International Journal of Scientific Study

General Information

About The Journal

International Journal of Scientific Study (IJSS) is a monthly journal publishing research articles after full peer review and aims to publish scientifically sound research articles in across all science like Medicine, Dentistry, Genetics, Pharmacy, etc.

Each article submitted to us would be undergoing review in three stages: Initial Review, Peer Review & Final Review.

Abstracting & Indexing Information

PubMed - Selected Citations (As Mentioned on National Library of Medicine Catalog Website) - www.ncbi.nlm.nih.gov/nlmcatalog/101729001, Index Medicus (IMSEAR), Global Index Medicus, Google Scholar, WorldCat, SafetyLit, Genamics Journal Seek Ulrichsweb Serials Solutions, International Committee of Medical Journal Editors (ICJME) Geneva Foundation for Medical Education & Research (GFMER), Socolar, Bielefeld Academic Search Engine (BASE), Research Bible, Academic Journals Database, J-Gate, Jour Informatics, Directory of Research Journal Indexing (DRJI), Scientific Indexing Services (SIS) Rubriq-Beta, SHERPA RoMEO, New Journal (EIJASR), IndianScience.in, CiteFactor, Scientific Journal Impact Factor (SJIF), Journal Index.net, ROAD, Global Impact Factor (GIF), International Society for Research Activity (ISRA), Advanced Science Index (ASI)

Information for Authors

The authors should follow "Instructions to Authors" which is available on website http://www.ijss-sn.com/instructions-to-authors.html. Authors should fill the Copyright Transfer form & Conflict of Interest form. Manuscripts should be submitted directly to: editor@ijss-sn.com.

Publication Charges

International Journal of Scientific Study aims to encourage research among all the students, professionals, etc. But due to costs towards article processing, maintenance of paper in secured data storage system, databases and other financial constraints, authors are required to pay. However discount will be provided for the non-funding quality research work upon request. Details about publication charges are mentioned on journal website at: http://www.ijss-sn.com/publication-charges.html.

Advertising Policy

The journal accepts display and classified advertising Frequency discounts and special positions are available. Inquiries about advertising should be sent to editor@ijss-sn.com.

Publishing Details

Publisher Name: International Research Organization for Life & Health Sciences (IROLHS)

Registered Office: L 214, Mega Center, Magarpatta, Pune - Solapur Road, Pune, Maharashtra, India – 411028. Contact Number: +919759370871.

Designed by: Sinjore Technologies (www.sinjore.com)

Disclaimer

International Journal of Scientific Study

Editorial Board

International Journal of Scientific Study
June 2023 • Vol 11 • Issue 3

Contents

International Journal of Scientific Study
June 2023 • Vol 11 • Issue 3

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Case Report

Post-traumatic Abdominal Wall Hernia with Transmesocolic Hernia: A Case Report

Prarthana Bandekar[1], Kanchan Gupta[1], Mohammad Dungarpurwala[1], Meena Kumar[2], Niket Attarde[3]

[1]3rd Year Resident, Department of General Surgery, Dr. D Y Patil University and School of Medicine, Navi Mumbai, Maharashtra, India, [2]Professor and Head, Department of General Surgery, Dr. D Y Patil University and School of Medicine, Navi Mumbai, Maharashtra, India, [3]Associate Professor, Department of General Surgery, Dr. D Y Patil University and School of Medicine, Navi Mumbai, Maharashtra, India

Abstract

Traumatic abdominal wall hernia is rare, with incidence of 1%. There is a disruption in the abdominal wall musculature along with fascial defect. This can occur due to high-velocity trauma or rather alternatively due to low-velocity trauma against a small blunt object. Transmesocolic hernia is a subtype of internal hernia with an incidence of 8%. We present a case of 29-year-old male with high-velocity road traffic accident with intra-operative findings of abdominal wall disruption along with internal herniation of gangrenous bowel segment. Resection of gangrenous bowel with temporary ileostomy was done initially. The stoma was closed at a later date.

Key words: Internal hernia, Transmesocolic hernia, Traumatic abdominal wall hernia

INTRODUCTION

Traumatic abdominal wall hernia or TAWH is a rare entity among the hernias, with reported incidence of approximately 1%.[1] In TAWH, there is breach in the abdominal wall musculature with fascial defect, leaving the skin without any breach within, caused due to high-velocity trauma. TAWH was first reported in 1906.[2] The criterion for a hernia is to be labeled as TAWH is the absence of hernia before trauma, absence of breach in skin, and presence of abdominal hernia. Internal hernia indicates herniation of bowel within the peritoneal cavity. Transmesocolic hernia is a type of internal hernias which can either be congenital or acquired post-surgery or trauma. In order of frequency, these are paraduodenal hernias (53%), pericecal (13%), transmesenteric (8%), hernias through the foramen of Winslow (8%), supravesical and pelvic (6%), intersigmoid (6%), and finally, transomental (1–4%).[2] In this study, we report a case of TAWH with a transmesocolic hernia.[3]

Access this article online

www.ijss-sn.com

Month of Submission : 04-2023
Month of Peer Review : 05-2023
Month of Acceptance : 06-2023
Month of Publishing : 06-2023

CASE REPORT

A 29-year-old gentleman presented to the emergency ward of our hospital with alleged history of road traffic accident with polytrauma. The patient was sitting on the front passenger seat of a 4 wheeler with seatbelt on, when his vehicle collided with a heavy vehicle on a highway. He was taken to a primary center nearby wherein first aid was provided to him and then was referred to a tertiary center.

On presentation, he had his vitals: Pulse rate, blood pressure, and respiration rate within normal limits with GCS of 15/15. His primary symptom was abdominal pain which was acute in onset, colicky in nature and continuous, generalized, transiently relieved on analgesics and was associated with nausea. The patient was provided management according to advanced trauma life support protocol on arrival to the casualty. On detailed per abdomen examination, his abdomen was distended with bluish discoloration of periumbilical skin with multiple linear abrasions over the abdomen [Figure 1] and bilateral lower limbs. On palpation, he had generalized tenderness and guarding present.

After primary survey, e-FAST was done which was suggestive of minimal fluid in the abdominal cavity. X-ray chest and X-ray Pelvis and Both Hips(X-ray PBH) were unremarkable. The patient did not have any known co-

Corresponding Author: Dr. Prarthana Bandekar, 1401, Spiro Tower, V B Phadke Road, Neelam Nagar, Mulund (East), Mumbai - 400 081, Maharashtra, India.

morbidities. After adequate fluid resuscitation and analgesics, the patient was shifted for contrast-enhanced computed tomography (CT) abdomen and pelvis with IV contrast which revealed the following findings - 7.6 cm × 5 cm sized defect in the supraumbilical region in the anterior abdominal wall through which omentum and bowel loops were seen herniating. Minimal free fluid was seen in the herniated sac with fat stranding and minimal free fluid in the pelvic cavity, suggestive of hemoperitoneum. Significant short segment narrowing of celiac trunk with 80% luminal compromise for a length of 9 mm was seen at its origin with 7 mm × 4 mm hypodense filling defect, suggestive of chance of it being a thrombus [Figure 2].

The patient was taken for emergency exploratory laparotomy with due written informed consent. A transverse incision was taken in view of periumbilical hematoma. Intraoperatively following findings were seen; A 25 cm segment of gangrenous small bowel [Figure 3] was noted approximately 15 cm proximal to ileoceacal junction which was seen herniating though the defect in the anterior abdominal wall. There was also a tear in the mesentery of the same as well as adjacent small bowel through which the herniated gangrenous bowel was seen protruding causing internal herniation. There is no evidence of any solid organ trauma and rest of the peritoneal cavity was unremarkable. Resection of the gangrenous bowel segment was done and a temporary double barrel ileostomy was taken out. The transverse abdominal wall incision was closed enmass.

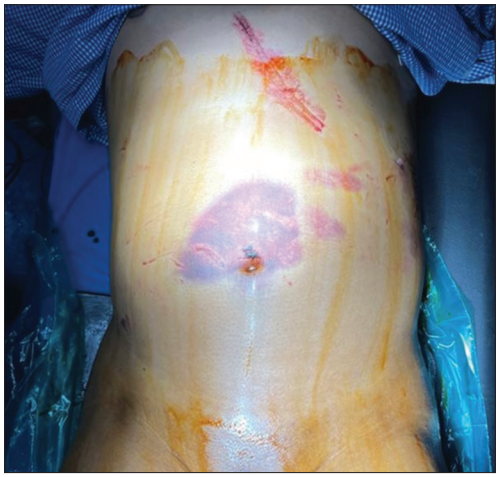


Figure 1: Clinical image of the abdomen findings of the patient

The patient was initially shifted to the intensive care unit for immediate post-operative management. The rest of the course of the patient in the hospital was uneventful. The patient was discharged with stoma and was later re-admitted for stoma closure after 8 months which was uneventful as well.

DISCUSSION

TAWH is caused by herniation of visceral organ or a part of it through disrupted musculature and fascia following trauma, when the skin is intact and there is no prior evidence of hernia detected at the site of injury.[4]

For abdominal wall disruption to occur, the traumatic force must be abrupt, tangential, and powerful enough to cause an acute rise in intra-abdominal pressure leading to TAWH.[5-7]

Wood *et al.*[8] described two forms of TAWH:

The first is sustained with high-velocity trauma, such as a motor vehicle crash or a fall from a height. Associated intra-abdominal visceral injury is common and depends on the location of the herniation. Infraumbilical ventral hernias are rarely associated with intra-abdominal injury.[7] Supraumbilical and flank hernias have a higher incidence with both solid and hollow organ injuries. The fascial defect is generally large.[19-21]

The second type is caused by low-velocity impact against a small blunt object, such as a bicycle handlebar infrequently associated with intra-abdominal injuries.[9,10]

Patients usually complaints of a bulge in the abdominal wall that is tender on palpation. Clinically, a subcutaneous fluctuant swelling may be seen that may or may not be reducible.[10,11]

Abdominal wall bruising and ecchymosis are common presentations.

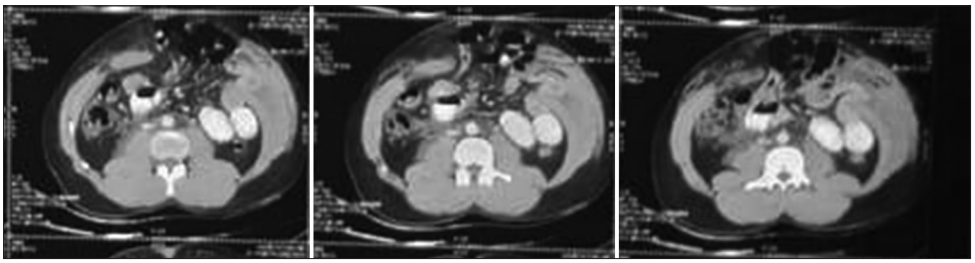


Figure 2: Contrast-enhanced computed tomography abdomen and pelvis plates demonstrating herniation of bowel loops through anterior abdominal wall

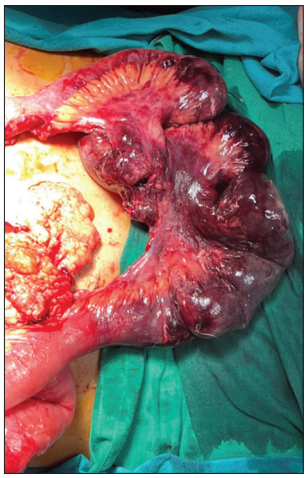


Figure 3: Gangrenous segment of small bowel with mesenteric tear

CT scan with intravenous contrast should be used as a diagnostic modality in vitally stable patients with blunt abdominal trauma and suspected TAWH.[13-19]

Complications due to internal herniation can be either early or late following injury. Early complications can be bowel wall ischemia and perforation. Bowel perforation is caused by the high-energy blow to the abdomen, direct injury to an intestinal wall or blood vessels, or as a result of strangulation. Due to such high risk of complications, the need for high degree of suspicion and timely interventions is of utmost importance to reduce the level of resection required along with associated high morbidity and mortality with such hernia.[12]

Late complications include recurrent abdominal wall herniation due to the breakdown of the primary repair and delayed bowel obstruction due to entrapment of the bowel in an unrecognized or concealed hernia.[13]

CONCLUSION

Acute TAWH are usually rare, thus in vitally stable patient, a CT scan with IV contrast should be performed after primary resuscitation of the patient and careful attention given to the abdominal wall and muscular insertions.

Delay in repair of such hernia can lead to complications such as strangulation of bowel and necrosis leading to resection of the strangulated bowel and anastomosis or exteriorization, and hence, early operative measures should be taken.

Primary closure of the defect may be performed if a tension-free approximation can be obtained. If this is not feasible, prosthetic mesh closure is the preferred option.

However, the ideal time for definitive management of such hernia remains a topic of continued discussion.

ACKNOWLEDGMENT

Authors would like to thank Dr. Nida Khan and Dr. Abhishek Mahadik for their guidance.

REFERENCES

1. Salam DH, Al-Tarakji M, Alaieb AI, Singh R, El-Menyar A, Al-Thani H, *et al.* Post-trauma transmesocolic hernia: A case report. J Surg Case Rep 2020;2020:rjaa417.
2. Selby CD. Direct abdominal hernia of traumatic origin. JAMA 1906;XLVII:1485-6.
3. Bharatam KK, Kaliyappa C, Reddy RR. Right sided transmesentric hernia: A rare cause of acute abdomen in adults. Int J Surg Case Rep 2014;5:1154-7.
4. Donald D, Jeffrey L, Randel T. Acute traumatic abdominal hernia: Case reports. J Trauma 1994;36:273.
5. Martinez BD, Stubbe N, Rakower SR. Delayed appearance of traumatic ventral hernia: A case report. J Trauma 1976;16:242-3.
6. Manuola R, Kekomaki M. Traumatic hernia: Two cases of traumatic subcutaneous rupture of the abdominal wall. Acta Chir Scand 1965;130:256.
7. Clain A. Traumatic hernia. Br J Surg 1964;51:549-50.
8. Wood RJ, Ney AL, Bubrick MP. Traumatic abdominal hernia: A case report and review of the literature. Am Surg 1988;54:648-51.
9. Guly HR, Stewart IP. Traumatic hernia. J Trauma 1983;23:250-2.
10. McWhorter GL. Inguinal hernia due to direct trauma: Technique of operation. Am J Surg 1939;45:316.
11. Fraser N, Milligan S, Arthur RJ, Crabbe DCG. Handlebar hernia masquerading as an inguinal haematoma. Hernia 2002;6:39-41.
12. Gomes R, Rodrigues J. Spontaneous adult transmesentric hernia with bowel gangrene. Hernia 2011;15:343-5.
13. Wechsler RJ, Kurtz AB, Needleman L, Dick BW, Feld RI, Hilpert PL, *et al.* Cross-sectional imaging of abdominal wall hernias. AJR Am J Roentgenol 1989;153:517-21.
14. Arnaud JP, Eloy R, Adloff M, Grenier JF. Critical evaluation of prosthetic materials in repair of abdominal wall hernias: New criteria of tolerance and resistance. Am J Surg 1977;133:338-45.
15. Dayton MT, Buchele BA, Shirazi SS, Hunt LB. Use of an absorbable mesh to repair contaminated abdominal-wall defects. Arch Surg 1986;121:954-60.
16. Gutteridge I, Towsey K, Pollard C. Traumatic abdominal wall herniation: Case series review and discussion. ANZ J Surg 2014;84:160-5.
17. Kaude J. Traumatic rupture of the abdominal wall with subcutaneous herniation of the transverse colon and perforation of the small bowel. Br J Radiol 1966;39:950-1.
18. Dubois PM, Freeman JB. Traumatic abdominal wall hernia. J Trauma 1981;21:72-4.
19. Losanoff JE, Richman BW, Jones JW. Handlebar hernia: Ultrasonography-aided diagnosis. Hernia 2002;6:36-8.
20. Fredlund P, Dahn I. Traumatic subcutaneous rupture of the abdominal wall with intestinal prolapse. Case report. Acta Chir Scand 1967;133:501-3.
21. Dajee H, Nicholson DM. Traumatic abdominal hernia. J Trauma 1979;19:710-1.

How to cite this article: Bandekar P, Gupta K, Dungarpurwala M, Kumar M, Attarde N. Post-traumatic Abdominal Wall Hernia with Transmesocolic Hernia: A Case Report. Int J Sci Stud 2023;11(3):1-3

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Case Series

Replacement of Defective Restorations in Posterior Teeth: An Inlay Case Series

Juhi Dubey[1], Vishakha Rungta[2], Rashmi Saini[2], Anushriya Dutta[2], Priyanka Agrawal[2]

[1]Assistant Professor, Department of Conservative Dentistry and Endodontics, K. D. Dental College and Hospital, Mathura, [2]Clinical Practitioner, Department of Conservative Dentistry and Endodontics, Sardar Patel Post Graduate Institute of Dental and Medical Sciences, Lucknow, Uttar Pradesh, India

Abstract

The restoration of severely damaged teeth can be a real challenge for dental practitioners to follow the rules of contemporary conservative dentistry and preserve as much tooth structure as possible. Inlays are a type of indirect restoration that is used to restore extensively damaged or decayed teeth. Inlays are an alternative to a direct restoration which is used to fill cavities and are made up of metal, amalgam, composite, and ceramic and then cemented onto the tooth surface to make the tooth in proper functioning.

Key words: Ceramic inlay, Indirect composite inlay, Metal inlay, Posterior restoration, Resin cement

INTRODUCTION

An ideal restoration has required the development of several restorative techniques and materials. Although metallic alloys were used due to their favorable physiomechanical properties, to enhance the development of materials with better performance to accomplish clinical requirements and meet the patient's esthetic expectations.[1]

Although amalgam and gold have illustrated persistent clinical success and biocompatibility, novel tooth-colored restorations provide an esthetic appearance and preserve the sound tooth structure.[2] Nowadays, composite materials and non-metallic ceramic restorations are most commonly used.[1]

According to Jose *etal.*, the first generation of an indirect resin composite was used in the early 1980s. Although there is a successful accomplishment in a direct composite restoration, using composite restoration with indirect or extra-oral methods remains obscure.[2]

Ceramic materials have relatively high compressive strength, low flexural strength, and fracture toughness, but the limitation is the brittleness of this material and the high potential of wearing the enamel or resin restoration of the antagonist's teeth. Nowadays, ceramic compositions have added an abrading potential of dental enamel which appears as natural teeth, which have less aggressive behavior.[1]

There are certain indications and contraindications of indirect inlay;

INDICATIONS

- Large restorations
- Faulty restorations or repeated fracture
- Restorations within the body of the tooth that does not require cuspal coverage
- Difficulty in achieving good contact and contour or occlusion using direct restorations.[3]

CONTRAINDICATIONS

- Poor oral hygiene
- Parafunctional habits and heavy occlusal forces
- Developing deciduous teeth
- Extensive caries[4]

ADVANTAGES OF INLAYS

These are the indirect restoration that is used to restore extensively damaged or carious teeth when compared to direct restorations.

Access this article online

www.ijss-sn.com

Month of Submission : 04-2023
Month of Peer Review : 05-2023
Month of Acceptance : 06-2023
Month of Publishing : 06-2023

Corresponding Author: Dr. Juhi Dubey, 173/16, Om Nagar Chamunda Colony, Jaisinghpura, Mathura, Uttar Pradesh, India.

- Strong and durable

Provides natural tooth appearance:

- For example., ceramic inlays have excellent esthetic and are almost indistinguishable from the surrounding sound tooth
- Ceramic inlays have better physical properties than composite restorations[5]
- Aim to achieve better contact and contours because they are custom-made and fabricated in the laboratory[4]
- Less microleakage and less post-operative sensitivity than direct resin composite fillings.[6]

DISADVANTAGES

- Higher cost, due to the need for a dental laboratory
- Lengthier process as two appointments are required i.e., increased chair time for the patient
- Marginal leakage and staining
- Technique sensitive.[7]

Despite all these advantages, the longevity and success of this type of restoration depend on the correct indication, the clinical experience of the operator, and the accurate work of the laboratory technician.[1] The aim of this case report is to restore the faulty restoration with indirect restoration to make the tooth functional by conserving the intact facial and lingual enamel and maintaining the healthy periodontium and thus prolonging the longevity of the restoration.

CLINICAL PROCEDURE

Case-1

A 21-year-old female patient reported to the department of conservative dentistry and endodontics with the chief complaint of food lodgment in the left lower back region of mouth for the past 1 month. The medical history was not significant. The patient had undergone restoration irt 36. On clinical examination, there was a faulty restoration in irt 36 [Figure 1a]. The pulp vitality test with cold test (Roeko Endo-Frost, Coltene) showed a normal response, and on electric pulp, testing (Waldent) showed a positive response. On radiographic examination, fractured restoration with proximal caries Irt 36 was seen [Figure 1b]. The final diagnosis of reversible pulpitis irt 36 was made.

The final treatment plan was indirect composite inlay irt 36. All the procedures were explained to the patient and written informed consent was taken.

In the first appointment

The faulty restoration was removed, and cavity preparation was done for inlay restoration [Figure 1c] with no sharp angles; slightly flared walls of 8°–10° and a minimum preparation depth of 1.5 mm. After cavity preparation, the impression was made using a polyvinyl silicone material, cast was made [Figure 1d] and shade selection was done.

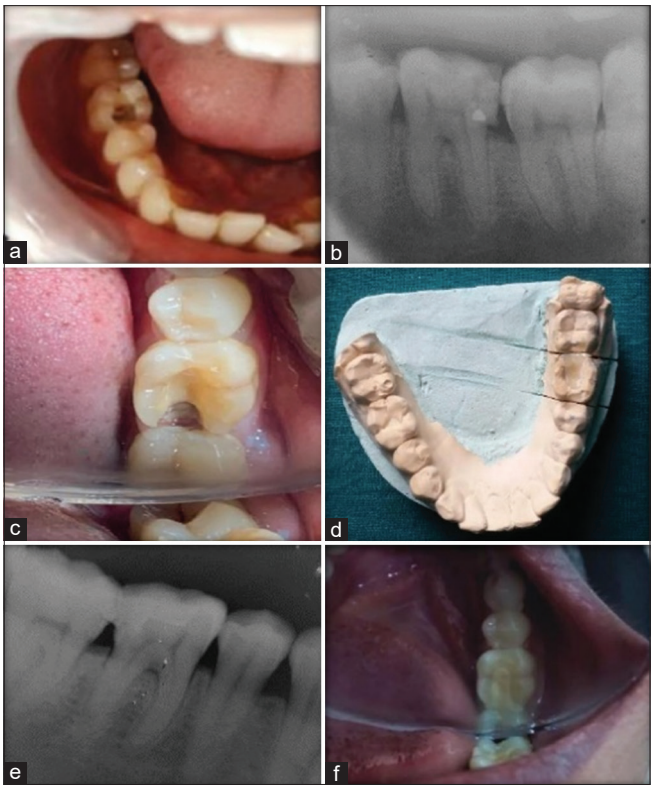


Figure 1: (a) Pre-operative picture (b) pre-operative radiograph (c) cavity preparation (d) cast (e) post-operative radiograph (f) post-operative picture

In the second appointment

The inlay was placed on the prepared tooth surface, and the contact points were checked. The tooth surface was etched for 20 s, rinse and dried, and apply the bonding system. Pre-treatment of restoration was done by sandblasting. The treatment of tooth surface allows with etchant and bonding agent which cause microlocking in enamel and hybrid layer in dentin by tangling between adhesive system and dentin collagen matrix thus allowing the adhesion of composite. A thin layer of dual-cure composite resin (Sirona, Dentsply) was applied to the inner surface of the restoration. After that inlay was placed in the prepared cavity and excess material is removed with the probe, occlusion was checked and flossing was done on proximal surfaces before polymerization. The final step includes the polymerization of tooth walls for 60 s, polishing, and finishing using diamond burs and disks, and a radiograph was taken [Figure 1e and f].

Case-2

A 28-year-old female patient reported to the department of conservative dentistry and endodontics with the chief

complaint of dislodged restoration in the left lower back region of the mouth for the past 2 months. The medical history was not significant. The patient had undergone restoration irt 36. On clinical examination, there was a faulty restoration in irt 36 [Figure 2a]. The pulp vitality test with cold test (Roeko Endo-Frost, Coltene) showed a normal response, and on electric pulp, testing (Waldent) showed a positive response. On radiographic examination, fractured restoration with proximal caries Irt 36 was seen [Figure 2b]. The final diagnosis of reversible pulpitis irt 36 was made. The final treatment plan was metal inlay irt 36. All the procedures were explained to the patient and written informed consent was taken.

The initial old restoration was removed and inlay cavity preparation was made [Figure 2c] which extended 1mm into dentin at the central fossa. For inlay cavity preparation, the pulpal floor should be flat over most of its extent. Moreover, the pulpal depth should be 1–1.5 mm from the DEJ. Burs 169 L were used for giving 3°–5° divergence and bur no. 8862 for giving bevels. After cavity preparation, the impression was made using polyvinyl silicone material, and a cast was made [Figure 2d].

The inlay is tried in [Figure 2e] and cementation was done as discussed earlier. Post-operative radiograph was taken [Figure 2f].

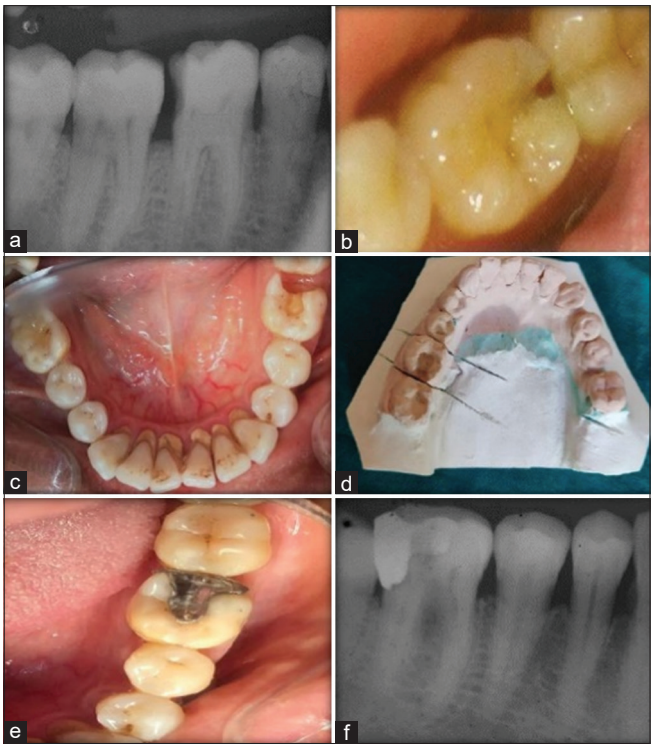


Figure 2: (a) Pre-operative radiograph (b) pre-operative picture (c) cavity preparation (d) cast (e) post-operative picture (f) post-operative radiograph

Case-3

A 30-year-old female patient reported to the department of conservative dentistry and endodontics with the chief complaint of dislodged restoration in the left lower back region of the mouth for the past 1 month. The medical history was not significant. The patient had undergone restoration irt 36. On clinical examination, there was a faulty restoration in irt 36. The pulp vitality test with cold test (Roeko Endo-Frost, Coltene) showed a normal response, and electric pulp testing (Waldent) showed a positive response. On radiographic examination, fractured restoration with proximal caries Irt 36 was seen [Figure 3a]. The final diagnosis of reversible pulpitis irt 36 was made. The final treatment plan was ceramic inlay irt 36. All the procedures were explained to the patient and written informed consent was taken.

The old restoration was removed. An inlay cavity preparation was made [Figure 3b], in which the pulpal floor should be flat over most of its extent. The occlusal divergence per wall is kept at 6°–8°. The depth of the occlusal step is in the range of 1.5–2.0 mm. The width of the isthmus should be a minimum of 1.5 mm and the axial reduction in the proximal box also on average be 1.5 mm. After cavity preparation, the impression was made using polyvinyl silicone material [Figure 3c], and a cast was made

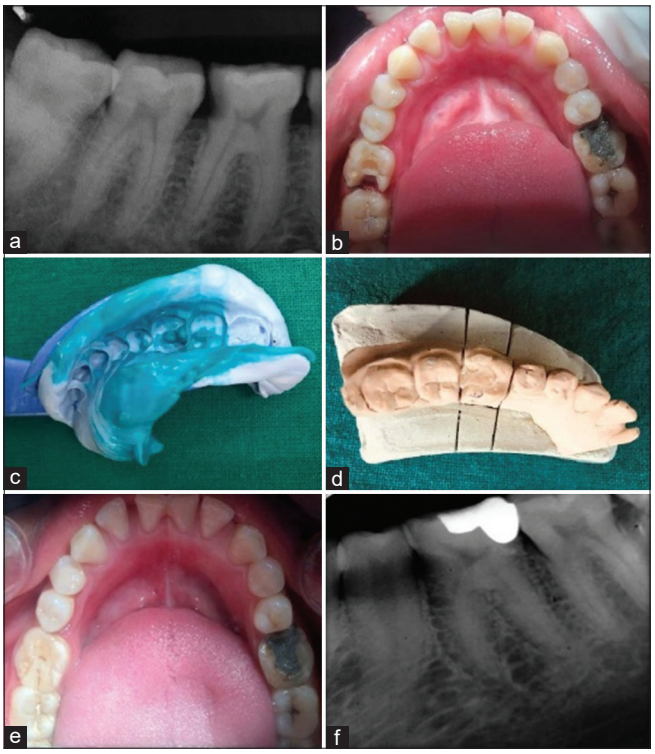


Figure 3: (a) Pre-operative radiograph (b) cavity preparation (c) polyvinyl impression (d) cast (e) post-operative picture (f) post-operative radiograph

[Figure 3d] and send to the laboratory for fabrication. The inlay was tried in [Figure 3e] and cementation was done

as above cases. A post-operative radiograph was taken [Figure 3f].

DISCUSSION

The primary emphasis for dentistry now is the preservation of tooth structure and reinforcement of tooth by reducing the fracture incidence of the restored tooth.[8]

Newer modifications of composite resin and adhesive systems are increasing the demand for esthetic restorations in both anterior and posterior teeth. Depending on the respective clinical indication, resin composite materials are suitable for both direct and indirect restorations.[9]

According to various clinical studies, composite resin restorations have the advantage to be more user-friendly and less expensive than ceramic inlay.[5] The indirect composite resins are superior in esthetics, hue, and reduced post-operative sensitivity than the direct composite.[10] Moreover, indirect restorations are more successful to achieve great morphology of the tooth and ideal proximal contacts. Another advantage is better integrity of the tooth/restoration interface which can result in increased longevity and reduced marginal leakage. The indirect composite resin provides greater stress distribution and reparability and it has lower cost and ease of manageability compared to ceramic materials.[2]

In past years, silver amalgam was the oldest restorative material. It has good compressive strength but the drawback of this material was fracture of the restoration when used in large cavities. The composite is a tooth-colored restorative material but it has several disadvantages such as less strength, polymerization shrinkage, and hypersensitivity. Stainless steel or porcelain fused to metal or all ceramic are indicated for extensive caries but the limitations are not being conservative, thus the best treatment for proximal caries is Class II inlay cast restoration. The inlay is advisable for conservative restoration as it has the advantage of well-compressive strength which can withstand to heavy masticatory forces.[11]

Recreating the original anatomy of the tooth resembling its natural appearance is a big challenge for the dentist. A good personalized smile comprises shade, shape, and surface texture of the material which preserves sound tooth structure using a minimally invasive bonded restoration leading to less trauma and a superior prognosis. Hence, ceramic inlays are in great demand and acceptance in the field of esthetic dentistry. The excessively wide cavities may preclude the use of direct posterior composite restorations and here, the indirect restorations came into action for restoration of the tooth, as they found it superior over direct restorations in numerous ways, such as high biocompatibility, they do not encourage the concentration of dental plaque in their surfaces with perfect color stability, and ceramic stronger than composite resins and offers superior physical properties.[9]

CONCLUSION

Indirect restorations provide excellent esthetics, better contact and contour, and longevity of the restoration in posterior dental arches.

