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Radiographic Measurements of Inferior Alveolar Nerve Anterior Loop, Mandibular Interforamen and Interloop for Implant Placement among Saudi Population of Aseer Province

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Abstract

Introduction: The anatomical variation of inferior alveolar nerve anterior loop (IANAL) is benign, but an accurate identification and measurement of anterior loop length is essential for surgical planning in this region.

Purpose: The purpose of this study was to assess the occurrence and extent of IANAL and also to determine mandibular interforamen and interloop measurements for implant placement in Saudi population of Aseer province.

Materials and Methods: The panoramic radiographs were retrospectively accessed for a period of 1 year before start of the study from the patient database system. The presence of IANAL was identified by carefully observing the course of mandibular canal and reverse looping upward and backward. The length of IANAL and interforamen and interloop distances was measured using digital ruler.

Results: Among a total of 236 radiographs, IANAL was visualized in 54 (22.9%) subjects, of which 33 (61%) were males and 21 (39%) females. The length of IANAL was significantly greater in males than females ($P = 0.000$). There was no statistically significant difference found in interloop distance between males and females ($P = 0.361$). The interforamen distance was significantly greater in males than females ($P = 0.000$).

Conclusions: The occurrence of IANAL was found to be 22.9%. The males had greater occurrence of IANAL than females. Interforamen distance was significantly greater in males than females. Author recommends a distance of around 5 mm from the most anterior point of mental foramen could be considered safe for placing implants among Saudi population of Aseer province.

Key words: Anatomic variations, Implant dentistry, Panoramic radiographs

INTRODUCTION

The inferior alveolar nerve is a branch of the mandibular nerve, which, in turn, is a branch of trigeminal the fifth cranial nerve. After once, it enters the mandibular foramen branches out to give sensory innervation to mandibular teeth (molars and second premolars) eventually these form into the inferior alveolar plexus and give off small gingival branches. The course of the nerve continues anteriorly to give off the mental nerve branch at about the level of the mandibular second premolars, which exits the mandible through the mental foramen and branches out to give sensory innervation to the chin and lower lip. Sometimes, the inferior alveolar nerve might continue and extends beyond the mental foramen in an anterior and inferior direction, curving back to the foramen and forming a loop, which has been termed as “anterior loop of the inferior alveolar/mental nerve.”[2,10] While some investigators have evaluated the diameter of anterior loop and the incisive canal to differentiate between these two structures with consideration of minimum 3 mm indicates the presence of inferior alveolar nerve anterior loop (IANAL).[24,11]
Although the anatomical variation of IANAL is benign, an accurate identification and measurement of anterior loop length is essential for surgical planning in this region. Recent advancements in dental implants have shifted focus on the characteristics of bone recipient area. A careful diagnosis of IANAL not only helps to prevent iatrogenic complications but also ensures an effective and uneventful surgical procedures. The literature is also inundated with case reports on implant failure and complications owing to improper assessment of the vital structures in interforaminal region during or after surgical intervention.

The prevalence of IANAL has found to be highly variable ranging from 22% to 94%. Some variations in the prevalence of IANAL also exist between different population and ethnic groups. The interforamen and interloop distances are other important spaces for strategic planning of dental implants placement. Understanding the prevalence of IANAL and other traits such as interforamen and interloop distances in a specific population group gives background information to the operating surgeon which are critical during surgical interventions. To the best of our knowledge, there are no studies on the prevalence of IANAL among Saudi population. Hence, the aim of this study was to assess the prevalence and extents of IANAL and also to determine mandibular interforamen and interloop measurements for placement of implants in Saudi population of Aseer province.

MATERIALS AND METHODS

The present study follows a retrospective observation of panoramic radiographs at College of Dentistry, King Khalid University, Saudi Arabia. Ethical clearance was obtained from Scientific Research Committee at the institution (Approval No: SRC/ETH/2016-17/023).

Data Collection

The panoramic radiographs were retrospectively accessed for a period of 1 year before start of the study (January 2016–December 2016) from the patient database system. The patient's personal information was deidentified. Further, the radiographs were selected by the following inclusion criteria: Completely edentulous patients, images free from any evidence of fracture or with impacted/supernumerary teeth, or bone disease that could occult the appearance of the anterior loop of the mental foramen, images with no positioning errors, and images free from the presence of implants or metal artifacts in the interforamen region.

The images were acquired using CLINVIEW™ software utilizing the industry-standard DICOM format (Instrumentarium Dental, USA). The density and contrast of the images were adjusted at a fixed value to standardize the radiographic interpretation. All the radiographs were interpreted by a single investigator. The prevalence of IANAL was identified by carefully observing the course of mandibular canal and reverse looping upward and backward. The length of IANAL was measured by digital ruler measuring distances between the two points: Most anterior point of mental foramen to most anterior point of anterior loop [Figure 1]. Similarly, interloop and interforamen distances were estimated on each side by measuring the distances between the most anterior point of mental foramen and the most anterior point of anterior loop, respectively.

Statistical Analysis

The information collected was entered into the computer (MS-Excel Sheet) and analyzed using SPSS, Version 20. The results were obtained for descriptive statistics and inferential statistics using unpaired Student’s t-test. The alpha (α) was set at 0.05.

RESULTS

A total of 236 panoramic radiographs fulfilled the inclusion criteria among whom 118 (50%) were male and 118 (50%) were female, with age ranging between 50 and 77 years. The IANAL was visualized in 54 (22.9%) radiographs [Table 1 and Graph 1]. Among the total 54 radiographs, 33 (61%) were males and 21 (39%) females.

The average loop length was found to be 4.3 ± 0.4 mm with a range from 2.2 to 6.5 mm. The length of IANAL was significantly greater in males than females (P = 0.000). There was no statistically significant difference in length of IANAL between right and left sides (P = 0.420) [Table 2].
The average interloop distance was found to be 42.5 ± 1.7 mm with a range from 38.8 to 48.8 mm. There was no statistically significant difference found in interloop distance between males and females (P = 0.361). The average interforamen distance was found to be 51.3 ± 1.7 mm with a range from 47.7 to 56.5 mm. The interforamen distance was significantly greater in males than females (P = 0.000) [Table 3].

**DISCUSSION**

In the last two decades, implant therapy has seen significant progress in various aspects of imaging modalities for diagnostic purposes. Bone being the crux of implant placement has obviously received lot of attention. Due to the presence of anatomical variations like IANAL in mandibular anterior region, it is very much indicated to incorporate various imaging modalities in diagnostic procedures before proceeding with implant surgeries.

In the present study, the prevalence of IANAL was found to be 22.9% which is comparable to studies conducted elsewhere.[6,7,17] Few studies, like the one conducted by Jalili et al. and Neiva et al., have shown a very high prevalence of 88% and 94%, respectively.[14,15] The variation in IANAL could be attributed to different assessment techniques used for identifying IANAL. Previous research has used radiographic assessment techniques such as conventional panoramic radiographs and cone beam computed tomography (CBCT) while some have used direct anatomical assessments on skulls.[2,6,15] Our study used panoramic radiographic imaging techniques since the same is most commonly used method in general dental practice. Although the exact course of IANAL could only be explored through CBCT imaging, the mere presence and length of IANAL could be easily determined by a panoramic radiograph.

The criteria set for defining the IANAL could also have resulted in high variation in its prevalence reported till date. The anterior limit of mandibular canal was identified using anatomical planes by some investigators,[3,9,10,17] whereas others have evaluated the diameters of anterior loop and incisive canal to differentiate between these two structures.[2,4,11] In our study, the presence of IANAL was based on measurements between anterior most point of mental foramen to anterior most point of the canal loop irrespective of its length. In one particular study, the authors discarded loops smaller than 2 mm in length as they considered them clinically insignificant.[7] However, in our study, the minimum loop length was found to be 2.2 mm which indicates the clinical implications among our study population.

In the present study, the prevalence of IANAL was greater in males than in females. This finding is in agreement with other studies.[6,16] Similarly, the interforamen distance was greater in males than in females (P < 0.05). Our results also confirmed that there was no statistically significant difference in interloop distance between the genders (P > 0.05). This indicates that the bigger jaw size and greater interforamen space in males should not be taken for granted while planning an implant placement. One particular study recommends a safe guideline of 4 mm from the mental foramen for placing implants.[17] The same might not be
relevant to our study population since the average IANAL length was found to be slightly higher (4.3 ± 0.4). Based on confidence interval values (4.40, 4.64) of the present study, a distance of around 5 mm from the most anterior point of mental foramen could be considered safe for placing implants among Saudi population of Aseer province.

Clinical Significance of IANAL
Failure to recognize the presence of anatomical variation IANAL before placement of implant in the interforamen region might lead to post-operative complications like neuropraxia and disturbances in the sensation of lower lip.

Limitations of the Present Study
• The panoramic images used in the present study were two-dimensional and lesser precise when compared to CBCT imaging.
• In cases where there is overlapping canal loop, the possibility of missing the condition might have led to slight underestimation of the IANAL images.

Hence, the present study emphasizes on the mandatory use of panoramic radiograph as a screening aid for the identification of anatomical variation like IANAL in patients selected for implant placement. On confirmation of such finding, the same patients may be further subjected to advanced imaging modality like CBCT for accurate measurement of IANAL.

However, further research using advanced imaging techniques like CBCT is warranted.

CONCLUSIONS
The occurrence of IANAL was found to be 22.9%. The males had greater occurrence of IANAL than females. Interforamen distance was significantly greater in males than females. Author recommends a distance of around 5 mm from the most anterior point of mental foramen could be considered safe for placing implants among Saudi population of Aseer province.

REFERENCES


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Study of Anatomical Variations in Middle Cerebral Artery

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Abstract

Introduction: Middle cerebral artery (MCA) is the largest and most complex arterial system of the brain. An attempt has been made in this study to enhance our perception of the variations in the microvascular anatomy of MCA in our population.

Aim: The aim of the study was to study the variations in the microsurgical anatomy of the MCA in our population and to compare the variables with the studies on Western population and to discuss its importance with anatomic and surgical considerations.

Materials and Methods: A total of 15 fresh adult cadavers of both sexes were studied in the autopsy room in Madurai Medical College, Madurai, between June 2008 and January 2009. The different variables with regard to the MCA in our population were analyzed and compared with the studies in Western population as well as with other Indian studies.

Results: The mean length of the MCA in this study was 16.37 mm. It was also found to be shorter in length with bifurcating MCA and longer with trifurcating MCAs. The perforators were found to arise predominantly from the inferomedial aspect of the M1 segment. The branching pattern of MCA showed bifurcation in 73% and trifurcation in 27%.

Conclusion: MCA is larger of the two branches of internal carotid artery (ICA), and it is direct continuation with the ICA which favors any emboli to get lodged or secondaries to get deposited or abscess formation. Thorough knowledge of the microvascular anatomy and the myriads of variations are very essential for the operating surgeon to choose the ideal technique to avoid any catastrophe during and after surgery and to give the best possible functional outcome for the patients.

Key words: Digital subtraction angiography, Internal carotid artery, Middle cerebral artery

INTRODUCTION

The field of microsurgery has gone leaps and bounds over the years which help in better understanding of the normal anatomy and its intricate variations in the vascular and other minute structures in brain. Cadaveric microdissection is of immense help which forms the basis of our understanding of the intricate anatomy of the structures of the brain.

Vascular anatomy of the brain is fascinatingly complex of all the variations in the brain, but yet they are so conspicuous by their distinct anatomy and its unique features.

The evolution of micro neurosurgery and the awareness of the arrangement of tiny perforating features vessels at the base of the brain have markedly and significantly improved the outcome and quality of the life of the patients subjected to surgery related to the vascular structures of the brain.

Middle cerebral artery (MCA) is the largest and most complex arterial system of the brain. Thorough knowledge of the microvascular anatomy and the myriads of variations are very essential for the operating surgeon to choose the ideal technique to avoid any catastrophe during and after surgery and to give the best possible functional outcome for the patients.

Various studies have been conducted in different sets of the population by various authors on MCA in an elaborate manner which includes a few studies on Indian population as well. With these various studies as guidelines, an attempt has been made in this study to enhance our perception of
the variations in the microvascular anatomy of MCA in our population.

**Aims and Objectives**
The aim of the study was to study the variations in the microsurgical anatomy of the MCA in our population and to compare the variables with the studies on Western population and to discuss its importance with anatomic and surgical considerations.

**MATERIALS AND METHODS**
A total of 15 fresh adult cadavers of both sexes were studied in the autopsy room in Madurai Medical College, Madurai, between June 2008 and January 2009.

26 gauge needle, microscissors, 11 blade knife, bayonet forceps, fine-toothed forceps, poster color, cotton, and artery forceps were used for the dissection of the sylvian fissure.

×4 magnification using Heine magnifying Loupe was used for the dissection of the brain throughout the study.

8 megapixels Canon Ixus digital camera was used for taking photographs.

Tabulation chart was used for entering the data and for further interpretation.

**Procedure**
During postmortem examination of the cadavers after the skull vault was removed taking special care not to injure the dura. The dura was opened from the frontal base in a transverse direction, and after cutting the falx, the frontal lobes were retracted slowly, and the optic nerves were exposed and carefully cut along with the internal carotid artery (ICA) at their entrance into the cranial cavity. Both the cerebral hemispheres were lifted carefully after dividing the cranial nerves one by one.

At the level of the tentorial hiatus, the brain stem along with the basilar artery was cut, and entire cerebral hemispheres delivered, after dividing the posterior attachment of falx. The specimen was soaked for 10–15 min in 10% formaldehyde solution.

Further dissections were carried out using a magnifying loupe with ×4 magnification. The sylvian fissure was opened with 26 gauge needle below the sylvian vein, and the dissection was extended with bayonet forceps.

The bifurcation of ICA is traced, and then MCA was traced with its branches coursing over the insula, the opercular and cortical branches were further dissected. The origin of the ICA is ligated with a silk, and red poster color solution was injected to make the vessels and perforators prominent and for ease of dissection.

The MI segment of MCA was carefully dissected, and the early branches from the superior aspect and the perforators from the inferior aspect were exposed.

The distribution of perforators along the MCA and their number were noted.

The branching pattern of MCA into different trunks was noted.

The division of the trunks into stem arteries and their further course over the insular region, opercular region, and cortical region was noted by further dissection.

The distribution of the cortical branches was noted.

The entire architecture of the MCA and its branches were photographed.

**Observations**
The following observations were made
1. Length of the MCA (M1 segment)
2. Early branches from the MCA
3. Perforators from.
   a. M1 segment.
      • Proximal
      • Distal.
   b. M2 segment.
4. Branching pattern of MCA into
   a. Bifurcation
   b. Trifurcation
   c. Multiple branches.

**RESULTS AND ANALYSIS**
The recorded data were analyzed with descriptive statistics and student t-test.

**M1 Segment Length (M1SL) [Table 1]**
The average length of M1 segment was:
- Longest M1 was 24 mm
- Shortest M1 was 12 mm.

**M1 Length in Variously Dividing MCA [Table 2]**
- The average length of M1 in bifurcating cases: 15.32 mm
- The average length of M1 in trifurcating cases: 19.25 mm.
The differences in M1SL in variously dividing MCA were found to be statistically significant using the student t-test.

**Early Branches (Table 3)**
The arteries supplying the cortical areas which take their origin directly from M1 segment of MCA are called early branches.

It varies from 1 to 3 in each hemisphere.

33.33% had 1 early branch.
- 46.6% had 2 early branches
- 20.0% had 3 early branches.

In this study, where there were more than 2 early branches; one of the vessels supplied the frontal lobe by replacing the orbitofrontal artery.

**Accessory MCA**
Accessory MCA is arteries arising from ICA, anterior cerebral artery (ACA), or AcomA which traverse through the sylvian fissure to supply the cortical areas.
- In this study, there was no accessory MCA.

**Perforating Arteries (Tables 4 and 5)**
Perforators are small twigs of blood vessels that arise from major arteries such as ICA, ACA, AcomA, and MCA. The majority of perforators of the MCA were from the inferomedial surface, and they divide in a candelabra pattern before entering the anterior perforated substance.
- Average number of perforators from proximal half of MCA is 7.07.
- Average number of perforators from distal half of MCA is 2.
- The MCA was divided into two groups as short MCA and long MCA taking into consideration 16 mm as the arbitrary cut off point.

**Short MCA**
- Proximal perforators contribute to 6.27
- Distal perforators contribute to 2.91.

**Long MCA**
- Proximal perforators contribute to 7.53
- Distal perforators contribute to 2.74.

There was no significant difference in the distribution of perforators in both long and short MCAs.

M2 segment of the MCA also contributed to as few perforators.

No significant contribution of perforators from the frontal and temporal cortical branches as it is reported in other studies.

**Division of MCA (Table 6)**
- MCA - bifurcated into superior and inferior trunk in 22 cases (73.3%).
- On the right side 12 trifurcations were noted, and on the left side, 10 trifurcations were noted.
- MCA - trifurcated into superior, middle, and inferior trunks in 8 cases (26.6%).
- On the right side 5 trifurcated and on the left side 3 trifurcated.
- There were no multiple divisions of MCA in this study.

With regard to the pattern of division between two sides, there was symmetry in most cases.
Side versus Division Cross Tabulation [Table 7]
Only in 2 cases the MCA bifurcated on the right side and trifurcated on the left side.

There were no cases wherein the MCA divided into multiple branches in this sample.

Largest of Cortical Arteries [Table 8]
Either of an angular artery or temporal occipital artery was the largest cortical artery (LCA) in this sample, or there were instances where both compensated when either of these arteries was absent.

- The angular artery was the LCA in 53.4% of cases.
- The temporal occipital artery was the LCA in 46.6% of cases.

When compared with the western studies the MCA1 length was longer by a few mm, but it was longer in another Indian study [Figure 1]

Table 6: Division of MCA

<table>
<thead>
<tr>
<th>Type of division</th>
<th>Frequency (%)</th>
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<tr>
<td>Bifurcation</td>
<td>22 (73.3)</td>
</tr>
<tr>
<td>Trifurcation</td>
<td>8 (26.6)</td>
</tr>
<tr>
<td>Multiple</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Total</td>
<td>30 (99.9)</td>
</tr>
</tbody>
</table>

MCA: Middle cerebral artery

Table 7: Side versus division cross tabulation

<table>
<thead>
<tr>
<th>Side</th>
<th>Division</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bifurcation</td>
<td>Trifurcation</td>
</tr>
<tr>
<td>Right</td>
<td>12</td>
<td>5</td>
</tr>
<tr>
<td>Left</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>22</td>
<td>8</td>
</tr>
</tbody>
</table>

Table 8: Largest of cortical arteries

<table>
<thead>
<tr>
<th>Type of cortical artery</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LCA</td>
<td>16 (53.4)</td>
</tr>
<tr>
<td>LCTO</td>
<td>14 (46.6)</td>
</tr>
</tbody>
</table>

LCA: Largest cortical artery, LCTO: Largest cortical temporo occipital

Accessory MCA
There were no cases which have an accessory MCA whereas Yasargil has recorded an incidence of 2.9%.

Branching Pattern of MCA [Figure 3]

<table>
<thead>
<tr>
<th>Study</th>
<th>Bifurcation</th>
<th>Trifurcation</th>
<th>Multiple</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rhoton</td>
<td>78%</td>
<td>12%</td>
<td>10%</td>
</tr>
<tr>
<td>Present Study</td>
<td>73%</td>
<td>27%</td>
<td>10%</td>
</tr>
<tr>
<td>Yasargil</td>
<td>77%</td>
<td>13%</td>
<td>10%</td>
</tr>
<tr>
<td>Balaji</td>
<td>80%</td>
<td>20%</td>
<td>10%</td>
</tr>
</tbody>
</table>

Perforators of M1 Segment [Figure 4]
The average number of M1 segment perforators in this study was compared with the other study by Rhoton.

- The average number of perforator in study by Rhoton study - 10
- The average number of perforator in this study - 9.2.

DISCUSSION

The different variables with regard to the MCA in our in population were analyzed and compared with the studies...
in Western population as well as with another Indian study with respect to the anatomical perspectives and surgical considerations.

1. MCA is the largest branch of the ICA, and it is in direct continuation with the ICA whereas the ACA forms an angle with that of ICA.

2. The mean length of the MCA in this study was 16.37 mm. It was also found to be shorter in length in cases with bifurcating MCA and longer in length in cases with trifurcating MCAs. This was also found to be shorter in length in cases with bifurcating MCA. This has been compared with the western studies which showed a slightly shorter MCA compared with this study sample.

3. Early branches were noted in all cases in this study, and they were either single, two and two branches and in the last category which constituted 20% in this study one of the branches supplied the frontal lobe. This was compared with few, studies where Rhoton reported 10% incidence of frontal lobe supply and Pai et al. reported 30% incidence.[1-3, 10]

4. The incidence of accessory MCA though reported in different studies it was not found in this study sample.[12]

5. The perforators from the MCA were found to arise predominantly from the inferomedial aspect with a uniform distribution throughout the length of the M1 segment. They entered the anterior perforated substance as described by the other studies. The average number of perforators distributed both in the proximal and distal segment was similar to other studies done in the Western population.

6. The branching pattern of MCA showed bifurcation in 73% and trifurcation in 27%. In the majority of the cases, there was symmetry in the division of the MCA between the two sides, but a few cases showed the difference between the two sides.

7. Similar to the way the MCA originates from ICA the dominant trunk of MCA is more in line with that of parent vessel and the nondominant trunk offshoots from the MCA at an angle.

8. The angular or temporo-occipital artery was the largest of the cortical arteries observed.

   - Embolic stroke, (the most common cause of stroke) and secondary deposits tend to affects the MCA territory as it is more parallel and in line with the MCA and comparatively larger in caliber and cross section.[5,7]
   - Involvement of the individual cortical branch may produce symptoms pertaining to the area supplied by that branch due to the variations in size and area of the cortex supplied it is difficult to identify the exact branch it is difficult to identify the block in these vessels even with angiography.

**Surgical Consideration**

   - The MCA is mostly uniform in size than the gross variation in size of its counterpart the ACA poses a difficulty in locating the division preoperatively. A detailed angiographic evaluation before surgery is mandatory.
   - Irrespective of the adequate length of MCA it is not freely mobile, and mobility is being restricted by the perforators.[9]
   - During aneurysm surgery, the early branches from the super lateral aspect should be preserved as they supply the cortical areas replacing the cortical branches.[4]
   - Even though few perforators can arise from the accessory MCA they do not predominate in supply to any cortical area, hence, they can dispensed during surgery safely of at all needed.
   - During surgery in and around MCA, the dissection is kept to a bare minimum in the inferomedial aspect since the likelihood of injury to the perforators is more in the event of doing so.[6,11,13]
   - In aneurysm surgery of MCA, the application of temporary clips should be as distal as possible to minimize the injury to the perforators as far as possible.
   - The perforators in the insula are dealt with care to avoid injury since it may cause limb weakness due to corona

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**Figure 3: Branching pattern of middle cerebral artery**

**Figure 4: Average perforators of the M1 segment**
radiata and internal capsule involvement as a result of perforator injury. Therefore, extreme care should be taken to prevent the mobilization of these vessels.

- In case of MCA occlusion, the most preferred vessel for STMC bypass is an angular artery or temporal occipital artery.

CONCLUSION

MCA is larger of the two branches of ICA, and it is direct continuation with the ICA which favors any emboli to get lodged there resulting in a stroke of that territory or secondaries to get deposited or abscess formation in that territory. The length of M1 segment is shorter in the bifurcating MCA and longer in trifurcating MCA. The mobility of the M2 segment is hampered by the interomedial perforators of the M1 segment. Accessory MCA or duplication of MCA is a rare phenomenon, and they do not have specific cortical supply, hence they can be sacrificed if necessary. There is uniform distribution or perforators from the inferomedial aspect of MCA, hence, dissection in that area should be minimal to avoid injury. During aneurysm surgery, the application of temporary clips should be distal as possible to avoid injury to the perforators. The branching pattern of the MCA should be elucidated with pre-operative catheter angiogram or DSA since it is the common site of aneurysm.

ACKNOWLEDGMENT

I take this opportunity to thank and honor a host of well-intended individuals who helped me in the completion of this voluminous and arduous task.

- I hereby thank the Dean of Madurai Medical College, Madurai, for allowing me to use the college and hospital facilities during my study.
- I thank my colleagues, family friends, and well-wishers for their unequivocal support they gave me during this process.
- I owe my prayers to The Lord, who gave me the inner strength to complete this work.

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Study of Histopathological Pattern and Frequency of Ovarian Tumors in Western Region of India: A Study at Tertiary Care Centre

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Abstract

Objective: The objective of the study was to study and analyze the various histopathological pattern and age distribution of ovarian neoplasms.

Materials and Methods: This is a study of ovarian neoplasm at tertiary care hospital over a period of 5 years. A total of 308 ovarian lesions were studied. Specimens were received in formalin, and hematoxylin and eosin stained slides were examined.

Results: Out of 308 total ovarian lesions studied, 100 (32.46%) were found neoplastic lesions. Out of which 88% were benign, 4% borderline and 8% were malignant. Except four cases, all 96 cases were unilateral neoplasms. Benign neoplasms were more common than borderline and malignant neoplasms in all age groups.

Conclusion: All kinds of neoplastic lesions were most common in 20–59 years of age. Mature cystic teratoma was the most frequent neoplasm observed.

Key words: Dermoid cyst (mature cystic teratoma), Mucinous tumors, Ovary, Serous tumors

INTRODUCTION

Ovary is an important organ as it is concerned with the production of progeny. The ovary consists of sex cells and mesenchymal cells which are totipotential and multipotential, respectively. Hence, when it becomes neoplastic, almost any type of tumor can result.[1] A number of non-neoplastic and neoplastic lesions occur within the ovaries. They can present from the neonatal age to post-menopause. Most are functional in nature and fade away with minimal treatment. However, ovarian cysts can herald an underlying malignant process. When cysts are large, persistent, or painful, surgery may be required.[2] Detection of various histological patterns of ovarian tumors is very important in diagnosis, prognosis as well as treatment of ovarian tumors. Prognosis of the tumors can also be predicted from the degree of differentiation of the tumors.[3]

Ovarian tumors are insidious in onset and usually diagnosed at a late stage. They commonly present with abdominal pain, a lump or menstrual irregularities. In addition to biopsy, various diagnostic modalities include transvaginal ultrasonography, magnetic resonance imaging, positron emission tomography, and markers like serum CA-125.[3]

Diverse histopathologies are common in ovarian lesions. Relative frequency of different ovarian tumors is different for the Western world and Asian countries.[3]

It is a well-established fact that neoplastic conditions of ovaries form a complicating and baffling subject in the history of oncology. The neoplasm arising from it inherits a spectrum of histogenetic background, much more varied than any other.[1] Early diagnosis is difficult due to its asymptomatic nature, inaccessible site and the limited use
of various techniques such as cytology and biopsy. Thus, ovarian neoplasm offers a good field for research.

The understanding of the molecular pathogenesis of ovarian cancer has been hindered by the lack of sufficient number of specimens at the early-stage disease. As a result, identifiable precursor lesions that ultimately develop into ovarian cancer are still debatable.\[4\]

In the ovary, the problem is further complicated by the endocrine activities of tumor causing a variety of clinical symptoms and signs, and some feminizing ovarian tumors are associated with endometrial carcinoma. Further, ovary is a target organ for a variety of hormones from menarche to menopause and repeatedly undergoes involutions thereby giving rise to tumor formation.\[5\]

This prospective study is carried out in the Pathology Department of this institute. The purpose of this study was to see the frequency and pattern of ovarian tumors in our setup and compare it with the pattern reported within the country and abroad.

### MATERIALS AND METHODS

A prospective case-series study was carried out on 308 specimens of ovary retrieved by surgical oophorectomy, cystectomy, and hysterectomy. Samples were analyzed in the Pathology Department of GMERS Medical College, Ahmedabad, Gujarat, for the period of 5 years from 2012 to 2016.

All the cases of ovary specimen sent for histopathological examination were included in the study. Clinical details were provided along with the specimen by the Obstetrics and Gynecologic Department of the same hospital.

The specimens were received in 10% neutral buffered formalin, processed and Hematoxylin and Eosin staining done. Gross and Microscopic findings of these cases were analyzed.

Neoplastic lesions from representative sections were studied and classified according to the World Health Organization classification, and staging is done according to International Federation of Gynaecology and Obstetrics staging.

### RESULTS

Out of 308 total ovarian lesions studied, 100 (32.46%) were found neoplastic lesions.

Table 1 shows distribution of class of neoplasm of ovary. Dermoid cyst is most common tumor of the ovary.

Out of 100 cases studied, 88% were benign, 4% borderline and 8% were malignant [Table 2]. Except four cases, all 96 cases were unilateral neoplasms. Benign neoplasms were more common than borderline and malignant neoplasms in all age groups [Table 3].

Amongst 100 cases of neoplasms of ovary studied during study period, percentage distribution of epithelial tumor is highest (52%) [Figure 1].

### Table 1: Distribution of class of neoplasms of ovary

<table>
<thead>
<tr>
<th>Neoplasm of ovary</th>
<th>Number of cases (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epithelial tumors</td>
<td></td>
</tr>
<tr>
<td>Serous cystadenoma</td>
<td>27 (27)</td>
</tr>
<tr>
<td>Mucinous cystadenoma</td>
<td>15 (15)</td>
</tr>
<tr>
<td>Serous cystadenofibroma</td>
<td>01 (01)</td>
</tr>
<tr>
<td>Borderline serous cystadenoma</td>
<td>02 (02)</td>
</tr>
<tr>
<td>Borderline mucinous cystadenoma</td>
<td>02 (02)</td>
</tr>
<tr>
<td>Serous cystadenocarcinoma</td>
<td>03 (03)</td>
</tr>
<tr>
<td>Mucinous cystadenocarcinoma</td>
<td>01 (01)</td>
</tr>
<tr>
<td>Endometrioid carcinoma</td>
<td>01 (01)</td>
</tr>
<tr>
<td>Dermoid cyst</td>
<td>40 (40)</td>
</tr>
<tr>
<td>Struma ovarii</td>
<td>01 (01)</td>
</tr>
<tr>
<td>Immature teratoma</td>
<td>01 (01)</td>
</tr>
<tr>
<td>Dermoid cyst with sarcoma</td>
<td>01 (01)</td>
</tr>
<tr>
<td>Sex cord stromal tumor</td>
<td></td>
</tr>
<tr>
<td>Fibroma-thecoma</td>
<td>04 (04)</td>
</tr>
<tr>
<td>Metastatic carcinoma</td>
<td>01 (01)</td>
</tr>
<tr>
<td>Total</td>
<td>100 (100)</td>
</tr>
</tbody>
</table>

### Table 2: Distribution of neoplasms of ovary

<table>
<thead>
<tr>
<th>Neoplasms of ovary</th>
<th>Number of cases (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benign</td>
<td>88 (88)</td>
</tr>
<tr>
<td>Borderline</td>
<td>4 (4)</td>
</tr>
<tr>
<td>Malignant</td>
<td>8 (8)</td>
</tr>
<tr>
<td>Total</td>
<td>100 (100)</td>
</tr>
</tbody>
</table>

Figure 1: Percentage distribution of type of neoplasm of ovary
DISCUSSION

Ovarian lesions appear with a variety of clinical appearance and behavior. Histopathological examination of them very essential to know the type and pattern based on the origin, which is a key for management.

In the current study, 308 ovarian specimens were received, 100 (32.46%) lesions were found to be neoplastic. Except four cases, each of mature cystic teratoma, serous cystadenoma, borderline serous cystadenoma, metastatic carcinoma, all of them were unilateral.

In the current study, 88% were benign, 4% borderline and 8% were malignant [Table 2] which correlates with various studies done in Saudi Arabia,[6] Pakistan,[7] and South India[8] by Abdullah and Bondagji.[6]

Ovarian tumor may occur at any age but incidence, however, increases with age, with highest cases being diagnosed in 3rd to 5th decade of life [Table 3]. In the present study, youngest patient was of 17 years old and eldest of 72 years.

The most common histopathological category of ovarian neoplasm is epithelial tumor followed by germ cell tumors [Table and Figure 1]. The most common benign tumor was mature cystic teratoma followed by serous cystadenoma. However, Guppy et al. documented a higher incidence of epithelial tumors than in our study, i.e., 90% and no borderline tumor was found in Ameena et al. study. This difference may be due to sample size, but genetic, socioeconomic and environmental factors may also be involved.[9]

The most common benign tumor is mature cystic teratoma [Table 1] which is comparable with a study by Ahmed et al.[9] showing 35.17%, Mansoor,[10] Thanikasalam et al.,[11] and Ong and Chan.[12]

Serous tumors were found to be more common than mucinous tumors. Which is comparable with study done in India,[8,13] Egypt,[2] and Pakistan.[14] The frequency of malignant tumors was highest for serous cystadenocarcinoma followed by malignant germ cell tumor. This correlates well with studies done in India,[8] Pakistan,[14,15] and Nepal[16] having serous cystadenocarcinoma with the highest frequency.

Some molecular and histological evidence suggests that mucinous epithelial ovarian cancers build up through a sequence from benign tumor through the borderline tumor to invasive cancer which suggests the potential preventability of borderline and invasive mucinous ovarian cancer by surgical excision of identifiable precursor lesions.[5] The borderline tumors characterized by epithelial proliferation greater than that of the benign tumor more than two layers and <4 layers stratification, but there is no destructive invasion of the stroma.[2] In our study, we encountered 4 cases of ovarian borderline tumor which correlates well with Gupta et al.[17]

Most of the tumors were found during 20–51 years of age in present study similar to study done in our neighboring country Nepal.[18] Epithelial tumors are hardly seen in children, but their prevalence increases with age and peaks in the 4th and 5th decade of life.[2] We found no case of epithelial neoplasm in the 1st and 2nd decade of life. Borderline ovarian tumors are of low malignant potential having favorable prognosis and relatively early age at onset. They comprise 4%–14% of all epithelial ovarian neoplasms.[2] In the present study, we observe total 8 (8%) cases of malignant neoplasms.
This study shows the prevalence of ovarian malignancy of 12.5% in the age group between 3rd decade of life and 87.5% in 4th–6th decade of life which is comparable to study by Abdullah and Bondagji. [6]

Germ cell tumors whether benign or malignant found more commonly in below 50 years age groups.

The sex cord stromal tumors are not so common. The incidence of these tumors is variable in different studies. These tumors are of interest because of their hormonal effects which are rare with another ovarian neoplasm. In the present study, it is 4% correlates with Shaikh et al. [18] (5.03%) and Khan et al. [19] (5.15%).

Relative frequency of different ovarian tumors is different for the Western world and Asian countries. For example, surface epithelial tumors account for 50.0–55.0% of all ovarian tumors and their malignant counterpart for approximately 90.0% of all ovarian cancers in the Western world whereas this figure is 46.0–50.0% and 70.0–75.0%, respectively, in Japan. Similarly, mucinous tumors account for 12.0–15.0% of all ovarian tumors in the Western world. This figure is 20.0–23.0% for Japan. Germ cell tumors account for 30.0% of primary ovarian tumors, and malignant germ cell tumors account for 3.0% of all ovarian cancers in the Western world. [14]

Japanese women have reported a lower incidence of ovarian cancer, especially of epithelial type than US or European women. Approximately 90% of all the ovarian tumors are benign. Ovarian carcinoma represents the sixth most common female cancer and the fourth leading cause of death due to cancers in women. [7]

CONCLUSION

Diversity of ovarian pathologies creates challenges in research of timely diagnosis and management.

Histopathological examination of the ovarian tumor is necessary to find out the type and staging of tumor, which helps in the proper management of ovarian neoplasm.

These findings may contribute significantly in the understanding of the distribution of different ovarian neoplasms among our population in comparison with different regions of India and other Asian as well as the Western world, which may help to define the risk factors. Multicentric study with larger sample size for better understanding is recommended for future.

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REFERENCES

A Retrospective Comparative Study on Use of Slow Speed Micro Drill Versus Hand Held Micro Burr Drill for Stapedotomy in Otosclerosis Patients

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Abstract

Background: Stapedotomy is the standard procedure adopted in the surgical treatment of otosclerosis. In spite of advanced methods like laser being used in higher centers, handheld burr and low-speed drill remain the choice of method for the beginners.

Aim of the Study: The aim of this study is to compare the two methods of stapedotomy: Handheld burr and slow-speed drill in stapedotomy in terms of results and complications.

Materials and Methods: A retrospective study of 68 stapedotomy procedures performed in the past 6 years was reviewed. Both handheld burr and slow speed micro drill were used in creating stapedotomy. Post-operative evaluation was done using audiometric results (air-bone gap closure and pure tone audiogram). The immediate and late complications were noted and analyzed. In Group A, slow-speed drill was used to cut the posterior crus of stapes as close to the footplate as possible. Fenestration is made in the central area of the footplate using the micro drill. In Group B, handheld 0.2 mm burr was used to drill an initial hole followed by enlargement using a right-angled pick. In both the groups, appropriate size Teflon piston was used.

Conclusions: There was no statistical significant difference in the auditory gain in both the groups. Both procedures were safe for stapedotomy and the natures of complications were similar and manageable without permanent long-term effects.

Key words: Hearing loss, Micro drill, Otosclerosis, Stapedotomy, Stapes

INTRODUCTION

Otosclerosis is a familial, progressive disease affecting the bony otic capsule, characterized by replacement of compact bone with spongy bone, resulting in fixation of the foot plate of stapes, and clinically characterized by slow progressive hearing loss of conductive type in majority of patients; also, sensorineural type of deafness occurs in a few. The disease is more common in women of childbearing age. It occurs between the second and third decades of life. Surgery is the method of choice in the treatment of otosclerosis. The stapes surgery can lead to 95% improvement in hearing.[1] As a technical advancement in instrumentation nowadays surgeons are using laser to create fenestration in the foot plate of stapes as it improves precision. As the thickness and diameter of the bone charred while creating a fenestration in the foot plate is controlled with high precision laser, complications are reported to be less frequent.[2-3] However, several earlier and latter studies showed no significant differences between laser-assisted, micro drill, and manual microsurgical stapedotomy in regard with auditory gain.[4-10] Many authors who used laser opined that instead of better hearing outcome, the micro drill and/or laser were very helpful in providing greater accuracy during precise manipulations and thereby reduce surgical trauma, which has important advantage over patients’ safety compared to handheld instruments.[11-14] In this context, the present study was undertaken to evaluate and compare the clinical auditory gain after primary stapedotomy both with handheld micro burr and slow-speed micro drill methods of fenestration.
Type of Study
This was a retrospective, comparative clinical study.

Institute of Study
This study was conducted at Kakatiya Medical College, Warangal, Telangana.

Period of Study
The study duration was from January 2015 to September 2017.

MATERIALS AND METHODS
A total of 68 patients’ case studies were included in the present study from the medical records section of a tertiary teaching hospital over 6 years. These patients had undergone stapedotomy procedure for their condition of otosclerosis. An ethical committee clearance was obtained before the commencement of the study.

Inclusion Criteria
The following criteria were included in the study:
1. Patients aged above 25 years and below 55 years
2. Patients undergoing primary stapedotomy
3. Patients with purely conductive deafness.

Exclusion Criteria
The following criteria were excluded from the study:
1. Patients aged above 25 years and below 55 years
2. Patients with cochlear otosclerosis
3. Patients with history of tinnitus and vertigo
4. Patients with history of middle ear surgery
5. Patients with history of intake of ototoxic drugs
6. Patients with sensorineural deafness.

Case records of the patients from medical records section were taken and studied carefully to include the records of those with the diagnosis of otosclerosis based on a history of progressive hearing loss, negative Rinnes’ test, conductive hearing loss in pure tone audiometry, normal speech discrimination, and the absence of acoustic reflexes. High-resolution computed tomography temporal bone had been done preoperatively in cases when there was a history of previous middle ear pathology and if congenital inner ear anomalies were suspected. Records showing surgery performed using stapedotomy techniques using either handheld micro burr of 0.02 mm initially and the micro drill system were taken for evaluation. Patients undergoing surgery under local anesthesia were used. In all the patients, no antibiotics were given before surgery and were given only after surgery. In all cases, an endomeatal approach was used and the tympanomeatal flap was elevated. All operations were performed with the small-fenestra stapedotomy technique which creates a fenestration in the stapes footplate for the placement of prosthesis. The surgical technique is described as follows:

A total of 68 patients were divided into 2 groups. Group A consisted of 33 patients whose stapedotomy was done using handheld micro burr and Group B consisted of 35 patients in whom slow-speed micro drill was used. In Group A, there were 19 females and 16 males with a male-to-female ratio of 1:1.18. The mean age was 31.46 ± 2.10. In Group B, there were 20 females and 15 males
with a male-to-female ratio of 1:1.33. The mean age was 33.18 ± 3.70 [Table 1].

The mean pre-operative pure tone average (PTA) for air conduction in Group A was 66.18 ± 2.30, and in Group B, it was 64.30 ± 3.98. The mean post-operative PTA for air conduction in Group A was 21.454.21, and in Group B, it was 23.47 ± 2.61. The mean pre-operative PTA for bone conduction in Group A was 44.20 ± 2.30, and in Group B, it was 42.40 ± 3.98. The mean post-operative PTA for bone conduction in Group A was 19.76 ± 3.15, and in Group B, it was 20.75 ± 2.18. The mean pre-operative a-b gap in Group A was 38.37 ± 2.42, and in Group B, it was 39.50 ± 3.15. The mean post-operative a-b gap in Group A was 15.26 ± 2.43, and in Group B, it was 17.11 ± 1.86. Comparison of values of both the groups showed no statistical significance as the p value was above 0.05 for all values (P taken as statistically significant <0.05), [Table 2].

The incidence of complications was similar in both the groups in the study and there was no statistical significance [Table 3].

**DISCUSSION**

The present study is a comparison between the two methods of stapedotomy used all over the world. The study revealed that stapedotomy with the use of the micro drill technique was a safe surgical method for the treatment of otosclerosis. The micro drill (skeeter) has low noise intensity, low torque, and the duration of a few seconds, and it seems to be a safe tool in the perforation of the footplate of the stapes, without causing acoustic trauma. Intraoperative monitoring of the facial nerve is not done when performing stapedotomy in the present study. In a study by Sedwick et al.,[14] it was shown that there was no significant difference in either post-operative air-bone gap closure or post-operative sensorineural hearing loss, regardless of whether the fenestra was created by micro drill or laser. Somers et al.[9] reported that no statistically significant difference was found between the laser stapedotomy and the micro drill technique in the creation of calibrated hole, whereas Mangham[14] reported that hearing results were better after fenestration of the footplate with a micro drill when compared to results with a hand drill. In the present study, there was no statistical significance between handheld micro burr or slow-speed micro drill. Gjuric[5] was of the opinion that the micro drill in experienced hand is not more traumatic than the perforator to the inner ear. Barbara et al.[15] reported that micro drill stapedotomy showed good hearing results. Cuda et al.[10] in their comparison of three different devices used to perforate the stapes footplate in otosclerosis patients opined that there was no significant difference in the auditory gain or complications observed; the study reported that the use of the CO₂ laser does not differ significantly from that obtained with micro drill stapedotomy and the piezoelectric stapedotomy is associated with a slight but significant deterioration of bone conduction at high frequency and a higher vertigo rate. Yavuz et al.[9] compared micro drill and pick stapedotomy techniques; their study revealed that the micro drill and pick stapedotomy techniques produced similar hearing results and complication rates and no evidence of micro drill-induced acoustic trauma. The post-operative audiometry showed closure of the air-bone gap and improvement of the hearing result. The micro drill stapedotomy is a safe surgical technique to perforate the stapes footplate in otosclerosis patients. The question as to which surgical technique is better depending on the experience of the surgeon.

### Table 1: Age and gender incidence, (n=A-33; B-35)

<table>
<thead>
<tr>
<th>Observation</th>
<th>Group A</th>
<th>Group B</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean age</td>
<td>31.46±2.10</td>
<td>33.18±3.70</td>
<td></td>
</tr>
</tbody>
</table>

### Table 2: The pre- and post-operative PTA values, a-b gap (n =A-33; B-35)

<table>
<thead>
<tr>
<th>Observation</th>
<th>Group A</th>
<th>Group B</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean pre-operative PTA</td>
<td>66.18±4.25</td>
<td>64.30±3.80</td>
<td>0.643</td>
</tr>
<tr>
<td>Air conduction</td>
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<td>Mean post-operative PTA</td>
<td>21.45±4.21</td>
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<td>Bone conduction</td>
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<tr>
<td>Mean pre-operative PTA</td>
<td>44.20±2.30</td>
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<td>19.76±3.15</td>
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<td>Mean pre-operative a-b gap</td>
<td>38.37±2.42</td>
<td>39.50±3.15</td>
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<tr>
<td>Mean post-operative a-b gap</td>
<td>15.26±2.43</td>
<td>17.11±1.86</td>
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</table>

**a-b gap:** Air-bone gap, PTA

### Table 3: The incidence of complications in the study Group (n=A-33, B-35)

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<th>Complications</th>
<th>Group A</th>
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<td>Severe</td>
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<td>Slippage or displacement of prosthesis</td>
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<td>1</td>
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<td>Recurrent CD</td>
<td>3</td>
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<td>Serous labyrinthitis</td>
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<td>1</td>
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<tr>
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<td>Delayed</td>
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</tr>
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<td>0</td>
</tr>
<tr>
<td>Tinnitus</td>
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<tr>
<td>Chorda tympani damage</td>
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HL: Hearing loss, CD: Conductive deafness
CONCLUSIONS

There was no statistical significant difference in the auditory gain in both the groups. Both procedures were safe for stapedotomy and the natures of complications were similar and manageable without permanent long term effects.

REFERENCES

Functional Outcome of Primary Total Elbow Arthroplasty for Intra-articular Distal Humerus Fractures in Elderly Patients: A Prospective Study

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Abstract

Introduction: Treatment of fractures of distal humerus after the age of 50 years is challenging due to osteoporotic bone and comminution of the articular surface. Distal humerus has complex anatomy with limited options for internal fixation. Open reduction and internal fixation carry risks of loss of fixation, stiffness, infection, and non-union. Arthroplasty carries the risk of loosening, infection, and periprosthetic fractures. The aim is to study the functional outcome of primary total elbow arthroplasty (TEA) for intra-articular distal humerus fractures.

Design: This was an institution-based prospective study.

Patients: A total of 15 patients in the age group more than 50 years having distal humerus fractures that required surgical treatment with minimal clinical follow-up of 1 year were selected. All fractures were OTA classification 13.C2 or 13.C3. No patient lost the follow-up.

Intervention: We used Bakshi’s sloppy hinge elbow prosthesis (³rd generation) as the intervention procedure.

Main Outcome Measurement: Mayo Elbow Performance Score was used.

