± 2.1 min) and Chattopadhyay *et al.*[14] (8.9 ± 51 min). The duration of sensory and motor block in Group L (264.47 ± 29.97 min and 173.80 ± 31.47 min, respectively) are consistent with the results of the study done by Attri *et al.*[12] (270.98 ± 28.60 min and 188.52 ± 9.81 min, respectively). The duration of analgesia in Group L was 259.83 ± 29.60 min which was comparable to the results of Attri *et al.*[12] (265 ± 26.18 min) and Honca *et al.*[15] (250 min). In the present study, time to micturate was 214.12 ± 22.44 min and time to ambulate was 195.10 ± 20.4 min in Group L. Girgin *et al.*[3] conducted a study using 25 μg fentanyl as an adjuvant to 5 mg levobupivacaine intrathecally and found that time to micturition was 221 ± 58 min and time to ambulate was 201 ± 51 min, which was slightly more than the present study using 10 mg dose.

Hemodynamics remained stable and comparable in both the groups intraoperatively and postoperatively. Bradycardia was observed in 4 patients (13.33%) in Group C and 3 patients (10%) in Group L. Hypotension in 6 (20%) patients in Group C and 4 (13.33%) patients in Group L. Similar findings were observed by Lacasse *et al.*[16] using 40 mg of chloroprocaine, where 6 patients (8%) had bradycardia and 4 patients (8%) had a fall in blood pressure. Chattopadhyay *et al.*[14] observed that 2 (9.1%) patients had bradycardia and 4 (18.2%) patients had hypotension while using 10 mg levobupivacaine and 25 μg fentanyl. Similar findings were also observed by Attri *et al.*,[12] Goyal *et al.*,[17] and Krobot *et al.*[18] using levobupivacaine and fentanyl intrathecally.

The most common side effect observed was pruritus which was comparable in both the group's none of the patient developed urinary retention in both the groups. No other side effects and complications were observed in both groups.

The limitation of the present study was that we had used different volumes of two study drugs to meet the requirement of equipotent doses. We tried to do blinding of the study by not involving the person who performed

the block in monitoring, that is, monitoring was done by the second person who was blinded to the drug given. However, as block regression was much earlier in Group C, the blinded observer could guess the group to which the patient belonged; hence, observer bias could not be ruled out.

CONCLUSION

To conclude, both the drugs were effective in providing surgical anesthesia and hemodynamic stability, but Group C provided earlier onset and offset of sensory and motor block, whereas Group L provided the prolonged duration of analgesia. As voiding and ambulation were earlier in Group C; hence, patients could have been discharged earlier as compared to Group L. This suggests that intrathecal chloroprocaine 40 mg plus fentanyl 25 μg provides adequate duration and depth of surgical anesthesia for short surgical procedures with the advantages of faster block resolution and earlier hospital discharge as compared to intrathecal levobupivacaine 10 mg plus fentanyl 25 μg.

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Original Article

A Study of Cognitive Impairment in Patients with Type 2 Diabetes Mellitus – A Prospective Observational Study

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Abstract

Introduction: Type 2 diabetes mellitus (DM) is the most lifestyle risk factor for cognition. Regular treatment and management of Type 2 DM could prevent the onset and progression of cognitive impairment. Cognitive decline associated with DM may influence one's ability to perform self-care and affect glycemic control.

Aim: Our prospective observational study aimed to analyze the cognitive impairment using a mini-mental status examination (MMSE) in patients with Type 2 DM.

Materials and Methods: This prospective observational study was conducted to analyze the cognitive impairment using MMSE in patients with Type 2 DM. A total of 50 patients diagnosed with Type 2 diabetes were included in the study. All the demographic and laboratory investigation data so obtained was tabulated and was analyzed statistically, and results were discussed.

Results: Of 50 patients, 26 patients were male and 24 patients were female. Based on the age group, 11 patients were in the age group below 40 years, 21 patients between 40 and 50 years, 16 patients between 51 and 60 years, and 2 patients >60 years. Based on the duration of Type 2 diabetes, 16 patients had <5 years and MMSE score of 24.28 and 34 patients had >5 years and MMSE score of 22.14. Based on cognitive impairment, 44 patients had mild cognitive impairment and 6 patients had moderate cognitive impairment.

Conclusion: From this study, we concluded that the duration of Type 2 DM and level of HbA1c affect the cognitive status of the individuals. A greater understanding of the mechanisms linking Type 2 DM and cognitive impairment may facilitate the development of new ways for the treatment of cognitive impairment.

Key words: Cognition, Mini-mental status examination score, Type 2 diabetes mellitus

INTRODUCTION

Type 2 diabetes is a chronic metabolic condition characterized by abnormally high blood glucose levels as a result of insufficient usage of insulin. Diabetes often involves disturbances of carbohydrate, fat, and protein metabolism. Type 2 diabetes mellitus (DM) increases the risk of developing complications. Some of these diabetic complications can ultimately lead to cardiovascular disease, kidney disease, neuropathy, and diabetic retinopathy.[1,2] DM patients have 1.2–1.5-fold greater rate of cognitive dysfunction. Even prediabetes stages and insulin resistance status are associated with increased risk of cognitive decline and brain atrophy. However, Type 2 diabetes may be present in up to 80% of individuals with cognitive impairment who are aged 65 years or older.[3] Poor glycemic control and long-term episodes of hypoglycemia or hyperglycemia may lead to microangiopathy, neuronal loss, and cognitive impairment.[4]

DM may present with characteristic symptoms such as thirst, polyuria, blurring of vision, and weight loss.

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A fasting plasma glucose (FPG) test measures blood glucose in a person who has not eaten anything for at least 8 h. Oral glucose tolerance test measures blood glucose after a person fasts at least 8 h and 2 h after the person drinks a glucose-containing beverage. Both the test is used to detect diabetes and prediabetes. The current WHO diagnostic criteria for diabetes should be maintained – FPG ≥7.0 mmol/l (126 mg/dl) or 2–h plasma glucose ≥11.1 mmol/l (200 mg/dl) HbA1c is regarded as the best tool in analyzing long-term glycemic control in DM. The major glycosylated hemoglobin is the HbA1c. The normal value is 4–6%.

Cognitive impairment is a syndrome caused by a range of neurological conditions and characterized by progressive functional impairment of mental processes (also known as cognitive domains) such as memory, attention, speed of processing information, executive function, reasoning, visuospatial abilities, and language. In Type 2 DM, cognitive changes mainly affect learning and memory, mental flexibility, and psychological speed.

Domains of cognition are the gold standard until today for assessing the neurocognitive functions.[5] Among the neurocognitive tests, the mini-mental status examination (MMSE), which was introduced in the year 1975, is most commonly used.[6] The MMSE is a questionnaire which tests several aspects of cognitive domains – "orientation, registration, verbal recall, calculation, visual construction, attention, and language."[7] Although Type 2 DM is considered as a risk factor for cognitive decline, it is not regularly assessed in routine clinical care. Diabetes associated cognitive decline is not caused by only one factor, but the multi-factor and multi-link complex pathological changes.[8] Cognitive decline may lead to bad diabetic control and poor adherence to treatment modalities, including diet plans.[7] Hence, this study has been done to evaluate the cognitive status of individuals with Type 2 DM.

Aim

Our prospective observational study aimed to analyze the cognitive impairment using MMSE in patients with Type 2 DM.