REFERENCES

1. Silva RH, Ribeiro AP, Catirze AB, Pinelli LA, Fais LM. Clinical performance of indirect esthetic inlays and onlays for posterior teeth after 40 months. Braz J Oral Sci 2009;8:154-8.
2. Jose LM, Jose B, Jose J, Babu K. Indirect composite inlay restoration: A case report. IP Indian J Conserv Endod 2022;7:49-54.
3. Ricketts D, Bartlett D. Advanced Operative Dentistry. 1st ed: Elsevier; 2011. ISBN 9780702045660
4. Ricketts James DN, Bartlett DW. Advanced Operative Dentistry: A Practical Approach. Edinburgh: Churchill Livingstone; 2011.
5. Hopp CD, Land MF. Considerations for ceramic inlays in posterior teeth: A review. Clin Cosmet Investig Dent 2013;5:21-32.
6. Summitt JB. Fundamentals of Operative Dentistry: A Contemporary Approach. Berlin: Quintessenz Verlag; 2011.
7. Summitt JB. Fundamentals of operative Dentistry: A Contemporary Approach. 3rd ed. Chicago: Quintessence Pub; 2006.
8. Mital P, Thanvi C, Raisingani D, Prasad AB, Bhamboo A, Srivastava H. Tooth-colored restoration in molars: Three case reports. J Mahatma Gandhi Univ Med Sci Tech 2017;2:176-80.
9. D'Arcangelo C, Vanini L, Casinelli M, Frascaria M, De Angelis F, Vadini M, *et al.* Adhesive cementation of indirect composite inlays and onlays: A literature review. Compend Contin Educ Dent 2015;36:570-7.
10. Basudan TA, Alshareef SM, Alshehri AJ, Alkhalil HA, Alhowifi SD, Alhusain AM, *et al.* Differences of direct and indirect resin composite and its effect on esthetic restoration. Int J Community Med Public Health 2021;8:4622.
11. Deshpande PM, Metta K, Prashanth BR, Naik RR. Adjacent interproximal caries – The best treatment of choice is mod inlay: A case report. IJADS 2016;2:81-4.

How to cite this article: Dubey J, Rungta V, Saini R, Dutta A, Agrawal P. Replacement of Defective Restorations in Posterior Teeth: An Inlay Case Series. Int J Sci Stud 2023;11(3):4-7.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Review Article

Is Early Management of Acute Coronary Syndrome with Rosuvastatin Important?

Raghav Sharma[1], Deepak Basia[1], Harsimran Singh[1], H S Bharath[2], Shital Sarda[2]

[1]Meditrina Heart Centre, Civil Hospital, Ambala, Haryana, India, [2]Medical Affairs, AstraZeneca Pharma India Ltd, Bengaluru, Karnataka

Abstract

Acute coronary syndrome (ACS) continues to be a leading reason for premature death in both developing and developed nations despite significant advancements in its prevention and therapy. The initial period following an ACS is very critical with chances of risk of recurrent episodes; hence, the stabilization of susceptible coronary plaques is warranted. Statins have been strongly recommended for the prevention and management of cardiac diseases in several clinical guidelines for two decades. They are known to suppress the pathologic processes that lead to ACS episodes. Rosuvastatin is documented as the most potent statin in lowering lipid profiles and inflammatory markers associated with atherosclerosis. Early initiation of high-dose rosuvastatin therapy has been shown to produce significantly positive results and meet the goals of various clinical guidelines in lowering low-density lipoprotein values. The superiority in the effectiveness as well as the potency of rosuvastatin over atorvastatin in lowering lipid profiles and inflammatory markers and causing a reduction in the atherosclerotic burden has been reported in many studies. Few studies found no difference in the effectiveness of these two drugs. Hence, this paper aims to review the recent scientific evidence and guidelines to ascertain the role of rosuvastatin in the management of ACS.

Keywords: Acute coronary syndrome, Atorvastatin, Cardiovascular disease, Rosuvastatin, Secondary prevention, Statins

INTRODUCTION

Coronary artery disease (CAD) is perhaps the most significant reason for early morbidity and mortality in both industrialized and developing nations.[1] Acute coronary syndrome (ACS) is among the most frequent presentations of CAD.[2] ACS is triggered by the acute obstruction of the coronary vessels, and it includes conditions such as unstable angina, ST-elevation myocardial infarction (STEMI), and non-STEMI (NSTEMI).[3] Multiple ACS registries in India report the prevalence of STEMI as 37–72.4%, NSTEMI as 27.8–54.5%, and overall mortality as varying between 2.04% and 10.2%.[1] The period immediately after an episode of ACS is critical with a considerable risk of frequent episodes and mortality from vulnerable plaque occlusion. Hence, measures to treat susceptible plaques are crucial. Numerous treatment strategies, including antithrombotic drugs, beta-blockers, and angiotensin-converting enzyme inhibitors, were previously employed to stop episodes after ACS; however, the likelihood of catastrophic events remained high.[4] The advent of statins as a frontline treatment in the management of ACS has significantly reduced cardiovascular risks and events.[5-8] These drugs are known to suppress inflammation, endothelial dysfunction, and thrombus development, all of which are involved in the mechanism of ACS.[8]

Statins are extensively recognized for the prevention of cardiac diseases in several clinical guidelines, such as the American College of Cardiology (ACC)/American Heart Association (AHA) task force and European society of cardiology (ESC)/European atherosclerosis society (EAS) and have already been incorporated in the World Health Organization (WHO) guidelines for cardiovascular disease prevention from 2007.[6,9] In addition, WHO's target by 2025 is to achieve 50% coverage of statin therapy among eligible people who already have cardiovascular ailments or are at risk of acquiring them.[9] The 2019 guidelines from the ESC and EAS state that each patient's response to statin therapy differs and hence recommend raising the statin dose before starting any further low-density lipoprotein (LDL)-lowering therapies.[10]

Access this article online

www.ijss-sn.com

Month of Submission : 04-2023
Month of Peer Review : 05-2023
Month of Acceptance : 06-2023
Month of Publishing : 06-2023

Corresponding Author: Raghav Sharma, Meditrina Heart Centre, Civil Hospital, Ambala, Haryana, India.

Literature has described the three generations of statins depending on their increased potency in decreasing LDL cholesterol (LDL-C) values. The third-generation, such as rosuvastatin and pitavastatin, is known as superstatins because of their high potency and efficacy.[7] The high potency of rosuvastatin is attributed to its fluorinated phenyl group and methane sulfonamide along with the side chain of dihydroxyheptenoic acid structure. The unique chemical composition and thermodynamically lowest free energy (ΔG) values of this molecule are responsible for its high binding affinity with 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase enzymes when compared to other statins.[7,11] In addition, rosuvastatin is not extensively metabolized, only 10% of it is metabolized by the interactions with cytochrome-P450-2C9 enzyme, cytochrome-P450-2C19 enzyme, organic anion transporting polypeptide 1B1, and breast cancer resistance protein.[12,13] The hydrophilic nature of rosuvastatin prevents drug interactions and inhibits biotransformation into water-soluble metabolites for elimination. Compared to other statins, rosuvastatin interacts less with other drugs as it is mainly metabolized by CYP2C9.[7]

A systematic review of 42 trials concluded that the lipid-lowering capacity of the commonly used atorvastatin ranged from 37 to 51% and was 3 times less effective than the newer agent rosuvastatin.[14] Rosuvastatin is concluded to be the most potent statin in lowering blood levels of LDL-C, apolipoprotein B (Apo-B), and total cholesterol and increasing high-density lipoprotein cholesterol (HDL-C) and apolipoprotein A-1 (Apo-A1).[15,16] It is also effective in lowering coronary atherosclerotic plaques.[10,17,18]

In addition, rosuvastatin is available in a range of doses (5–40 mg), providing health-care professionals the ability to adjust treatment doses to maximize the therapeutic benefit while simultaneously minimizing adverse effects.[10] Hence, this paper aims at reviewing the recent scientific evidence and guidelines to ascertain the role of rosuvastatin in the management of ACS.

POTENTIAL MECHANISM OF ACTION OF ROSUVASTATIN IN ACS MANAGEMENT

Statins are a group of amphiphilic structures and are frequently preferred drugs for the effective management of dyslipidemia.[11] They inhibit the production of endogenous cholesterol, especially in hepatic cells, which lowers cellular cholesterol levels and boosts the activity of LDL receptors on hepatocytes. Enhanced LDL receptor concentration leads to the catabolism of atherogenic lipoproteins and inhibits hepatic very LDL production. In addition, statins elevate HDL and reduce the imbalance between atherogenic and antiatherogenic lipoproteins, which improves the nature and integrity of atherosclerotic lesions [Figure 1].[8,11,19]

Statins offer multiple pleiotropic benefits, such as increased anti-inflammatory, antioxidant, and antiplatelet effects, coronary plaque stabilization, enhancement of endothelial

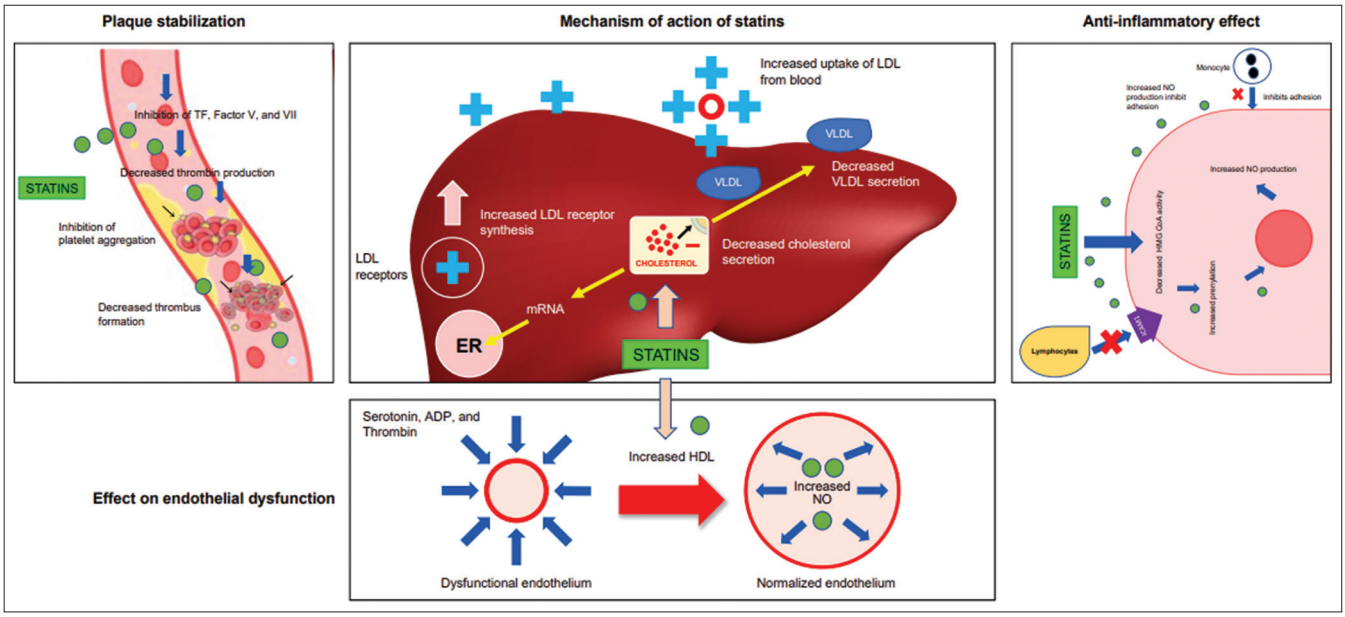


Figure 1: Mechanism of action of statins in preventing ACS episodes. ACS: Acute coronary syndrome; ADP: Adenosine diphosphate; ER: Endoplasmic reticulum; HDL: High-density lipoprotein; HMG CoA: 3-Hydroxy-3-methylglutaryl coenzyme A; ICAM1: Intercellular adhesion molecule 1; LDL: Low-density lipoprotein: mRNA: Messenger ribonucleic acid; NO: Nitric oxide; TF: Tissue factor; VLDL: Very low-density lipoprotein

function, and an increase in adiponectin, which suppresses the cascade of events in ACS.[6,8] Therefore, these pleiotropic effects strongly support the idea of utilizing statins to treat ACS.

Anti-inflammatory Effect

Inflammation plays a vital role in atherosclerosis progression and the formation of coronary lesions. Higher concentrations of several inflammatory markers, such as serum amyloid A, C-reactive protein (CRP), interleukin-6 (IL-6), heat-shock protein 65, intercellular adhesion molecule 1 (ICAM-1), and vascular cell adhesion protein 1, are associated with the severity and prognosis of atherosclerosis. It is well known that statins lower CRP levels. In addition, statins reduce the production of monocyte chemoattractant protein-1, tumor necrosis factor-alpha, IL-1, IL-8, and matrix metalloproteinase. The mechanism involved in the anti-inflammatory effect is mentioned below:

1. Inhibiting lymphocyte adhesion: By directly interacting with ICAM-1, statins reduce T-cell activation and decreases lymphocyte adherence to endothelial cells
2. Altering the Rho–Rho-kinase pathway: Statins block the mevalonate pathway by inhibiting HMG-CoA reductase. This reduces the intracellular pool of isoprenoids, which, in turn, inhibits the prenylation activity. Decreased prenylation further inhibits the stimulation of nuclear factor-kB and boosts the production of nitric oxide synthase (NOS)
3. Lowering serum LDL levels: Oxidized LDL inhibits NO production and suppresses endothelial NOS activity. Statins lower plasma LDL levels, which, in turn, reduce the production of oxidized LDL. Thus, statin therapy enhances NO bioavailability and lowers monocyte adherence to epithelial cells by lowering LDL substrate [Figure 1].[8,19]

Plaque Stabilization

Treatment with statins decreases the expression of tissue factors on macrophages, which prevents the triggering of the coagulation system. In addition, statins prevent the production of thrombin by suppressing the activation of factors V, Va, and factor VII. Finally, statins also inhibit the activation of factor XIII and inhibit the formation of clots. Furthermore, statins reduce platelet aggregation, which prevents thrombus formation [Figure 1].[8,19]

Effect on Endothelial Dysfunction

Endothelial dysfunction occurs when an imbalance arises between the compensatory mechanisms that cause vasoconstriction and vasodilation. The dysfunctional endothelial cells become vasoconstrictive following acute cardiovascular events in response to various stimuli, including thrombin, serotonin, adenosine diphosphate, reduced intracoronary blood pressure, and other factors. Statins increase NO production, which protects against CAD through its vasodilating effects, alteration in the inflammatory reaction, and activation of leukocytes and platelets. In addition, statin-mediated decrease in atherogenic lipoproteins and increase in HDL improve endothelial function.[8,19] Figure 1 represents the various mechanisms by which statins prevent ACS episodes, including plaque stabilization, anti-inflammatory effect, and the reduction in endothelial dysfunction.

EVIDENCE FOR EARLY INITIATION OF ROSUVASTATIN THERAPY IN ACS

The management of ACS is significantly influenced by the degree of occlusion and the timing of the onset of symptoms. The acute phase is managed by antithrombotic drugs, percutaneous coronary intervention (PCI), and heart bypass surgery. The secondary level of prevention involves changing one's lifestyle and behavior (smoking cessation, exercising, etc.) and the use of medications. Adequate compliance with the suggested treatment regimen usually ensures an enhancement in the quality of life and a reduction in subsequent ischemic episodes and death in ACS cases.[20]

The AHA/ACC and the ESC advise that, before discharge, all patients should be given medications as a secondary level of prevention after an ACS.[20] Furthermore, ESC/EAS guidelines suggest that the intake of statin should begin 1–4 days after an ACS-related hospitalization. Japanese guidelines also recommend management using early statin therapy in all patients with STEMI therapy. The ESC/EAS guidelines' "treat-to-target" strategy of a 50% decrease from the baseline values of LDL-C in patients with ACS, validates the use of strong statins as early-phase therapy. Thus, early and intensive lipid-lowering therapy with statins is currently recommended worldwide.[6]

Based on LDL-C being reduced, the intensity of statin therapy is categorized into three groups: high intensity aims to reduce by 50%, moderate intensity by 30–49%, and low intensity by <30% LDL-C. The dosage of 20–40 mg/day for rosuvastatin and 40–80 mg for atorvastatin is classified as high intensity, whereas the dosage of 5–10 mg and 10–20 mg is classified as moderate intensity for rosuvastatin and atorvastatin, respectively.[21]

ROLE OF HIGH-INTENSITY ROSUVASTATIN IN ACS

The implications of prescribing high-intensity rosuvastatin treatment during the initial phase of ACS had several

benefits. A study by Luo *et al*. (2022) shows that high-dose rosuvastatin therapy has a stronger therapeutic impact than regular-dose rosuvastatin for enhancing lipid metabolic activity, lowering inflammatory process, and managing ventricular remodeling and fibrosis of myocardium.[22] A meta-analysis has reported that preloading with high-dose rosuvastatin significantly improves myocardial perfusion and reduces both cardiac events and myocardial injury in PCI patients.[23]

Studies using high-dose rosuvastatin during the initial phase of ACS treatment are summarized in Table 1. Most of the studies showed a significant decrease in primary outcome values from baseline values. Reduction in LDL-C was reported by yellow, lunar, asteroid, Stellar, Centaurus, and orion trials. An increase in HDL was reported by LUNAR and ASTEROID trials. The CENTAURUS trial indicated a reduction in the Apo-B/Apo-A1.

ROLE OF MODERATE-INTENSITY ROSUVASTATIN IN ACS

Very few studies have evaluated the efficiency of moderate-dose rosuvastatin during the early phase of ACS. The multicentric SPACE ROCKET trial evaluated the effectiveness of 10 mg of rosuvastatin over 40 mg of simvastatin for the secondary prevention of ACS episodes. Rosuvastatin decreased LDL-C and TC by 78 mg/dL and 150 mg/dL, respectively. A total of 79.9% of patients met the lipid target goals of ESC-2003.[31] In the PULSAR trial, 10 mg of rosuvastatin was evaluated on 996 individuals who

Table 1: Evidence for early initiation of high-dose rosuvastatin therapy in ACS

Author, Year	Study population; sample size	Drug	Endpoints	Duration	Outcome
Kini *et al*.; 2013 (Yellow)[24]	CAD; 87	RSV40 versus standard care	Change in LCBI at the 4-mm maximal segment in the lesion	7 weeks	LDL-C and TC decreased. CRP levels remained unchanged. There was a reduction in LCBI 4 mm max. Short-term intensive therapy may reduce lipid content in obstructive lesions.
Pitt *et al*.; 2012 (LUNAR)[25]	ACS; 825	RSV20/RSV40 versus ATV80	LDL-C, HDL Apo-A1, Apo-B/Apo-A1	6–12 weeks	RSV40 was effective in improving Apo-A1 and several lipid ratios, including LDL-C/HDL-C, non-HDL-C/HDL-C, TC/HDL-C, and Apo-B/Apo-A1.
Nicholls *et al*.; 2011[26]	CAD; 1039	RSV40 versus ATV80	PAV, TAV	104 weeks	Decrease in LDL-C and increase in HDL-C values. The decrease in PAV was 1.22%. The reduction in normalized TAV was−6.99 mm^3. The percentage of patients who showed regression for PAV was 68.5% with RSV40.
Lablanche *et al*.; 2010 (CENTAURUS)[27]	ACS; 753	RSV20 versus ATV80	Apo-B/Apo-A1 ratio	3 months	RSV20 was effective in decreasing the Apo-B/Apo-A1 ratio, and LDL-C decreased by~50%.
Chhatriwalla *et al*.; 2006 (ASTEROID)[28]	CAD; 349	RSV40	PAV, TAV	24 months	Mean LDL-C decreased by 53.2% and mean HDL-C increased by 14.7%. A significant reduction in PAV (−0.79%) and TAV (−12.5 mm3) was observed.
Jones *et al*.; 2003 (Stellar)[16]	Hypercholesterolemia; 2431	RSV10, RSV20, RSV40	LDL-C, HDL, triglycerides, TC	6 weeks	LDL-C: The percentage decrease for RSV20 and RSV40 was 52.4% and 55%, respectively. HDL: Percentage increase change for RSV20 and RSV40 was 9.5% and 9.6%, respectively. Triglycerides: The percentage decrease for RSV20 and RSV40 was 23.7% and 26.1%, respectively. TC: The percentage decrease for RSV20 and RSV40 was 37.6% and 40.2%, respectively.
Underhill *et al*.; 2008 (ORION)[29]	Moderately hypercholesterolemic patients; 43	RSV5 or RSV40/RSV80	Carotid plaque volume and composition	24 months	RSV40/RSV80 reduced LDL by 59.9%, and no significant changes in carotid plaque volume were observed. There was a 41.4% reduction in the lipid-rich necrotic core.

ACS: Acute coronary syndrome, Apo-A1: Apolipoprotein-A1, Apo-B: Apolipoprotein-B, ATV: Atorvastatin, CAD: Coronary artery disease, CRP: C-reactive protein, HDL-C: High-density lipoprotein cholesterol, LCBI: Lipid-core burden index, LDL-C: Low-density lipoprotein cholesterol, PAV: Percent atheroma volume, PCI: Percutaneous coronary intervention, RSV: Rosuvastatin, TAV, Total atheroma volume, TC: Total cholesterol

had atherosclerosis or CAD or were at risk of developing CAD. Rosuvastatin slashed LDL-C by 44.6% and enhanced HDL-C by 6.4%. Approximately 68% of patients met the ESC-2003 (<2.5 mmol/L [100 mg/dL]) and the National Cholesterol Education Program Adult Treatment Panel III LDL-C (<2.6 mmol/L) goal.[31] Another multicentric COSMOS trial was conducted in Japan among 214 patients with stable CAD using 2.5 mg/day rosuvastatin as the initial treatment. After 76 weeks, LDL-C had reduced by 38% and HDL-C had risen by 19.8%. Sixty percent of patients experienced plaque regression.[32]

COMPARISON WITH ATORVASTATIN

A plethora of literature including meta-analysis and RCTs has concluded the superiority of rosuvastatin in lowering serum levels of lipid and inflammatory markers over atorvastatin. However, very few studies failed to report differences between them for primary outcomes.

Meta-analysis among Caucasians has shown that the efficacies of all doses of rosuvastatin are 3–3.5 times more potent than those of equivalent therapy of atorvastatin. With 5 mg of rosuvastatin, LDL-C and non-HDL-C were reduced by 39% and 35%, respectively. It took 15 mg of atorvastatin for LDL-C and 14 mg for non-HDL-C to lower the same amount. Rosuvastatin 10 mg lowered LDL-C by 44% and non-HDL-C by 40%, whereas 29 mg and 27 mg of atorvastatin were required to attain comparable reduction. LDL-C was lowered by 50% and non-HDL-C by 45% with rosuvastatin 20 mg, whereas 70 mg and 62 mg of atorvastatin were required to attain a similar reduction. A maximum dose of 80 mg of atorvastatin did not result in a comparable reduction of LDL-C and non-HDL-C with a 40 mg dose of rosuvastatin.[33]

Another meta-analysis among Southeast Asian populations by Zhang *et al.* included 16 RCTs with 5930 participants. When atorvastatin and rosuvastatin were compared, patients on rosuvastatin had significantly lower LDL-C (weighted mean difference [MD] = 7.15 mg/dL; 95% confidence interval: 10.71−3.60 mg/dL; $P = 0.0001$). Age, gender, LDL-C, and follow-up did not affect the advantages of rosuvastatin in meta-regression analysis.[34]

Rosuvastatin was demonstrated to be more potent than atorvastatin for lowering the volume of coronary atherosclerotic plaque. Atheroma volume percent decrease (MD: 0.36 [0.65–0.05]; $P = 0.02$) and atheroma total reduction (MD: 1.63 [2.86–0.41]; $P = 0.0009$) were higher in the rosuvastatin group. Furthermore, LDL-C reduced while HDL-C increased.[18] According to another meta-analysis of five RCTs, rosuvastatin offered enhanced benefits over atorvastatin in the regression of atherosclerotic lesions.[17]

A comparison of rosuvastatin and atorvastatin is presented in Table 2. The studies are combined based on primary outcomes.

Table 3 compares the efficacy of rosuvastatin and atorvastatin for various parameters. The tick (✔) shows rosuvastatin was more potent than atorvastatin, whereas the cross (X) denotes no significant difference between the drugs for that parameter.

PROPROTEIN CONVERTASE SUBTILISIN/KEXIN TYPE 9 INHIBITORS (PCSK9I)—CONSIDERATIONS FOR USE IN ACS

Although statins are used as frontline therapy drugs in ACS patients, many individuals also require additional therapy to meet their target goals in lowering LDL-C values.[46] With the introduction of PCSK9i, the concept of lipoprotein metabolism has been drastically altered. The enzyme PCSK9 hinders the elimination of LDL-C by accelerating the degradation of LDL receptors.[47] Patients with familial hyperlipidemia and atherosclerotic cardiovascular disease (ASCVD) and those who are unable to tolerate high-intensity statins because of adverse effects may require other drugs to reduce serum LDL-C levels such as ezetimibe and PCSK9i. The therapeutic advantages of adding PCSK9i to statin therapy have been shown in the FOURIER and ODYSSEY OUTCOMES investigations. It is significantly more expensive than other lipid-reducing medications while being the most effective in lowering LDL-C.[46,48]

To decrease the LDL-C levels below 70 mg/dL (1.8 mmol/L), the ACC/AHA guidelines advise starting with a rigorous drug regimen. The addition of ezetimibe and anti-PCSK9 antibodies is recommended by ESC/EAS if the ACS patients do not achieve a 50% reduction in LDL-C and LDL-C of >1.4 mmol/L (>55 mg/dL).[49] Overall, the recommendations from the 2018 AHA/ACC and 2019 ESC/EAS guidelines restrict the use of PCSK9i to very high-risk ASCVD cases. According to the Japan atherosclerosis society (JAS) statement from 2018, PCSK9i is exclusively advised for people with CAD.[46] The 2020 Taiwan National Health Insurance regulation, 2018 AHA/ACC guidelines, and 2018 JAS recommend making ezetimibe necessary before adding PCSK9i, whereas the 2019 ESC/EAS guidelines and 2017 National Lipid Association advocate the addition of ezetimibe optional by clinical judgment.[46] Although most patients on PCSK9i achieve the anticipated lowering of 50–60% LDL-C levels from the baseline, there are sporadic reports of patients who have a lesser LDL-C-lowering response.[49]

Table 2: Summary of studies comparing rosuvastatin and atorvastatin

Author; Year	Study population; sample size	Drug	Endpoints	Follow-up	Result
MACE					
Rahhal *et al*.; 2022[35]	ACS; 1253	RSV20 or RSV40 versus ATV40 or ATV80	CVD-associated death, nonfatal ACS, and nonfatal stroke at 1 and 12 months	12 months	No significant difference at 1 and 12 months.
Schuetz *et al*.; 2012[36]		RSV20 versus ATV40 RSV40 versus ATV80	MACE (first occurrence of fatal or nonfatal MI, fatal or nonfatal stroke, or cardiovascular death)	5 years and 20 years	The incidence of MACE was lower in rosuvastatin 20 mg and 40 mg at 5 and 20 years.
hs-CRP					
Tran *et al*.; 2021[37]	ACS; 96	RSV20 versus ATV40	LDL-C and hs-CRP levels	4 days	No difference between the groups for LDL-C and hs-CRP.
Umrani *et al*.; 2020[38]	ACS; 128	RSV40 versus ATV20	hs-CRP and ESR	4 weeks	Rosuvastatin was superior.
Kumar *et al*.; 2019[39]	ACS; 207	RSV40 versus ATV20	hs-CRP and ESR	4 weeks	RSV was superior in reducing hs-CRP (51% versus 35%) and ESR levels (16% versus 14%).
Mostafa *et al*.; 2018[40]	ACS; 100	RSV40 versus ATV80	ESR, hs-CRP, and TLC after 4 weeks; lipid profile after 3 months	3 months	No significant difference for ESR, hs-CRP, or TLC. RSV was more potent for reducing LDL-C and increasing levels of liver enzymes, alanine, and aspartate aminotransferases.
Khurana *et al*.; 2015[41]	ACS; 100	RSV20 versus ATV40	CRP, lipid profiles, ESR	4 weeks	RSV was more effective in reducing CRP (44% versus 35%).
LDL-C					
Altunkeser *et al*.; 2019[42]	ACS; 106	RSV40 versus ATV80	LDL-C, oxidized-LDL, and triglyceride levels	4 weeks	No significant difference was observed.
Aydin *et al*.; 2015[43]	STEMI; 121	RSV20 versus ATV80	LDL-C, oxidized-LDL, hs-CRP, TNF-1 and 2, IL-6, HDL-C level	4 weeks	No significant difference for LDL-C, oxidized-LDL, hs-CRP, TNF-1 and 2, and IL-6. HDL-C increased with RSV20.
Pitt *et al*.; 2012 (LUNAR)[25]	ACS; 825	RSV20/RSV40 versus ATV80	LDL-C, HDL-C	6–12 weeks	RSV20≈ATV80; RSV40>ATV80 for LDL-C. HDL-C was significantly greater with RSV20/RSV40.
Clearfield *et al*.; 2006 (PULSAR)[31]	Hypercholesterolemia, CHD, atherosclerosis, or CHD risk; 996	RSV10 versus ATV20	LDL-C	6 weeks	RSV10 reduced LDL-C significantly more than ATV20.
Jones *et al*.; 2003 (STELLAR)[16]	Hypercholesterolemia; 2431	RSV10, RSV20, RSV40 versus ATV10, ATV20, ATV40, ATV80	LDL-C, HDL, triglycerides, TC	6 weeks	RSV was more efficient than ATV for non-HDL-C.
Apo-B/Apo-A1 ratio					
Lablanche *et al*.; 2010 (CENTAURUS)[27]	ACS; 753	RSV20 versus ATV80	Apo-B/Apo-A1 ratio	3 months	RSV20 was superior at 1 month, whereas no difference at 3 months.
NLR, PLR, and MHR					
Tuncez *et al*.; 2019[44]	STEMI and NSTEMI; 128	RSV40 versus ATV80	NLR, PLR, MHR	1 month	No significant differences between the groups for NLR, PLR, and MHR. Both the statins did not affect PLR.
Oxidative parameters					
Kilit *et al*.; 2017[45]	AMI; 55	RSV40 versus ATV80	Serum paraoxonase, serum arylesterase, TAS, and OSI	4 weeks	No significant difference in oxidative parameters. HDL-C was raised by RSV40 more than ATV80.

(Contd...)

Table 2: *(Continued)*

Author; Year	Study population; sample size	Drug	Endpoints	Follow-up	Result
Atheroma burden Nicholls *et al.*; 2011[26]	CAD; 1039	RSV40 versus ATV80	PAV, TAV	104 weeks	Both PAV and TAV decreased significantly higher with RSV40.