Results: Among total elbow replacement group after 1 year, all the patients satisfied (14 excellent and 1 good result). No patients treated with TEA require revision surgery.

Conclusion: We recommend TEA which may be a viable option for intra-articular distal humerus fracture in the patients with age more than 50 years. Our study population is small and also the follow-up period is short. Further study with large population with longer duration follow-up is needed.

Key words: Distal humerus fracture, Old age patient, Total elbow arthroplasty

INTRODUCTION

Distal humerus are approximately one-third of all elbow injury (7%) which comprises around 2% of all adult fractures, 5% of osteoporotic stress fractures in subjects over the age of 60 with bimodal age of distribution⁶ with peak incidences occurring between age 12 and 19 years usually in males, and those elderly 80 or elderly mainly in females. In the elderly, more than 60% of distal humerus fractures in elderly are due to low energy injuries like fall from standing height.[²,⁴]

The overall incidence of distal humerus is increasing mimicking the increasing incidence of hip, proximal humerus, and wrist fractures.[⁵,⁷] An aging population with increasing life expectancy combined with the fact that most of the fractures require surgical treatment which is likely to increase the health expenditure. Now, mainstay is to prevent fractures by screening for osteopenia and osteoporosis with bone mineral density and then to treat with medication.[⁸]
During old age, if any patient having comorbidity like immunological disease and chronic obstructive pulmonary disease which require steroid regularly further increase in the risk of osteopenia. Distal humerus fractures remain the most challenging injuries to manage due to multi fragmented and commonly seen in osteoporotic bone with complex anatomy of the elbow with limited options for internal fixation.

The treatment options for distal humerus fracture range from conservative management to operative management such as open or closed reduction with internal or external fixation and elbow arthroplasty surgery. Evans in 1953 termed the mode of treatment “bag of bones” and thought appropriate for elderly patients but not ideal for young active patients. In last quarter of century, improved outcome surgery for distal humerus headed toward surgical management. The principles set out by AO association for the study of internal fixation group including anatomical articular reduction and rigid internal fixation which allows for healing and early post-operative motion after understanding anatomy, improved surgical approaches, new innovative fixation devices, and post-operative rehabilitation protocols, and the result of surgical management is increased. However, in the elderly, restoration of anatomy and obtain rigid fixation may be difficult because of poor bone quality and comminution of articular surface and metaphysis. Hence, when rigid fixation not achieved to allow early range of motion, prolonged immobilization required leads to poor outcomes like stiffness. The failure of fixation may lead to non-union or implant failure leads to increased reoperation rate associated with open reduction and internal fixation (ORIF) may convert previously independent individual into a dependent. Total elbow arthroplasty (TEA) has been shown to offer a solution for post-traumatic deformities of the elbow, particularly for selected elderly patients with articular fragmentation, comminution, and osteopenia.

To evaluate better the role of TEA as a definitive treatment solution for comminuted distal humeral fractures in older age group, we study the functional outcome of TEA. In developing country like India where physiological age is more than actual age, we have taken the age of more than 50 years for the study in contrast to the elder (age more than 65 years).

**MATERIALS AND METHODS**

This was an institution-based, prospective longitudinal study. The study was conducted in our institution after getting ethical permission. All the patients were counseled about the advantages, disadvantages, and complications of the procedure. After obtaining written consent from patients, we performed total elbow arthroplasty (TEA) procedure. The study period was from December 2013 to November 2015 (24 months’ duration).

Inclusion criteria of our study were patients above age 50 years of both sexes with isolated fresh or <90 days traumatic close comminuted distal humerus fracture with articular involvement or displaced or involving fracture with elbow dislocation. Exclusion criteria were age below 50 years, open fracture around elbow, previous history of sepsis, excessive use of elbow, neurotropic joint, poor functioning of flexor and extensor mechanism of elbow joint, and extensive loss on either side of elbow joint or severe comorbidity patients.

The surgical technique described by Baksi was principally followed but with addition of an insertion technique of the humeral stem flanges of the new version of the sloppy hinge into the shaft of the humerus. Patients were operated with supine position with the arm, forearm supported in the side table under general anesthesia/brachial block, and full thickness flap developed mediially and laterally, and then, the ulnar nerve was isolation done. Soft tissues around the medial epicondyle and the muscles from the fractured fragments of the anterior and posterior surfaces of the lower humerus were detached. The medial articular capsule was detached from the upper articular margin of the ulna. Further dissection was done laterally over the triceps posterior surface to reveal the lateral epicondyle and fractured lateral supracondylar ridge while soft tissue around them was separated. The distal humerus was sectioned transversely just proximal to the olecranon fossa and upper limit of fracture, and a subarticular L-shaped cut was made over the upper end of the ulna to explore its medullary canal, preserving triceps insertion over the olecranon process and brachialis in front of the coronoid process. Reaming of the ulnar and reaming of the ulnar and humeral medullary canals were done with a harpoon-shaped reamer and rasp for humerus triangular-shaped rasp and ulna quadrangular-shaped rasp to provide snug fitting of the prosthetic stems. A longitudinal groove of 13 mm was cut on each side of the lower end of the humerus [Figure 1] in its coronal plane, extending from its transverse cut end for seating of the humeral stem flanges. Trial implants were used to finalize actual implant size. Cementing was done manually with the help of a bladder wash syringe and tube. Elbow kept in flexed position, assembled sloppy hinge elbow prosthesis inserted both in humerus and ulna simultaneously is such a that both the humeral stem and ulnar stem was then snugly fitted within the medullary canal with the help of bone cement and humeral stem flanges seated in the corresponding longitudinal slots already.
created over the sides of the humerus. Elbow kept in extension till cement sets [Figure 2]. Full range of elbow flexion and extension was tested. Triceps muscle repaired at insertion by drilling hole over the proximal ulna through which suture passed [Figure 3]. The wound was closed in layers, over a suction drain, around the prosthesis, and a well-padded compression bandage placed around the elbow. Splinting was done with a plaster slab in 30° flexion.

During the post-operative period, suction removed after 48 h, plaster slab removed after 5 days kept in turnbuckle splinting maximum flexion and extension 4 h in a day during 1st week, 3 h in next week, and then 2 h a day. Intermittent active and passive elbow movements were promoted out of the splint till satisfactory recovery of elbow motion. Removal of stitch done after 2 weeks and an elbow splint was used for 1 week, and if active elbow movements were free and painless, the splint was discarded. Weightlifting over 2½ kg and physically strenuous work with the replaced elbow were banned permanently.

All patients were evaluated at 4 weeks, then 2, 4, 8, 12, and 24 months, and periodically thereafter. However, if any patient complained of pain and increased local temperature around the elbow and limited post-operative elbow motion, he or she was instructed to see us at our follow-up clinic without delay. At each visit, we recorded Mayo Elbow Performance Score (MEPS), elbow and forearm range of motion, elbow stability, presence of any local pain, ability to carry out routine daily activities, overall subjective assessment of the outcome, and radiographic study of replaced elbow.

**RESULTS**

About 15 patients in the age group of more than 50 years were included in the group with mean age 61.5 years with 9 females and 6 males. Of 15 patients, 11 patients had left elbow affected and 4 patients right elbow affected with majority of right handed (14 right handed and 1 left handed). Out of 15 patients, two were diabetic, two were hypertensive, one was with both diabetes and hypertension while one had both hypertension and osteoporosis Table 1.

All the patients with distal humerus comminuted fracture humerus were treated with third-generation Baksi sloppy hinge elbow prosthesis. The mean interval between the injuries and the operation was 25 days (10–90 days). Among all the patients operated, 1 patient had superficial skin infection which was treated by oral antibiotics, 1 patient ulnar neuropraxia which recovers within few days, 2 patients had post-operative hematoma treated by drain, and 1 patient had triceps weakness (IV/V) seen.

The mean post-operative arc of elbow motion (F/E) was 110 and 107 after 3 and 12 months’ post-operative period, respectively. The mean range of elbow motion (F/E) at 3 month post operative period was 20 to 130° which was nearly equal to 12 month follow up period. The mean range of motion after 3 months and 12 months was 60% more than 100° and 40% between 50 and 100°. All the patients had >50 supination and pronation after 3 and 12 months.
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MEPS: Mayo Elbow Performance Score, ADL: Adjusted disability living
Among all the patients operated, 2 patients after 3 months had pain due to hematoma which improved after drainage, and during 12 months, all are pain free.

Mean MEPS was 95.333 and 97.333 after 3 and 12 months, respectively. After 3 months of post-operative period, out of 15 patients, 13 showed excellent results and rest two patients showed good results. This improved after 12 months, 14 showing excellent results and one good result [Figure 4]. All the patients were satisfied (excellent and good result) after 3 months and 12 months.

**DISCUSSION**

Distal intra-articular humerus fractures among old age patients remain the most challenging injuries to manage as these fractures are usually multi fragmented with osteoporotic bone and complex anatomy. Treatment outcomes often associated with stiffness, pain, and weakness. To perform daily activity, we require a painless, stable, and mobile elbow joint. Hence, there is a decreased functional outcome managed by fixation as published by numerous authors.

In our study, 15 patients with distal humerus fractures were operated female predominance (60% female and 40% male). Average age of our study population was 61.27 years. Among operated patients, maximum patients were in the age group 51–60 years (15 patients), 12 patients were between 60 and 70 years, and 3 patients were above 70 years. Hence, in our study, there was female predominance which is comparable with other studies such as John et al.[15] and Frankle et al.,[16] but in our series, there was no loosening of any component or heterotropic calcification. It may be due to short-term follow-up. We found that fixation problem occurs on patient with osteoporosis.

In our series, ulnar apraxia and infection rate are comparable with the studies of Cobb and Morrey,[17] Ray et al.,[18] Frankle et al.[16] and Tian et al.,[19] but in our series, there was no loosening of any component or heterotropic calcification. In contrast, Gambirasio et al.[20] reported the functional outcome of primary total elbow replacement (TER) in the treatment of the distal humerus fractures in ten elderly patients and concluded that the treatment of multifragmentary, intra-articular fractures of the distal humerus are difficult and found no complications in regard to the soft tissues, bone, or prosthesis. Garcia et al.[21] studied 19 patients and found that 1 patient had loosening of a component of prosthesis and no other complication.

In our study, we found that, among TEA group, 1 patient had triceps weakness (IV/V), mean post-operative arc of elbow motion (F/E) of TER group was 110 and 107 after 3 and 12 months’ post-operative period, respectively, and 2 patients after 3 months had pain due to hematoma which improved after drainage, and during 12 months, all are pain free.

All the patients were stable and arc of pronation and supination normal functional range. In our study, the mean arc of elbow flexion-extension, stability, pain, and pronation-supination of elbow are comparable with the result of the studies by Cobb and Morrey,[17] Ray et al.,[18]
McKee et al.,[12] and Tian et al.,[13] but flexion-extension arc is less than few studies which may be due to late start of physiotherapy following fixation due to fixation problems in a osteoporotic bone and intra-articular incongruity.

In our study, we found triceps muscle weakness in 1 patient among TER groups which is comparable to the result of Cobb and Morrey,[14] and Tian et al.[13] study which may be due to late start of physiotherapy following fixation due to fixation problems in a osteoporotic bone and intra-articular incongruity.

In our series, the mean MEPS after 12 months was 97 (minimum 80 to 100), and of 15 patients, 14 excellent and 1 good with no fair or poor results.

Gambirasio et al.[20] reported the MEPS Score was 94 points (80 to 100) and the patient satisfaction was high. Garcia et al.[21] conducted a study of 16 patients (TER) after 3-year follow-up found that mean MEPS was 93 (80–100). Of the 16 patients, 15 were satisfied. Frankle et al.[16] conducted a retrospective study taking a total of 24 patients to compare ORIF with TEA, and the outcomes of the 12 patients treated with ORIF were as follows: 4 excellent, 4 good, 1 fair, and 3 poor with mean MEPS score 95. Outcomes of the 12 patients treated with TEA were as follows: 11 excellent and 1 good. There were no fair or poor outcomes in the TEA group with mean MEPS of 81.

Kamineni and Morrey[22] retrospectively reviewed 49 acute distal humeral fractures in 48 patients who were treated with TEA, and as the primary option, the MEPS averaged 93 of a possible 100 points. Sørensen et al.[23] evaluated short- to medium-term outcome of TEA in complex fractures of the distal humerus and after 6-year follow-up of 24 cases found that mean MEPS was 94 (range 65–100) with 15 excellent, 4 good, and 1 fair result. Tian et al.[13] analyzed the outcomes of TEA in the treatment of 8 cases of elderly Type C distal humeral fractures and found that the average Mayo elbow score was 85.2 ± 3.4 (75–95), four cases of excellent and four cases of good. In our series, MEPS score was comparable to these studies.[16,20,21,23] It was relatively better as compared to other studies.[19,25] which may be due to the short follow up period in our series. In contrast, Ducrot et al.[24] studied 20 patients undergone TER and found that the average MEPS was 83 (range 60–100, median 80) which was due to 4 patients died and 1 lost follow-up.

In our study, we did not found component loosening, periprosthetic fracture, or revision surgery. It may be due to the limitation of our study that we do not have a long-term follow-up and a large patients number. If we use disabilities of the arm, shoulder, and hand score, then the study would be more effective and informative. Most of the studies done on this topic had used MEPS to assess the result like we did.

CONCLUSION

Distal comminuted intra-articular fracture humerus can be managed by ORIF or with primary TEA. Our study shows good results using TER. Primary TEA may be a viable option for elderly patient with comminuted intra-articular distal humerus fracture with osteoporosis expecting failure of fixation but not to the manual laborer or heavy weight lifter.

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Source of Support: Nil, Conflict of Interest: None declared.
Psychogenic Status as a Risk Factor in Minimal Pathological Conditions of the Vocal Cords - A Clinical Study in a Tertiary Teaching Hospital of Telangana

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Abstract
Background: Voice disorders are encountered in patients of all ages, gender, and social status. The risk factors are often multifactorial and cannot always be fully described in anatomical or functional terms. Furthermore, voice disorders are much more varied than mere hoarseness. Psychosocial factors can be risk factors and affect the voice in patients with some types of the minimal associated pathological lesions (MAPLs) of the vocal folds.

Aim of the Study: The aim of this study is to evaluate patients with MAPLs of the vocal folds to understand the role of psychogenic stress as a risk factor and pathogenesis of this clinical entity.

Materials and Methods: A total of 72 patients with MAPLs of the vocal folds were included and evaluated with voice and psychiatric protocols, and the results obtained were compared with a control group of 50 subjects who were also evaluated with the same voice and psychiatric protocols.

Conclusions: There was a statistical significance between the both groups in relation to some of the psychiatric scales. The results obtained showed clear evidence of psychogenic background acting as a risk factor in the pathogenesis of certain types of MAPLs of the vocal folds, vocal folds nodules, vocal folds polyps, and contact granuloma.

Key words: Dysphonia, Mood changes, Psychosocial, Speech therapy, Vocal cords, Vocal nodules, Voice

INTRODUCTION

Voice changes sometimes are produced by the emotional and psychological status of mind of the individuals.[1] A person’s voice is peculiar in quality to him alone and depends on its pitch, volume, resonance, and tone. It depends on the anatomical configurations of the pharynx, larynx, upper airways, and size of the thoracic cavity.[2] Voice is said to be the exact reflection of one’s mood and self-image. Whereas, the listeners recognize a person by the quality of his voice and use it to reflect that individual’s emotions from the way they sound. Dysphonia affects the way of communication as it affects the basic elements of language.[3] An expression of emotions in voice is modified by well-balanced tone in the laryngeal musculature and not only helps in making the language understandable but also provides a “psychological impact” in it to the listener. As the voice disorders can result from emotional stresses, the voice disorders themselves could be produced by emotional stresses acting as risk factors. Patients who lose their voice feel their personality changes experiencing a “loss of self.” This “loss of self” returns only after they regain their original voice.[4,5] A group of minimal associated pathological lesions (MAPLs) of the vocal folds include benign lesions of vocal cords as a result of trauma. They may result as a consequence to prolonged non-organic voice disorders. They include vocal nodules, vocal polyps, contact ulcers, vocal cord granuloma, vocal cord cysts, and Reinke’s edema.[6] Among many factors causing these benign disorders, one is the psychological factor.[6] They
include personality traits and psychiatric illness which may be a cause or effect of voice disorder. In addition to various predisposing factors being considered in the etiology of voice disorders, the treating physician should also consider the psychosocial aspects of the etiology also. Failure to consider the psychosocial etiological agent in the diagnosis of voice disorders may result in misdiagnosis, delayed treatment, and reduced success rates in the final long-term cure rates of the disease. Little is known about the prevalence of major psychiatric illnesses in patients with MAPLs. The present study is an attempt to identify such psychosocial factors acting as risk factors in the pathogenesis of MAPLs of vocal cords.

**Type of Study**
This was a prospective cross-sectional and analytical study.

**Institute of Study**
The study was conducted at Kakatiya Medical College, Warangal, Telangana.

**Period of Study**
The study duration was from March 2015 to April 2017.

**MATERIALS AND METHODS**
A total of 122 subjects were included in the present study. They were divided into two groups. Group A consisted of patients with hoarseness of voice and voice disorders. Group B consisted of 50 normal subjects. The Institutional Ethics Committee approval was obtained to conduct this prospective study. An ethics committee approved consent form was used in all the patients and normal subjects.

**Inclusion Criteria**
1. Patients aged above 18 years and below 68 years were included.
2. Patients with dysphonia for more than 6 months were included.
3. Patients with minimal benign pathological lesions of the vocal cords were included.

**Exclusion Criteria**
1. Patients with age below 18 years and above 68 years were excluded.
2. Patients with dysphonia for <6 months were excluded.
3. Patients with malignant diseases of the vocal cord were excluded.
4. Patients with a history of surgeries on the vocal cords were excluded.

Demographic data of all subjects were collected. All the subjects were evaluated for their voice using the full voice evaluation protocol. Psychiatric evaluation of the subjects was performed by the institute psychologist from the department of psychiatry. He used the following protocols to highlight the psychological aspects relevant to voice disorders:

1. The Social Readjustment Rating Questionnaire,
2. Symptoms checklist,
3. Manifest Anxiety Scale of Minnesota Multiphasic Personality Inventory (MMPI),
4. Hysteria (Hy) and hypochondriasis (Hs) scales of MMPI,
5. The Zung Self-Rating Depression Scale.

All the data collected were analyzed using standard statistical methods.

**OBSERVATIONS AND RESULTS**
A total of 72 patients of Group A consisted of patients with dysphonia due to MAPLs attending the outpatient (OPD) department of Ear, Nose, and Throat (ENT) in a tertiary teaching hospital. Among the 72 patients, 47 (65.27%) were males and 25 (35.72%) were females. Patients belonging to the age group of 38 to 48 were 50/72 (69.44%). The lowest incidence was 4 (05.55%) in patients of 58–68 years age group in the study. History of smoking was observed in 29/72 (40.27%) of the patients, abuse of voice in 31/72 (43.05%), and upper respiratory tract infections (URTIs) were in 18/72 (25.00%) of them. 50 patients of Group B consisted of subjects attending the ENT OPD with other than voice complaints and included in the study as a control group. Among the 50 patients, 25 (50%) were males and 25 (55%) were females. Patients belonging to the age group of 58–68 years were 5 (10%) in the study. The mean age in males of Group A was 34.28 ± 4.35, and in group B, it was 33.15 ± 3.90. History of smoking was observed in 16/50 (32%) of the patients, abuse of voice in 14/50 (28%), and URTIs were in 10/50 (20%) of them [Table 1]. There was no statistical significant difference in the two groups of the study as the p value was >0.05 (P statistically significant at <0.05).

The MAPLs of the vocal folds observed in the study were tabulated in Table 2; 27 patients had vocal nodules, 13 had Reinke’s edema, 10 had contact ulcer, 09 had vocal cord cysts, 08 had vocal cord polyps, and 05 had vocal cord granuloma [Table 2]. Whereas, the control group (Group B) was selected randomly from OPD patients suffering any voice disorders.

Both the groups were evaluated using the social readjustment rating questionnaire to assess the stressful life events and observed that in Group A 11/72 (15.27%) patients had such life events when compared to 3/50 (6%) in Group B. The incidence of life events values in the groups was not statistically significant as the P value was 0.231 (P statistically significant at <0.05), [Table 3].
Comparison between the control group and the group of vocal cord nodules revealed highly significant difference ($P < 0.05$) in interpersonal sensitivity, depression, and anxiety of symptom check-list (SCL). The group of vocal cord polyps revealed significantly higher somatization and anxiety of SCL than the normal group ($P > 0.05$), [Table 4].

Comparison between the control group and the group of vocal folds nodules revealed highly significant difference ($P < 0.001$), in the incidence of anxiety, while evaluating with Taylor anxiety scale [Table 5].

### Table 1: The demographic data (n- A-72; B-50)

<table>
<thead>
<tr>
<th>Observation</th>
<th>Group A 72 (%)</th>
<th>Group B 50 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>47 (65.27)</td>
<td>25 (50)</td>
</tr>
<tr>
<td>Female</td>
<td>25 (35.72)</td>
<td>25 (50)</td>
</tr>
<tr>
<td>18–28 years</td>
<td>11 (15.27)</td>
<td>07 (14.00)</td>
</tr>
<tr>
<td>28–38 years</td>
<td>23 (31.94)</td>
<td>15 (30.00)</td>
</tr>
<tr>
<td>38–48 years</td>
<td>27 (37.50)</td>
<td>17 (34.00)</td>
</tr>
<tr>
<td>48–58 years</td>
<td>07 (09.72)</td>
<td>06 (12.00)</td>
</tr>
<tr>
<td>58–68 years</td>
<td>04 (05.55)</td>
<td>05 (10.00)</td>
</tr>
<tr>
<td>Smoking</td>
<td>29 (40.27)</td>
<td>16 (32.00)</td>
</tr>
<tr>
<td>Abuse of voice</td>
<td>31 (43.05)</td>
<td>14 (28.00)</td>
</tr>
<tr>
<td>URTI</td>
<td>18 (25.00)</td>
<td>10 (20.00)</td>
</tr>
</tbody>
</table>

URTI: Upper respiratory tract infection, $P$ value was $>0.05$ for the above values

### Table 2: The MAPLs in Group A (n-72)

<table>
<thead>
<tr>
<th>MAPLs</th>
<th>Group A 72 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vocal nodules</td>
<td>27 (37.05)</td>
</tr>
<tr>
<td>Rienke’s edema</td>
<td>13 (18.05)</td>
</tr>
<tr>
<td>Contact ulcer</td>
<td>10 (13.88)</td>
</tr>
<tr>
<td>Vocal cord cysts</td>
<td>09 (12.50)</td>
</tr>
<tr>
<td>Vocal cord polyps</td>
<td>08 (11.11)</td>
</tr>
<tr>
<td>Vocal cord granuloma</td>
<td>05 (06.94)</td>
</tr>
</tbody>
</table>

MAPLs: Minimal associated pathological lesions

### Table 3: The results of social readjustment rating scale, comparison between the two groups (n- A-72; B-50)

<table>
<thead>
<tr>
<th>Stressful life events</th>
<th>Group A (%)</th>
<th>Group B (%)</th>
<th>$P$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Present</td>
<td>11 (15.27)</td>
<td>3 (6.00)</td>
<td>0.231</td>
</tr>
<tr>
<td>Absent</td>
<td>61 (84.72)</td>
<td>47 (94.0)</td>
<td></td>
</tr>
</tbody>
</table>

### Table 4: The results of SCL; comparing 2 groups (n- A-72; B-50)

<table>
<thead>
<tr>
<th>Observation</th>
<th>Group A (%)</th>
<th>Group B (%)</th>
<th>$P$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Somatization</td>
<td>19 (26.38)</td>
<td>05 (06.94)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Depression</td>
<td>22 (30.55)</td>
<td>03 (06.00)</td>
<td>0.041</td>
</tr>
<tr>
<td>OCD</td>
<td>06 (06.94)</td>
<td>07 (14.00)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Interpersonal</td>
<td>17 (23.61)</td>
<td>02 (04.00)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>sensitivity Hostility</td>
<td>04 (05.55)</td>
<td>03 (06.00)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Anxiety</td>
<td>28 (38.88)</td>
<td>02 (04.00)</td>
<td>0.021</td>
</tr>
<tr>
<td>Phobic anxiety</td>
<td>03 (04.16)</td>
<td>01 (02.00)</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>

OCD: Obsessive-compulsive disorder, SCL: Symptom checklist

Comparison between each group of MAPLs and the normal group with MMPI Scales for the assessment of hysteria and hypochondriasis revealed significant statistical values with $P$ value at 0.017 [Table 6].

Comparison between each group of MAPLs and the normal group with Zung scale for depression showed greater values in the nodules group than the control group with $P = 0.031$ [Table 7].

Patients with contact granuloma showed significantly higher values concerning the somatization, depression, and anxiety of SCL, anxiety by Taylor anxiety scale, hypochondriasis by MMPI scale, and depression by the Zung scale; the values were below 0.05 ($P$ statistically significant at $<0.05$). Whereas, the patients with vocal cord cysts and Reinke’s edema showed not much significant values from the normal group in all psychiatric scales as the $P$ value was $>0.05$.

### DISCUSSION

A group of MAPLs develop on the vocal cords in patients caused by repeated vocal trauma. The vocal cords are made vulnerable due to long-standing irritation which leads to the development of organic changes in non-organic (functional) voice disorders.[13] These psychosocial factors are now increasingly being accepted as important etiological factors of many other diseases also; however, there is lack of instruments to identify and prove these findings.[16]

<table>
<thead>
<tr>
<th>Table 5: The results of manifest anxiety scale of Taylor comparing between the two groups (n- A-72; B-50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observation</td>
</tr>
<tr>
<td>No anxiety</td>
</tr>
<tr>
<td>Total anxiety</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 6: Results of MMPI scales for the assessment of hysteria and hypochondriasis comparison between the two groups (n- A-72; B-50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observation</td>
</tr>
<tr>
<td>Hysteria</td>
</tr>
<tr>
<td>Hypochondriasis</td>
</tr>
</tbody>
</table>

MMPI: Minnesota Multiphasic Personality Inventory

<table>
<thead>
<tr>
<th>Table 7: Results of Zung self-rating depression scale among the two groups (n- A-72; B-0)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression</td>
</tr>
<tr>
<td>No depression</td>
</tr>
<tr>
<td>Total depression</td>
</tr>
</tbody>
</table>
Even though many studies theorize that the symptoms of psychological distress accompany dysphonia, their validity is questionable in the absence of definite proof and instruments to identify the risk factors, whether such vocal cord lesions are non-organic or organic with some pathology (MAPLs) or purely organic is still unclear.\textsuperscript{[15]} Nerrière et al.\textsuperscript{[16]} in showed comorbidity between voice disorders and commune mental health troubles, such as major depressive episode and general anxiety disorder. Such association of voice disorders with mental health troubles confirms that a situation may exist which is more complex than simple mechanical failure. Kotby et al.\textsuperscript{[17]} in their extensive study on estimating the etiological factors, functional dysphonia concluded that there was always evident psychogenic background for some types, namely, incomplete mutation, phonaesthesien, and non-organic aphasis, while other functional dysphonia types did not show or little evidence of psychogenic etiology. In a study by Butcher,\textsuperscript{[18]} majority of patients with psychogenic voice disorders were women with high degrees of stress and above average musculoskeletal tension, rather than a conversion symptom. Mirza et al.\textsuperscript{[19]} described evidence of certain abnormal personality traits including interpersonal sensitivity and distrust of others in their patients’ functional aphasis. White et al.\textsuperscript{[20]} could not find any significant personality trait differences between three groups of subjects: A control group (with normal voices), patients with psychogenic voice disorders, and patients with structural laryngeal changes. In the present study, comparison between each group of MAPLs and the normal group with MMPI Scales for the assessment of hysteria and hypochondriasis revealed significant statistical values with p value at 0.017 [Table 6]. Millar et al.\textsuperscript{[21]} in their study showed no differences in personality traits of patients with organic and the functional groups of dysphonia. However, they found that dysphonic patients showed marked distress compared with norms, but there were no differences in the amount of psychological distress between the organic and the functional groups. Comparison between the control group and the group of vocal cord nodules revealed highly significant difference \(P<0.05\) in interpersonal sensitivity, depression, and anxiety of SCL. The group of vocal cord polyps revealed significantly higher somatization and anxiety of SCL than the normal group \(P>0.05\), [Table 4]. Physicians treating MAPLs should have better knowledge about the risk factors such as anxiety, depression, hysteria, and hypochondriasis as the etiology of certain types of voice disorders which may help in understanding the exact voice problems, proper management, and designing proper therapeutic programs for voice. Hence, for all these reasons, it becomes necessary to select the category of MAPLs as a common type of voice disorder. In this study, an attempt was made to assess the presence of the psychogenic factors as possible risk factors in the pathogenesis of MAPLs of the vocal cords of patients. Full voice evaluation protocol including psychological tools was used to assess the psychological profile of the patients. Although all the subjects including control group experienced stress, anxiety, and depression, the reason why certain people only developed MAPLs with dysphonia could not be explained. It may be assumed that few patients have responded with dysphonia when their psychological status was disturbed with anxiety, depression, or hysteria; in the form of hyper-reactive physiology? Seifert and Kollbrunner\textsuperscript{[22]} concluded that dysphonia is due to events that trigger them such as acute vocal abuse, acute laryngitis, episode of gastroesophageal reflux, or even simply acute conflict situation (e.g., stress in partnership, family, or workplace). In the present study, stressful life events were noted in Group A 11/72 (15.27\%) when compared to 3/50 (6\%) in Group B subjects. The incidence of life events in the groups was not statistically significant as the \(P\) value was 0.231 \(P\) statistically significant at \(<0.05\), [Table 3]. House and Andrews\textsuperscript{[23]} were of the opinion that stress factors can be risk factors for MAPLs only if their duration, frequency, and strength exceed the level of capability of the individual to overcome. In the present study, there was a highly significant difference between the control group and the group of MAPLs concerning depression (23.61\% of patients and 10\% in control group) and anxiety (34.72\% in patients and 6\% in control group), while other psychiatric symptoms showed non-significant difference between both groups.

CONCLUSIONS

There is a definite evidence of psychogenic background acting as risk factors for some types of MAPLs of the vocal cords. The MAPLs which were likely to be produced by these risk factors are vocal nodules, vocal polyps, and contact granuloma. A combined assessment of dysphonia in patients and assessment of their psychological profile with MAPLs, followed by suitable therapeutic psychological counseling programs such as behavioral readjustment voice therapy as well as, psychiatric treatment should be thought of while treating such patients.

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A Prospective, Randomized Study Comparing Bupivacaine and Levobupivacaine through Ultrasound-guided Supraclavicular Block in Patients Undergoing Elective Upper Limb Surgeries

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Abstract

Introduction: Levobupivacaine is a pure S-enantiomer of bupivacaine, and it has similar anesthetic profile with racemic bupivacaine but reduced toxic potential. We conduct the present study to evaluate and compare the intraoperative hemodynamics and onset and duration of sensory and motor blockade.

Aim: This study aims to compare ultrasound-guided supraclavicular block using bupivacaine or levobupivacaine in patients undergoing elective upper limb surgery.

Methods: After clearance from ethics committee, single-blinded randomized study carried out on ASA-PS I and II patients, undergoing elective upper limb surgeries under supraclavicular block, was randomly assigned two groups Group A - supraclavicular block with 0.5% bupivacaine (0.4 ml/kg) and Group B - supraclavicular block with 0.5% levobupivacaine (0.4 ml/kg).

Results: The duration of sensory and motor blockade was prolonged with levobupivacaine. The onset of sensory and motor blockade and intraoperative hemodynamics was same as bupivacaine. Complete failure and toxicity were not reported in both groups.

Conclusion: Levobupivacaine is safer and longer acting local anesthetic and its clinical profile is similar to racemic bupivacaine with reduced toxicity.

Key words: Bupivacaine, Levobupivacaine, Supraclavicular block

INTRODUCTION

Peripheral nerve blocks provide ideal operating condition when used in optimal conditions. They reduce the stress response and least interferes with the vital physiological functions of the body compared to conventional techniques. Adequately administered regional anesthesia not only provide excellent intraoperative pain relief but also give best post-operative analgesia. When we trace regional anesthesia origin, Dr. Carl Koller, a young ophthalmologist, employed a cocaine solution for topical corneal anesthesia in patients undergoing eye surgeries in 1884.[3] Most of the local anesthetic agents developed in the 1st half of the 20th century (1900–1940) were basically ester compounds. They lost their importance due to their short duration of action, systemic toxicity, and associated allergic reactions. These paved the way for the synthesis of newer agents, namely, amide type of local anesthetic agents.[3] Brachial plexus block was first performed by William Stewart Halsted in 1889. He directly exposed the brachial plexus in the neck to perform the block using cocaine.[3] Hirschel first performed the percutaneous approach of brachial plexus block.[4] Kulenkampf was the first to perform the classical supraclavicular approach to the brachial plexus block.[3] Then, Winnie and Collins...
introduced the subclavian perivascular block.[6] Raj was the first to perform the brachial plexus block through infraclavicular approach.[7] The axillary approach was first performed by Accardo and Adriano in 1949.[8] On subsequent days, regional blocks have been performed using nerve stimulation, anatomical landmarks and of fascia clicks. Blind blocks that rely solely on anatomical landmarks are known to produce serious complications. Even the nerve stimulation technique, recommended as the gold standard for nerve identification in regional blocks over the past decade fails to ensure an adequate level of nerve block. It also carries a risk of damage to nerve structures by direct puncture.[9] Ultrasound visualization of anatomical structures offers safe block of superior quality by optimal needle positioning. La Grange et al. in 1978 were the first to perform the supraclavicular block through ultrasound blood flow detector.[10] Kapral et al., in 1994, published the first reported use of direct sonographic visualization for regional anesthesia.[11] However, dramatic progress has been made over the past 10 years.

Aim
This study aims to compare ultrasound-guided supraclavicular block using bupivacaine or levobupivacaine in patients undergoing elective upper limb surgery.

MATERIALS AND METHODS
A prospective, randomized study conducted on 60 ASA PS I and II presenting for elective upper limb surgeries under supraclavicular block that fulfill the inclusion criteria were divided into two groups: Group-A: Pre-operative ultrasound-guided supraclavicular block with 0.5% bupivacaine (0.4 ml/kg) and Group-B: Pre-operative ultrasound-guided supraclavicular block with 0.5% levobupivacaine (0.4 ml/kg). Systolic blood pressure, diastolic blood pressure, mean arterial pressure, and heart rate changes during intraoperative period were recorded. Onset and duration of sensory, motor blockade, and post-operative opioid requirements were recorded.

RESULTS
A total of 60 patients were included in this study, 30 patients in each group. There was no statistical difference in the age, gender, and BMI. 21 in bupivacaine group and 23 in levobupivacaine group are ASA status 1 and others in ASA status 2. There is no difference observed between both groups in pulse rate, blood pressure, and mean arterial pressure. Onset of sensory block in bupivacaine group was 7.41 ± 2.58 min and in levobupivacaine group was 6.52 ± 1.68 min which is statistically insignificant Figure 1. Onset of motor block in bupivacaine group was 10.37 ± 2.82 min and in levobupivacaine group was 9.41 ± 2.18 min which is statistically insignificant. Duration of sensory block in bupivacaine group was 591.11 ± 109.06 min and in levobupivacaine group was 746.90 ± 98.64 min (26.35%) more in the levobupivacaine group compared to the bupivacaine - by 155.79 min which is statistically significant \( P = 0.008 \) Figure 2. Duration of motor block is increased to 672.62 ± 89.43 min in comparison with bupivacaine which takes 534.44 ± 110.71 min (26.98%) more in the levobupivacaine group compared to the bupivacaine group by 114.18 min which is statistically significant \( P = 0.02 \) Figure 3. There was no complication in both groups during the study. Levobupivacaine group was successful in 19 out of 20 cases and in the bupivacaine group was successful in 18 out of 20 cases (2 cases of bupivacaine group and 1 case of levobupivacaine group have considered unsatisfactory block and there was no failure case Table 1).

DISCUSSION
Peripheral nerve block is a well-accepted modality to achieve clinical and economic benefits to patients in the perioperative period. The benefits include intraoperative surgical anesthesia, post-operative analgesia, and avoid general anesthetic complications. Brachial plexus block provides ideal anesthetic technique for upper limb surgeries. It was first described by Kulenkampff in 1911.[5] The use of this block has tempered by some technical complications. However, interest in supraclavicular block has been rekindled by ultrasonography. It localizes the brachial plexus structures, shows the local anesthetic distribution, and minimizes the usual technical complications. Even though we had ideal technique to block the brachial plexus, the ideal local anesthesia devoid of any toxicity is still on quest. Racemic bupivacaine is widely used local anesthetic agent for brachial plexus block.[12] However, high dosage or any inadvertent intravascular injection may cause fatalities through cardiovascular 10 and central nervous system toxicity.[13,14] These toxic effects attributed mainly from dextroenantiomer of R(+)-bupivacaine.[13,15] Hence, the another enantiomer of levorotatory form of S(+) bupivacaine has less toxic effects. Hence, it emerged as safer alternative with similar clinical profile as racemic bupivacaine. Levobupivacaine has less tendency to cause cardiac toxicity due to dextroenantiomer R(+) bupivacaine has 2.4 times higher affinity for cardiac sodium channels and dissociates it from slowly than levorotatory

<table>
<thead>
<tr>
<th>Table 1: Distribution of Quality of block</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of block</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>Bupivacaine</td>
</tr>
<tr>
<td>Levobupivacaine</td>
</tr>
</tbody>
</table>
Plasma protein binding of levobupivacaine is >97%, whereas bupivacaine is 95% which means availability of drug is less in levobupivacaine (<3%) to cause undesired toxic effects.\cite{14,17} Levobupivacaine has inherent vasoconstrictor activity which gives prolonged duration of action and less systemic toxicity. Aps Reynolds study demonstrated this postulation\cite{18}. Numerous studies have been done to evaluate the efficiency of levobupivacaine as anesthetic agent in respect to onset time, duration, and analgesic qualities of brachial plexus.\cite{18}

In the study by Sardesai \textit{et al.}, the onset of sensory block was faster in levobupivacaine group (6.13 ± 0.34 min) than bupivacaine group (7.59 ± 1.43). In the study by Cox \textit{et al.}, the onset of sensory block was faster in levobupivacaine group (6 min) than bupivacaine (8 min). In the present study, the onset of sensory block is faster in levobupivacaine group (6.52 ± 1.68) than bupivacaine group (7.41 ± 2.58) and \( P = 0.1358 \) so the difference is statistically insignificant.\cite{18,19}

In the study by Shalini \textit{et al.}, the onset of motor block was faster in levobupivacaine group (5.05 ± 0.29) than bupivacaine group (5.99 ± 0.49). In the present study, the onset of motor block is faster in levobupivacaine group (9.41 ± 2.18) than bupivacaine group (10.37 ± 2.82) and \( P = 0.1637 \) so the difference is statistically insignificant.\cite{19}

In the study by Shalini \textit{et al.}, the onset of motor block was faster in levobupivacaine group (1036.57 ± 93.7) than bupivacaine group (871.48 ± 174.33). In the present study, the onset of sensory block in levobupivacaine group (746.90 ± 98.64) is faster than bupivacaine group (591.11 ± 109.06) and the difference is statistically significant.\cite{19}

In the study by Shalini \textit{et al.}, the onset of motor block was faster in levobupivacaine group (1049.46 ± 95.02) than bupivacaine group (902.37 ± 181.46). In the present study, the onset of motor block in levobupivacaine group (678.62 ± 89.43) is faster than bupivacaine group (534.44 ± 110.71) and the difference is statistically significant.\cite{19}

In the present study, blocks with levobupivacaine group were successful in 19 out of 20 cases and in the bupivacaine group were successful in 18 out of 20 cases (2 cases of bupivacaine group and 1 case of levobupivacaine group have considered unsatisfactory block and there was no failure case). The difference is statistically insignificant.

**CONCLUSION**

From the study, it can be inferred that levobupivacaine is longer acting than bupivacaine and its clinical profile closely resembles to bupivacaine. Safe outcome from anesthesia is the main goal for anesthesiologist so the reduced toxic potential of this drug should be considered for regional anesthesia wherever large volume is required.

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Transarterial Embolization of Renal Vascular Lesions after Percutaneous Nephrolithotomy

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Abstract

Introduction: Percutaneous nephrolithotomy (PCNL) is a safe and effective procedure in the surgical management of renal stone disease. Hematuria is one of the most common complications following PCNL. In most cases, the bleeding is self-limited and do not require surgical intervention. Renal arteriography with selective angiographic embolization is required in patients with massive hemorrhage or continuous hematuria. Our aim was to evaluate the effectiveness of percutaneous transarterial embolization for the treatment of renal pseudoaneurysms following post-PCNL bleeding.

Materials and Methods: A total of 852 patients who underwent PCNL for renal calculus, between March 2014 and October 2017 and included 12 patients who had undergone renal embolization due to significant post-PCNL renal artery bleeding. The site, number, and type of bleeding lesions, and the result of the embolization procedure were recorded. We report on the incidence, treatment, radiological and clinical results of these serious vascular injuries at our institution.

Results: Our study has included a large group of patients, the 100% angiographic success rate confirming that percutaneous transcatheter embolization is a valuable treatment for most renal vascular injuries. Renal angiography revealed pseudoaneurysm in 10 patients, arteriovenous fistula in 1, and arterial laceration in 1 patients. Significant risk factors on univariate analysis for severe hematuria requiring superselective angiography were multiple/staghorn calculi, upper calix puncture, and history of pyelonephritis. The severity of the hematuria after PCNL is influenced by many factors, including mean stone size and mean operative time, and is correlated with duration of hospitalization and mean hemoglobin drop.

Conclusions: Percutaneous transarterial embolization of the injured vessel is an effective, minimally invasive and relatively easy procedure in experienced centers, with a high rate of success and immediate benefits, thus saving the patient from the morbidity that result from severe renal bleeding.

Key words: Angioembolization, Post-PCNL bleeding, Renal pseudoaneurysms

INTRODUCTION

Percutaneous nephrolithotomy (PCNL) is a safe and effective Minimally invasive procedure for the renal stone disease. Nevertheless, surgeons have to face specific complications during and after the procedure, hemorrhage being one of the most common, with a reported incidence that varies between 0.8% and 7.6%. Usually, renal injuries are self-limited and conservative measures are adequate to control bleeding in most of the cases. Renal arteriography with selective or over selective angiographic embolization is needed in patients with massive hemorrhage or continuous hematuria, while nephrectomy is reserved only for the cases in which the minimally invasive endovascular treatment fails. The purpose of this study is to review the severe hemorrhagic complications that are associated with PCNL and to prove the efficacy of endoluminal management in taking control of them. We report on the incidence, treatment, radiological and clinical results of these serious vascular injuries at our institution.

MATERIALS AND METHODS

The data from all 852 patients undergoing PCNL for removal of renal calculi between March 2014 and October
2017 were retrospectively reviewed. A number of 102 hemorrhagic complications were observed, but only 12 patients (1.4%) had significant bleeding that required angiography and embolization for bleeding control. Hemogram, coagulation profile, serum electrolytes, glucose, serum creatinine levels, urinalysis and urine culture, liver function tests, ultrasonography, and computed tomography (CT) were performed before the patients underwent PCNL. Our operative technique involved percutaneous puncture under multidirectional C-arm fluoroscopic guidance, dilation of the nephrostomy track up to 30F, and use of an Amplatz sheath. Smaller stones were removed with the help of forceps, larger ones being crushed with pneumatic lithotripsy before extraction. For all patients, we have used “tubeless” PCNL, in which the nephrostomy tube was replaced with internal drainage provided by a double-J stent or a ureteral catheter. After informed consent was obtained and digital subtraction angiography confirmed the diagnosis of pseudoaneurysm (PA) or arteriovenous fistula (AVF), percutaneous embolization was performed by our interventional radiologist. For the DSA procedure, the left brachial or right main femoral artery was punctured under local anesthesia using Seldinger technique and a 6F vascular sheath was inserted as an introducer. Over a 0.035-inch diameter guidewire, an abdominal aortography was obtained with a 5F Cobra catheter (Cordis, Johnson and Johnson, Miami, USA) by injecting a 8–10 ml contrast media, which shows the main or accessory renal arteries on either side. Thereafter, a selective renal DSA was performed by advancing the catheter into the injured branch of the renal artery feeding the lesion. Rapid filming sequences and careful examination of all phases of the arteriogram are necessary to assess the site and feeding pedicle, flow pattern, and venous drainage of the vascular lesion. In 8 cases in which the lesion was at or near a segmental branch, we used a 4F catheter for selective catheterization and embolization; while in the remaining 8 patients the location of the injury at a subsegmental branch necessitated the use of a superselective microcatheter (Progreat, Terumo). The catheters were inserted as near as possible to the lesion, and the embolizing agent inserted. Pushable fibered coils (VortX, Boston Scientific), 3–5 mm diameter, were deployed for superselective vascular occlusion (10 patients), the number and size of them being adapted to the lesion size. Microparticles (MCP) (Embozene, CeloNova Biosciences), 1100–1300 μi, or Amplatzer vascular plugs (AVP II, AGA Medical) were applied in 2 patients in whom the lesion could not be superselective catheterized. A combination of coils and MCP was necessary in 4 patients. The procedure was completed when total occlusion of the lesion and cessation of the hemorrhage on the control angiogram was seen. After institutional review board approval, we extracted from the patient medical charts and examined in relation to bleeding the following variables: Patient characteristics, renal function prior and after embolization, hemoglobin concentration and requirement of blood transfusion, timing of embolization, intraoperative variables, interventional radiology procedure details, and outcomes. Data were analyzed using MedCalc for Windows, version 11.6.1.0, MedCalc Software, Mariakerke, Belgium. Quantitative variables were provided as mean ± standard deviation and compared by independent samples t-test, $P < 0.05$ being considered statistically significant.