MATERIALS AND METHODS

This prospective observational study was conducted to analyze the cognitive impairment using MMSE in patients with Type 2 DM under different study parameters such as gender, age, duration of Type 2 DM, HbA1c values, and MMSE score. A total of 50 patients diagnosed with Type 2 diabetes were included in the study. Inclusion criteria: Age should be between 30 and 70 years and laboratory and clinically confirmed Type 2 DM patients and exclusion criteria: Patients with a history of Type 1 DM, h/o taking CNS medications, h/o cerebrovascular disease, known case of dementia/psychiatric disease, and h/o difficulty in doing daily activities. The procedure was explained in detail to the subjects and written informed consent was obtained. A detailed history was taken from the patients and a complete clinical examination was done. Patient blood samples are collected for laboratory investigation of HbA1c.

Cognitive status of the study subjects assessed using MMSE questionnaire. The MMSE is composed of 11 major items; temporal orientation (5 points), spatial orientation (5 points), immediate memory (3 points), attention/concentration (5 points), delayed recall (3 points), naming (2 points), verbal repetition (1 point), verbal comprehension (3 points), writing (1 point), reading a sentence (1 point), and constructional praxis (1 point). The MMSE has a maximum score of 30, with five different domains of cognition analyzed: (1) Orientation, contributing a maximum of 10 points, (2) memory, contributing a maximum of 6 points, (3) attention and calculation, as a measure of working memory, contributing a maximum of 5 points, (4) language, contributing a maximum of 8 points, and (5) design copying, contributing a maximum of 1 point. Individuals scoring two points below the maximum in any independent domain (except design copying) were considered to be impaired. These cutoff scores were used to grade the level of cognition. The cutoff scores for the classification of cognitive impairment include:

- MMSE scores ≥27 – normal cognition
- MMSE scores 21–26 – mild cognitive impairment
- MMSE scores 11–20 – moderate cognitive impairment
- MMSE score ≤10 – severe cognitive impairment.

The data so obtained were tabulated and were analyzed statistically and results were discussed.

RESULTS

Of 50 patients, 11 patients were in the age group below 40 years, 21 patients between 40 and 50 years, 16 patients between 51 and 60 years, and 2 patients >60 years [Figure 1].

Of 50 patients, 26 patients were male and 24 patients were female [Figure 2].

Of 50 patients16 patients had <5 years and 34 patients had >5 years [Figure 3].

Of 50 patients, 44 patients had mild cognitive impairment and 6 patients had moderate cognitive impairment [Figure 4].

Patients with HbA1c >7.1 had MMSE score of 21.82 and HbA1c <7 had MMSE score of 25.4 [Figure 5].

Patients with the duration of Type 2 DM >5 years had MMSE score of 22.14 and <5 years had MMSE score of 24.28 [Figure 6].

DISCUSSION

DM is a chronic condition, but people with diabetes can lead a normal life, provided they keep their diabetes under control. Lifestyle modifications (LSM) are an essential component of any diabetes management plan. LSM can be a very effective way to keep diabetes in control. Improved blood glucose control can slow the progression of long term complications. Small changes can lead to improvements in diabetes control, including a decrease in the need for medication. Cognitive dysfunction is also considered as an important chronic complication. Even though advancement is being made, cognitive dysfunction is still a neglected field in diabetes. A conserved cognitive status is vital for the awareness of the disease and its compliance. Both DM and cognitive impairment are mutually exclusive as hyperglycemia increases cognitive impairment occurs, which leads the patients to decrease in memory attention which further increases the hyperglycemia.

In the present study, cognitive impairment is assessed for 50 patients with Type 2 DM using MMSE questionnaire. About 88% had mild cognitive impairment and 12% had moderate cognitive impairment. It states that patients diagnosed with

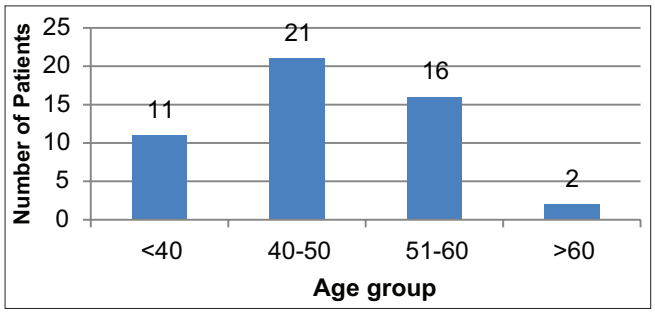

Figure 1: Age distribution

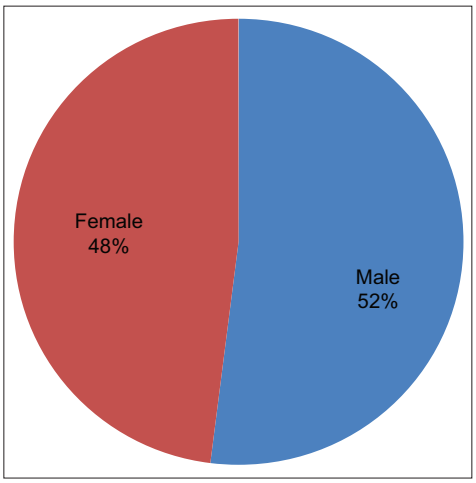

Figure 2: Gender distribution

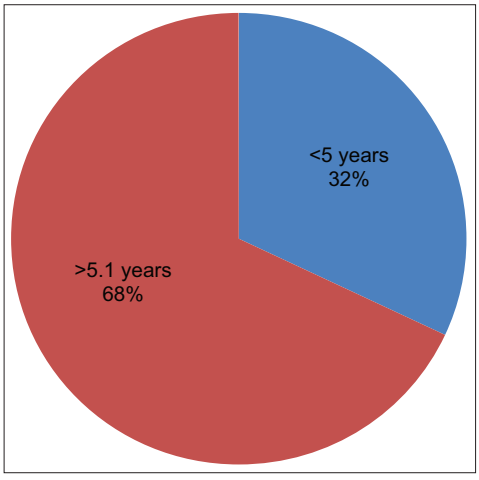

Figure 3: Duration of diabetes mellitus Type 2

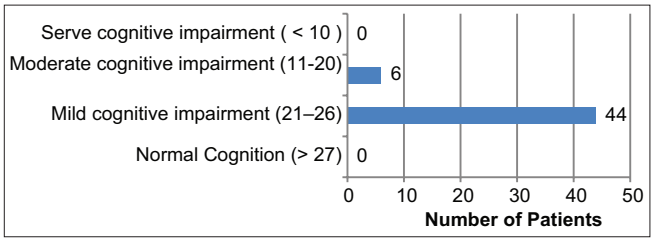

Figure 4: Cross-tabulation between no. of patients and cognitive impairment

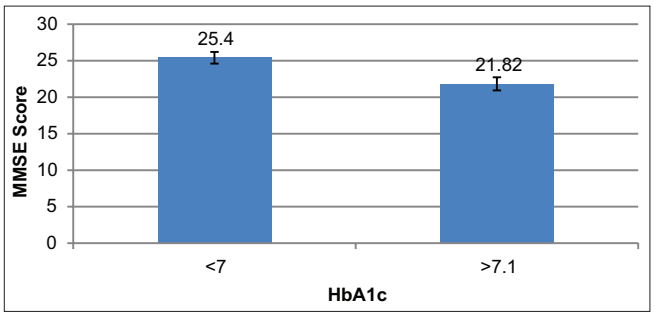

Figure 5: Cross-tabulation between HbA1c and mini-mental status examination score