ACS: Acute coronary syndrome, AMI: Acute myocardial infarction, Apo-A1: Apolipoprotein-A1, Apo-B: Apolipoprotein-B, ATV: Atorvastatin, CAD: Coronary artery disease, CHD: Coronary heart disease, CVD: Cardiovascular disease, ESR: Erythrocyte sedimentation rate, HDL-C: High-density lipoprotein cholesterol, hs-CRP: High-sensitivity C-reactive protein, IL: Interleukin, LCBI: Lipid-core burden index, LDL-C: Low-density lipoprotein cholesterol, MACE: Major adverse cardiac events, MI: Myocardial infarction, MLR: Monocyte-to-high-density lipoprotein cholesterol ratio, NLR: Neutrophil-to-lymphocyte ratio, NSTEMI: Non–ST-segment elevation myocardial infarction, OSI: Oxidative stress index, PAV: Percent atheroma volume, PCI: Percutaneous coronary intervention, PLR: Platelet-to-lymphocyte ratio, RSV: Rosuvastatin, STEMI: ST-elevation myocardial infarction, TAV: Total atheroma volume, TAS: Total antioxidant status, TC: Total cholesterol, TLC: Total leukocyte count, TNF: Tumor necrosis factor

Table 3: Comparison of rosuvastatin and atorvastatin

Author; Year	Drug	LDL-C	HDL-C	CRP	ESR	Atheroma burden	Apo-B/Apo-A1 ratio	MACE	Others
Rahhal *et al.*; 2022[35]	RSV20 or RSV40 versus ATV40 or ATV80							X	
Tran *et al.*; 2021[37]	RSV20 versus ATV40	X		X					
Umrani *et al.*; 2020[38]	RSV40 versus ATV20			✔	✔				
Kumar *et al.*; 2019[40]	RSV40 versus ATV20			✔	✔				
Altunkeser *et al.*; 2019[42]	RSV40 versus ATV80	X (LDL-C, oxidized-LDL)							X (NLR, PLR, MHR)
Tuncez *et al.*; 2019[44]	RSV40 versus ATV80								X (NLR, PLR, MHR)
Mostafa *et al.*; 2018[40]	RSV40 versus ATV80	✔		X	X				X (TLC)
Kilit C *et al.*; 2017[45]	RSV40 versus ATV80		✔						X (Serum paraoxonase, serum arylesterase, TAS, and OSI)
Aydin *et al.*; 2015[43]	RSV10 or ATV80	X (LDL-C, oxidized-LDL)	✔	X					X (TNF-1 and TNF-2 and IL-6)
Khurana *et al.*; 2015[41]	RSV40 versus ATV80			✔					
Pitt *et al.*; 2012 (LUNAR)[25]	RSV20 or RSV40 versus ATV80	✔ (RSV40)	✔						
Schuetz *et al.*; 2012[36]	RSV20 versus ATV40 and RSV40 versus ATV80							✔	
Nicholls *et al.*; 2011[26]	RSV40 versus ATV80					✔ (PAV, TAV)			
Lablanche *et al.*; 2010 (CENTAURUS)[27]	RSV20 or RSV40 versus ATV80						✔ (at 1 month) X (at 3 months)		
Clearfield *et al.*; 2006 (PULSAR)[31]	RSV10 versus ATV20	✔							
Jones *et al.*; 2003 (STELLAR)[16]	RSV10, RSV20, RSV40, RSV80 versus ATV10, ATV20, ATV40, ATV80	✔							

Apo-A1: Apolipoprotein-A1, Apo-B: Apolipoprotein-B, ATV: Atorvastatin, hs-CRP: High-sensitivity C-reactive protein, ESR: Erythrocyte sedimentation rate, HDL-C: High-density lipoprotein cholesterol, IL: Interleukin, LDL-C: Low-density lipoprotein cholesterol, MACE: Major adverse cardiac events, MLR: Monocyte-to-high-density lipoprotein cholesterol ratio, NLR: Neutrophil-to-lymphocyte ratio, OSI: Oxidative stress index, PAV: Percent atheroma volume, PLR: Platelet-to-lymphocyte ratio, RSV: Rosuvastatin, TAV: Total atheroma volume, TAS: Total antioxidant status, TC: Total cholesterol, TLC: Total leukocyte count, TNF: Tumor necrosis factor

In addition to the controversy surrounding the use of PCSK9i in the literature, the availability of such novel therapy is an additional concern. The expense involved in PCSK9i therapy prevents its broad use; therefore, this therapy is usually restricted to patients with a substantial risk of ASCVD complications. Numerous studies conducted in Western countries on the economic evaluation of PCSK9i therapy have generally concluded that they are not economically viable at the current cost. Hence, appropriate and judicious use should be the guiding factor in the current scenario.[50]

GUIDELINE RECOMMENDATIONS

There are multiple guidelines for the management of dyslipidemia in the treatment of ACS. Most of these guidelines advocate intense lipid-reduction therapy for

Table 4: Clinical guidelines for the management of ACS

Guidelines	Threshold versus goals in ACS patients	Treatment strategy
ESC guidelines	• LDL goals in ACS patients are both a reduction of≥50% and<55 mg/dL. • LDL goal in recurrent ASCVD events within 2 years is<40 mg/dL.	• Healthy lifestyle. • High-intensity maximal statin. • If LDL-C≥55 mg/dL within 4–6 weeks, add ezetimibe. • If LDL-C≥55 mg/dL within 4–6 weeks, add PCSK9i. • If LDL-C≥40 mg/dL within 4–6 weeks and recurrent ASCVD event within 2 years, may add PCSK9i.

ACC: American college of cardiology, ACS: Acute coronary syndrome, AHA: American Heart Association, ASCVD: atherosclerotic cardiovascular disease, ESC: European Society of Cardiology, LDL-C: Low-density lipoprotein cholesterol, PCSK9i: Proprotein convertase subtilisin kexin 9 inhibitors

higher risk. However, the parameters for risk estimation vary among guidelines. Over the years, the ESC guidelines have developed very strict parameters and recommend the use of statin to achieve lipid-related goals. The AHA/ACC guidelines do not recommend combination treatments very frequently and do so only for individual cases.[51] All guidelines support the use of non-fasting lipid profiles for screening and propose LDL-C level as the gold standard for the assessment in the diagnosis and management of cases.[52] Table 4 presents a comparison of the American and European secondary preventive guidelines for ACS.[52]

ADVERSE EFFECTS OF ROSUVASTATIN

Rosuvastatin has a safety profile equivalent to other approved statins when administered in a range of 10–40 mg doses. Rosuvastatin is sharing the adverse effects of other statins and is dose dependent. Various side effects of statins include musculoskeletal complaints (myalgia, muscle stiffness, and weakness), elevated creatine kinase, myopathy, rhabdomyolysis, liver dysfunction (elevation of alanine transaminase and aspartate transaminase), renal insufficiency, gastrointestinal effects (diarrhea, constipation, nausea, abdominal pain, and dyspepsia), central nervous system effects (headache, dizziness, and paresthesias), interstitial lung disease, and cardiovascular conditions (myocardial infarction and death).[5,53,54] However, the risks of severe myopathy, rhabdomyolysis, and renal failure are lower for rosuvastatin than those of other statins.[53] On the contrary, the JUPITER study demonstrates that rosuvastatin is linked to a slight increase in the incidence of diabetes mellitus in elderly individuals with other comorbidities.[53,55]

CLINICAL TIPS

Statins are the preferred frontline drug of choice in decreasing lipid levels and preventing recurrent cardiac episodes. The "earlier the intervention, the greater the benefit" strategy can be applied when a patient first presents for evaluation for ACS.[56] As the superior efficacy of rosuvastatin in the management of ACS has been convincingly demonstrated, it can be preferred over other statins wherever indicated. Physicians should evaluate each patient's comorbidities, lipid profiles, and statin-related adverse effects to determine the optimal statin type and dose.[57,58]

A higher dose of rosuvastatin should be decided based on increasing cardiovascular risks, and the risk should be determined using evidence-based tools from standard guidelines. Patients should be well-informed and engaged in discussion before initiating statin therapy and lifestyle changes. In addition, patients should be routinely monitored for compliance with lifestyle changes and appropriate intensity of statin therapy. Combination therapy should be considered if a statin alone does not sufficiently lower cholesterol levels.[58]

CONCLUSION

Statins are the preferred agents for the effective management of dyslipidemia. In addition, the pleiotropic effects greatly promote the application of statins in treating ACS. This review paper demonstrates that rosuvastatin showed an improvement in lipid profile and inflammatory markers. Rosuvastatin appeared to be superior to atorvastatin in lowering LDL-C and Apo-B and increasing Apo-A1. Early initiation of high-intensity rosuvastatin is more beneficial in ACS as it not only promotes treatment adherence but also reduces the risk of new events. Non-statin treatments, such as ezetimibe and PCSK9i, are effective in lowering LDL-C along with statins. Although rosuvastatin is linked to various adverse effects, it is safe when used at appropriate doses and patients are monitored regularly. Collaborative decision-making should be used to commence statin treatment.

ACKNOWLEDGMENTS

The authors thank BioQuest Solutions for medical writing and editorial support for the manuscript, which is done in accordance with GPP 2022 guidelines.

AUTHORS' CONTRIBUTIONS

All named authors meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship for this article, take responsibility for the integrity of the work as a whole, and have given their approval for this version to be published.

REFERENCES

1. Sharma YP, Vemuri KS, Bootla D, Kanabar K, Pruthvi CR, Kaur N, *et al*. Epidemiological profile, management and outcomes of patients with acute coronary syndrome: Single centre experience from a tertiary care hospital in North India. Indian Heart J 2021;73:174-9.
2. Joshi P, Dahiya A, Thakur M, Sinha RP, Wardhan H. Clinical presentation, risk factors, and coronary angiographic profile of very young adults (≤30 years) presenting with first acute myocardial infarction at a tertiary care center in Rajasthan, India. Heart India 2022;10:21-5.
3. Shah CP, Shah BP, Dani SI, Channa BB, Lakshmanan SS, Krishnamani NC, *et al*. Efficacy and safety of the intensive dose of rosuvastatin 40mg/day in patients with acute coronary syndrome and at high risk of cardiovascular disease-ROSUVEES-2. Indian Heart J 2016;68:766-71.
4. Sacks FM. Do statins play a role in the early management of the acute coronary syndrome? Eur Heart J 2004;6:A32-6.
5. Cai T, Abel L, Langford O, Aronson JK, Stevens RJ, Lay-Flurrie S, *et al*. Associations between statins and adverse events in primary prevention of cardiovascular disease: Systematic review with pairwise, network, and dose-response meta-analyses. BMJ 2021;374:n1537.
6. Fujisue K, Tsujita K. Current status of lipid management in acute coronary syndrome. J Cardiol 2017;70:101-6.
7. Maji D, Shaikh S, Solanki D, Gaurav K. Safety of statins. Indian J Endocrinol Metab 2013;17:636-46.
8. Ostadal P. Statins as first-line therapy for acute coronary syndrome? Exp Clin Cardiol 2012;17:227-36.
9. Marcus ME, Manne-Goehler J, Theilmann M, Farzadfar F, Moghaddam SS, Keykhaei M, *et al*. Use of statins for the prevention of cardiovascular disease in 41 low-income and middle-income countries: A cross-sectional study of nationally representative, individual-level data. Lancet Glob Health 2022;10:e369-79.
10. Mehta A, Jain P, Patil R, Kant TS, Indurkar SA, Kota SK, *et al*. Real-world clinical experience of rosuvastatin as a lipid-lowering therapy for primary and secondary prevention of cardiovascular events (REAL ROSE). Cureus 2022;14:e31468.
11. Murphy C, Deplazes E, Cranfield CG, Garcia A. The role of structure and biophysical properties in the pleiotropic effects of statins. Int J Mol Sci 2020;21:8745.
12. Hua WJ, Hua WX, Fang HJ. The role of OATP1B1 and BCRP in pharmacokinetics and DDI of novel statins. Cardiovasc Ther 2012;30:e234-41.
13. Luvai A, Mbagaya W, Hall AS, Barth JH. Rosuvastatin: A review of the pharmacology and clinical effectiveness in cardiovascular disease. Clin Med Insights Cardiol 2012;6:17-33.
14. Adams SP, Tsang M, Wright JM. Lipid-lowering efficacy of atorvastatin. Cochrane Database Syst Rev 2015;2015:CD008226.
15. Zhang X, Xing L, Jia X, Pang X, Xiang Q, Zhao X, *et al*. Comparative lipid-lowering/increasing efficacy of 7 statins in patients with dyslipidemia, cardiovascular diseases, or diabetes mellitus: Systematic review and network meta-analyses of 50 randomized controlled trials. Cardiovasc Ther 2020;2020:3987065.
16. Jones PH, Davidson MH, Stein EA, Bays HE, McKenney JM, Miller E, *et al*. Comparison of the efficacy and safety of rosuvastatin versus atorvastatin, simvastatin, and pravastatin across doses (STELLAR* Trial). Am J Cardiol 2003;92:152-6.
17. Qian C, Wei B, Ding J, Wu H, Cai X, Li B, *et al*. Meta-analysis comparing the effects of rosuvastatin versus atorvastatin on regression of coronary atherosclerotic plaques. Am J Cardiol 2015;116:1521-6.
18. Kumar A, Shariff M, Doshi R. Impact of rosuvastatin versus atorvastatin on coronary atherosclerotic plaque volume-a systematic review and meta-analysis with trial sequential analysis of randomized control trials. Eur J Prev Cardiol 2020;27:2138-41.
19. Sposito AC, Chapman MJ. Statin therapy in acute coronary syndromes: Mechanistic insight into clinical benefit. Arterioscler Thromb Vasc Biol 2002;22:1524-34.
20. Ahmed KO, Ahmed AM, Wali MB, Ali AH, Azhari MM, Babiker A, *et al*. Optimal medical therapy for secondary prevention of acute coronary syndrome: A retrospective study from a tertiary hospital in Sudan. Ther Clin Risk Manag 2022;18:391-8.
21. Reiter-Brennan C, Osei AD, Uddin SM, Orimoloye OA, Obisesan OH, Mirbolouk M, *et al*. ACC/AHA lipid guidelines: Personalized care to prevent cardiovascular disease. Cleve Clin J Med 2020;87:231-9.
22. Luo R, Sun X, Shen F, Hong B, Wang Z. Effects of high-dose rosuvastatin on ventricular remodelling and cardiac function in ST-segment elevation myocardial infarction. Drug Des Devel Ther 2020;14:3891-8.
23. Pan Y, Tan Y, Li B, Li X. Efficacy of high-dose rosuvastatin preloading in patients undergoing percutaneous coronary intervention: A meta-analysis of fourteen randomized controlled trials. Lipids Health Dis 2015;14:97.
24. Kini AS, Baber U, Kovacic JC, Limaye A, Ali ZA, Sweeny J, *et al*. Changes in plaque lipid content after short-term intensive versus standard statin therapy: The YELLOW trial (reduction in yellow plaque by aggressive lipid-lowering therapy). J Am Coll Cardiol 2013;62:21-9.
25. Pitt B, Loscalzo J, Monyak J, Miller E, Raichlen J. Comparison of lipid-modifying efficacy of rosuvastatin versus atorvastatin in patients with acute coronary syndrome (from the LUNAR study). Am J Cardiol 2012;109:1239-46.
26. Nicholls SJ, Ballantyne CM, Barter PJ, Chapman MJ, Erbel RM, Libby P, *et al*. Effect of two intensive statin regimens on progression of coronary disease. N Engl J Med 2011;365:2078-87.
27. Lablanche JM, Leone A, Merkely B, Morais J, Alonso J, Santini M, *et al*. Comparison of the efficacy of rosuvastatin versus atorvastatin in reducing apolipoprotein B/apolipoprotein A-1 ratio in patients with acute coronary syndrome: Results of the CENTAURUS study. Arch Cardiovasc Dis 2010;103:160-9.
28. Chhatriwalla AK, Nicholls SJ, Nissen SE. The ASTEROID trial: Coronary plaque regression with high-dose statin therapy. Future Cardiol 2006;2:651-4.
29. Underhill HR, Yuan C, Zhao XQ, Kraiss LW, Parker DL, Saam T, *et al*. Effect of rosuvastatin therapy on carotid plaque morphology and composition in moderately hypercholesterolemic patients: A high-resolution magnetic resonance imaging trial. Am Heart J 2008;155:584.e1-8.
30. Hall AS, Jackson BM, Farrin AJ, Efthymiou M, Barth JH, Copeland J, *et al*. A randomized, controlled trial of simvastatin versus rosuvastatin in patients with acute myocardial infarction: The secondary prevention of acute coronary events--reduction of cholesterol to key European targets trial. Eur J Cardiovasc Prev Rehabil 2009;16:712-21.
31. Clearfield MB, Amerena J, Bassand JP, García HR, Miller SS, Sosef FF, *et al*. Comparison of the efficacy and safety of rosuvastatin 10 mg and atorvastatin 20 mg in high-risk patients with hypercholesterolemia--prospective study to evaluate the use of low doses of the statins atorvastatin and rosuvastatin (PULSAR). Trials 2006;7:35.
32. Takayama T, Hiro T, Yamagishi M, Daida H, Hirayama A, Saito S, *et al*. Effect of rosuvastatin on coronary atheroma in stable coronary artery disease: Multicenter coronary atherosclerosis study measuring effects of rosuvastatin using intravascular ultrasound in Japanese subjects (COSMOS). Circ J 2009;73:2110-7.
33. Karlson BW, Palmer MK, Nicholls SJ, Lundman P, Barter PJ. Doses of rosuvastatin, atorvastatin and simvastatin that induce equal reductions in LDL-C and non-HDL-C: Results from the VOYAGER meta-analysis. Eur J Prev Cardiol 2016;23:744-7.
34. Zhang L, Zhang S, Yu Y, Jiang H, Ge J. Efficacy and safety of rosuvastatin vs. Atorvastatin in lowering LDL cholesterol: A meta-analysis of trials with East Asian populations. Herz 2020;45:594-602.
35. Rahhal A, Khir F, Orabi B, Chbib S, Al-Khalaila O, Abdelghani MS, *et al*. A comparative study of high-intensity rosuvastatin versus atorvastatin therapy post-acute coronary syndrome using real-world data. Curr Probl Cardiol 2022;47:100956.
36. Schuetz CA, van Herick A, Alperin P, Peskin B, Hsia J, Gandhi S.

Comparing the effectiveness of rosuvastatin and atorvastatin in preventing cardiovascular outcomes: Estimates using the Archimedes model. J Med Econ 2012;15:1118-29.
37. Tran AV, Nguyen TT, Tran LN, Nguyen PM, Nguyen T. Efficacy of rosuvastatin and atorvastatin in Vietnamese patients with acute coronary syndrome: A randomized trial. Pharm Sci Asia 2021;48:413-9.
38. Umrani S, Jamshed W, Rizwan A. Comparison of atorvastatin and rosuvastatin in reduction of inflammatory markers in acute coronary syndrome. Cureus 2020;12:e11760.
39. Kumar B, Shah MA, Kumar R, Kumar J, Memon A. Comparison of atorvastatin and rosuvastatin in reduction of inflammatory biomarkers in patients with acute coronary syndrome. Cureus 2019;11:e4898.
40. Mostafa SA, Elrabat K, Mahrous M, Kamal M. Short term comparison between safety and efficacy of rosuvastatin 40 mg and atorvastatin 80 mg in patients with acute coronary syndrome. Ration Pharmacother Cardiol 2018;14:636-45.
41. Khurana S, Gupta S, Bhalla H, Bhalla H, Nandwani S, Gupta V. Comparison of anti-inflammatory effect of atorvastatin with rosuvastatin in patients of acute coronary syndrome. J Pharmacol Pharmacother 2015;6:130-5.
42. Altunkeser BB, Tuncez A, Ozturk B, Tezcan H, Ates MS, Yilmaz C, *et al*. Comparative effects of high-dose atorvastatin versus rosuvastatin on lipid parameters, oxidized low-density lipoprotein, and proprotein convertase subtilisin kexin 9 in acute coronary syndrome. Coron Artery Dis 2019;30:285-90.
43. Aydin MU, Aygul N, Altunkeser BB, Unlu A, Taner A. Comparative effects of high-dose atorvastatin versus moderate-dose rosuvastatin on lipid parameters, oxidized-LDL and inflammatory markers in ST elevation myocardial infarction. Atherosclerosis 2015;239:439-43.
44. Tunçez A, Altunkeser BB, Öztürk B, Ateş MS, Tezcan H, Aydoğan C, *et al*. Comparative effects of atorvastatin 80 mg and rosuvastatin 40 mg on the levels of serum endocan, chemerin, and galectin-3 in patients with acute myocardial infarction. Anatol J Cardiol 2019;22:240-9.
45. Kilit C, Koçak FE, Kilit TP. Comparison of the effects of high-dose atorvastatin and high-dose rosuvastatin on oxidative stress in patients with acute myocardial infarction: A pilot study. Turk Kardiyol Dern Ars 2017;45:235-43.
46. Lin JL, Huang PH, Yeh HI, Li YH. Appropriate use of proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors for atherosclerotic cardiovascular disease: Comparison of recommendations from different guidelines or consensus around the world. Acta Cardiol Sin 2020;36:403-8.
47. Cho KH, Hong YJ. Proprotein convertase subtilisin/kexin Type 9 inhibition in cardiovascular disease: Current status and future perspectives. Korean J Intern Med 2020;35:1045-58.
48. Singh C, Valero DJ, Nisar J, Ramirez JI, Kothari KK, Isola S, *et al*. Statins versus proprotein convertase subtilisin/kexin Type 9 inhibitors-are we doing better? A systematic review on treatment disparity. Cureus 2020;12:e10965.
49. Iannuzzo G, Gentile M, Bresciani A, Mallardo V, Di Lorenzo A, Merone P, *et al*. Inhibitors of protein convertase subtilisin/kexin 9 (PCSK9) and acute coronary syndrome (ACS): The state-of-the-art. J Clin Med 2021;10:1510.
50. Iyengar SS, Bansal M, Sawhney J, Wander G, Narasingan SN, Chandra KS, *et al*. Appropriate use of PCSK9 inhibitors in India. J Assoc Physicians India 2019;67:74-85.
51. Aygun S, Tokgozoglu L. Comparison of current international guidelines for the management of dyslipidemia. J Clin Med 2022;11:7249.
52. Gencer B, Giugliano RP. Management of LDL-cholesterol after an acute coronary syndrome: Key comparisons of the American and European clinical guidelines to the attention of the healthcare providers. Clin Cardiol 2020;43:684-90.
53. Kostapanos MS, Milionis HJ, Elisaf MS. Rosuvastatin-associated adverse effects and drug-drug interactions in the clinical setting of dyslipidemia. Am J Cardiovasc Drugs 2010;10:11-28.
54. Ramkumar S, Raghunath A, Raghunath S. Statin therapy: Review of safety and potential side effects. Acta Cardiol Sin 2016;32:631-9.
55. de Pádua Borges R, Degobi NA, Bertoluci MC. Choosing statins: A review to guide clinical practice. Arch Endocrinol Metab 2021;64:639-53.
56. Gov-Ari H, Stevermer JJ. PURLs: Prescribing statins for patients with ACS? No need to wait. J Fam Pract 2014;63:735-8.
57. Rossini E, Biscetti F, Rando MM, Nardella E, Cecchini AL, Nicolazzi MA, *et al*. Statins in high cardiovascular risk patients: Do comorbidities and characteristics matter? Int J Mol Sci 2022;23:9326.
58. American Heart Association. Cholesterol Management Guide for Health Care Practitioners. Available from: https://professional.heart.org/-/media/files/health-topics/cholesterol/cholesterol-guide-for-HC-practitioners-english.pdf [Last accessed on 2022 Dec 21].

How to cite this article: Sharma R, Basia D, Singh H, Bharath HS, Sarda S. Is Early Management of Acute Coronary Syndrome with Rosuvastatin Important? Int J Sci Stud 2023;11(3):8-17.

Source of Support: AstraZeneca Pharma India Ltd., **Conflicts of Interest:** Bharath HS, Dr Shital were employees of AstraZeneca Pharma India Ltd.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Comparison of the Efficacy of Infraclavicular Block: Land Mark Technique versus Nerve Stimulator versus Ultrasound Technique through Coracoid Approach for Upper-Limb Surgeries

Joginder Pal Attri[1], Ranjana Khetarpal[1], Harjot Singh[2], Aditi Samparna[3]

[1]Professor, Department of Anaesthesiology and Critical Care, Government Medical College, Amritsar, Punjab, India, [2]3rd Year Post Graduate Student, Department of Anaesthesiology and Critical Care, Government Medical College, Amritsar, Punjab, India, [3]Intern, Department of Surgery, D.Y. Patil Medical College, Pune, Maharashtra, India

Abstract

Introduction: Regional anesthesia for upper-limb surgeries has minimal side effects and complications and is cost effective. In upper-limb surgeries, infraclavicular block (ICB) is a good alternative to axillary and supraclavicular block as it prevents the side effects and complications such as vessel puncture and pneumothorax because of consistent bony landmarks.

Purpose: The present study aims to compare the efficacy of ICB using ultrasound, nerve stimulator, and landmark techniques through coracoid approach in patients undergoing upper-limb surgeries.

Materials and Methods: In a prospective, randomized study, 90 patients of either sex belonging to ASA Grades I and II, 20–60-year old undergoing forearm, elbow, wrist, and hand surgeries under ICB were randomly divided into three groups using computer-generated software in ultrasound-guided Group U, nerve stimulator guided Group N, and landmark technique Group L. 30 patients in each group were selected randomly.

Aims: Procedural time, Onset and time for peak effect of sensory and motor block, VAS Score, Number of doses of rescue analgesia.

Results: Compared with the landmark and nerve stimulator-guided block, the ultrasound-guided ICB had lesser procedural time (3.35 ± 1.05 min), early onset of sensory and motor block (6.02 ± 2.47 min, 7.93 ± 3.73 min, respectively), less time to achieve peak sensory and motor effect (14.66 ± 2.47 min, 19.62 ± 3.43 min, respectively), and more rate of a successful blockade (96.67%).

Conclusion: The use of ultrasound guidance for ICB decreases the procedural time, time for onset of sensory, motor block as well as time for peak effect of sensory, motor block and has better success rates.

Key words: Infraclavicular brachial plexus block, Nerve stimulator guidance, Onset of sensory and motor block, Procedural time, Success rate, Ultrasound guidance

INTRODUCTION

Brachial plexus block is a well-accepted technique for anesthesia and post-operative analgesia for upper-limb orthopedic surgeries. Surgeries of hand and forearm can be taken up under infraclavicular brachial plexus block (ICBPB). ICBPB is gaining support because of its consistent bony landmarks, lower probability of Vessel puncture, intense block and lesser incidence of pneumothorx.[1] ICBPB reduces tourniquet pain, prevents the side effects of general anesthesia, and requires shorter duration of hospital stay.[2-4] Among various approaches of ICBPB, the coracoid approach is the most popular[5] because of the presence of a consistent bony landmark, lesser chances of vascular puncture, and adequate neural blockage.[6] Historically, ICBPB was performed through

Access this article online

www.ijss-sn.com

Month of Submission : 04-2023
Month of Peer Review : 05-2023
Month of Acceptance : 06-2023
Month of Publishing : 06-2023

Corresponding Author: Dr. Ranjana Khetarpal, Department of Anaesthesiology and Critical Care, Government Medical College, Amritsar, Punjab, India.

blind technique using anatomical landmarks, Later on, nerve stimulator was used which ensures somewhat better blockade but both of these can cause neurovascular and pleural injuries, leading to permanent nerve damage and pneumothorax, respectively.[7-9] In recent years, with the ultrasound guidance (USG), we can know the exact location of nerves plexus and vessels. With USG, complete blocks have been demonstrated with a prolonged analgesic effect even exceeding the sensory block,[10] with higher success rates and fewer complications, lesser time to perform the block, and volume of the local anesthetic drugs.[11] Ultrasound guidance is the gold standard for peripheral regional anesthesia.[12-14]

Therefore, the present study is designed to compare the efficacy of ICBPB: Landmark technique versus nerve stimulator versus ultrasound technique through coracoid approach for upper-limb surgeries. Such a study had never been conducted in our institute with a very few studies done in the past comparing these.

MATERIALS AND METHODS

After obtaining the approval from Institutional Ethics and Thesis Committee along with the written and informed consent, this prospective, observational clinical study was conducted on 90 patients of either sex belonging to ASA Grade I and II, 18–60 years of age, admitted in tertiary hospital undergoing forearm, elbow, wrist, and hand surgeries under ICBPB. The ICBPB was attained with the injection ropivacaine 0.5% + injection butorphanol 1 mg using landmark, nerve stimulator, and ultrasound-guided techniques. Patients were randomly divided using computer-generated software into three groups of 30 each as Group L: Landmark technique, Group N: Nerve stimulator, and Group U: USG. A detailed pre-anesthetic check-up of the patients was carried out a day before surgery. General physical examination and systemic examination were done. Routine investigations were reviewed. The procedure to be performed was explained in detail; written informed written consent was obtained from each patient before the procedure. All patients were reassessed in the pre-operative room and vitals were noted. Then, the patients were shifted to the operation theater. An IV line using 18/20G IV line was secured. An infusion of ringer lactate solution was started. Patients' monitoring was started using the multipara monitors (NIBP, ECG, and SpO_2) which were attached and baseline readings were recorded. All patients were given tablet alprazolam 0.25 mg orally night before surgery and in morning with a sip of water, injection midazolam 0.04 mg/kg, injection butorphanol 1 mg, and injection ondansetron 0.1 mg/kg before the start of the surgery. Patients were made to lie in the supine position with arms by side and the head is turned away from the side to be blocked. The area was cleaned with povidone iodine solution and draped properly.

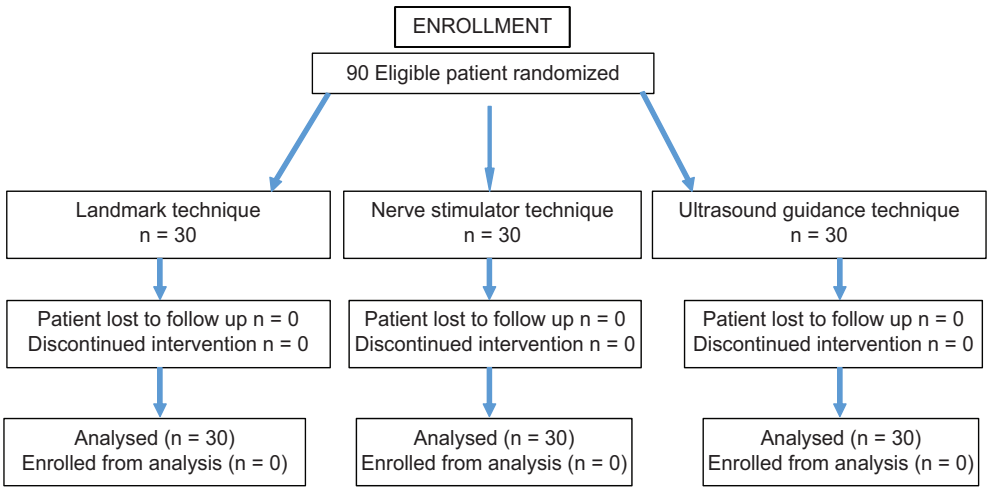
Group L: Received 30 mL of 0.5% ropivacaine + injection butorphanol 1 mg by ICBPB using landmark technique.

Group N: Received 30 mL of 0.5% ropivacaine + injection butorphanol 1 mg by ICBPB using nerve stimulator.

Group U: Received 30 mL of 0.5% ropivacaine + injection butorphanol 1 mg by ICBPB using USG.

Exclusion criteria patients who refused to take part in the procedure or to enlist in study, ASA Grade III and IV, clinically significant pulmonary pathology, coagulation disorders, anticoagulation therapy, having history of allergy to local anesthetic and known neuropathies involving forearm and hand, uncooperative patients, and pregnant patients were excluded from the study.

Study Design



Analysis: Required sample size calculated	
Input	Effect size f=0.34
	α err prob=0.41
	Power (1-β err prob) = 0.95
	Numerator df=10
	Number of groups=3
	Number of covariates=1
Output	Noncentrality parameter λ = 9.9416000
	Critical F=1.0502587
	Total sample size=84
	Actual power=0.95006

Thus, sample size taken for the ease of distribution into three groups was 90.

Block Assessment

The attainment of a successful block was determined by the following methods –

1. Procedural time taken to complete the block in each technique was noted. It was defined as the time after cleaning and draping of site, till the injection of local anesthetic drug
2. Sensory block was assessed by Hollmen scale

Onset of sensory block was defined when the patient achieved a score of Grade II (pin prick felt as a sharp pointed but weaker compared with the same area in other limbs).

Time taken to achieve peak sensory block was defined when the patient achieved score of Grade IV (no perception of pin prick).

3. Motor block was assessed by modified Bromage scale

Onset of motor block was defined when the patient achieved a score of Grade II (decreased motor strength with ability to move fingers only).