**RESULTS**

Of the 852 PCNL procedures, 10 patients (1.25%), 7 males and 3 females, aged 28–69 years (mean, 52.8), required superselective renal angiography due to severe/persistent hematuria from the right (6 cases) or left kidney (4 cases). As the first imaging modality, DSA was used in 6 patients, while remaining 6 patients underwent USG/CT (PLAIN) renal CT angiogram. Indications for renal DSA were severe hematuria with hemodynamic instability associated with important decrease of the hemoglobin and hematocrit values during the first 24 h after surgery (3 patients); frank renal hemorrhage necessitating blood transfusion in the early post-operative period, 2–14 days after PCNL (8 patients); and sudden hemorrhage more than 14 days postoperatively (4 patients). The severity of the hematuria after PCNL is influenced by many factors, including mean stone size and mean operative time, and is correlated with duration of hospitalization and mean hemoglobin drop. All patients had a normal coagulation profile before surgery. Patients’ blood loss, need for transfusion and number of units transfused according to the moment of the post-PCNL bleeding debut. Hematuria in the early post-operative period required a mean of 2.88 ± 1.49 U of blood transfused in addition to replacement of the intraoperative blood loss. The mean interval between the debut of hematuria and embolization was 5.33 ± 0.47 h for patients with severe hematuria during the first 24 h after surgery, 156.72 ± 41.76 h for gross renal hemorrhage in the early post-operative period, and 15.6 ± 1.69 h for those with tardive post-PCNL bleeding. Significant risk factors on univariate analysis for severe hematuria requiring superselective angiography were multiple/staghorn calculi, upper calix puncture, and history of pyelonephritis.[Table 1] After successful embolization no patient required transfusion, and no further deterioration of renal function was observed. Renal angiography revealed PA [Figure 1] in 10 patients, AVF in 1, and arterial laceration in 1 patients. In one patient, we observed the presence of 2 PA, filled from different subsegmental arteries that were successively catheterized and occluded with coils [Figure 2]. Bleeding was controlled with superselective angiography and embolization.
Chandru, et al.: Post-PCNL Bleeding-Renal Angioembolization

Table 1: Risk Factors for Hematuria Requires Angiography

<table>
<thead>
<tr>
<th>Characters</th>
<th>Mild to moderate hematuria</th>
<th>Hematuria requires angiography</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper calyceal puncture</td>
<td>35</td>
<td>4</td>
<td>0.032</td>
</tr>
<tr>
<td>Multiple tracts</td>
<td>30</td>
<td>5</td>
<td>0.021</td>
</tr>
<tr>
<td>Renal failure</td>
<td>25</td>
<td>6</td>
<td>0.020</td>
</tr>
<tr>
<td>UTI</td>
<td>89</td>
<td>8</td>
<td>0.011</td>
</tr>
</tbody>
</table>

As the kidney is an extremely vascular organ, blood loss is a normal feature of PCNL, necessitating transfusion in 3–23% of cases. Excessive bleeding usually arises from injury of the segmental arteries, which are surrounded by dense parenchyma and, thus, easier to tampon with the nephrostomy sheath or tube. The bleeding may occur during renal puncture, Amplatz tract dilatation, manipulation of the nephroscope, or in the post-operative period. The arterial system is an increased pressure one, which means that the risk of an AVF (blood passage from the high pressure of the injured artery to the injured adjacent vein) or a PA (blood passage to the parenchyma) is high. Venous bleeding can usually be managed conservatively with tamponade nephrostomy tubes, whereas severe arterial bleeding requires selective angiographic embolization (range 0.3–1.4%). The transfusion and embolization rates in our series were comparable to these ranges (15.5% and 1.05%, respectively). US, multidetector spiral CT and magnetic resonance angiography (MRA) may detect vascular renal lesions and offers information about lesion site, type, and flow pattern, while angiography remains the gold standard procedure, capable to provide endovascular treatment during the same imaging session. Duplex ultrasound may be used initially to detect clinically suspected PA, the images showing sonolucent lesions with turbulent flow. Ultrasound with color Doppler assessment could suggest AVF in the presence of a focal flurry of disorganized color.
beyond the vessel lumen thought to be due to vibration of the tissue surrounding the fistula. The feeding artery will demonstrate a high-velocity, low-resistance waveform and the draining vein may show pulsatile, arterialized flow. In this study, DSA was performed as first imaging method in 6 patients with ongoing hematuria, who required transfer to the angiography unit as soon as possible. However, in 6 patients with irregular or intermittent bleeding, US and CT exam provided important clues for the diagnosis and influenced interventional treatment decisions. In patients with decreased renal function, we have avoided CT exam due to the risk of contrast-induced nephropathy. We have also excluded the possibility of performing a MRA exam since it can be associated with the risk of developing cutaneous changes of nephrogenic systemic fibrosis after exposure to gadolinium-containing contrast. Our study has included a large group of patients, the 95.45% angiographic success rate confirming that percutaneous transcatheter embolization is a valuable treatment for most renal vascular injuries. The majority number, 72.72% (8/12), of massive bleeding episodes occurred in the early post-operative period (2–14 days after PCNL). The decision to transfer the patient to an interventional radiology department is delayed in most of the cases by the intermittent character of the bleedings. Optimal monitoring of hemoglobin and hematocrit values, together with quantity of transfused units evaluation, represent an indicator of the moment when selective angiography should be used. A particular situation is represented by the cases with severe bleeding, hemodynamic instability, and a significant decrease of hemoglobin value in the 1st h after the surgery (an average of 4.33 g/dL), that require immediate investigation and treatment (5.33 ± 0.47 h). We have registered 1 AVF forming as a late complication, confirming the results of Gavant et al. that have reported bleeding as late as 13 weeks after PCNL. We performed a comparison between patients with mild, moderate and severe post-PCNL hematuria and found statistically significant differences in terms of number of blood unit transfused (P = 0.0001), mean hemoglobin drop (P = 0.0001), and duration of hospitalization (P = 0.0001). The patients with severe post-PCNL hematuria had a statistically significant difference in stone size (P = 0.018) and mean operative time (P = 0.0023) when compared with mild hematuria patients, but no difference was observed with regard to moderate hematuria ones. This phenomenon implies that excessive manipulation of the rigid nephroscope to access stones in different calices should be avoided, especially in the group with massive bleeding and increased intraoperative blood transfusion. Our results and those of Srivastava et al. stated that stone size significantly predicted severe vascular lesions after PCNL, while Lam et al. reported that we can decrease the transfusion rate with the use of a flexible nephroscope and by improving the operator skills. The incidence of chronic renal failure between the three groups was similar. The number of renal punctures was not correlated with the degree of hematuria, contradicting the assumption that minimizing the number of needle punctures is a key factor in preventing excessive blood loss and sustaining the results of Kessaris et al. Multiple/staghorn stones, upper calix puncture, and history of pyelonephritis, significantly predicted severe vascular lesions after PCNL. However, in this study, the data were collected retrospectively and, therefore, the influence of some factors could not be tested or are subject to bias. Ideally, a multicenter, randomized, prospective study comparing post-PCNL renal hemorrhage treated with embolization, surgery or conservative management would define the most effective treatment modality. The choice of the embolization material is important to achieve good results and depends on the accessibility, size and the flow pattern of the vessels to be occluded. Platinum microcoils are the most commonly used embolic agents because of their accuracy and radiopacity, designed to provide complete vascular occlusion. The main disadvantage was represented by the use of more than one coil in 5 patients for adequate occlusion, which increased the cost and time of the procedure. The microspheres are designed to regain their original shape and volume after passage through the catheter, and represent a versatile embolic platform with superior biocompatibility and structural integrity that provides a tightly calibrated sizing system designed for targeted embolization. The Amplatzer Vascular plug II’s unique design significantly reduces the time to occlusion for transcatheter embolization procedures and can be used to occlude larger vessels that would previously have required numerous coils for occlusion.

CONCLUSION

PCNL is currently the procedure of choice for removal of large renal calculi. Percutaneous transarterial embolization of the injured vessel is an effective, minimally invasive and relatively easy procedure in experienced centers, with high rate of success and immediate benefits, thus saving the patient from the morbidity that result from severe renal bleeding. The variations of hemoglobin, together with the quantity of transfused units represent the indicator and decide the moment when selective angiography should be used. By shortening the period between the complication diagnostic and the endovascular treatment the number of hospitalization days could be reduced.

REFERENCES

Comparative Evaluation of Fracture Resistance of Endodontically Treated Teeth with Epoxy Resin-based Sealer AH Plus and Zinc Oxide Eugenol: An In Vitro Study

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Abstract

Introduction: Endodontic treatment while trying to save a tooth reduces the tooth structure which, in turn, reduces the fracture resistance of the tooth. Certain root canal sealers by improving the bond between the root canal filling materials and the tooth structure increase the fracture resistance of the tooth.

Aim: This study aims to evaluate and compare the fracture resistance of endodontically treated teeth obturated with gutta-percha using two sealers, AH Plus and zinc oxide eugenol.

Materials and Methods: A total of 60 single-rooted mandibular premolars, decoronated at cementoenamel junction, were divided into two groups \((n = 30\) each). Cleaning and shaping of root canals were done using ProTaper rotary files and 3% sodium hypochlorite irrigation. Obturation was done using sealers, AH Plus in Group 1 and zinc oxide eugenol in Group 2 and gutta-percha. The teeth were subjected to vertical loading using a universal testing machine, and the readings were recorded at the point at which fracture of the roots occurred.

Results: According to the study, it was found that AH Plus showed better fracture resistance than zinc oxide eugenol. Statistically significant difference was found between the two groups.

Conclusion: AH Plus showed better fracture resistance than zinc oxide eugenol when used as root canal sealer with gutta-percha.

Key words: AH Plus, Root canal sealers, Root fracture zinc oxide eugenol

INTRODUCTION

Endodontic treatment reduces fracture resistance of teeth. The amount of remaining tooth structure plays a key role in the strength of the endodontically treated teeth. When the tooth had vertical root fracture, extraction is the only remaining choice to be done. Vertical root fracture usually had the poor prognosis. Predisposing factors for vertical root fracture are root canal configuration and anatomy, dehydration, caries with extensive tissue loss, trauma, craze lines, and loss of bone support. Iatrogenic factors that lead to vertical root fracture include instrumentation, the effect of irrigation solutions, prolonged use of calcium hydroxide, condensation pressure exerted during obturation, and intracanal post space preparation. By selecting appropriate root canal filling material, we can reinforce the dentin, and hence, increasing the fracture resistance of the tooth.

Glass ionomer cement or composite resins were used to reinforce the endodontically compromised teeth, were better than zinc oxide eugenol cement. Root canal sealers should strongly adhere to dentine, which increases the strength of the restored teeth. Bondable root canal sealers create monoblocks. The use of adhesive root canal obturating material is known as monoblock effect.

The success of endodontically treated teeth depends on the obturation of the root canals. Gutta-percha has been
the most frequently used material for root canal obturation. Resin-based sealers have the advantage of adhesion to the dentinal walls that, in turn, results in less microleakage and some strengthening effect to the teeth. Studies have shown that the bond strength of AH Plus, the epoxy resin-based sealer, was significantly higher than zinc oxide eugenol, glass ionomer, and calcium hydroxide-based sealers.

The purpose of this in vitro study was to compare the fracture resistance of endodontically treated teeth obturated with conventional gutta-percha using epoxy resin-based sealer AH Plus (Dentsply, Germany) and zinc oxide eugenol sealer.

**Aim**

This study aims to evaluate and compare the fracture resistance of endodontically treated teeth obturated with gutta-percha using two sealers, AH Plus and zinc oxide eugenol.

**MATERIALS AND METHODS**

A total of 60 samples, divided into 30 in each group extracted single-rooted mandibular human incisor teeth were selected with their buccolingual, and mesiodistal dimensions were similar. Teeth were immersed in 5% sodium hypochlorite (NaOCl) solution for 2 h for surface disinfection. Pre-operative radiographs were taken to ensure that the collected teeth did not have open apices, calcifications, many canals, and fractures. All teeth were decoronated using a flexible diamond disk in a slow speed handpiece to a standardized length of 12 mm as measured from the apex to the facial cement-enamel junction (CEJ). The teeth were divided into two experimental groups, 30 in each group. Coronal access was made. The working length was determined. Cleaning and shaping of the root canals were completed with ProTaper rotary NiTi files (Dentsply Maillefer, Switzerland) at a speed of 300 rpm. Finally, F1 master cone gutta-percha (Dentsply, Maillefer) was placed into the canal and checked radiographically.

**Grouping method:**

- Group 1: Obturation with gutta-percha and sealer as AH Plus.
- Group 2: Obturation with gutta-percha and sealer as zinc oxide eugenol.

Sealers were mixed according to the manufacturer instructions. Root canals were coated with sealers using Lentulo spirals and obturated using F1 ProTaper gutta-percha points. Post-obturation radiographs were taken for all the experimental root samples. The filled roots were stored in an incubator for 7 days at 37°C with 100% relative humidity to allow the sealer to set completely. Each tooth was mounted vertically to a depth of 2 mm below the CEJ in polystyrene resin block. The universal testing machine was used to test the resistance against vertical root fracture. The amount of force required for fracture was recorded in Newton’s. A load of fracture in Newton’s was converted to megapascals.

The fracture load data were subjected to statistical analysis using SPSS software version 16. Comparisons among the two groups were performed by independent sample t-test. The statistical analysis was performed at 95% confidence level.

**RESULTS**

The number of samples after analyzing the values of all the 60 samples, 30 for each group AH Plus proved to be better than zinc oxide eugenol. The resin sealer AH Plus (27.65) showed higher fracture resistance than zinc oxide eugenol (18.89), the results were statistically significant (P < 0.0001) [Table 1 and Figure 1].

**DISCUSSION**

Endodontic procedures such as access preparation, use of calcium hydroxide as an intracanal medicament, instrumentation, and irrigation with NaOCl and EDTA reduces fracture resistance of endodontically treated teeth. A study concluded that instrumented but unfilled roots are much weaker than filled roots that, in turn, increases fracture.

Finite element analysis study results showed that circular canals have more uniform stress distribution than oval canals. Oval canals have greater stresses present at the labial and lingual canal extensions and the cervical and middle thirds.

**Table 1: Comparison of two groups with respect to fracture resistance in megapascals by independent sample t-test**

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Mean±SD</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>AH plus</td>
<td>30</td>
<td>27.65±2.51</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Zinc oxide eugenol</td>
<td>30</td>
<td>18.89±2.45</td>
<td></td>
</tr>
</tbody>
</table>

SD: Standard deviation

**Figure 1: Comparison of fracture resistance of the two sealers**
The aim of three-dimensional obturation is to attain a fluid tight seal within the root canal system to prevent reinfection and to provide a favorable biological environment for tissue healing. Some studies report that rotary instrumentation increases the risk for craze lines and dentin cracks and reduced root fracture resistance when compared to hand files. When the cleaning and shaping are done up to the root canal length, apical cracks are more likely to appear. It is better to confine shaping 1.0 mm short of the root apex.

Apical enlargement was done with ProTaper F1 in this study. EDTA and sodium hypochlorite were used to remove the smear layer which, in turn, enhances bonding of the materials to the dentinal surface of the roots. The two key factors that improve the fracture resistance of endodontically treated teeth are stable adhesion to root canal dentin walls and an elastic modulus similar to dentin. AH Plus is an epoxy-based endodontic sealer. It can be used with gutta-percha. It comes as a two paste system. It has a working time of 4 h and setting time of 8 h, has good adhesion to dentin and gutta-percha.

Zinc oxide eugenol sealer has a powder base and liquid catalyst. This radiopaque canal sealant is a non-toxic and non-irritating formulation that has a long history of clinical success. Phukan et al. in their study showed that AH Plus had significantly high resistance to fracture than all other tested root canal sealers including zinc oxide eugenol and calcium hydroxide-based sealers.

Mandava et al. in their study concluded that teeth obturated with AH Plus + GP are more resistant to fracture than those obturated with Resilon-Epiphany, with zinc oxide eugenol the least resistance to fracture. AH Plus showed the higher fracture resistance than MetaSEAL and MTA Fillapex.

In the present study, there was a definite statistically significant difference between AH Plus and zinc oxide eugenol sealer in the fracture resistance of endodontically treated teeth. AH Plus sealer showed much higher fracture resistance of endodontically treated teeth than the zinc oxide eugenol sealer.

**CONCLUSION**

The bonding of endodontic sealers to intraradicular dentin after obturation might enhance the resistance to fracture of endodontically treated teeth. Within the limitations of the present study, it can be concluded that AH Plus showed higher fracture resistance than zinc oxide eugenol sealers. The results were statistically significant ($P<0.0001$).

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A Study of Canal Wall down Mastoidectomy with Soft-wall Reconstruction

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Abstract

Introduction: CSOM is a common clinical disease seen in an outpatient setting which causes social disability due to accompanying hearing loss. Treatment may be medical or surgical but aims to limit the disease and improve hearing loss.

Aim: Aim of this study is to evaluate the outcome of canal wall down (CWD) mastoidectomy with soft-wall reconstruction using cartilage in an unsafe ear.

Method: Prospective study conducted in 38 patients who had the atticotrance disease (cholesteatoma and granulations in attic). Clinical examination, pure tone audiogram was done before and after surgery.

Results: Of 38 patients 84% had significant hearing improvement following surgery. After surgery, 79% showed well-healed ear with 10% showing no significant hearing outcome. 8% had ear discharge after surgery while 2% showed recurrence.

Conclusion: Early identification of cholesteatoma and intervention with soft-wall reconstruction lead to auditory and cosmetic improvement.

Key words: Canal wall down mastoidectomy, Cholesteatoma, CSOM, Soft-wall reconstruction

INTRODUCTION

Chronic otitis media is a common clinical ailment that affects people. Acute or recurrent infections of the middle ear may result in permanent perforation of the tympanic membrane and irreversible inflammatory changes within mastoid and middle ear known as chronic otomastoiditis. CSOM can be classified as mucosal and squamous type.[1,2] Mucosal is perforation of pars tensa with or without inflammation of middle ear mucosa whereas Squamous is a retraction of pars flaccida or tensa with or without retained squamous debris associated with inflammation of adjacent mucosa. Further, it can be classified as active and inactive types.

Aural cholesteatoma is epidermal inclusion cysts of the middle ear or mastoid and can be classified as congenital or acquired. Expansion of cholesteatoma results in erosion of surrounding structures leading to local and intracranial complications.[3] Cholesteatoma can be eradicated only by surgical resection. Canal wall up mastoidectomy maintains an intact posterior canal wall. Disease exposure is more difficult when the canal wall is left intact. Leaving a small focus of squamous epithelium behind is possible. Maintenance of the canal wall also provides potential spaces into which retraction pockets can form.[4,5] The resulting increased incidence of residual or recurrent cholesteatoma is not trivial. The canal wall down mastoidectomy involves complete removal of the mastoid air cells, aggressive saucerization of the cortical edges of the mastoid, complete removal of the superior and posterior canal walls, and a wide meatoplasty. The advantages of canal wall down (CWD) mastoidectomy include excellent exposure for disease eradication and post-operative monitoring and low rates of residual and recurrent disease. However, the disadvantages of CWD mastoidectomy include cavity problems, such as continuous

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ear drainage, accumulation of keratin debris, caloric induced vertigo, and difficulty in fitting a hearing aid.\textsuperscript{[6,7]}

**Aim**

The aim of the study was to evaluate the outcome in CWD mastoidectomy with posterior canal wall reconstruction using cartilage.

**MATERIALS AND METHODS**

This prospective study conducted in the Department of Otorhinolaryngology, Tirunelveli Medical College Hospital, Tirunelveli. Inclusion criteria: Chronic suppurative otitis media, atticotympanic pathology, retraction/perforation, posterosuperior marginal pathology, retraction/perforation, cholesteatoma or granulations, and secondary acquired cholesteatoma. Exclusion criteria: Chronic otitis media without cholesteatoma, acute otitis media with coalescent mastoiditis, persistent secretry otitis media, CSOM-tubotympanic type, and CSOM with intracranial complications. All selected patients had a detailed history taken based on the pro forma. They underwent thorough general and systemic examination. Complete ear nose and throat examination was done. Ears were examined by otoscopy and otoendoscopy to confirm pre-operative diagnosis of unsafe ear and to evaluate post-operative outcome. Pure tone audiogram was done preoperatively and postoperatively to assess the hearing outcome. Blood investigations, aural culture and sensitivity, X-ray mastoid, and computed tomography temporal bone were taken for pre-operative evaluation. Complications were documented. Patients were counseled about 3rd and 6th-month follow-up.

**RESULTS**

Our study group comprised 38 subjects. Only patients who had squamosal active disease were managed surgically and post-operative hearing outcome assessed. Higher predominance in males in the younger age group 0–20 years and higher incidence in females in the middle age group 20–40 years was observed Tables 1 and 2. 25 clients had moderate to severe HL Table 3, and 13 clients had Mod HL. 28 Clients presented with cholesteatoma while 10 had associated granulations Table 4. Conchal cartilage was utilized in 30 clients and nasal cartilage in 8 Table 5. There was a significant post-operative auditory improvement Table 6. Majority of clients had drastic improvement with complications occurring in a few Tables 7 and 8.

**DISCUSSION**

Conchal and septal cartilages were used for reconstruction. Pre-operative audiogram done showed moderately severe HL in 65.7% of patients and moderate HL in 34% of patients. 73% of patients had cholesteatoma, and 27% had granulations along with cholesteatoma. Patients who had florid granulations were found to have poor outcome postoperatively. Conchal cartilage and septal cartilage were used in 78% and 28%, respectively. However, no significant difference in outcome was noted between both groups. All patients were followed up for a total period of 6 months. The post-operative audiological assessment was done at 3rd and 6th-month of review. Complications were looked for at 3rd and 6th-month. 84% had statistically significant auditory improvement while 11% had no significant change in hearing. 5% had worse hearing. Complications taken into account were discharging ear, recurrence and worsened hearing. 79% had dry, disease-free mastoid cavity with significant audiological improvement. Patients who had excessive disease had more chances of complications. Ear discharge was seen in 8% of cases. Recurrences were as low as 2%. No change or worse hearing was seen in 10% of subjects. Soft canal wall reconstruction seems to be effective as the disease is cleared from the mastoid cavity by CWD followed by reconstruction of canal wall. However, long-term outcome needs to be addressed. Till 6 months post-operative patients who underwent surgery showed no retraction pockets had good hearing and minimum complications. In a study by Black and Kelly,\textsuperscript{[8]} The authors used autograft conchal cartilage, hydroxyapatite

<p>| Table 1: Distribution of study patients in age group |</p>
<table>
<thead>
<tr>
<th>Age in years</th>
<th>Number of patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0–20</td>
<td>14 (36.84)</td>
</tr>
<tr>
<td>20–40</td>
<td>13 (34.21)</td>
</tr>
<tr>
<td>40–60</td>
<td>9 (23.68)</td>
</tr>
<tr>
<td>&gt;60</td>
<td>2 (5.2)</td>
</tr>
</tbody>
</table>

<p>| Table 2: Distribution of study patients in gender |</p>
<table>
<thead>
<tr>
<th>Sex</th>
<th>Number of patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>17 (44.73)</td>
</tr>
<tr>
<td>Female</td>
<td>21 (55.26)</td>
</tr>
</tbody>
</table>

<p>| Table 3: Distribution of study patient's pre-operative hearing loss |</p>
<table>
<thead>
<tr>
<th>Hearing loss</th>
<th>Number of patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderate to severe HL</td>
<td>25 (65.78)</td>
</tr>
<tr>
<td>Moderate hearing loss</td>
<td>13 (34.21)</td>
</tr>
</tbody>
</table>

<p>| Table 4: Distribution of study patient's pre-operative findings |</p>
<table>
<thead>
<tr>
<th>Disease</th>
<th>Number of patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cholesteatoma</td>
<td>28 (73.68)</td>
</tr>
<tr>
<td>Cholesteatoma with granulations</td>
<td>10 (26.31)</td>
</tr>
</tbody>
</table>
granulate for cavity obliteration. 25 cases analyzed showed an airborne gap of <30 db can be reached in more than 70%. In our study, 84% showed improvement of 8–10 db in hearing with pre-operative AB gap of 38 ± 10 db and post-operative AB gap of 28 ± 10db. 11% showed no change and 5% showed deterioration. P value was found to be statistically significant (<0.0001). Saunders 53 and associates compared the results of posterior canal wall skin with temporalis fascia to anterior based musculoperiosteal flap and found no significant differences in both groups in the long term. In our study, conchal cartilage and septal cartilage were used. 79% showed marked improvement. No significant difference was noted in the outcome with the use of different cartilage materials. Smith et al[9] reconstructed using an autogenous, bilaminar membrane. The resulting air-filled mastoid cavity is an anatomic extension of the middle ear cleft and is separated from the ear canal by a functional barrier that is continuous with the tympanic membrane. Compared to other methods the semitransparent nature allows inspection of the underlying cavity for residual or recurrent disease. In 30 cases long-term functional results in these cases remain satisfactory. In our study, opaque nature of cartilage restricted from visualizing the mastoid cavity, but post-operative recurrence and ear discharge were 3% and 8%, respectively. In a study by Hosoi et al[10] soft-wall reconstruction followed by gel foam, fibrin glue was done with good cavity results and minimum retraction pockets. Our study uses cartilage, and no obvious retraction pockets were identified. In a study by Ishimoto et al[11] seven patients after radical mastoidectomy with tragal cartilage fashioned for tympanic membrane and conchal cartilage for the posterior wall of EAC were followed up for 4 years postoperatively. 6 patients had dry ears with no post-operative complications with no hearing improvement. In our study, 79% had well-healed ears with worse hearing in 10%. In a study by Lee et al[12] reconstruction using free-floating cartilages and double musculoperiosteal flaps. Air conduction thresholds were statistically improved (P = 0.008). The air-bone gap was significantly reduced following surgery (P = 0.001). There were no other major complications in any of the patients. Long-term follow-up demonstrated gradual widening of the neo-EAC in 18 patients. In our study air-bone gap reduced significantly. In a study by Ravishankar and Datta,[13] studied staged reconstruction and concurrent reconstruction and found that hearing improvement was same in both types. Disease severity decided the treatment modality. In our study, middle ear reconstruction was done according to the middle ear finding along with posterior wall reconstruction with good auditory improvement.

**CONCLUSION**

CWD mastoidectomy with posterior canal wall reconstruction is a better option in unsafe ear in our study. This technique has the advantage of complete disease clearances we do the CWD technique. As we also reconstruct the posterior canal wall, the incidence of complications decreases and the better hearing outcome is achieved. Long-term follow-up is needed to assess the long-term complications.

**REFERENCES**

7. Kurien G, Greeff K, Gomaa N, Ho A. Mastoidectomy and mastoid...


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Relationship Between Cholesterol and Gallstones, is There Really a Link? A Review of 80 Cases

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¹Associate Professor, Department of General Surgery, Sri Ramachandra Medical College and Research Institute, Chennai, Tamil Nadu, India, ²Junior Resident, Department of General Surgery, Sri Ramachandra Medical College and Research Institute, Chennai, Tamil Nadu, India, ³Assistant Professor, Department of General Surgery, Sri Ramachandra Medical College and Research Institute, Chennai, Tamil Nadu, India

Abstract

Background: Cholelithiasis or gallstones and symptomatic or incidental forms a major chunk of general surgical outpatient population, with laparoscopic cholecystectomy being a very commonly done procedure. Many risk factors have been associated with the development of gallstones. The authors study a possible link between gallstones and levels of the different components of cholesterol.

Objective: This study aims to identify and establish a positive link between gallstones and cholesterol by analyzing of lipid profile.

Materials and Methods: This is a prospective study done from October 2015 to August 2017 and included 80 patients with cholelithiasis or choledocholithiasis diagnosed through radiological studies. Fasting lipid profiles were done for all of them.

Results: A total of 80 patients were evaluated in this study. 12 patients had hypercholesterolemia contributing to 15% of the study population, equivalent to similar studies on general population. 23 patients (28.7%) had high triglyceride levels, equivalent to general population prevalence. 79/80 patients had a low high-density lipoproteins (HDLs), much higher than general prevalence of 72.3%, showing a strong correlation between gallstones and decreased HDL levels. 35/80 had high levels of low-density lipoproteins (LDLs) (43.8%), compared to national level 11.8%, showing a strong correlation between gallstones and increased LDL.

Conclusion: With the above data, it was surprisingly proved that low HDL levels and high LDL levels played a more important role in the formation of gallstones. This is of more importance because serum LDL and HDL levels can be controlled by change of lifestyle and dietary patterns.

Key words: Cholelithiasis, Cholesterol, High-density lipoprotein, Low-density lipoprotein

INTRODUCTION

Cholelithiasis or gallstones and symptomatic or incidental forms a major chunk of general surgical outpatient population, with laparoscopic cholecystectomy being a very commonly done procedure. Gallstones are broadly classified into pigmented, cholesterol, and mixed stones. Cholesterol gallstones develop when bile contains too much cholesterol and not enough bile salts. We here, study possible link between gallstones and levels of the different components of cholesterol.

Objective

This study aims to identify and establish a positive link between gallstones and cholesterol by analysis of lipid profile in patients with established gallstone disease.

MATERIALS AND METHODS

Prospective study was done from October 2015 to August 2017.

Inclusion Criteria

Patients above the age of 18, both sexes, with cholelithiasis or choledocholithiasis diagnosed through radiological studies.

Exclusion Criteria

Patients with carcinoma gallbladder or on current anticholesterol medication were excluded from the study.
Fasting lipid profiles were done for all of them with the following normalized values of serum cholesterol levels 0–200 mg/dL, serum triglycerides 0–150 mg/dL, serum high-density lipoproteins (HDLs) 60–85 mg/dL, and serum low-density lipoproteins (LDLs) 0–100 mg/dL.

**RESULTS**

A total of 68 patients had serum cholesterol within normal limits and 12 high levels of serum cholesterol were identified. It accounts to 85% and 15%, respectively. The results were compared to an ICMR study regarding prevalence of dyslipidemia in India [Table 1].

A Chi-square test [Table 2] was done with comparison to the prevalence of dyslipidemia in urban and rural India: The ICMR–INDIAB study.\(^2\)

It was found not to be statistically significant (\(P > 0.01\)).

Fasting lipid profile was sent in 80 patients with cholelithiasis, of which serum triglycerides levels with parameters 0–150 mg/dL were considered normal and >150 mg/dL high or hypertriglyceridemia serum triglycerides in 57 patients were within normal limits and 23 patients with high serum triglycerides were identified. It accounts to 71.3% and 28.7%, respectively [Table 3].

A Chi-square test [Table 4] was done with comparison to the prevalence of dyslipidemia in urban and rural India: The ICMR–INDIAB study.\(^2\)

It was found not to be statistically significant (\(P > 0.01\)).

Serum HDL levels with parameters 60–85 mg/dL were considered normal and <60 mg/dL low or >85 mg/dL high.

A total of 80 patients were tested and 1 was within normal limits and 79 low levels of serum HDL were identified. It accounts to 1.3%, 98.7%, and 0%, respectively [Table 5].

A Chi-square test [Table 6] was done with comparison to the prevalence of dyslipidemia in urban and rural India: The ICMR–INDIAB study.\(^2\)

It was found to be statistically significant (\(P < 0.01\)).

Serum LDL levels between 0 and 100 mg/dL were considered normal and >100 mg/dL high.

A total of 80 patients were tested, 45 patients were within normal limits, and 35 high levels of serum LDL were identified. It accounts to 56.3% and 43.7%, respectively [Table 7].

---

**Table 1: Number of patients with gallstones and hypercholesterolemia**

<table>
<thead>
<tr>
<th></th>
<th>80 patients</th>
<th>Frequency</th>
<th>Valid percent</th>
<th>Cumulative percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>68</td>
<td>85.0</td>
<td>85.0</td>
<td></td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>12</td>
<td>15.0</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>80</td>
<td>100.0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 2: Cholesterol in cholelithiasis and general population**

<table>
<thead>
<tr>
<th>Cholesterol in cholelithiasis and general population</th>
<th>Observed N</th>
<th>Expected N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>12</td>
<td>283</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>68</td>
<td>1759</td>
</tr>
<tr>
<td>Total</td>
<td>80</td>
<td>2042</td>
</tr>
</tbody>
</table>

**Table 3: Number of patients with triglyceridemia**

<table>
<thead>
<tr>
<th></th>
<th>80 patients</th>
<th>Frequency</th>
<th>Valid percent</th>
<th>Cumulative percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>57</td>
<td>71.3</td>
<td>71.3</td>
<td></td>
</tr>
<tr>
<td>Hypertriglyceridemia</td>
<td>23</td>
<td>28.7</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>80</td>
<td>100.0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 4: Triglycerides in cholelithiasis and general population**

<table>
<thead>
<tr>
<th>Triglycerides in cholelithiasis and general population</th>
<th>Observed N</th>
<th>Expected N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>57</td>
<td>1440</td>
</tr>
<tr>
<td>High</td>
<td>23</td>
<td>602</td>
</tr>
<tr>
<td>Total</td>
<td>80</td>
<td>2042</td>
</tr>
</tbody>
</table>

**Table 5: Distribution of patients with regard to HDL levels**

<table>
<thead>
<tr>
<th></th>
<th>80 patients</th>
<th>Frequency</th>
<th>Valid percent</th>
<th>Cumulative percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>79</td>
<td>98.7</td>
<td>98.8</td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>1</td>
<td>1.3</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>80</td>
<td>100.0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 6: HDL in cholelithiasis and general population**

<table>
<thead>
<tr>
<th>HDL in cholelithiasis and general population</th>
<th>Observed N</th>
<th>Expected N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>79</td>
<td>1476</td>
</tr>
<tr>
<td>Normal</td>
<td>1</td>
<td>325</td>
</tr>
<tr>
<td>High</td>
<td>0</td>
<td>241</td>
</tr>
<tr>
<td>Total</td>
<td>80</td>
<td>2042</td>
</tr>
</tbody>
</table>
A Chi-square test [Table 8] was done with comparison to the prevalence of dyslipidemia in urban and rural India: The ICMR–INDIAB study.[2]

It was found to be statistically significant ($P < 0.01$).

**DISCUSSION**

A total of 80 patients were included in this study, and the serum cholesterol, triglycerides, HDL, and LDL levels were checked and results interpreted.

**Cholesterol**

Of 80 patients, 68 were normal (0–200 mg/dL) and 12 patients had hypercholesterolemia, this accounted for 85% normal and 15% high cholesterol levels, i.e., hypercholesterolemia. Based on “the prevalence of dyslipidemia in urban and rural India: The ICMR–INDIAB study[2]” done on 2042 people.

High cholesterol levels in the general population were found to be in 13.9%, i.e., 283 patients. This was similar to our findings and showed no statistical significance ($P > 0.01$). Even though the cholesterol level is expected to be high in cases of cholelithiasis,[3] our study did not show a very significant increase, indicating that there might be other pathways to gallstone formation and this needs further study.

**Triglycerides**

Of 80 patients, 23 patients had high triglyceride levels (normal 0–150 mg/dL) and 57 patients had normal serum triglyceride levels, i.e., 28.7% and 71.3%, respectively. The national prevalence of hypertriglyceridemia was 29.5%. The study showed no statistical significance. Therefore, patients with cholelithiasis did not have altered triglyceride levels compared to the general population.

**HDL**

The same 80 patients were evaluated for the HDL levels and 60–85 mg/dL was considered normal according to our institution’s charts. The findings were 79 low HDL, and 1 had normal, it accounted for 98.8% and 1.3%, respectively. The national prevalence for the same was 72.3% low HDL. This showed a statistical significance ($P < 0.01$). Hence, it was concluded that low HDL levels predisposed the formation of gallstones.

**LDL**

Of 80 patients, 45 patients were within the normal limits of 0–100 mg/dL and the other 35 were having high LDL levels, i.e., 56.3% and 43.8%, respectively. This when compared to the national data of 11.8% high LDL[3] showed statistical significance, i.e., $P < 0.01$.

With the above data, it was surprisingly proved that low HDL levels and high LDL levels played a more important role in the formation of gallstones.

**CONCLUSION**

The study proved that low HDL levels and high LDL levels possibly played an important role in the formation of gallstones. This is of some importance because serum LDL and HDL levels can be controlled by change of lifestyle and dietary patterns. Furthermore, prophylactic statins may have a role in the development of cholesterol gallstones.

**REFERENCES**

Effect of Employees’ Communication Skills on the Development of Health Services Management in the Jordanian Hospitals

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Assistant Professor, AlGhad International College for Applied Medical Sciences, Buraydah, AlQassim, Saudi Arabia

Abstract
At any organization, communication between the employees plays a significant role in improving its operations. In hospitals, communication between employees is more critical since they are dealing with lives of patients, where a single error could be devastating. In hospitals, communication between the employees plays a significant role in enhancing the health services through patients handling between the different teams and in knowledge sharing that have many advantages including saving effort and time, avoiding repeated procedures, raising the experience, and increasing the patients’ satisfaction.

Key words: Communication, Employees, Health services, Jordanian hospitals

INTRODUCTION

In the context of hospitals, nurses have gradually taken the responsibility of team, personnel, as well as process management, in a direct or indirect way associated to care that includes articulating and coordinating activities with many professional performances in the hospitalization units. Therefore, communication skills emerge to be a strategic tool aimed for nursing management.\[1\]

Communication is considered as an act inherent behavior in individuals, including the understanding and sharing of messages received, and sent between people, and in the setting, they influence, relate, and have the ability to modify the real situation in which they are inserted. In the communication process, a variety of materializations that imply the demonstrations of what the person wants to say are expressed and outlined in non-verbal and verbal forms, mostly by postures, gestures, and words.\[2\]

In Jordan, interorganizational communication in hospitals has not been studied in a way that focuses on the effect of it on the development of health services. In this study, we will focus on evaluating the role of communication between the employees in the hospital in Jordan.

Study Problem
Rising evidence specifies that errors that are existed in intraorganizational health-care communication are conveyed by an increase in medical errors, which result in mortality and morbidity. Communication failures that are due to an insufficient information exchange between the health-care providers are between the most spread reasons that help in the incidence of adverse drug. Communication errors are the leading reason besides insufficient clinical skills in medical errors. Some studies showed that 37% of medical errors in the critical care unit are caused by the wrong verbal exchange of information among doctors and nurses.\[3\]

Study Questions
1. What is the employees’ perspective toward communication with other team members?
2. What is the level of successful communication management in the Jordanian hospitals?
3. Is there is an effect of employees’ communication in improving healthcare services in the Jordanian hospitals in terms of knowledge sharing and handling patients?
4. Is there a relation between the demographic variables of the study and the study variables?

Hypothesis
There is a positive effect of employees’ communication skills on the development of health services management in the Jordanian hospitals.

Communication in Nursing
In administrative processes, communication process is important to exchange ideas, information, orders as well as facts, allowing coordinated actions accomplishment, reducing modifications, and resembling people to shared objectives. Messages can be formally and informally transmitted. Formal communication is happened mainly in writing such as in the file notes case besides standards and elaboration of reports. It takes place constantly in daily contact between individuals, independently of their function or job, and is related to professional activities or sometimes not. Furthermore, communication can be categorized as downward (management-subordinate) and upward (subordinate-management).[4]

Communication, in nursing management, is based on the connections nurses create as they perform management roles in the context of nursing work, specifically human care, and in the overall context of hospitals. Particular activities face nurses usually done are orientation and elaboration regarding routines, standards, and performance valuation of the members of the nursing team, writing memos, explanation of work scales, and other types of fine-tuning with people by written, face-to-face, computerized, and telephone messages.[5]

Challenges Facing Communication Between Nurses
Communication skills in nursing management are not successful always. There are some conflicts in the communication process in the communication between nursing leaders and subordinates including lack of honesty in interpersonal relations, lack of respects from direct superior to nurses, lack of constructive criticism on the professional performance of nurses as well as lack of acknowledgement of nursing work and non-welcoming of the opinions of nurses. Additional problem related to the decision process centralization in nursing management obstructs that obstructs the flow of communication and delays the decision, which leads to hampering agility and information distortions.[6]

In that logic, it must be emphasized that effective communication as a social process is related directly with the objectiveness and clarity of the speakers about what must be communicated, awareness of the bodily and basic communication knowledge that influence management practice and human relations of nurses.[1]

METHODOLOGY
In this study, the questionnaire was used as the study tool to collect the primary data. The questionnaire was distributed on a sample of 200 employees working on the Jordanian hospitals. The main questions that were asked to the sample members include the following main topics:
1. Employees’ perspective toward communication with other team members.
2. Communication management.
3. Effect of employees’ communication in improving health-care services in handling of patients and knowledge sharing.

The statistical software was used to analyze quantitatively the collected data. The main results were then organized in tables to extract the needed information to answer the study questions.

RESULTS

Cronbach’s Coefficient Alpha Reliability Test
A total of 25 items hypothesized to represent ten scales were developed for use in the present study. The scales were developed for the use in the present study. The scales were developed based on a thorough review of relevant theoretical and empirical literature, which provides some evidence of their content validity. This section describes the selection of items for the evaluation of the reliability and validity of these measurement scales. In this study, the reliability of scales was measured using Cronbach’s coefficient alpha based on the internal consistency of the items in each scale. The acceptable and unacceptable levels of the Cronbach’s Alpha coefficient are presented in Table 1.

Beside that in Nunnally’s (1978) guideline, scale reliability of 0.70 and above is preferred. Nunnally (1978) also suggests that items that have <0.30 values to total correlation could be deleted to improve the reliability of the scale. The results of this study show that the value of Cronbach’s coefficient alpha for scales is different in the values according to analysis data. In this study, we computed Cronbach’s coefficient alpha for the scales before data screen and after data screen.

<table>
<thead>
<tr>
<th>Alpha coefficient</th>
<th>Implied reliability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Below 0.60</td>
<td>Unacceptable</td>
</tr>
<tr>
<td>Between 0.60 and 0.65</td>
<td>Undesirable</td>
</tr>
<tr>
<td>Between 0.65 and 0.70</td>
<td>Minimally acceptable</td>
</tr>
<tr>
<td>Between 0.70 and 0.80</td>
<td>Respectable</td>
</tr>
<tr>
<td>Between 0.80 and 0.90</td>
<td>very good</td>
</tr>
</tbody>
</table>
Respondents’ Characteristics

The profile of the respondents with respect to their education, type of hospital, job title, age, and gender is shown in Table 3.

Table 3 shows that:
1. Most of the respondents in the gender group are male (45.5%) and are female (54.5%) respondents.
2. With regard to the age, most of the respondents (54.0%) are in the age group of <35 years and 46.0% are more than 35 years of age.
3. With regard to the job title, most of the respondents (65.5%) are in the nurse and 8.5% per doctor.
4. With regard to the education, most of the respondents (83.5%) are in the bachelor, and 2.0% are high school.
5. With regard to the type of hospital, most of the respondents (71.5%) are in the private, and 28.5% are public.

Results of the First Question

What is the employees’ perspective toward communication with other team members?

Table 4 shows some descriptive results for the research variables used in this study. Table 4 shows the mean and standard deviation for the research variables of employees’ perspective toward communication with other team members.

Table 4 shows that the means for the sample’s approval for the level of the employees perspective toward communication with other team members ranged from 3.03 to 4.31 and the highest was item No. (2), which reads: “Confident communicating with interdisciplinary teams,” while the lowest was item (3), which reads: “Satisfied with communication skills,” and the mean for the field as a whole was 3.59 with a medium degree.

Results of the Second Question

What is the level of successful communication management in the Jordanian hospitals?

Table 5 shows some descriptive results for communication management used in this study. Table 5 shows mean and standard deviation for the research variables of communication management.

Table 5 shows that the means for the sample’s approval for the level of communication management ranged from 2.44 to 4.32 and the highest was item No. (8), which reads: “Staff caution each other about potentially dangerous situations,” while the lowest was item (1), which reads: “Staff seek information from all available sources,” and the mean for the field as a whole was 3.55 with a medium degree.

Results of the Third Question

What is the level of handling of patients situations in the Jordanian hospitals?

Table 6 shows some descriptive results for handling of patients situations used in this study. Table 6 shows mean and standard deviation for the research variables of handling patients’ situations.

Table 6 shows that the means for the sample’s approval for the level of the handling of patients’ situations ranged from 3.91 to 4.17 and the highest was item No. (1), which reads: “Decrease medical errors,” while the lowest was item (3), which reads: “Save time,” and the mean for the field as a whole was 4.06 with a high degree.

Results of the Fourth Question

What is the level of knowledge sharing in the Jordanian hospitals?

Table 2: The stability of the instrument (Cronbach’s alpha) for the variables of the study

<table>
<thead>
<tr>
<th>Fields</th>
<th>Cronbach’s alpha</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employees perspective toward communication</td>
<td>0.89</td>
</tr>
<tr>
<td>with other team members</td>
<td></td>
</tr>
<tr>
<td>Communication management</td>
<td>0.93</td>
</tr>
<tr>
<td>Effect of employees’ communication in improving health-care services</td>
<td></td>
</tr>
<tr>
<td>In handling of patients situations</td>
<td>0.90</td>
</tr>
<tr>
<td>Knowledge sharing</td>
<td>0.78</td>
</tr>
<tr>
<td>Effect of employees’ communication in improving health-care services</td>
<td>0.91</td>
</tr>
<tr>
<td>Total</td>
<td>0.94</td>
</tr>
</tbody>
</table>

All alpha values were acceptable

Table 3: Frequency and percentage for demographic information

<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>91 (45.5)</td>
</tr>
<tr>
<td>Female</td>
<td>109 (54.5)</td>
</tr>
<tr>
<td>Total</td>
<td>200 (100.0)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
</tr>
<tr>
<td>&lt;35 years</td>
<td>108 (54.0)</td>
</tr>
<tr>
<td>More than 35 years</td>
<td>92 (46.0)</td>
</tr>
<tr>
<td>Total</td>
<td>200 (100.0)</td>
</tr>
<tr>
<td>Job title</td>
<td></td>
</tr>
<tr>
<td>Doctor</td>
<td>17 (8.5)</td>
</tr>
<tr>
<td>Nurse</td>
<td>131 (65.5)</td>
</tr>
<tr>
<td>Other</td>
<td>52 (26.0)</td>
</tr>
<tr>
<td>Total</td>
<td>200 (100.0)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
</tr>
<tr>
<td>Graduate</td>
<td>29 (14.5)</td>
</tr>
<tr>
<td>Bachelor</td>
<td>167 (83.5)</td>
</tr>
<tr>
<td>High school</td>
<td>4 (2.0)</td>
</tr>
<tr>
<td>Total</td>
<td>200 (100.0)</td>
</tr>
<tr>
<td>Type of hospital</td>
<td></td>
</tr>
<tr>
<td>Public</td>
<td>57 (28.5)</td>
</tr>
<tr>
<td>Private</td>
<td>143 (71.5)</td>
</tr>
<tr>
<td>Total</td>
<td>200 (100.0)</td>
</tr>
</tbody>
</table>
Table 7 shows some descriptive results for knowledge sharing used in this study. Table 7 shows mean and standard deviation for the research variables of knowledge sharing.

Table 7 shows that the means for the sample’s approval for the level of the knowledge sharing ranged from 3.89 to 4.34 and the highest was item No. (1), which reads: “Built the experience of the employees,” while the lowest was item (3), which reads: “Enhance the communication between the employees and patients,” and the mean for the field as a whole was 4.11 with a high degree.