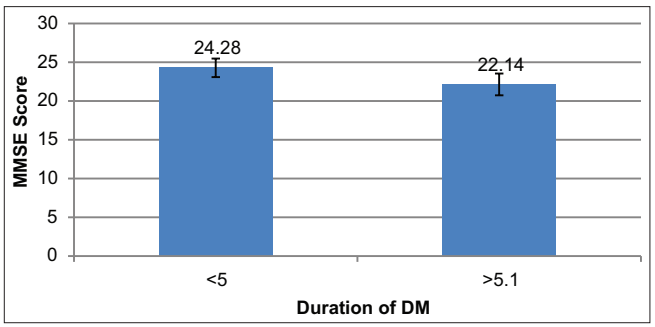

Figure 6: Cross-tabulation between duration of Type 2 diabetes mellitus and mini-mental status examination score

Type 2 DM will have mild cognitive impairment. Hence, early diagnosis prevents the progression of diseases and complications. This is similar to a study conducted by Kataria *et al.* identified a high frequency of cognitive decline in several domains of cognitive function in Type 2 DM subjects.[9] Another study conducted by Priyam *et al.* also described that impairment in cognition is related to Type 2 DM.[10]

In our study, it states that patients with HbA1c >7.1 have MMSE score of 21.82 and patients with HbA1c <7 have MMSE score of 25.4. It suggests that if the glycated hemoglobin level increases, the MMSE score will decreases. It is similar to the study conducted by Roy *et al.*, cognitive impairment was observed in 11.6% of the patients who had optimal glycemic control (HbA1c under 7%) and 30.2% with HbA1c 7% or above.[11] Another study conducted by Luchsinger *et al.* showed that improving HbA1c levels in an elderly population over a period of 5 years was associated with the slowing down of global cognitive.[12]

In the present study, it was also seen that MMSE score in Type 2 DM subjects having a duration above 5 years is 22.14 when compared to those with a duration <5 years is 24.28. It suggests that as the duration of Type 2 DM increased, then MMSE score will decreases. It is similar to the study conducted by Grodstein *et al.*, who identified that increase in the duration of Type 2 DM might be correlated with low scores on neurocognitive tests.[13] Another study conducted by Kataria *et al.* studies states that longer the duration of Type 2 DM which indirectly proportional to the MMSE score.[9]

CONCLUSION

From this study, we concluded that the duration of Type 2 DM and the level of HbA1c affect the cognitive status of the individuals. A greater understanding of the mechanisms linking Type 2 DM and cognitive impairment may facilitate the development of new ways for the treatment of cognitive impairment.

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Original Article

A Predictive Model of Hearing Outcome for Cochlear Implantation in Children below 5 Years of Age

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ABSTRACT

Background: Cochlear Implantation (CI) has become an important modality of treatment for children with severe to profound pre-lingual sensorineural hearing loss who do not benefit from hearing aids (HAs). The final outcome is not totally predictable, as there are a large number of factors which either alone or in combination will play their roles in the final outcome of CI.

Aim of the Study: This study aims to evaluate prospectively the relative impact of multiple pre-, peri-, and post-operative factors on the final outcome of the CI in pre-lingual hearing impaired children aged 5 years under "Sruthitharangam" free cochlear implant program of Government of Kerala.

Materials and Methods: This study was conducted at Government Medical College, Kozhikode (GMC-KKD), Kerala, from January 2014 to January 2015. The study group consisted of 60 patients screened from the patients who have attended Auditory verbal habilitation (AVH) categories of Auditory Performance (CAP) test, Meaningful auditory integration scale (MAIS) and Speech intelligibility rating test (SIR) at GMC-KKD, Kerala. Counseling of parents was done regarding regular follow-ups and therapy/support to the child at home.

Observations and Results: Pearson correlation test and Spearman correlation test were done to check the correlation between age at which HA was first fitted and MAIS scores. Correlation between the age at which HA first fitted and MAIS was negative. As the age at which HAs were fitted increases, the MAIS score decreases. This indicates the significance of using the residual hearing and stimulation of auditory nerve as early as possible. Pearson correlation and Spearman correlation tests were applied to check the correlation between age of surgery and MAIS score and found that there was negative correlation existing between age of surgery and MAIS scores. This meant, as the age at which surgery was done increases, the MAIS score decreases. Pearson correlation test and Spearman correlation tests were applied to check the MAIS scores and duration of AVH with HAs.

Conclusions: A Cochlear implant was not a passive sensory aid or sensory substitution device that simply replaces a damaged or defective cochlea to restore normal hearing but requires prolonged period of aural rehabilitation that involves perceptual learning, adaptation, and readjustment of their attention. The various risk factors that affect the auditory gain and speech perception either acting singly or in combination and the statistical analysis of the present study showed are the age at implantation, duration of auditory deprivation, and the residual hearing which have a direct impact on the outcome over a period of 1 year.

Key words: Categories of auditory performance (CAP) test, Meaningful auditory integration scale (MAIS), Speech intelligibility Rating test (SIR)

INTRODUCTION

Speech perception has improved in children with pre-lingual sensorineural hearing loss (SNHL) after the cochlear implantation (CI) became the standard procedure for managing such cases. However, the post-CI rapidity of gain in hearing perception and speech development was varying in different groups of study and patients. Therefore, studies investigating the causes for slow in gain in auditory perception and speech development have become a necessity. Moreover, the development of approaches for doing so has become a principal focus in this field.[1] Among the various factors considered for gain in speech perception in children after CI, the important ones were demographic and hearing characteristics and the features of the implant

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device.[2] Identification of the factors contributing to poor speech perception after CI was necessary, and several studies have addressed this issue.[3,4] Pre-CI assessment of the responsible factors in each candidate will allow us to better predict outcomes after CI. Various retrospective multicenter studies are found in the literature that attempted to identify the prognostic factors using a three-stage model of auditory performance that assesses speech perception overtime.[5] However, these studies were based on models used for post-lingual deaf adults who underwent CI, hence, the age at the time of CI did not significantly affect post-CI outcomes,[6] whereas the studies conducted in children with pre-lingual SNHL showed that CI at earlier ages resulted in better speech perception than did CI at later ages.[7] In a study of children who underwent CI, pre- and post-implantation concerns were more evident in the poor speech perception group than the randomized good performance group.[8] Linguistic competence for complete speech perception was absent in most children with SNHL before and 1 year after CI.[9] As experience in listening using the cochlear implant increases, speech perception generally improves. Pediatric cochlear implant users in particular exhibit enhanced auditory performance for up to 10 years after CI.[8] Because improved speech perception overtime correlates with improved speech production and language, appropriate evaluation of speech perception in children after CI is important for optimal long-term post-CI performance.[10] A study done by Gupta[11] in 2007 found out that age at implantation, duration of auditory deprivation, and the pre-implant residual hearing affected the outcome of cochlear implantation in children below the age of 5 years. The children who had been fitted with HAs at a younger age and undergone longer duration of pre-implant therapy showed better outcome. Furthermore, children with good family support showed better results.

Aims and Objectives

The aims of the study were as follows:

- To assess the various pre-, peri-, and post-operative factors which are likely to affect the outcome of cochlear implant on a numerical scoring system and to evaluate the outcome using subjective criteria at predefined period after implantation.
- To statistically analyze the data using appropriate statistical tools to assess the predictive potential of the various factors alone or in combination.
- To develop a predictive model for outcome of CI in children aged 5 years and below.

MATERIALS AND METHODS

This study was conducted at Government Medical College, Kozhikode (GMC-KKD), from January 2014 to January 2015. The study group consisted of 60 patients screened from the patients who have attended auditory verbal habilitation (AVH) at GMC-KKD, Kozhikode, Kerala. An ethical committee clearance was obtained before commencement of the study. An ethical committee cleared consent form was use for the study. An ethical committee clearance was obtained.