Time taken to achieve peak motor block was defined when the patient achieved a score of Grade III (complete motor block with inability to move fingers).

4. Post-operative pain was assessed using VAS Score.

VAS was assessed post-operatively at every 1 h interval for the first 4 h and then 2 h for the next 8 h and then every 4 h till 24 h. Rescue analgesia was given if VAS was more than 3 in the form of i/v paracetamol infusion. If pain is not relieved by paracetamol, injection tramadol 100 mg i/v was given.

5. Success rate of each technique was noted.

A successful block was defined if surgery was done without patient discomfort or without the need for supplementation or sensory blockade of Grade IV and motor blockade of Grade III.

A failed block was defined if a sensory region involved in the surgery was not completely anesthetized and the block needed supplementation by injection propofol or any other drug or sensory and motor blockade was less than Grades IV and III, respectively.

6. Number of inadvertent vessel punctures were noted in each block
7. Number of pricks taken in each block were noted in each block
8. Hemodynamic changes, side effect, and complication were also noted in each block.

RESULTS

In the present study, we included 90 patients into the study $n = 30$ each. Patient's demographics were comparable ($P > 0.05$) in all the three groups. The duration of surgery was also comparable between the groups as shown in Table 1.

Procedure time (time after cleaning and draping of site, till the injection of local anesthetic drug) of Group L was 9.59 ± 4.63 min, Group N was 6.62 ± 2.49 min, and of Group U was 3.35 ± 1.05 min ($P < 0.01$) as shown in Table 2.

The mean onset of sensory block in Group L was 9.01 ± 4.13 min, Group N was 7.99 ± 3.69 min, and Group U was 6.02 ± 2.47 min. Onset of sensory block was nonsignificant between Group L/N ($P = 0.313$ NS) but was significant between Group N/U ($P = 0.023$ S) and was highly significant between Group L/U ($P = 0.001$ HS). Mean time for peak effect of sensory block of Group L was 19.61 ± 5.13 min, Group N was 17.58 ± 3.69 min, and Group U was 14.66 ± 2.47 min. Time for peak sensory block was nonsignificant between Group L/N ($P = 0.117$ NS), significantly between Group N/U ($P = 0.014$ S), and highly significant between Group L/U ($P = 0.001$ HS) as shown in Table 2.

The mean onset of motor block in Group L was 12.28 ± 6.02 min, Group N was 10.35 ± 5.27 min, and Group U was 7.93 ± 3.73 min. Onset of motor block was nonsignificant between Group L/N ($P = 0.191$ NS) but was significant between Group N/U ($P = 0.040$ S) and was highly significant between Group L/U ($P = 0.001$ HS). Mean time for peak effect of motor block of Group L was 23.28 ± 5.16 min, Group N was 22.35 ± 4.27 min, and Group U was 19.62 ± 3.43 min. Time for peak motor block was nonsignificant between Group L/N ($P = 0.450$ NS), significantly between Group N/U ($P = 0.008$ S), and Group L/U ($P = 0.004$ S) as shown in Table 2.

Success rate of Group L was 80%, Group N was 90%, and Group U was 96.67%. Success rate was non-significant between Group L/N and N/U ($P > 0.05$ NS) but was significant between Group L/U with $P = 0.044$(S).

Table 1: Demographic characteristic of patients in Groups L, N, and U

Demographics	Group L	Group N	Group U	*P*-value		
				L/N	N/U	L/U
Mean age	39.60±13.14	37.06±15.53	36.53±14.33	0.847 (NS)	0.988 (NS)	0.767 (NS)
Gender						
Male	20 (66)	23 (76)	21 (70)	0.389 (NS)	0.559 (NS)	0.781 (NS)
Female	10 (33)	7 (23)	9 (30)			
ASA Grade						
I	21 (70)	21 (70)	24 (80)	1.00 (NS)	0.371 (NS)	0.371 (NS)
II	9 (30)	9 (30)	6 (20)			
Mean duration of surgery (in hours)	1.65±0.64	1.58±0.59	1.61±0.74	0.661 (NS)	0.862 (NS)	0.823 (NS)

Table 2: Procedure time, sensory and motor block characteristics, and success rate among Groups L, N, and U

Parameters	Group L	Group N	Group U	*P*-value		
				L/N	N/U	L/U
Procedure time (minutes)	9.59±4.63	6.62±2.49	3.35±1.05	0.001 (HS)	0.001 (HS)	0.001 (HS)
Mean onset of sensory block (minutes)	9.01±4.13	7.99±3.69	6.02±2.47	0.313 (NS)	0.023 (S)	0.001 (HS)
Mean time to peak sensory block (minutes)	19.61±5.13	17.58±3.69	14.66±2.47	0.117 (NS)	0.014 (S)	0.001 (HS)
Mean onset of motor block (minutes)	12.28±6.02	10.35±5.27	7.93±3.73	0.191 (NS)	0.040 (S)	0.001 (HS)
Mean time to peak motor block (minutes)	23.28±5.16	22.35±4.27	19.62±3.43	0.450 (NS)	0.008 (S)	0.004 (S)
Success rate	24 (80)	27 (90)	29 (96.67)	0.687 (NS)	0.300 (NS)	0.044 (S)
Number of inadvertent vessel puncture	2 (6.6)	1 (3.3)	0	0.553 (NS)	0.523 (NS)	0.150 (NS)
Number of patients requiring multiple pricks	7 (23.3)	5 (16.6)	1 (3.3)	0.518 (NS)	0.085 (NS)	0.020 (S)

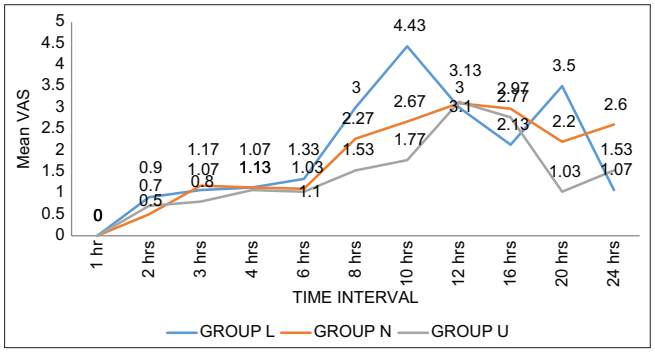
NS: Non significant (*P*>0.05); S: Significant (*P*<0.05); HS: Highly significant (*P*<0.001)

There were 6.67% vessel punctures in Group L, 3.3% vessel puncture in Group N, and no vessel puncture seen in Group U. However, no significant difference was seen among the 3 groups ($P > 0.05$). In these cases, the needle was withdrawn and redirected. The drug was then injected after negative aspiration. Thus, sign and symptoms associated with intravascular injection were not encountered in any of these patients as shown in Table 2.

Needle pricks were repeated twice in 7 patients in Group L, 5 patients in Group N, and 1 patient in Group U. However, the difference between the three groups was non-significant ($P > 0.05$) as shown in Table 2.

During post-operative period, patients were monitored for pain using VAS score at every 1 h interval for the first 4 h and then 2 h for the next 8 h and then every 4 h till 24 h. VAS scores were comparable among three groups for the first 8 h of the study. At 12th h, VAS was comparable between the three groups. At 16 h, VAS was significant between Group L/N ($P = 0.04$) and non-significant between Group N/U and L/U ($P > 0.05$). Latter on, VAS was comparable and statistically non-significant ($P > 0.05$) among all the groups till 24 h as shown in Graph 1. Rescue analgesia was given when VAS was more than three and total number of rescue analgesia given was maximum in Group L and minimum in Group U.

Baseline hemodynamic parameters were comparable in all the three groups at all measured intervals and remained stable. None of the patient developed pneumothorax, Horner's syndrome, hoarseness, arrhythmias, respiratory depression, and neuropathy in the post-operative period.



Graph 1: VAS score

DISCUSSION

Coracoid approach is better because of easy identification of coracoid process and there is no need for limb movement. ICBPB provides certain advantages over interscalene, supraclavicular, and axillary approaches, as the complications such as pneumothorax and vessel puncture are less, and the block is more consistent.[14] Using USG to identify nerves, further improves the success rate of block as the drug is deposited close to the nerve sheath, and chances of vascular and neurological injuries are less. In the present study, we compared landmark versus nerve stimulator versus ultrasound technique using coracoid

approach for ICBPB. Only two patients in Group L and one patient in Group N had vascular puncture while performing the block. None of the patients developed pneumothorax, Horner's syndrome, hoarseness, and neuropathy in the post-operative period. In the present study, the primary outcome was shorter procedure time, faster onset of the sensory and motor block, time to achieve peak sensory and motor effect was less, and the success rate achieved was more with the use of USG for the block.

Procedural time was shorter in USG (3.35 ± 1.05 min) in our study. This fact is supported by studies done by Taboada[15] *et al*. where they observed that time to perform the ICBPB was shorter using USG (3 ± 1 min) vs. 6 ± 2 min with nerve stimulator and Trabelsi[16] *et al*. who found the procedural time for ICBPB was 3.6 min ± 2.1 with ultrasound versus 4.6 ± 2.2 min with nerve stimulator.

The mean onset of sensory and motor block was significantly less in Group U (6.02 ± 2.47 and 7.93 ± 3.73 min) which was almost comparable with a study done by Dakshinamurthy[17] with USG supraclavicular BPB in where they found that the time for onset of sensory block with ropivacaine was 5.22 ± 1.28 min and motor block was 7.90 ± 1.68 min. Time for peak sensory onset with ropivacaine was in 14.93 ± 2.14 min and the peak motor onset was in 18.82 ± 3.01 min. Time to achieve peak sensory and motor effect were also significantly less in Group U (14.66 ± 2.47 and 19.62 ± 3.43 min, respectively) which is also comparable to above study. Similarly, Kyizom *et al*.[18] did a study with 30 mL of 0.5% ropivacaine for USG brachial plexus block and found the mean time to achieve peak sensory and motor effects of 14.37 ± 3.7 min and 19.63 ± 3.96 min, respectively.

In the present study, the success rate was significantly higher with Group U (96.67%) which was comparable with a study done by Desroches[19] in which they observed the success rate of 91% for ICBPB by coracoid approach using nerve stimulator and with a study done by Ootaki *et al*.[20] in which they found the success rate of 95% in ultrasound-guided ICBPB and they concluded that ICBPB using USG produced more accurate block with lesser discomfort of the patient when compared with landmark technique. Likewise, Taboada *et al*.[15] did a comparative study between ultrasound and nerve stimulator-guided ICBPB using coracoid approach and found 89% success with ultrasound versus 91% with nerve stimulator. However, the difference was statistically nonsignificant ($P = 0.881$).

Limitations

The anesthesiologist performing the block was also monitoring the block parameters. Hence, double blinding is not possible. As the sample size was small, the study had significantly important results, so future studies should be undertaken with a large population size. We used VAS score as a pain measurement method which is not an objective method and could have some variability in patient's ability to use that scale. To perform the USG-guided block techniques, trained and registered anesthesiologist is needed which may me not available in all the other centers.

CONCLUSION

Finally, it can be concluded that ultrasound-guided ICBPB is a better choice as compared to peripheral nerve stimulator-guided or landmark-guided technique as it provides better placement of drugs near the nerve plexus producing better results. It was observed that with the use of USG for ICBPB, the procedural time is shortened, time for onset of sensory, motor block as well as time for peak effect of sensory, motor block is reduced, better success rates are achieved, and number of inadvertent vessel punctures and number of pricks taken are also reduced.

ACKNOWLEDGMENT

I bow with reverence, all humility and gratitude to thank the Almighty for giving me the opportunity and strength to undertake this work and the ability to successfully complete it.

Mere words are insufficient to express adequately my profound indebtedness and deep gratitude to my most revered teacher, encouraging mentor Dr. Joginder Pal **Attr**i, MD, Professor, Department of Anaesthesia and Intensive Care Unit, Govt. Medical College, Amritsar. His unconditional help, affectionate guidance from the very inception of the study has contributed more to the accomplishment of my task than my over diligence and devotion. It has been a matter of great pride and privilege for me to have worked under the able guidance of teacher of such a great caliber. I owe him, a lifelong gratitude. I would like to express my gratitude towards Dr. Ranjana Khetarpal, MD, Professor, Department of Anaesthesia and Intensive Care Unit, Govt. Medical College, Amritsar, for her meticulous advice, sustained encouragement, generous help, and invaluable guidance throughout the course of the study. I wish to express my sincere appreciation to Dr. Aditi Samparna, Intern, D.Y. Patil Medical College, Pune, for her invaluable contribution in the study.

REFERENCES

1. Heid FM, Jage J, Guth M, Bauwe N, Brambrink AM. Efficacy of vertical infraclavicular plexus block vs. Modified axillary plexus block: A prospective, randomized, observer-blinded study. Acta Anaesthesiol Scand 2005;49:677-82.
2. Schoenmakers KP, Wegener JT, Stienstra R. Effect of local anesthetic

volume (15 vs 40 mL) on the duration of ultrasound-guided single shot axillary brachial plexus block: A prospective randomized, observer-blinded trial. Reg Anesth Pain Med 2012;37:242-7.
3. Casati A, Baciarello M, Di Cianni S, Danelli G, De Marco G, Leone S, *et al*. Effects of ultrasound guidance on the minimum effective anaesthetic volume required to block the femoral nerve. Br J Anaesth 2007;98:823-7.
4. Koscielniak-Nielsen ZJ, Rasmussen H, Hesselbjerg L, Nielsen TP, Gürkan Y. Infraclavicular block causes less discomfort than axillary block in ambulatory patients. Acta Anaesthesiol Scand 2005;49:1030-4.
5. Neal JM, Gerancher JC, Hebl JR, Ilfeld BM, McCartney CJ, Franco CD, *et al*. Upper extremity regional anesthesia: Essentials of our current understanding, 2008. Reg Anesth Pain Med 2009;34:134-70.
6. Wilson JL, Brown DL, Wong GY, Ehman RL, Cahill DR. Infraclavicular brachial plexus block: Parasagittal anatomy important to the coracoid technique. Anesth Analg 1998;87:870-3.
7. Brown DL, Cahill DR, Bridenbaugh LD. Supraclavicular nerve block: Anatomic analysis of a method to prevent pneumothorax. Anesth Analg 1993;76:530-4.
8. Kulenkampff D. Brachial plexus anaesthesia: Its indications, technique, and dangers. Ann Surg 1928;87:883-91.
9. Winnie AP, Collins VJ. The subclavian perivascular technique of brachial plexus anesthesia. Anesthesiology 1964;25:353-63.
10. Katz J, Clarke H, Seltzer Z. Review article: Preventive analgesia: Quo vadimus? Anesth Analg 2011;113:1242-53.
11. Gautier P, Vandepitte C, Ramquet C, DeCoopman M, Xu D, Hadzic A. The minimum effective anesthetic volume of 0.75% ropivacaine in ultrasound-guided interscalene brachial plexus block. Anesth Analg 2011;113:951-5.
12. Pappin D, Christie I. The Jedi Grip: A novel technique for administering local anaesthetic in ultrasound-guided regional anaesthesia. Anaesthesia 2011;66:845.
13. Griffin J, Nicholls B. Ultrasound in regional anaesthesia. Anaesthesia 2010;65 Suppl 1:1-12.
14. Raj PP, Montgomery SJ, Nettles D, Jenkins MT. Infraclavicular brachial plexus block-a new approach. Anesth Analg 1973;52:897-904.
15. Taboada M, Rodríguez J, Amor M, Sabaté S, Alvarez J, Cortés J, *et al*. Is ultrasound guidance superior to conventional nerve stimulation for coracoid infraclavicular brachial plexus block? Reg Anesth Pain Med 2009;34:357-60.
16. Trabelsi W, Amor MB, Lebbi MA, Romdhani C, Dhahri S, Ferjani M. Ultrasound does not shorten the duration of procedure but provides a faster sensory and motor block onset in comparison to nerve stimulator in infraclavicular brachial plexus block. Kor J Anesthesiol 2013;64:327-33.
17. Dakshinamurthy G. Original research comparison of efficacy of 0.5% levobupivacaine and 0.5% ropivacaine in ultrasound guided brachial plexus block by supraclavicular approach in upperlimb elective procedures. Eur J Molecul Clin Med 2022;9:10319-28.
18. Kyizom T, Parag K, Negi AS, Khandelwal H, Govil N. Ultrasonography guided supraclavicular brachial plexus block: Comparison of sensori-motor blockade and duration of postoperative analgesia between ropivacaine and levo-bupivaine: A prospectivetriple blind randomized control study. Int J Health Sci 2022;6:4157-68.
19. Desroches J. The infraclavicular brachial plexus block by the coracoid approach is clinically effective: An observational study of 150 patients. Can J Anaesth 2003;50:253-7.
20. Ootaki C, Hayashi H, Amano M. Ultrasound-guided infraclavicular brachial plexus block: An alternative technique to anatomical landmark-guided approaches. Reg Anesth Pain Med 2000;25:600-4.

How to cite this article: Attri JP, Khetarpal R, Singh H, Samparna A. Comparison of the Efficacy of Infraclavicular Block: Land Mark Technique Versus Nerve Stimulator Versus Ultrasound Technique through Coracoid Approach for Upper-Limb Surgeries. Int J Sci Stud 2023;11(3):18-23.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Comparative Study on the Incidence of Port-site Infection, With and Without Local Infiltration of Antibiotics to the Port Site after the Removal of Ports in Laparoscopic Surgeries

L Madhu Shankar[1], U Chinmaye Melur[2]

[1]Professor, Department of General Surgery, KIMS, Bengaluru, Karnataka, India, [2]Postgraduate Student, Department of General Surgery, KIMS, Bengaluru, Karnataka, India

Abstract

One of the most popular surgeries performed during laparoscopic surgery is a laparoscopic cholecystectomy (LC). The aim of the study was to examine the prevalence of port-site infections (PSI) in patients having LC, either with or without local antibiotic infiltration at the port site. An 18-month period witnessed the use of systematic random sampling at Bengaluru's Kempe Gowda Institute of Medical Science. LC participants who met the criteria for inclusion were divided into two groups at random (n = 50 in each group). Antibiotics were not locally injected into one group at the port site, while they were locally injected into the other group (amikacin). Patients were observed for symptoms of inflammation, purulent leaking from the port site, and dehiscence of skin sutures after surgery. Follow-up examinations were also performed for patients on the 3rd, 5th, and 7th days, and 4th week of the postop period. Considering a minimum age of 20 and a maximum age of 80, patients' mean ages ranged from 42.66 ± 14.42 years to 20 years. Women dominated (77%), according to the gender distribution. The prevalence of infection at the port site was 5%, and all post-operative problems were observed in the patient group without antibiotic infiltration at the port site. When compared to patients who did not have antibiotic infiltration, the mean LOS was lower in the antibiotic-infiltrated patients. This research demonstrated the difference between patients without antibiotic infiltration to the port site and patients with antibiotic infiltration to the port site in terms of the presence of PSI, postoperative complications, and an increase in the LOS.

Key words: Antibiotics to port site, Cholecystectomy, Laparoscopic surgery, Port-site infection

INTRODUCTION

With the rapid advancement of medical technology, surgeons now have the ability to perform limitedly invasive surgery in addition to surgical disease treatment. The best example is minimal access surgery (MAS), also known as laparoscopic surgery (LS)/keyhole surgery, which has led to a paradigm shift in how modern surgery is approached by reducing access-related morbidities. LS uses trocars, which are microscopic skin incisions or ports made on the skin away from the actual site of surgery. These trocars can be either reusable metallic or disposable plastic, and both types are utilized. With the aid of a telescope and specially designed instruments, the surgical procedure can be carried out through this port. It has grown in popularity as a result of less pain, better anesthesia, early ambulation, early hospital discharge, and an early return to work, which reduces the patient's financial burden. Since Philips Mouret published the first laparoscopic cholecystectomy (LC) in 1987,[1] the technique has been used for a variety of additional surgical operations, such as herniorrhaphy, appendectomy, gastric surgery, colonic surgery, urological as well as gynecological surgery.[2-6] The reason for this is that the horizons of LS have been expanded as a result of a combination of technological advancement and the rising acceptance of MAS by patients. Nevertheless, LS comes with a unique set of complications. Port-site infection (PSI) is one such complication that can be prevented. The benefits of LS are soon eroded by PSI as the patient develops

Access this article online

www.ijss-sn.com

Month of Submission : 04-2023
Month of Peer Review : 05-2023
Month of Acceptance : 06-2023
Month of Publishing : 06-2023

Corresponding Author: Dr. L Madhu Shankar, Department of General Surgery, KIMS, Bengaluru, Karnataka, India.

worries about the nagging and indolent infection and loses confidence in the surgeon performing the surgery. Morbidity, hospital stays, and financial losses to the patient all rise significantly. The patients' quality of life is severely affected, destroying the entire goal of MAS—to produce the maximum number of cosmesis and turning it into an unsightly wound. To study the effectiveness of local antibiotic infiltration (Amikacin injection) at the port site following port removal and to ascertain the incidence of PSI in LC, this study was conducted.

MATERIALS AND METHODS

With the General Surgery Department at the Kempegowda Institute of Medical Science in Bangalore, this prospective comparative study was conducted from March 2021 to November 2022. One hundred (100) patients over the age of 18 who underwent LC and had symptomatic gallstone disease were examined. A study group as well as a control group of fifty patients each were randomly divided into two groups. Patients under the age of 18, those who had laparoscopic surgeries other than an LC, those who were immunocompromised, and those who had acute cholecystitis, cholangitis, obstructive jaundice, or gall bladder ruptures during surgery were excluded. A 4-port approach was used to perform LC on each patient. Both groups underwent the same preoperative preparation of the wound region. Following the removal of the ports, the study group was given a local injection of the antibiotic amikacin, while the control group did not receive any antibiotic infiltration on the port site. Postoperatively, patients in both groups were evaluated for symptoms of inflammation, purulent leaking from the port site, and dehiscence of skin sutures. Follow-up was also completed on the 3rd, 5th, 7th days, and 4th week postoperatively. Post op follow up was done on 3rd, 5th, 7th and 30th day. The mean, standard deviation, and frequency for quantitative variables, as well as the proportions and frequencies for qualitative variables, were used to produce descriptive statistics for the explanatory and outcome variables. Regarding qualitative variables, a chi-square test was used to determine the association. In order to evaluate the duration of hospital stays between the groups, an independent sample t-test was used (based on antibiotic to port site). The level of significance is 5%.

RESULTS

With a minimum age of 20 and a maximum age of 80, the patients in the current study had a mean age of 42.66 ± 14.42 years. Ages 36–50 made up the majority of the patients (36/36%) in this group. 77 (77%) of the 100 (100%) patients were female, compared to 23 (23%) male patients, demonstrating the majority of female patients. About 93 (93%) had cholelithiasis and 7 (7%) had chronic cholecystitis [Table 1].

According to the antibiotic-to-port site, an equal number of patients were divided. The mean (LOS) length of hospital stay was 7.29 ± 3.71 days, with a minimum of 3 days and a maximum of 24 days. Among 100 (100%) patients, histopathology showed that 79 (79%) had chronic cholecystitis, 15 (15%) had acute chronic calculous cholecystitis, and 6 (6%) had chronic calculous cholecystitis with cholesterosis [Table 2].

Among 100 (100%) patients, about 93 (93%) patients had cholelithiasis, 48 (48%) patients had to no antibiotic at the port site, and out of 7 (7%) patients with chronic cholecystitis, and 5 (5%) patients were given antibiotics at the port site. A chi-square test was applied to associate the antibiotic at the port site with the diagnosis and showed no statistically significant association between the antibiotic at the port site and the diagnosis ($\chi^2 = 1.38$, $P = 0.24$) [Table 3].

According to histopathology, cholecystitis was observed in 79 (79%) patients with chronic cholecystitis; acute and chronic calculous cholecystitis was observed in 15 (15%) patients; chronic calculous cholecystitis with cholesterosis was observed in 6 (6%) patients. The Chi-square test showed no statistically significant association between antibiotics at the port site and histopathology ($\chi^2 = 0.74$, $P = 0.68$) [Table 4].

Table 1: Distribution of the patients based on age, age groups, gender, and diagnosis

Distribution of the patients based on age				
Variables	***n***	**Minimum**	**Maximum**	**Mean±SD**
Age	100	20.0	80.0	42.66±14.42
Distribution of the patients based on age groups				
Age groups (years)			**Frequency (%)**	
20–35			33 (33.0)	
36–50			36 (36.0)	
51–65			25 (25.0)	
66–80			6 (6.0)	
Total			100 (100.0)	
Distribution of the patients based on gender				
Gender				
Females			77 (77.0)	
Males			23 (23.0)	
Total			100 (100.0)	
Distribution of the patients based on diagnosis				
Diagnosis				
Cholelithiasis			93 (93.0)	
Chronic cholecystitis			7 (7.0)	
Total			100 (100.0)	

SD: Standard deviation

During the postoperative day (POD) 5, erythema was observed in 4 (4%) patients, purulent discharge was observed in 4 (4%) patients at POD 7, and edema, as well as purulent discharge, were observed in 1 (1%) patient at the POD 4th week. Those without exposure to an antibiotic at the port site had all the complications. A connection between complications at PODs 5 and 7 and antibiotic application to the port site was statistically significant, according to the Chi-square test ($\chi^2 = 4.16$, $P = 0.041$) [Table 5].

Among patients who had not received an antibiotic at the port site, the mean length of hospital stays increased by 7.46 ± 4.127 as compared to patients with an antibiotic at the port site by 7.12 ± 3.287. To compare the average duration of hospital stays between the groups, an independent sample t-test was used. A random sample t-test conducted independently revealed no statistically significant variation between the groups ($P = 0.65$) [Table 6].

Postop complications were present in 5 (5%) patients, and all the patients belonged to the group with no antibiotic at the port site. The Chi-square test showed a statistically significant association between antibiotic at the port site and post-operative complications ($\chi^2 = 5.26$, $P = 0.022$) [Table 7].

Table 2: Distribution of the patients based on the antibiotic to the port site, mean duration of hospital stay (days), and histopathology

Distribution of the patients based on the antibiotic to the port site				
Antibiotic to port site				**Frequency (%)**
No				50 (50.0)
Yes				50 (50.0)
Total				100 (100.0)
Distribution of the patients based on the mean duration of hospital stay (days)				
Days of hospital stay	***n***	**Minimum**	**Maximum**	**Mean±SD**
	100	3	24	7.29±3.71
Distribution of the patients based on histopathology				
Histopathology				**Frequency (%)**
Acute on chronic calculous cholecystitis				15 (15.0)
Chronic calculous cholecystitis with cholesterosis				6 (6.0)
Chronic cholecystitis				79 (79.0)
Total				100 (100.0)

SD: Standard deviation

Table 3: Cross-tabulation of antibiotic to port site with the diagnosis

Diagnosis	Count (%)		
	Antibiotic to port site		Total
	No	Yes	
Cholelithiasis	48 (48.0)	45 (45.0)	93 (93.0)
Chronic cholecystitis	2 (2.0)	5 (5.0)	7 (7.0)
Total	50 (50.0)	50 (50.0)	100 (100.0)
χ^2, *P*	1.38, 0.24		

Table 4: Cross-tabulation of antibiotic to port site with histopathology

Histopathology	Count (%)		
	Antibiotic to port site		Total
	No	Yes	
Acute on chronic calculous cholecystitis	8 (8.0)	7 (7.0)	15 (15.0)
Chronic calculous cholecystitis with cholesterosis	2 (2.0)	4 (4.0)	6 (6.0)
Chronic cholecystitis	40 (40.0)	39 (39.0)	79 (79.0)
Total	50 (50.0)	50 (50.0)	100 (100.0)
χ^2, *P*	0.74, 0.68		

DISCUSSION

With the advantages of decreased postoperative pain, a quicker recovery to normal activities, a reduction in wound size, and other advantages, laparoscopic procedures have transformed surgery in recent years. However, a number of LS complications have recently been identified. According to statistics from all across the world, Karthik *et al.* found that the frequency of port-site complications ranged from

Table 5: Cross-tabulation of antibiotic to port site with complications at postoperative day 5, day 7, and 4th week

Complications	Count (%)			χ^2	*P*
	Antibiotic to port site		Total		
	No	Yes			
POD 5					
Absent	46 (46.0)	50 (50.0)	96 (96.0)	4.16	0.041*
Erythema present	4 (4.0)	0	4 (4.0)		
POD 7					
Absent	46 (46.0)	50 (50.0)	96 (96.0)	4.16	0.041*
Purulent discharge	4 (4.0)	0	4 (4.0)		
POD 4th week					
Absent	49 (49.0)	50 (50.0)	99 (99.0)	1.01	0.315
Swelling and purulent discharge	1 (1.0)	0	1 (1.0)		

POD: Postoperative day, * P value – 0.05

Table 6: Mean comparison of the duration of the hospital days based on the antibiotic to port site

Antibiotic to port site	*n*	Minimum	Maximum	Mean±SD	Mean different	*P*
No	50	4	24	7.46±4.127	0.34	0.65
Yes	50	3	21	7.12±3.287		

SD: Standard deviation

Table 7: Cross-tabulation of antibiotic to port site with postoperative complications

Postoperative complications	Count (%)		
	Antibiotic to port site		Total
	No	Yes	
Absent	45 (45.0)	50 (50.0)	95 (95.0)
Present	5 (5.0)	0	5 (5.0)
Total	50 (50.0)	50 (50.0)	100 (100.0)
χ^2, *P*	5.26, 0.022*		

*Significant

0.2% to 6%. A port-site infection was the most frequent portsite complication, and it was more prevalent in secondary ports.[7] To prevent wound infection that could result in unacceptable cosmetic outcomes, an incisional hernia, and a longer hospital stay, it is crucial to identify the risk factors. One of them, an unnoticed tear in the endobag while retrieving the specimen, might be the cause. Wound infection is one of the most common reasons for morbidity after LS, despite the fact that it is much less prevalent than in open surgery. A lower risk of wound infection is likely connected with LS's smaller wounds and very little tissue damage.

In the current study, the average age of the patients was 42.66 ± 14.42 years, with a minimum age of 20 years and a maximum age of 80 years. Out of 100 (100%) patients, more than 3/4th of the patients were females: 77 (77%) and 23 (23%) were males, showing female predominance. Amonkar *et al*.'s study included 112 patients and showed male predominance, i.e., 61 (54.4%) were males and 51 (45.6%) were females, which is in contrast with the current study.[8] In general, men are more likely than women to get appendicitis. The Kotwal and Jadav study, which shows that 73.66% of the patients are male, reflects this.[9] Nevertheless, the role of laparoscopy is more significant in females because it assists in visualizing and treating any disorders of the female pelvic organs in the same environment, as in many such circumstances, a precise preoperative evaluation may be impossible or exceedingly difficult.

According to the clinical diagnosis distribution in our study, symptomatic cholelithiasis (93/93%) was the most common diagnosis among the 100 patients (100%), followed by chronic cholecystitis in 7 (7%) individuals. The mean LOS in the group that got antibiotics was 7.29 3.71 days, with a minimum of 3 days and a maximum of 10 days. The preoperative stay should be kept to a minimum, only long enough for the patient to become somewhat familiar with the location as well as the staff. During the postoperative period, this is quite helpful. The risk of postoperative wound infection is definitely decreased by shortening the hospital stay before surgery. Histopathology assessment showed that 79 (79%) had chronic cholecystitis, 15 (15%) had acute chronic calculous cholecystitis, and 6 (6%) had chronic calculous cholecystitis with cholesterosis. In the study of Jha *et al*., a total of 921 patients were examined during the study period. Histopathological lesions seen in gall bladder specimens were categorized as benign, premalignant, and malignant. Most of them were benign lesions (97.6%), followed by incidental carcinoma, the burden of which was 1.8%. The most common pathology (95.01%) overall and among benign lesions was discovered to be chronic calculus cholecystitis. Cholesterosis was reported in one out of ten cholecystectomy specimens (9.9%). Out of 93 (93%) patients who had cholelithiasis, 48 (48%) patients belonged to the no antibiotic port site, and out of 7 (7%) patients with chronic cholecystitis, 5 (5%) patients were in the antibiotic port site.[10] We observed a statistically insignificant association between antibiotic use at the port site and histopathology.