Testing the Study Hypotheses
Tests of the hypothesis in the desired model were made based on three measures, the significance of correlation coefficients (R), the coefficient of determination ($R^2$), and the multiple regression (beta).

Possible correlations range from +1 to –1. As a rule of thumb, r values of 0–0.2 are generally considered weak, 0.3–0.6 moderate, and 0.7–1 strong (Brace et al., 2000). The coefficient of determination ($R^2$) is useful because it gives the proportion of the variance of one variable that is predictable from the other variable. It is a measure that allows us to determine how certain one can be in making predictions from a certain model/graph. The multiple regression measured by beta which is a measure of how strongly each set of predictor variables (independent variables) influence the criterion variable (dependent variable). Using multiple regressions, we can test theories (or models) about precisely which set of variables is influencing our behavior. In general, the correlation coefficients (R) measure the relation between only two variables while the multiple regression, beta, measures the relation between a set of variables with one variable. The coefficient of determination ($R^2$) shows the linearity between variables. In this research, we examine r using Pearson correlation coefficients calculated for pairs of variables to test the significance of correlation

Table 4: Means and SD for the approval of the members of the study sample on the level of employees’ perspective toward communication with other team members in a descending order

<table>
<thead>
<tr>
<th>Rank</th>
<th>No</th>
<th>Item</th>
<th>Mean±SD</th>
<th>Degree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>Confident communicating with interdisciplinary teams</td>
<td>4.31±0.70</td>
<td>High</td>
</tr>
<tr>
<td>2</td>
<td>6</td>
<td>Willing to share my knowledge with others</td>
<td>4.04±0.84</td>
<td>High</td>
</tr>
<tr>
<td>3</td>
<td>5</td>
<td>Prepared to integrate cultural awareness/sensitivity into practice</td>
<td>3.58±1.14</td>
<td>Medium</td>
</tr>
<tr>
<td>4</td>
<td>4</td>
<td>Confident communicating with my team</td>
<td>3.50±1.20</td>
<td>Medium</td>
</tr>
<tr>
<td>5</td>
<td>4</td>
<td>Able to ask colleagues for help with challenging situations</td>
<td>3.12±0.94</td>
<td>Medium</td>
</tr>
<tr>
<td>6</td>
<td>3</td>
<td>Satisfied with communication skills</td>
<td>3.03±1.12</td>
<td>Medium</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Employees’ perspective toward communication with other team members</td>
<td>3.59±0.40</td>
<td>Medium</td>
</tr>
</tbody>
</table>

Table 5: Means and standard deviations for the approval of the members of the study sample on the level of communication management in a descending order

<table>
<thead>
<tr>
<th>Rank</th>
<th>No</th>
<th>Item</th>
<th>Mean±SD</th>
<th>Degree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>8</td>
<td>Staff caution each other about potentially dangerous situations</td>
<td>4.32±0.79</td>
<td>High</td>
</tr>
<tr>
<td>2</td>
<td>9</td>
<td>There are special devices used for communication between the medical staff</td>
<td>4.19±0.71</td>
<td>High</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>Staff follow a standardized method of sharing information when handling of patients</td>
<td>4.13±0.84</td>
<td>High</td>
</tr>
<tr>
<td>4</td>
<td>3</td>
<td>Staff verbally verify information that they receive from one another</td>
<td>3.98±0.81</td>
<td>High</td>
</tr>
<tr>
<td>5</td>
<td>5</td>
<td>Staff relay relevant information in a timely manner</td>
<td>3.97±0.80</td>
<td>High</td>
</tr>
<tr>
<td>6</td>
<td>7</td>
<td>Staff request assistance from colleagues when they feel overwhelmed</td>
<td>3.21±1.04</td>
<td>Medium</td>
</tr>
<tr>
<td>7</td>
<td>6</td>
<td>Staff assist colleagues during high workload</td>
<td>3.13±0.89</td>
<td>Medium</td>
</tr>
<tr>
<td>8</td>
<td>4</td>
<td>Staff use common terminology when communicating with each other</td>
<td>2.57±0.81</td>
<td>Medium</td>
</tr>
<tr>
<td>9</td>
<td>1</td>
<td>Staff seek information from all available sources</td>
<td>2.44±0.77</td>
<td>Medium</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Communication management</td>
<td>3.55±0.37</td>
<td>Medium</td>
</tr>
</tbody>
</table>

Table 6: Means and standard deviations for the approval of the members of the study sample on the level of handling of patients’ situations in a descending order

<table>
<thead>
<tr>
<th>Rank</th>
<th>No</th>
<th>Item</th>
<th>Mean±SD</th>
<th>Degree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>Decrease medical errors</td>
<td>4.17±0.79</td>
<td>High</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>Save the efforts</td>
<td>4.11±0.78</td>
<td>High</td>
</tr>
<tr>
<td>3</td>
<td>5</td>
<td>Increase patient satisfaction</td>
<td>4.07±1.02</td>
<td>High</td>
</tr>
<tr>
<td>4</td>
<td>4</td>
<td>Avoid repeated tests and treatments</td>
<td>4.06±0.88</td>
<td>High</td>
</tr>
<tr>
<td>5</td>
<td>3</td>
<td>Save time</td>
<td>3.91±0.95</td>
<td>High</td>
</tr>
<tr>
<td></td>
<td></td>
<td>In handling of patients’ situations</td>
<td>4.06±0.75</td>
<td>High</td>
</tr>
</tbody>
</table>

Table 7: Means and standard deviations for the approval of the members of the study sample on the level of knowledge sharing in a descending order

<table>
<thead>
<tr>
<th>Rank</th>
<th>No</th>
<th>Item</th>
<th>Mean±SD</th>
<th>Degree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>Built the experience of the employees</td>
<td>4.34±0.67</td>
<td>High</td>
</tr>
<tr>
<td>2</td>
<td>4</td>
<td>Save costs</td>
<td>4.18±0.65</td>
<td>High</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>Strengthen the team you are included in</td>
<td>4.11±0.77</td>
<td>High</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
<td>Increase the feeling of the team spirit</td>
<td>4.07±0.73</td>
<td>High</td>
</tr>
<tr>
<td>5</td>
<td>3</td>
<td>Enhance the communication between the employees and patients</td>
<td>3.89±1.01</td>
<td>High</td>
</tr>
</tbody>
</table>

SD: Standard deviation
coefficients. Beta is measured by applying the linear regression test.

$H_o$: The major hypothesis: There is a statistically significant effect at $\alpha \leq 0.05$ for employees’ communication skills on the development of health services management in the Jordanian hospitals:

According to the results of Table 8, there is a relationship statistically significant at the significance level ($0.05 = \alpha$) between employees’ communication skills and the development of health services management in the Jordanian hospitals. The value of the correlation coefficient ($R$) is 0.67, which is a statistically significant value and indicates that the degree of correlation is statistically significant between the independent variables and the dependent variable, and the value of ($R^2$) is (0.45), a which is a statistically significant value, and the value of the test ($F$) is (81.35) where it is statistically significant at the significance level ($0.05 = \alpha$); therefore, the alternative hypothesis is accepted.

$H_{10}$: The sub-hypothesis: There is no statistically significant effect at $\alpha \leq 0.05$ for employees’ communication skills on the in handling of patients’ situations in the Jordanian hospitals:

According to the results of Table 9, there is a statistically significant relationship at the significance level ($0.05 = \alpha$) between employees’ communication skills and handling of patients’ situations in the Jordanian hospitals. The value of the correlation coefficient ($R$) of (0.66), is statistically significant and indicates that the degree of correlation are statistically significant between the independent variables and the dependent variable. The value of ($R^2$) is (0.44), which is a statistically significant value, and the value of the test ($F$) is (76.45) where it is statistically significant at the significance level ($0.05 = \alpha$); therefore, the alternative hypothesis is accepted.

$H_{01}$: The sub-hypothesis: There is no statistically significant effect at $\alpha \leq 0.05$ for employees’ communication skills on the knowledge sharing in the Jordanian hospitals:

According to the results of Table 10, there is a relationship statistically significant at the significance level ($0.05 = \alpha$) between employees’ communication skills and knowledge sharing in the Jordanian hospitals, as the value of the correlation coefficient ($R$) of 0.58, a value statistically significant and indicate that the degree of correlation is statistically significant between the independent variables and the dependent variable. The value of ($R^2$) is (0.33), which is a statistically significant value, and the value of the test ($F$) is (48.84) where it is statistically significant at the significance level ($0.05 = \alpha$); therefore, the alternative hypothesis is accepted.

**DISCUSSION**

The results showed that the employees’ perspective toward communication with other team members was in a medium degree where this result can be attributed to the fact that there are some competitiveness and careless in the communication process. However, this attention to the

---

**Table 8: The results of the application of the regression employees’ communication skills on the development of health services management in the Jordanian hospitals**

<table>
<thead>
<tr>
<th>Item</th>
<th>$\beta$</th>
<th>$T$</th>
<th>Significant</th>
<th>$R$</th>
<th>$R^2$</th>
<th>$F$</th>
<th>Significant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employees perspective toward communication with other team members</td>
<td>0.32</td>
<td>4.67</td>
<td>0.00</td>
<td>0.67</td>
<td>0.45</td>
<td>81.35</td>
<td>0.00</td>
</tr>
<tr>
<td>Communication management</td>
<td>0.42</td>
<td>6.21</td>
<td>0.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 9: The results of the application of the regression employees’ communication skills on the in handling of patients situations in the Jordanian hospitals**

<table>
<thead>
<tr>
<th>Item</th>
<th>$\beta$</th>
<th>$T$</th>
<th>Significant</th>
<th>$R$</th>
<th>$R^2$</th>
<th>$F$</th>
<th>Significant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employees perspective toward communication with other team members</td>
<td>0.31</td>
<td>4.40</td>
<td>0.00</td>
<td>0.66</td>
<td>0.44</td>
<td>76.45</td>
<td>0.00</td>
</tr>
<tr>
<td>Communication management</td>
<td>0.42</td>
<td>6.14</td>
<td>0.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 10: The results of the application of the regression employees’ communication skills on the knowledge sharing in the Jordanian hospitals**

<table>
<thead>
<tr>
<th>Item</th>
<th>$\beta$</th>
<th>$T$</th>
<th>Significant</th>
<th>$R$</th>
<th>$R^2$</th>
<th>$F$</th>
<th>Significant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employees perspective toward communication with other team members</td>
<td>0.29</td>
<td>3.78</td>
<td>0.00</td>
<td>0.58</td>
<td>0.33</td>
<td>48.84</td>
<td>0.00</td>
</tr>
<tr>
<td>Communication management</td>
<td>0.35</td>
<td>4.66</td>
<td>0.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
importance of communication is raised when dealing with dangerous and emergency situations where the interest of the patient came first.

There are some great advantages of good communication between the staff when handling of patients from one team to another. Those advantages include decreasing the medical errors where recognizing the medical history of the patient and his medicines will help in a better diagnosis and hence a better treatment. Moreover, communication in handling off the patients can help in decreasing the time and effort spent in conducting unnecessary tests and repeated procedures.

Knowledge sharing is one of the great results of communication between the staff where this can contribute in building the experience of the staff, which will lead to strengthen the team they are included in and improve the communication skills between them and the patients.

REFERENCES

Evaluation of Anatomical Variations in Ostiomeatal Unit by Computed Tomography

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Abstract

Introduction: The ostiomeatal unit has a lot of anatomical variations. Evaluation of these variations is important in patients who undergo computed tomography (CT) scan for their Rhinological complaints. These anatomical variants are responsible for chronic ailments like rhinosinusitis, and their knowledge is essential to not only reduce complications during procedures like functional endoscopic sinus surgery but also to explain the disease recurrence and allow surgeons to decide their operative approach.

Purpose: The purpose of the study was to evaluates and determine the incidence of anatomical variations of ostiomeatal unit on CT and to assess the relation of these variations with sinonasal mucosal diseases.

Materials and Methods: This is a prospective cross-sectional study done at the Department of Radiodiagnosis in a tertiary care center over a period of 24 months with 100 subjects having sinonasal complaints which were referred from various departments for CT scan.

Results: The attachment of the uncinate process had many variations with attachment to the lamina papyracea being 84%, attachment to the skull in 8%, attachment to the middle turbinate in 6%, and free lying in 2%. The uncinate process pneumatization was seen in 6% cases. Giant ethmoid bullae were noted in 11% cases while hypoplastic ethmoid bullae were seen in 4%. In terms of association with sinusitis, only uncinate process pneumatization was found to have a significant statistical association.

Conclusion: The most common ostiomeatal unit anatomical variant was varied attachment of the uncinate process. The least common variant noted was the uncinate process pneumatization; however, only this variant was found to have a positive correlation with sinusitis in comparison to other ostiomeatal unit variants.

Key words: Computed tomography, Ethmoid bulla, Functional endoscopic sinus surgery, Ostiomeatal unit, Pneumatization, Uncinate process

INTRODUCTION

Ostiomeatal unit is a complex anatomic region that houses the drainage areas of frontal, maxillary and the anterior ethmoid sinuses. Ostiomeatal unit anatomy is highly variable from one person to another. The diverse variations in the anatomy of the ostiomeatal unit have been studied worldwide since long. Different studies have quoted different percentages for these anatomic variations.³

Embryology

The ostiomeatal unit develops during late fetal life and in infancy⁴ from two of the five parallel lamellae. Initially, these lamellae appear as slits, but then quickly grow into a tubular form and then into a round or globular shape at term. The first lamella corresponds to the uncinate process while the second to the bulla ethmoidalis.

Anatomy⁵

Ostiomeatal unit comprises the bulla ethmoidalis, uncinate process, hiatus semilunaris, infundibulum, and maxillary sinus ostium. Bulla ethmoidalis, the largest and anterior most ethmoidal cell, is a rounded elevation produced by the underlying middle ethmoidal sinus. It is the largest and anteriormost ethmoidal cell. The uncinate process is sickle-shaped with a horizontal and a vertical limb. It has a free margin posteriorly and has a variable attachment superiority.

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Hiatus semilunaris is a deep semicircular sulcus below the bulla, best seen on parasagittal sections. Infundibulum is a short passage at the anterior end of the hiatus. Maxillary sinus ostium is the opening of the maxillary sinus into the nasal cavity.

**Anatomical Variants**

The anatomical variants of the ostiomeatal unit can be categorized as follows.

**Uncinate process attachment variations**
The superior end has a varied attachment. It can attach to the lamina papyracea, the skull base, the middle turbinate, or even lie free in the middle meatus.

**Uncinate process pneumatization**
It is also called as an uncinate bulla. It occurs due to the growth of agger nasi cells into the most anterosuperior region of the uncinate process. Pneumatization can result in narrowing of infundibulum and sinus drainage occlusion.

**Ethmoidal bulla variations**
It can be absent, hypoplastic, or enlarged.

Computed tomography (CT) scan is the choice of investigation for ostiomeatal unit. Coronal scans are best used to visualize the ostiomeatal unit.

**Purpose of the Study**
The purpose of the study was to evaluate and determine the incidence of anatomical variations of ostiomeatal unit on CT and to assess the relation of these variations with sinonasal mucosal diseases.

**MATERIALS AND METHODS**

This is a prospective cross-sectional study conducted at the Department of Radiodiagnosis in a tertiary care center over a period of 24 months from November 2015 to October 2017. The proportion of the population with an anatomic variation of paranasal sinuses was estimated by calculating the sample size which came out to 100. A clearance certificate was obtained from the Ethical Committee of the Institute. Subjects having sinonasal complaints which were referred from various outpatient departments (OPDs), and wards for CT examination were, thus, taken after applying the inclusion and exclusion criteria as follows.

**Inclusion Criteria**
The following criteria were included in this study:
- Patients with sinonasal symptoms, who were referred from various clinical OPDs and wards to the Department of Radiodiagnosis.
- Both males and females.
- Patients age more than 12 years.
- Patients who are willing to participate in the study.

**Exclusion Criteria**
The following criteria were excluded from this study:
- Trauma to face.
- Previous surgery to the sinonasal region.
- Diseases invading and eroding the bones of sinuses
- Invasive, polypoidal, expansile, and neoplasms of PNS.

After obtaining a written informed consent, patients were subjected to undergo CT scan of the ostiomeatal unit in GE Bright Speed Edge Select 8 slice CT scanner. Axial images were acquired with 2.5 mm collimation, and from this raw data sagittal and coronal reformation were obtained with 0.625 mm collimation.

Data from the CT examination were collected in a compact disc and entered in a pro forma and stored in both hard and soft copies. Variables from the data so collected were analyzed using Epi Info 6.

Since the participants were already referred to the Department of Radiodiagnosis for CT evaluation of the ostiomeatal unit, no extra budget was incurred in this study.

**OBSERVATIONS AND RESULTS**

In the 100 cases evaluated, a variety of ostiomeatal unit anatomical variants were found. The following were assessed:

1. Ostiomeatal unit
   a. Uncinate process attachment
   b. Uncinate process pneumatization
   c. Ethmoid bulla size.

2. Sinusitis wise association of anatomical variants of the ostiomeatal unit.

The most common ostiomeatal unit anatomical variant was noted to be varied attachment of the uncinate process. The least common variant noted was the uncinate process pneumatization.

**Uncinate Process Attachment**
The superior attachment of the uncinate process to the lamina papyracea (84%) was the most common attachment noted followed by attachment to the skull base (8%) and then to the middle turbinate (6%). Free lying type of uncinate process was noted only in 2% of cases and was the least common variant of uncinate process attachment noted.

**Uncinate Process Pneumatization**
The uncinate process was found to be pneumatized in 6% cases. Out of these, the left-sided pneumatizations
(4%) were the most common ones while bilateral pneumatizations (2%) were the least common.

**Ethmoid Bulla Size**
Bilateral giant ethmoid bulla (6%) was the most commonly noted variant while unilateral hypoplastic bulla (1% each) was the least common variant.

**Association of Ostitomeatal Unit Anatomical Variants with Sinusitis**
The anatomical variation that had a significant correlation with the presence of sinusitis was the pneumatized uncinate process ($P = 0.001$). Rest of the variations of the ostitomeatal unit did not have a statistically significant association with sinusitis.

**DISCUSSION**
CT is an important modality in the evaluation of the ostitomeatal unit. With the advent of newer procedures like functional endoscopic sinus surgery (FESS) for the treatment of sinonasal ailments, the use of CT for pre-operative workup of these cases has even more increased. This not only has an improved treatment outcome but also due to the adequate delineation of anatomy and the variations of the ostitomeatal unit, there are lesser chances of complications such as bony injury, cerebrospinal fluid (CSF) leak, vascular injury, or neural injury.[4]

The basic principle of FESS is removal of disease in the ostitomeatal complex region, which is best appreciated on CT scan as documented by Dua et al.[9]

Mamatha et al. emphasized the concept that ostitomeatal complex is the key factor in the causation of chronic sinusitis and that the coronal plane is preferred since it best displays the ostitomeatal complex.[6]

**Uncinate Process Pneumatization**
Uncinate process pneumatization also called the uncinate bulla, can cause ostitomeatal unit obstruction and can impede drainage of the sinuses. In the present study, uncinate process pneumatization was found in 6% of the patients. Similar proportions were noted in studies conducted by Adeel et al.[10] which showed 5.2% cases, Kumar et al.[11] showed 5% cases, and Leunig et al.[12] showed 8.8% of cases.

**Ethmoid Bulla Size**
Giant ethmoid bulla can be a cause of sinus infection due to the potential airspace within it just like any other sinus.

In the present study, giant ethmoid bulla was present in 11% of the patients. Similar proportions were found in studies conducted by Amita et al.[13] with 10% cases, Dua et al.[9] with 14%, and Ahmed and Kanmadi[11] with 16.2% cases.

Hypoplastic ethmoid bullae were noted in 4% cases in the present study which was consistent with the study conducted by Earwaker,[14] in which they were found to be in 8.2% cases.

However, we did not get any case of an un pneumatized or atrophic ethmoid bulla, while Earwaker[14] had noted about 11% cases with un pneumatized ethmoid bulla. This could be because of a large sample size of his study (800 cases).

**Sinusitis Wise Association of Anatomical Variants of the Ostitomeatal Unit**
In the present study, the anatomical variation that had a significant correlation with the presence of sinusitis was the uncinate process pneumatization.

Fadda et al., in their study of 200 CT scans, found that medial deviation of uncinate process, hypertrophic ethmoidal bulla, and the presence of sinus mucosal disease had a statistically significant association ($P < 0.05$).[15]

Likewise, Dasar and Gokce studied CT scan in 400 patients with an age range of 20–83 years to see the frequency of anatomical variations of the paranasal sinuses and their association in sinonasal mucosal diseases. They found that the uncinate bulla with sinonasal mucosal diseases ($P = 0.004$) and that of giant ethmoid bulla with sinonasal mucosal diseases ($P = 0.002$) was significant.[16]

As is evident from the discussion above, most of the anatomical variants and its proportions noted in the present study were consistent with other similar studies in literature.
However, few of the variants show different proportions of their prevalence and their association with sinusitis. This could be because of different sample sizes, different age ranges, different study techniques, demographic, and ethnic differences in different study population and different statistical methodology for data analysis.

Implications

FESS

The knowledge of the anatomy of the ostiomeatal unit and its variations plays an immense role in guiding the surgeons appropriately during FESS. This not only allows them to decide a proper course of action according to the type of pathology and the exact site involved but also provides them a roadmap so that inadvertent complications during surgery, like a CSF leak, vascular injury or neural injury can be avoided.

Association with sinusitis

Although a majority of the normal anatomic variants of the ostiomeatal unit have not been found to be significantly associated with causation of sinusitis, it is a well-known fact that other factors that lead to the narrowing or blocking of the ostiomeatal unit lead to pathologies such as sinusitis and polyps.

Strengths of the Study

Budget

Since the data will be collected from the participants who are already referred to the Department of Radiodiagnosis for CT evaluation of the paranasal sinuses, no extra budget was incurred in this study.

No extra radiation

Since the CT examination findings were evaluated after performing a routine imaging in the same protocol, if the patients were not included in the study, the study subjects were not exposed to any additional radiation.

Limitations of the Study

Less sample size

The sample size of a 100 patients seems inadequate while compared to many other studies done in the past, according to the available literature.

Less sliced CT machine

The CT machine used in the study was of 8 slices only. However, if a higher resolution machine was available, better images would have been procured, and the detailed anatomy of the ostiomeatal unit could have been better delineated.

CONCLUSIONS

Anatomical variations of the ostiomeatal unit are best evaluated by CT. These variations may sometimes lead to recurrent sinusitis, mainly due to impaired sinus drainage and ventilation. Understanding the different variations and location, hence, is important not only in evaluating the disease extent but also to pave a roadmap for FESS surgeons.

The superior attachment of the uncinate process to the lamina papyracea was the most common type of anatomical variant noted, while the uncinate process pneumatization was the least common anatomical variant noted.

Although many anatomical variants were noted, the variant that had a significant correlation with the presence of sinusitis was only the pneumatized uncinate process.

This study, hence, concludes that, though there were many anatomical variants noted, only one of them had an association with sinusitis, which very well depicts that the anatomical variants are as such not a causal factor in sinus inflammation. However, the knowledge of them is imperative for the surgeons so that they have an ease to differentiate the normal anatomy variants during FESS and avoid surgery-related complications.

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Intravenous Infusion of Ketamine in Children Undergoing Strabismus Surgery - A Prospective Study

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Abstract

Introduction: Strabismus surgery may be associated with significant post-operative pain. Conjunctiva is the main source of this pain.

Aim: The aim of the study was to study the effects of intravenous infusion of ketamine in children undergoing strabismus surgery.

Materials and Methods: A total of 40 patients were enrolled in the study. 20 patients were infused 1–3 mg/kg/h ketamine, (a bolus of 0.1–0.2 mg/kg and a maintenance infusion of 0.0025–0.02 mg/kg/min) after giving fentanyl 1 mic/kg and atracurium 0.5 mg/kg patient were intubated (ketamine group) and for other 20 patients after giving fentanyl 1 mic/kg and atracurium 0.5 mg/kg patient were intubated and supplemented with sevoflurane 2% (control group).

Results: The consumption of anesthetics and antiemetics, the incidence of oculocardiac reflex (OCR) in these patients was significantly low. The recovery time, Ramsay sedation score, and face pain scale were significantly lower in ketamine anesthesia.

Conclusion: The ketamine infusion is more advantageous and safer in pediatrics for strabismus surgery with an insignificant incidence of intraoperative OCR and post-operative pain, post-operative nausea and vomiting.

Key words: Ketamine, Pediatrics, Strabismus surgery

INTRODUCTION

Strabismus surgery is associated with significant oculocardiac reflex (OCR) (14–90%), intractable post-operative pain and post-operative nausea and vomiting (PONV) (20–30%). As these complications cause distress for children and anxiety among the parents, it is important to provide safe and effective analgesia, antiemetics, and anesthesia.[1,2] For the effective management of these cases with less incidence of undesired events, there were so many clinical studies have been done like a good premedication with various drug combinations and pre-operative counseling for the parents and the children.[3,4] In spite of all these preparatory measures intraoperative and post-operative unwanted physiological sequel is likely to occur but with less intensity.

OCR occurs through the trigeminal-vagal reflex arc and can be triggered by mechanical stimulation such as pressure on the eye, traction, on extraocular muscles. OCR may be the life-threatening event if not monitored vigilantly, immediate remedial measures such as withholding the surgical procedure and administering necessary pharmacological agents swiftly will prevent catastrophe. A variety of methods such as normoxia, normocapnia, premedication using atropine or glycopyrrolate, and adequate anesthetic depth have been to prevent OCR. However, none of them has been found satisfactory.[5]

Ketamine anesthesia is associated with a relatively rapid onset of action and fast recovery and will minimize the hemodynamic changes induced by OCR during strabismus surgery in pediatric patients.[6]
Aim
The aim of the study was to study the effects of intravenous infusion of ketamine in children undergoing strabismus surgery.

MATERIALS AND METHODS

This observational study was undertaken in 40 patients at the Department of Anaesthesiology, Chengalpattu Medical College, informed consent obtained with all 40 patients belonging to age group 4–10 years of age from both gender and ASA status 1 and 2 are included. Patient excluded include those with ASA physical status >2; those with congenital anomalies, drug allergy, and coagulopathy; or those whose families did not approve inclusion. After securing an intravenous line and Anaesthesia Workstation check, multiparameter monitor connected to read pulse, NIBP, SpO₂, and emergency drugs were kept ready, patient premedicated with injection: Glycopyrrolate 20 µg/kg injection, Midazolam 0.05 mg/kg, and Ondansetron 75 µg/kg.

After preoxygenation, with oxygen 6 L/min, fentanyl 1 µg/kg and ketamine 1 mg/kg, and atracurium 05 m/kg and patient were intubated. The patient was infused with ketamine 1–3 mg/kg/h. During surgery, if any traction over extraocular muscles and if associated with a decrease in heart rate by 20 beats per minute surgeon was asked to release extraocular muscle and to locally infiltrate the surgical site with local anesthesia lignocaine 2%. If bradycardia do not resolve, atropine 10 µg/kg was given. Neuromuscular blockade was reversed. The pre-operative and post-operative status of the children were observed and evaluated through numeric rank score for PONV, FPS pain scale and Ramsay Sedation Score for post-operative pain and sedation status and for agitation using an emergency agitation score.

Statistical Methods
The results of the study were evaluated using statistical analysis package. Among the patients, age, weight, recovery time, heart rate, mean arterial pressure, the consumption of anesthetics and antiemetics, and anesthesia time were compared using independent sample t-test. The incidence of OCR, FPS, RSS the incidence of PONV was compared using Kruskal–Wallis test. Data were presented as the mean, standard deviation, or median values.

RESULTS

The mental orientation, agitation score was compared and PONV and hemodynamic status and recovery time in Group K were significantly shorter (P = 0.008) [Figure 1]. The consumption of ketamine was 53.3 ± 19.3 mg. The consumption of anesthetic and antiemetic drugs was significantly lower, respectively. Agitation score in ketamine infusion was significantly lower. The time of intraoperative OCR (P = 0.02) and FPS (P = 0.001) during awakening is significantly lower. The heart rate and blood pressure significantly higher (P < 0.05).

DISCUSSION

The main findings of this paper indicate that ketamine anesthesia is more effective in decreasing the consumption of anesthetics, antiemetics, the incidence of OCR, FPS, agitation score, and shortening the recovery time of children undergoing strabismus surgery. Furthermore, ketamine provides a higher grade of sedation. Strabismus surgery is performed to restore single binocular vision and for cosmetic reasons (extensively in childhood). There are some undesired effects of surgery such as post-operative pain, anxiety, agitation, PONV, and OCR. These effects are frequent complications secondary to anesthesia and

Figure 1: Post-operative nausea and vomiting
Ketamine has intrinsic analgesic and amnestic properties and protects airway reflexes. Ketamine is N-methyl-D-aspartate receptor antagonist. It is an anti-inflammatory drug. This drug provides safe and effective sedation for short, painful procedures performed. Excessive pain can significantly lengthen the post-operative stay, induce PONV [Figure 2].[10]

It is also cost-effective. Thorp et al.[11] reported that intravenous doses of ketamine associated vomiting are not related to either initial loading dose or total dose but the modest increase in receiving high cumulative doses (>7 mg/kg), heart rate and mean arterial blood pressure were within an acceptable range consequently no patient needed treatment. Hence ketamine anesthesia which can eliminate the discomfort of children by increasing sedation, decreasing the pain and thus agitation. Ketamine seems to protect against the parasympathetic activation induced by OCR. Oh et al.[12] reported that 1–2 mg/kg of ketamine for anesthetic induction results in lower incidence of OCR [Figure 3]. Demographic status of the children has no role to play in all these events.

CONCLUSION

Our data suggest ketamine infusion as anesthetic with a single dose of fentanyl as analgesic without volatiles may form a better combination in children undergoing strabismus surgery to provide excellent post-operative pain relief and negligible incidence of PONV and OCR irrespective of the different demographic status of the children.

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Comparison of Three Different Tests for Diagnosis of Enteric Fever

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Abstract

Background: Enteric fever is a systemic illness caused by Salmonella Typhi and Salmonella Paratyphi. The different methods for diagnosis of enteric fever are blood, bone marrow, rarely stool and urine culture, nucleic acid detection, antibody detection by Widal test, and other rapid diagnostic tests.

Aim: The study was performed to evaluate the performance of tube Widal test, Typhiwell enzyme-linked immunosorbent assay (ELISA) test, and Typhifast, an immunochromatographic (ICT) test.

Materials and Methods: This study was carried out in the Department of Microbiology in a tertiary care center for 1 year (January–December 2015). The serum samples were collected from the patients with fever who had positive blood culture report. A total of 50 samples were included, of which 21 were positive for S. Typhi, 9 were positive for S. Paratyphi A, and 20 samples were positive for other organisms such as Escherichia coli (8 isolate), Klebsiella pneumoniae (8 isolate), and Staphylococcus aureus (4 isolate) by blood culture. The serum samples were used for doing the various tests for diagnosis of enteric fever such as tube Widal test, Typhiwell, ELISA test, and Typhifast, an ICT test.

Results: The three serological tests were performed and compared with blood culture, and it was found that Typhifast had a sensitivity of 70% and specificity of 100%, Typhiwell had a sensitivity of 90% and specificity of 75%, and Widal test had a sensitivity of 83.3% and specificity of 80%.

Conclusion: Widal test had a fairly good sensitivity and specificity, whereas Typhifast had a very good specificity but a lower sensitivity.

Key words: Blood culture, Enzyme-linked immunosorbent assay, Immunochromatography, Salmonella, Widal

INTRODUCTION

Enteric fever is a systemic infection caused by Salmonella enterica serovar Typhi (S. Typhi) and Salmonella enterica serovar Paratyphi (S. Paratyphi). It is a common cause of morbidity in the developing countries including South and South-east Asia. Typhoidal Salmonella is transmitted predominantly through water or food contaminated with human feces. The diagnosis of enteric fever poses several problems due to the non-specific and wide array of clinical features. The common symptoms and signs are fever, vomiting, cough, anorexia, diarrhea, abdominal pain, hepatomegaly, splenomegaly, and coated tongue. Enteric fever should be considered in the differential diagnosis of febrile patients with abdominal symptoms. The common tropical infections such as dengue, enteric fever, leptospirosis, typhus fever, and malaria having similar early presentations can cause confusion in decision-making. Recognition of these diseases is important to diagnose them and treat them early, to avoid potentially fatal complications.

In endemic areas, diagnostic tests are needed to diagnose acute cases of enteric fever for clinical management, to detect convalescent and chronic fecal carriage, and for contact tracing. A suitable test may also allow an assessment of disease burden in a community to determine the need for vaccination programs. The definitive diagnosis of enteric
fever relies on the isolation of Salmonella species from blood and bone marrow. In untreated patients with enteric fever, the blood culture is positive in 80% of patients or more. In areas of endemicity where antimicrobials are frequently taken before evaluation, the yield from blood culture can be as low as 40%. Although bone marrow cultures are more sensitive, they are difficult to obtain, relatively invasive, and of little use in public health settings. In addition, Salmonella serovars that cause human infection can change over time and location. In certain areas of Asia, multidrug-resistant S. Typhi has been the main cause of enteric fever, but now S. Typhi is being displaced by infections with drug-resistant S. Paratyphi A. Nucleic acid amplification tests, including conventional polymerase chain reaction (PCR) and real-time PCR, have been developed for the detection of both Salmonella serovars Typhi and Paratyphi A, mainly in blood.

The Widal agglutination test detects serum antibodies to the somatic and flagellar antigens of S. Typhi and S. Paratyphi A and B. The interpretation of the Widal test remains problematic to this day. In many places, instead of the standard tube agglutination test, a quantitative slide agglutination test is used, but this should always be interpreted with reference to clinical data. A rise in titer over time or a single high test, the result is diagnostically significant in Widal test. False negative results may occur if the blood is collected too early in the disease. False positive results may be associated with a history of immunization for typhoid fever, cross-reacting antibodies, or a host of infections and conditions. Although commercial point-of-care rapid diagnostic tests (RDTs) for enteric fever are available as alternatives to the current reference standard test of blood or bone marrow culture, or to the widely used Widal test, their diagnostic accuracy is unclear.

The objective of this study was to evaluate the performance of tube Widal test, Typhiwell enzyme-linked immunosorbent assay (ELISA) test, and Typhifast, an ICT test and to compare the diagnostic accuracy of these tests with the isolation of organism by blood culture for diagnosis of enteric fever.

MATERIALS AND METHODS

This study was carried out in the Department of Microbiology in a tertiary care center for 1 year (January–December 2015). After obtaining ethical clearance from the Institutional Review Board and consent from the patients, 4 ml of blood was collected in clotted vial. The patients included were those who had positive blood culture report. Blood culture was done by automated Bact T/ALERT three-dimensional (bioMérieux Inc., France). Serum was separated from blood by centrifugation at 1500 rpm for 10 min. A total of 50 samples were included, of which 21 were positive for S. Typhi, 9 were positive for S. Paratyphi A, and 20 samples were positive for other organisms such as Escherichia coli (8 isolates), Klebsiella pneumoniae (8 isolates), and Staphylococcus aureus (4 isolates) by blood culture which served as control for the study.

The serum samples were used for doing the various tests for diagnosis of enteric fever such as Widal test (Tulip Diagnostics Private Limited, Goa, India), Typhiwell (Anand Brothers and AB Diachem Systems Pvt., Ltd., New Delhi, India), and Typhifast (Anand Brothers and AB Diachem Systems Pvt., Ltd., New Delhi, India). Widal test was performed by semi-quantitative tube method using different antigens such as S. Typhi O (TO), S. Typhi H (TH), S. Paratyphi A H (AH), and S. Paratyphi B H (BH). The test was performed according to the manufacturer’s instructions and positive was taken as titer ≥ 80. Typhiwell was an ELISA for the detection of immunoglobulin (IgM) antibodies specific to enteric fever in human serum. The test was performed according to the manufacturer’s instructions, and positive was taken as optical density >0.5 after proper validation of the test. Typhifast was a rapid ICT test to detect specific IgM antibodies against S. Typhi. The test was performed according to the manufacturer’s instructions, and reading was taken after seeing the control line showing the test to be valid. All data were entered in Excel spreadsheet (Microsoft, USA) and analysis was done. The performances of the tests were compared, and diagnostic accuracy (sensitivity, specificity, positive predictive value, and negative predictive value) of these tests were calculated.

RESULTS

Among the patients included in the study, there were 33 (66%) male and 17 (34%) female. The age of the patients was between 5 and 66 years (mean = 21.67, SD = 8.36). The serum samples were used for doing the various tests for diagnosis of enteric fever such as tube Widal test, Typhiwell ELISA test, and Typhifast ICT test, and the results obtained in the different tests are noted in Table 1.

Culture is the gold standard for diagnosing a Salmonella infection. Using blood culture as the standard and reference test for diagnosis of enteric fever, the sensitivity, specificity, positive predictive value, and negative predictive value of the different tests were calculated from the samples having growth of Salmonella species as true positives and samples with growth of other organisms as true negatives. It was found that Typhifast has the lowest sensitivity of 70% but highest specificity of 100% while Widal test has sensitivity and specificity of both around 80% [Table 2].
Among the 30 patients with enteric fever, the duration of fever was between 5 and 30 days (mean = 12.2 days). Among the 5 patients who were negative by Widal test but had blood culture positive, 3 had fever duration of 5–7 days and 2 had fever duration of 8–10 days. Among the 3 patients who were negative by Typhiwell but positive by blood culture, 1 had fever for 5–7 days and 2 had fever for 8–10 days.

DISCUSSION

The diagnosis of enteric fever currently depends on the isolation of Salmonella from a patient, most commonly by blood culture. This facility is not available in many areas where the disease is endemic. The other method is PCR-based amplification of DNA from the blood of enteric fever patients, but this technique requires expertise and a well-equipped laboratory. Antigen detection has not been investigated much and detecting an immune response specific for typhoid fever has been done only with antibody detection. Serodiagnosis depends on the age-old Widal test and other serological diagnostic tools.[8]

In a study done by Andualem and group among 270 febrile patients with symptoms clinically similar to typhoid fever, 7 (2.6%) cases of S. Typhi and 4 (1.5%) cases of S. Paratyphi were identified with the total prevalence of typhoid fever 4.1%. The total number of patients who had indicative of infection by either of O and H antigens by Widal test was 88 (32.6%). The sensitivity, specificity, positive predictive value, and negative predictive value of Widal test were 71.4%, 68.44%, 5.7%, and 98.9%, respectively.[11]

The rapid test is emerging as a mode of diagnosis of enteric fever. Among the different rapid tests, the Typhi Dot is a DOT enzyme immunoassay that detects either IgM or IgG antibodies against a specific antigen on the outer membrane protein of serotype Typhi.[8] Application of a dipstick assay for the detection of S. typhi-specific IgM antibodies on samples collected from S. Typhi or S. Paratyphi culture-positive patients at the day of admission to the hospital revealed the presence of specific IgM antibodies in 43.5%, 92.9%, and 100% for samples collected 4–6 days, 6–9 days, and >9 days after the onset of fever, respectively.[12] The advantages of any dipstick assay are that the result can be obtained on the same day, allowing a prompt treatment; only a small volume of serum is needed; no special laboratory equipment is needed to perform the assay; and the reagents remain stable when stored at room temperature.[8] Hence, newer methods of RDTs are being developed.

A study was done by Sultana et al. in the Department of Microbiology, Mymensingh Medical College, Mymensingh, between 2010 and 2011, including 200 individuals, of whom 150 were clinically suspected cases of typhoid fever and 50 controls. Among 150 blood samples from the suspected cases, 106 (70.7%) were positive for IgM of S. Typhi by ICT and 67 (44.7%) were positive by Widal test. Whereas, among the 50 controls, 4 (8%) were positive by ICT and 6 (12%) were positive by Widal test. The sensitivity, specificity, positive predictive value, and negative predictive value of the ICT was found as 83.3%, 92.00%, 91.9%, and 83.6%, respectively. On the other hand, corresponding values for Widal test were of 44.4%, 88%, 80%, and 59.5%, respectively. The ICT (IgM) is rapid, easy to perform, applicable for field use, and highly sensitive and specific for the detection of antibodies in patients with typhoid fever.[13] Another ICT test devised by Preechakasedkit P et al. provided a lower detection limit and analysis time than a Dot blot immunoassay and was employed to detect S. Typhi in human serum, with high accuracy. This strip test offers great promise for a rapid, simple, and low-cost analysis of S. typhi.[14] In another study done in Bangladesh, it was found that a lateral flow dipstick assay had a sensitivity of 98% compared to blood culture results and a specificity that ranged from 78% to 100%. Unfortunately, microbiological culture of blood is only 30% to 70% sensitive although 100% specific.[15] In
the present study, the ICT test had a sensitivity of 70%, specificity of 100%, positive predictive value of 100%, and negative predictive value of 68.9%.

Various studies have been done for evaluation of ELISA for the diagnosis of enteric fever. Enzyme-linked immunosorbent assays (ELISAs) have been used to study the normal antibody response during enteric fever to LPS, flagella, Vi capsular polysaccharide, or outer membrane protein antigens.[2] In a study done by Rastawicki et al. for detection of antibodies to S. Typhi lipopolysaccharide O and capsular polysaccharide Vi antigens in persons from outbreak of typhoid fever by ELISA, it was found that anti-LPS and anti-Vi antibodies were detected in 80% and 53.3% of sera obtained from patients with laboratory-confirmed typhoid fever, respectively.[16] In this study, the sensitivity, specificity, positive predictive value, and negative predictive value of ELISA for the diagnosis of enteric fever was found to be 90%, 75%, 84.4%, and 83.3%, respectively.

The Widal test measures agglutinating antibodies against LPS (O) and flagellar (H) antigens of Salmonella serovar Typhi in the sera of individuals with suspected enteric fever. Although usually discouraged due to inaccuracy, it is simple and inexpensive to perform and is still widely used. The performance of the method has been hampered by a lack of standardization of reagents and inappropriate result interpretation. The Widal test ideally requires both acute and convalescent-phase serum samples taken approximately 10 days apart, and a positive result is determined by a 4-fold rise or fall of antibody titer. However, antibody titers in infected patients often rise before the clinical onset, making it difficult to demonstrate the required 4-fold rise between initial and subsequent samples. In practice, the result from a single, acute phase serum sample is often used, but false negative and false positive results are common. Knowledge of the background levels of antibodies in the local population may aid interpretation of the Widal test, and performance is best among patients with a high prior probability of enteric fever.[2]

In a study done by Adhikari et al. among 1371 febrile cases, 237 were found to be S. Typhi positive by blood culture. Blood culture-confirmed patients had ≥1:40 anti-TH and anti-TO titer in 45.56% (n = 108) and 43.88% (n = 104) patients, respectively. The sensitivity and specificity of IgG (0.96 and 0.95) and IgM (0.95 and 0.94) at 95% confidence level were significant compared to Widal anti-TH (0.72 and 0.58) and TO (0.80 and 0.51) test (P = 0.038) at titer level ≥1:200. Further, the PPV of Widal TH and TO (0.38 and 0.23) was low compared to IgG and IgM ELISA (0.78 and 0.77) (P = 0.045).[17]

In another study, 92 Bangladeshi patients with suspected enteric fever were categorized into four groups: S. Typhi bacteremic patients (n = 28); patients with a 4-fold change in Widal test from day 0 to convalescent period (n = 7); patients with Widal titer ≥1:320 (n = 13) at either acute or convalescent stage of disease; and patients suspected with enteric fever, but with a negative blood culture and Widal titer (n = 44), healthy endemic zone controls (n = 20), and Bangladeshi patients with other febrile illnesses (n = 15). Of 28 S. Typhi bacteremic patients, 28 (100%), 21 (75%), and 18 (64%) patients were positive by TP test, Tubex, and Typhidot, respectively. In healthy endemic zone controls, the TP test method was negative in all, whereas Tubex and Typhidot were positive in 3 (15%) and 5 (25%), respectively. The sensitivity and specificity of all diagnostic tests were calculated using Bayesian latent class modeling. The sensitivity of TP test, Tubex, and Typhidot was estimated at 96.0%, 60.2%, and 59.6%, respectively. Specificity was estimated at 96.6% for TP test, 89.9% for Tubex, and 80.0% for Typhidot.[18] In this study, the sensitivity, specificity, positive predictive value, and negative predictive value of Widal test for diagnosis of enteric fever were found to be 83.3%, 80%, 86.2%, and 76.2%, respectively.

CONCLUSION

This study showed that immunochromatography test (Typhifast) has a very good specificity, but the sensitivity is low. However, as it is easy to perform and can be done in field setting, it may be used in certain places where other methods of diagnosis of enteric fever are not available or feasible. Widal test, an age-old test, has a relatively good sensitivity and specificity, especially from 2nd week of illness and can still be used for the diagnosis of enteric fever.

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Prevalence and Clinical Presentation of Fissure-in-ANO in A Tertiary Care Centre

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Abstract

Introduction: Fissure-in-ano is a common proctologic problem encountered. It is a tear in anal mucosa distal to dentate line usually seen in the posterior midline. Hypertonia of internal anal sphincter and local ischemia is thought to be the pathology behind anal fissures.

Aim: The present study aims at determining the prevalence and clinical presentation of fissure-in-ano.

Materials and Methods: This study is a cross-sectional study conducted at Tirunelveli Government Medical College in patients with anorectal ailments who were randomly selected in this study. The diagnosis was made on the basis of anorectal examination which included inspection, digital rectal examination, and proctoscopic examination.

Results: Our study found out that out of the 325 patients with anorectal ailments, 100 patients (30.7%) were having anal fissures. Out of them, 54 were males and 46 were females, majority were under 40 years age. Pain during defecation, bleeding and constipation were reported as the common clinical symptoms. 76% of patients with fissure-in-ano had an acute presentation and the most common location was reported to be posterior midline (98%).

Conclusion: Our study reveals that fissure-in-ano is a common proctologic disease. Lifestyle modification plays a major role in cure of this condition as constipation, and low fiber diet are the direct etiological factors.

Key words: Anal fissure, Clinical presentation, Constipation

INTRODUCTION

Fissure-in-ano is one of the most common causes of anal pain. It is a linear tear in the squamous epithelial lining of anal canal distal to dentate line.¹ It affects both men and women and are common in all age groups especially young people.² Usually, it is located in the posterior midline or anterior midline. It can extend from dentate line proximally to anal verge distally. The etiopathogenesis of fissure-in-ano is not well understood. Internal anal sphincter hypertonia and local ischemia are the proposed pathology of anal fissures due to the association of these factors with painful fissures. Passage of hard stools, poor anal hygiene, intake of spicy food, and iatrogenic causes are the documented causes for fissure-in-ano.¹³⁴ Fissure-in-ano is of two types - acute and chronic. Acute fissure presents within 3–6 weeks of onset of symptoms.³ It usually resolves spontaneously with high fiber diet and stool softening agents.³ Chronic fissure presents with more than 6 weeks of symptoms. Unlike acute anal fissure, it does not heal spontaneously. It requires intervention. Anal fissures are classified based on etiology as primary and secondary. Primary is idiopathic whereas secondary fissure is due to some pathologies such as inflammatory bowel disease, tuberculosis, and malignancy.