Inclusion Criteria

1. Children with bilateral severe to profound sensorineural hearing loss were included in the study
2. Children aged <5 years were included in the study
3. Children with pre-lingual hearing impairment were included in the study
4. All the children who had undergone cochlear implantation from GMC-KKD, Kozhikode, under Sruthitharangam scheme, a government initiated free cochlear implant program in Kerala were included in the study.

Exclusion Criteria

1. Children above 5 years were not included in the study
2. Children who were not fitted with hearing aid (HA) and undergone auditory training before surgery were not included in the study
3. Children with associated mental retardation were not included in the study
4. Children with congenital cochlear abnormalities were not included in the study.

Evaluation Protocol

An ethical committee clearance certificate was obtained before the commencement of the study. An ethical committee cleared informed written consent was taken from the parents for the study. Speech perception was also assessed by Categories of Auditory Performance (CAP) test (Archbold, 1995) and Meaningful Auditory Integration Scale (MAIS) (Robbins *et al.*, 1991). Speech Intelligibility Rating test (SIR) (Robyn M. Cox, 1989) was also done. Counseling of parents was done regarding regular follow-ups and therapy/support to the child at home.

Outcome Measures

Post-operative follow-up of the subjects was carried out for 12 months after CI. During these visits, the outcome measures were carried out under: CAP, MAIS, and SIR scales.

Evaluation of factors

Factors were grouped into subject-related and parental factors.

Subject factors

Factors such as age of onset, duration of auditory deprivation, duration of use of HAs, and age at implantation was elicited.

Parental factors

Factors like family support were observed and necessary counseling was done.

OBSERVATIONS AND RESULTS

This study was conducted at GMC-KKD, Kozhikode, Kerala, from January 2014 to January 2015. The study group consisted of 60 patients screened from the patients who have attended AVH at GMC-KKD, Kozhikode, Kerala. The family support was categorized into three grades: Good, average, and poor. Kruskal–Wallis test was also undertaken which is a non-parametric test for comparing two or more groups to check relation between different family support groups and MAIS score, CAP score, and SIR score.

The null hypothesis H_0: Three groups were identical
Grouping variable
1=Poor,
2=Average,
3=Good.

In this study, statistical significance was considered when $P < 0.05$ was obtained. Here, $P = 0.001$ was obtained, which is <0.05. Hence, we reject the null hypothesis, that is, the three groups were considered not identical.

The error bar diagram shows high scores for MAIS in good family support group children [Figure 1]. Pearson correlation test and Spearman correlation test were done to check the correlation between age at which HL detected and MAIS score. The study showed the correlation between age and MAIS as negative. As the age at which HL was detected increases, MAIS score decreases. This underlines the importance of early identification of hearing impairment and further intervention programs. Pearson correlation test and Spearman correlation test were done to check the correlation between age at which HA was first fitted and MAIS scores. Correlation between the age at which HA first fitted and MAIS was negative. As the age at which HAs were fitted increases, the MAIS score decreases. This indicates the significance of using the residual hearing and stimulation of auditory nerve as early as possible. Pearson correlation and Spearman correlation tests were applied to check the correlation between the age of surgery and MAIS score and found that there was negative correlation existing between age of surgery and MAIS scores. This meant, as the age at which surgery was done increases, the MAIS score decreases. Pearson correlation test and Spearman correlation tests were applied to check the MAIS scores and duration of audiovisual training (AVT) with HAs. The tests showed positive correlation. The longer the duration of AVT with HAs before cochlear implant (CI), the better was the outcome after CI. Pearson correlation test and Spearman correlation test were applied to check the correlation between age at which HL detected and CAP scores, which showed negative correlation. That meant earlier the detection of hearing impairment; the better was the CAP scores. Pearson correlation test and Spearman correlation test were applied to check the correlation between ages at which HA first fitted and CAP scores, which showed negative correlation. It confirms that earlier the stimulation of auditory nerve starts, better the CAP scores after CI. Pearson correlation test and Spearman correlation test were applied to check the correlation between age of surgery and CAP scores, which showed negative correlation. That meant children who had undergone CI at a younger age showed higher CAP scores [Figure 2].

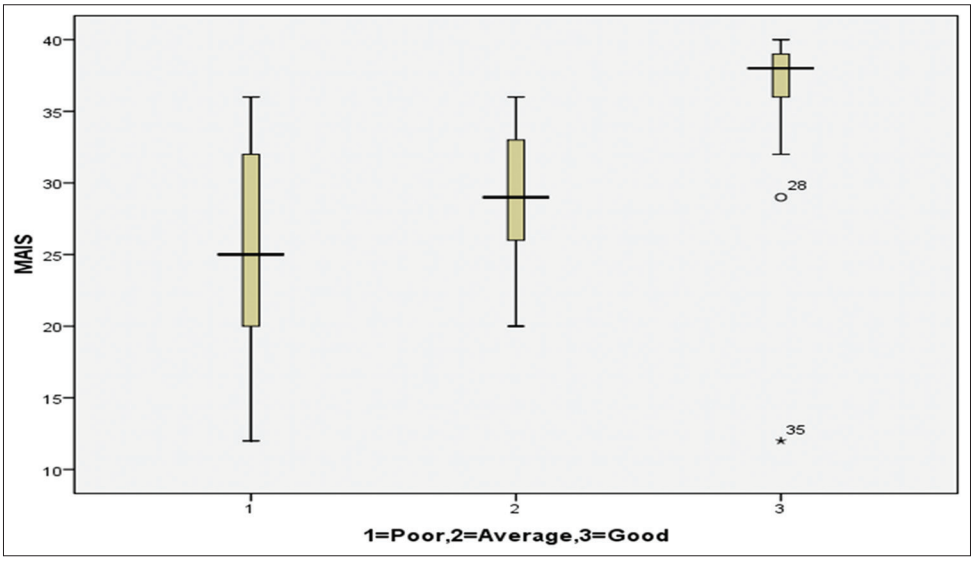

Figure 1: The error bar diagram of meaningful auditory integration scale score with family support groups

As the age at the time of surgery increases, the mean CAP score decreases. Positive correlation exists between the duration of AVT with HAs and CAP scores as per Pearson test and Spearman correlation test. Longer the duration of AVT with HAs, better the CAP scores after CI. Pearson correlation and Spearman correlation tests were applied to check the correlation between SIR scores and age at which HL detected which showed negative correlation. This means that as the age at which the hearing impairment detected increases, the SIR score decreases after CI surgery. Pearson correlation test and Spearman correlation tests were administered to check the correlation between SIR scores and age at which HA first fitted which again showed negative correlation. The children who were fitted with HA at younger age showed better SIR score after CI. Pearson correlation test and Spearman correlation tests were administered to check the correlation between SIR scores and age of surgery which again showed negative correlation. The children who had undergone CI at a younger age showed better SIR score after CI. After applying Pearson and Spearman correlation tests, it was found to have a positive correlation between SIR scores and duration of AVT with HA. Longer the duration of AVT with HA before CI, better the SIR score after CI. Multiple linear regressions were done to get a predictive model for predicting the scores of MAIS, CAP, and SIR [Table 1].