On days 3, 5, 7, and 4 weeks following surgeries, all postoperative complications were observed in patients who had not received any antibiotics at the port site. This resulted in a statistically significant association between the presence or absence of antibiotic infiltration at the port site in the current study. 17 of the 112 participants studied by Amonkar *et al*. experienced complications at the port site (17/15.1%).[8] According to data from throughout the world, Karthik *et al*. found that the incidence of complications at the port site ranged from 0.2% to 6%; the most prevalent of these complications was an infection at the port site, which was more prevalent in secondary ports.[7] According to a review of the literature, there are different levels of PSI frequency. It has been recorded as low as 2.3% in Israel[11] and as high as 9.2% in Cairo, Egypt.[12] It was reported as 5.3% by Raina *et al*.,[13] which is comparable to the 5.7% reported by Waqar and Sabir[11] and the 5.3% reported by Den Hoed PT.[14] Shindholimath *et al*.[15] reported a relatively higher percentage of 6.3%.

According to Darzi *et al*., surgical site infections (SSI) occurred at different rates in patients who had LC and were given prophylactic antibiotics or not, i.e., 1.7% and 2.1%, respectively. However, the variance was not statistically significant.[16] Cefazolin is an efficient antibiotic used in open cholecystectomy as well as other biliary operations.[17,18] Moreover, investigations have shown that cephalosporin should be given intravenously in a single dosage for the induction of anesthesia or right before cutting in clean as well as clean-contaminated surgeries.[19] Therefore, the goal of antimicrobial prophylaxis is not to totally eradicate microorganisms from the tissue but rather to lower the number of microorganisms to the point where the host's

defense mechanisms can effectively avoid infection by the contaminated microorganisms.[20] Controversy remains over the impact of antibiotic prophylaxis on developing postoperative infections in LC.[21-23] Prophylactic antibiotics are the primary method of preventing infectious side effects during LC.[24,25] However, their results were in conflict with those of other prospective surveys, indicating that their use is not necessary given the low risks of infection during LC.[22,23] Less postoperative pain, a shorter hospital stay, a faster resumption to work and food intake, and a considerable decline in perioperative infection problems are just a few of the advantages of laparoscopy, which is considered as an elective procedure.[26,27] Foster *et al.* conducted a study to determine the function of a single shot of ampicillin plus sulbactam during laparoscopic appendicectomy in a city hospital in Nottingham, England, where 8% of patients had infections.[28] The risk of wound infection in a study at Agakhan Hospital was 8.5%. After administering prophylactic antibiotics throughout the recovery period following LS, Chang *et al.* reported an 8.9% wound infection rate.[22] This is about equivalent to our infection rate (2–6%).

In our research, patients without infiltration antibiotics at the port site had a greater mean LOS than those with antibiotics at the port site. The most frequent procedure was a LC, and the rate of port-site complications in our sample was 5%, which is comparable to global figures (0.2–6%). Regarding SSI, the bacteria responsible for the infection may differ in different patients, whether prophylactic antibiotics are given or not.[29] Antibiotic prophylaxis plays no part, particularly in cholecystectomy instances, but there is a definite risk of SSIs compared to other surgeries.[30] A different antibiotic regime also produces the same number of infections in patients, so we cannot say which one prevents the infection. The organisms cultured may be different, with the same antibiotic prophylaxis or other.[31] Although laboratory costs may be substantial and unusual findings are rarely seen. However, performing a routine histopathological examination of all appendectomy specimens is still recommended to rule out unusual pathologies.

Infection at the port site has been recorded following laparoscopic procedures in Egypt,[12] Pakistan,[32] China,[33] Turkey,[34] and Georgia,[35] according to a study of the literature that is currently available. As far as we are aware, no similar studies have been carried out in the state of Karnataka, and the current study is the first to investigate operational issues at the port site with or without the infiltration of antibiotics into the port site. In this context, it is important to note that developing nations have reported higher PSIs than developed countries in laparoscopic procedures.[33]

CONCLUSION

In our investigation, we observed that the incidence of PSI was 5%. Only the patients who did not get antibiotic infiltration experienced any post-operative problems. Compared to patients without antibiotic infiltration, the mean LOS was lower in patients with antibiotic infiltration.

REFERENCES

1. Litynski GS. The laparoscopic breakthrough in Europe. JSLS 1999;3:163-7.
2. Lei QC, Wang XY, Zheng HZ, Xia XF, Bi JC, Gao XJ, *et al*. Laparoscopic versus open colorectal resection within fast track programs: An update meta-analysis based on randomized controlled trials. J Clin Med Res 2015;7:594-601.
3. Deng Y, Zhang Y, Guo TK. Laparoscopy-assisted versus open distal gastrectomy for early gastric cancer: A meta-analysis based on seven randomized controlled trials. Surg Oncol 2015;24:71-7.
4. Mehrabi A, Hafezi M, Arvin J, Esmaeilzadeh M, Garoussi C, Emami G, *et al*. A systematic review and meta-analysis of laparoscopic versus open distal pancreatectomy for benign and malignant lesions of the pancreas: It's time to randomize. Surgery 2015;157:45-55.
5. Chittawar PB, Franik S, Pouwer AW, Farquhar C. Minimally invasive surgical techniques versus open myomectomy for uterine fibroids. Cochrane Database Syst Rev 2014;10:CD004638.
6. Esposito C, St Peter SD, Escolino M, Juang D, Settimi A, Holcomb GW 3rd. Laparoscopic versus open inguinal hernia repair in pediatric patients: A systematic review. J Laparoendosc Adv Surg Tech A 2014;24:811-8.
7. Karthik S, Augustine AJ, Shibumon MM, Pai MV. Analysis of laparoscopic port site complications: A descriptive study. J Minim Access Surg 2013;9:59-64.
8. Amonkar A, Balla R, Jha AA. A comparative study of the various port site complications of laparoscopic surgery. Int J Res Anal Rev 2018;5:95.
9. Kotwal SR, Jadav JS. Retrospective study of a single dose of antibiotic in laparoscopic appendicectomy. Int Surg J 2018;5:1897-901.
10. Jha AK, Ali A, Kumar M, Kumar M, Bhadani PP, Murthy NB, *et al*. Outcome of routine histopathological examination of gallbladder specimen following elective laparoscopic cholecystectomy. J Carcinog 2021;20:19.
11. Jan WA, Ali IS, Shah NA, Ghani A, Khan M, Khan AS. The frequency of port site infection following laparoscopic cholecystectomies. J Postgrad Med Inst 2008;22:66-70.
12. Abd-Elhamid N, Kasim K. Port site non-tuberculous mycobacterial infection after laparoscopic cholecystectomy: A case series. TAF Prev Med Bull 2013;12:481-4.
13. Raina B, Malhotra AS, Gupta S, Meht KS. The study of postoperative, port-site mycobacterium tuberculosis infection in laparoscopic surgeries in Jammu. JK Sci 2018;20:16-20.
14. Den Hoed PT, Boelhouwer RU, Veen HF, Hop WC, Bruining HA. Infections and bacteriological data after laparoscopic and open gallbladder surgery. J Hosp Infect 1998;39:27-37.
15. Shindholimath VV, Seenu V, Parshad R, Chaudhry R, Kumar A. Factors influencing wound infection following laparoscopic cholecystectomy. Trop Gastroenterol 2003;24:90-2.
16. Darzi AA, Nikmanesh A, Bagherian F. The effect of prophylactic antibiotics on post laparoscopic cholecystectomy infectious complications: A double-blinded clinical trial. Electron Phys 2016;8:2308-14.
17. Hopkins P. Referrals in general practice. Br Med J 1956;2:873-7.
18. Mirabella A, Lupo M. Acute appendicitis. In: The Role of Laparoscopy in Emergency Abdominal Surgery. Milano: Springer; 2012. p. 61-76.
19. Nichols RL. Preventing surgical site infections. Clin Med Res 2004;2:115-8.
20. Page CP, Bohnen JM, Fletcher JR, McManus AT, Solomkin JS, Wittmann DH. Antimicrobial prophylaxis for surgical wounds. Guidelines for clinical care. Arch Surg 1993;128:79-88.
21. McGuckin M, Shea JA, Schwartz JS. Infection and antimicrobial use in laparoscopic cholecystectomy. Infect Control Hosp Epidemiol 1999;20:624-6.
22. Chang WT, Lee KT, Chuang SC, Wang SN, Kuo KK, Chen JS, *et al*. The

impact of prophylactic antibiotics on postoperative infection complication in elective laparoscopic cholecystectomy: A prospective randomized study. Am J Surg 2006;191:721-5.
23. Mir MA, Malik UY, Wani H, Bali BS. Prevalence, pattern, sensitivity and resistance to antibiotics of different bacteria isolated from port site infection in low risk patients after elective laparoscopic cholecystectomy for symptomatic cholelithiasis at tertiary care hospital of Kashmir. Int Wound J 2013;10:110-3.
24. Uchiyama K, Kawai M, Onishi H, Tani M, Kinoshita H, Ueno M, *et al*. Preoperative antimicrobial administration for prevention of postoperative infection in patients with laparoscopic cholecystectomy. Dig Dis Sci 2003;48:1955-9.
25. Dervisoglou A, Tsiodras S, Kanellakopoulou K, Pinis S, Galanakis N, Pierakakis S, *et al*. The value of chemoprophylaxis against *Enterococcus* species in elective cholecystectomy: A randomized study of cefuroxime vs ampicillin-sulbactam. Arch Surg 2006;141:1162-7.
26. Shea JA, Berlin JA, Bachwich DR, Staroscik RN, Malet PF, McGuckin M, *et al*. Indications for and outcomes of cholecystectomy: A comparison of the pre and postlaparoscopic eras. Ann Surg 1998;227:343-50.
27. Berggren U, Gordh T, Grama D, Haglund U, Rastad J, Arvidsson D. Laparoscopic versus open cholecystectomy: Hospitalization, sick leave, analgesia and trauma responses. Br J Surg 1997;81:1362-5.
28. Foster MC, Morris DL, Legan C, Kapila L, Slack RC. Perioperative prophylaxis with sulbactam and ampicillin compared with metronidazole and cefotaxime in prevention of wound infection in children undergoing appendicectomy. J Pediatr Surg 1987;22:869-72.
29. Darkahi B, Videhult P, Sandblom G, Liljeholm H, Ljungdahl M, Rasmussen IC. Effectiveness of antibiotic prophylaxis in cholecystectomy: A prospective population-based study of 1171 cholecystectomies. Scand J Gastroenterol 2012;47:1242-6.
30. Yan RC, Shen SQ, Chen ZB, Lin FS, Riley J. The role of prophylactic antibiotics in laparoscopic cholecystectomy in preventing postoperative infection: A meta-analysis. J Laparoendosc Adv Surg Tech A2011;21:301-6.
31. Kim KH, Park CS, Chang JH, Kim NS, Lee NS, Choi BR, *et al*. Association between prophylactic antibiotic use and surgical site infection based on quality assessment data in Korea. J Prev Med Public Health 2010;43:235-44.
32. Horan TC, Gaynes RP, Martone WJ, Jarvis WR, Emori TG. CDC definitions of nosocomial surgical site infections, 1992: A modification of CDC definitions of surgical wound infections. Infect Control Hosp Epidemiol 1992;13:606-8.
33. Chuang SC, Lee KT, Chang WT, Wang SN, Kuo KK, Chen JS, *et al*. Risk factors for wound infection after cholecystectomy. J Formos Med Assoc 2004;103:607-12.
34. Leblebicioglu H, Erben N, Rosenthal VD, Sener A, Uzun C, Senol G, *et al*. Surgical site infection rates in 16 cities in Turkey: Findings of the International Nosocomial Infection Control Consortium (INICC). Am J Infect Control 2015;43:48-52.
35. Richards C, Edwards J, Culver D, Emori TG, Tolson J, Gaynes R, *et al*. Does using a laparoscopic approach to cholecystectomy decrease the risk of surgical site infection. Ann Surg 2003;237:358-62.

How to cite this article: Shankar LM, Melur UC. Comparative Study on the Incidence of Port-site Infection, With and Without Local Infiltration of Antibiotics to the Port Site after the Removal of Ports in Laparoscopic Surgeries. Int J Sci Stud 2023;11(3):24-29.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Comparison between King Vision Channeled versus C-MAC D-Blade Video Laryngoscope for Ease of Intubation – A Prospective Randomized Study

Harjinder Kaur[1], Rajan Kumar[2], Rishabh Khurana[3], Harpreet Kaur[1], Veena Chatrath[4]

[1]Assistant Professor, Department of Anaesthesiology and Critical Care, Government Medical College, Amritsar, Punjab, India, [2]Professor, Department of Anaesthesiology and Critical Care, Government Medical College, Amritsar, Punjab, India, [3]3rd Year Junior Resident, Department of Anaesthesiology and Critical Care, Government Medical College, Amritsar, Punjab, India, [4]Professor and Head, Department of Anaesthesiology and Critical Care, Government Medical College, Amritsar, Punjab, India

Abstract

Introduction: The approach to airway management has completely changed since the introduction of video laryngoscopes. Video laryngoscopes have quickly gained interest as an intubation device in a variety of clinical scenarios and settings, as well as in the hands of experts and novices. Their indirect view with the help of camera improves glottic visualization, including in anticipated and unanticipated difficult airways.

Purpose: The purpose of conducting this study is to compare C-MAC D Blade video laryngoscope with King Vision channeled video laryngoscope to form a protocol in our department for anticipated and unanticipated difficult airway for orotracheal intubations in general elective surgeries.

Methods: Eighty patients between the age of 18 and 60 years, ASA Grade I and II posted for general surgeries under general anesthesia were randomly selected. Both groups were assigned 40 patients each, Group KC patients were intubated using King Vision channeled and Group CM patients were intubated using C-MAC D-Blade video laryngoscope. Time for visualization of glottis, duration of intubation, number of attempts, success rate, and hemodynamic parameters up to 120 min was observed. Quality of visualization of glottis, airway injuries, and assisted maneuvers were also noted.

Results: The mean time taken for visualization of glottis in group KC was 12.67 ± 1.39 s and in group CM was 10.74 ± 1.01 s. The mean time taken for intubation in group KC was 25.74 ± 3.874 s and in group CM was 28.06 ± 2.23 s. There was no significant difference in the number of attempts and quality of visualization of the glottis achieved by each device in both groups. Devices were also comparable with respect to airway injuries and assisted maneuvers required for successful intubation.

Conclusion: Although KVVL and C-MAC video laryngoscopes have been efficient video laryngoscope in this study, we conclude that KVVL is a faster alternative to C-MAC for endotracheal intubation in patients with normal airways.

Key words: C-MAC D-blade video laryngoscope, Duration of intubation, Ease of intubation, General elective surgeries, King Vision channeled laryngoscope

INTRODUCTION

Laryngoscopy is a medical procedure performed by anesthesiologists for the purpose of placing an endotracheal tube (ETT) into the airway of patients to secure the airway and to administer inhalational agents for maintenance of anesthesia. The ultimate aim is to safely intubate the trachea and secure the airway.[1]

In routine practice, direct laryngoscopy (DL) using a Macintosh laryngoscope remains the gold standard technique as an effective means for securing the airway. In the presence of certain anatomical variants or airway pathology, visualization of the glottis by DL can be difficult or impossible.[2]

Access this article online

www.ijss-sn.com

Month of Submission : 04-2023
Month of Peer Review : 05-2023
Month of Acceptance : 06-2023
Month of Publishing : 06-2023

Corresponding Author: Dr. Harpreet Kaur, Department of Anaesthesiology and Critical Care, Government Medical College, Amritsar, Punjab, India.

Table 1

Parameters	Mean±SD		*P*
	Group KC	Group CM	
Time to visualization (s)	12.67±1.39	10.74±1.01	0.001
Duration of intubation (s)	25.74±3.74	28.06±2.23	0.001

SD: Standard deviation

Table 2

Number of attempts	Age	
	Group KC, *n* (%)	Group CM, *n* (%)
1	40 (100.00)	37 (92.50)
2	0	3 (10.00)
Total	40 (100.00)	40 (100.00)
P	0.070	

Table 3

Quality of visualization (Cormack-Lehane grade)	Age	
	Group KC, *n* (%)	Group CM, *n* (%)
1	37 (92.50)	38 (95.00)
2a	3 (7.50)	2 (5.00)
2b	0	0
3	0	0
Total	40 (100.00)	40 (100.00)

Table 4

Ease of intubation	Age	
	Group KC, *n* (%)	Group CM, *n* (%)
0 - easy	26 (65.00)	22 (55.00)
1 - difficult	12 (30.00)	15 (37.50)
2 - very difficult	2 (5.00)	3 (7.50)
Total	40 (100.00)	40 (100.00)
P	0.436	

DL has a variable learning curve requiring training, experience, and regular practice to acquire and maintain. It requires a direct line of sight to align airway axes (oral pharyngeal-laryngeal) for optimal glottic visualization. DL and passage of ETT through larynx can lead to sympathetic stimulation and adverse effects in the cardiovascular, respiratory, and nervous systems.[3,4] The hemodynamic responses caused due to this are mostly short-lived and well-tolerated by healthy individuals.[5] However, they can be detrimental in susceptible patients resulting in a myriad of complications such as myocardial ischemia, cardiac failure, arrhythmia, intracranial bleed, and increased bleeding from wounds.[6]

All the above complications of DL can be reduced using video laryngoscope, Hence, it can be safely called the potential replacement of DL in such scenarios.[7]

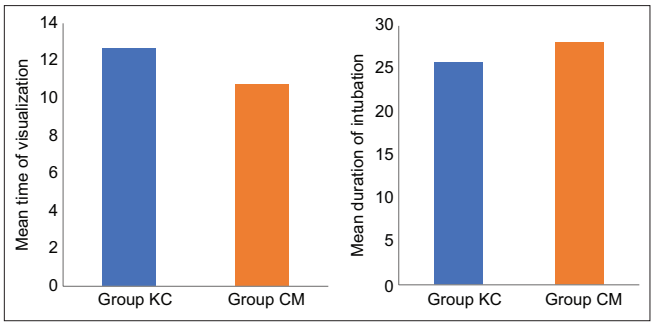


Figure 1: Mean time for visualisation of glottis and mean time for intubation

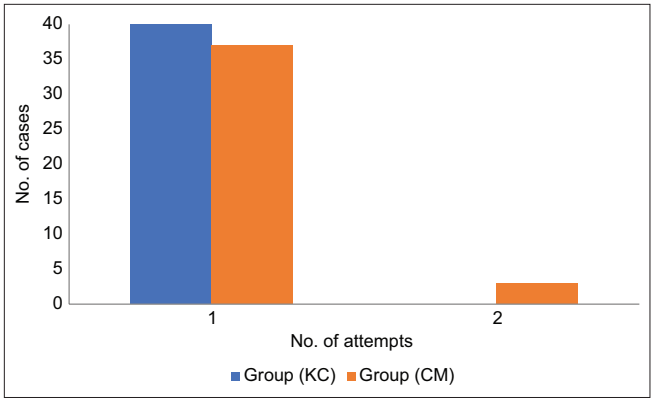


Figure 2: Number of attempts

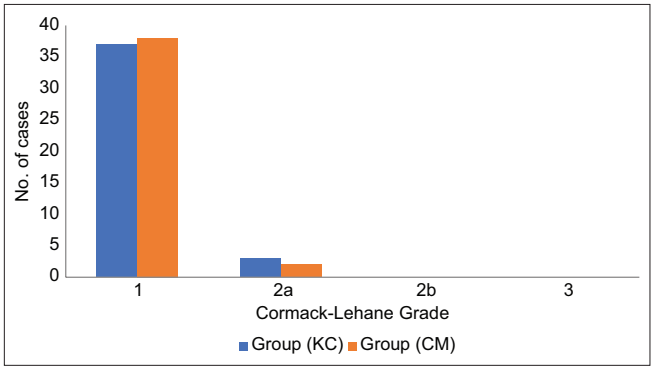


Figure 3: Quality of visualization of glottis assessed by Cormack-Lehane grades

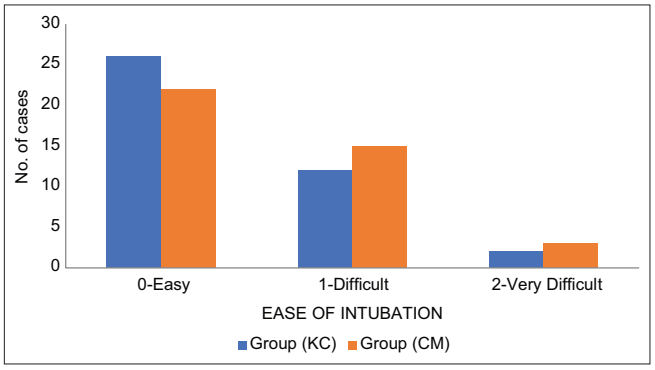


Figure 4: Ease of intubation

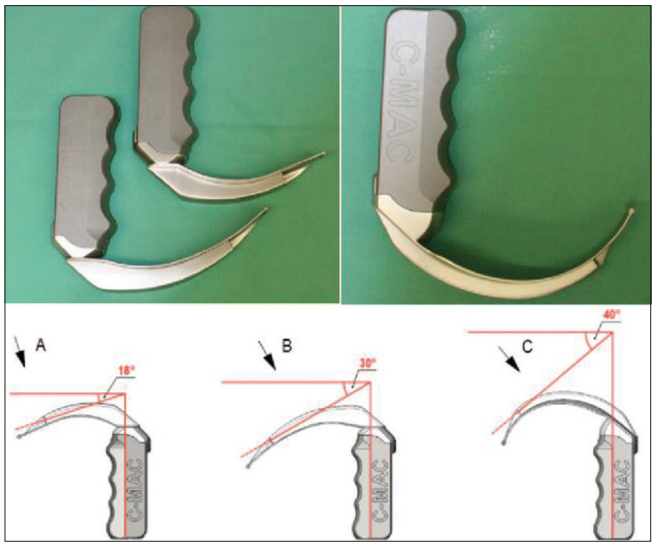


Figure 5: Diagrammatic representation of angulation of C-MAC video laryngoscope - Macintosh blade and D-blade

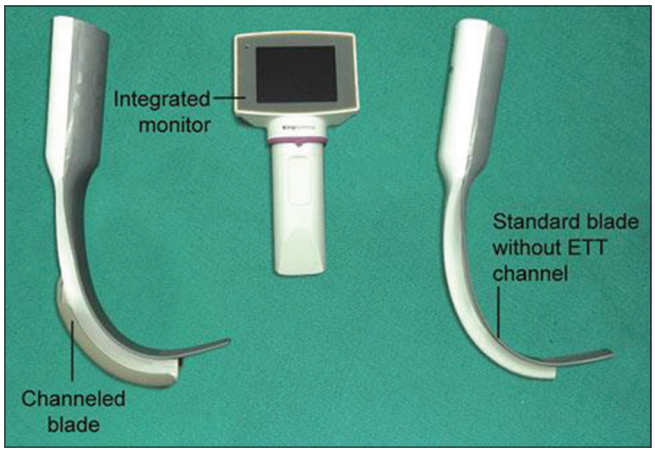


Figure 6: Kings vision laryngoscope and the channeled and non-channeled disposable blades

Video laryngoscopes have surely made their way as a routinely used laryngoscope, we conducted this study to compare C-MAC D-Blade video laryngoscope with King Vision channeled video laryngoscope to form a protocol in our department for anticipated and unanticipated difficult airway for orotracheal intubations in general elective surgeries.

MATERIALS AND METHODS

This study was conducted on 80 patients, aged 18–60 years, ASA grade I and II, MPG Grade I and II scheduled to undergo elective surgery under general anesthesia. Written informed consent was obtained from each subject after explaining the technique and procedure before the addition of the subject in the study in their own vernacular language. Patients giving refusal, MPG Grade III and IV, history of hypertension, heart failure, or with any predictors of difficult airway were excluded from the study.

A detailed pre-anesthetic and airway examination was done 1 day before surgery and pre-operative routine investigations. Each patient was kept fasting for 8 h pre-operatively. Tablet alprazolam 0.25 mg orally was given at night before surgery.

In the preparation room, an intravenous (I.V) cannula 20 gauge was inserted and Ringer lactate was started. Injection of midazolam 0.02–0.03 mg/kg and injection of glycopyrrolate 0.2 mg were given I.V to all patients. In the operating room, an injection of butorphanol 0.015–0.02 mg/kg was given, and standard monitors were applied. Patients were pre-oxygenated through face mask for 3 min. General anesthesia was induced using propofol 1.5–2.5 mg/kg. Ventilation was assessed using face mask and manual ventilation and if proved satisfactory, an injection of succinylcholine 1–1.5 mg/kg I.V was given. Then, intubation was performed using C-MAC D-Blade video laryngoscope in the group (CM) and King Vision laryngoscope with channeled blade in the group (KC) with 40 patients in each group. Then, the cuff was inflated and ETT was connected to the breathing circuit and checked by EtCO2, five-point auscultation of chest, observation of B/L chest movement, and misting of the tube.

The parameters measured and observed were as follows -Time taken for visualization of glottis and intubation time was measured using a stopwatch. Ease of intubation was assessed using a subjective scale – It was graded as easy, difficult, or very difficult. The success rate was calculated for each group. Failure to intubate was considered if the time taken was more than 120 s or more than 2 attempts were required. The number of attempts was calculated, an intubation attempt will be defined insertion of laryngoscope blade into the oropharynx, regardless of whether an attempt was made to pass the ETT. The quality of visualization was assessed using Modified Cormack and Lehane grading. If any assisted maneuvers were required for successful intubation which included external laryngeal manipulation, aided by bougie, changing blade size was recorded and noted.

Hemodynamic variables were measured during baseline just before induction of anesthesia, at time of laryngoscopy, at time of ETT insertion then after every 15 min till 120 min, or end of surgery. Any airway injury was recorded, it was assessed by the presence of any blood in the oropharyngeal airway or blood on the ETT when the patient was extubated.

Statistical Analysis

Duration of intubation was taken as the outcome measure of interest for the purpose of sample size calculation. Sample size was calculated keeping in view at most 5% risk, with minimum 80% power, and 5% significance level (significant at 95% confidence interval). Data were recorded in a Microsoft Excel spreadsheet and analyzed using Statistical Package for the IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp., Chicago. Continuous data were presented as mean with standard deviation. Categorical data were expressed as numbers and percentages. Power analysis was done to calculate the power of the study which was 95% by taking α error of 0.05. The *P*-value was then determined to evaluate the level of significance. The results were analyzed and compared to previous studies to draw relevant conclusions.

RESULTS

The results of our study were as follows:

- The two groups were comparable in view of demographic data and patient characteristics
- The mean time is taken for visualization of the glottis in both groups. The mean time taken for visualization of glottis in group KC is 12.67 ± 1.39 s which is longer than the mean time taken in group CM which is 10.74 ± 1.01 s. The groups showed a highly statistically significant difference ($P = 0.001$)
- The mean time taken for intubation in group KC was 25.74 ± 3.874 s and in group CM was 28.06 ± 2.23 s. The difference in the groups was found to be statistically highly significant ($P = 0.001$)
- The number of attempts were - All 40 patients in group KC were intubated in the first attempt although 3 patients in group CM required second attempt. The difference between both groups was found to be statistically non-significant ($P > 0.05$)
- First attempt's success rate was 100% in group KC and 92.5% in group CM. Rest 7.5% of group CM patients were intubated in the second attempt. All the patients were successfully intubated and no intubation failure was recorded ($P > 0.05$)
- The ease of insertion of the laryngoscope blade was compared. In group KC, in 28 patients were labeled as easy, 10 were slightly difficult, and 2 were labeled as difficult. In group CM, 33 patients were labeled as easy and 7 were labeled slightly difficult ($P > 0.05$)
- Quality of visualization was compared with Cormack-Lehane Grading. Cormack-Lehane Grade I was achieved in both the groups in all the patients ($P > 0.05$)
- The two groups were found to be comparable with respect to the hemodynamic and ventilatory parameters such as BP, SpO_2, and $EtCO_2$ with the difference being statistically non-significant at all time points ($P > 0.05$)
- In group KC, 3 patients out of 40 (7.50%) recorded airway injury indicated by blood on laryngoscope blade or on the ETT seen after extubation, whereas in group CM, only 1 patient out of 40 (2.50%) was recorded to have an airway injury ($P > 0.05$)
- In group KC, 2 patients (5.00%) required any additional maneuver and in group CM, 4 patients (10.00%) required the same ($P > 0.05$) (Figures 1-6).

DISCUSSION

Video laryngoscopes are rapidly gaining popularity in airway management and several devices with different design features are now available. Their use is not only being advocated for difficult airways[8] but is also now being suggested by many airway experts as the first-line technique device for tracheal intubation in all patients.[9-11] The C-MAC video laryngoscope and King Vision laryngoscope are two revolutionary devices in this field which have made the skill of laryngoscopy much easier to learn.

C-MAC VL has two types of blades – conventional Macintosh and D-Blade, which are hyper-angulated. The screen is located on a separate stand for C-MAC but in the case of King Vision, the screen is located on the top of laryngoscope itself. King Vision has two types of blades – channeled and non-channeled. The one used in this study has a channel into which an ETT is pre-loaded before laryngoscope is inserted into the patient's oral cavity.

Both groups did not differ with respect to any of the patient characteristics such as age, sex, BMI, Wilson scoring, and ASA grading.

The time for visualization of the glottis was recorded from the time of laryngoscope insertion into the patient's mouth until the glottis was visible on the camera screen. The mean time taken for visualization of glottis in group KC is 12.67 ± 1.39 s which is longer than the mean time taken in group CM which is 10.74 ± 1.01 s. The reason for a slightly longer time in group KC, the patients intubated with KVVL is the bulkier nature of the channeled blade than the C-MAC D-Blade which makes it slightly more difficult than the C-MAC Blade to enter the mouth of the patient. Similarly, in a study conducted by Sahajanandan *et al.*, they compared KVVL with C-MAC D-Blade laryngoscope in patients with anticipated difficult airways. The mean time for visualization of glottis with King Vision was 12.93 s and with C-MAC D-Blade was 10.32 s. Our results also coincide with the study conducted by Chandy *et al.*, as the results of the study conducted by them also showed a significantly

shorter time for visualization of the glottis with C-MAC D-Blade as compared to KVVL. They also concluded in their study that KVVL was difficult to introduce into the mouth of the patient during laryngoscopy.[12]

The duration of intubation was recorded from the time of KVVL or the C-MAC D-Blade laryngoscope insertion into the patient's mouth until the passage of ETT into the trachea in a fully anesthetized patient. The mean time taken for intubation in both groups was calculated. The mean time taken in group KC was 25.74 ± 3.874 s and in group CM was 28.06 ± 2.23 s. The longer duration of intubation with C-MAC D-Blade video laryngoscope even after the shorter time for visualization of glottis might be due to the hyperangulated shape of the D-Blade which is more than the curvature of the normal ETT. Hence, it was slightly difficult to aim the tube directly into the trachea on the first attempt. This was overcome by adjusting the laryngoscope blade or use of a stylet to match the curvature of the blade. Other problem with the C-MAC D-Blade VL was a blind phase when the ETT is entered into the patient's mouth till it reaches the front of the camera which makes it slightly difficult to angle the tube directly toward the vocal cords. With the KVVL, the ETT was pre-loaded into the channel of the blade. Hence, it took comparatively a shorter time to push the ETT into the trachea as compared to the C-MAC. Even with King Vision, the most common cause of failure was the tube impinging on the right arytenoid. The use of a smaller ET tube facilitated 90° counter-clockwise rotation within the channel which rectified impingement on the right arytenoid and facilitated intubation. Shravanalakshmi *et al.* compared ease of intubation and glottic visualization with C-MAC Conventional and D-Blade and King Vision channeled blades. Time for intubation in seconds was significantly faster with conventional C-MAC video laryngoscope (23.3 ± 4.7) compared to D blade C-MAC video laryngoscope (26.7 ± 7.1), whereas conventional C-MAC and King Vision were comparable (24.9 ± 7.2).[13]

The number of attempts required in each patient to successfully intubate the trachea was noted. All 40 patients in group KC were intubated in the first attempt, although 3 patients in group CM required the second attempt. The groups showed that this difference is non-significant ($P = 0.07$). First attempt success rate in group KC was 100% that is all the patients were intubated in the first attempt whereas in group CM, the first attempt success rate was 92.5%. Rest 7.5% of patients in group CM were successfully intubated in the second attempt. Although the result was found to be statistically insignificant.

The systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) showed no significant statistical difference among the two groups. Baseline mean SBP in group KC was (119.93 ± 5.56) mmHg which was comparable to baseline mean SBP in group CM (117.88 ± 6.72) mmHg ($P = 0.07$). The SBP at 5 min, just around 1 min after intubation, in group KC was (136.83 ± 6.84) mmHg and in group CM was (134.80 ± 5.32) mmHg. The mean diastolic pressure in group KC was 82.88 ± 6.31 mmHg and in the group at baseline was 83.20 ± 3.73 mmHg. The MAP in group KC was (95.18 ± 4.28) mmHg and in group CM at baseline was (94.83 ± 3.29) mmHg. The SBP, DBP, MAP, HR, and SpO2 were noted at 1 min, 3 min, 5 min, 10 min, and every 10 min for the rest of the duration of surgery and no statistically significant differences were found in both the groups ($P > 0.05$)

Quality of visualization was assessed using modified Cormack-Lehane grading. In group KC, 37 out of the 40 (92.5%) patients and in group CM, 38 of the 40 (95%) patients achieved CL grade I, and CL grade 2a was observed in 3 (7.5%) and 2 (5%) patients out of the 40 patients in group KC and CM, respectively($P > 0.05$). Similar to our study, Shetty *et al.* recorded Cormack-Lehane grade 1 in 90% of the patients in the KVL group and 93.3% of patients had grade 1 view in the C-MAC group.[14] Variations are recorded over different studies conducted comparing the quality of visualization of glottis as laryngoscopy is a skillful procedure and one's experience adds a great depth to it.

In group KC, 2 patients (5.00%) required any additional maneuver and in group CM, 4 patients (10.00%) required the same ($P > 0.05$). In the case of C-MAC, it was noted that the mistake was in the correct placement of the laryngoscope blade with respect to the glottis or the vocal cords and with King Vision channeled laryngoscope the most encountered problem was impingement of the tube on the right arytenoid. The ETT had to be turned in the clockwise direction in the case of C-MAC VL in contrast to the channeled blade of King Vision in which an anti-clockwise turn to the pre-loaded ETT was found to be beneficial, which was recognized and corrected over time of the study.

Limitations

Limitations of our study are as follows -

- Single-blinded study, as it is not possible to blind the anesthesiologist to the device used for the intubation
- Second, study findings might not be applicable to a larger population, bigger sample size might be required to document its advantages
- Our study was conducted on patients with normal airways without the predictors of difficult airways. Hence, the results might not extrapolate to a difficult airway

- The hemodynamic responses were recorded in ASA I and II patients. The hemodynamic parameters might vary in a hypertensive or ASA III or ASA IV patient
- Out of several that are currently available in the market, we can only comment on what we found better out of the two devices included in our study.

CONCLUSION

- C-MAC D-Blade video laryngoscope was found to be faster than the King Vision laryngoscope channeled blade in the aspect of time taken to visualize the glottis
- In spite of that, King Vision channeled blade was found to take a shorter duration for successful intubation when compared to the total duration taken by the C-MAC D-Blade video laryngoscope
- There was no significant difference in the number of attempts and quality of visualization of the glottis achieved by each device in both the groups
- There was no statistically significant difference in hemodynamic changes in both the groups
- In aspect to airway injuries and assisted maneuvers, no statistically significant difference was found between both the groups.

ACKNOWLEDGMENT

I bow with reverence, all humility and gratitude to thank The Almighty for giving me the opportunity and strength to undertake this work and the ability to successfully complete it.

Mere words are insufficient to express adequately my profound indebtedness and deep gratitude to my most revered teacher, encouraging mentor Dr. Veena Chatrath, MD, Professor and Head, Department of Anesthesia and Intensive Care Unit, Govt. Medical College, Amritsar. Her unconditional help, affectionate guidance from the very inception of the study has contributed more to the accomplishment of my task than my over diligence and devotion. It has been a matter of great pride and privilege for me to have worked under the able guidance of teacher of such great caliber. I owe her, a lifelong gratitude. I would like to express my gratitude toward Dr. Rajan Kumar, MD, Professor, Department of Anesthesia and Intensive Care Unit, Govt. Medical College, Amritsar, for his meticulous advice, sustained encouragement, generous help, and invaluable guidance throughout the course of the study. I wish to express my sincere appreciation to Dr. Harpreet Kaur, Assistant Professor, Department of Anesthesia and Intensive care Unit, Government Medical College, Amritsar, for her invaluable guidance and encouragement.

REFERENCES

1. Rosenstock CV, Thøgersen B, Afshari A, Christensen AL, Eriksen C, *et al*. Awake fiberoptic or a wake video laryngoscopic tracheal intubation in patients with anticipated difficult airway management: A randomized clinical trial. Anesthesiology 2012;116:1210-6.
2. Soliman R, Mofeed M, Alamoudy O, Farouk A. A prospective randomized comparative study between Macintosh and Glide scope in adult patients undergoing cardiac surgery. Egypt J Cardiothorac Anesth 2015;9:8-13.
3. Kaplan MB, Hagberg CA, Ward DS, Brambrink A, Chhibber AK, Heidegger T, *et al*. Comparison of direct and video-assisted views of the larynx during routine intubation. J Clin Anesth 2006;18:357-62.
4. Sun DA, Warriner CB, Parsons DG, Klein R, Umedaly HS, Moult M. The GlideScope video laryngoscope: Randomized clinical trial in 200 patients. Br J Anaesth 2005;94:381-4.
5. Ratnani E, Sanjeev OP, Singh A, Tripathi M, Chourasia HK. A comparative study of intravenous esmolol, labetalol and lignocaine in low doses for attenuation of sympathomimetic responses to laryngoscopy and endotracheal intubation. Anesth Essays Res 2017;11:745-50.
6. Jalali A, Nasiri E, Khoramian M, Saghafinia M, Siamian H. Hemodynamic responses to tracheal intubation in elderly patients: Intravenous or spray of lidocaine versus fentanyl. Med Arch 2017;71:424-9.
7. Nouruzi-Sedeh P, Schumann M, Groeben H. Laryngoscopy via Macintosh blade versus GlideScope: Success rate and time for endotracheal intubation in untrained medical personnel. Anesthesiology 2009;110:32-7.
8. Myatra SN, Shah A, Kundra P, Patwa A, Ramkumar V, Divatia JV, *et al*. All India Difficult Airway Association 2016 guidelines for the management of unanticipated difficult tracheal intubation in adults. Indian J Anaesth 2016;60:885-98.
9. Zaouter C, Calderon J, Hemmerling M. Videolaryngoscopy as a new standard of care. Br J Anaesth 2015;114:181-3.
10. Cook TM, Boniface NJ, Seller C, Hughes J, Damen C, MacDonald L, *et al*. Universal videolaryngoscopy: A structured approach to conversion to videolaryngoscopy for all intubation in an anaesthetic and intensive care department. Br J Anaesth 2018;120:173-80.
11. Cooper RM. Implementing universal videolaryngoscopy: How to do it and what to expect. Br J Anaesth 2018;120:13-5.
12. Sahajanandan R, Dhanyee AS, Gautam AK. A comparison of King vision video laryngoscope with CMAC D-blade in obese patients with anticipated difficult airway in tertiary hospital in India-randomized control study. J Anaesthesiol Clin Pharmacol 2019;35:363-7.
13. Shravanalakshmi D, Bidkar PU, Narmadalakshmi K, Lata S, Mishra SK, Adinarayanan S. Comparison of intubation success and glottic visualization using King Vision and C-MAC videolaryngoscopes in patients with cervical spine injuries with cervical immobilization: A randomized clinical trial. Surg Neurol Int 2017;8:19.
14. Shetty SM, Vyshnavi S, Dharanindra M, Archana KN. Comparison of laryngoscopy and intubating conditions using Kings Vision laryngoscope and C-MAC video laryngoscope. Indian J Clin Anaesthesiol 2018;5:282-6.

How to cite this article: Kaur H, Kumar R, Khurana R, Kaur H, Chatrath V. Comparison between King Vision Channeled versus C-MAC D-Blade Video Laryngoscope for Ease of Intubation – A Prospective Randomized Study. Int J Sci Stud 2023;11(3):30-35.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Comparison between Channeled versus Non-Channeled Blade of King Vision Video Laryngoscope in General Surgical Procedures

Kamal Jyoti Kashyap[1], Dheeru Marwaha[2], Arshdeep Singh[3], Rajan Kumar[4], Harmanjot Kaur[5]

[1]Associate Professor, Department of Anaesthesia, Government Medical College, Amritsar, Punjab, India, [2]Assistant Professor, Department of Anaesthesia, Government Medical College, Amritsar, Punjab, India, [3]Senior Resident, Department of Anaesthesia, Government Medical College, Amritsar, Punjab, India, [4]Professor, Department of Anaesthesia, Government Medical College, Amritsar, Punjab, India, [5]Junior Resident, Department of Anaesthesia, Government Medical College, Amritsar, Punjab, India

Abstract

Background and Aims: Direct laryngoscopy remains the gold-standard technique as an effective means for securing the airway by placing an endotracheal tube into the glottis called endotracheal intubation. It is a complicated technical skill. It has a variable learning curve requiring training, experience, and regular practice. King Vision Video Laryngoscope (KVVL) has revolutionized the skill of difficult airway management. The present study was carried out to investigate laryngoscopic view and intubation success using the channeled and non-channeled blade of KVVL in anaesthetized patients as these laryngoscopes can be used effectively by junior residents for emergency intubation in patients with respiratory tract infections with minimal exposure.

Materials and Methods: After proper pre-anesthetic checkup, prospective randomized clinical trial involving 80 patients with ASA physical status I-II, in the age group of 18–60 years, was carried out dividing the patients into two groups; Group [I] - patients intubated with non-channeled blade of KVVL and Group [II] - patients intubated with channeled blade of KVVL. Time for visualization of the glottis, intubation time, success rate of intubation, and number of attempts were noted.

Results: Time for visualization of glottis was significantly shorter with non-channeled blade (group I) as compared to channeled (Group II) but intubation time was significantly shorter in Group II as compared to Group I. Success rate and number of attempts were not statistically different. Both groups achieved Cormack–Lehane Grade I in all the patients.

Conclusion: The time to glottis visualization is longer but intubation time is shorter when using channeled blade as compared to non-channeled blade.

Key words: Channeled King Vision Video Laryngoscope, Cormack–Lehane grade, Non-channeled King Vision Video Laryngoscope

INTRODUCTION

Laryngoscopy is a procedure performed by anesthesiologists for the purpose of placing an endotracheal tube into the airway (trachea) of anesthetized patients to secure the airway. Direct laryngoscopy (DL) is a gold-standard technique but requires a number of manipulations for optimal glottic visualization. These manipulations of the airway have adverse implications such as significant hemodynamic disturbance, cervical instability, injury to oral and pharyngeal tissues, and dental damage.[1] Due to certain limitations of DL, videolaryngoscopy has gained a strong foothold in routine anesthesia practice and becomes a recommended alternative technique in cases of expected difficult airway situations.[2] It has increased first pass success in difficult airway situations and has less peri-intubation complications by reducing the amount of intubation attempts and shortening its time.[3,4]

The King Vision™ Video Laryngoscope (KVVL) is a new novel device developed to aid the anesthesiologist in managing the difficult as well as routine airways quickly and safely.[5] It has two types of blades: Channeled and non-channeled.[6] King vision is a portable device which

Access this article online

www.ijss-sn.com

Month of Submission : 04-2023
Month of Peer Review : 05-2023
Month of Acceptance : 06-2023
Month of Publishing : 06-2023

Corresponding Author: Dr. Rajan Kumar, Professor, Department of Anaesthesia, Government Medical College, Amritsar, Punjab, India.

consists of two parts, i.e., stem and blade. The stem of the laryngoscope is reusable.[7] It has a colored video screen and a battery housing. The blade of the laryngoscope is disposable and for single use only. It has L-shaped blade. VL must be held in the left hand and the endotracheal tube (ETT) has to be steered independently with the right hand.

The non-channeled blade of King Vision did not allow simultaneous manipulation of ETT and VL. Moreover, it required the use of malleable stylet for insertion of ETT. The difficulties encountered in non-channeled version were overcome when channeled blade came into practice. Channeled blades have a channel for loading ETT for easier passage through glottis once larynx is visualized.

In this prospective, randomized, single center investigation, we aimed to compare time required for glottic visualization and duration of successful intubation of channeled vs. non-channeled versions of commercially available KVVL. The study was conducted in Guru Nanak Dev hospital attached to Government Medical College, Amritsar, after taking written informed consent of patients in vernacular language and approval from Institutional Ethics Committee (IEC). It was conducted on 80 patients, aged 18–60 years of ASA Grades I and II, scheduled to undergo elective surgery under general anesthesia.

MATERIALS AND METHODS

Following the approval of IEC, and after obtaining a written informed consent, 80 patients with ASA physical status I–II, in the age group of 18–60 years, of both sexes, scheduled for elective surgeries under general anesthesia with endotracheal intubation (ETI) were included. The trial was registered with clinical trial registry-India [Table 1].

In the preparation room, intravenous (I.V) cannula 20 gauges were inserted. Injection midazolam 0.02–0.03 mg/kg and injection glycopyrrolate 0.2 mg were given I.V to all patients.

Table 1: Demographic parameters

Parameter	Group I (*n*=40)	Group II (*n*=40)	*P*-value (NS)
Mean age (in years.)	36.18±13.18	38.45±12.76	0.221
Sex			0.644
Male	26	24	
Female	14	16	
Mean BMI	25.70±1.39	25.43±1.21	0.387
ASA grade			0.495
I	25	22	
II	15	18	
Wilson score			0.898
0	13	12	
1	13	12	
2	14	16	

Then, the patients were transferred to the operating room, standard monitors were applied (non-invasive blood pressure, pulse oximeter, electrocardiogram) before, and capnography after induction of anesthesia. Patients were pre-oxygenated through antistatic mask for 3 min. General anesthesia was induced using propofol 1.5–2 mg/kg. After assessing adequate ventilation, neuromuscular blocking agent was given in the form of succinylcholine 1.5 mg/kg. The patients were given intermittent positive pressure ventilation. Then, intubation was performed using non-channeled blade of KVVL in Group I and using channeled blade of KVVL in Group II.

We measured and recorded the characteristics of laryngoscopy and intubation:

- Time taken for visualization of glottis and duration of intubation was measured using a stopwatch
- Success rate was calculated for each group. Intubation was considered a failure if it takes more than 3 attempts to intubate the patient or time taken more than 120 s
- Number of attempts - an intubation attempt was defined insertion of laryngoscope blade into the oropharynx, regardless of whether an attempt was made to pass the endotracheal tube.
- Ease of laryngoscope insertion was assessed. It was graded as easy, slightly difficult, or difficult
- Quality of visualization was assessed using Cormack and Lehane grading
- Hemodynamic variables
- Assisted maneuvers - if any assisted maneuvers were required for successful intubation which include external laryngeal manipulation, aided by bougie, changing blade size, any lifting force required, redirecting the laryngoscope was recorded and noted
- Any airway injury was recorded - it was assessed by any blood from lips, mucosa, in the oropharyngeal passage or blood on the ETT when patient was extubated.

Duration of intubation was taken as the outcome measure of interest for the purpose of sample size calculation. Sample size was calculated keeping in view at most 5% risk, with minimum 80% power and 5% significance level (significant at 95% confidence interval). Data were recorded in a Microsoft excel spreadsheet and analyzed using the Statistical Package for the IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp., Chicago. Exact *P*-values were computed and $P < 0.05$ was considered as statistically significant.

RESULTS

A total of 80 patients were analyzed [Table 1]. Patient baseline characteristics with respect to age, gender

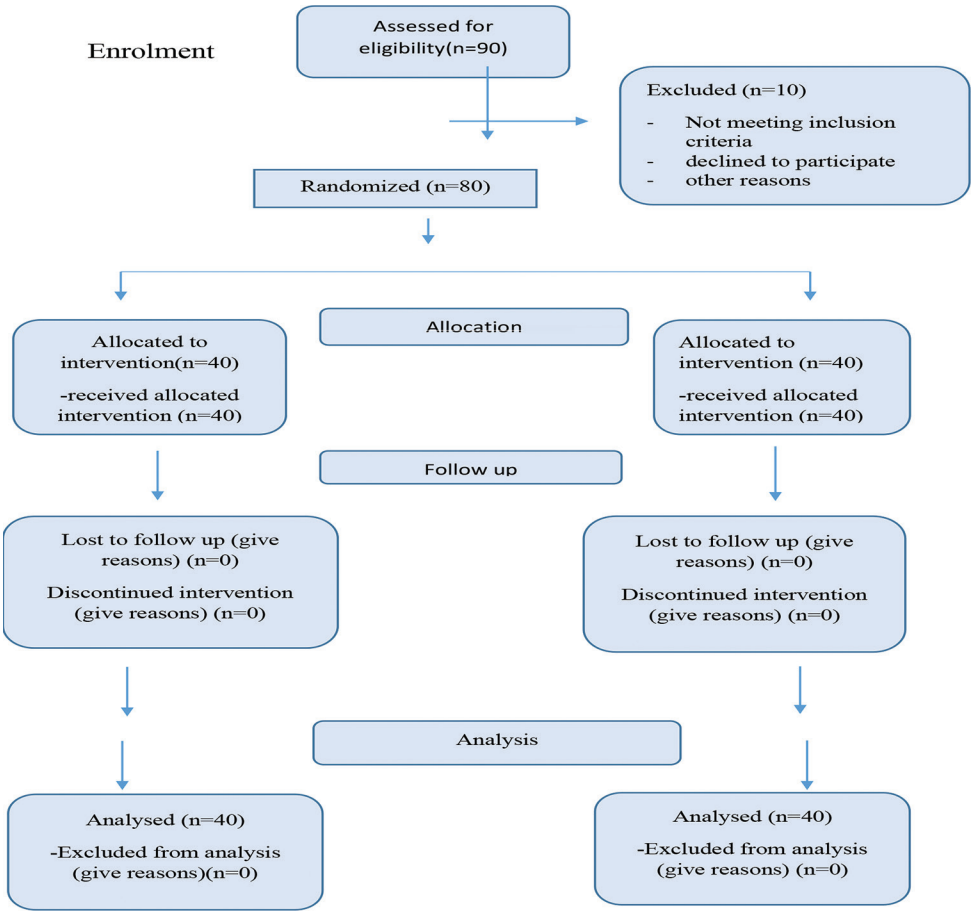


Figure 1: Consort flow diagram

distribution, BMI, and Wilson score were similar in the two groups. There was also no statistically significant difference in the distribution of patient's Mallampati grades and ASA class distribution [Figure 1].

Time to Visualization of Glottis

The time to glottis visualization was significantly shorter when using non-channeled blades as compared to channeled blades. The mean time taken for visualization of glottis in Group I was 6.09 ± 0.72 s and the mean time taken in Group II was 10.57 ± 2.20 s. The groups showed a highly statistically significant difference ($P < 0.03$). The grade of glottis visibility and number of insertions were similar [Figure 2].

Duration of Intubation

The total duration of intubation was significantly longer using non-channeled blade compared to channeled blade. The mean time taken in Group I was 30.24 ± 6.28 s and in Group II was 19.26 ± 3.42 s. The duration of intubation is shorter in Group II than in Group I. The groups showed a highly statistically significant difference ($P < 0.03$) [Figure 3].

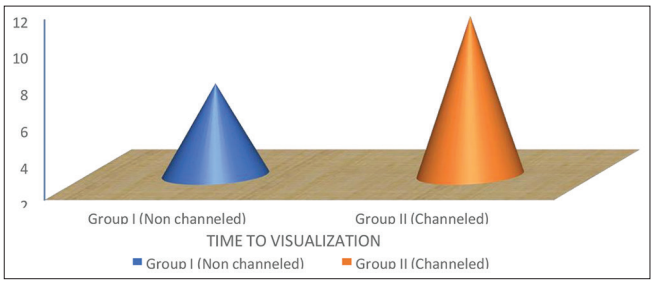


Figure 2: Time to visualization of glottis

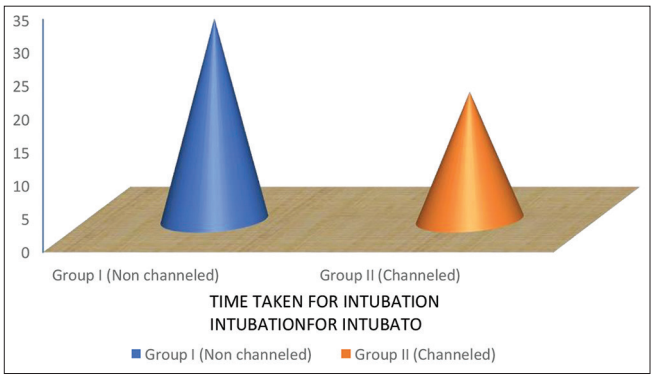


Figure 3: Time taken for intubation

The results of number of attempts, ease of laryngoscope insertion, quality of visualization, and hemodynamic variables were comparable in both the groups [Table 2].

Airway injury was noted in 4 patients in Group I and 2 patients in Group II. The difference in airway injuries was statistically non-significant in both the groups ($P > 0.05$). Assisted maneuver was required in 4 patients in Group I and 1 patient in Group II. The difference was statistically non-significant in both the groups ($P > 0.05$) [Table 3].

DISCUSSION

The prime responsibility of an anesthesiologist is to secure and maintain a patent airway. Complications such as hypoxic brain damage could happen from delayed intubation, misplaced tracheal tube, or airway trauma.[8,9] Laryngoscopy is a procedure performed by anesthesiologists for the purpose of placing an endotracheal tube into the airway of patients to secure airway or administer inhalational drugs during surgery and suctioning of secretions. DL remains gold-standard technique for securing airway but with advancement in technology, videolaryngoscopy has become widely accepted method in both emergency medicine and clinical anesthesia. It has become an alternative technique in cases of anticipated difficult airway situations.

King Vision is a new device; it has two blades: Non-channeled and channeled blades. Minimum of 18-mm mouth opening is required in one with channel while minimum 13 mm mouth opening is required in one without channel.[10] Non-channeled blades are generally thinner, easier to insert, and provide good quality view to the vocal cords even in case of significantly limited mouth opening. Their main disadvantage is that insertion of tracheal tube needs a special angulated introducer and there may be risk of trauma to oro-pharyngeal soft tissues. The channeled blade provides a more reliable direct guide for tracheal tube insertion but may be more difficult to insert in case of limited mouth opening, intra-oral swelling, and large tongue due to its bulkiness.

Table 2: Intubation characteristics

Parameters	Group I	Group II	*P*-value
Success rate			
1st pass success rate	36	39	0.165
2nd pass success rate	4	1	
Number of attempts			
1	36	39	0.165
2	4	1	
Ease of laryngoscope insertion			
Easy	35	32	0.367
Slightly difficult	5	8	
Difficult	0	0	
Quality of visualization			
1	40	40	1
2a	0	0	
2b	0	0	
3	0	0	

Table 3: Complication

Complications	Group I (%)	Group II (%)	*P*-value
Airway injuries	4 (10)	2 (5)	0.398
Assisted maneuvers	4 (10)	1 (2.5)	0.165

The findings of our study suggest that, the mean time taken in Group I was 6.09 ± 0.72 s which is shorter than mean time taken in Group II which was 10.57 ± 2.20 s. The result was statistically highly significant ($P < 0.03$). The reason for longer time in Group II that is patient intubated with channeled blade of King Vision is due to larger width of tip of blade and its bulkiness which makes it slightly difficult to insert it in patient's mouth.

Similar results in context to our findings were reported by Biro and Schlaepfer.[11] In their study, they compared tracheal intubation with channeled versus non-channeled video laryngoscope blades in patients undergoing elective urological surgeries. The authors found that the time to larynx visualization was significantly shorter when non-channeled blade (5 s [4–8 s]) was used compared to channeled blade (11 s [7–14 s]).

Our results also coincide with study conducted by Shah *et al*.[12] They conducted a study on comparison of channeled blade with non-channeled blade of KVVL for oro-tracheal intubation. The laryngeal exposure time was 5.27 ± 3.2 s in non-channeled group whereas it was 7.84 ± 9.01 sec in channeled group.

A similar study was performed by Bajpai that compared intubation performance between channeled and non-channeled blade of King Vision in orotracheal intubation.[13] The time for glottis visualization was 8.5 ± 3 s for Group C (channeled) and 7 ± 2 s for Group NC (non-channeled). These results are in concordance with our study.

Our study also recorded total duration of intubation. Our findings suggest that, the mean duration of intubation in Group II was 19.26 ± 3.42 s compared to 30.24 ± 6.28 s in Group II which was statistically highly significant ($P < 0.03$). The reason for faster intubation time despite slower larynx recognition time is because the channeled blade makes more demanding steering of ETT and omits the blind phase during advancement of ETT.

The results of our study are comparable with study conducted by Shah *et al*. in which they found that the time to

successful intubation was 15.24 ± 10.6 s in channeled blade whereas it was 28.57 ± 14.09 s in non-channeled blade. The time taken was significantly less with channeled blade.

Our results also coincide with study conducted by Biro and Schlaepfer where the time to successful intubation was significantly longer when using non-channeled blade [29s [25–51 s]) compared to channeled blade (17 s [12-27]).

A similar study was performed by Bajpai that compared intubation performance between channeled and non-channeled blade of King Vision in orotracheal intubation. The duration of intubation was found to be shorter when using channeled (24 ± 8.5 s) blade as compared to non-channeled blade (44 ± 5 s) of King Vision.

Both the laryngoscope blades included in our study showed 100% success rate. The 1st pass success rate was 90% in Group I and 97.50% in Group II. 100% patients were intubated in the second pass in both the groups. The difference in the success rate in both the groups was found to be statistically non-significant ($P > 0.05$). No intubation failure was recorded in any of the patients in both the groups.

The success rate findings of VL channeled blade of our study were in concordance to study conducted by Ali *et al*. in which a comparative evaluation of KVVL (channeled blade), McCoy, and Macintosh laryngoscopes for tracheal intubation in patients with immobilized cervical spine. Similarly, the findings of success rate for ETT insertion were comparable to study conducted by Kleine-Brueggeney *et al*. in which evaluation of three non-channeled video laryngoscopes and the Macintosh laryngoscope in patients with a difficult airway was done. Primary outcome was first attempt orotracheal intubation success.[7,14]

The number of attempts, ease of laryngoscope insertion, quality of visualization, hemodynamic variables, oxygen saturation, and end-tidal Co_2 showed no statistically significant difference.

Assisted maneuvers were stated as any external laryngeal manipulation, aided by bougie, changing blade size, any lifting force required, or any redirection of blade. It was noted that patients had some form of impingement in the case of the both the blades. Impingement with the channeled blade occurred over the right aryepiglottic fold. Anticlockwise rotation of the endotracheal tube as it slides off the dedicated slot redirects it toward left overcomes the impingement on the right aryepiglottic fold.

In the case of non-channeled blade, impingement occurred at various places such as epiglottis and anterior subglottic area including the right aryepiglottic fold. Withdrawal of the stylet endotracheal tube and redirection toward the center was done most of the time to facilitate passage of the tube toward the glottic opening.

The reason for impingement at right aryepiglottic fold was central insertion of device. The reasons behind impingement to the anterior glottic structures, especially in the case of the non-channeled blade, could be due to the hyperangulated stylet required to position the endotracheal tube. However, the difference was statistically non-significant in both the groups ($P > 0.05$).

In a similar study conducted by Shah *et al*.,[12] comparing channeled blade versus non-channeled blade of the King Vision™, various impingements which occurred at the laryngeal inlet were observed and maneuvers used to accomplish intubation were noted. Impingement of the endotracheal tube at the glottic inlet was similar in both the groups.

Injury to the airway was assessed by looking for signs of blood lips, mucosa, in oropharyngeal passage, on laryngoscope blades, or endotracheal tube when removed during extubation. There was no statistically significant difference between two groups.

CONCLUSION

The following conclusions are drawn from our study:

- Both the blades of KVVL showed promising results with respect to successful intubation
- The time taken to visualize the glottis by King Vision non-channeled blade was shorter as compared to channeled blade of King Vision
- Although time taken to visualization of glottis was shorter with non-channeled blade, time to intubation was shorter with channeled blade of King Vision
- There was no significant difference in number of attempts and quality of visualization of glottis with both the blades of King Vision
- There was no statistically significant difference in hemodynamic changes in both the groups
- There was also no statistically significant difference with respect to assisted maneuvers and injury to airway in both the groups.

We conclude with our study that the time to video laryngoscopic glottis recognition is longer when using a channeled blade, but time to intubation and the total time to secure the airway are shorter. King Vision channeled blade is better compared to non-channeled blade for laryngoscopy and ETI in general surgical procedures.

REFERENCES

1. Thong SY, Lim Y. Video and optic laryngoscopy assisted tracheal intubation the new era. Anaesth Intensive Care 2009;37:219-33.
2. Apfelbaum JL, Hagberg CA, Caplan RA, Blitt CD, Connis RT, Nickinovich DG, *et al*. Practice guidelines for management of the difficult airway: an updated report by the American Society of Anesthesiologists Task Force on Management of the Difficult Airway. Anesthesiology 2013;118:251-70.
3. Wayne MA, McDonnell M. Comparison of traditional versus videolaryngoscopy in out-of-hospital tracheal intubation. Prehosp Emerg Care 2010;14:278-82.
4. Nouruzi-Sedeh P, Schumann M, Groeben H. Laryngoscopy via Macintosh blade versus GlideScope: Success rate and time for endotracheal intubation in untrained medical personnel. Anesthesiology 2009;110:32-7.
5. Namazi IJ, Sahni S. A comparison of two video laryngoscopes: Truview and kingvision in routine airway management. Int J Anesth Res 2014;2:48-52.
6. Aziz MF, Dillman D, Fu R, Brambrink AM. Comparative effectiveness of the C-MAC video laryngoscope versus direct laryngoscopy in the setting of the predicted difficult airway. J Am Soc Anesthesiol 2012;116:629-36.
7. Ali QE, Amir SH, Ahmed S. A comparative evaluation of King Vision video laryngoscope (channeled blade), McCoy, and Macintosh laryngoscopes for tracheal intubation in patients with immobilized cervical spine. Sri Lankan J Anaesthesiol 2017;25:70-5.
8. Woodall NM, Benger JR, Harper JS, Cook TM. Airway management complications during anaesthesia, in intensive care units and in emergency departments in the UK. Anaesth Crit Care 2012;2:58-64.
9. Metzner J, Posner KL, Lam MS, Domino KB. Closed claims' analysis. Best Pract Res Clin Anaesthesiol 2011;25:263-76.
10. Singhal V, Bhandari G, Shahi KS, Chand G. Comparative study of Mccoy, Airtraq and King's Vision videolaryngoscope in simulated difficult laryngoscopy using rigid neck collar. Ann Int Med Dent Res 2020;6:AN05-9.
11. Biro P, Schlaepfer M. Tracheal intubation with channeled vs. non-channeled videolaryngoscope blades. Rom J Anaesth Int Care 2018;25:97-101.
12. Shah A, Patwa A, Burra V, Shah D, Gandhi B. Comparison of channelled blade with non-channelled Blade of King Vision™ videolaryngoscope for orotracheal intubation: A randomised, controlled, multicentric study. Airway 2019;2:10-6.
13. Bajpai S. A comparative study of intubation performance between channelled vs. non-channelled blade of King Vision Video laryngoscope in orotracheal intubation. J Evid Based Med Healthc 2021;8:732-6.
14. Kleine-Brueggeney M, Buttenberg M, Greif R, Nabecker S, Theiler L. Evaluation of three unchannelled videolaryngoscopes and the Macintosh laryngoscope in patients with a simulated difficult airway: A randomised, controlled trial. Anaesthesia 2017;72:370-8.