Aim

The present study aims at determining the prevalence and clinical presentation of fissure-in-ano in patients in Tirunelveli.
MATERIALS AND METHODS

This cross-sectional study was conducted in the Department of General Surgery at Tirunelveli Government Medical College; in patients with anorectal ailments after obtaining written informed consent. The inclusion criteria include patients with age group 20–60 years with anorectal ailments who attended the outpatient department. Exclusion criteria include patients with anorectal malignancies, pregnant/lactating mother, and patients with a history of prior anal surgery. Patients were subjected to a clinical examination which consisted of digital rectal examination and proctoscopic examination. Colonoscopy and sigmoidoscopy were done as needed. The data collected were statistically analyzed using SPSS software.

RESULTS

Out of 325 patients studied, 100 patients had fissure-in-ano, consisting 30.7% of patients with anorectal ailments [Table 1].

In our study, out of 100 patients with fissure-in-ano, 54 were males and 46 were females, and most of the patients belonged to the age group 31–40 years with overall male predominance except for the age group 20–30 years which showed a slight female preponderance [Table 2].

Majority of the patients presented with pain during defecation (86%) followed by bleeding (62%), constipation, pruritus, and discharge [Table 3].

Painful defecation and constipation were predominant in males whereas in females bleeding per anum was more predominant [Table 4].

Patients with younger age group presented mostly with pain and bleeding per rectum wherein pruritus and discharge were more in older age group [Table 5].

Majority of fissure were posterior midline in location (98%) followed by anterior midline, especially in females.

In our study, 76% patients presented with acute anal fissure and 24% with a chronic fissure. Most of the patients with chronic anal fissure had sentinel pile.

DISCUSSION

Anal fissure is a linear tear in the anal canal distal to dentate line.[1] Posterior midline is the most common location followed by anterior midline in females.

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**Table 1: Age and sex distribution of patients**

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<thead>
<tr>
<th>Age group</th>
<th>Number of patients</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>20–30</td>
<td>35</td>
<td>11</td>
<td>24</td>
</tr>
<tr>
<td>31–40</td>
<td>42</td>
<td>28</td>
<td>14</td>
</tr>
<tr>
<td>41–50</td>
<td>12</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>51–60</td>
<td>11</td>
<td>8</td>
<td>3</td>
</tr>
</tbody>
</table>

**Table 2: Clinical presentation of fissure-in-ano**

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain during defecation</td>
<td>86</td>
</tr>
<tr>
<td>Bleeding</td>
<td>62</td>
</tr>
<tr>
<td>Constipation</td>
<td>56</td>
</tr>
<tr>
<td>Pruritus</td>
<td>12</td>
</tr>
<tr>
<td>Discharge</td>
<td>6</td>
</tr>
</tbody>
</table>

**Table 3: Clinical presentation and sex distribution**

<table>
<thead>
<tr>
<th>Clinical presentation</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain during defecation</td>
<td>52</td>
<td>34</td>
</tr>
<tr>
<td>Bleeding</td>
<td>30</td>
<td>32</td>
</tr>
<tr>
<td>Constipation</td>
<td>39</td>
<td>17</td>
</tr>
<tr>
<td>Pruritus</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>Discharge</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

**Table 4: Clinical presentation and age group**

<table>
<thead>
<tr>
<th>Age group</th>
<th>Pain</th>
<th>Bleeding</th>
<th>Constipation</th>
<th>Pruritus</th>
<th>Discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>20–30</td>
<td>32</td>
<td>23</td>
<td>19</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>31–40</td>
<td>36</td>
<td>18</td>
<td>17</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>41–50</td>
<td>9</td>
<td>11</td>
<td>10</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>51–60</td>
<td>9</td>
<td>10</td>
<td>10</td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>

**Table 5: Position of fissure-in-ano**

<table>
<thead>
<tr>
<th>Position</th>
<th>Number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Posterior midline</td>
<td>98</td>
</tr>
<tr>
<td>Anterior midline</td>
<td>2</td>
</tr>
<tr>
<td>Others</td>
<td>0</td>
</tr>
</tbody>
</table>

The etiopathogenesis of fissure-in-ano is unclear.[3] The initiation of anal fissure is commonly associated with chronic constipation and passage of hard stools.[6] Some of the common associations of anal fissures are inflammatory bowel disease and tuberculosis. Women in childbearing age group are at risk of developing anal fissure during pregnancy and following delivery due to poor muscular support to the pelvic floor.[7]

The clinical features of anal fissures are pain during defecation followed by passage of bright red blood per rectum.[10] In acute fissure, pain may be very severe such that patient will not pass stool which further leads to hardening of stools thereby complicating anal fissure.[7] Sentinel pile and hypertrophied anal papillae are the characteristic
findings in a chronic anal fissure in addition to spasm of the internal anal sphincter.

In our study, out of 325 patients with anorectal ailments, 100 had fissure-in-ano accounting for 30.7% of study population. Khan et al. reported the prevalence as 15.62% in his study population.[8]

In our study, most affected age group was 31–40 years, with a slight male preponderance. Giridhar et al. reported increased prevalence of fissure-in-ano in age group 21–30 years with male predominance.[5] Gupta et al. reported that the mean age of presentation of fissure-in-ano is 40.13 years with male to female ratio 1.47:1.[9] The reason of this may be due to the higher attendance of male patients in our hospital, or it may be due to that the females are too shy to talk about or to consult the physician for anorectal disorders.[8] In young and middle-aged persons muscles are toned, and this tonicity resists the passage of hard stool and will result in the formation of fissure and may be due to this reason fissures are rare in aged persons due to muscular atony.[10,11]

Popat et al. and Khan et al. reported pain during defecation as the most common presentation followed by bleeding and constipation.[2,8] This is in concordance with our study.

Anal fissure can occur in posterior or anterior midline due to lack of muscular support posteriorly and poor blood supply. In our study, posterior midline was the most common location (98%). Suverna et al. also reported the most common location as posterior midline.[3]

CONCLUSION

The anal fissure is one of the most common painful anorectal problems that trouble the common population. It is more common in young and middle-aged persons with slight male preponderance. The exact etiology is still unknown, but some factors such as constipation and low fiber diet are found to be significantly associated with this condition. This can be prevented with lifestyle modifications. In acute stages change in diet habit by including fiber-rich diet, and stool softeners can itself cure the condition. If it is left unattended, the fissure-in-ano will take a chronic course which will need intervention to manage. Hence, the patients and people who are at risk should be educated about the preventive measures of anal fissures, and they should be motivated to adopt a healthy lifestyle for the better quality of life.

REFERENCES

Perception of Anesthesiology Students of Zahedan University of Medical Sciences from Clinical Learning Environment

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Abstract

Introduction: An appropriate learning environment is crucial for delivering quality education. Students’ expectations from the clinical learning environment differ from the real environment. The purpose of this study is to determine the perception of anesthesiology students of Zahedan University of Medical Sciences from clinical learning environment in the academic year of 2016–2017.

Methodology: This is descriptive, cross-sectional study in the academic year of 2016–2017 on 100 anesthesiology students of Faculty of Paramedics of Zahedan University of Medical Sciences, Iran. They all had passed at least two courses of internship in the operating room. A researcher-designed questionnaire of clinical perception was employed to evaluate the students’ perception. To develop the questionnaire, the questionnaire for nursing students’ perception of clinical learning environment by Mirzaee et al. (2009) was used.

Findings: Evaluations show that 53% of the students are female and 47% are male. 26.8% of the participants were married, while 73.2% were single. The age of the students ranged from 18 to 23 years. In terms of gender, 55 were female and 45 were male. From the perspective of the students, the most effective factor in clinical training is supported learning by the trainer. "Ward’s environment," "supervisory relationship," "personalization," and "independence" are also found to be important.

Discussion: Research shows that students claim that clinical training is the most stressful course. Most medical students believe that clinical experiences are the cause of anxiety. In this study, trainer is the most important factor in clinical training from the perspective of students. 41.29% of students believe that the clinical trainer is on time in clinical environment and 97.3% state that trainers care about the students’ timely presence in the clinical environment.

Key words: Anesthesiology, Clinical, Students

INTRODUCTION

All majors engaged with practical activities are experiencing the changing paradigm from emphasizing theoretical knowledge to valuing practical training. The output of such change is better understanding of practical training and the coherence with theoretical knowledge. Its purpose is to enrich the theoretical knowledge and professional identity. On the other hand, clinical environment is of great importance in the training process of medical professions[1-3] An appropriate learning environment is crucial for delivering quality education. A proven relationship is found between the environment and the student’s academic progress, satisfaction, and success.[5] Students’ expectations from the clinical learning environment differ from the real environment. They are always looking for better learning environment. Therefore, finding the factors affecting the clinical learning is of vital importance.
in clinical training programs. In this regard, learning environment can be divided into academic and clinical. Clinical environment covers all items surrounding students including clinical ward, equipment and tools, personnel, patients, and teachers. The academic environment covers only students and teachers, controlled by latter. Learning in clinical environments creates challenges, which cannot be found in the classrooms such as less control over the environmental condition in the clinical environment, the necessity to mix cognitive, psychomotor and emotional skills to respond the help seekers, and the maintenance of patients’ safety in the care process, and fact that teachers need to maintain both patients’ and students’ needs.

Studies show that students recall the clinical training as the most stressful course. Many medical students claim their clinical experiences as the factor of creating anxiety. Some of the stressors reported by students are the first clinical experience, lack of clinical knowledge and attention to carry out the tasks as students, the use of equipment and tools, responsibility and mistakes, care of dying patients, fear of unknowns, fear of hurting patients, limited time for carrying out duties, ward’s unfriendly environment, interaction with teachers, the feeling of being abandoned by the patient, clinical performance evaluation, self-evaluation, exposure to dying, and very sick patients.

Shin (1972) defines the clinical work as “exposing students in conditions with real problems.” He concludes that the nature of clinical environment provides students with opportunities to apply both theory and real clinical problems. However, clinical work is beyond the provision of opportunity to take advantage of opportunity in reality. Bener (1983) states that theory states what can be shaped explicitly. However, clinical work is always more complicated and introduces numerous realities which cannot be covered by theory.

Learning and training process for becoming anesthesiology technicians is a multi-dimensional process requiring long time spent with patients and a supportive-supervised relationship by the trainer. The emphasis on clinical practices accounts for over half of training experience for bachelor anesthesiology program. Therefore, the clinical performance is a vital component of medical and paramedical curricula, located in a complicated social context.

Considering the fact that anesthesiology students need to be trained in clinical environment due to the nature of their course leads educational centers to strengthen their students’ clinical skills to have better clinical performance in their future jobs. In fact, anesthesiology students are trained in clinical wards such as operating rooms and intensive care unit rather than classrooms. According to Masarore, the clinical learning environment is a clinical classroom. Therefore, working environment is a key factor for anesthesiology students. Taking clinical training into account leads educational centers to care about promoting the quality of students to provide better performance in their jobs. As a result, the purpose of this study is to examine the anesthesiology students’ (bachelor program) perception.

**METHODOLOGY**

This is descriptive, cross-sectional study in the academic year of 2016–2017 on 100 anesthesiology students of Faculty of Paramedics of Zahedan University of Medical Sciences, Iran (Ethic code: IR. ZAUMS. REC. 1396.6). They all had passed at least two courses of internship in the operating room. A researcher-designed questionnaire of clinical perception was employed to evaluate the students’ perception. To develop the questionnaire, the questionnaire for nursing students’ perception of clinical learning environment by Mirzae et al. (2009) was used. An 80-question questionnaire was developed and forwarded to the lecturers and faculty members of Zahedan University of Medical Sciences, Iran. Their opinions were then collected. Finally, the number of questions reduced to 69 assigned into 12 items (10 questions for support provided by lectures from the student’s learning, 4 questions for the support provided by hospital personnel from the student’s learning, 5 questions for feedback-based relationships, 6 questions for supervisory relationship, 7 questions for hospital environment, 6 questions for innovation and creativity, 5 questions for focus on task, 5 questions for clinical training personalization, 6 questions for satisfaction with clinical learning, 5 questions for student’s involvement, 5 questions for student’s involvement, and 5 questions for independence).

The opinions of 10 faculty members working in Zahedan University of Medical Sciences were taken to ensure the content validity. It was reported 0.8. For the reliability, the questionnaires were forwarded to 20 anesthesiology students out of the statistical population. After 10 days, they were asked to recomplete the questionnaire. Correlation was reported 0.47 using the test-retest method. The items are scored on six scales (fully appropriate, appropriate, almost appropriate, almost inappropriate, inappropriate, and fully inappropriate). The items are scored from 0 to 5. Finally, the total score of each item is divided by the number of questions. As a result, the score of each item is calculated out of 5. The scores between 0 and 1.66 are considered weak. Those between 1.67 and 3.32 are medium and 3.33–5 are good. The questionnaires are to be forwarded in the last
session of internship and they are then asked to carefully fill them in. They are also ensured regarding the confidentiality. The questionnaires are collected after 3 min. The data are collected by a two-section questionnaire (demographic section [gender, course of study, type of program, age, and semester] and 69 questions). After collecting the data, they are analyzed using descriptive statistics, central and dispersion indicators. Analytical methods are also used including independent t-test (mean comparison), ANOVA, and correlation coefficient (the correlation among the total score).

Findings
Findings in terms of the individuals’ characteristics of anesthesia students show that 53% of participants are female and 47% are male. In this study, 26.8% are married, while 73.2% are single. No significant difference is found between two groups in terms of demographic variables. The participants are 18–23 years old. In terms of gender, 55 are female and 45 are male. From the perspective of the students, the support from the students’ learning provided by the trainer is the most important factor in the clinical training. The other important areas are “ward’s environment,” “supervisory relationship,” “personalization,” and “independence” [Table 1].

The mean and standard deviation of support from students’ learning by trainer and Zahedan students’ perception of clinical environment experienced a minimum and maximum of 14 and 59, respectively. Statistically, it has the greatest mean score (41.29) compared to other variables. It means that the mean score self-efficacy in greater in the obese group than other two groups and the different is statistically significant using ANOVA ($P = 0.04$). In terms of supervisory relationship, ward’s environment, satisfaction, involvement of students, independence, learning opportunities, and Zahedan anesthesia students’ perception of clinical environment, the difference was statistically significant using ANOVA ($P < 0.05$).

Concerning the support from students’ learning by personnel, feedback-based relationship, innovation and creativity, focus on task, personalization, and Zahedan anesthesia students’ perception of clinical environment, the difference was not statistically significant using ANOVA ($P > 0.05$) [Table 2].

In this study, 64.7% of had a medium level of perception from their major. According to the Goal 13, determining mean and standard deviation of total score of the questionnaire of Zahedan anesthesia students’ perception from clinical environment; medium perception was found to be almost 60% among these students [Table 3].

### Table 1: Comparing total scores of Zahedan anesthesia students’ perception according to questionnaire variables

<table>
<thead>
<tr>
<th>Area</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean±SD</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Support from students’ learning by trainer</td>
<td>14</td>
<td>59</td>
<td>41.29±9.5</td>
<td>0.04</td>
</tr>
<tr>
<td>Support from students’ learning by personnel</td>
<td>6</td>
<td>23</td>
<td>21.18±4.14</td>
<td>0.2</td>
</tr>
<tr>
<td>Feedback-based relationship</td>
<td>5</td>
<td>30</td>
<td>21.15±4.88</td>
<td>0.4</td>
</tr>
<tr>
<td>Supervisory relationship</td>
<td>9</td>
<td>36</td>
<td>25.63±6.03</td>
<td>0.02</td>
</tr>
<tr>
<td>Ward’s environment</td>
<td>15</td>
<td>42</td>
<td>28.69±5.97</td>
<td>0.02</td>
</tr>
<tr>
<td>Innovation and creativity</td>
<td>11</td>
<td>30</td>
<td>19.65±4.40</td>
<td>0.3</td>
</tr>
<tr>
<td>Focus on task</td>
<td>12</td>
<td>30</td>
<td>21.90±3.68</td>
<td>0.4</td>
</tr>
<tr>
<td>Personalization</td>
<td>7</td>
<td>30</td>
<td>19.62±5.02</td>
<td>0.1</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>6</td>
<td>36</td>
<td>21.80±6.08</td>
<td>0.01</td>
</tr>
<tr>
<td>Involvement of students</td>
<td>9</td>
<td>30</td>
<td>20.40±4.57</td>
<td>0.02</td>
</tr>
<tr>
<td>Independence</td>
<td>12</td>
<td>30</td>
<td>21.18±4.30</td>
<td>0.02</td>
</tr>
<tr>
<td>Learning opportunities</td>
<td>5</td>
<td>30</td>
<td>21.04±5.09</td>
<td>0.02</td>
</tr>
</tbody>
</table>

SD: Standard deviation

### Table 2: Relative frequency distribution of “anesthesia students’ perception” in the faculty of paramedics of Zahedan University of Medical Sciences

<table>
<thead>
<tr>
<th>Frequency/perception</th>
<th>Number</th>
<th>Relative frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>11</td>
<td>7.4</td>
</tr>
<tr>
<td>Medium</td>
<td>60</td>
<td>64.7</td>
</tr>
<tr>
<td>High</td>
<td>29</td>
<td>28.2</td>
</tr>
</tbody>
</table>

### Table 3: Mean and standard deviation of anesthesia students from the clinical training status quo in each area

<table>
<thead>
<tr>
<th>Area</th>
<th>Mean±SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shaping student’s personality in clinical environment</td>
<td>23.65±5.39</td>
</tr>
<tr>
<td>Student’s satisfaction with clinical training</td>
<td>21.38±6.71</td>
</tr>
<tr>
<td>Students’ participation in clinical activities</td>
<td>21.28±3.43</td>
</tr>
<tr>
<td>Paying attention to differences among students during clinical period</td>
<td>17.62±3.91</td>
</tr>
<tr>
<td>Clear task description for students during clinical period</td>
<td>23.16±4.78</td>
</tr>
<tr>
<td>Using educational innovation during clinical period</td>
<td>17.20±5.10</td>
</tr>
</tbody>
</table>

SD: Standard deviation

### DISCUSSION
From the perspective of the students, trainer is the most important factor in clinical training. 41.29% of students believe that clinical trainer is punctual. 97.3% of students’ state that the trainer cares about the punctuality of students in the clinical environment. Peyman reports that most clinical trainers want the punctuality. 75.8% of students believe that the trainer plays a key role in reducing stress in the clinical environment while dealing with patients and increasing self-confidence and efficiency. The role of trainer in empowering trainees is the most important factor in clinical training. Such effect was verified in the study by
Wilcox and Lewis.\textsuperscript{[12]} The study by Zahraee et al. concludes that trainer is an important factor in clinical training,\textsuperscript{[13]} which is consistent with the results of our study. Student's reduced stress in clinical wards leads to better learning and performance. Concerning the student's perception in clinical learning environment using different experiences, Quinn et al. stated that despite the benevolent intentions of curriculum planners, several factors might block the efforts made by teachers to optimize the learning environment. First of all, students sometimes misunderstand the materials and the second more complicated issue is that not only does a difference exists between teachers and trainers in terms of learning environment perception but also certain differences are observable among the students.\textsuperscript{[11]}

In terms of the support from the student's learning by the personnel, 15% of students rated the cooperation undesirable. In the study by Aghvami, students were satisfied with the staff cooperation in various clinical wards.\textsuperscript{[6]} From the perspective of students in Hamedan, Iran, nursing staff rarely cooperates. Henderson believes that the optimal clinical support leads to skill and empowerment.\textsuperscript{[5,14]} The study by Rahimi et al. shows that trainers believe that inappropriate dealing blocks clinical training.\textsuperscript{[17]} The study by Hadizadeh shows that most students rated the cooperation of staff with students between good and medium.\textsuperscript{[15]} The cooperation of clinical staff with educational trainers and students leads to better performance of students in the students' future jobs. The authors of this research believe that inappropriate support by the staff is a feature if teaching hospitals affiliated to Zahedan University of Medical Sciences. Frequent clients, massive numbers of students in the operating room, and staff's sensitive responsibilities have led to the failure of support in the working environment.

In terms of learning opportunities, 21% of students believe that there is enough number of patients in clinical training, from the perspective of Waton, when there are few numbers of patients, students cannot achieve the educational goals. In such cases, films and clinical training centers can help increase learning and facilitate the educational goals.\textsuperscript{[9]}

Jafari et al. stated that theoretical lessons delivered in classrooms are not fully transferred to clinical situations. Therefore, students are not able to fully take advantage of their lessons directly. On the other hand, limitations in clinical environment and the rights of patients have given importance to clinical and communicative skills and attitudes among students.\textsuperscript{[12]} Therefore, learning opportunities need to be equally divided among students. In clinical centers, theories are linked to the clinical skills, leading to reduced stress while dealing with patients.\textsuperscript{[14]}

The study by Wern et al. (1999) on the effect of tracheal intubation training in the progress of medical students concludes that 70% of cases were successful in the experiment group, while it was 29% in the control group, showing the role of practice in helping students for learning tracheal intubation.\textsuperscript{[17]} In our study, learning opportunities are of great importance from the perspective of students.

As far as supervisory relationship is concerned, 25% of students claim that a supervisory relationship is found in operating rooms. The study by Peyman et al. shows that 28.9% of students rated the supervision in the clinical process medium and only 18.9% of students are aware of the clinical evaluation at the beginning of the internship, which is consistent with our study.\textsuperscript{[6]} 48% of students state that insufficient supervision is found in the clinical training. Knowing about the evaluation leads students to try their best in line with learning to achieve the training goals. Students were almost satisfied with the clinical evaluation, associated with higher scores given by trainers. This is mainly because most students believe that good evaluation means higher scores. The study by Abedini et al. shows that inappropriate evaluation is a problem of clinical training. Almost all students were satisfied with the evaluation.\textsuperscript{[33]} From the perspective of students, effective communication is influential in performance. When students are welcomed by the staff, they are more willing to provide care. Therefore, they try their best in this regard.

For the ward's environment, 28% of students were satisfied with the relationship between the staff and students. The trainer also showed maximum responsibility regarding the assigned patients to the students. In this regard, operating rooms have provided a positive learning environment. An important reason associated with the satisfaction is taking advantage of experienced trainers and sometimes staff as trainers in the clinical center. Compared to the traditional methods, taking advantage of experienced trainers provided greater acceptability and sufficiency among students and trainer.\textsuperscript{[33]} On the other hand, friendship is seen in operating rooms, evident while dealing with the students. Another factor is that operating rooms suffer from lack of personnel and students are believed to be helpers.\textsuperscript{[6]} The qualitative study by Morkami et al. (2009) conducted in a medical university, on the effect of learning environment on medical training among six paramedical students with the content analysis approach shows that six criteria are of importance, namely, relationship with colleagues, positive and negative patterns, underestimation of attitudes, perception from training as the lowest priority, overfocus on medical knowledge and skills, sexual attitudes, and emphasis on trainer's features.\textsuperscript{[23]} As stated earlier, relationship with colleagues is an important factor, also stated in the study Morkami in learning environment. It
is also consistent with our study. In terms of the support from learning by the trainer, emphasis on the trainer’s features is consistent with our study. For the involvement of students, 20% of students were able to provide appropriate opportunities for students regarding planning in operating rooms. In these wards, students follow the instructions provided by the trainers and skillful staff, leading to obtaining experience and satisfaction with the clinical environment. The qualitative study by Borhani et al. (2011) on the perception of nursing students from sensitive barriers of professional ethics with the content analysis approach among six master’s nursing students led to the discovery of personality traits, educational planning, and clinical environment. If the moral sensitivity is stimulated among students, it leads to the increased presence, showing the compatibility of the dimensions.[25]

For the independence, students feel responsible and accountable to care the patients. This dimension accounts for 21% of the total score. Based on the trainer’s decisions, students were classified. All the operation procedures and responsibilities were supervised by the trainer, creating a sense of self-confidence and independence. The qualitative study by Mirzaee et al. (2014) on the perception of nursing students from clinical learning environment reached four dimensions (experience, imagination experience and processing and initial expectations; planned environment experience and processing; clinical learning environment processing and experience; and the feeling nurturing talents and professional and personal competencies).[26] According to these dimensions taken from the study by Mirzaee et al., greater nurturing of student’s talents and competencies leads to responsibility and accountability, which is consistent with the results of our study.[29]

When it comes to satisfaction, students are willing to participate in clinical environment, and they enjoy such a kind of presence.

In terms of the effect of clinical learning environment on students’ tastes, Dale states that this environment teaches hope to students and provides the motivation for coping with the problems of help seekers. Since our study focuses on anesthesiology students, this willingness provides satisfaction among students, leading to increased responsibility, sensitivity, and accountability.

The least favorite dimension was innovation and creativity, accounting for 19%. The most adverse condition stated by anesthesiology students was clinical facilities and equipment. From the perspective of operating room students, modern innovations were the lowest. From the perspective of students, facilities and equipment in the clinical environment was not optimal in terms of quality and quantity. Other studies in Iran also reported clinical training problems including the study in Yazd where almost half of the students believed that qualitative and quantitative facilities were not optimal.[28] The study by Del Aram in Shahr-e Kord also indicates that the educational environment was not optimal from the perspective of most students as a result of lack of equipment and low technology.[29]

Focus on task was another less favorite dimension. It mainly covers task determination and classification. In teaching hospitals, students are sometimes overwhelmed due to the frequent number of patients, leading to reduced focus on task and responsibility.[24,31] The study by Helen Edward et al. in England shows that the change of internship center leads to significant differences in learning and acquired skills. They concluded that numerous factors are effective in the quality of learning in clinical environment.[32] They also found out that acquiring practical skills in local and rural hospitals were more than the large hospitals in the capital. This study shows that fewer number of patients leads to better accuracy, responsibility, and quality of medical services.

**CONCLUSION**

Clinical training is medium for the anesthesiology in Zahedan University of Medical Sciences. Compared to previous years, this major has experienced greater promotion in terms of educational space, faculty members, clinical wards, and postgraduate programs, linked to the efforts made by faculty members. This study can help students in terms of nurturing talents and professional and personal competencies. According to the aforementioned issues, various factors are effective in learning environment. They act like stimuli. Using these stimuli, students judge the clinical environment. If these stimuli are optimal, then the environment is rated optimal by the students and they take advantage of nurturing their talents and competencies. Therefore, teachers and planners can identify these stimuli and examine the effects on students’ perception. This leads to the perception improvement and enhancement of learning motivation and academic progress. The study shows that the perception of student from clinical environment is not a sudden phenomenon but develops gradually over time through a 4-stage process. Students have certain perception and expectations regarding the clinical environment and interaction with various people. These initial imaginations and expectations are, in fact, the initial and immature core of student’s perception from the clinical environment. In the second stage, before the exposure to real stimuli affecting the perception, students develop their perception by exposure to clinical
environment stimuli. In the third stage, students enter the real clinical environment. In the fourth stage, students meet their concerns based on the stimuli in previous stages. The main concern of all students is nurturing talents and personal and professional competencies. When students are exposed to numerous stimuli in line with the clinical learning environment, if they are positive or interpreted positively, they feel that their personal and professional talents are nurtured and have obtained them. Otherwise, they feel being suppressed. Since this study was conducted only among anesthesiology students, more studies are recommended among other majors including medicine, midwifery, and operation.

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A Study on the Risk Factors for Conversion of Laparoscopic Cholecystectomy to Open Cholecystectomy

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Abstract

Background: Cholecystectomy is the most commonly performed surgery for gallbladder (GB) diseases. Presently Laparoscopic Cholecystectomy is performed routinely due its advantages over Open Cholecystectomy. However in certain conditions conversion to Open Cholecystectomy is required. Knowledge regarding the underlying reasons for conversion could help surgeons during pre-operative assessment and obtain consent of patients with all information provided to them about the conversion to be done if required so that they could have adequate psychological preparation and planning of convalescence. The prediction of a high risk of conversion or a difficult laparoscopic procedure would also allow efficient and appropriate arrangement of the operating schedule and the availability of experienced laparoscopic surgeons for the procedure. It would also allow an earlier intra-operative decision to convert if difficulty is encountered.

Study Design: The study design is of case series.

Aim of the Study: The aim is to study and identify the risk factors for conversion of LC to OC in Indian conditions (Telangana) and to determine the predictive factors of conversion in patients undergoing LC.

Results: This study was done prospectively over a period of 2 years, from September 2014 to September 2016, among 206 patients who underwent LC for symptomatic GB disease in all Surgical Units of Mahatma Gandhi Memorial Hospital, Warangal. Among the 206 patients in the study, 23 (11.16%) patients were converted to OC. The most common reasons for conversion are severe adhesions caused by tissue inflammation (12 patients [52%]) and inability to define anatomy due to fibrosis of Calot’s triangle (5 patients [21.7%]). Conversion to OC due to intraoperative hemorrhage occurred in three patients. Conversion was enforced due to uncontrolled bleeding from GB bed in one patient (4.35%), which occurred during diathermic dissection of GB. In another two patients (8.7%), there was uncontrolled bleeding from Calot’s triangle, which occurred during dissection of cystic duct and artery. Conversion to OC was required to achieve successful hemostasis, as they could not be controlled laparoscopically. Conversion to OC caused by injury of the common bile duct (CBD) occurred in one patient (4.35%), and the injury is identified intraoperatively and repaired over a T-tube. In one patient (4.35%), conversion to OC was required to perform CBD exploration for suspected choledocholithiasis, based on laparoscopic finding of dilated CBD; pre-operative liver function tests (LFTs) and ultrasound were normal in this patient, and intraoperative OC facility was unavailable. Conversion to OC occurred due to equipment failure in one patient (4.35%). Conversion was due to inability to establish and/or maintain sufficient pneumoperitoneum during the course of LC and due to clip applicator failure.

Conclusions: (1) In this study, the following factors are identified as significant risk factors for conversion of LC to open cholecystectomy. (i) Advanced age (>60 years), (ii) obesity (body mass index >27.5 kg/m²), (iii) leukocytosis, (iv) abnormal LFT; ultrasonography findings (1) thickened GB wall >4 mm, (2) evidence of pericholecystic fluid; (v) LC done in emergency setting for acute cholecystitis; no significant risk factors: (a) Gender, (b) previous upper abdominal surgery, (c) comorbidities; (2) In patients with these risk factors, management can be improved by (i) pre-operative counseling of the patient regarding these risk factors and high chances of conversion and (ii) early conversion to OC.

Key words: Laparoscopic cholecystectomy, Conversion, Open cholecystectomy cholelithiasis
INTRODUCTION

Biliary diseases constitute a major portion of digestive tract disorders. Among these, gallstone disease is the most common biliary pathology. Cholecystectomy is the most commonly performed surgery for gallbladder (GB) diseases. Alternative treatments such as chemical dissolution, percutaneous extraction, and ultrasonic lithotripsy have been tried. Although these methods are minimally invasive, most individuals require subsequent therapy for recurrent symptoms. Due to the frequency of recurrent calculi after stone removal alone, cholecystectomy remains the standard therapy. Carl–Langenbucher formed the first ever open cholecystectomy (OC) on July 15, 1882, in Berlin on a 42-year-old man. The most common complications that occur after cholecystectomy are post-operative ileus, atelectasis, and wound infection; other rare complications include pulmonary embolus, pneumonia, myocardial infarction, biliary peritonitis, subphrenic abscess, bacterial peritonitis, and delayed hemorrhage, due to which patients are hospitalized for several days and disabled from normal activity for several months in a year. In an attempt to reduce morbidity and disability, OC has been replaced by minimally invasive laparoscopic cholecystectomy (LC). LC was first performed in March 1987 by Philippe Moret in Lyon, France, a revolution in the treatment of cholecystitis. Since the National Institutes of Health Consensus Conference in 1993, LC has replaced OC as the standard treatment in patients with symptomatic cholelithiasis. In the last decade, more than 90% of cholecystectomies were performed laparoscopically due to its advantages such as decreased post-operative pain and ileus, shorter hospital stay, earlier return to normal activity, earlier oral intake, and improved cosmetic result over OC. However, there is still a substantial proportion of patients who need OC such as patients with severe cardiac disease, pulmonary disease, concomitant disease, multiple previous abdominal incisions and in whom LC cannot be successfully performed, and conversion to open surgery is required because of technical difficulties, to avoid or repair intra-operative injury, not clearly visualized anatomic relationships, or to treat associated conditions.

Conversion to OC has been associated with an increased overall morbidity, surgical site and pulmonary infections, longer hospital stays, increased total cost, and dissatisfaction of the patients. Knowledge regarding the underlying reasons for conversion could help surgeons during pre-operative assessment and obtain consent of patients with all information provided to them about the conversion to be done if required so that they could have adequate psychological preparation and planning of convalescence.

The prediction of a high risk of conversion or a difficult laparoscopic procedure would also allow efficient and appropriate arrangement of the operating schedule and the availability of experienced laparoscopic surgeons for the procedure. It would also allow an earlier intra-operative decision to convert if difficulty is encountered.

METHODOLOGY

Inclusion Criteria

The inclusion criteria were as follows: All patients with symptomatic cholelithiasis, ultrasound (US) abdomen demonstrating cholelithiasis and normal common bile duct (CBD) and patients with a calculous cholecystitis.

Exclusion Criteria

Patients with severe heart and/or pulmonary diseases, concomitant disease requiring open surgery, or multiple previous upper abdominal incisions and patients who were not willing for surgery were excluded from the study. The total number of cases were 206.

All the patients (n = 206) selected as per the criteria from September 2014 to September 2016 were admitted in the surgical unit of Mahatma Gandhi Memorial Hospital, Kakatiya Medical College, Warangal, Telangana State, India, after ethical committee approval and patient consent.

The variables recorded and studied in this study are as follows:

- Sex,
- Age,
- Obesity,
- History of previous upper abdominal surgeries,
- Comorbid illnesses (chronic obstructive pulmonary disease, ischemic heart disease, hypertension, chronic renal failure, and diabetes),
- The surgery setting (emergency or elective),
- White blood cell (WBC) count,
- Serum total bilirubin, and
- Sonographic findings, including GB wall thickness, pericholecystic fluid, CBD stone, and CBD diameter,
- Operative details such as operation time,
- Causes for the conversion to open surgery.

Cholecystitis was diagnosed by clinical and laboratory assessments and radiological report. Patients who presented with acute cholecystitis in the 1st 72 h underwent emergency LC. The patients whose radiological results did not support the clinical and laboratory data were not considered to have acute cholecystitis. If the patients with acute
infection were admitted more than 72 h after the onset of symptoms, elective LC was carried out 8–10 weeks later following a course of conservative treatment (delayed cholecystectomy). Obesity was defined as body mass index (BMI) above the cutoff value of 27.5 (kg/m²).

A patient was categorized as having comorbidity when at least one of the following conditions was present at the time of cholecystectomy:

- Diabetes mellitus,
- Hypertension,
- Myocardial infarction,
- Congestive heart failure or
- Chronic obstructive pulmonary disease,
- Chronic renal failure.

LC was performed by experienced surgeons and surgical residents under supervision. The operation was performed using a four-port technique, with the surgeon standing on the left side of the patient. Veress needle insertion was attempted in all patients. Minimal diathermy was used to dissect a critical view of safety. Method of dissecting the GB from the liver bed, using the diathermy spatula or hook, was left to the preference of the surgeon. Conversion to OC was performed through a right subcostal incision. The cystic artery and cystic duct were ligated separately. The duration of operation was taken from the time of the initial skin incision to the time of skin closure. The post-operative duration of hospital stay was taken as the number of nights the patient stayed in the hospital after the procedure. Total patients in this study are divided into two groups based on completion of LC. One group is LC-completed group and the other one is LC converted to OC group.

### RESULTS

This study was done prospectively over a period of 2 years, from September 2014 to September 2016, including 206 patients who underwent LC for symptomatic GB disease in all Surgical Units of Mahatma Gandhi Memorial Hospital, Warangal. Among the 206 patients in the study, 23 (11.16%) patients were converted to OC.

The most common reasons for conversion are severe adhesions caused by tissue inflammation (12 patients [52.17%]) and inability to define anatomy due to fibrosis of Calot’s triangle (5 patients [21.7%]).

Conversion to OC due to intraoperative hemorrhage occurred in three patients. Conversion was enforced due to uncontrolled bleeding from GB bed in one patient (4.35%), which occurred during diathermic dissection of GB. In another two patients (8.7%), there was uncontrolled bleeding from Calot’s triangle, which occurred during dissection of cystic duct and artery.

Conversion to OC was required to achieve successful hemostasis, as they could not be controlled laparoscopically.

Conversion to OC caused by injury of the CBD occurred in one patient (4.35%), and the injury is identified intraoperatively and repaired over a T-tube.

In one patient (4.35%), conversion to OC was required to perform CBD exploration for suspected choledocholithiasis, based on laparoscopic finding of dilated CBD; pre-operative liver function tests (LFTs) and US were normal in this patient and there was no intraoperative OC facility available.

Conversion was due to an inability to establish and/or maintain sufficient pneumoperitoneum during the course of LC and due to clip applicator failure.

### Gender

Of the 206 patients in the study, 145 were female and 61 were male. Successful LC was performed in 131 females and 52 males, whereas conversion was required in 14 females (9.7%) and 9 males (14.8%).

### Age

In this study, patients aged under 60 years constituted 177 and over 60 years constituted 29; successful LC was performed in 161 patients aged under 60 years and 22 patients over 60 years, whereas conversion was required in 16 (9.03%) patients aged under 60 years and in 7 (24.1%) patients over 60 years.

### BMI

In this study, out of 140 non-obese patients, 130 are in LC-completed group and 10 (7.14%) in converted group. Out of 66 obese patients, 53 are in LC-completed group and 13 (19.7%) in converted group.

### Previous Upper Abdominal Surgery

In this study, five patients had upper abdominal scar, of these three patients were in LC-completed group and

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**Table 1: Summary of reasons for conversion**

<table>
<thead>
<tr>
<th>Reasons for conversion</th>
<th>n=23 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dense adhesions between GB and bowel</td>
<td>12 (52.17)</td>
</tr>
<tr>
<td>Inability to define anatomy at Calot’s triangle</td>
<td>5 (21.7)</td>
</tr>
<tr>
<td>Bleeding from cystic artery injury</td>
<td>2 (8.7)</td>
</tr>
<tr>
<td>Bleeding from GB bed</td>
<td>1 (4.35)</td>
</tr>
<tr>
<td>Choledocholithiasis (preoperatively undiagnosed)</td>
<td>1</td>
</tr>
<tr>
<td>Bile duct injury</td>
<td>1</td>
</tr>
<tr>
<td>Equipment failure</td>
<td>1</td>
</tr>
</tbody>
</table>

GB: Gallbladder
2 (40%) were in converted group. A total of 201 patients had no upper abdominal scar, of these, 180 patients were in LC-completed group and 21 (10.44%) were in converted group.

**Comorbidity**
Sixty-four patients had comorbidity, of these 55 were in LC-completed group and 9 (14.06%) were in converted group. One hundred and forty-two patients were without comorbidity, of these 128 were in LC-completed group and 14 (9.85%) were in converted group.

**Leukocytosis**
In this study, 22 patients had elevated WBC, out of these, 16 were in LC-completed group and 6 (27.3%) were in converted group. About 184 patients had normal WBC, out of these, 167 were in LC-completed group and 17 (9.2%) were in converted group.

**Abnormal LFT**
Among the 206 patients in this study, 18 patients had abnormal LFT, of these, 5 (27.8%) were converted to OC. About 188 patients had normal LFT, of these 18 (9.57%) were in converted group.

**Ultrasoundography (USG) Findings**
In this study, 66 patients had thickened GB wall, of these 13 (19.7%) patients were in converted group. About 140 patients had normal GB wall thickness, of these 10 (7.14%) were in converted group.

**Pericholecystitis**
In this study, pericholecystitis was found in 7 patients, of these 3 (42.9%) were in converted group. About 199 patients were without pericholecystitis, of these 20 (10.05%) were in converted group.

**Surgery Setting: Emergency or Elective**
Among the 206 patients in the study, chronic cholecystitis was found in 187 patients and acute cholecystitis in 19 patients. Emergency LC for acute cholecystitis was done in 19 patients, of these 5 (26.3%) required conversion elective LC in 187 patients with cholecystitis was done of these 18 (9.62%) required conversion.

**DISCUSSION**
LC is regarded as the gold standard in treating all GB diseases. Its benefits compared to OC are lower morbidity, shorter hospital stay, quicker recovery, and decreased post-operative pain.[30] Conversion to OC is, however, still necessary in up to 20% of the overall cases.[33] This study was conducted prospectively over a period of 2 years, from September 2014 to September 2016, including 206 patients who underwent LC for indicated GB disease in all Surgical Units of Mahatma Gandhi Memorial Hospital, Warangal.

This study evaluated the effects of patient characteristics on conversion, such as gender, age, BMI, history of previous upper abdominal operation, associated comorbid illnesses, leucocytosis, LFTs and USG findings including GB wall thickness, pericholecystic fluid, acute or chronic cholecystitis, surgery setting, and operative details such as operation time and causes for conversion.

This study prospectively analyzed 206 patients who underwent LC for indicated GB diseases, of these 23 (11.16%) patients required conversion to OC.

In this study, the overall conversion rate was 11.16%, comparatively higher than reports that have been published from highly specialized centers with extensive and special expertise in laparoscopic surgery.[11-13] General surgical practice might have somewhat less favorable results.

**CONCLUSION**

(1) In this study, the following factors were identified as significant risk factors for conversion of LC to open cholecystectomy: (i) Advanced age (>60 years), (ii) obesity (BMI >27.5 kg/m²), (iii) leucocytosis, (iv) abnormal LFTs; USG findings (1) thickened GB wall >4 mm, (2) Evidence of pericholecystic fluid; (v) LC done in emergency setting for acute cholecystitis; no significant risk factors: (a) Gender, (b) previous upper abdominal surgery, (c) comorbidities, (2) In patients with these risk factors, management can be improved by (i). Pre-operative counseling of the patient regarding these risk factors and high chances of conversion and (ii) early conversion to OC.

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An Easy Method to Reduce Complex Second Metacarpophalangeal Joint Dislocation

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Abstract

Introduction: Dislocation of metacarpophalangeal joint of index finger is an uncommon injury encountered in day today practice. Though closed reduction is tried, the head of the metacarpal bone is button holed within capsule-ligamentous attachments resulting in the need of surgical intervention. In this study, we advocate a percutaneous dorsal approach to reduce the dislocation.

Aim: To evaluate the effectiveness of percutaneous dorsal incision over open surgical intervention in the patients with metacarpophalangeal joint dislocation.

Materials and Methods: This prospective study was done in Thanjavur medical college from 2010-2017 for a period of seven years after getting approval from the ethical committee. Twenty patients with complex MCP joint dislocation were included in the study. Informed and written consent is obtained from the participants. All the patients were subjected to X-ray examination of the hand to assess the bony injuries and joint status. Percutaneous dorsal incision was made to reduce the dislocation. All the patients were followed up for 3 months and the results were analysed.

Results: The final results showed good joint mobility without stiffness in 16 patients, stiffness of the joint in 4 patients and no recurrent dislocations were noted.

Conclusion: Complex dislocation of Metacarpophalangeal joint of index finger which is irreducible by closed manipulation is best approached by percutaneous incision. This technique is easier, simpler with minimal neurovascular injuries. Further clinical evaluation is to be done to assess the effectiveness of this method.

Key words: Complex MCP joint dislocation, Dorsal approach, Percutaneous incision, Volar plate

INTRODUCTION

Hand injuries are very commonly encountered in orthopedic practice. Metacarpophalangeal joint dislocations are less common than interphalangeal joint dislocation because the MCP joint dislocation is prevented by the strong capsuloligamentous attachments. Kaplan’s original description clearly indicates the pathoanatomy of metacarpophalangeal (MCP) dislocation - the fibrocartilaginous plate avulses from its weakest attachment, that is, the volar aspect of the metacarpal neck with the flexor tendons and the pre-tendinous band displaced ulnarily and the lumbricals displaced radially to the metacarpal head.¹

Complex MCP joint dislocation is frequently seen in the index finger. Closed reduction under regional anesthesia often fails as the flexor tendons along with the pre-tendinous band of palmar fascia and the lumbricals form a tight constriction noose around the head, leading to irreducibility of the dislocation.

Therefore, open reduction is preferred in the majority of the cases. The common method of open reduction is Kaplan method when there is no associated fracture. If an associated fracture of the metacarpal head is present, then Becton’s method of open reduction by dorsal method is preferred.

This study was conducted to evaluate the effectiveness of percutaneous dorsal incision over open surgical intervention in the patients with MCP joint dislocation.
MATERIALS AND METHODS

This prospective study was conducted in Thanjavur Medical College from 2010 to 2017 for 7 years after getting approval from the Ethical Committee. 20 patients with complex MCP joint dislocation were included in the study. Informed and written consent is obtained from the participants before enrollment into the study.

Of the 20 cases, 14 were male and 6 were female patients. Time of presentation is between 0 and 18 days. 14 patients has history of alleged self fall on the outstretched hand. 6 patients has history of alleged RTA. The classical history of hyperextension of the MCP joint could not be made out even with specific leading question All the patients were subjected to X-ray examination of the hand to assess the bony injuries and joint status. All the cases were assessed for emergency reduction under regional anesthesia [Figures 1 and 2].

Procedure

Under local anesthesia with sterile aseptic precautions, upper limb is painted and draped. Metacarpal dorsal surface is palpated with deep palpation. Using 11 size blade soft tissue that is present over the dorsal surface of metacarpal shaft is incised longitudinally till the neck of metacarpal bone. This incision will usually incise dorsally displaced volar plate which lies as a block. Once after incising the soft tissues, with gentle traction and corrective manipulation, dislocation is reduced by easy means [Figures 3 and 4] intraoperative post-reduction picture. The hand is immobilized in ball bandage with 2nd MCP joint in 90° flexion.

Post-operative Protocol

The hand is immobilized in ball bandage for 1 week, later dressing is removed and active mobilization of hand is started. The patient regained full range of movements by 3 weeks. The patient is reviewed by 6 weeks and 12 weeks for evaluation regarding disability.
The patient’s active range of motion of MCP joint hyperextension to 10° and 90° of flexion, proximal interphalangeal joint extension to 0° and flexion to 70°, and distal interphalangeal joint extension to 0° and flexion to 60° is evaluated.