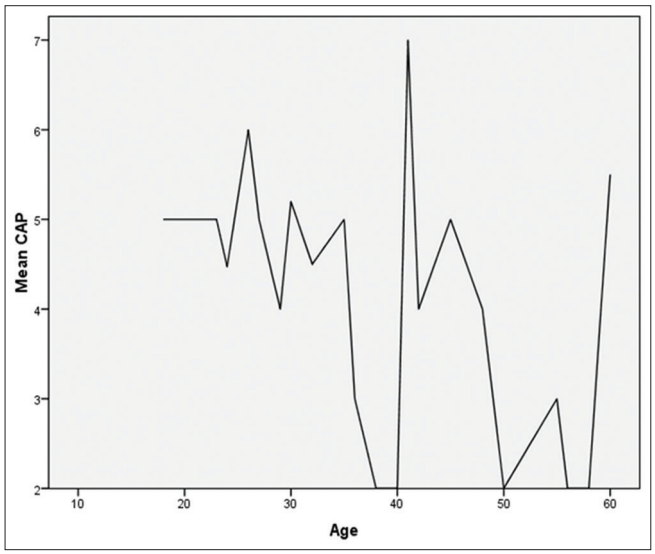

Figure 2: The correlation graph showing negative correlation between mean CAP scores and age at the time of surgery

Table 1: The different variables in the multiple linear regression model

Variable 1	Age at which HL detected (months)
Variable 2	Age of bilateral HA fitted (months)
Variable 3	Duration of AVT with HA (months)
Variable 4	Age of CI surgery (months)

Multiple linear regression models for MAIS.

MAIS = 39.518–0.085 (VAR1)–0.078 (VAR2)+0.338 (VAR3)–0.301(VAR4)

CAP = 5.106–0.000 (VAR1)–0.008 (VAR2)+0.055 (VAR3)–0.038 (VAR4)

SIR = 3.440–0.022 (VAR1)–0.017 (VAR2)+0.051 (VAR3)–0.039 (VAR4)

DISCUSSION

The present study was conducted to not only to observe the efficacy of the CI but also to predict the post-implantation results by scrutinizing the different risk factors involved. Most of the literature of clinical research on CIs since 25–30 was concerned with device efficacy. They have worked to prove and designed to demonstrate that CIs work in individuals or samples of patients with severe-to-profound hearing loss. However, very little sustained longitudinal research was focused on the reasoning as to why they often work very well in some patients, sometimes work more poorly or not at all in other patients of the same age, gender, demographics, and medical hearing history.[12] Only recently, the "process" measures of performance were obtained from patients with CIs to study the underlying elementary information processing mechanisms used to perceive and produce spoken language in this clinical situations.[13] The children who were diagnosed with hearing impairment at a younger age also showed good family support. The same category also had undergone regular pre implant therapy. This shows the significance of newborn hearing program and counseling regarding the rehabilitation options. Community awareness programs regarding hearing impairment and different intervention programs should also be conducted more effectively. The present study was in concert with the study conducted by Tomblin *et a*l. (2005)[14] who concluded that cochlear implantation early in the 2nd year of life was likely results in an early burst of language growth. Tomblin reports that this rapid rate of initial language growth is a phenomenon that was not evident in the language scores of children implanted after the age of about 18 months, a finding confirmed by these data. Whereas Nicholas and Geers (2004)[15] reported from his study that only 43% of a nation-wide sample of 8–9-year-old deaf children who received a cochlear implant between 24 and 35 months of age achieved combined speech and language skills within the average range for hearing children of that chronological age.

Results of the current study indicate that children who receive a cochlear implant and oral education before 24 months developed speech and hearing much better than other children. In sum, the total amount of language produced, the breadth of vocabulary, complexity of sentences, and use of varied morphology seem to be directly affected by both the amount of hearing available to the child before the implant as well as the age at which the cochlear implant surgery was performed. We should also promote research work to look into the reasons for auditory deprivation even after diagnosis of hearing impairment. The children who had been fitted with HAs at a younger age and undergone longer duration of pre-implant therapy showed better outcome. Furthermore, children with good family support showed better results. This was supported by a study which revealed that three variables, namely, age at implantation, duration of auditory deprivation, and the residual hearing had a direct impact on the outcome over a period of 1 year (Gupta, 2007).[11] Patients performed significantly better as length of cochlear implant use increased and age at implantation decreased (Kileny *et al*., 2001).[13] In a previous work by Nicholas and Geers, 2006,[15] who have shown that the age at diagnosis of the hearing loss and the length of time that a HA was used were not significant predictors of later spoken language outcomes, unless the child received a cochlear implant within this training time period. These results favor early diagnosis of profound hearing loss, early initiation of a HA trial, and cochlear implantation by 18 months of age, especially for children with better ear aided pure tone average thresholds greater than 65 dB. We should also promote research work to look into the reasons for auditory deprivation even after diagnosis of hearing impairment. The children who had been fitted with HAs at a younger age and undergone longer duration of pre-implant therapy showed better outcome. Furthermore, children with good family support showed better results. This was supported by a study which revealed that three variables, namely, age at implantation, duration of auditory deprivation, and the residual hearing had a direct impact on the outcome over a period of 1 year (Gupta, 2007).[11] Patients performed significantly better as length of cochlear implant use increased and age at implantation decreased (Kileny *et al*., 2001).[13] We, as professionals, should implement newborn hearing screening effectively and should also take necessary steps for proper rehabilitation program soon after the detection of hearing impairment. Community awareness programs regarding hearing impairment and the intervention options should also be conducted periodically.

CONCLUSIONS

A cochlear implant was not a passive sensory aid or sensory substitution device that simply replaces a damaged or defective cochlea to restore normal hearing but requires prolonged period of aural rehabilitation that involves perceptual learning, adaptation, and readjustment of their attention. The various liability factors that determine the auditory gain and speech perception either acting singly or in combination and the statistical analysis of the present study showed are, the age at implantation, duration of auditory deprivation, and the residual hearing have a direct impact on the outcome over a period of 1 year. These results confirm previous findings indicating continued improvement of speech recognition with time in implanted children. Furthermore, the results support the concept of the advantage of a younger age at implantation.

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Original Article

Hearing Loss in Thalassemic Children on Chelation Therapy

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Abstract

Background: Thalassemia is a common genetic hematological disorder worldwide. It is also common in North India including Jammu region. These patients need lifelong repeated blood transfusions and iron chelation therapy for their survival. Chelation therapy is known to be associated with various complications including sensorineural hearing loss (SNHL). Till now, no data are available regarding SNHL in pediatric thalassemia major patients in Jammu region. Hence, we planned a study to assess the prevalence of hearing loss in children with thalassemia major in the age group of 10–20 years.

Methods: All the children with beta-thalassemia major in the age group of 10–20 years registered with Thalassemia Day Care Center, Department of Pediatrics, SMGS Hospital, Government Medical College, Jammu, were enrolled in this cross-sectional study. Hearing was assessed by pure tone audiometry. Clinical and demographic data of these patients were recorded on pretested pro forma and analyzed.

Results: A total number of 34 children with thalassemia in the age group of 10–20 years were enrolled in this study which comprised 18 males and 16 females. Out of these 34 patients, 5 (14.7%) were found to have SNHL and 1 (2.9%) had conductive hearing loss. Four of the five patients in SNHL group had low- as well as high-frequency mild hearing loss (25–40 db) while one patient had high-frequency mild hearing loss at 4000 HZ. Four out of these five patients had unilateral hearing loss on the left side while one had bilateral SNHL. Two out of five patients in the SNHL group were taking chelation therapy in the form of combination of deferiprone and deferasirox at the dose of 75–100 mg/kg/day and 30–40 mg/kg/day, respectively, for more than 5 years. The other three patients were taking only deferasirox at the dose of 30–40 mg/kg/day for more than 5 years.

Conclusions: Regular blood transfusions and chelation therapy are essential for long-term survival of thalassemia major patients but are also associated with complications like SNHL.