How to cite this article: Kashyap KJ, Marwaha D, Singh A, Kumar R, Kaur H. Comparison between Channeled versus Non-Channeled Blade of King Vision Video Laryngoscope in General Surgical Procedures. Int J Sci Stud 2023;11(3):36-41.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Comparative Study between Actofit Pro/Max and Inbody 270 BIA Machine for Measuring Body Composition Parameters

Ajit Dabholkar[1], Pratik Sarogi[2], Ketan Pakhale[3,4,5,6], Ateeb Shaikh[7], Tushar Patil[8]

[1]Professor and Head, Department of Sports Physiotherapy, D. Y. Patil University, Navi Mumbai, Maharashtra, India, [2]Chief Technical Officer, Actofit, Mumbai, Maharashtra, India, [3]Fellow, Department of Obesity Medicine and Diabetes, NHS, United Kingdom, [4]Department of Endocrine and Diabetes, RCP, United Kingdom, [5]Assistant Professor, D.Y Patil University, Navi Mumbai, Maharashtra, India, [6]Chief Scientific Officer, Actofit, Mumbai, Maharashtra, India, [7]Chief Pductro Officer, Actofit, Mumbai, Maharashtra, India, [8]Chief Executive Officer, Actofit, Mumbai, Maharashtra, India

Abstract

Background: The measurement of body parameters such as body weight, body fat %, and body water % is crucial in assessing the health and fitness status of individuals. The Actofit Pro Max/Max and Inbody 270 bioelectrical impedance analysis (BIA) machine are commonly used for this purpose, but their comparative accuracy has not been extensively studied.

Methods: A comparative study was conducted over 319 subjects comprising athletes, standard body type, and obese subjects. The aim of the study was to determine the correlation between the body parameters measured over 30 days of interval with Actofit Pro Max/Max and Inbody 270 BIA machine. Pearson correlation coefficient (r) was used to calculate the data correlation.

Results: The results of the study showed that the change in the body weight, body fat %, and body water % measured over 30 days of interval with Actofit Pro Max/Max is highly correlated with that of the Inbody 270 BIA machine ($r = 0.95$, $P < 0.001$).

Conclusion: The Actofit Pro Max/Max and Inbody 270 BIA machine showed a high correlation in measuring body parameters such as body weight, body fat %, and body water %. These findings suggest that both devices can be used interchangeably for body parameter measurement.

Key words: Accuracy, Actofit Pro Max/Max, Athletes, Body fat %, Body parameters, Body water %, Body weight, Comparative study, Correlation, Fitness status, Health, Inbody 270 BIA machine, Interval, Measurement, Obese subjects, Pearson correlation coefficient, Standard body type

INTRODUCTION

Body composition analysis has become a critical tool for assessing the health and fitness of individuals across a wide range of populations. Accurate measurement of body composition parameters such as body weight, body fat percentage, and body water percentage is essential for personalized nutrition and exercise plans, tracking changes in body composition over time, and monitoring the progress of weight loss or muscle gain programs.[1-4]

Bioelectrical impedance analysis (BIA) is one of the most commonly used methods for measuring body composition due to its non-invasive nature, low cost, and ease of use.[5-7] BIA works by passing a small electrical current through the body and measuring the resistance or impedance to the flow of that current. This resistance is used to calculate body composition parameters, including body fat percentage, lean body mass, and body water percentage.[8-10]

Despite the widespread use of BIA, the accuracy of BIA measurements can vary depending on the type of BIA machine used.[11] There are various BIA machines available on the market with different features, such as different

Access this article online

www.ijss-sn.com

Month of Submission : 04-2023
Month of Peer Review : 05-2023
Month of Acceptance : 06-2023
Month of Publishing : 06-2023

Corresponding Author: Dr. Ateeb Shaikh, Actofit, Mumbai, Maharashtra, India.

frequencies of electrical current, number of electrodes, and algorithms for calculating body composition parameters. Therefore, it is crucial to evaluate the accuracy of different BIA machines before using them for clinical or research purposes.[12]

In this study, we aimed to compare the accuracy of two BIA machines, the Actofit Pro Max/Max and Inbody 270, in measuring body composition parameters such as body weight, body fat percentage, and body water percentage. The Actofit Pro Max/Max is a relatively new BIA machine that uses eight electrodes, while the Inbody 270 is a well-established machine that uses four electrodes.[13] By comparing the measurements obtained from these two machines, we can provide insights into the accuracy of these BIA machines and help healthcare professionals and individuals make informed decisions about which BIA machine to use for their body composition analysis needs.[14]

METHODS

Participants

The study included 319 participants aged between 11 and 90 years, consisting of athletes, standard body type, and obese individuals. The participants were selected based on the criteria of having no known medical conditions that could affect their body composition. The participants were distributed as 101 females and 218 males. Participants were recruited from sports centers, gyms, and community centers.

Instruments

The study utilized two body composition analyzers, the InBody 270 and the Actofit Smart Scale Pro/Max. Both instruments utilize direct segmental multi-frequency BIA to measure various body parameters including body weight, body fat %, and body water %. The InBody 270 operates at frequency ranges of 1 kHz, 5 kHz, and 50 kHz and has a measurement time of <15 s, while the Actofit Smart Scale Pro/Max operates at frequency ranges of 5 kHz and 50 kHz and has a measurement time of <30 s.

The Actofit Pro Max and InBody 270 are both popular body composition analyzers that use BIA technology to measure various body composition parameters such as body fat percentage, muscle mass, and basal metabolic rate.

The technology used in Actofit Smart Scale Pro/Max and InBody Body Impedance Analysis involves the use of BIA.

BIA is a method of assessing body composition by measuring the electrical conductivity of body tissues. Both machines use multiple frequencies of electrical currents to penetrate different layers of body tissues, including fat, muscle, and bone. As the electrical current passes through the body, the machine measures the resistance to the current. Since different types of body tissues have different levels of electrical conductivity, the machine is able to determine the relative amounts of fat, muscle, and water in the body.

The Actofit Smart Scale Pro/Max machine is designed with advanced algorithms that can account for factors such as age, gender, height, and weight to provide accurate and personalized body composition measurements. In addition, the machine is equipped with on scale color displays and user-friendly mobile to make it easy to use and understand the results.

Design

The study was designed as a comparative study between the two body composition analyzers, with the aim of determining the correlation between the measurements obtained from the InBody 270 and Actofit Smart Scale Pro/Max. The study was conducted in two phases, with a 30-day interval between them. During both phases, each participant's body weight, body fat %, and body water % were measured on both the InBody 270 and Actofit Smart Scale Pro/Max. The order in which the instruments were used was randomized to minimize the order effect. The measurements were taken at the same time of day, in a standardized testing environment, and participants were asked to refrain from eating or drinking for at least 2 h before the test. In addition, participants were asked to avoid intense physical activity for 24 h before the test.

Data Analysis

The differential data observed over Phase 1 and Phase 2 were recorded and analyzed to determine the reliability of both instruments. The correlation between the Actofit Smart Scale Pro/Max and InBody 270 data change over Phase 1 and Phase 2 was calculated using the Pearson correlation coefficient. Bland-Altman plots were also used to assess the level of agreement between the two instruments. Furthermore, a multivariate regression analysis was performed to identify the factors that may affect the correlation between the two instruments.

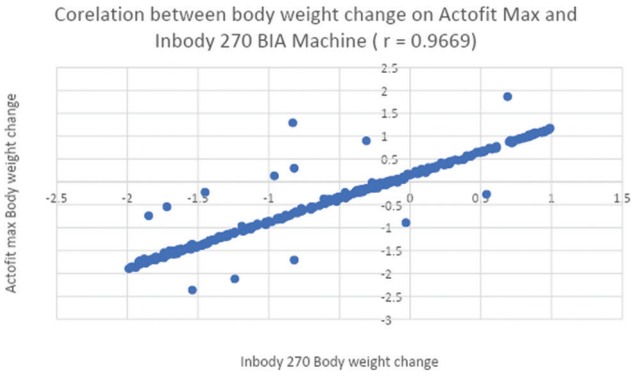
RESULTS

The correlation between body weight change on Actofit Max and Inbody 270 BIA Machine was found to be highly correlated with a Pearson correlation coefficient (r) of 0.9669. The correlation between body fat % change on Actofit Max and Inbody 270 BIA Machine was found to be highly correlated with a Pearson correlation coefficient (r) of 0.9353. The correlation between body water % change on Actofit Max and Inbody 270 BIA Machine was

found to be highly correlated with a Pearson correlation coefficient (r) of 0.9839.

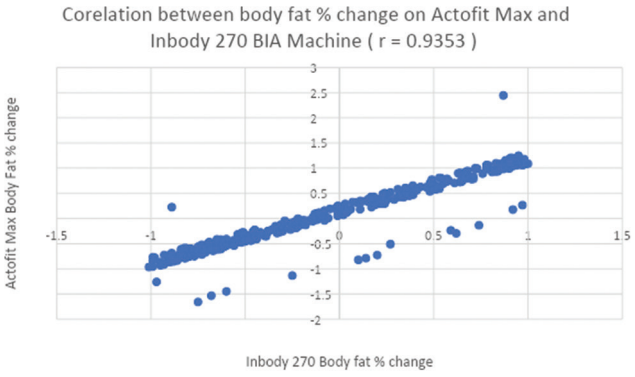
Correlation between Body Weight Change on Actofit Max and Inbody 270 BIA Machine

The change in the body weight over Phase 1 and Phase 2 is measured with Inbody 270 and Actofit Pro Max/Max. Then, the data correlation is plotted as shown. The Pearson correlation coefficient (r) is observed as 0.9669.



Correlation between Body Fat % Change on Actofit Max and Inbody 270 BIA Machine

The change in the body fat % over Phase 1 and Phase 2 is measured with Inbody 270 and Actofit Pro Max/Max. Then the data correlation is plotted as shown. The Pearson correlation coefficient (r) is observed as 0.9353.

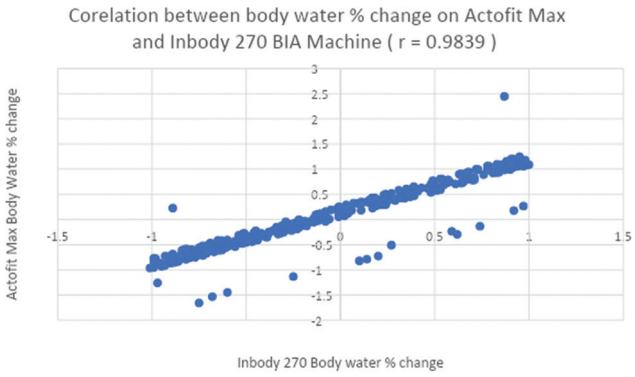


Correlation between Body Water % Change on Actofit Max and Inbody 270 BIA Machine

The change in the body water % over Phase 1 and Phase 2 is measured with Inbody 270 and Actofit Pro Max/Max. Then, the data correlation is plotted as shown. The Pearson correlation coefficient (r) is observed as 0.9839.

SUMMARY

During this comparative study, it is observed that the change in the body parameters such as body weight, body fat %, and body water % measured over 30 days of interval with Actofit Smart Scale ProMax/Max is highly correlated with that of the Inbody 270 BIA machine.



Change in parameter over 30 days	Pearson correlation coefficient between Actofit Pro Max/Max and Inbody 270
Body Weight	0.9669
Body Fat %	0.9353
Body Water %	0.9839

CONCLUSION

The comparative study between Actofit Pro Max/Max and Inbody 270 BIA machine conducted on a sample of 319 subjects has demonstrated that Actofit Smart Scale ProMax/Max is a highly accurate and reliable tool for measuring body composition parameters such as body weight, body fat %, and body water %. The results indicate that the change in the body parameters measured over a period of 30 days using Actofit Pro Max is highly correlated with that of the Inbody 270 BIA machine. This suggests that Actofit Pro Max can be used as a viable alternative to Inbody 270 for measuring body composition parameters. Overall, this study provides evidence supporting the effectiveness of Actofit Pro Max/Max and its potential utility in clinical settings.

REFERENCES

1. Baumgartner RN, Chumlea WC, Roche AF. Estimation of body composition from bioelectrical impedance of body segments. Am J Clin Nutr 1989;50:221-6.
2. Houtkooper LB, Going SB, Lohman TG, Roche AF, Van Loan M. Bioelectrical impedance estimation of fat-free body mass in children and youth: A cross-validation study. J Appl Physiol (1985) 1992;72:366-73.
3. Kushner RF, Gudivaka R, Schoeller DA. Clinical characteristics influencing bioelectrical impedance analysis measurements. Am J Clin Nutr 1996;64:423S-7.
4. Schaefer F, Georgi M, Wuhl E, Scharer K. Body mass index and percentage fat mass in healthy German schoolchildren and adolescents. Int J Obes Relat Metab Disord 1998;22:461-9.
5. Piccoli A, Rossi B, Pillon L, Bucciante G. A new method for monitoring body fluid variation by bioimpedance analysis: The RXc graph. Kidney Int 1994;46:534-9.

6. Kyle UG, Bosaeus I, De Lorenzo AD, Deurenberg P, Elia M, Gómez JM, *et al*. Bioelectrical impedance analysis--part I: Review of principles and methods. Clin Nutr 2004;23:1226-43.
7. Malavolti M, Mussi C, Poli M, Fantuzzi AL, Salvioli G, Battistini N, *et al*. Cross-calibration of eight-polar bioelectrical impedance analysis versus dual-energy X-ray absorptiometry for the assessment of total and appendicular body composition in healthy subjects aged 21-82 years. Ann Hum Biol 2003;30:380-91.
8. Lee SY, Gallagher D. Assessment methods in human body composition. Curr Opin Clin Nutr Metab Care 2008;11:566-72.
9. Duren DL, Sherwood RJ, Czerwinski SA, Lee M, Choh AC, Siervogel RM, *et al*. Body composition methods: Comparisons and interpretation. J Diabetes Sci Technol. 2008;2:1139-46.
10. Kyle UG, Bosaeus I, De Lorenzo AD, Deurenberg P, Elia M, Gómez JM, *et al*. Bioelectrical impedance analysis--part II: Utilization in clinical practice. Clin Nutr 2004;23:1430-53.
11. Dehghan M and Merchant AT. Is bioelectrical impedance accurate for use in large epidemiological studies?. Nutr J 2008;7:26.
12. Deurenberg P, Weststrate JA, Seidell JC. Body mass index as a measure of body fatness: Age-and sex-specific prediction formulas. Br J Nutr 1991;65:105-14.
13. Ling CH, de Craen AJ, Slagboom PE, Gunn DA, Stokkel MP, Westendorp RG, *et al*. Accuracy of direct segmental multi-frequency bioimpedance analysis in the assessment of total body and segmental body composition in middle-aged adult population. Clin Nutr 2011;30:610-5.
14. Bosy-Westphal A, Booke CA, Blöcker T, Kossel E, Goele K, Later W, *et al*. Measurement site for waist circumference affects its accuracy as an index of visceral and abdominal subcutaneous fat in a Caucasian population. J Nutr 2010;140:954-61.

How to cite this article: Dabholkar A, Sarogi P, Pakhale K, Shaikh A, Patil T. Comparative Study between Actofit Pro/Max and Inbody 270 BIA Machine for Measuring Body Composition Parameters. Int J Sci Stud 2023;11(3):42-45.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Assessment of Oral Health Status among Garment Industry Workers in Bangalore City: A Cross-sectional Study

J N Rukmini[1], Niharika Benjamin[2], D Satyanarayana[3], Deepmala Pande[4]

[1]Assistant Professor, Department of Public Health Dentistry, M.R. Ambedkar Dental College and Hospital, Bangaluru, Karnataka, India, [2]Assistant Professor, Department of Public Health Dentistry, Hitkarini Dental College and Hospital, Jabalpur, Madhya Pradesh, India, [3]Associate Professor, MNR Dental College, Sangareddy, Telangana, India, [4]Assistant Professor, Department of Prosthodontics and Crown and Bridge, Hitkarini Dental College and Hospital, Jabalpur, Madhya Pradesh, India

Abstract

Aim: The aim of this study was to assess oral health status among garment industry workers in Bangalore city.

Methodology: A cross-sectional study was conducted among 1022 garment industry workers, to assess the oral health status in Bangalore city. The type III clinical examination was carried out as per the American Dental Association Specification (1970), and oral health status was assessed using the WHO Oral Health Assessment Form 1997. Data were analyzed using SPSS version 15. Categorical data were analyzed using Chi-square test, and $P < 0.05$ was considered statistically significant.

Results: In the present study out of total 1022 study subjects, 21.9% of subjects were male and 78.1% of subjects were female. 0.5% had ulceration, sores, erosions, and fissures on head, neck, and limbs, all of them were female ($P = 0.235$). 4.9% of the population had ulceration (aphthous, herpetic, and traumatic) which was found to be the most common oral mucosal condition and more prevalent among males ($P < 0.001$**). The most common enamel opacity was demarcated opacity, and females ($P < 0.001$**) were most affected. Mild fluorosis was prevalent among females ($P < 0.001$**). The prevalence of periodontitis was 33.8% and dental caries was 73.9%, of which females were more prevalent.

Conclusion: The findings of the study showed that despite the low prevalence of extraoral lesions, temporomandibular joint signs and symptoms, and intraoral lesions, the Community Periodontal Index and loss of attachment scores were found high. The mean decayed, missing, and filled teeth scores were also high, and prosthetic status was poor.

Key words: Community periodontal index, Cross-sectional study, Decayed, missing, and filled teeth, Loss of attachment, Oral health status

INTRODUCTION

Health is a fundamental right of every individual, and oral health is an integral part of general health. Various factors such as socioeconomic status, occupation, and education play a major role in maintenance of good oral health.[1] Occupation is an important component of socioeconomic status which plays a vital role in both individual's life and a nation's progress.[2] Health at work and healthy working environment are among the most valuable assets for individual, community, and the country. In light of rapid economic growth and industrial progress in our country, it becomes imperative that safety and health at the workplace be given its due importance. Instead of investigating accidents after they have occurred, taking a high toll of human life, it is now felt that preventing the occurrence of industrial disasters and occupational diseases is a much better idea.[3]

Majority of people employed in various industries are exposed to hazardous environment. This exposure deteriorates the general and oral health of people, and every occupation is associated with one or other ill effects on health. Various studies have shown the association between occupational exposure and greater incidence of oral diseases, thus occupational health is quite significant.[3,4]

Access this article online

www.ijss-sn.com

Month of Submission : 04-2023
Month of Peer Review : 05-2023
Month of Acceptance : 06-2023
Month of Publishing : 06-2023

Corresponding Author: J N Rukmini, M.R. Ambedkar Dental College and Hospital, Bangaluru, Karnataka, India.

In India, there are many industries, and recently, garment industry has been emerged in a big way competing at global level and has provided employment to lakhs of people.[5] It employs about 40 million people in various countries of the world.[6] The garment industry in India is among the largest in Asia and, indeed, in the world. Karnataka has a huge garment industry sector, producing finished material both for National and international markets. Officially, there are 780 garment manufacturing units in Bangalore alone with nearly 80% of the workforce comprising women.[7]

The unhealthy and unsafe work environment in garment industries results in several health problems. Various studies have reported that many of textile workers suffered from cancer, backache, joint pains, headache, and general tiredness.[8-10] Several previous reports indicate that damage may occur to hard oral tissues as a result of occupational hazards. The science of occupational health hazards covers a wide field, such as work physiology, occupational hygiene, occupational psychology, and occupational toxicology.[11,12] Their effect on dental health includes notching of the enamel of tooth, sometimes dentin, and tooth abrasion in noise-exposed workers.[2,13] Occupation stress can affect both physical and emotional well-being; eventually, it leads to gingivitis, periodontitis, and poor oral hygiene.[14-16]

The garment industry, which has been traditionally a low-profile sector, has shown a tremendous growth over the last two decades. In Bangalore, the workforce is made up largely of female workers.[17] There has been no study done so far regarding the oral health status and treatment needs of garment industry workers in Bangalore. Hence, the present study has been undertaken to assess oral health status so that a suitable plan for the preventive and curative treatments for them can be made.

MATERIALS AND METHODS

This cross-sectional study was conducted among 1022 garment industry workers in Bangalore city. Bangalore city is divided into four zones (North, East, West and South) and for the purpose of this study a multistage random sampling method was used to select the study population from these zones. In the first stage, South zone was selected using lottery method. South zone has four major garment industries from which Aditya Birla Nuvo Ltd. was selected in the second stage, again by using lottery method. Ethical clearance was taken from the Ethical Committee, Dr. Syamala Reddy Dental College, Hospital and Research Centre, Bangalore. Informed consent was taken from study subjects before the beginning of examination. Workers present in the industry on the day of examination and those workers who were willing to give consent to participate were included in the study. Workers with any systemic conditions and who were taking medication for any illness were excluded from the study. Demographic data, tobacco habits, and oral hygiene practices were collected from individuals, prior to the examination. Oral examination was conducted by one examiner using a plane mouth mirror and Community Periodontal Index (CPI) probe on ordinary chair under natural daylight. The WHO Oral Health Assessment Form (1997) was used to assess extraoral lesions, temporomandibular joint symptoms and signs, oral mucosal lesions, periodontal status as per CPI, loss of attachment (LOA), caries status as per decayed, missing, and filled teeth (DMFT) index, and dentofacial anomalies.

Statistical Analysis

Descriptive and inferential statistical analysis was carried out with SPSS 15 software. Results on continuous measurements were presented as mean ± SD (min–max), and results on categorical measurements were presented in number (%). Significance was set at 5% level; Chi-square/ Fisher's exact and Student's *t*-tests were used to find the significance of study parameters.

RESULTS

A total of 1022 study subjects were examined, of which 21.9% of subjects were male and 78.1% of subjects were female. In the present study 71.1% of the study subjects were literate, among which higher number of females (72.6%) than males (66.1%) were found literate. According to the occupational classification as stated by the garment industry, a number of tailors were highest among the workers, and among them, female workers were more ($P < 0.001$** [Table 1]). Majority (93.2%) of workers used toothpaste and brush to clean their teeth, in which majority of them were female. Eight-five percent of the participants had no deleterious habits. Among all deleterious habits, smoking was found to be most prevalent among males than females [Table 2]. When oral mucosa was examined, ulceration was found to be the most common oral mucosal condition affecting 4.9% of the study population, the mucosal ulcerations were more prevalent among males as compared to females ($P < 0.001$**). The buccal mucosa among various oral mucosal location was found to be most commonly affected with the mucosal lesions and the occurrence of mucosal lesions on buccal mucosa was more prevalent among males than females ($P < 0.001$** [Table 3]). Among all study subjects, the most common enamel opacity was demarcated opacity followed by diffused opacity, which was more prevalent among females ($P < 0.001$**); the present study showed a high prevalence of mild fluorosis, which was more prevalent among females (3.6%) as compared to males (2.2%, $P < 0.001$** [Table 4]). The

Table 1: Distribution of study population in relation to gender according to demographic characteristics, oral hygiene practice, brushing, and personal habits

Demographic details	Gender		*P*-value
	Male (%)	Female (%)	
Age in years			<0.001**¥
19–20	5 (2.2)	74 (9.3)	
21–30	131 (58.5)	364 (45.6)	
31–40	65 (29)	321 (40.2)	
41–50	23 (10.3)	23 (2.9)	
>50	0 (0)	16 (2)	
Education			
Illiterate	76 (33.9)	219 (27.4)	0.066+†
Primary school certificate	21 (9.4)	58 (7.3)	
Middle school certificate	20 (8.9)	122 (15.3)	
High school certificate	85 (37.9)	318 (39.8)	
Intermediate or post-high school diploma	22 (9.8)	81 (10.2)	
Graduate or post-graduate	0 (0)	0 (0)	
Profession or honors	0 (0)	0 (0)	
Occupation			
Tailor	134 (59.8)	668 (83.7)	<0.001**¥
Operator	10 (4.5)	27 (3.4)	
Checker	16 (7.1)	8 (1)	
Cutters	15 (6.7)	0 (0)	
Helpers	15 (6.7)	56 (7)	
Ironer	8 (3.6)	29 (3.6)	
Mechanic	10 (4.5)	0 (0)	
Supervisor	0 (0)	10 (1.3)	
Trimmer	8 (3.6)	0 (0)	
Miscellaneous	8 (3.6)	0 (0)	

**Strongly significant (*P*-value: *P*≤0.01), ¥Chi-square test , †Fisher's exact test

Table 2: Distribution of study population in relation to gender according to frequency of brushing and oral hygiene practice

Oral hygiene and personal habits	Gender		*P*-value
	Male (%)	Female (%)	
Frequency of brushing			
Lesser than once daily	3 (1.3)	2 (0.3)	0.119¥
Once daily	214 (95.5)	771 (96.6)	
Twice daily	7 (3.1)	25 (3.1)	
Oral hygiene practices			
Toothpaste and toothbrush	200 (89.3)	752 (94.2)	<0.001**†
Tooth powder with brush	3 (1.3)	5 (0.6)	
Toothpaste with hand	2 (0.9)	13 (1.6)	
Tooth powder with hand	17 (7.6)	23 (2.9)	
Neem stick	2 (0.9)	0 (0)	
Charcoal	0 (0)	5 (0.6)	
Personal habits			
No habits	94 (42)	775 (97.1)	<0.001**¥
Smoking	82 (36.6)	2 (0.3)	
Pan chewing	36 (16.1)	2 (0.3)	
Tobacco chewing	0 (0)	18 (2.3)	
Smoking and Pan	12 (5.4)	1 (0.1)	

**Strongly significant (*P*-value: *P*≤0.01), ¥Chi-square test, †Fisher's exact test

Table 3: Distribution of study population in relation to gender according to oral mucosal conditions and its location

Oral Mucosa	Gender		*P*-value
	Male (%)	Female (%)	
Oral mucosa			001**¥
Condition			
No abnormal condition	192 (85.7)	762 (95.5)	
Malignant tumor (oral cancer)	0 (0)	0 (0)	
Leukoplakia	0 (0)	0 (0)	
Lichen planus	0 (0)	0 (0)	
Ulceration (aphthous, herpetic, and traumatic)	32 (14.3)	18 (2.3)	
Acute necrotizing gingivitis	0 (0)	8 (1)	
Candidiasis	0 (0)	0 (0)	
Abscess	0 (0)	10 (1.3)	
Other conditions	0 (0)	0 (0)	
Not recorded	0 (0)	0 (0)	
Location			
Normal	192 (85.7)	762 (95.5)	<0.001**¥
Vermillion border	0 (0)	0 (0)	
Commissure	0 (0)	0 (0)	
Lips	0 (0)	0 (0)	
Sulci	0 (0)	10 (1.3)	
Buccal mucosa	32 (14.3)	23 (2.9)	
Floor of mouth	0 (0)	0 (0)	
Tongue	0 (0)	0 (0)	
Hard and/or soft tissue	0 (0)	0 (0)	
Alveolar ridges/gingival	0 (0)	8 (1)	
Not recorded	0 (0)	0 (0)	

**Strongly significant (P-value: *P*≤0.01), ¥Chi-square test

Table 4: Distribution of study population in relation to gender according to enamel opacities or hypoplasia and dental fluorosis

Dental defects	Gender		*P*-value
	Male (%)	Female (%)	
Enamel opacity/hypoplasia			
Normal	189 (84.4)	698 (87.5)	<0.001**¥
Demarcated opacity	0 (0)	52 (6.5)	
Diffuse opacity	6 (2.7)	30 (3.8)	
Hypoplasia	12 (5.4)	5 (0.6)	
Other defects	0 (0)	0 (0)	
Demarcated and diffuse opacities	5 (2.2)	0 (0)	
Demarcated opacity and hypoplasia	12 (5.4)	8 (1)	
Diffuse opacity and hypoplasia	0 (0)	0 (0)	
All three conditions	0 (0)	5 (0.6)	
Not recorded	0 (0)	0 (0)	
Dental fluorosis			
Normal	212 (94.6)	725 (90.9)	<0.001**¥
Questionable	0 (0)	10 (1.3)	
Very mild	7 (3.1)	2 (0.3)	
Mild	5 (2.2)	29 (3.6)	
Moderate	0 (0)	27 (3.4)	
Severe	0 (0)	5 (0.6)	
Excluded	0 (0)	0 (0)	
Not recorded	0 (0)	0 (0)	

**Strongly significant (*P*-value: *P*≤0.01), ¥Chi-square test

study suggests that the participants had a high prevalence of calculus, which was more prevalent among females (52%) as compared to males (67.9%) ($P < 0.001$**), 74.6% of males had 0–3 mm of LOA, 18.8% had 4–5 mm of LOA, and 4.5% of them had 6–8 mm of LOA. Among all the study subjects, majority (66.1%) of them had 0–3 mm of LOA,

which was more prevalent among females ($P < 0.001$** [Table 5]). There was a statistically significant association between gender and LOA, whereas an association between gender and CPI was not significant (CPI: $P = 0.518$ and LOA: $P = 0.016$* [Table 5]). In the present study, DMFT and gender showed a statistically significant association with greater number of females having a DMFT score of 3–5 ($P < 0.001$** [Table 6]). This study suggested that females had significantly higher mean DMFT (3.53 ± 2.85) as compared to males (2.28 ± 2.28 [Table 7]).