Neurovascular evaluation was within normal limits. X-rays confirmed maintenance of reduction. Patients did not have any functional disability, collateral ligaments healed well by a period of 12 weeks and did not show any instability [Figure 5].

DISCUSSION

Kaplan’s lesion is a rare injury. This injury commonly involves the index finger at the MCP joint. Kaplan was the first to describe this injury, where the capsulo-ligamentous structures prevent the closed reduction necessitating the open reduction.

Two main approaches have been described for open reduction - volar and dorsal. In volar approach, it was required to extensively release the volar structures along with the volar plate. The risk to radial neurovascular bundle (digital nerve and vessel) is high.[4] In dorsal approach, the risk of injury to the neurovascular bundle is much less as it lies between the MC head and skin volar wards. It was Becton et al. who reported a series of 9 cases complex MP joint dislocations treated by both approaches.

A direct dorsal longitudinal incision through the skin and extensor tendon gives full exposure. The volar plate attached to the proximal phalanx and trapped over the dorsal aspect of the metacarpal head is in full view.[4]

He found that patients treated with volar approach had a sensory loss on the radial aspect of the injured finger while those treated with dorsal approach had full recovery with normal function. He concluded that dorsal approach was the right approach to treat such lesions.[1]

Kaplan also advocated the need to release the superficial transverse metacarpal ligament and distal transverse fibers (nataatory ligament). The risk of iatrogenic dislocation following release of ligaments is also reported. The deep transverse metacarpal ligament is also an important impediment for reduction at times.[3] It was Murphy who reported the role of volar subluxation of deep transverse metacarpal ligament which forms a part of the noose around the head of MC and prevents reduction.[3] This needs release if it prevents reduction.

The structure which is blocking the reduction is the volar plate which dislocates dorsally and lies between the joint.[4,5]

Based on the above studies, we preferred the dorsal approach as it is less invasive. In this technique, the volar plate is released by the percutaneous method. The tip of the knife rests over the bone and release is made along the shaft till it reaches the neck of metacarpal bone. This incision releases the volar plate by splitting it in the middle. Once the blocking tissue is released, the reduction is attained with minimal manipulation.

Volar plate, as mentioned earlier, provides stability to the joint volar wards. Longitudinal splitting of this volar plate is usually criticized as it causes delay in the recovery, needs more immobilization, and leads to instability of the joint which may result in iatrogenic dislocation or subluxations later.[7] However, in our study, we did not encounter any of this complication. The final outcome did not change.

CONCLUSION

Complex dislocation of MCP joint of index finger which is irreducible by closed manipulation is best approached by percutaneous incision. This technique is easier, simpler with minimal neurovascular injuries. However, extensive follow-up and clinical evaluation should be executed to thoroughly assess the effectiveness of this method.

REFERENCES

Study of the Level of Awareness of Chronic Kidney Diseases among Diabetic Patients in Al-Ahsa Governorate, Kingdom of Saudi Arabia (Cross-Sectional Study)

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INTRODUCTION

Diabetes mellitus (DM) is a growing health problem worldwide.¹ In 2016, it is estimated globally that 422-million adults suffering from diabetes, mainly in developing countries.¹ The Middle Eastern regions have the second highest rate of increases in diabetes compared to rest of the world. In Saudi Arabia, the prevalence was 17.6% of the population in 2015.² Previous studies conducted in eastern provinces of the country have found that the prevalence of DM is 31% among the population.³ DM has many complications in different organs in the body. The kidney is one of these organs that is well known to be affected by uncontrolled DM.⁴ Chronic kidney disease (CKD) is one of the most common complications affected by DM in the world.⁵ It is a life-threatening complication in

Abstract

Introduction: Chronic kidney disease (CKD) is one of the most common complications affected by diabetes mellitus (DM) in the world. It is a life-threatening complication in diabetic patients, and this will cause end-stage renal disease in developed countries. No study has been done before in the eastern region of Saudi Arabia. Making it important to do such kind of studies.

Purpose: The purpose of this study is to determine the level of awareness of CKD among diabetic patients in Al-Ahsa Governorate, Kingdom of Saudi Arabia.

Materials and Methods: This cross-sectional study was conducted in Al-Ahsa Governorate of Saudi Arabia, from March 2017 to December 2017. The researchers have done the questionnaire on 372 individuals of diabetic patients. Data analysis was done using SPSS program version 24.

Results: The minimum age of the participants was 19, and the maximum age was 65. More than half of them are in the age group (40–70). The number of male participants is 107 (28.8) and females 265 (71.2). The mean score of the level of awareness was 7.5 ± 3.2. However, the number of the participants who know that DM can cause CKD are 196 (52.7.9%). 100 (26.9%) were not aware of the association between CKD and uncontrolled diabetes. 76 (20.4%) of the participants did not hear about CKD. However, the majority of Saudi populations were not aware of the association between CKD and uncontrolled diabetes. We summarize our findings that our patients had poor attitude and knowledge of awareness compared to the others, which emphasize the needs for implementation of awareness campaigns, future public health, and educational interventions.

Conclusion: CKD is common and growing problem worldwide but not adequately recognized problem among diabetic population in Al-Ahsa Governorate, Kingdom of Saudi Arabia. As there is lack of awareness among Saudi diabetic population about this problem, there is a strong need for health and educational intervention programs to increase the knowledge level and awareness about this disease as well as the necessity of screening and periodic follow-up programs.

Key words: Awareness, Chronic kidney disease, Diabetes mellitus, Knowledge, Practice

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diabetic patients, and this will cause end-stage renal disease in developed countries. CKD defined as either persistent albuminuria or decreased glomerular filtration rate (GFR) or both. It affects approximately one-third of people with DM either Type 1 or Type 2. The pathogenesis of CKD has been described as progressive albuminuria that will lead to a steady loss of GFR.

To the best of the researcher’s knowledge, no study has been done before in the eastern region of Saudi Arabia. Making it important to do such kind of studies.

MATERIALS AND METHODS

Study design
This cross-sectional study was conducted in Al-Ahsa Governorate of Saudi Arabia, from March 2017 to December 2017.

Participants
A total of 372 participants aged from 18 years and above were selected randomly from Al-Ahsa, using simple random sampling to assess the level of awareness toward diabetic nephropathy.

Data Collection
Electronic questionnaire was validated for data collection. The study population was randomly selected from the population in Al-Ahsa city. After obtaining informed consent, the questionnaire was distributed among the participants. The participants were assured that confidentiality would be maintained. The questionnaire consisted of four sections: (i) Sociodemographic data, (ii) early signs and symptoms of the disease, (iii) risk factors, and (iv) the regular screening. The questionnaire was pre-tested and translated into Arabic and then back-translated to English to validate the translation.

The level of awareness was assessed on 29 questions about the awareness of the disease. Ethical approval was obtained from the Research Ethics Committee from King Faisal University.

Data Analysis
Data analysis was performed using SPSS (version 24). Chi-square test was run for analyzing qualitative data. P-values were considered statistically significant if P < 0.05.

RESULTS

A total of 375 individuals with diabetes in Al-Ahsa city were included in this study. The minimum age of the participants was 19, and the maximum age was 65. More than half of them are in the age group of 40–70. The number of male participants is 107 (28.8) and females 265 (71.2).

The primary educational level was found in 13 (3.5), 68 (18.3) had secondary, and 291 (78.2) had academic educational level. The demographic characteristics are shown in Table 1.

We found in this study that the age group (21–50) has the highest awareness level (26.8%) compared to the other age groups. Another finding in this study was level of awareness between males and females. 50% of females was aware compared with 17.5% of males [Table 1].

Furthermore, we found that 2.4% was aware in primary educational level compared with 11.3% in secondary school and 43.5% in academic educational level. [Table 2].

The responses of all the participants related to the awareness of diabetic nephropathy are shown in Table 3.

Regarding the type of diabetes, Type 1 was 21 (6.5%) of the participants, and 308 (82.8%) were Type 2 diabetic participants. Rest of the participants were not sure about their type. They were 43 (11.6%) patients. Most of the participants discovered that they are diabetic in age between 30 and 50 years which equal to 194 (52.2%). The others were variable, 82 (22.6%) were diabetic ≤30 years, and 92 (24.7%) discovered the disease ≥50 years.

The mean score of the level of awareness was 7.5 ± 3.2. However, the number of the participants who know

<table>
<thead>
<tr>
<th>Table 1: Demographical data (n=372)</th>
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<tbody>
<tr>
<td><strong>Demographical data</strong></td>
</tr>
<tr>
<td>Age</td>
</tr>
<tr>
<td>≥20</td>
</tr>
<tr>
<td>20–50</td>
</tr>
<tr>
<td>&lt;50</td>
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<tr>
<td>Gender</td>
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</tr>
<tr>
<td>Single</td>
</tr>
<tr>
<td>Married</td>
</tr>
<tr>
<td>Divorced</td>
</tr>
<tr>
<td>Educational level</td>
</tr>
<tr>
<td>Primary</td>
</tr>
<tr>
<td>Secondary</td>
</tr>
<tr>
<td>Academic</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 2: Awareness</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Level of awareness</strong></td>
</tr>
<tr>
<td>Valid</td>
</tr>
<tr>
<td>Not aware</td>
</tr>
<tr>
<td>Aware</td>
</tr>
<tr>
<td>Highly aware</td>
</tr>
</tbody>
</table>
that DM can cause CKD are 196 (52.7%). 100 (26.9%) were not aware of the association between CKD and uncontrolled diabetes. 76 (20.4%) participants did not hear about CKD.

This study shows that only 93 (25%) diabetic patients are aware about the effects of DM on their kidney. On the other hand, we found that 121 (22.5%) of participants have a low level of awareness about the disease which shown in Table 2.

**DISCUSSION**

DM is well known to be a common metabolic disease in Saudi Arabia and risk for many complications. CKD is one of the major complications of DM according to the past epidemiological studies. Early recognition of CKD could prevent complications and slow progression.

The aim of the study was to determine the level of awareness of CKD among diabetic patients in Al-Ahsa Governorate, Kingdom of Saudi Arabia.

This study showed that there is no significant difference between males and females in the level of awareness of CKD among diabetic patients in Al-Ahsa region.

Regarding the age variable, the study found that the age group between 21 and 50 has a higher level of awareness toward CKDs. We attribute that this age group has more knowledge about the disease and more experiences about its effects compared with younger age group. However, no significant difference was found between the age groups in the level of awareness.

Furthermore, the study results showed that the participants who have academic educational levels had the highest scores in the questionnaire regarding the impact of the educational intervention on the level of knowledge and awareness about the disease.

In addition, this study concluded that more physicians informing the patients about the risk of CKD will increase the level of awareness. As Chi-square ($P = 0.001$) showed that patients who have been informed by the physicians have a higher level of awareness score than the others.

An important significant finding in this study is the higher knowledge and positive attitude toward the disease, which shows that the level of awareness should be increasing among the diabetic population.

Unfortunately, there is no scientific study about CKD which was done in Saudi Arabia, but globally, there were some studies conducted in different countries. Such as, a study conducted in the United States in 2011 among African–American adults about CKD concluded that the level of awareness of CKD is low (13.6%).

Another study conducted in Iran in 2014 showed that there is a deficiency in the level of awareness of CKD among Iranian population (21.2%).

Although if we compared this study which was done in the selected region of Saudi Arabia and limited patients, We will find that the knowledge score (6.9%) is low compared to other studies that conducted widely in different countries such as Iran (21.2%), the United States (13.6%), and Australia (8.6%). We found that the knowledge score (6.9%) is low.

However, the majority of Saudi populations were not aware of the association between CKD and uncontrolled diabetes.

We summarize our findings that our patients had poor attitude and knowledge of awareness compared to the others, which emphasize the needs for implementation of awareness campaigns, future public health, and educational interventions.

**CONCLUSION**

CKD is a common and growing problem worldwide but not adequately recognized problem among diabetic population in Al-Ahsa Governorate, Kingdom of Saudi Arabia. As there is a lack of awareness among Saudi diabetic population about this problem, there is a strong need for health and educational intervention programs to increase the
knowledge level and awareness about this disease as well as the necessity of screening and periodic follow-up programs.

REFERENCES


Source of Support: Nil, Conflict of Interest: None declared.
Breastfeeding and Weaning Practices among Mothers Coming to Primary Health Care Center: An Experience from Rural Bihar

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Abstract

Background: Breastfeeding is an ideal form of infant feeding. Breastfeeding and weaning are not properly practiced by many mothers in all corners of the country. There are a number of factors that influence breastfeeding and weaning practices.

Aim: The aim of this study was to find out the pattern of breastfeeding and weaning practices among mothers in this part of the country.

Materials and Methods: It was a cross-sectional study conducted at Primary Health Care Center, a Rural Health Training Center of Indira Gandhi Institute of Medical Sciences. Mothers coming for measles immunization were enrolled in the study. Interviews were conducted with semi-structured questionnaire.

Result: A total of 160 mothers were enrolled in the study. More than half of them (63%) were in the age group of 20–25 years and less than a quarter were illiterate. Almost all mothers (92%) started breastfeeding same day after delivery but only one-third fed colostrums to their newborn. A good number of mothers (73%) started weaning before 6 months.

Conclusion: Emphasis on importance of colostrum and exclusive breastfeeding need to be dispensed at the time of interaction with health-care delivery personnel.

Key words: Breastfeeding, Prelacteal feed, Weaning

INTRODUCTION

Breastfeeding is an ideal form of infant feeding and is crucial for lifelong health and well-being. It provides unique nutritional, immunological, psychological, and child spacing benefits apart from being cost effective. It has been established that breastfeeding has short-term benefits particularly the reduction of morbidity and mortality due to infectious diseases in childhood. Studies carried out in middle- and low-income countries showed that breast feeding substantially lowers the risk of death from infectious diseases in the first 2 years of life.[1] Breastfeeding continues to be the norm in low-income countries, but the period of exclusive breastfeeding after birth is variable. The World Health Organization (WHO) recommends that breastfeeding must be done for the first 6 months of life.[2] The United Nations Children’s Fund has estimated that exclusive breastfeeding in the first 6 months of life can reduce under-five mortality rates in developing countries by 13%.[3] Gain in terms of incidence and prevalence of maternal breastfeeding has not been as great as is to be desired even after efforts on promotion of maternal breastfeeding.[1] There are a number of factors that influence the breastfeeding practices such as motivation, mother’s education, family support, and cultural practices. These factors may influence the practices of weaning...
process and lead to early start of supplementary foods to their infants. It has been found that in India; only 58% of the infants are exclusively breastfed between 0–4 months.\[4\]

Infant mortality is high in many states. Breastfeeding is almost universal, but studies have shown a decline in breastfeeding trends, especially in urban areas in our country.\[5\] The information about breastfeeding and weaning practices in rural Bihar is scarce. The present study was conducted with the objective to find out the pattern of breastfeeding and weaning practices among mothers from one of the Primary Health Care Centers (PHCs) of Bihar.

**MATERIALS AND METHODS**

The present cross-sectional study was conducted at one of the PHCs that has been allocated as Rural Health Training Center of Indira Gandhi Institute of Medical Sciences. The PHC caters around 2 lakhs population with facilities such as antenatal care checkup, immunization, delivery, and regular OPDs. Routine immunization is done for infants and children as well as women on schedule dates. The present study was conducted using convenient sampling from February to March 2014 for 2 months. All mothers visiting for measles vaccination of their child/children on Tuesdays and Thursdays were enrolled in the study. Mothers were asked to stay after vaccination of their infants to look for any untoward effects of vaccination. Mothers were interviewed at this time using a semi-structured questionnaire after getting a verbal consent from them. Those mothers who were not willing to participate and/or who did not give their consent for the said purpose were excluded from the study. The questionnaire included demographic profile, details on breastfeeding and weaning practices, and place of delivery. Mothers were asked in Hindi and response noted on the pre-designed pro forma. Mothers were asked about their age (in nearest years), age at marriage, and their educational status. They were also asked about the place of delivery, weaning, prelacteal feed, and period of exclusive breastfeeding. At the end of the interview, any doubt among mothers was cleared by the interviewer.

**Statistical Analysis**

Descriptive statistics were used and presented as frequency and percentages.

**RESULT**

There were a total of 160 mothers that were enrolled for the study. Out of the total mothers, 63% were in the age group of 20–25 years and around one-third (28%) in <20 years age group. Only 9% were in the age group of >26–30 years and less than a quarter (23%) were illiterate. Half (48%) of them got married in <20 years and the rest after that [Table 1]. It has been seen that almost all mothers (98%) started breastfeeding same day after delivery and one-quarter (23%) within 1 h. Rest of the mothers did not start breastfeeding same day because they delivered their babies by caesarian section. More than half (59%) of deliveries were conducted at home. More than three-quarter (78%) of the mothers did exclusive breastfeeding up to 4 months
of age. 73% mothers started weaning before 6 months of age since they could not produce enough milk for their child. Cow milk was the commonest prelacteal feed for infants [Table 2].

DISCUSSION

The WHO recommends that breastfeeding should be started within 1 h of birth. For the promotion of early action on breastfeeding, baby-friendly hospital initiative has been designed so that mother can start breastfeeding as early as possible.[8] The present study revealed that 63% of the subjects were in the age group of 20–25 years. One-fifth were illiterate (23%) and half (48%) of the subjects married before the age of 20 years. 59% deliveries conducted at home and 78% mothers breastfed their infants up to 4 months of age. Three-quarter (73%) subjects started weaning before 6 months of age. 23% of newborns were breastfed within 1 h of delivery. It has been observed in study by Chandrashekhar et al. in rural Karnataka and Bhatt et al. at tertiary health care of Vadodara that there is lower percentages of breastfeeding initiation within 1 h of delivery,[7,8] but there is also evidence of the higher rate of breastfeeding within 1 h by Madhu et al.[9] There is a lot of difference in cultural beliefs and practices in different regions of this country that may lead to difference in practices of breastfeeding.

Colostrum as the first feed to newborn is a rich source of minerals, vitamins, and immunoglobulin.[10] Prelacteal feed should be avoided as much as possible but it had been seen that there were number of mothers (19%) who gave prelacteal feed to their newborns. It has been observed by Raut et al. in Vidarbha region of Maharashtra and Khan et al. in the peripheral area of Aligarh that there is a large difference in prelacteal feeding practices.[11,12] It is now established that exclusive breastfeeding should be continued for first 6 months of a child’s life to reduce the chances of malnutrition and infection. Exclusive breastfeeding helps in the development of infants as the mother’s milk is suitable for the infants and children. We observed that 52% of women were doing exclusive breastfeeding for first 4 months that are similar to the observations found by Benjamin et al.[13] in Punjab. Premature initiation of weaning may have a long-term effect on the physical growth of the child that has been observed by Hop et al. in Vietnamese children.[14] Mothers elaborate different reasons for the early initiation of weaning, the most common reason being insufficient milk. Hop et al. also showed that less than one-fifth mothers continued exclusive breastfeeding for first 6 months.[14] Contrary to this, there have been studies which have shown that number of mothers exclusively breastfed their newborn, depending on the education of mothers, place of delivery, and other factors.[14,15] Sharma et al. found that decision of mother-in-law plays a major role in child care including exclusive breastfeeding and weaning and colostrum feeds in rural India.[10] The same is true for the present study too.

Limitations

Sample size may be a limitation as the study was conducted only for 2 months. There are other health facilities including private practitioners available in that area. Hence, all mothers might not have utilized the services of Primary health care centre, and hence, were not included in the study. Mothers, who did not come for vaccination of their infants, were consequently not enrolled and are other limitations of this study.

CONCLUSION

There is a need to emphasize the importance of colostrums, exclusive breastfeeding among mothers of rural areas. It is also important to convince mothers and other valuable person of family regarding the proper weaning process for proper development of infant and child at the same time intervention in customs and belief in the community as whole is also important.

REFERENCES

Sinha, et al.: Breastfeeding and Weaning Practices Among Mothers Coming to Primary Health Care Center: An Experience From Rural Bihar


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Study on Retinopathy of Prematurity and Its Risk Factors in Preterm Babies and Birth Weight <2 kg Admitted in a Rural Medical College

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Abstract

Background: Retinopathy of prematurity (ROP) is a potentially blinding condition commonly seen among premature infants. The most important aspect about ROP is that it is preventable and treatable by adequate and early screening. Hence, the present study has been designed to evaluate the incidence and risk factors of ROP in premature babies.

Objective: The objective of this study was to study ROP and its risk factors in preterm babies (<34 weeks and <2 kg).

Methods: This is a descriptive study conducted among all preterm babies <34 weeks and all preterm babies <2 kg admitted during the period of August 2016–July 2017. ROP screening was done in these babies on day 28 and complete history was recorded. Every week follow-up was done for babies with ROP and the risk factors were assessed.

Results: Among a total of 301 babies screened, 29 babies were diagnosed to have ROP. Our study showed normal vaginal delivery, birth weight, respiratory distress syndrome (RDS), surfactant, apnea, sepsis, and blood transfusion as the statistically significant risk factors (P < 0.05). The mode of oxygen delivery also played an important role. Statistically significant relationship was present between RDS and ROP.

Conclusion: With greater recognition of the risk factors of ROP and the understanding that timely treatment can save our vision, our community may be able to reduce the high burden of ROP, leading to morbidity.

Key words: Preterm babies, Respiratory distress syndrome, Retinopathy of prematurity

INTRODUCTION

Retinopathy of prematurity (ROP) is a potentially blinding condition. This mainly involves the developing retinal vasculature. This condition is commonly seen in premature and low birth weight infants. Terry explained this condition first in 1942 as retrolental fibroplasia.[1]

Improvements in neonatal care and increasing survival of very low birth weight infants in developing countries like India found to show rapid increase in the incidence of this condition. In India, according to the recent statistics, the incidence of ROP was found to be 47.2% by Dogra et al.[5] The incidence in various Western countries has been reported to range from 21% to 65.8%.[3-5] Variations in the incidence rates reported reflect differences in referral patterns, survival rates, the criteria used for examination, as well as levels of maternal and neonatal care.

Preliminary studies examining ROP from India reveal that ROP occupies an important area of public health. In spite of the variability in screening criteria in different regions of India, more recent studies have reported lower rates of ROP ranging from 20% to 30%.[6-8]

Several studies have shown that the incidence and severity of ROP rises with decreasing birth weight and gestational age (GA) and are attributed to the improved survival of low

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birth weight babies. The ROP incidence as demonstrated by Gopal et al.\textsuperscript{[6]} was 45.5% in babies with birth weight <1500 g and 23.5% in babies with birth weight more than 1500 g and 42.9% in babies <32 weeks and 34.5% in more than 32 weeks GA.

Given that the possible disease burden for a child blind from ROP is high, dramatic vision loss may be prevented by the institution of appropriate treatment. Laser photocoagulation or cryotherapy of the avascular retina offers some promise in halting the progression of ROP to sight-threatening complications. Major improvements in the screening methods of susceptible infants play an important role in saving more vision in premature infants in India.

The mainstay of any ROP management program is an effective screening strategy. However, the screening guidelines used in the Western countries may not be applicable to Indian population. Hence, in addition to a different patient population, there is wide difference in the Indian neonatal intensive care units as they vary in the quality of care provided to patients. The factors include the use of oxygen therapy, comorbid conditions, and use of other medications.

In India, standardized screening system for neonates relies on three questions that must be answered. What babies need to be screened? When is the best time and duration for screening? What is the most practical and effective method for screening? The most important aspect about ROP is that it is preventable and treatable by adequate and early screening.

An increase in the number of survival rates among premature babies is seen due to advances in the neonatal care. Hence, the present study has been designed to examine the incidence and risk factors in premature birth babies in a two-tier city, in southern part of Tamil Nadu which caters to the people in the district of Theni equipped with a good pediatric care and referral system.

### MATERIALS AND METHODS

**Study Design**
Descriptive study.

**Study Area**
SNCU Department of Pediatrics, Government Theni Medical College, Theni, Tamil Nadu, India.

**Study Period**

**Study Population**
Babies admitted in SNCU Government Theni Medical College, Theni, Tamil Nadu, India.

**Inclusion Criteria**
1. All preterm babies (<34 weeks)
2. All preterm babies (weight <2 kg).

**Methodology**
ROP screening was done for all preterm babies with birth weight <2 kg and GA 34 weeks. Initial examination was carried out after the 28\textsuperscript{th} day.

A complete history including birth weight, GA, weight for GA, and problems during NICU stay and their management were studied. Eye examination was done with an indirect ophthalmoscope by Ophthalmologist. An infant speculum and a Kreissig sclera depressor were used under topical anesthesia with 2% proparacaine drops, 0.5% cyclopentolate +2.5% phenylephrine eye drops 2 or 3 times, were used to dilate the pupils.

As per the international classification (ICROP), ROP was graded into zones and stages. Infants with normal vascularization were not examined again. Every week follow-up and screening was done for babies with ROP and the risk factors were assessed.

**OBSERVATIONS AND RESULTS**

This study was conducted between August 1, 2016 and July 31, 2017. It was a descriptive study. The follow-up data are based on assessment of babies done at the ophthalmology department of our medical college hospital.

The information collected was recorded in a master sheet. Frequencies, percentages, means, standard deviation, Chi-square, P value, and coefficient of correlation values were calculated for the available data. Chi-square test was used to test the significance of difference between quantitative variables. “P” value of <0.05 is considered to show statistically significant relationship.

A total of 301 babies were included in the study based on the inclusion and exclusion criteria.

The profile of the study participants was shown in Table 1. ROP screening was done for high-risk babies and 29 babies were diagnosed to have the disease. Development of the disease based on the individual risk factors has been discussed. Development of ROP is almost equal among male and female babies. From the above study, normal vaginal delivery, birth weight, respiratory distress syndrome (RDS), surfactant, apnea, sepsis, and blood transfusion are the statistically significant risk factors (P < 0.05).

The significant risk factors for the development of ROP were identified, of which mode of oxygen delivery for the
infants also played a statistically significant role ($P < 0.05$) as shown in Table 2.

Babies diagnosed of ROP were categorized mainly into 3 zones and 5 stages. More number of babies were in zone 3 (23) and zone 2 (6) with no babies in zone 1. Regarding the stages of ROP, many babies were in stage 1 (15) and stage 2 (10). Only four babies were in stage 3 and no babies were in stage 4 and stage 5 [Table 3].

Of the total 301 babies screened, around 6% (18 babies) did not complete full follow-up and were dropped out. 254 babies did not develop ROP [Table 4].

There is statistically significant relationship between babies with RDS and development of ROP as shown in Table 5.

There is a significant correlation between birth weight and ROP as shown in Table 6. Babies with birth weight <1.5 kg had more chance of developing ROP. Birth weight is an individual risk factor for ROP.

### DISCUSSION

Screening for ROP is essential in high-risk babies, which is almost not possible in developing countries like India with poor resources. However, early screening and treatment of ROP among high-risk babies is essential. Approximately 8.7% of 26 million annual live births in India are <2000 g in weight. This suggests that almost 2 million newborns are at risk for developing ROP.

Babies with birth weight <2000 g or with GA <34 weeks were screened. 301 babies were screened in our study. Of which, 29 babies were diagnosed as having ROP. Incidence

### Table 1: Profile of study participants

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No ROP (n=272)</th>
<th>ROP (n=29)</th>
<th>Chi-square</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>140 (51.5)</td>
<td>15 (51.7)</td>
<td>0.001</td>
<td>0.979</td>
</tr>
<tr>
<td>Female</td>
<td>132 (48.5)</td>
<td>14 (48.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mode of delivery</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Natural</td>
<td>158 (58.1)</td>
<td>11 (37.9)</td>
<td>4.324</td>
<td>0.038</td>
</tr>
<tr>
<td>LSCS</td>
<td>114 (41.9)</td>
<td>18 (62.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Birth weight</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;1.25 kg</td>
<td>9 (3.3)</td>
<td>11 (37.9)</td>
<td>69.062</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>1.26–1.5 kg</td>
<td>57 (21)</td>
<td>13 (44.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.6–1.75 kg</td>
<td>68 (25)</td>
<td>5 (17.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;1.75 kg</td>
<td>138 (50.7)</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RDS</td>
<td>79 (29)</td>
<td>25 (86.2)</td>
<td>37.867</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Surfactant</td>
<td>30 (11)</td>
<td>21 (72.4)</td>
<td>70.168</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Apnea</td>
<td>0</td>
<td>3 (10.3)</td>
<td>28.421</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>HIE</td>
<td>25 (9.2)</td>
<td>7 (24.1)</td>
<td>6.114</td>
<td>0.513</td>
</tr>
<tr>
<td>Multiple births</td>
<td>38 (14)</td>
<td>3 (10.3)</td>
<td>0.293</td>
<td>0.588</td>
</tr>
<tr>
<td>Jaundice requiring phototherapy</td>
<td>38 (14)</td>
<td>4 (13.8)</td>
<td>0.107</td>
<td>0.948</td>
</tr>
<tr>
<td>Blood transfusion</td>
<td>7 (2.6)</td>
<td>6 (20.7)</td>
<td>20.813</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Sepsis</td>
<td>28 (10.7)</td>
<td>10 (34.5)</td>
<td>13.960</td>
<td>0.001</td>
</tr>
<tr>
<td>PDA</td>
<td>23 (8.5)</td>
<td>4 (13.8)</td>
<td>0.901</td>
<td>0.343</td>
</tr>
<tr>
<td>MSAF</td>
<td>8 (2.9)</td>
<td>0</td>
<td>0.876</td>
<td>0.349</td>
</tr>
</tbody>
</table>

### Table 2: Risk factors for ROP

<table>
<thead>
<tr>
<th>Risk factors for ROP</th>
<th>n (%), Mean±SD</th>
<th>Chi-square/ T statistic</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ventilator</td>
<td>0 (51.5)</td>
<td>5 (17.2%)</td>
<td>47.689</td>
</tr>
<tr>
<td>Hood oxygen</td>
<td>2.70±1.781</td>
<td>4.97±2.934</td>
<td>-6.050</td>
</tr>
<tr>
<td>CPAP</td>
<td>0.298±6339</td>
<td>6.172±3.576</td>
<td>-24.063</td>
</tr>
</tbody>
</table>

### Table 3: Zone involved and stage in children with ROP

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zone</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>0 (0)</td>
</tr>
<tr>
<td>2</td>
<td>6 (20.7)</td>
</tr>
<tr>
<td>3</td>
<td>23 (79.3)</td>
</tr>
<tr>
<td>Stage</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>15 (51.7)</td>
</tr>
<tr>
<td>2</td>
<td>10 (34.5)</td>
</tr>
<tr>
<td>3</td>
<td>4 (13.8)</td>
</tr>
</tbody>
</table>

### Table 4: Follow-up observation among all children

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drop out</td>
<td>18 (6.0)</td>
</tr>
<tr>
<td>Observation</td>
<td>23 (7.6)</td>
</tr>
<tr>
<td>Laser</td>
<td>6 (2.0)</td>
</tr>
<tr>
<td>No evidence of ROP</td>
<td>254 (84.4)</td>
</tr>
</tbody>
</table>

### Table 5: RDS as a risk factor for ROP

<table>
<thead>
<tr>
<th>RDS</th>
<th>No ROP</th>
<th>ROP</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No RDS</td>
<td>193 (98.0)</td>
<td>4 (2.0)</td>
<td>197 (100.0)</td>
</tr>
<tr>
<td>RDS</td>
<td>79 (76.0)</td>
<td>25 (24.0)</td>
<td>104 (100.0)</td>
</tr>
<tr>
<td>Total</td>
<td>272 (90.4)</td>
<td>29 (9.6)</td>
<td>301 (100.0)</td>
</tr>
</tbody>
</table>

### Table 6: Birth weight and ROP

<table>
<thead>
<tr>
<th>Birth weight</th>
<th>No ROP</th>
<th>ROP</th>
<th>Chi-square</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1.25 kg</td>
<td>9 (3.3)</td>
<td>11 (37.9)</td>
<td>69.062</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>1.26–1.5 kg</td>
<td>57 (21)</td>
<td>13 (44.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.6–1.75 kg</td>
<td>68 (25)</td>
<td>5 (17.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;1.75 kg</td>
<td>138 (50.7)</td>
<td>0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
of ROP is common in both male and female babies. Gestational diabetes and antepartum hemorrhage of the mothers of the screened babies were the major maternal risk factors.

Analysis showed that the following risk factors such as GA, birth weight, oxygen administration, and respiratory distress were used as statistic tools to assess the correlation reported outborn, RDS, and severe ROP.

Of the 29 babies diagnosed as ROP, 15 babies (15/29 - 51.7%) had Stage I ROP, 10 babies (10/29 - 35.5%) had Stage II ROP, and 4 babies (4/29 - 13.8%) had Stage III ROP. Regarding the zone of ROP, no babies were in zone 1, 6 babies (20.7%) were in zone 2, and 23 (79.3%) babies were in zone 3. Among the diagnosed 29 babies, 23 babies had spontaneous regression of ROP and developed mature retina. Six babies needed laser therapy.

Babies with birth weight <1500 g and around 80% babies with respiratory distress went on for laser treatment. Chi-square test and P value were used as statistic tools to assess the correlation of incidence between birth weight/RDS and ROP.

Univariate analysis showed that the following risk factors were statistically significant: Birth weight, RDS, mode of delivery, post-conceptional age, oxygen administration, and sepsis.

Multivariate regression analysis of these univariately significant factors showed only the following remained significant: Birth weight, RDS, and oxygen administration. Anandvinekar et al. showed that ROP occurs at higher birth weights (>1250 g). In the Indian population, our study showed that 29% of the ROP occurred in 1.01–1.25 birth weight and 27% cases of ROP occurred in the 1.26–1.50 birth weight subgroup.

Shah et al. more specifically examined a south Indian population that may more closely resemble our population, but our results showed higher prevalence of ROP in GA <28 weeks, in lower (1–1.5 kg) birth weight subgroups and in oxygen therapy babies. Anandvinekar et al. reported outborn, RDS, and exchange transfusion as independent risk factors for severe ROP.

All the six babies who underwent laser therapy showed regression of ROP and had good visual results and are on long-term follow-up.

### CONCLUSION

ROP is emerging as one of the major causes of preventable childhood blindness in India. Timely screening and early management is the key management of ROP. Most of the studies including ours show that not all cases of ROP need treatment, but those few which really do need should not be missed. With greater recognition of the devastating consequences of ROP and the understanding that timely treatment can save our vision, our community may be able to reduce the high burden of childhood illness. RDS, low birth weight, and oxygen administration are the significant risk factors for ROP. Laser photocoagulation is the best mode of management with better results.

### REFERENCES

Clinico-Radiological and Pathological Profile of Lung Cancer Patients: An Experience from Tuberculosis and Chest Department of Indira Gandhi Institute of Medical Sciences, Patna: A Tertiary Health Care Centre of Bihar

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Abstract

Introduction: Today, lung cancer is the leading cause of cancer-related morbidity and mortality worldwide. Lung cancer especially shows varied epidemiological, clinico-radiological, and pathological profile. Majority of patients are at advanced stages before reaching to hospital. Lung cancers are growing at fast pace due to smoking habits, especially in Bihar. There are very sparse data of lung cancer patients especially in this part of the world.

Aim: This study aims to evaluate the clinico-radiological, demographic, and pathological profile of lung cancer patients reaching to Tuberculosis (TB) and Chest Department of Indira Gandhi Institute of Medical Sciences (IGIMS), Patna, Bihar and to assess the yield of various diagnostic processes used for the diagnosis.

Materials and Methods: This is a retrospective observational study done between September 2016 and February 2018 at TB and Chest Department of IGIMS, Patna, Bihar which is a tertiary health-care institute. Around 216 of proven lung cancer patients were enrolled for the study. Their history, clinical details, radiological, pathological, and demographic profiles recorded in the departmental records were analyzed in details using SPSS software.

Results: A total of 216 patients were included in our study of which 154 (71.29%) were male and 62 (28.7%) were female. Most patients were in the age bracket 66–75 years (33.88%). Most of the patients belonged to rural background (65.27%). About 71.29% of patients were smokers or former smokers. Adenocarcinoma was the most common histological subtypes documented, i.e., 89 patients (41.20%).

Computed tomography scan and ultrasonography-guided percutaneous biopsy combined was the most common modality of successfully diagnosing lung cancer, in about 25.92%. Majority of patients reached in advanced stage 63.88% among non-small cell lung cancer before arriving to health care facility (in Stage IVA). Mass was the most common radiological diagnosis in about 42.59%.

Conclusion: Adenocarcinoma is the leading type of lung cancer found in this study especially in this part of the world. Moreover, there is growing trend of lung cancer among females. Smoking is still the leading cause. Majority of patients reach at an advanced stage before diagnosis. Hence, aggressive approach is needed for earlier diagnosis of lung cancer for timely management.

Key words: Clinico-radiological profile, Lung cancer, Patna, Tuberculosis and chest

INTRODUCTION

Lung cancers are leading cause of cancer-related deaths (28%) worldwide.¹ The clinicopathological profile of lung cancer, its frequency and demographic profile are changing in recent years due to changes in smoking habits and exposure to other source of pollution and occupational exposure.²⁻⁹
There is increasing prevalence of lung cancer in India and smoking is still the most common causative agent, but there is rising trend of development of adenocarcinoma among non-smokers. Bihar constitutes a large chunk of patients having lung cancer, but there is scarce data available, so we undertook this study to retrospectively analyze the clinico-radiological and pathological profile of lung cancer patients attending the Tuberculosis (TB) and Chest Department in Indira Gandhi Institute of Medical Sciences (IGIMS), Patna, Bihar.

**MATERIALS AND METHODS**

The lung cancer data were collected from the TB and Chest Department, of IGIMS, Patna between September 2016 and February 2018. Only biopsy-proven lung cancer patients were included in this study. Their personal history, demographic profiles, smoking history, symptoms duration, signs and symptoms, radiographic findings, histopathological subtypes, and clinical staging of lung cancer were recorded in detail. Only patients with biopsy and histopathologically confirmed lung cancer were included in the study.

**Exclusion Criteria**

1. Age <25 years.
2. Patients with secondary lung cancer, lymphoma, sarcoma, malignant pleural effusion of unknown primary or non-pulmonary site, and other rare varieties were excluded from this study.
3. Patient not willing to undergo various diagnostic and interventional procedures.

Routine hematological examinations, sputum for malignant cytology, chest radiology including computed tomography (CT) thorax were done of nearly all patients. However, CT scan of abdomen, brain, or other parts of the body were done in selected cases as per requirement due to economic constraints. CT-ultrasound guided fine-needle aspiration cytology (FNAC)/biopsy, pleural fluid malignant cytology were done where indicated. Fiber optic bronchoscopy (FOB) was done in selected patients where indicated and biopsy and bronchial aspirate taken. Lymph node biopsy was also taken where indicated. Thoracoscopic biopsy could not be done due to unavailability of the instruments in our institute.

**RESULTS**

A total of 216 histopathologically proven cases of lung cancer were analyzed between September 2016 and February 2018. Most of the patients were in the age group of 66–75 years (34.25%) [Table 1].

**Table 1: Clinicopathological and demographic profile of lung cancer patients**

<table>
<thead>
<tr>
<th>Feature</th>
<th>NSCLC n=180 (%)</th>
<th>SCLC n=36 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;45</td>
<td>6 (3.33)</td>
<td>0</td>
</tr>
<tr>
<td>45–55</td>
<td>26 (14.44)</td>
<td>3 (8.33)</td>
</tr>
<tr>
<td>56–65</td>
<td>45 (25)</td>
<td>9 (25)</td>
</tr>
<tr>
<td>66–75</td>
<td>61 (33.88)</td>
<td>13 (36.11)</td>
</tr>
<tr>
<td>&gt;75</td>
<td>42 (23.33)</td>
<td>11 (30.55)</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>126 (70)</td>
<td>28 (77.77)</td>
</tr>
<tr>
<td>Female</td>
<td>54 (30)</td>
<td>8 (22.22)</td>
</tr>
<tr>
<td><strong>Occupation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Farmer</td>
<td>74 (41.11)</td>
<td>14 (38.88)</td>
</tr>
<tr>
<td>Household worker</td>
<td>19 (10.55)</td>
<td>6 (16.66)</td>
</tr>
<tr>
<td>Laborer</td>
<td>51 (28.33)</td>
<td>9 (25)</td>
</tr>
<tr>
<td>Office goers</td>
<td>36 (20)</td>
<td>7 (19.44)</td>
</tr>
<tr>
<td><strong>Geographical distribution</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urban</td>
<td>67 (37.22)</td>
<td>8 (22.22)</td>
</tr>
<tr>
<td>Rural</td>
<td>113 (62.77)</td>
<td>28 (77.77)</td>
</tr>
<tr>
<td><strong>Smoking history</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoker</td>
<td>102 (56.66)</td>
<td>29 (80.55)</td>
</tr>
<tr>
<td>Non-smoker</td>
<td>58 (32.22)</td>
<td>4 (11.11)</td>
</tr>
<tr>
<td>Former smoker</td>
<td>20 (11.11)</td>
<td>3 (8.33)</td>
</tr>
<tr>
<td><strong>Type of smoking</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bidi</td>
<td>124 (68.88)</td>
<td>29 (80.55)</td>
</tr>
<tr>
<td>Cigarette</td>
<td>49 (27.22)</td>
<td>4 (11.11)</td>
</tr>
<tr>
<td>Hukka, Biomass fuel</td>
<td>7 (3.88)</td>
<td>3 (8.33)</td>
</tr>
<tr>
<td><strong>Carcinoma subtypes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SCC</td>
<td>58 (32.22)</td>
<td></td>
</tr>
<tr>
<td>Adenocarcinoma</td>
<td>89 (49.44)</td>
<td></td>
</tr>
<tr>
<td>Large cell carcinoma</td>
<td>2 (1.11)</td>
<td></td>
</tr>
<tr>
<td>Poorly differentiated carcinoma</td>
<td>31 (17.22)</td>
<td></td>
</tr>
<tr>
<td>Small-cell carcinoma</td>
<td>36 (100)</td>
<td></td>
</tr>
<tr>
<td><strong>Mode of diagnosis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FOB/BAL</td>
<td>56 (31.11)</td>
<td>8 (22.22)</td>
</tr>
<tr>
<td>CT-guided percutaneous</td>
<td>42 (23.33)</td>
<td>14 (38.88)</td>
</tr>
<tr>
<td>FNAC USG-guided percutaneous</td>
<td>27 (15)</td>
<td>10 (27.77)</td>
</tr>
<tr>
<td>FNAC/Tru cut biopsy</td>
<td>21 (11.66)</td>
<td>2 (5.55)</td>
</tr>
<tr>
<td>Pleural fluid cytology</td>
<td>21 (11.66)</td>
<td>2 (5.55)</td>
</tr>
<tr>
<td>Lymph node biopsy</td>
<td>25 (13.88)</td>
<td>2 (5.55)</td>
</tr>
<tr>
<td>Sputum malignant cytology</td>
<td>8 (4.44)</td>
<td>1 (2.77)</td>
</tr>
<tr>
<td><strong>AJCC staging (8th ed.)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IA</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>IB</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>IIA</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>IIB</td>
<td>2 (1.11)</td>
<td></td>
</tr>
<tr>
<td>IIIA</td>
<td>9 (5)</td>
<td></td>
</tr>
<tr>
<td>IIIB</td>
<td>16 (8.88)</td>
<td></td>
</tr>
<tr>
<td>IIIC</td>
<td>23 (12.77)</td>
<td></td>
</tr>
<tr>
<td>IVA</td>
<td>115 (63.88)</td>
<td></td>
</tr>
<tr>
<td>IVB</td>
<td>9 (5)</td>
<td></td>
</tr>
<tr>
<td>NS</td>
<td>6 (3.33)</td>
<td></td>
</tr>
<tr>
<td>Limited</td>
<td>7 (19.44)</td>
<td></td>
</tr>
<tr>
<td>Extensive</td>
<td>29 (80.55)</td>
<td></td>
</tr>
</tbody>
</table>

154 (71.29%), females were 62 (28.70%) in totality. One hundred twenty-six (70%) of males were having NSCLC out of 180 cases, whereas 28 (77.77%) were males in SCLC group of 36. Among the occupation, farmers (40.74%) were the most vulnerable group to develop lung carcinoma probably due to smoking habits. Patients from rural areas (65.27%) were mostly diagnosed with lung carcinoma as compared to urban group (34.72%). Active smoking history was present in 131 cases (60.66%) whereas 23 (10.64%) were former smokers. Hence, smoking was still the most common cause of lung cancer in this study. Bidi smoking was the most common cause in 153 (70.83%). Adenocarcinoma was the most common subtype identified in 89 patients (49.44%) among NSCLC in the present study surpassing squamous cell carcinoma (SCC) as per national average. This may be due to growing incidence of adenocarcinoma in non-smokers in this region. CT and ultrasonography (USG)-guided biopsy combined were the most common modality of diagnosis in 93 (43.05%) whereas FOB was diagnostic in 64 patients (29.62%). Most of the NSCLC 115 (63.88%) were of the American Joint Committee on Cancer (AJCC) stage (8th edition) IVA whereas SCLC was of extensive stage in 29 patients (80.55%). Most of the patients had metastasis to different organs during evaluation 155 (71.75%) with adrenals being the most common organ to be metastasized in 43 (27.74%). Multiple metastasis was seen more commonly in SCLC 10.34% as compared to NSCLC in 7.14% [Graph: 1].

Most common symptoms were weight loss 189 (87.5%) followed by a cough 113 (52.31%). Most common clinical examination findings were pallor 78 (36.11%) whereas superior vena cava obstruction (SVC) was found in 27 (12.5%) [Graph 2 and Table 2].

Among radiological distribution, right lung was involved more commonly in 113 (52.31%) and mass was most common finding on radiology in 92 (42.59%) [Table 3].

**DISCUSSION**

Our study represents the clinical, radiological, demographic, and histopathological profile of lung cancer patients...
presenting to TB and Chest Department, in IGIMS, Patna, a tertiary health-care center from different parts of Bihar and adjoining states including Nepal. Most of the patients were diagnosed falsely having pulmonary TB and were taking antituberculous therapy in the peripheral health center. That leads to patients being diagnosed late and arriving at our center in advanced stage. Most of the patients fall into higher age group (>56 years) with Non small cell lung cancer (NSCLC) comprising 68.51% and Small cell lung cancer (SCLC) 15.27% in this age group.