Key words: Blood transfusion, Iron chelation, Sensorineural hearing loss, Thalassemia

INTRODUCTION

Thalassemia is a common hematological disorder resulting into chronic anemia. It was first described by Cooley in 1925 and the first case of β-thalassemia in India was reported by Dr. Mukherjee from Calcutta in 1938.[1] The frequency of thalassemia trait in India is around 3.5–15% and every year more than 10,000 affected children are born in India.[2] Thalassemia is a hemoglobinopathy which is characterized by reduction or absence of β-globin chain production due to mutation in gene encoded for the same on the short arm of chromosome 11p.[3] In β-thalassemia, β-chain synthesis is decreased, so excessive α-chains precipitate in red blood cells membrane and damage it leading to hemolysis both in bone marrow and peripheral circulation mainly in spleen.

Beta-thalassemia major presents in early infancy (6–18 months) as hemoglobin levels decline with progressive pallor, splenohepatomegaly, and boney changes. These patients require lifelong regular blood transfusion

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which leads to iron overload. Other mechanisms causing iron overload in thalassemic patients are increased absorption from intestines to provide adequate iron to accelerated erythropoiesis although ineffective as seen in poorly transfused thalassemia major patients or those with thalassemia intermedia.[4] Now, as iron overload occurs, transfusion and other iron-binding proteins get progressively saturated and free iron radicals are generated that cause damage to vital organs such as liver, heart, and endocrine organs resulting in liver fibrosis and eventually cirrhosis, cardiac siderosis which causes acute cardiac death with arrhythmia or intractable cardiac failure and endocrine disturbances such as diabetes mellitus, hypogonadism, growth hormone deficiency hypothyroidism, and adrenal insufficiency.[5] Hence, thalassemic patients require iron chelation therapy to remove excess iron from body. Iron chelation is indicated when serum ferritin levels increase to more than 1000 ng/ml. Desferrioxamine (DFO) is the gold standard iron chelator. It usually reverses functional complications due to iron overload such as liver fibrosis and arrhythmia, but the complication due to extensive tissue damage such as diabetes, hypothyroidism, and myocardial sclerosis cannot be reversed. It has disadvantages like poor bioavailability and can be administered only by parenteral route. It is also known to cause retinal and optic dysfunction and high-frequency hearing loss.[6]

Deferiprone is an oral iron chelator. It chelates cardiac iron better than DFO but is less efficacious for hepatic iron. Its side effects are arthropathy, agranulocytosis elevation of hepatic enzymes, and adverse redistribution of iron. Deferasirox has good bioavailability and a long half-life so used as once daily dose. Its side effects include renal toxicity, gastrointestinal disturbance, rash, and elevation of hepatic enzymes. It has been reported that these agents when used in high doses for long duration in patients with high ferritin can lead to auditory disturbances, although reversible on early cessation of offending chelating agent.[7]

Therefore, we planned a study in the Department of Pediatrics in collaboration with the Department of ENT, Head and Neck Surgery, SMGS Hospital, Government Medical College, Jammu, to assess the hearing status of all the thalassemic patients in the age group of 10–19 years registered with Thalassemia Day Care Center, SMGS Hospital , Jammu.

METHODS

All of the children with beta-thalassemia in the age group of 10–20 years registered with Thalassemia Day Care Center, Department of Pediatrics, SMGS Hospital, Jammu, were enrolled in this cross-sectional study after obtaining written informed consent from the subjects and clearance from the Institutional Ethical Committee, Government Medical College, Jammu. Hearing was assessed by pure tone audiometry (PTA) with pure tone air and bone conduction thresholds at the frequency of 250–4000 HZ in the Department of ENT, Head and Neck Surgery, SMGS Hospital, Government Medical College, Jammu. Clinical and demographic data of these patients were recorded in pretested pro forma and analyzed which included age, gender, hearing status, average hemoglobin, and average serum ferritin levels over last 1 year and chelating agent and its dose and duration. Hemoglobin estimation was done by automated analyzer, whereas quantitative estimation of serum ferritin was done by chemiluminescence microparticle immunoassay.

Statistical Analysis

Descriptive statistics were used to describe baseline variables. Numerical variables were fisted tested for normality using Kolmogorov–Smirnov test for normality. Normal distributed independent variable was compared by Student's t-test after evaluating equality of variance by Levene's test, whereas nonparametric test (Mann–Whitney U) was used for variable with a skewed distribution.

RESULTS

A total number of 34 children with thalassemia in the age group of 10–20 years were enrolled in this study which comprised 18 males and 16 females.

Out of these 34 patients, 5 (14.7%) were found to have sensorineural hearing loss (SNHL) and 1 (2.9%) had conductive hearing loss (CHL). Four out of the five patients in the SNHL group had low- as well as high-frequency mild hearing loss (25–40 db) while one patient had high-frequency mild hearing loss at 4000 HZ. Four out of these five patients with SNHL had unilateral hearing loss on the left side while one had bilateral SNHL. One patient with CHL had unilateral hearing loss in the left ear at all frequencies.

Average hemoglobin was observed to be 7.5 g%, 8.5 g%, and 8.3 g% in the SNHL group, CHL group, and normal hearing group, respectively [Figure 1]. Patients in the SNHL group received on an average 315 blood transfusions while the patients with normal hearing received an average of 285 blood transfusions. Patients in the SNHL group had an average serum ferritin of 6015.20 ng/ml while patients without any hearing loss had average serum ferritin of 4179.79 ng/ml with no statistically significant difference ($P = 0.13$) [Table 1]. Two out of five patients in the SNHL group were taking chelation therapy in the form

of combination of deferiprone and deferasirox at the dose of 75–100 mg/kg/day and 30–40 mg/kg/day, respectively, for more than 5 years. The other three patients were taking only deferasirox at the dose of 30–40 mg/kg/day for more than 5 years [Table 2].

DISCUSSION

Of the 34 patients with beta-thalassemia major in the age group of 10–20 years, five were found to be having SNHL which gave the prevalence of 14.7% which is relatively lower as compared to the findings made by other studies such as Kong *et al.*[8] reported 57.4% and Khan *et al.*[9] 45.45%. Relatively lower prevalence in our study may be due to the fact that none of these patients were on DFO which is known to cause ototoxicity and small cohort size in our study. Tanphaichitr *et al.* also in their study observed that there was a low incidence of ototoxicity in beta-thalassemia patients after exposure to iron chelators. Out of 100 enrolled thalassemia patients on iron chelation therapy with single deferasirox, deferiprone, DFO, or combination, they detected SNHL in seven cases, but only four were found to be associated with iron chelation.[10]

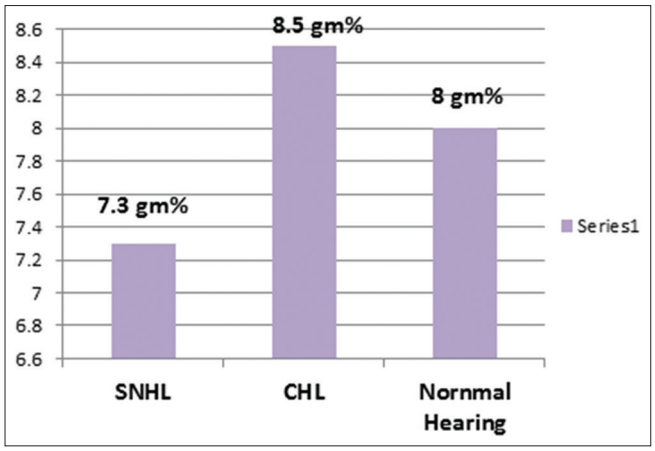

Figure 1: Average hemoglobin levels

Table 1: Average serum ferritin levels

Group	Mean±(SD) serum ferritin levels (in ng/ml)
Sensorineural hearing loss	6015.20 (1526.10)
Normal hearing	4179.79 (2546.70)

P=0.13, SD: Standard deviation

Table 2: Correlation between hearing loss and iron chelation drug

Hearing status	Deferasirox	Deferiprone+Deferasirox
Sensorineural hearing loss	3	2
Conductive hearing loss	0	1
Normal hearing	24	4

No significant difference in average serum ferritin levels ($P < 0.05$ was taken as significant) was observed among patients with and without SNHL. However, Porter *et al.* in their study reported a protective effect of iron overload against ototoxicity in patients with thalassemia major on DFO as chelation therapy.[11]

We observed that all the five patients with SNHL were on deferasirox as chelation therapy for more than 5 years. Two of them were also taking deferiprone in addition to deferasirox. Khan *et al.* in their study reported a prominent relationship between the chelating agents and SNHL. In their study, it was observed that out of a total of 198 cases in the age group of 60–300 months, 98 (45.45%) cases had SNHL. They reported that chances of SNHL increase with longer duration of deferasirox usage.[9] Yadav *et al.* in their study reported that usage of DFO for longer duration and in higher doses was associated with increased incidence of SNHL in patients with beta-thalassemia major.[12] Similarly, Kong *et al.* in their study observed that out of 54 enrolled beta-thalassemia major cases, 31 (57.4%) showed hearing loss. They reported a significant positive correlation between average daily DFO dose and hearing loss in the left ear in the range of 2000 Hz and 4000 Hz.[8] In our study, we observed that out of five cases with SNHL, four had hearing loss on the left side and the remaining one had bilateral hearing loss.

None of the five patients with SNHL in the study complained of any difficulty in hearing or tinnitus and it was only on PTA that hearing loss was diagnosed. Hence, all thalassemic major patients while on chelation therapy should be assessed for hearing status on regular basis so that even mild SNHL could be picked up early and enabling the early intervention in the form of titrating the dose of chelating agent or switching to alternative agent.

One patient who had CHL was found to be having secretary otitis media on otoscopy which was an incidental finding.

CONCLUSIONS

Regular blood transfusion and iron chelation therapy are the key elements in the management of thalassemia major patients. In this study, it was observed that patients on deferasirox as chelation agent can also develop SNHL , hence need regular auditory assessment. A larger study is recommended to ascertain these observations.

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Original Article

Orodental Changes Associated with Hepatic Disorders and it's Clinicopathological Implications

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Abstract

Background: Hepatic complex can be vulnerable to numerous diseases ascribed to the intake of few drugs, alcohol, or infections which manifests itself in oral cavity.

Materials and Methods: The patients diagnosed as acute or chronic liver disease by clinical examination, liver function tests, and morphological examination which was selected. Detailed dental and oral examination was done and manifestations such as the presence of gingival bleeding, oral lichen planus, xerostomia, sialadenitis, stomatitis, periodontal disease, and others were noted. The data were then subjected to statistical analysis.

Results: Jaundice due to viral hepatitis (44.7%), alcoholic liver diseases (28%), alcoholic cirrhosis (18.7%), cirrhosis of liver (16%), hepatomegaly (14.7%), hepatic carcinoma (7.3%), and hepatitis B (6%) were the various liver disorders encountered. On oral examination, a significantly higher number of study subjects were detected with one or more oral abnormalities when compared to subjects ($P \leq 0.05$). Oral manifestations include periodontitis, halitosis, xerostomia, bald tongue, fissured tongue, hyperpigmentation, candidiasis, and oral lichen planus.

Conclusion: The complex mechanism of liver and its susceptibility to a variety of dysfunction can not only have systemic but also many oral manifestations.

Key words: Hepatic disorders, Liver diseases, Orodental manifestations

INTRODUCTION

Oral cavity is the gateway to diagnosis of many systemic disorders.[1] It has a role in many physiologic processes among which digestion is an important complex process. Liver is the largest internal organ which serves in bile production, excretion of bilirubin, cholesterol, hormones, drugs, metabolism of fats, proteins, carbohydrates, and enzyme activation.[2] Thus, the liver diseases cause systemic disturbances which manifest itself in oral cavity.

The most common systemic disorders are associated with liver diseases. These can be acute or chronic depending on the onset, deranged function, and extent of organ damage. Infectious diseases of liver include hepatitis A, B, C, D, and E. The non-infectious may range from steatosis or fatty liver to hepatocellular carcinoma, including hepatitis, fibrosis, and cirrhosis of liver. This may be due to substance abuse such as alcohol and drugs, for example, paracetamol, ketoconazole, methotrexate, etc. Liver dysfunction includes change in metabolism of carbohydrates, fats, lipids, proteins, bilirubin, and hormones.[3] Evidence of these disorders can be appreciated in the oral cavity which includes gingival bleeding, ecchymosis, hematoma, delayed mucosal healing, and lichen planus.[4] The early findings in hepatitis B and C are infection of the periodontium and compromised oral hygiene. In patients with chronic hepatitis C virus (HCV) liver disease, the common oral manifestations are xerostomia, Sjogren's syndrome, lichen planus, sialadenitis, and oral malignancies.[5-7] A mandibular swelling can be an initial manifestation in metastatic hepatocellular carcinoma.[8] This study aims to evaluate the orodental manifestations in the various infectious, non-infectious, and acute and chronic liver diseases.

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MATERIALS AND METHODS

This cross-sectional study comprised 200 individuals including 150 diagnosed cases of various liver diseases and 50 healthy age- and sex-matched individuals who were randomly selected as control group. The patients diagnosed as acute or chronic liver disease by clinical examination, liver function tests, and morphological examination which was selected from the outpatient and inpatient Department of Hepatology, Sri Ram Chandra Bhanja (SCB) Medical College and Hospital, Cuttack, Odisha. Demographic data as well as details such as liver function test which includes serum glutamic oxaloacetic transaminase (SGOT), serum glutamic pyruvic transaminase (SGPT), serum albumin, serum bilirubin, and alkaline phosphatase were recorded. These patients were subjected to detailed dental and oral examination and manifestations such as the presence of gingival bleeding, oral lichen planus, xerostomia, sialadenitis, stomatitis, periodontal disease, and others were noted. Patients diagnosed with acute or chronic liver disease and without other systemic conditions such as diabetes mellitus and hypertension were included in the study. Individuals with other systemic diseases such as cardiac failure, on diuretic therapy, chronic kidney disease, on drugs which alter renal profile and electrolytes, patients undergoing hemodialysis and peritoneal dialysis, recent trauma, surgery, and burns were excluded from the study. This study was approved by the Institutional Ethics Committee, S.C.B Dental College and Hospital, Cuttack, Odisha, and informed consent was obtained from the participants participating in the study.

The data collected were subjected to statistical analysis by Statistical Package for the Social Sciences software, version 22.0. Chi-square test was applied and $P \leq 0.05$ was considered statistically significant.

RESULTS

A total of 200 subjects comprising of both the genders were observed in the present study of which 136 were male and 64 were female, that is, 68% and 32%, respectively. The age of the patients ranged from 24 to 82 years. Jaundice due to viral hepatitis (44.7%), alcoholic liver diseases (28%), alcoholic cirrhosis (18.7%), cirrhosis of liver (16%), hepatomegaly (14.7%), hepatic carcinoma (7.3%), and hepatitis B (6%) were the various liver disorders encountered [Figure 1]. On oral examination, a significantly higher number, that is, 126 among 150 study subjects were detected with one or more oral abnormalities when compared to 19 among 50 control subjects ($P \leq 0.05$). The oral lesions which were detected are charted in percentage in Figure 2. They include periodontitis, halitosis, xerostomia, bald tongue, fissured tongue, hyperpigmentation, candidiasis, and oral lichen planus [Table 1].