In different studies from west as well as from India, it is reported that 50%–70% cases of NSCLC and up to two-thirds of SCLC usually present in advanced stage.\[10,11\]

Male-female ratio constitutes about 2.4:1 which appears to be slightly lower than most of the studies from India and abroad.\[2,7,12,13\] This may be due to growing incidence of adenocarcinoma in female non-smoker. Smoking is associated with most of the lung cancer cases. In present study, bidi smoking, a form of unfiltered tobacco smoke was associated with a large number of NSCLC, i.e., 56.66% and SCLC in 80.55%, especially in rural background. Previous Indian series have shown that majority of patients with lung cancer were bidi smokers.\[13-15\] This may be due to growing awareness about the smoking hazard and anti-smoking campaign in urban areas leading to less number of lung cancer cases among them. The risk of lung cancer in former smoker remains high than never-smoker even after >40 years of abstinence.\[2\]

In our study, lung cancer was found in former smokers in 11.11% in NSCLC and in 8.33% in small-cell lung cancer (SCLC). There has been a shift of histological profile towards adenocarcinoma worldwide these days.\[16-18\]

In our study also, adenocarcinoma was the predominant subtype in 49.44% among NSCLC with females constituting 28.08%. Poorly differentiated carcinoma was found in 31 (17.22%) [Graph 3]. This is due to lack of immunohistochemistry available in our institute and also financial constraints. Most of the patients were in an advanced stage in our study with stage IVA according to AJCC 8th edition constituting 63.88% among NSCLC and extensive stage 80.55% in SCLC.

As positron emission tomography scan, mediastinoscopy thoracoscopy was not available and in our institutes and also due to financial constraints, we could not go for extensive investigations. CT/USG-guided FNAC/biopsy was the most common modality of diagnosis followed by FOB in our study as former is easy and relatively cheap and safe. We could diagnose lung cancer by sputum examination only in 8 patients in NSCLC and 1 patient

### Table 2: Distribution according to clinical examination findings

<table>
<thead>
<tr>
<th>Findings</th>
<th>Number of patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pallor</td>
<td>78 (36.11)</td>
</tr>
<tr>
<td>Clubbing</td>
<td>54 (25)</td>
</tr>
<tr>
<td>Cyanosis</td>
<td>24 (11.11)</td>
</tr>
<tr>
<td>Peripheral lymphadenopathy</td>
<td>42 (19.44)</td>
</tr>
<tr>
<td>SVC obstruction</td>
<td>27 (12.5)</td>
</tr>
</tbody>
</table>

SVC: Superior vena cava obstruction

### Table 3: Radiological lesion distribution

<table>
<thead>
<tr>
<th>Radiological lesion</th>
<th>Number of patients n=216 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilateral</td>
<td>22 (10.18)</td>
</tr>
<tr>
<td>Right lung</td>
<td>113 (52.31)</td>
</tr>
<tr>
<td>Left lung</td>
<td>81 (37.5)</td>
</tr>
<tr>
<td>Mass</td>
<td>92 (42.59)</td>
</tr>
<tr>
<td>Mass with effusion</td>
<td>41 (18.98)</td>
</tr>
<tr>
<td>Effusion</td>
<td>32 (14.81)</td>
</tr>
<tr>
<td>Coin shadow</td>
<td>13 (6.01)</td>
</tr>
<tr>
<td>Mass with collapse/consolidation</td>
<td>26 (12.03)</td>
</tr>
<tr>
<td>Hydropneumothorax</td>
<td>5 (2.31)</td>
</tr>
<tr>
<td>Cavity</td>
<td>7 (3.24)</td>
</tr>
</tbody>
</table>

Graph 3: Lung carcinoma distribution among different sex
CONCLUSION

This study signifies that smoking is the principal risk factor of lung carcinoma. Adenocarcinoma appears to be the most common type of lung cancer in this region. There is growing trend of female lung cancer patients which need further studies to find out the etiological factors responsible. Lung cancer patients present with some specific sign and symptoms which mimics with TB or COPD leading to patients presenting late to the specialized centers. Hence, every effort is needed to find out the etiology, prevent the risk factors, to diagnose early and treat effectively so that patients can lead a comfortable life.

REFERENCES

Effect of Proper Lifestyle Modifications on the Management of Type 2 Diabetes Mellitus

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Abstract

Introduction: Diabetes mellitus (DM) comprises a group of metabolic disorders that share the common feature of hyperglycemia. It is closely linked to change in lifestyle such as decreased physical activity, a change in diet to the one of high-fat, high-energy intake, and rapid modernization into a western society. Patients with DM can be managed by lifestyle modifications in the form of diet, physical activity, and psychological assessment with care along with drugs.

In this, we studied the effects of comprehensive lifestyle modifications and their effect on glycemic control, blood pressure, lipid profile, body weight, and 24 h urinary protein for the management of DM.

Material and Methods: This study was performed between November 2015 and May 2016 at Indira Gandhi Institute of Medical Sciences, Patna. Lifestyle modification included diet instruction, exercise, weight reduction programs, and de-stressing session. Body weight, glycated hemoglobin (HbA1C), serum triglyceride, serum low-density lipoprotein (LDL), blood pressure, and 24 h urinary proteins were measured at baseline and after 6 months of lifestyle modification program.

Results: The results of lifestyle modification after 6 months of lifestyle modification were favorable with a mean reduction in HbA1C, LDL cholesterol, triglycerides, systolic blood pressure, diastolic blood pressure, and 24 h urinary protein are 0.09, 3.32, 16.88, 00.64, 3.68, 2.04, and –232.04, respectively.

Conclusion: Comprehensive lifestyle management is an important aspect of diabetes management.

Key words: Diabetes mellitus, Lifestyle modification, Treatment of diabetes mellitus

INTRODUCTION

Diabetes mellitus (DM) comprises a group of metabolic disorders that share the common feature of hyperglycemia. Type 2 DM is common and accounting 85% of diabetes in worldwide.[1] It is closely linked to industrialization, affluence, and increased life expectancy. India is rapidly changing into the diabetic capital of the world. The number of diabetic people in India will increase to 57.2 million in 2025. The prevalence of diabetes in rural India is low unlike the prevalence in an urban area. The reason for this is a change in lifestyle such as decreased physical activity, a change in diet to the one of high-fat, high-energy intake, and rapid modernization into a western society. Patients with DM can be managed by lifestyle modifications in the form of diet, physical activity, and psychological assessment with care along with drugs.

This study is intended to know the effect of lifestyle modification such as dietary advice, exercise, and de-stressing session with yoga and weight reduction in diabetes management.
MATERIALS AND METHODS

Design
This study used a single-group experimental design with a proper assignment with repeated measures.

Subject
A total of 50 patients were recruited in the study from outdoor of General Medicine Department of Indira Gandhi Institute of Medical Sciences, Patna. All patients in this study were suffering from DM type 2. Key inclusion and exclusion criteria are shown in Table 1. Written informed consent was obtained from the patients. They were screened properly and recruited for the study. Patients with advanced complications such as severe cardiovascular comorbidities, renal failure, and retinopathy were excluded from the study. Patients from both sexes were included in the study Table 1.

Procedure
Each patient was counseled and educated about the diet management, exercise, and de-stressing session with yoga.

Diet instructions were given according to the patient dietary habit and were on the basis of ADA 2010 recommendation which includes:
1. 60–65% of carbohydrates of total calorie.
2. 10–15% of protein of total calorie.
3. <25% of fats of total calorie.
4. 25 g fiber/1000 Kcal.

The physical program was well instructed to the patients after proper screening. They were instructed to do brisk walking at least 150 min/week in different divided sessions. This moderate-intensity aerobic physical activity should raise not more than 50–70% of maximum heart rate. People were encouraged to perform resistance exercise at least 3 times a week. Resistance exercise advised to the patient was seated leg press, chest press, pull down, and leg extension.

De-stressing program included yoga and pranayama. Patients were instructed with proper counseling about the importance of distressing session and their effect on mental and physical well-being. Deep breathing pranayama and concentration yogasana were instructed to the patients.

Pharmacological Treatment
All patients were instructed to take antidiabetic drugs as usual they were taking before the start of the study. They were also instructed to continue other medications such as antihypertensive and lipid-lowering drugs.

Measurements and Data Collection
Following measurements were collected at baseline and again measured after 6 months. The change in outcome measure was analyzed after 6 months.
1. Glycosylated hemoglobin.
2. Serum low-density lipoprotein (LDL).
3. Serum triglyceride.
5. Body weight.
6. 24 h urinary protein.

Change in drugs, being used by the patient, was not included in measure of lifestyle modification effect on diabetes type 2 management due to complexity in measurement.

RESULT
Clinical and biochemical variables such as weight, blood pressure, glycosylated hemoglobin, serum LDL, serum triglyceride, and 24 h urinary protein were measured at baseline and at the end of follow-up period (6 months) and shown in Table 2. It was noticed that after lifestyle modification, all clinical and biochemical variables were improved and mean changes in these variables are shown in Table 2.

In my study, mean reduction in HbA1C, LDL cholesterol, triglycerides, systolic blood pressure (SBP), diastolic blood pressure (DBP), and 24 h urinary protein is 0.09, 3.32, 16.88, 00.64, 3.68, 2.04, and −232.04, respectively.

DISCUSSION
We conducted a study on 50 patients of type 2 DM to know the effect of lifestyle modification such as dietary advice, exercise, and de-stressing session with yoga and weight reduction. Lifestyle modification in diabetes management is well-known fact but not well practiced by physicians in field.

In my study, mean reduction in HbA1C, LDL cholesterol, triglycerides, SBP, DBP, and 24 h urinary protein is 0.09, 3.32, 16.88, 00.64, 3.68, 2.04, and −232.04, respectively.

In this study, there is an improvement in glycated hemoglobin (HbA1C) by 0.09 that is less than the results of the meta-analysis reported by Norris et al.[2] which showed a decrease in HbA1C of 0.28% at the end of 3 months. For a 1% reduction in HbA1C, there was 14%
reduction in mortality of diabetic patient in the United Kingdom.\textsuperscript{13} This suggests that my finding of 0.09% reduction at 6 months of study could not have much effective impact on the patient mortality. Sanghani et al.\textsuperscript{14} conducted a study on 279 patients of DM and observed 0.14% reduction in HbA1c. They observed significant reduction, that is, 0.59% when structured exercise program training group.

A few studies have shown that a lifestyle change program is as effective as other treatments such as drugs. Lifestyle changes were almost twice as effective as metformin therapy in those with impaired glucose tolerance.\textsuperscript{15} In my study, results suggest that lifestyle interventions are just an added factor to pharmacological treatment as all the patient in our study group were still taking medication to control glucose level.

In my study, mean weight loss in patients was 0.64 kg. After 6 months and this was a smaller magnitude that found in other studies.\textsuperscript{16} This might have been due to a lower mean body weight in my participants than the participants in other studies.

The mean change in SBP in my study group is 3.68 mmHg after 6 months. The mean change in DBP is 2.04 mmHg. This change in blood pressure is consistent with the previous studies. In the Premier trial\textsuperscript{7} of hypertensive adults, multi-component behavioral interventions or multiple behavioral intervention plus DASH were compared to on “advice only” group. In the multiple behavioral intervention plus DASH group, the mean net reduction in SBP was 11.1 mmHg and in DBP was 6.4 mmHg.

In this study, the change in lipid components such as LDL and triglyceride also compared from baseline value after 6 months of lifestyle modification program. The mean change in serum LDL after 6 months of lifestyle intervention program is 3.3 mg/dl. The mean change in triglyceride is 16.88 mg/dl. A study done by Ratner\textsuperscript{8} found that the change in LDL cholesterol is not significant, but the change in triglyceride is more significant in intensive lifestyle group.

The change in 24 h urinary protein is mainly due to change in blood pressure and glycemic control. For people with microalbuminuria, controlling blood pressure and achieving near normoglycemia slows the progression to macroalbuminuria and end-stage renal disease.

Chen et al.\textsuperscript{9} conducted a meta-analysis to evaluate the effects of comprehensive lifestyle change, such as diet, exercise, and education, on clinical markers that are risk factors for cardiovascular disease in patients with type 2 diabetes. A total of 16 studies were included in the meta-analysis. The standardized difference in means of change from baseline significantly favored the intervention compared with the control group in BMI (−0.29; 95% CI, −0.52–0.06, \(P = 0.014\)), HbA1c (−0.37; 95% CI, −0.59–0.14, \(P = 0.001\)), SBP (−0.16; 95% CI, −0.29–0.03, \(P = 0.016\)), and DBP (−0.27; 95% CI = −0.41–0.12, \(P < 0.001\)). There was no difference between the intervention and control groups in high-density lipoprotein cholesterol (0.05; 95% CI, −0.10–0.21, \(P = 0.503\)) and LDL-cholesterol (−0.14; 95% CI, −0.29–0.02; \(P = 0.092\)).

CONCLUSION

Comprehensive lifestyle management is an important aspect of diabetes management but the most neglected part of the management program. This study is of very short duration and includes only 50 patients. Further research is needed with larger group with longer follow-up to see the effect of lifestyle modification.

REFERENCES


Table 2: Variables before start of study and variables after 6 months of life style modification program

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean at the start of study</th>
<th>Standard deviation</th>
<th>Mean the end of study</th>
<th>Standard deviation</th>
<th>Change in mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c (%)</td>
<td>7.52</td>
<td>0.47</td>
<td>7.43</td>
<td>0.38</td>
<td>0.09</td>
</tr>
<tr>
<td>LDL (mg/dl)</td>
<td>98.32</td>
<td>13.57</td>
<td>95.00</td>
<td>10.45</td>
<td>3.32</td>
</tr>
<tr>
<td>Triglyceride (mg/dl)</td>
<td>166.04</td>
<td>46.15</td>
<td>149.16</td>
<td>25.5</td>
<td>16.88</td>
</tr>
<tr>
<td>Body weight (Kg)</td>
<td>58.56</td>
<td>6.49</td>
<td>57.92</td>
<td>6.18</td>
<td>0.00</td>
</tr>
<tr>
<td>SBP (mmHg)</td>
<td>135.88</td>
<td>12.86</td>
<td>132.2</td>
<td>9.72</td>
<td>3.68</td>
</tr>
<tr>
<td>DBP (mmHg)</td>
<td>85.48</td>
<td>5.39</td>
<td>83.44</td>
<td>3.86</td>
<td>2.04</td>
</tr>
<tr>
<td>24 h urinary protein (mg/24 h)</td>
<td>279.6</td>
<td>173.9</td>
<td>262.00</td>
<td>145.9</td>
<td>−234.04</td>
</tr>
</tbody>
</table>

HbA1c: Glycated hemoglobin, SBP: Systolic blood pressure, DBP: Diastolic blood pressure, LDL: low-density lipoprotein, HDL: High-density lipoprotein.
Saha, et al.: Effect of Proper Lifestyle Modifications on the Management of Type 2 Diabetes Mellitus


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Comparative Evaluation of Ropivacaine and Lignocaine with Ropivacaine, Lignocaine, and Clonidine Combination during Peribulbar Anesthesia for Cataract Surgery

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Abstract

Background: Peribulbar is the most commonly used technique of anesthesia in cataract surgery, and ropivacaine is a new amino amide local anesthetic with the safer pharmacological profile.

Aim: A double-blind, prospective, and randomized study carried out in our institution after getting approval from the Ethical Committee, to compare the anesthetic effects of ropivacaine with the combination of ropivacaine and clonidine in the administration of peribulbar block in cataract surgery.

Materials and Methods: A total of 80 patients of both sexes aged 40–80 years of ASA PS I, II, scheduled for cataract surgery was included in this study. Patients were allocated to two groups of 40 each; ropivacaine, lignocaine group (R group) who received peribulbar block with 2.5 ml of lignocaine (2%) + 2.5 ml of ropivacaine (0.75%) + 50 units of hyaluronidase to a total volume of 5 ml and ropivacaine, lignocaine, clonidine group (RC group) received peribulbar block with 2 ml lignocaine (2%) + 2 ml of ropivacaine (0.75%) + 50 units of hyaluronidase +1 µg/kg of clonidine to a total volume of 5 ml. Heart rate (HR), mean arterial pressure (MAP), pulse oximetry (SpO₂), intraocular pressure (IOP), and quality of peribulbar block were observed throughout the intraoperative period at regular intervals. Duration of analgesia was observed in the post-operative period.

Results: Demographic characteristics, SpO₂ were comparable in both groups. The onset of sensory and motor blockade was significantly earlier in RC group. IOP does not vary significantly in both groups. The HR, MAP was on the lower side in RC group. The duration of analgesia was prolonged in RC group (6.16 h) as compared to R group (3.48 h).

Conclusion: On adding clonidine to local anesthetic agent augments early onset and prolonged offset of sensory analgesia. It also reduces the volume of local anesthetic requirement. They maintain the hemodynamic throughout the procedure.

Key words: Peribulbar block, Ropivacaine, Clonidine, Cataract surgery

INTRODUCTION

Regional anesthesia is the common technique for most of the surgeries within the orbit. In our institution, cataract surgery is commonly carried out under regional anesthesia. Regional anesthesia for ophthalmic surgery can be administered by the anesthesiologist, provided they receive appropriate training in performing the technique and are fully conversant with the associated risks and complications and can treat them accordingly. Regional anesthesia is a better alternative, whenever general anesthesia is undesirable or contraindicated.

Today anesthesia for cataract surgery needs a comfortable environment for both patient and surgeon during surgery and recovery of function quickly without risk. There is only a limited role for general anesthesia which is indicated especially in cases where topical or local anesthesia is contraindicated.
The two most commonly used regional anesthesia techniques are retrobulbar block and peribulbar block. They provide adequate anesthesia for surgery of cornea, anterior chamber, and lens. Retrobulbar block technique involves deposition of the drug into the muscle cone, so termed as the intraconal block. Peribulbar block technique involves deposition of the drug outside the muscle cone so termed as an extraconal block.[1-4]

Peribulbar anesthesia was first performed by Kelman in 1970, which was unpublished. Then, the use of peribulbar block was reported by Davis and Mandel in 1985.[5] It offers a measure of safety as the drug is deposited outside the muscle cone but within the orbit. It is very easy to perform and less painful. No need for accessory facial nerve block less chance of retrobulbar hemorrhage, perforation of the globe and optic nerve injury.

The complications and need for accessory facial nerve block in case of the retrobulbar block have led to the popularity of peribulbar block in ocular anesthesia.

In our study, we compare the efficacy of peribulbar block in cataract surgeries with combination of 1:1 mixture of 0.75% ropivacaine with 2% lignocaine and 1:1 mixture of 0.75% ropivacaine with 2% lignocaine with 1 µg/Kg of clonidine regarding the time of onset of sensory blockade, motor blockade, intraoperative hemodynamics, and duration of analgesia.

**Aim**
The aim of the study was to compare the onset of blockade and duration of analgesia using ropivacaine and lignocaine with ropivacaine and lignocaine and clonidine combination for a peribulbar block in cataract surgery.

**MATERIALS AND METHODS**

A total of 80 patients of ASA Grades I and II patients of both sexes aged 40–80 years undergoing cataract surgery are included in this clinical trial. Written informed consent is obtained from all patients.

This study is a prospective, randomized, double-blind study conducted in Regional Institute of Ophthalmology, Chennai, after getting approval from the Ethical Committee. Informed consent was obtained, and the procedure was explained to the patient in his/her own language. An initial preoperative counseling and reassurance were done.

80 patients were allocated into two groups - R Group, RC Group on the basis of simple randomization.

**Figure 1**: Comparison of mean heart rate in R group and RC group

**Figure 2**: Comparison of mean arterial pressure in R group and RC group

**R Group** - consists of 40 patients receive peribulbar block with 2.5 ml of lignocaine (2%) + 2.5 ml of ropivacaine (0.75%) + 50 units of hyaluronidase.

**RC Group** - consists of 40 patients receive peribulbar block with 2 ml lignocaine (2%) + 2 ml of ropivacaine (0.75%) + 50 units of hyaluronidase + 1 µg/kg of clonidine.

Patients in both the groups were of comparable demographic status.

**Inclusion Criteria**
The following criteria were included in this study:
- Adults 40–80 years
- Both sex
- ASA PS I and II
- Side of eye R/L
- Duration of surgery 20–50 min
- Weight 40–80 Kg

**Exclusion Criteria**
The following criteria were excluded from the study:
- Patient with active ocular infection
- Patient on any anti-glaucoma medications
- Patient with a single eye
- Patient allergic to amide-type local anesthetics
Rajashree, et al.: Comparison of Anaesthetic drugs in cataract surgery

All patients are examined thoroughly in pre-operative room. Baseline parameter such as heart rate (HR), blood pressure (BP), electrocardiography (ECG), and baseline investigations such as hemoglobin, blood sugar, urea, and creatinine, should be checked.

In operation room, Boyle’s machine, oxygen source, oxygen cylinder, appropriate airway equipment, and emergency drugs were made ready.

The patient was asked to maintain the eye in primary gaze directly ahead. Eye was painted with povidone-iodine. A 22G 2.5 cm needle was inserted in inferotemporal region through the skin at the junction of lateral 1/3rd and medial 2/3rd of lower orbital margin once the needle was under the globe, it was directed along the orbital floor up to the depth of midorbit in the lateral extraconal space and not an upward and inward direction to avoid injury to optic nerve. After careful negative aspiration, 3 ml of the local anesthetic was given. Manual compression and massage of eyeball were done to spread the local anesthetic solution.

The patient was assessed for a sensory block at 2–7 min, motor block at 4–10 min, and IOP at the 1st min. The HR, systolic BP, and diastolic pressure were monitored at 1, 5, 10, 15, 20, 30, and 40 min.

**Sensory Block**

Sensory block was tested by the loss of sensation of cornea with a wisp of cotton. This assessment was done at 2–7 min after injection. The onset of sensory block was taken from the time from injection to loss of sensation of the cornea.

**Motor Block**

Ocular globe mobility was tested in four quadrants using three-point scoring system.

Score-0 Akinesia (ocular movement <1 mm)
Score-1 Reduced movement (ocular movement >1 mm but <4 mm)
Score-3 Normal movement (ocular movement >4 mm).

This scoring system gives a maximal aggregated score of 8 for the four muscles. A score <2, reduced movement in all direction, was taken to indicate a successful block. Once successful block had been achieved, no further assessment was made.

**Quality of Surgical Anesthesia**

Surgical anesthesia was graded as follows:

- Excellent: No pain at any time during surgery
- Good: Minimal pain or discomfort
- Poor: Failed block.

Intraoperatively oxygen 4 L/min was given through nasal cannula to all patients under sterile drapes.

The patient was shifted to the post-operative ward after completion of surgery. Duration of pain relief was assessed in these patients. Pain assessment was done using visual analog scale (VAS) score. VAS score >3 indicates pain.

Duration of effective analgesia was defined as time interval between peribulbar block and the time to reach VAS score >3.

Table 1: Comparison of peribulbar block characteristics

<table>
<thead>
<tr>
<th>Block characteristics</th>
<th>Mean difference</th>
<th>S.E difference</th>
<th>95% C.I</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onset of sensory anesthesia (min)</td>
<td>2</td>
<td>0.138</td>
<td>1.73</td>
<td>2.27</td>
</tr>
<tr>
<td>Onset of motor blockade (min)</td>
<td>2.68</td>
<td>0.222</td>
<td>2.23</td>
<td>3.12</td>
</tr>
<tr>
<td>Duration of analgesia (h)</td>
<td>−2.68</td>
<td>0.165</td>
<td>3.01</td>
<td>−2.35</td>
</tr>
</tbody>
</table>

S.E: Standard error, C.I: Confidence interval

Table 2: Comparison of peribulbar block characteristics in both groups

<table>
<thead>
<tr>
<th>Block characteristics (mean±SD)</th>
<th>Group R</th>
<th>Group RC</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onset of sensory blockade (min)</td>
<td>4.93±0.656</td>
<td>2.93±0.572</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Onset of motor blockade (min)</td>
<td>8.23±0.974</td>
<td>5.55±1.01</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Duration of analgesia (h)</td>
<td>3.48±0.72</td>
<td>6.16±0.75</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

SD: Standard deviation
Resolution of motor blockade could not be assessed, as these patients' eye were bandaged and covered after the operation.

The data collected were subjected to statistical analysis. The patient group was comparable in the distribution of age and sex. These characteristics were analyzed using Student’s \( t \)-test and Pearson's Chi-square test.

### RESULTS

The mean time of onset of sensory blockade in the R group was 4.93 min, and RC group was 2.93 min. The mean difference was 2, with 95% confidence interval (C.I) ranging from 1.73 to 2.27. The onset of sensory anesthesia was 2 min earlier on an average in the RC group. The difference was statistically significant.

The onset of the motor blockade in R group was 8.23 min, and RC group was 5.55 min. The mean difference was 2.68 with 95% C.I ranging from 2.23 to 3.12. The onset of motor blockade was 2.68 min earlier on an average in the RC group. The difference was statistically significant.

The mean duration of analgesia in the R group was 3.48 h, and RC group was 6.16 h. The mean difference was −2.68 with 95% C.I ranging from 3.01 to −2.35. The difference was statistically significant. Participants in the RC group had analgesia lasting for an average of 2.68 h more than the R group Table 1 and 2.

There was a transient increase in HR in the 1st min after administering peribulbar block in both the groups. It declined gradually after that patient in the RC group had a more stable decline in HR compared to the R group; the difference was statistically significant after 20 min.

Overall, the RC group of patients had a significantly lower HR on an average than the R group Figure 1.

Similar results were observed with the systolic BP, diastolic BP, and mean arterial pressure (MAP) between the R group and RC group of patients. Throughout the entire period, RC group of patients had a lower BP on an average, and the difference was statistically significant Figure 2.

The difference in IOP between the two groups pre-block and after administering the block was not statistically significant. There was no significant variation in IOP between the two groups Table 3.

None of the participants experienced nausea. 3 participants in the R group had a headache, compared to 2 in the RC Group, 1 participant in the R group had vomiting, while none in the RC Group, 3 participants in the RC group reported dry mouth as a side effect, which was absent in the R group Table 4.

### DISCUSSION

The use of regional anesthesia is popular in ophthalmic surgery because it is associated with less hemodynamic and less respiratory complications with good recovery compared to general anesthesia. This is because of improved surgical technology, reduced operating time, and improvement in anesthetic techniques.

The two commonly used regional anesthesia technique in ophthalmic surgery is retrobulbar block and peribulbar block.

The complications of the retrobulbar block are rare but severe when it occurs. The complications are severe retrobulbar hemorrhage, extraocular muscle paralysis, direct optic nerve injury, central retinal vascular occlusion, ocular perforation, contralateral amaurosis, and systemic local anesthetic toxicity.
Rajashree, et al.: Comparison of Anaesthetic drugs in cataract surgery

To avoid these complications, Davis and Mandel introduced peribulbar block. It is associated with less complication when compared to retrobulbar block.

Hence, nowadays, peribulbar block is chosen as a safe and effective technique.

In our Institute of Ophthalmology, the protocol is to use lidocaine alone for cataract surgery. However, the lidocaine-ropivacaine mixture for the peribulbar block has an advantage of lidocaine faster onset time and ropivacaine longer post-operative pain relief. Thus, this mixture is better compared to lignocaine alone.

This study was conducted in our institution where we used the mixture of ropivacaine, lignocaine, and clonidine. The aim of the study is to find out the usefulness of clonidine in prolongation of the duration of analgesia.

On the statistical analysis of the data obtained from the group of 80 patients with similar demographic profile showed that there is a statistically significant difference between R group and RC group about sensory and motor blockade. The onset of sensory blockade was 2 min earlier on an average in RC group. The onset of motor blockade was 2.68 min earlier on an average in RC group. This corresponds to study conducted by Khan et al.,[10] who concluded that the addition of clonidine augments early onset of sensory blockade.

Regarding duration of analgesia, our study showed a statistically significant difference in prolongation of the duration of analgesia in RC group. The analgesia lasting for an average of 2.68 h in RC group compared to R group which corresponds to study conducted by Mjahed et al.[9] which showed the addition of clonidine prolongs the duration of action.

The total volume of local anesthetics used in R group is 5 ml (with 2.5 ml lignocaine [2%] + 2.5 ml of ropivacaine [0.75%] + 50 U hyaluronidase) and in RC group is 5 ml (with 2 ml lignocaine [2%] + 2 ml of ropivacaine [0.75%] + 50 units of hyaluronidase + 1 µg/kg of clonidine). From our study, the total volume of local anesthetics required for the blockade is reduced. This corresponds to study by Bajwa et al.[1] which showed the addition of clonidine to ropivacaine results in effective, complete and longer analgesia with the similar blockade and there is the reduction in the effective dose of ropivacaine when compared with plain ropivacaine for cesarean delivery.

From the statistical analysis obtained from our study the difference in IOP between the two groups pre-block and after administering the block was not statistically significant.

There was no significant variation in IOP between the two groups. This corresponds to the study by Connelly et al.[9] which concluded that there were no differences between groups with respect to pain. There was no difference with respect to onset of akinesia. This study revealed no significant difference in baseline IOP and posted peribulbar IOP.

In our study, we have used 0.75% ropivacaine. Ropivacaine is a pure S-enantiomer drug compared to Bupivacaine which contains both S and R enantiomer. Ropivacaine is less cardiotoxic and has better akinesia which corresponds to study by Gillart et al. which showed that 1% ropivacaine may be a better agent than 0.5% bupivacaine for single medial injection technique of peribulbar anesthesia. This in addition of lidocaine, it provides better akinesia and similar analgesia.[9]

This also corresponds to the study by Gioia et al. which concluded that use of 0.75% or 1% concentrations are preferred in that they provide quick sensory and motor blockade.[10]

The results of our study showed that there is a statistically significant difference in HR, BP in two groups. Patients in the RC group had a more stable decline in HR compared to the R group; the difference was statistically significant after 20 min. Throughout the entire period, RC group of patients had a lower BP on an average. This corresponds to study by Mjahed et al.;[9] they concluded that the addition of clonidine to lidocaine increase the duration of analgesia and akinesia, with relatively stable hemodynamic parameters.

There is an increase in HR and BP at 1 min in both the groups. This corresponds to study of Luchetti et al. which compares ropivacaine 0.75% versus bupivacaine 0.5% - mepivacaine 2% for the peribulbar block. After injection of local anesthetic drug increase in MAP and HR noted in both the groups after 1 min.[11]

In our study, the incidence of side effects in both groups was observed. No one experienced nausea. 3 participants in the R group has headache, compared to 2 in the RC Group, 1 participant in the R group had to vomit, while none in the RC Group, 3 participants in the RC group reported, dry mouth as a side effect, which was absent in the R Group.

This corresponds to study of Khan et al. which showed side effect profile revealed a higher incidence of nausea, vomiting, headache, and dizziness in R Group, while a considerably higher incidence of dry mouth was observed in RC Group.[1]
CONCLUSION

We conclude from our study that addition of clonidine to ropivacaine-lignocaine mixture provides better sensory, motor blockade and significantly prolongs the duration of analgesia compared to ropivacaine-lignocaine mixture alone. It reduces the volume of local anesthetics. It maintains stable hemodynamics throughout the procedure.

REFERENCES


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Role of Minimally Invasive Urological Intervention in Acute Pyelonephritis - A Prospective Study

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INTRODUCTION

Acute pyelonephritis (APN) is an acute bacterial infection of the renal pelvis and parenchyma.¹ Majority of these infections are acquired by ascending infections from the lower urinary tract.² They may also be acquired by hematogenous route. Diabetes is a common predisposing factor in these cases.³ The clinical spectrum of APN may range from a very mild presentation which may mimic cystitis to a florid and severe infection in the form of emphysematous pyelonephritis where there is a destruction of the parenchyma with gas formation.⁴

These patients present with a definite set of symptoms and signs, with varying severity. Based on the severity and clinical condition of the patient, the decision of medication, stenting, or in rare cases nephrectomy, as a treatment option is taken. Nephrectomy is reserved for severe infections - emphysematous pyelonephritis with endotoxemia and with frank pus formation and parenchymal destruction. If the disease occurs bilaterally,
Care is taken for conservation of nephrons to prevent the patient from becoming anephric.

Patients with APN are primarily started on broad-spectrum antibiotics and response monitored. If responding well, antibiotics continued and changed as per culture report and the patient recovers with conservative measures. If not responding, patients may require interventions in the form of Double J stenting (DJS) to drain the infection. Although hydrenephrosis may not be seen in these cases, it is proven that infection per se can lead to decreased or aperistalsis of the ureter and impedes drainage or could be the presence of necrosed papilla causing obstruction. These patients benefit from DJS.

Thus, conservative therapy is a first step modality of the treatment for these patients before subjecting them to DJS. However, this is a gray zone, with no definite protocol that helps decision-making easy for the treating doctor. The purpose of this study was to analyze the factors determining the need for DJS in patients with APN and also to study the clinical profile and predisposing factors associated with APN.

MATERIALS AND METHODS

A total of 100 patients were recruited in the prospective study. Ethics committee clearance and permission from the institutional review board to carry out the study were obtained. Informed consent was taken from all the patients before including them in the study. These patients were subdivided into Group 1 (who had DJS done) and Group 2 (who were conservatively managed). All patients admitted with diagnosis of APN, including emphysematous pyelonephritis in the Department of Urology, Sri Ramachandra Medical College and Research Institute, from September 2015 to March 2017 were included in our study. Patients with pyonephrosis or perinephric abscess, who either needed percutaneous nephrostomy or an external drainage of the collection were excluded from our analysis group. All patients who presented to the hospital either in the outpatient department or in the emergency department with complaints of fever, chills, rigor, nausea, vomiting, and dysuria, were evaluated and imaging done as appropriate. If ultrasound proved bulky kidney or perinephric fat stranding or perinephric fluid collection, or if clinically strong suspicion of APN was present, a plain computed tomography (CT) KUB (with contrast enhanced, if the renal parameters were not raised) was done.

On admission, all history and previous hospital admissions and treatment history data were collected, including age, sex, duration of illness, duration and treatment of diabetic status, hypertensive history, previous kidney disease, stone disease, or previous urological intervention and documented. Patients underwent complete physical examination including looking for a rise in body temperature, tachycardia, abdominal, or renal angle tenderness, and a baseline laboratory investigations including complete blood count (CBC), random blood sugar, total count, renal function test, serum electrolytes, hemoglobin A1c (HbA1c), urine routine microscopy, urine culture, blood culture, and sensitivity.

Patients were initially started on broad-spectrum antibiotics usually consisting of third-generation cephalosporins with or without aminoglycosides, which were then changed to culture-specific antibiotics subsequently as required.

Patients who responded well to medical treatment were continued with the same conservative treatment until full recovery. Those patients who did not respond in terms of persistent fever spikes, unexplained tachycardia, bothersome tenderness, grossly elevated total counts, and/or high serum creatinine values were deemed as non-responders and were subsequently switched over to the DJS group. On the other hand, if the patients presented with either a failed trial of conservative measure elsewhere, or if they had gross symptoms or clinical signs or parameters warranting emergency intervention, they were taken up in the stented group straightaway. The clinical and laboratory parameters which were significantly present in these non-responders were analyzed. Post-operative resolution of symptoms was monitored and documented.

Statistical Analysis

Our study data were collected and variables categorized as parametric or non-parametric variables. To describe the data, descriptive statistical frequency analysis and percentage analysis were used for categorical variables, and the mean and standard deviation was used for continuous variables. To find the significant difference between the bivariate samples in independent groups, the unpaired sample t-test was used. To find the significance in categorical data, Chi-square test and Fisher's exact test were used.

RESULTS

A total of 100 patients were analyzed in our study. Of those, 52 patients who underwent DJS were in Group 1 and the remaining 48 who were conservatively managed were in Group 2. Table 1 summarizes the demographic data of the patients studied. The mean age of patients in our study was 60 years. The youngest was 14 years and the oldest was 90 years. Females were slightly more commonly affected (n = 54) by urinary tract infection (UTI) than
Table 1: Demographic data of the all the 100 patients studied

<table>
<thead>
<tr>
<th>Demographic data</th>
<th>Group 1</th>
<th>Group 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age</td>
<td>60</td>
<td>59</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male (n=46)</td>
<td>24</td>
<td>22</td>
</tr>
<tr>
<td>Female (n=54)</td>
<td>30</td>
<td>24</td>
</tr>
<tr>
<td>Laterality</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>17</td>
<td>20</td>
</tr>
<tr>
<td>Left</td>
<td>20</td>
<td>26</td>
</tr>
<tr>
<td>Bilateral</td>
<td>15</td>
<td>2</td>
</tr>
<tr>
<td>Diabetes mellitus (%)</td>
<td>92</td>
<td>89</td>
</tr>
<tr>
<td>Mean HbA1c</td>
<td>10.2</td>
<td>7.3</td>
</tr>
<tr>
<td>Mean serum creatinine levels on admission</td>
<td>3.8</td>
<td>2.5</td>
</tr>
<tr>
<td>Mean nadir creatinine levels at discharge</td>
<td>1.4</td>
<td>1.2</td>
</tr>
<tr>
<td>Mean total count levels on admission</td>
<td>17758</td>
<td>16085</td>
</tr>
<tr>
<td>Mean total count levels at discharge</td>
<td>8594</td>
<td>8338</td>
</tr>
<tr>
<td>Associated comorbidities n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td>26 (25)</td>
<td>24 (25)</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>50 (96)</td>
<td>6 (12.6)</td>
</tr>
<tr>
<td>Previous UTI</td>
<td>7 (13.5)</td>
<td>15 (31.3)</td>
</tr>
<tr>
<td>Previous endoscopic instrumentation</td>
<td>7 (13.5)</td>
<td>6 (12.5)</td>
</tr>
</tbody>
</table>

Table 2: Details of the symptomatology and clinical signs of the patients studied

<table>
<thead>
<tr>
<th>Features</th>
<th>Group 1</th>
<th>Group 2</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms (n=52+48=100)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fever</td>
<td>52</td>
<td>47</td>
<td>0.4800</td>
</tr>
<tr>
<td>Chills/rigor</td>
<td>52</td>
<td>5</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>Loin pain</td>
<td>46</td>
<td>26</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>Lower tract symptoms</td>
<td>30</td>
<td>22</td>
<td>0.3166</td>
</tr>
<tr>
<td>Nausea/vomiting</td>
<td>46</td>
<td>30</td>
<td>0.0043</td>
</tr>
<tr>
<td>Turbid urine</td>
<td>41</td>
<td>1</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>Signs (n=52+48=100)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temperature&gt;100 F</td>
<td>52</td>
<td>16</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>Persistent tachycardia</td>
<td>52</td>
<td>28</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>Palpable tender kidney</td>
<td>50</td>
<td>30</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>Leukocytosis</td>
<td>41</td>
<td>36</td>
<td>0.6665</td>
</tr>
<tr>
<td>High serum creatinine (at presentation)</td>
<td>41</td>
<td>38</td>
<td>0.3747</td>
</tr>
<tr>
<td>Nadir creatinine reaching normal levels</td>
<td>0</td>
<td>38</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>Thrombocytopenia (&lt;1 lakh/cub mm)</td>
<td>46</td>
<td>10</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>HbA1C levels&gt;9.0</td>
<td>46</td>
<td>18</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>Urine microscopy (n=52+48=100)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glycosuria</td>
<td>12</td>
<td>8</td>
<td>0.4628</td>
</tr>
<tr>
<td>Proteinuria</td>
<td>19</td>
<td>9</td>
<td>0.0736</td>
</tr>
<tr>
<td>Urine culture positivity (%)</td>
<td>32</td>
<td>8</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>Blood culture positivity (%)</td>
<td>22</td>
<td>1</td>
<td>&lt;0.0001*</td>
</tr>
</tbody>
</table>

Table 3 summarizes the CT findings in both the groups. From Table 1 could infer that features of APN such as inflamed kidney with increased parenchymal thickness, perinephric, and periureteric stranding are seen in both the groups. Patients with emphysematous pyelonephritis more often needed DJS. However, associated stones and hydronephrosis were more commonly seen in Group 1 than with no statistically significant difference from the other group.

**DISCUSSION**

Pyelonephritis describes a severe infectious and inflammatory disease of the renal parenchyma. The major causative pathogens of APN are Gram-negative bacteria.[9,10] *Escherichia coli* cause approximately 60–80% of uncomplicated infections. Other Gram-negative pathogens include *Proteus mirabilis* as well as *Klebsiella, Enterobacter,* and *Pseudomonas* species. *P. mirabilis* does not commonly cause urinary tract infections in normal hosts but is frequently associated in patients with complicated UTIs. This is more prevalent in those who present with functional or anatomical abnormalities and in those with urolithiasis or a chronic indwelling urinary catheter.[13] In men (n = 46). The left kidney was more affected than the right. Overall, 46% left sided, 37% right sided, and 17% were bilateral. Diabetes mellitus constituted the single most common associated condition that predisposed to APN. About 84% (n = 84) of our study population were diabetics. The distribution of diabetics in both the groups was almost identical. The other comorbidities such as chronic kidney disease and coronary artery disease were more or less equal in both the groups. About 45 patients have had previous UTIs and 26 of them have had a history of previous endourological instrumentation.

*Indicates statistically significant value with P<0.05. HbA1c: Hemoglobin A1c, UTI: Urinary tract infection.*
older hospitalized patients, because of increased usage of catheters (portals to infection), Gram-negative organisms such as *P. mirabilis*, *Klebsiella*, *Serratia*, and *Pseudomonas* are more common etiologies.[14,15]

Pyelonephritis occurs predominantly in the diabetic population. The presence of glucose in urine is considered to enhance bacterial growth.[16] In our study, diabetes was an important prognostic factor. Although diabetes was commonly found in both groups, the levels of uncontrolled sugar were detrimental in deciding between two treatment modalities. The chances of a conservative medical treatment are inversely proportional to the blood sugar levels. Random blood sugar values were found to be variable with daily monitoring, but the HbA1c was found to be consistent with prognosis of the disease. Higher value of HbA1c (>9%) indicated lesser chance of resolution with medical management alone. In a retrospective study over 68 patients with pyelonephritis, the prevalence of diabetes was found to be as high as 36.8%.[17] In one of the largest prospective, observational, multicenter cohort studies of women with APN, involving 1062 women, Wie *et al.* concluded that diabetes mellitus constituted a major risk factor for early clinical failure of patients with community-onset APN.[18] In yet another retrospective chart review on 225 patients, Efstathiou *et al.* demonstrated that diabetes mellitus and immunosuppression lead to a prolonged hospital stay and a longer convalescence period.[19]

Emphysematous pyelonephritis is almost exclusively seen in diabetics with poorly controlled sugar levels. The high glucose levels in the tissue provide the gas-forming organisms a suitable environment for their rapid growth and rapid catabolism, which produces massive production of gases.[10,21] In cases with ureteric obstruction, hydronephrosis may increase the pelviccalyceal system pressures and compromise renal circulation and result in impaired transportation of gases and subsequent creation of gas chamber, compounded by diabetic nephropathy and result in further accumulation of gases in the pelviccalyceal system.

A report of fever and chills, flank pain, and irritative voiding symptoms (e.g., urgency, frequency, and dysuria) in a female patient should prompt a workup. Other key symptoms include nausea or vomiting. The triad of flank pain, fever, and nausea and vomiting occurs much more often in patients with pyelonephritis than in those with cystitis.[22] Symptoms such as fever with chills and rigors, loin pain, and nausea were the predominantly common presenting complaints noted in our study. Between the groups, symptoms of fever, chills and rigors, nausea, and loin pain were constant in the stented group. These were similar to findings by Wie *et al.*[18]

Temperature >100.4°F (38.0°C) is a key finding supporting the diagnosis. In one study, temperature ≥100°F (37.8°C) was strongly correlated with APN.[23] All these three clinical signs were analyzed and found to be statistically significant. This indicates that the presence of fever spikes, tachycardia, and loin tenderness predisposed the patient to enter the stenting group.

Urinalysis shows pyuria, bacteriuria, and varying degrees of hematuria. Turbidity and proteinuria were more commonly seen in the stented group, with more number of normal test results being found in the non-stented group.

The commonly noted organism in culture was *E. coli*, noted in 25 cases. *Klebsiella* species noted in 4 patients, Enterobacter species in 2 patients, and *Candida* species in 1 patient. These were similar to results noted in Christopher *et al.*[24] In a total of 1062 women patients in study by Wie *et al.*, 784 (73.8%) gave positive urine cultures. *E. coli* was the most common pathogen (90.3% in 708 patients).

Bacteriuria was accompanied by bacteremia (with the same pathogen) in 60 men (58.8%) and 75 women (60.9%).[19] Blood cultures are indicated in all patients. Blood cultures are positive for the causative pathogen in approximately 10–20% of women with acute uncomplicated pyelonephritis. Blood C/S - shows the presence of blood culture being positive as a strong indicator of patient requiring stenting as a treatment option.

Other initial laboratory tests indicated in the initial workup are CBC, erythrocyte sedimentation rate (ESR), and serum C-reactive protein (CRP). The CBC shows elevated
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total leukocyte counts, decreased platelet counts, ESR elevation, and CRP elevation and all are in favor of acute inflammatory process in the system, helpful in diagnosis.

Total counts found to be one of the parameters reflecting the severity of infection in the blood. WBC counts of >20,000/cubic mm were significantly found to have early clinical failure after the treatment of pyelonephritis.[18]

In our study, total count being elevated and persistently elevated despite medical management indicated need for DJS for better outcome. The falling trend of total counts was noted and documented and observed that patients with total count responding to medical therapy predominantly settled with medication alone and patients with total count not responding to medicines were candidates who required stenting for disease resolution.

The platelet count turned out to be a prognostic factor, with high levels signifying better recovery and lesser chance of need for DJS and lower platelet counts being clinically more toxic, requiring DJS. This was similar to the finding noted by Chung et al.[17]

The derangement of renal parameters was the most commonly noted laboratory finding. The trend of serum creatinine rise/fall was studied and taken as a variable to be included in our study. The trend was found to be statistically significant and was similar to the results of Wie et al.[18]

Computerized tomography of kidney, ureter, and bladder gives excellent anatomic detail and helps us in clearly establishing the diagnosis. CT study can often be useful when patients are not responding to treatment as expected or after 72 h.[15,26] CT study with the presence of emphysematous pyelonephritis, stone, or Hydroureteronephrosis (HUN) was strong factors tilting treatment outcome toward DJS group.

The main goals of treatment are infection control and symptom reduction. The decision whether to treat the patient empirically, and whether to admit the patient for intravenous antibiotic treatment, should be based on the patient’s symptoms and comorbidities.

The role for stenting in APN with obstruction due to necrosed papilla, turbid pus flakes or stone are straightforward. It is also accepted and recommended for DJS in pyelonephritis even in the absence of hydronephrosis, due to - ureteric dyskinesia. Infection per se can cause decreased ureteric mobility by two mechanisms - bacterial toxins acting directly on the ureteric smooth muscle and bacteria producing products - act on ureteral peristalsis mechanism.[27] These products are – inflammatory exudates, histamine, serotonin, bradykinin, and prostaglandin.[28]

The highly statistically significant factors (P = 0.001) in our study included gross pyuria, significant fever spikes despite medication, persistent tenderness, persistently high total count despite medication, persistently high serum creatinine, low platelet counts, positive blood culture, and HbA1c >9%. These factors were analyzed between the stented and the non-stented groups, and it was inferred that the presence of one factor made medical management a viable option. Patients with two or more of these factors make DJS the ideal treatment option. In our study, majority of the patients had more than five positive factors and hence carried a poorer outcome.