DISCUSSION

Chronic alcohol abuse causes extensive damage to the liver which, in turn, manifests as acute and chronic systemic

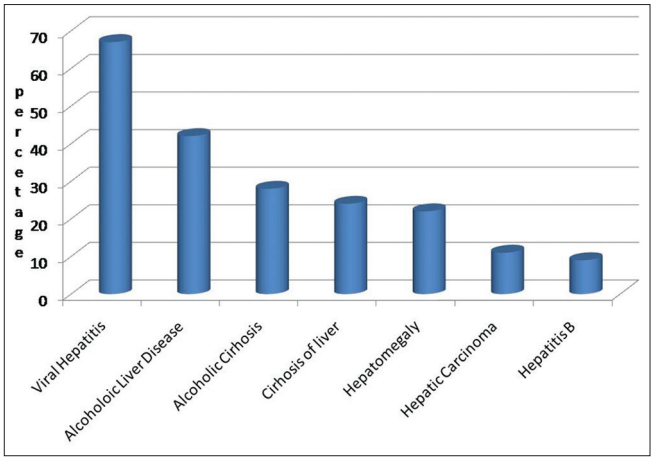

Figure 1: The various hepatic diseases encountered

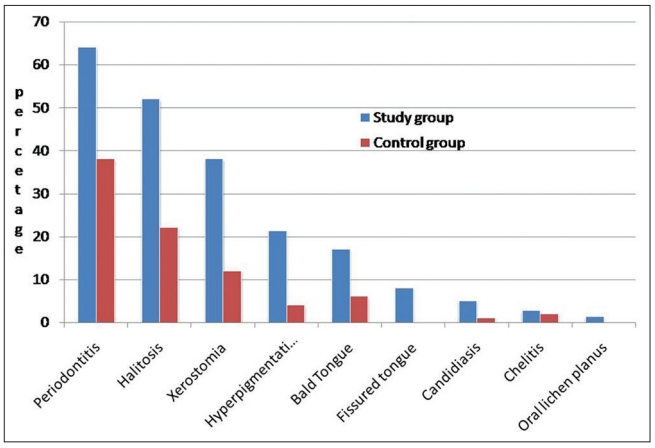

Figure 2: The various orodental manifestations found in the hepatic disorders

Table 1: Orodental manifestations associated with liver disorders

Oro-dental manifestations	Study group (*n*=150) (%)	Control group (*n*=50) (%)	Significance
Periodontitis	96 (64)	16 (38)	$P \leq 0.05$
Halitosis	78 (52)	11(22)	
Xerostomia	57 (38)	6 (12)	
Hyperpigmentation	32 (21.3)	2 (4)	
Bald tongue	26 (17.3)	3 (6)	
Fissured tongue	12 (8)	0	
Candidiasis	7 (5.3)	1 (2)	
Cheilitis	3 (2.7)	1 (2)	
Oral lichen planus	2 (1.3)	0	

dysfunction. This systemic dysfunction causes wide range of oral changes which in the current study we have attempted to bring to light.

A significantly higher incidence of periodontitis (65%) was observed in patients with liver diseases than the healthy individuals in our study. Paraschiv *et al*.[9] in his study among 150 patients of hepatitis B found 46.7% of patients suffering with periodontitis. According to a systematic review on periodontal disease and liver cirrhosis, the prevalence of periodontal disease in cirrhosis patients ranged from 25.0% to 68.75%.[10] Novacek *et al*.[11] observed a significant increase in loss of attachment in their study on patients with alcoholic cirrhosis due to poor dental care and alcohol abuse. Movin *et al*. in his study suggested that periodontal condition aggravates as the cirrhotic condition aggravates due to increasing negligence in oral hygiene.[12] Han *et al*. hypothesized that periodontitis might have an important role in the progression of liver disease in non-alcoholic liver diseases.[13]

Halitosis due to severe liver disease, also known as "Foetor hepaticus," is caused by excretion of dimethyl disulfide and methyl mercaptan arising from an excess of methionine. This results in a sweet and musty smell both on the breath and in urine.[14] Patients with viral hepatitis have an elevated level of dimethyl sulfide.[15] A significant number of patients (38.7%) had bad breath when compared with healthy individuals in our study.

Chronic alcoholics can develop sialadenosis which can be a result of ethanol-induced peripheral autonomic neuropathy giving rise to alterations in salivary metabolism and secretion.[16] In the present study, 38% of the study group presented with xerostomia in contrast to 12% of the control group. Guggenheimer *et al*.[17] reported clinical hyposalivation 28.7% of all patients and 70% of those who were on diuretic therapy. Many researchers also observed xerostomia among 5–55% of HCV-infected patients.[18-23]

About 21% of cases presented with hyperpigmentation in contrast with a lower percentage of case in a study by Sulka *et al*.[24] This finding might be secondary to drugs used for the treatment as stated by Tsilika *et al*.[23] and Erdoğan *et al*.[25]

In our study, about 3% of the study group showed angular cheilitis which was in consonance with the study by Guggenheimer *et al*.[17] who reported a prevalence of 4% in liver transplant cases. They also reported predominance of fissured tongue (37%) and atrophy of the papillae of the tongue (18%) in their study. Reports suggest that fissured tongue, atrophy of tongue papillae, and angular cheilitis can be observed in liver transplant patients which can be because of drug induced hyposalivation.[17,25] Patients with alcoholic liver disease can manifest with glossitis, angular cheilitis, and gingivitis, frequently along with nutritional deficiencies.[26]

Oral candidiasis is an opportunistic fungal infection caused mainly by *Candida albicans* primarily attributed to the immunocompromised conditions such as diabetes mellitus or in denture wearers. Paraschiv *et al*.[9] in their study on 380 patients with hepatitis B and C in association with diabetes mellitus, 14% presented with oral candidiasis. In the present study, we found significantly decrease prevalence of oral candidiasis (5.3%) which may be attributed to the fact that none of the cases had undergone liver transplantation and immunosuppression therapy.

A number of different liver pathologies have been found to be associated with lichen planus which is a chronic inflammatory disease affecting skin and mucous membrane.[27] In our study, we observed 3 patients (1.3%) with oral lichen planus without skin manifestations which was in accordance with the study by Paraschiv *et al*.[9] They also found three patients with both mucosal and cutaneous lesion among the 230 cases of viral hepatitis (hepatitis C) which were seen in patients over 60 years of age. A significantly higher percentage of 5.1% was observed by Friedrich *et al*.[28] among 156 patients and 4.7% among 126 patients by Figueiredo *et al*.[29] Gandolfo *et al*.[30] found 24% of hepatopathies among 96 OLP cases and 60% without definite liver disorders but having least one abnormal liver parameter. They concluded a frequent association of OLP with hepatic damage and OLP might be an important clinical sign of symptomless hepatopathies.

CONCLUSION

The complex mechanism of liver and its susceptibility to a variety of dysfunction can not only have systemic but also many oral manifestations. An extensive liver damage can cause destruction of liver cells causing hepatitis, cirrhosis. Hepatic carcinoma is considered to be one of the most common cancers in global population today. The causes for such damage vary from intake of alcohols, drugs, and viral infestation. The changes manifested in the oral cavity, thus help the clinicians to have a hint at a systemic disorder.

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