Limitations of the Study

Most of the patients referred to our center had tried a conservative treatment elsewhere before being referred to us. Being a tertiary care referral hospital, many such patients were admitted in a critical stage, necessitating an early intervention. If the number of patients in each group was higher, interpretation of the data would have had much more relevance. Resistance to antibiotics was yet another major factor that tilted the balance toward early intervention. As most of the patients had received a variety of antibiotics before reaching our hospital, the urine culture done at our center had grown pan-resistant strains that prompted us to directly recruit the patients in Group 1.

Future Recommendations

The physicians must be aware that pyelonephritis is a clinical condition that if diagnosed early and treated appropriately, can be fully treated. A study with more number of patients recruited in each arm would give us a much better data that could convince our statistical analysis in a better way. General practitioners and physicians must be forewarned about the possibility of pan-resistant organisms in cases of antibiotic abuse.

CONCLUSIONS

A high index of clinical suspicion, identification of the unfavorable prognostic parameters, and an early intervention are required to achieve a better outcome in such patients. The presence of poor prognostic factors like gross pyuria, high temperature, persistent loin tenderness, persistently high total count, persistently high serum creatinine, thrombocytopenia, positive blood or urine culture, and HbA1c of more than 9% strongly suggest a need for a minimally invasive urological intervention. The presence of air in the parenchyma or the collecting system
or hydroureronephrosis on CT imaging is an indication for DJS for disease resolution.

REFERENCES


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Value of Argyrophilic Nucleolar Organizer regions in Benign, Premalignant, and Malignant Lesions of Cervix Uteri

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Abstract

Objectives: The objective of this study is to evaluate the correlation of argyrophilic nucleolar organizer region (AgNOR) count between benign, premalignant cervical intraepithelial neoplasia (CIN), and malignant lesions of cervix.

Method: A retrospective study of 150 cases of paraffin-embedded blocks were histologically grouped as (A): Normal cervix, (B): Benign lesions - chronic cervicitis without dysplastic change, (C): Cervix with CIN I and II, (D): CIN III (E): Squamous cell carcinoma - well-differentiated, (F): Squamous cell carcinoma - moderately differentiated, (G): Squamous cell carcinoma - poorly differentiated (small cell non-keratinizing), and (H): Adenocarcinoma of cervix. The paraffin blocks were further subjected to thin sections, and silver staining (AgNOR) was done in the dark at room temperature. The AgNOR counting was done under oil immersion (×100). The number of black dots per 100 cells was counted and averaged.

Result: In this study, the mean AgNOR count was found to be statistically significant (t = 3.5 –21.8) at a confidence limit <0.0, clearly proving proliferative activity of the benign, premalignant, and malignant nucleoli.

Conclusion: AgNOR counting progressively increases directly in proportion to increased proliferative activity of the cells: (A+B) normal cervix and chronic cervicitis without dysplasia mean AgNOR count 3.5, (C): Cervix with CIN I and II mean AgNOR count 6.9, (D+E): CIN III and squamous cell carcinoma - well-differentiated mean AgNOR count 10.3, (F+G): Squamous cell carcinoma - moderately and poorly differentiated mean AgNOR count 16.16, and (H): Adenocarcinoma of cervix mean AgNOR count 21.8

Key words: AgNORs staining technique, AgNORs counting procedure, Benign and Malignant lesions of cervix, Proliferative index

INTRODUCTION

For a long time, it has been known that abnormalities of nucleolus such as hypertrophy and irregular shape were constant features of cancer cells, but little attention was given to nucleolar morphology. However, recently, it has been proved at ultrastructural levels[1] that nucleolar morphology corresponds to the interphase counterpart of the nucleoli organizer regions (NORs) of metaphase chromosome, and hence, they are called interphase NORs[2] It has been shown that these NORs can be visualized both at electron and light microscopic levels by a silver staining technique.[3] By means of this technique, the NOR proteins associated with ribosomal genes are potentially transcribable.[4] The NOR distribution pattern and their increased numbers have been successfully used to differentiate benign from malignant tumors in cytologic and histologic preparations.[5]

Carcinoma of the uterine cervix shares a large incidence of malignancies of the female genital tract.[6] Although the organ is readily accessible for biopsy, failure in early diagnosis, due to inadequate screening programs, and lack of awareness being the main cause for high mortality rate.
Cervical intraepithelial neoplasia (CIN) is a stage that precedes full-fledged carcinoma and is considered as a very vital stage as the diagnosis at this stage affords a very favorable outcome. A number of methods have been tried in the past to diagnose early carcinoma cervix, and only recently, argyrophilic nucleolar organizer region (AgNOR) staining has been proved to be a spark in darkness and its value is consistently increasing in diagnosing early carcinoma cervix and also a variety of other malignancies already mentioned.

The current work is an inspiration from the work of Pratiba and Kuruvilla.[7] The study of AgNOR count on benign, premalignant, and malignant lesions of the cervix gained importance as an indicator of cell proliferation, thus differentiating benign from malignant lesion. It was found that AgNOR count increased progressively from normal to CIN Grade I, II, and III and Invasive carcinoma.

**MATERIALS AND METHODS**

The present study has been undertaken in the Department of Pathology, Netaji Subhash Chandra Bose Medical College and Hospital, Jabalpur. A total of 150 paraffin-embedded cervical biopsies were studied for 1 year. They were classified broadly into eight groups:

- **Group I**  Histopathologically Normal cervix (control)
- **Group II**  Chronic Cervicitis without dysplastic changes
- **Group III**  CIN Grade I
- **Group IV**  CIN Grade II
- **Group V**  CIN Grade III
- **Group VI**  Squamous cell carcinoma large cell keratinizing type (well differentiated)
- **Group VII**  Squamous cell carcinoma large cell non-keratinizing type (moderately differentiated)
- **Group VIII**  Adenocarcinoma of cervix

All the paraffin blocks were cut at 4 μm thickness.

The sections were put on to slides and stained by the following methods:
1. Hematoxylin and Eosin (H & E stain) slides obtained from archives.
2. AgNOR staining method:

*AgNOR staining solution requires:*
1. Silver colloid solution
   a. 2 g per dl powdered gelatin dissolved in 1 g per dl aqueous formic acid.
   b. 50 g per dl aqueous silver nitrate solution.

The above-mentioned solutions are freshly prepared just before staining in the ratio of 1:2 (1 volume of 2% gelatin in 1% formic acid and 2 volumes of 50% aqueous silver nitrate).
2. 5 g per dl sodium thiosulfate solution.
3. 0.5 g per dl methyl green solution (optional for counterstaining).

*Steps of AgNORs staining:*
1. 4 μm thick paraflin sections were deparaffinized in xylene.
2. Hydrated through descending grades of ethanol to deionized water.
3. Sections were then incubated under safelight condition (dark) at room temperature in a silver colloid solution for 40 min.
4. Sections were then thoroughly washed with 5% sodium thiosulfate to remove the excess of silver colloid in the sections.
5. The sections were throughly washed in deionized water.
6. Sections were counterstained with 0.5% methyl green for 5–10 s (optional).
7. Sections were dehydrated in ascending grades of ethanol and finally to absolute alcohol.
8. Sections were cleared in 2–3 baths of xylene.
9. Sections were mounted in DPX.

Morphology of AgNOR stained tissue under microscope:

AgNORs are visualized as dark-brownish dots arranged in clumps or in clusters within the nuclei against yellowish background. Methyl green counterstaining makes the nuclear outline prominent and thus helps in distinguishing AgNOR dots within the nucleus from extranuclear silver colloid impurities.

**Counting Procedure**

The number of AgNOR present in each nucleus is counted as proposed by Evans *et al.*1991.[9] 100 nuclei are taken into account, using ×10 eyepiece and ×100 oil immersion lens. At this magnification, the AgNORs are visible both within and outside the nuclei. The mean AgNOR count of the specimen is then calculated taking into account both intra- and extranuclear AgNORs. The counting system is summarized as follows:
1. Nucleoli were counted as individual intra- and extranuclear AgNORs.
2. Two “total AgNOR’S figures” were thus derived “total
A” excluding intranucleolar AgNORs and “total B” including intranucleolar AgNORs.

For each group of 100 nuclei counted, the mean standard deviation and range of numbers of AgNORs were determined. Using Student’s t-test, the significance of differences in total AgNOR counts between the following groups was calculated:

Groups I and II: Normal cervix and chronic cervicitis without dysplastic changes.

Groups II and III: Chronic cervicitis and CIN Grade I and II.

Groups III and IV: CIN Grade I, II, and III.

Groups IV and V: CIN Grade III and squamous cell carcinoma large cell keratinizing type (well differentiated).

Groups V and VI: Squamous cell carcinoma well differentiated and moderately differentiated.

Groups VI and VII: Squamous cell carcinoma moderately differentiated and poorly differentiated (small cell non-keratinizing type).

Groups II and VIII: Chronic cervicitis and adenocarcinoma.

Statistical Analysis
The results obtained in counting procedure were analyzed statistically by means of unpaired t-test.

Observation
A total of 150 cases of cervical biopsy were included to study the value of AgNOR count in benign, premalignant, and malignant lesions of cervix uteri. The cases were distributed in eight groups based on histopathological diagnosis [Table 1].

Evaluation of AgNOR Count
AgNOR count was studied in a total of 150 cases distributed according to Table 1. Both intra- and extranucleolar AgNORs were counted at the magnification of ×1000 (oil immersion). Well-defined argyrophilic dots were identified. The AgNOR count was done in 100 representative nuclei in each case, and mean AgNOR per nucleus was calculated. From the values thus obtained, standard deviation was calculated for each group in comparison [Table 2].

RESULT
On comparing the AgNOR count between Groups I and II, a statistically significant value is obtained (t = 35) at confidence limit <0.001. The AgNOR count in Groups II and III is also statistically significant (t = 10.3) at confidence limit <0.001. Similarly, on comparing the other groups, the AgNOR count was found to be statistically significant at confidence limit <0.001 [Table 3].

DISCUSSION
Although uterine cervix is readily accessible for biopsy, failure in early diagnosis is one of the main causes for high mortality rate. CIN is a stage that precedes full-fledged carcinoma cervix. This is considered a very vital stage as diagnosis at this stage affords a very favorable outcome. A number of methods have been tried such as DNA flow cytometry and markers of proliferative activity such as Ki-67 and BK,j9.9. The former is quite expensive and space consuming while the later cannot be applied to formalin-fixed tissue. Recently, AgNOR staining has been proved to be a spark in darkness as far as diagnosis of early cancer is concerned, Its value is consistently increasing in diagnosing early carcinoma cervix and variety of other tumors. It is considered to be a marker of proliferative activity of a cell, and its results are in parallel to those of other proved markers of proliferative activity such as Ki-67.

In the present study, the relative incidence of different grades of cervical malignancy is shown in Table 4.

While chronic cervicitis was present in nearly 90% of biopsy, their relative incidence is restricted in this study just to avoid the overlap in AgNOR count and subsequent calculations. Mean age of cancer cervix in this study was.

<table>
<thead>
<tr>
<th>Table 1: Classification and number of cases studied</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group</strong></td>
</tr>
<tr>
<td>---------------------------------------------------</td>
</tr>
<tr>
<td>Group I</td>
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<tr>
<td>Group II</td>
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<td>Group III</td>
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<tr>
<td>Group IV</td>
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<tr>
<td>Group V</td>
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<tr>
<td>Group VI</td>
</tr>
<tr>
<td>Group VII</td>
</tr>
<tr>
<td>Group VIII</td>
</tr>
</tbody>
</table>

CIN: Cervical intraepithelial neoplasia
The most common clinical finding was DUB, leukorrhea, and post-coital bleeding.

Study of AgNOR

In normal cells, the AgNORs are tightly packed in the nucleoli and are indiscernible (mean AgNOR count in Group I lesion - 1.3). In rapidly proliferating cells such as neoplastic cells, nucleolar disaggregation may take place resulting in a dispersion of individual AgNORs (mean AgNOR count in Group III and IV lesions - 3.5 and 4.71, respectively).

Increase in cell ploidy and increased transcriptional activity may also result in higher AgNOR count (mean AgNOR count in Group II lesion - 1.9).

Therefore, benign and malignant lesion showed a significant difference in AgNOR counts. In this study, the mean AgNOR count was found to increase progressively from normal to CIN and invasive carcinoma. On comparing CIN with normal cervix and CIN with invasive carcinoma, there was a statistically significant difference in both the sets. These findings strongly support the view that proliferative activity and malignant potential of intraepithelial neoplastic lesion of the cervix increase progressively as the grade of the lesion becomes higher.

In small cell carcinoma of the cervix, AgNORs were dispersed as fine dots throughout the nucleus and could not be counted easily. This may indicate a very high proliferative activity of these tumours resulting in marked disaggregation of AgNOR dots thus indicating a poor prognosis (mean AgNOR count - 11.61).

**CONCLUSION**

AgNOR count progressively increases directly in proportion to increased proliferation of cells. In histopathologically normal cervical biopsy and chronic cervicitis without dysplasia, mean AgNOR count being 1.3 and 1.9, respectively, as compared to mean AgNOR count of 3.5-CIN I & II, 4.71-CIN III, 6.49-Squamous cell

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**Table 2: Mean AgNOR count in various groups of lesions with S.D**

<table>
<thead>
<tr>
<th>Group</th>
<th>Histological diagnosis</th>
<th>Number of Cases</th>
<th>Range of AgNOR</th>
<th>Mean AgNOR Count</th>
<th>S.D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group I</td>
<td>Normal cervix chronic</td>
<td>10</td>
<td>1.1–2.2</td>
<td>1.3</td>
<td>0.370</td>
</tr>
<tr>
<td>Group II</td>
<td>Cervicitis without dysplastic changes</td>
<td>20</td>
<td>1.4–3.2</td>
<td>1.9</td>
<td>0.476</td>
</tr>
<tr>
<td>Group III</td>
<td>CIN Grade I</td>
<td>30</td>
<td>2.2–4.6</td>
<td>3.5</td>
<td>0.575</td>
</tr>
<tr>
<td></td>
<td>CIN Grade II</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group IV</td>
<td>CIN Grade III</td>
<td>20</td>
<td>3.7–5.8</td>
<td>4.71</td>
<td>0.640</td>
</tr>
<tr>
<td>Group V</td>
<td>Squamous cell carcinoma large cell keratinizing type (well differentiated)</td>
<td>20</td>
<td>4.4–7.6</td>
<td>6.40</td>
<td>0.852</td>
</tr>
<tr>
<td>Group VI</td>
<td>Squamous cell carcinoma moderately differentiated</td>
<td>20</td>
<td>8.6–14.8</td>
<td>9.4</td>
<td>0.917</td>
</tr>
<tr>
<td>Group VII</td>
<td>Squamous cell carcinoma small cell non-keratinizing (poorly differentiated)</td>
<td>20</td>
<td>14.2–20.6</td>
<td>11.6</td>
<td>1.319</td>
</tr>
<tr>
<td>Group VIII</td>
<td>Adenocarcinoma of cervix</td>
<td>10</td>
<td>6.4–13.2</td>
<td>10.6</td>
<td>1.74</td>
</tr>
</tbody>
</table>

**Table 3: The P value for difference in count in various groups studied**

<table>
<thead>
<tr>
<th>Groups</th>
<th>Histological diagnosis</th>
<th>t value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Groups I and II</td>
<td>Normal cervix and chronic cervicitis without dysplastic changes</td>
<td>3.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Groups II and III</td>
<td>Chronic cervicitis and CIN Grade I and II</td>
<td>10.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Groups III and IV</td>
<td>CIN Grade I, II, and III</td>
<td>6.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Groups IV and V</td>
<td>CIN Grade III and squamous cell carcinoma large cell keratinizing type (well differentiated)</td>
<td>13.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Groups V and VI</td>
<td>Squamous cell carcinoma well differentiated and moderately differentiated</td>
<td>10.75</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Groups VI and VII</td>
<td>Squamous cell carcinoma moderately differentiated and poorly differentiated (small cell non-keratinizing)</td>
<td>6.16</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Groups II and VIII</td>
<td>Chronic cervicitis and adenocarcinoma</td>
<td>21.8</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**Table 4: Different grades of cervical lesions**

<table>
<thead>
<tr>
<th>Histopathological Diagnosis</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Histopathologically normal cervix</td>
<td>10 (6.66)</td>
</tr>
<tr>
<td>Chronic cervicitis without dysplasia</td>
<td>20 (13.33)</td>
</tr>
<tr>
<td>CIN I and II</td>
<td>30 (20.00)</td>
</tr>
<tr>
<td>CIN II</td>
<td>20 (13.33)</td>
</tr>
<tr>
<td>Squamous cell carcinoma large cell keratinizing type (well differentiated)</td>
<td>20 (13.33)</td>
</tr>
<tr>
<td>Squamous cell carcinoma large cell non-keratinizing type (moderately differentiated)</td>
<td>20 (13.33)</td>
</tr>
<tr>
<td>Squamous cell carcinoma small cell non-keratinizing type (poorly differentiated)</td>
<td>20 (13.33)</td>
</tr>
<tr>
<td>Adenocarcinoma of the cervix</td>
<td>10 (6.66)</td>
</tr>
</tbody>
</table>

CIN: Cervical intraepithelial neoplasia

---

40 years. The most common clinical finding was DUB, leukorrhea, and post-coital bleeding.
carcinoma well differentiated, 9.4-Moderately differential and 11.6-Poorly differentiated and 10.6 Adenocarcinoma respectively.

The findings in this study indicate that NOR5 can be demonstrated by means of argyrophilia of their associated proteins using a simple silver staining method.\footnote{The technique can be used as an adjunct to routine histopathological examination of cervical lesions, especially for grading cervical intraepithelial neoplasia, thus rendering earlier diagnosis and better prognosis.}

**REFERENCES**


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Clinical and Epidemiological Features of Psoriasis in Patients Visiting a Tertiary Care Centre in Eastern Uttar Pradesh

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Abstract

Background: Psoriasis is a worldwide disease and varies in its clinical profile and epidemiology in different regions of the world. In India, it is common and few epidemiological data are available in our country.

Aims: The purpose of this study was to evaluate the epidemiologic and clinical features of psoriasis in Baba Raghav Das Medical College, Gorakhpur.

Materials and Methods: A prospective investigation of a total of 400 patients visiting the Outpatient Department of Dermatology and Venereology of Baba Raghav Das Medical College, Gorakhpur, for psoriasis was done. The parameters included were age at onset of disease, current age, sex, type of disease, and distribution of lesions. Data and statistical analysis were done.

Results: The mean age of patients at onset of disease was 26.4 (standard deviation = 14.3) years. M:F ratio was 1.16. Palmoplantar psoriasis (PPP) was the most common variety of the disease. Plantar surface of the foot was most commonly involved.

Conclusion: Psoriasis is a common dermatological disease accounting 2.9% of all dermatology patients in our center. PPP is the most common clinical subtype. The disease is more frequent in the third decade of life and has a male predominance in our region. Treatment compliance has been found to be poor.

Key words: Clinical, Dermatologic, Epidemiology, Psoriasis

INTRODUCTION

Psoriasis is a common, chronic, disfiguring, inflammatory, and proliferative condition of skin in which both genetic and environmental influences play a critical role. Apart from skin, it affects nails, joints and is now being described as a metabolic disorder.¹ The characteristic lesions consist of red, scaly, and well-demarcated plaques mainly over extensors and scalp. The prevalence of psoriasis varies in different parts of the world. According to published reports, prevalence in different populations may vary from 0% to 11.8%.² In India, in a study by Okhandiar and Banerjee,³ incidence of psoriasis was found to be 1.02%. In another study by Bedi,⁴ the incidence was found to be 2.8%. A study from tertiary health care centre in north India,⁵ showed that psoriasis accounted for 2.3% of all dermatology outpatients. There are only few studies from India which have analyzed the clinical spectrum of the disease in psoriasis patients.⁶ In most of the studies, the most common type of psoriasis reported is chronic plaque-type psoriasis or psoriasis vulgaris. In the study conducted by Bedi,⁷ chronic plaque-type psoriasis was found to be the most common type (90% cases), followed by palmoplantar psoriasis. Chronic plaque-type psoriasis (93%) was also the most common clinical phenotype in the study conducted by Kaur et al.⁸ Although palmoplantar psoriasis produces considerable social and functional disability, there is a paucity of studies on the incidence of palmoplantar psoriasis. Palmoplantar psoriasis is shown to

Corresponding Author: Dr. Ali Mohammad, Room no 146 Gautam Hostel, Baba Raghav Das Medical College Gorakhpur, Uttar Pradesh, India. Phone: +91-8933097079. E-mail: alimohammadabdiderma@gmail.com
constitute 3–4% of all psoriasis cases in most of the studies conducted. Our study is the first of its type done in North India to find the incidence of palmoplantar psoriasis and compare its incidence with other forms.

The current study presents the clinical and epidemiological features of psoriatic patients attending the Dermatology Outpatient Department (OPD) of Baba Raghav Das Medical College, Gorakhpur, which is a 700-bedded multispecialty hospital in the urban area of Uttar Pradesh, India.

MATERIALS AND METHODS

All patients diagnosed with psoriasis from the OPD of Dermatology and Venereology of College were selected for the study. Their records were reviewed retrospectively. Patients visiting from June 1, 2016, to March 1, 2018, were included in the study.

Sociodemographic data and subtype of disease were studied. The descriptive statistics such as percentage, proportion, mean, and standard deviation were calculated. Statistical significance was analyzed at $P < 0.05$.

All the cases included were newly diagnosed cases. The study did not include palmoplantar pustulosis. Proper history taking at the first visit regarding onset, duration, progression of disease, and complains was done, and data regarding age, sex, family history, nail involvement, morphology of lesions, exacerbating or relieving factors, and histological findings in cases where biopsy was required were collected in each case. This was followed by thorough dermatological examination by the trained dermatologists before putting up the diagnosis of palmoplantar psoriasis. Diagnosis of psoriasis is usually clinical as characterized by typical scaly patches with silvery scales which is accentuated on scratching. Involvement of instep region over the soles is characteristic of psoriasis. However, diagnosis was doubtful in 12% cases; all these cases were subjected to biopsy and scrapping for fungus to rule out other dermatoses. Collected data were classified, tabulated, and analyzed using appropriate statistical tools (percentages and ratios) as per the requirement of the present study and interpretations/conclusions were made accordingly patients of eight districts visited our hospital (namely, Gorakhpur, Maharajganj, Deoria, Kushinagar, Azamgarh, Mau, Basti, and Gopalganj).

Most patients (40.2%) visited from Gorakhpur where the medical college is located.

RESULTS

The total number of new psoriasis patients attending the OPD during this period was 400. This was around 3% of the total cases coming to the OPD [Figure 1] and included various types of psoriasis such as chronic plaque type, palmoplantar psoriasis, scalp psoriasis, pustular psoriasis, flexural psoriasis, nail psoriasis, and erythrodermic psoriasis. Among these, 59.8% (241) were male and 40.2% (159) were female, showing slight male preponderance. Around 68% patients were in 20–40 years age group and 30% patients in 40–60 years age group, remaining 2% consisted of <20 years or >60 years patients. In our study, out of total 400 psoriasis cases, palmoplantar psoriasis constituted about 59% (237) cases [Figure 2], which was a huge number, followed by chronic plaque-type psoriasis. Mean age at onset was 26.4 ± 14.3 years (29.7 ± 13.8 in male and 21.4 ± 13.1 in female).

Mean age at the first presentation to the hospital was 28.9 ± 14.8 years. The difference in the mean age at onset of
Most of the patients presenting with palmoplantar psoriasis were manual laborers (32%) or drivers (15%) and farmers (14%) or housewives (30%). However, it was interesting to see a respectable number of patients belonged to office class (9%). In around 10% patients, the disease was asymptomatic.

However, most patients complained irritation (40%), fissuring (30%), difficulty in walking (48%), difficulty in manual work (33%), and pain (16%).

Both palms and soles involvement was seen in 52% cases (123). Exclusive palmar involvement was present in 28% cases (66) while only plantar involvement in 20% (47) cases. In Kumar et al. studied plantar involvement was twice as common as palmar involvement. Around 18% patients in our study showed evidence of psoriasis at other sites.

Psoriasis over palms and soles may present as typical scaly patches on which a fine silvery scale can be evoked by scratching or as less well-defined plaques resembling hyperkeratotic eczema or as pustulosis. Sparing of skin creases over palms may be seen. Increased pigmentation of skin often accompanies. Associated nail changes in the form of pitting, thickening of nail plate, and subungual hyperkeratosis were seen in about 39% patients. Nail involvement was present in 23.4% of the cases by Chopra et al.

The diagnosis of palmoplantar psoriasis may be missed, its differentiation from other morphologically similar conditions such as hyperkeratotic eczema, dermatophytosis, and contact dermatitis, is of prime importance. Dermatophytosis is usually unilateral and responds easily to antifungals. Hyperkeratotic eczema sometimes poses difficulty to distinguish and may overlap with psoriasis. Usually, the lesions are not well demarcated as in psoriasis and degree of erythema is also less. Presence of hyperkeratotic lesions over the knuckles favors psoriasis. The term psoriasiform eczema is applied when conditions overlap clinically and histologically.

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Diagnostic Significance of Polymerase Chain Reaction as Compare to Culture and Direct Microscopy in Cases of Pulmonary Tuberculosis

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INTRODUCTION

Tuberculosis is presently an important health problem throughout the world.[1] Despite its progressive decrease, situation has changed in recent years due to AIDS pandemic.[2] Classically, there is correlation between the presence acid-fast bacilli (AFB) in clinical samples and the isolation and culture of Mycobacterium TB. Moreover, the increase the incidence of atypical mycobacterium in patients with AIDS urge the need to introduce specific method for rapid diagnosis to avoid unnecessary or improper treatment.

At present, microscopic examination is the sole rapid diagnostic method available. The technique is simple and may be performed in any laboratory. However, the preparation and reading of the smear is time consuming and detects only 40–80%[3] of pulmonary TB (PTB) cases and only in more advanced cases.[4] Diagnosis of patients at an earlier stage, while still smear negative, would be advantages because they are less contagious[5,6] and have lower morbidity and mortality.[7] Culture through new radiometric systems,[8] biphase culture[9] may require more than 2 weeks to confirm diagnosis. Hence, the detection of Mycobacterium tuberculosis by enzymatic amplification (polymerase chain reaction [PCR]) has been found useful in diagnosis of pulmonary TB.

INTRODUCTION

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may also prove important for initial study in areas where atypical mycobacterium is prevalent in immunocompromised patients. However, insertion sequence IS6110 specific for *M. tuberculosis* is most frequently used for diagnosis\(^{23-25}\) and has high sensitivity and specificity.

**Aims and Objectives**
1. To evaluate all TB patients for direct microscopy, culture, and PCR.
2. To compare statistically each of these above tests.

**MATERIALS AND METHODS**

The study includes the patients of TB presenting to the OPD of Department of Medicine, TB and Chest, NSCB Medical College, Jabalpur (M.P).

The present study includes 45 sputum samples of patients presenting to OPD with productive cough for more than 2 weeks. Diagnosis of TB is based on the isolation and identification of *M. tuberculosis* in samples. Samples are subjected for testing at RNTCP laboratory, NSCB Medical College, Jabalpur, for direct microscopy by Ziehl–Neelsen (ZN) staining, culture by modified Petroff’s method, and PCR extraction ZN were done by commercially available kits (Bio basic INC).

**Smear Preparation**
The clinical specimens of fluids collected in sterilized bottles and sent to laboratory. Clean sterilized slides were taken, and appropriate portion of sample was transferred to the center of slide using inoculating wire loop. Thin smear was made by spreading the sample and then air dried for 15 min. Slide was then heat fixed on an electric slide warmer at 80°C for 20 min. Inoculating loop was sterilized by flaming for further use.

**Acid-fast Staining**
Mycobacteria retain the primary stain even after exposure to decolorizing with acid- alcohol, hence, termed “acid fast.” A counterstain is employed to highlight the stained organisms for easier detection. There are several methods of determining the acid-fast nature of mycobacteria. In the carbol fuchsin (ZN) procedure, acid-fast organism appears red against blue background.

**ZN staining**
- Slides were placed on a staining rack.
- Slide was first flooded with carbol-fuchsin and heated slowly using intermittent heat for 5 min.
- Slides were rinsed by running water till the stain was washed away.
- Then, the slides were flooded with decolorizing solution for 2–3 min, again rinsed with water and excess of water was drained from slides.

- Slides were then counterstained with methylene blue for 30 s, rinsed thoroughly with water and excess water was drained off the slides.
- Finally, slides were air dried and observed under oil emersion.

**Culture of Samples**

*Modified Petroff’s method*
The majority of clinical specimens submitted to laboratory are contaminated, to varying degree, by more rapidly growing normal flora organisms. These would rapidly overgrow the entire surface of the medium and digest it before the tubercle bacilli start to grow. The specimens must, therefore, be subjected to a proper digestion and decontamination procedure that liquefies the organic debris and eliminates the unwanted normal flora.

**Processing**
- Sample was taken and 4% NaOH (double the amount of samples) was added to it.
- Cap of the bottle was tightened and kept on shaker for 15 min.
- After shaking, it was centrifuged at 3000 rpm for 15 min.
- After centrifugation, supernatant was discarded in a 5% phenol jar (discard jar).
- 20 ml sterilized distilled water was added to the pellet.
- Sample was then centrifuged at 3000 rpm for 15 min supernatant was again discarded in phenol jar and pellet was used for inoculation of slopes of LJ Medium.

Two LJ medium slopes were taken per sample and inoculated with centrifuged sediment (pellet obtained by modified Petroff’s method over the entire surface of the medium using a sterilized inoculating wire loop). Loop was sterilized after inoculating each sample. Cap of bottles was tightened to minimize evaporation and drying up of medium. All the inoculated cultures were then kept in incubator at 35–37°C for 8 weeks. Examination and reading of cultures were done at regular weekly intervals. Typical colonies of *M. tuberculosis* appeared as, rough, crumbly, waxy, non-pigmented (buff colored), and slowly growing, i.e., only appeared 2–3 weeks after inoculation. Cultures were reported as positive or negative on the basis of growth of *M. tuberculosis* on the medium.

**PCR**

*DNA extraction*
The extraction of DNA was done by commercially available kit (Bio basic INC) Manufacturer’s instruction was followed. Briefly, the procedure was
1. 200 µl TE buffer was added in 100 µl sample.
2. 400 µl of digestion solution was added to sample from step and mixed well.
3. 3 µl of proteinase K solutions was added and incubated at 55°C for 15 min.
4. 260 µl of 100% ethanol was added and mixed well. The mixture was applied to column that is in a 2.0 ml collection tube. Spin at 10,000 rpm for 2 min.
5. Flow thoroughly was discarded in the collection tube, then 50 µl of waste solution was added and spin at 10,000 rpm for 2 min.
6. The wasting step was repeated (5).
7. The flow thoroughly was discarded and was spin at 10,000 rpm for an additional min. to remove residual amount 0 waste solution.
8. The EZ - 10 columns were placed into a clean 15 ml microcentrifuge tube and 30–50 µl elution buffer was added into the center part of membrane in the column. The tube was incubated at 37°C or 50°C for 2 min. Incubation at 37°C or 50°C could increase recovery yield.
9. For elution of DNA, the column was spin at 10,000 rpm for 2 min.

Aliquot of purified genomic DNA was kept at 20°C for long time storage.

**PCR mixture**

Required volume calculated as under:

Initial conc. × Vol. required = Final conc. × Vol. of reaction mix. PCR mixture can be prepared as follows:

<table>
<thead>
<tr>
<th>Component</th>
<th>Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>13 µl</td>
</tr>
<tr>
<td>10× buffer</td>
<td>2.5 µl</td>
</tr>
<tr>
<td>MgCl₂</td>
<td>1.5 µl</td>
</tr>
<tr>
<td>dNTPs mix</td>
<td>3.0 µl</td>
</tr>
<tr>
<td>Primers (F)</td>
<td>0.5 µl</td>
</tr>
<tr>
<td>(R)</td>
<td>0.5 µl</td>
</tr>
<tr>
<td>Taq polymerase</td>
<td>2.0 µl</td>
</tr>
<tr>
<td>Sample</td>
<td>2.0 µl</td>
</tr>
<tr>
<td>Total volume</td>
<td>25 µl</td>
</tr>
</tbody>
</table>

**Primers used for IS6110:**

• 5’-CCTGCGAGCGTAGGCGTGCGG and
• 5’-CTCGTCACCGCCGCTTCCG

**PCR Program**

Step I: Preheating at 94°C 5 min.
Step II: Denaturation at 95°C for 1 min.
Step III: Annealing at 60°C 30 s.
Step IV: Extension at 72°C for 1 min (Step II, III, and IV 40 cycles)
Step V: Final Extension at 72°C for 7 min.
Step VI: At 4°C forever.

**Electrophoresis**

• PCR product with 50 bp DNA ladder is loaded on 1.5% agarose gel (w/v) with ethidium bromide 0.5 mg/ml.

• Gel is electrophoresed at 100 V for 30 min.
• Gel is observed on gel documentation system.
• Gel photograph is taken and results are noted.
• Product size - 123b.

Results were noted for all samples.

**Inclusion Criteria**

Sputum samples of patients who are having productive cough for more than 2 weeks with clinical suspicion of TB.

**Exclusion Criteria**

• Old diagnosed case of PTB.
• Old treated case of PTB.
• History of ATT or the second line ATT intake.

**RESULTS**

The study was done to compare the tests - direct microscopy, culture, and PCR statistically for detection *M. tuberculosis* in samples. 45 patients with cough more than 2 weeks attending the TB and chest OPD were selected and sputum samples were collected. Mean age of presentation was 34 years (13–66) with 28 male patients and 17 females patients, out of these patients, TB was confirmed by culture in 19 patients, all of these patients were positive for PCR and AFB were detected in 18 of 19 patients on ZN staining [Table 1].

The sensitivity of PCR was 100% with specificity of 76.92% and positive predictive value 76%. The ZN staining was 94.74% sensitive and 82.46% specific.

Comparing the tests according to the clinical diagnosis of TB based on the radiological, clinical, and epidemiological data, 25 patients fulfilled the criteria for diagnosis of TB [Table 2].

PCR test was able to detect DNA of mycobacterium in all the samples (100%) of patients with clinical diagnosis, growth was seen in 19 (76%) of 25 patients, and AFB were found in 22 (88%) of 25 patients. The specificity of each of these tests was 100% [Figure 1].

**DISCUSSION**

In our study, it was observed that the sensitivity of PCR in all samples was higher than culture and direct microscopy.

**Table 1: Comparison of results obtained by PCR and ZN staining in patients confirmed by culture**

<table>
<thead>
<tr>
<th></th>
<th>PCR positive</th>
<th>PCR negative</th>
<th>AFB positive</th>
<th>AFB negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Culture positive</td>
<td>19.00</td>
<td>0.00</td>
<td>18.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Culture negative</td>
<td>6.00</td>
<td>20.00</td>
<td>4.00</td>
<td>22.00</td>
</tr>
</tbody>
</table>

PCR: Polymerase chain reaction, AFB: Acid-fast bacilli
The sensitivity of PCR for detection of IS6110 sequence in pulmonary samples was 100%. PCR was found to be specific test considering clinical diagnosis. The results obtained for PCR in sputum samples in this study were comparable with the results obtained by other authors - Eisenach et al.[26] and Brisson-Noël et al.[14].

There were 19 patients of PTB confirmed by culture. All were positive for PCR, making PCR 100% sensitive test, but the specificity of PCR was found to be 76.92%. Considering the clinical diagnosis, the PCR test was 100% specific and 100% sensitive.

Eisenach et al.[13] studied 162 sputum samples and found a correlation between culture and PCR are 100% of non-treated patients.

Brisson-Noël et al.[14] using amplification of groEL gene and the insertion sequence IS6110 also found a correlation between PCR and clinical or bacteriologic data in 97.4% of cases. Other studies have been made using genomic sequences different to groEL gene and insertion sequence IS6110 with similar sensitivity results.

CONCLUSION

Considering the results obtained and available literature, it is concluded that PCR is extremely helpful in detecting M. tuberculosis in sputum samples as compare to culture and direct microscopy. It can be conducted in short time allowing us to timely intervene and prevent complications.

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Correction of Transverse Discrepancy Using Rapid Maxillary Expansion with Hyrax Appliance: A Case Report

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Abstract
A 14 years young patient presented for the correction of a malocclusion that included a transverse maxillary deficiency. The patient had required to expand his upper jaw to correct his malocclusion. Recent evidence indicates that rapid palatal expansion (RPE) technique can be used without surgery in young adults; the decision was, therefore, made to treat the patient with RPE. RPE of the maxillary arch was achieved by means of a Hyrax appliance. The post-treatment radiographs revealed an opening of the midpalatal suture. It is still believed by clinicians that young adult patients require orthognathic surgery for palatal expansion, despite recent evidence supporting a nonsurgical approach after closure of the midpalatal suture.

Key words: Hyrax rapid expansion technique, Maxillary expansion, Transverse discrepancy, Posterior crossbite

INTRODUCTION
Maxillary width deficiencies are an orthodontic challenge which is detected before or during the adolescent growth spurt. Correction of these deficiencies with a maxillary rapid palatal expander was first popularized more than 40 years ago by Haas.[1] However, once patients are past their growth spurt, the age being 12–13 years in females and 14–15 years in males, the protocol for rapid palatal expansion (RPE) is questionable.[2] Expansion of the maxillary arch in mature patients is not feasible, according to some authors.[1-8] Proffit reports that “by the late teens, interdigitation, and areas of bony bridging across the suture develop to the point that maxillary expansion becomes impossible,” a belief based on Melsen’s study on histological suture appearance.[6] Other recent evidence suggests that it is indeed possible to successfully expand the palate in young adults.[7-11] This article reviews the RPE in young adults and provides a rationale for using this approach based on a case the authors successfully treated by RPE alone. Clinicians are thus faced with a dilemma when treating patients after the palatal sutures have closed. The palatal sutures are reported close as early as when a patient reaches 12–13 years of age.[12] Furthermore, other sutures adjacent to the midpalatal suture reportedly are too rigid to expand past the late teens.[3,4,6,13]

CASE REPORT
A 14-year-old male patient diagnosed as skeletal Class I malocclusion with contracted maxilla having Angle’s Class I malocclusion with bilateral posterior crossbite, severe crowding present in maxillary anteriors with palatally placed 12 and 22, mild crowding of mandibular anteriors with edge-to-edge bite having vertical growth pattern, and convex profile with incompetent lips [Figures 1-3]. Clinical examination and orthodontic records revealed a skeletal deficiency in the transverse dimension of the maxillary
arch; it was decided that nonsurgical RPE should be performed before placing full fixed orthodontic appliances. The patient was informed of all possible sequelae, risks, and benefits including possible termination of the nonsurgical treatment and use of surgical expansion should the nonsurgical RPE procedure fail.

Orthopantomogram, lateral cephalographs, and posteroanterior view of skull were taken to record the midpalatal suture before treatment for clinical assessment. A maxillary Hyrax appliance (Dentaurum, Germany) was designed for the patient and banding with upper premolar and molar during the expansion procedure.

The patient was instructed to turn the screw only once a day for the first few days to loosen the sutural juncture with minimal pain and discomfort. The patient turned the screw once a day for 10 days. The expansion measured on the Hyrax appliance was approximately 1.6 mm at the expansion screw. No midline diastema was present and the patient did not report any pain. The patient was then instructed to continue turning the expansion screw twice a day, once in the morning and once in the evening for the next 7 days. 1 week later, the expansion measured 6 mm and there was still no midline diastema present. The patient was then instructed to continue turning the screw twice a day for 3 days, then once a day for 2 days. 24 days after initial activation, the expansion measured on the Hyrax appliance was 7 mm and the patient presented with a midline diastema of 3 mm [Figures 4-8]. A post-treatment maxillary anterior occlusal radiograph was taken to verify that the midpalatal suture had opened. The acrylic was placed through the expansion screw to avoid any further movement. The patient’s midline diastema corrected with fixed appliance therapy. The patient reported minor discomfort for one short period when he thought he had mistakenly activated the appliance more than twice on the same day. Following RPE, a 3-month retention phase
was allotted to allow for osteogenic formation in the midpalatal suture.

After 3 months, fixed orthodontic MBT 0.022 slot mechanotherapy used for the correction of dental malocclusion. In settling stage, Class II elastics and Class III elastics used for proper intercuspation [Figure 9-11]. For retention, clear retainer was used [Figure 12-15] [Tables 1-4].

**DISCUSSION**

When RPE is being considered for a young adult, the palatal suture is often evaluated on an occlusal film. Radiographic

**Table 1: Sagittal skeletal relationship**

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Pre-treatment</th>
<th>Mid treatment</th>
<th>Post-treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>SNA</td>
<td>70</td>
<td>72</td>
<td>72</td>
</tr>
<tr>
<td>SAB</td>
<td>73</td>
<td>71</td>
<td>71</td>
</tr>
<tr>
<td>ANB</td>
<td>−3</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>YEN angle</td>
<td>124</td>
<td>123</td>
<td>122</td>
</tr>
<tr>
<td>W angle</td>
<td>56</td>
<td>56</td>
<td>55</td>
</tr>
<tr>
<td>BETA angle</td>
<td>35</td>
<td>35</td>
<td>34</td>
</tr>
<tr>
<td>WITS appraisal</td>
<td>−2 mm</td>
<td>−1</td>
<td>−1</td>
</tr>
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</table>

**Table 2: Dental relationship**

<table>
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<th>Post-treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper incisor to NA (mm/deg)</td>
<td>6 mm/30</td>
<td>10/35</td>
<td>10/35</td>
</tr>
<tr>
<td>Lower incisor to NB (mm/deg)</td>
<td>5 mm/23</td>
<td>6/26</td>
<td>6/27</td>
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<td>IMPA</td>
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<td>93</td>
<td>94</td>
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</table>

**Table 3: Vertical skeletal relationship**

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</thead>
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<tr>
<td>SN to mandibular plane</td>
<td>40</td>
<td>40</td>
<td>42</td>
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<tr>
<td>Jarabak ratio</td>
<td>57</td>
<td>57</td>
<td>56</td>
</tr>
<tr>
<td>FMA</td>
<td>41</td>
<td>43</td>
<td>44</td>
</tr>
<tr>
<td>Nasolabial angle</td>
<td>110</td>
<td>97</td>
<td>95</td>
</tr>
</tbody>
</table>

**Table 4: Soft tissue**

<table>
<thead>
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<th>Mid treatment</th>
<th>Post-treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>GSnPg</td>
<td>10</td>
<td>17</td>
<td>17</td>
</tr>
<tr>
<td>Nose prominence</td>
<td>15</td>
<td>15</td>
<td>15</td>
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<tr>
<td>GSn/SnMe</td>
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<td>0.9</td>
<td>0.7</td>
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<tr>
<td>CmSnLs</td>
<td>110</td>
<td>97</td>
<td>95</td>
</tr>
<tr>
<td>Ls-SnPg</td>
<td>3</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Li-SnPg</td>
<td>4</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Stms-Stmi</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>E line</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper lip</td>
<td>7</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Lower lip</td>
<td>5</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>S line</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Upper lip</td>
<td>3</td>
<td>2</td>
<td>3</td>
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<tr>
<td>Lower lip</td>
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studies have demonstrated that the midpalatal suture frequently begins to close during the early teens and that maxillary expansion is best performed before the end of adolescence. It is generally assumed that the palatal suture is a straight-running oronasal suture and that the radiographic path projects through this suture. Midpalatal sutures, however, do not always run straight. This finding is based on earlier research, which found that if a 5% midpalatal sutural closure is set as a limit for splitting the intermaxillary suture, this 5% closure will not have been reached in most patients younger than 25 years of age. Recent research indicates that a “radiologically closed” midpalatal suture is not the histological equivalent of a fused or closed suture. Researchers attempting RPE in 38 patients ranging in age from the late teens to adulthood (7 males aged 17–23 years [mean age: 21 years, 4 months] and 31 females aged 15–44 years [mean age: 20 years, 6 months]) found that although nonsurgical expansion failed in some subjects because of painful reactions, RPE in younger adults was completed successfully. The expansion was judged by clinical evidence of the creation of a midline diastema. Of the 38 patients, 33 were successfully treated with RPE alone in the age group of 15–28 years (mean age of 18 years, 9 months). The five individuals who required RPE with surgery ranged in age from 22 years to 44 years (mean age of 30 years, 7 months). It should be noted that most subjects in this study experienced a significant amount of pain, which can be attributed to the very rapid expansion regimen of 4 turns per day of the expansion screw until the appearance of a midline diastema. This is a very rapid rate of expansion reportedly creates pain and discomfort; the authors of this article and other researchers disagree with this protocol and prefers an expansion rate of a maximum of 2 turns per day.
Other similar studies also support the use of nonsurgical RPE in young adults. One such study assessed 82 patients under the age of 25 years who underwent successful RPE without surgery. Of the 82 patients, 12 were female (mean age of 16 years, 6 months), with the oldest being 20 years of age. 15 patients ranging in age from 15 to 39 years (mean age of 22.3 years) were followed for 11 years; none of the patients experienced recurrence of their crossbite, although the authors reported concerns over the level of gingival recession that was observed. Another recent report concluded that nonsurgical RPE in adults is a clinically successful and safe method for correcting transverse maxillary arch deficiency. There was no relapse of the crossbite in the adults treated with RPE following discontinuation of retainers for at least 1 year (mean time of discontinuation of 5.9 ± 3.9 years). The method of expansion used in this study was a Haas-type expander with acrylic pads on the hard palate. The expansion screw was turned once per day, which is a different method of achieving expansion. With this technique, no midline diastema appeared in any of the patients. The authors demonstrated that the alveolar bone was, in fact, translated with minimal molar tipping and the maxillae were not separated in their sample of successfully treated adults. Nine of the 47 subjects experienced pain or tissue swelling, but all were able to complete their expansion regimen after a rest period of 1 week, with the appliance turned back a few times and a slower expansion schedule every other day. Some buccal gingival attachment loss was seen in the female subjects, but the attachment loss was deemed clinically acceptable.

REFERENCES

Shirkande, et al.: Correction of Transverse Discrepancy Using Rapid Maxillary Expansion with Hyrax Appliance: A Case Report


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