DISCUSSION

Various studies have been conducted among garment industry workers to assess the general health, but there is no study done so far regarding the oral health status and treatment needs of garment industry workers. Hence, the present study results have been discussed along with general health of garment industry workers and oral health status and treatment needs of other factory workers. Demographic data of the respondents in the present study had more number of females (78%) when compared to males (22%). This difference is similar to the findings of study done by Joseph and Kiran, where women were the major workforce in garment industry.[7] Majority (39.4%) had just the higher school education, and among them, females were more. This is in equivalence with the study by Tirth *etal* in that educational qualification of the workers was low.[18] In the present study, smoking (8.2%) was found to be more prevalent among all the deleterious habits and it was more prevalent in males. The overall prevalence of tobacco (15%) was less than the study reported by Sudhanshu *et al.* among salt industry workers (49.4%).[19] Most of the health problems that the garment workers suffered are from the occupational hazards including long working hours, absence of leave facilities, congested and over-crowded working conditions, absence of health facilities and safety measures, absence of staff amenities, and lack of safe drinking water.[11] In the present study, ulceration, i.e., aphthous, herpetic, and traumatic (4.9%), was found to be the most common oral mucosal condition among males. The most common location involved was buccal mucosa (5.4%). It was comparable to the study

Table 5: Distribution of study population according to community periodontal index (CPI) and loss of attachment (LOA), in relation to gender

Periodontal status	Gender		*P*-value
	Male (%)	Female (%)	
CPI			
A. Healthy	5 (2.2)	66 (8.3)	<0.001**¥
B. Bleeding	5 (2.2)	18 (2.3)	
C. Calculus	152 (67.9)	415 (52)	
D. Pocket	47 (21)	233 (29.2)	
E. Pocket 6 mm or more (black band on probe not visible)	15 (6.7)	54 (6.8)	
F. Excluded sextant	0 (0)	0 (0)	
G. Not recorded	0 (0)	12 (1.5)	
LOA			
0–3 mm	167 (74.6)	509 (63.8)	<0.001**¥
4–5 mm (CEJ within black band)	42 (18.8)	222 (27.8)	
6–8 mm (CEJ between upper limit of black band and 8–5 mm ring)	10 (4.5)	49 (6.1)	
9–11 mm (CEJ between 8.5 mm and 11.5 mm rings)	0 (0)	0 (0)	
12 mm or more (CEJ beyond 11.5 mm ring)	5 (2.2)	0 (0)	
Excluded sextant	0 (0)	12 (1.5)	
Not recorded	0 (0)	6 (0.8)	

¥Chi-square test

Table 6: Distribution of study population according to decayed, missing, and filled teeth scores in relation to gender

Dental caries status	Gender		Total (*n*=1022)	*P*-value
	Male (*n*=224) (%)	Female (*n*=798) (%)		
Decay				
0	96 (42.9)	170 (21.3)	266 (26)	<0.001**¥
1–2	61 (27.2)	236 (29.6)	297 (29.1)	
3–5	54 (24.1)	258 (32.3)	312 (30.5)	
5–10	13 (5.8)	134 (16.8)	147 (14.4)	
11–20	0 (0)	0 (0)	0 (0)	
>20	0 (0)	0 (0)	0 (0)	
Missing				
0	154 (68.8)	606 (75.9)	760 (74.4)	0.014¥
1–2	65 (29)	162 (20.3)	227 (22.2)	
3–5	5 (2.2)	18 (2.3)	23 (2.3)	
5–10	0 (0)	12 (1.5)	12 (1.2)	
11–20	0 (0)	0 (0)	0 (0)	
>20	0 (0)	0 (0)	0 (0)	
Filled				
0	207 (92.4)	719 (90.1)	926 (90.6)	0.570¥
1–2	12 (5.4)	54 (6.8)	66 (6.5)	
3–5	5 (2.2)	25 (3.1)	30 (2.9)	
5–10	0 (0)	0 (0)	0 (0)	
11–20	0 (0)	0 (0)	0 (0)	
>20	0 (0)	0 (0)	0 (0)	
DMFT				
0	71 (31.7)	144 (18)	215 (21)	<0.001**¥
1–2	61 (27.2)	184 (23.1)	245 (24)	
3–5	67 (29.9)	269 (33.7)	336 (32.9)	
5–10	25 (11.2)	189 (23.7)	214 (20.9)	
11–20	0 (0)	12 (1.5)	12 (1.2)	
>20	0 (0)	0 (0)	0 (0)	

**Strongly significant (*P*-value: *P*≤0.01), ¥Chi-square test, DMFT: Decayed, missing, and filled teeth

Table 7: Distribution of mean number of decay, missing, and filled DMFT according to gender

Gender	Decayed	Missing	Filled	DMFT
Male	1.71±2.11	0.42±0.72	0.14±0.63	2.28±2.28
Female	2.9±2.51	0.43±1.07	0.2±0.73	3.53±2.85
Total	2.64±2.48	0.43±1	0.19±0.71	3.26±2.78
P-value	<0.001**€	0.979€	0.253€	<0.001**€

**Strongly significant (*P*-value: *P*≤0.01), €Student's *t*-test, DMFT: Decayed, missing, and filled teeth

done by Pinkerton *et al*., in which results suggest that persons exposed to higher levels of formaldehyde over a longer period of time may be at an increased risk for myeloid leukemia and for cancer of the buccal cavity.[20] This was supported by the study by Li *et al*., in which female workers in the Shanghai textile industry were found to be at increased risks of nasopharyngeal cancer associated with cotton dust, exposure to endotoxin, and dyes.[10] The most common enamel opacity was demarcated opacity 5.1%, followed by diffused opacity 3.5%, which was more prevalent among females. The reason for the present finding could be due to differences in prevalence and frequency of occurrence in different arches, study suggest the need for further research into the occurrence of this condition in particular the causal factors for the occurrence of enamel defects need to be researched. The study showed that the age group > 50 years had the highest mean CPI value (3.5 ± 0.52) and LOA (1.61 ± 1.160) was found to be highest among 41–50 years of age. The prevalence of periodontitis in the present study was 33.8%, which is less when compared to the study done by Sudhanshu *et al*., in which the prevalence was 96.4%.[19] The study suggests that the study population had a high prevalence of calculus 55.5% and majority 66.1% of them had 0–3 mm of LOA, which was more prevalent among females. The results of the present study are in accordance with the studies done on factory workers in China and in Brazil which observed that calculus was the most common finding among industrial workers.[10,21] Furthermore, it was observed that the prevalence of periodontal pockets was more among the industrial workers than the general population. The reason for the present finding could be due to the presence of metallic dust in the plaque and calculus of industrial workers which can act as an irritating factor causing periodontal disease and pathogenesis.[22] Overall, the present study shows that the prevalence of dental caries was 73.9%, and females (61.44%) were affected more. This is in support with the study done by Sudhanshu *et al*., in which the prevalence of dental caries was higher among the construction workers of Chennai, India.[19] However, it was lower than those which were obtained among the textile industry and sweet industry workers of Israel.[4] This might be due to the poor oral health knowledge and practices among the study population, as the subjects belonged to the rural communities of the third-world countries. It is verified that caries history most deeply involves some kind of manual workers, such as construction foremen and carpenters than those dealing with administrative functions, although no statistical differences were observed.[23] The workplace environment of the individuals has an influence on their oral health status through the behavior and habits which are exerted by their personal and work characteristics. The nature of this study was cross-sectional study, which thus precluded the ability in drawing inferences about causal relationships. Second, socioeconomic status, the duration of the exposure of the adverse habits, and the duration of the working years were not assessed in the present study. Since it was a baseline study, more research is required, which involves a longitudinal study on the same target population, which impinges on the risk factors which are involved in the causation of oral disease.

CONCLUSION

The findings of the study showed that despite the low prevalence of intraoral lesions, the enamel hypoplasia, dental fluorosis, CPI, and LOA scores were found high. The mean DMFT scores were also high indicating the urgent need of oral health care. It is seen that occupation plays an important role by providing an environment which could be health deleterious if proper awareness is not present about its effect on individual's life, further a person's occupation also influences the behavior which can incorporate some harmful habits in peoples lifestyle, as seen in the present study that majority of people were using the tobacco. It can be concluded that the garment industry workers are a part of very important economic sector of India and their overall health should be given the due consideration. Further studies assessing the treatment need and studies to establish the causative factors for the health problems are recommended.

REFERENCES

1. Bansal M, Veeresha K. Oral health status and treatment needs among factory employees in Baddi-Barotiwala-Nalagarh industrial hub, Himachal Pradesh, India. Indian J Oral Sci 2013;4:105.
2. Nahar N, Ali RN, Begum F. Occupational health hazards in garment sector. Int J Bio Res 2010;2:1-6.
3. Tirth A, Yadav V, Tangade PS, Ravishankar TL, Chaudhary S, Mathur A. Assessment of dental caries status, periodontal health and oral hygiene practices among two populations of Moradabad city, India. Int J Occup Saf Health 2013;3:8-11.
4. Sudhanshu S, Pankaj A, Sorabh J, Nidhi S. Dental diseases of acid factory workers globally-Narrative review article. Iran J Public Health 2014;43:1-5.
5. Chand A. Physical and psychological health problems of garment workers in the Fiji. Pac Public Health 2006;13:65-70.
6. Padmini DS, Venmathi A. Unsafe work environment in garment industries, Tirupur, India. J Environ Res Dev 2012;7:7-9.
7. Joseph B, Kiran PR. A stitch in a time. Annual health appraisal of garment industry employees. Pak J Med Sci 2008;24:104-8.
8. Prpić-Mehičić G, Buntak-Kobler D, Jukić S, Katunarić M. Occupational tooth-wear in clothing industry workers. Coll Antropol 1998;22 Suppl:241-9.
9. Chandra N. Occupational hazards among male and female sewing machine operators in a garment manufacturing units. Int J Multidiscip Res 2011;1:196-200.
10. Li W, Ray RM, Gao DL, Fitzgibbons ED, Seixas NS, Camp JE, *et al*. Occupational risk factors for nasopharyngeal cancer among female textile workers in Shanghai, China. Occup Environ Med 2006;1:39-44.
11. Mehta R. Major health risk factors prevailing in garment manufacturing units of Jaipur. J Ergonom 2012;2:102.
12. Tuominen M, Tuominen R, Ranta K, Ranta H. Association between acid fumes in the work environment and dental erosion. Scand J Work Environ Health 1989;15:335-8.
13. Kovacevic M, Belojevic G. Tooth abrasion in workers exposed to noise in

the Montenegrin textile industry. Ind Health 2006;44:481-5.
14. Liyanagea DM. Is Occupational Stress a Good Predictor of Turnover Intention? Evidence from a Leading Garment Manufacturer in Sri Lanka. In: Proceedings of the 3rd International Conference on Management and Economics. Sri Lanka: Faculty of Management and Finance, University of Ruhuna; 2014. p. 285-92.
15. Kumar P, Mugundhan K, Visagavel K. Occupational health and safety in textile industry. Int J Res Eng Technol 2014;3:168-172.
16. Jaiswal A. A study of the occupational health function among female textile workers. Int J Sociol Anthropol 2011;3:109-14.
17. Shanbhag DN, Joseph B. Mental health status of female workers in private apparel manufacturing industry in Bangalore City, Karnataka, India. Int J Collab Res Intern Med Public Health 2011;12:1893-900.
18. Tirth A, RaviShankar, Tandon V. Oral hygiene practices and periodontal health among brass industry workers and general population of Moradabad city, India. J Oral Health Res 2013;4:168-172.
19. Sanadhya S, Nagarajappa R, Sharda AJ, Asawa K, Tak M, Batra M, *et al*. The oral health status and the treatment needs of salt workers at Sambhar Lake, Jaipur, India. J Clin Diagn Res. 2013;7:1782-6.
20. Pinkerton LE, Hein MJ, Stayner LT. Mortality among a cohort of garment workers exposed to formaldehyde: An update. Occup Environ Med 2004;61:193-200.
21. Ind JE, Jeffries DJ. Needlestick injury in clothing industry workers and the risks of blood-borne infection. Occup Mod (Lond) 1999;49:47-9.
22. Sakthi SS. Periodontal health status and treatment needs among building construction workers in Chennai, India. J Int Oral Health 2011;3:12.
23. Tomita NE, Chinellato LE, Lauris JR, Kussano CM, Mendes HJ, Cardoso MT. Oral health of building construction workers: An epidemiological approach. J Appl Oral Sci 2005;13:24-7.

How to cite this article: Rukmini JN, Benjamin N, Satyanarayana D, Pande D. Assessment of Oral Health Status among Garment Industry Workers in Bangalore City: A Cross-Sectional Study. Int J Sci Stud 2023;11(3):46-51.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Ambu AuraGain versus Intubating Laryngeal Mask Airway (Fastrach) as Conduits for Blind Intubation – A Prospective Randomized Study

Harjeet Singh Arora[1], Brij Mohan[1], Anamika Badhan[2], Harjinder Kaur[3]

[1]Professor, Department of Anaesthesiology and Critical Care, Government Medical College, Amritsar, Punjab, India, [2]3rd year Junior Resident, Department of Anaesthesiology and Critical Care, Government Medical College, Amritsar, Punjab, India, [3]Assistant Professor, Department of Anaesthesiology and Critical Care, Government Medical College, Amritsar, Punjab, India.

Abstract

Introduction: The original laryngeal mask airway (LMA) was the first supraglottic airway introduced into clinical practice and was invented by DR. Archie Brain in 1981. There have been several modifications to the LMA over the years – camera attachments, conduits for endotracheal intubation, gastric channel, and so on. The present study was done to compare the efficacy of new second-generation SGA Ambu®AuraGain (AAG) and Intubating LMA as conduits for blind intubation.

Materials and Methods: This prospective study was carried out in the "Department of Anesthesiology, Government Medical College, Amritsar," on 60 patients in the age group of 18–60 years of either sex and the American Society of Anesthesiologists Grade I and II. The patients were randomly divided into two groups of 30 each and were comparable in terms of age, sex, duration, and nature of the procedure they underwent. The two groups were comparable in demographic data and patient characteristics.

Results: The successful intubation rate through FT-LMA and AG-LMA was 96.66% and 33.33%, respectively. The difference in the overall success rate of intubation between both groups was highly significant with $P < 0.05$.

Conclusion: Fastrach LMA has a higher success rate of intubation than AAG.

Key words: Airway management, Ambu AuraGain, Fastrach LMA, Intubation

INTRODUCTION

Airway management is the most essential skill that an anesthesiologist has to acquire. The most definite way of securing an airway is by endotracheal intubation. Today, we have far advanced from the conventional old red rubber tube. One such equipment that has stood out from all the other conventional equipment is the laryngeal mask airway (LMA).[1]

Supraglottic airway devices came into existence for short surgeries, and advancement came into supraglottic airway devices for gastric channels, for blind intubation. Supraglottic devices are easy to use and maintain and useful in many difficult situations where direct laryngoscopy is impossible or difficult. They remain above the vocal cords, but provide a hands-free means of ventilation and also cause lesser gastric distension.[2]

There have been several modifications to the LMA over the years, addition of venting ports, intubation aids, camera attachments, ability to use it as an endotracheal intubation conduit, gastric channel, and so on. LMA ProSeal is the most complex of the specialized laryngeal mask devices.[3]

Intubating LMA (FT-LMA) was first described by Brain[1] in 1997; it became available for commercial use in the United States shortly thereafter. It is specially designed to facilitate intubation either blindly or through fiberoptic assistance in a neutral head position similar to the position produced by the neck collar or manual in-line stabilization.[4] FT-LMA has been proven for its role in the anticipated difficult intubations, cervical spine injuries, and limited airway access situations.[5]

Access this article online

www.ijss-sn.com

Month of Submission : 04-2023
Month of Peer Review : 05-2023
Month of Acceptance : 06-2023
Month of Publishing : 06-2023

Corresponding Author: Dr. Harjinder Kaur, Government Medical College, Amritsar, Punjab, India.

A dedicated wire-reinforced silicone endotracheal tube is advocated for intubation through the FT-LMA. The unique characteristics of this tube are the straight alignment, wire reinforcement, and presence of a conical Touhy-like tip made of silicone, which is less traumatic than a conventional polyvinyl chloride endotracheal tube. However, the low-volume, high-pressure cuff of this tube makes it less suitable for prolonged use. Furthermore, it is very expensive and not so easily available.[6]

Ambu AuraGain (AAG) is a new single supraglottic airway device (SGA) with the gastric channel, made to facilitate ventilation and intubation. Its soft rounded curve follows the anatomy of the airway and ensures rapid placement and provides high seal pressures. It has an integrated gastric access channel; an integrated bite absorption area prevents airway occlusion.

MATERIALS AND METHODS

This study was conducted in the Department of Anesthesia and Intensive Care, Guru Nanak Dev Hospital, attached to Government Medical College, Amritsar, with permission of the Institutional Ethics Committee, Government Medical College, Amritsar. Prior informed consent was taken from all the cases. After obtaining approval from the Institutional Ethics Committee, Government Medical College, Amritsar, we planned to carry out a randomized prospective study of 60 patients of the American Society of Anesthesiologists (ASA) physical status I and II and age group of 18–60 years posted for elective general surgery under general anesthesia. The sample size has been calculated in consultation with the statistician to get the power of the study more than 85%. Written informed consent was obtained from every patient in the vernacular language.

Inclusion Criteria

- Age between 18 and 60 years
- Patients with ASA grade I and II undergoing surgical procedures
- MPG grade I and II
- BMI <35 kg/m^2.

Exclusion Criteria

- Age <18 or more than 60 years
- History of acid peptic disease and hiatus hernia pregnancy
- Laryngeal pathology
- MPG grade III and IV
- ASA grade III and IV
- BMI >35 kg/m^2.

Preanesthetic Checkup

- PAC, including a detailed history and thorough general physical examination of patients, including airway assessment, was carried out a day before surgery and was recorded
- Every patient was examined to ascertain the history of difficult intubation and was taken for surgery on the basis of mentioned criteria, and the following investigations were carried out.

Table 1: Number of insertion attempts of Fastrach LMA and Ambu AuraGain LMA

Number of insertion attempts	Group FT		Group AG	
	No.	%age	No.	%age
1	27	90.00	28	93.3
2	3	10.00	2	6.66
Total	30	100.00	30	100.00

X^2: 0.218; *P*=0.640 (non-significant)

Table 2: Time of insertion of either device

Group	Time taken (seconds)	
	Mean	SD
Group FT	12.891	1.9038
Group AG	21.08	10.61
P-value	0.0001	

(Highly significant)

Table 3: The success rate of intubation through either device

Groups	Group FT	Group AG	*P*-value	Significance
	%age	%age		
Intubation success	96.6	33.3	X^2: 41.85; *P*=0.001	HS

Table 4: Successful intubation through either device

Intubation success	Group FT		Group AG		*P*-value	Significance
	No.	%age	No.	%age		
Attempt	28	93.33	3	10.00	X^2: 41.85;	HS
Attempt	1	3.33	7	23.33	*P*=0.001	
Failed intubation through either device	1	3.33	20	66.6		

Routine Investigation

Routine investigations were Hb, TLC, DLC, BT, CT, platelets, urine complete examination, FBS, ECG, LFT, RFT, and PTI.

Patients were kept NPO 8 h before surgery. Tab. Alprazolam 0.5 mg at night and in the morning before surgery with a sip of water to prevent anxiety before surgery. The monitoring equipment and anesthetic drugs used during general anesthesia were kept as follows:

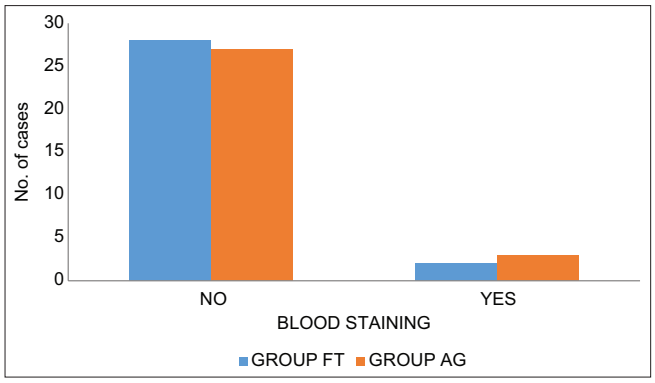


Figure 1: Blood staining in both groups

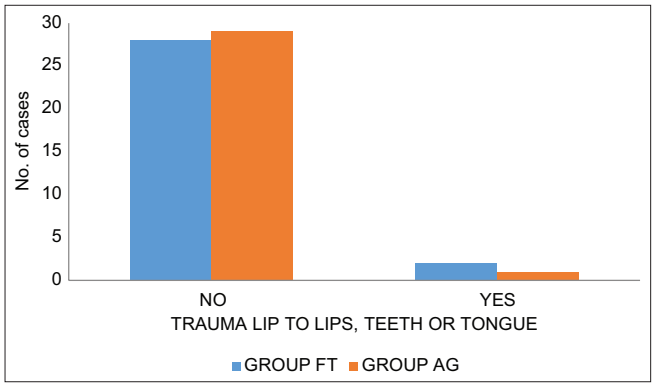


Figure 2: Trauma to the lips, teeth, tongue, or posterior pharyngeal wall in both the groups

i. IV set, Angiocath, fluid, drip stand, disposable syringes, and suction catheter
ii. BP apparatus, ECG electrodes, pulse oximeter, ETCO2, and laryngoscope
iii. On workstation - Inj. Midazolam, Inj. Glycopyrrolate, Inj. Butrum, Inj. Propofol, Inj. Succinylcholine, Inj. Lidocaine, Inj. Vecuronium, Inj. Neostigmine, and lignocaine jelly
iv. Gases isoflurane, N_2O, and oxygen
v. Flexometallic endotracheal tube (No. 7 mm internal diameter)
vi. AAG LMA (No. 4 and 5)
vii. Fastrach LMA (No. 4)
viii. Emergency drugs such as Inj. Atropine, Inj. Adrenaline, and Inj. Noradrenaline.

Type of the Study

This was a randomized prospective study. Blinding is not possible.

Study Design

A study was carried out by dividing patients into 2 groups of 30 each as follows.

1. Group FT – Blind endotracheal intubation using FT-LMA

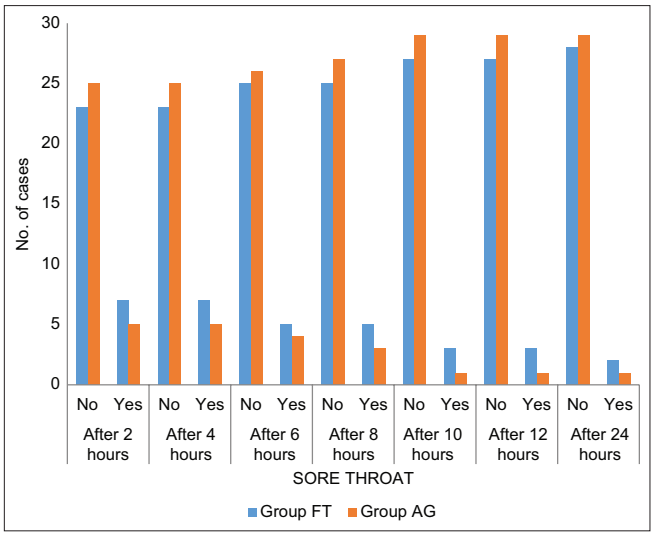


Figure 3: Sore throat (ST) up to 24 h postoperatively

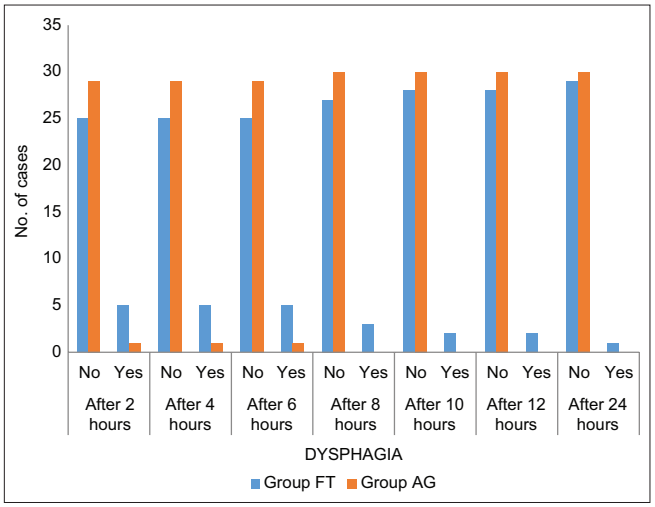


Figure 4: Dysphagia up to 24 h postoperatively

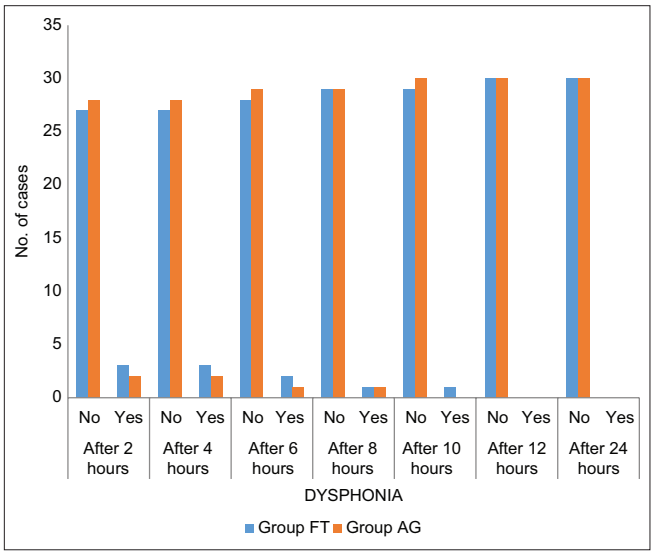


Figure 5: Dysphonia up to 24 h postoperatively

2. Group AG – Blind endotracheal intubation using AAG LMA.

All patients included in the study were kept nil orally for 8 h preoperatively after a thorough preanesthetic checkup and laboratory investigations. An airway examination of the patients was also done.

In the operation theater,
- Routine monitoring (ECG, pulse oximetry, NIBP, and ETCO2)
- An intravenous line was secured with 20-gauge Cannula
- IV fluids were started.

Premedication:
- Intravenous midazolam 1 mg
- Intravenous glycopyrrolate 0.2 mg
- IV fentanyl 2 mcg/kg.

Preoxygenation was done for 3 min with 100% oxygen using a facemask. Anesthesia was induced with I/V propofol 2 mg/kg and isoflurane 1–2%. After confirming mask ventilation, Inj. Vecuronium 0.1 mg/kg I/V was administered for muscle relaxation.

At the completion of the laryngoscopy, face mask was applied again, and 3–5 inflations of 100% oxygen were given. Then, with the patient's head in a neutral position, by standing at the head end of the patient, an appropriate size AAG or FT was inserted. Correct placement of the device was confirmed by easy bag ventilation and normal square-wave capnogram.

Insertion Technique for Supraglottic Airway Device FT/AG

An ideal FT-LMA or AAG LMA size was chosen according to the weight of the patient. The cuff of FT-LMA or AAG LMA was deflated, and the mask was lubricated using 2% lignocaine jelly. While maintaining the neutral head position of the patient, the mask of FT-LMA or AAG LMA was flattened against the hard surface, and it was inserted with a rotational movement along the hard palate and the posterior pharyngeal wall. After its insertion, the cuff was inflated, and proper placement of the device was confirmed by observing the chest rise and noting the presence of a normal capnograph trace. If the first attempt of the insertion of a supraglottic device was unsuccessful, a second attempt was undertaken. If the supraglottic device was not placed in two attempts, or oxygen saturation fell to 90%, the procedure was abandoned, and the patient was intubated through direct laryngoscopy, and was called a failure case of study and was included in the study.

After the successful placement of the supraglottic airway device, blind intubation of the trachea was attempted with an endotracheal tube with curvature facing anterior in the first attempt, and the tube was rotated 180° for the next two attempts.

In case of failed insertion or intubation, direct laryngoscopy and intubation is the alternative approach between the supraglottic device insertion and blind intubation attempts; patients were ventilated with 100% oxygen and an additional bolus of propofol 20–40 mg I/V was given to ensure adequate anesthetic depth.

Statistical Analysis

Duration of intubation was taken as the outcome measure of interest for the purpose of sample size calculation. The sample size was calculated keeping in view at most 5% risk, with a minimum of 80% power and 5% significance level (significant at a 95% confidence interval). Data were recorded in a Microsoft Excel spreadsheet and analyzed using the IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp., Chicago. Continuous data were presented as mean with standard deviation. Categorical data were expressed as numbers and percentages. Power analysis was done to calculate the power of the study, which was 95% by taking α error 0.05. The *P*-value was then determined to evaluate the level of significance. The results were analyzed and compared to previous studies to draw relevant conclusions.

RESULTS

Comparing the number of attempts for the insertion of FT-LMA and AG-LMA, the result was 100% ($P > 0.005$). The successful intubation rate through FT-LMA and AG-LMA was 96.66% and 33.33%, respectively. The difference in the overall success rate of intubation between both groups was highly significant with $P = 0.001$

The time of insertion was measured in seconds from the time the device was picked up by the operator until the square wave of the capnograph trace was obtained. The mean time of insertion between the groups was statistically significant ($P < 0.05$).

In group FT, intubation was successful in the first attempt in 28 (93.33%) patients, and in the 2nd attempt, no successful intubation in 2 (0.00%) patients. Intubation was not possible through LMA and was intubated through direct laryngoscopy in 2/30 (6.66%) patients. In group AG, intubation was successful in the first attempt in 3 (10%) patients, and in the second attempt in 7 (23.33%) patients, intubation was not possible through LMA and was intubated through direct laryngoscopy in 20/30 (66.6%) patients. The difference between successful

intubation devices through either device in both groups was statistically significant, $P = 0.001$.

The variation in the mean arterial pressure, HR, ETCO2, and SPO_2 in the group FT and AG from the baseline, till the end of surgery, remained non-significant ($P > 0.05$) (Figures 1-5 and Tables 1-4).

DISCUSSION

In our study, in the first attempt, insertion of Fastrach LMA was seen in 27 out of 30 (90%) patients, and in the second attempt seen in 3 out of 30 (10%) patients. In AAG LMA, insertion in the first attempt was seen in 28 out of 30 (93.3%) patients, and in the second attempt in 2 out of 30 (6.66%) patients. Our results are consistent with the study conducted in 2018 by Siamdoust *et al.*,[7] in which they compared the success rate of intubation between the LMA Fastrach and air-Q ILA in patients undergoing elective surgery during general anesthesia; they were able to insert in all patients, and out of which, 61/63 (96.8%) were inserted in the first attempt. In another study conducted in 2019 by Sudheesh *et al.*,[8] in which Fastrach LMA and AAG LMA were used in 60 patients; out of which in FT-LMA, 57/60 (95%) and 3/60 (5%), and in AAG, 56/60 (93.33%) and 4/60 (6.66%).

The time of insertion was measured in seconds from the time the device was picked up by the operator until attaching it to the breathing circuit. In groups FT-LMA and AG-LMA, the mean time for device insertion was 12.82 ± 1.90 s and 21.08 ± 1.60 s, respectively. The difference between the time taken for LMA insertion between both groups was non-significant. Our findings were supported by the study conducted in 2019 by Schiewe *et al.*,[9] in which they compared blind tracheal intubation through FT-LMA and AMBU AURA-I. The mean time for the insertion for FT-LMA was 15.2 ± 7.0 s, which is comparable to our study. Our findings were supported by the study conducted in 2021 by Sarma *et al.*,[10] in which they compared the mean time for the insertion of AAG, ILMA, and I-gel for blind tracheal intubation. The mean time for the insertion for AAG LMA was 25.07 ± 11.61 s.

The success rate was the ability to establish a definitive airway through blind tracheal intubation through either of device irrespective of the number of attempts taken.

In group FT, 28/30 (93.3%) were intubated successfully using FT-LMA. Our study results are in concordance with the studies conducted by Darlong *et al.*,[11] in which a comparison of FT-LMA and Cobra PLA as an aid for blind tracheal intubation was done. The overall success rate of blind tracheal intubation through FT-LMA was 90% (27/30), which is consistent with our study.

In another study conducted by Langeron *et al.*,[12] in which a comparison of the FT-LMA with the fiberoptic intubation in anticipated difficult airway management was done, intubation was successfully done using FT-LMA in 48/51 (94%), which is similar to our study.

In another study conducted by Sudheesh *et al.*,[8] in which they compared AAG versus intubating LMA as conduits for blind tracheal intubation, the success rate for blind intubation through FT-LMA and AG-LMA was 96.6% and 36.6%. Our study results are consistent with this study.

A particular set of complications can occur at any time during the insertion of the device. Since the larynx and pharynx are areas that are richly supplied by the plexus of nerves that originate from the vagus and glossopharyngeal, they can get easily injured if the proper technique of device placement is not employed. These injuries are only identified post operatively after cessation of anesthesia.[13]

The patient may complain of sore throat, dysphagia which would mean pain during swallowing, and dysphonia which could be due to injury of the superior, inferior, or recurrent laryngeal nerve.

Limitations of the Study

- We studied only low-risk patients (ASA I and II) who had normal airways with MPG grade I and II.
- Our data being derived from a single center may have referral bias
- The inferior success rate of blind intubation with AAG may be due to its malleability, following exposure to body temperature, and minor distortions in placement while passing the ETT, when compared with a more rigid ILMA.

CONCLUSION

We can say that Group FT with ease of insertion, for adequate ventilation but blind tracheal intubation through Group AG has a lower success rate compared to Group FT.

REFERENCES

1. Brain AI. The laryngeal mask-a new concept in airway management. Br J Anaesth 1983;55:801-5.
2. Pollack CV Jr. The laryngeal mask airway: A comprehensive review for the emergency physician. J Emerg Med 2001;20:53-66.
3. Brimacombe JR. Laryngeal mask anaesthesia. In: Principles and Practice. 2nd ed. Philadelphia, PA: Elsevier-Saunders; 2006. p. 105, 636.
4. Brain AI, Verghese C, Addy EV, Kapila A, Brimacombe J. The intubating laryngeal mask. II: A preliminary clinical report of a new means of

intubating the trachea. Br J Anaesth 1997;79:704-9.
5. Ferson DZ, Rosenblatt WH, Johansen MJ, Osborn I, Ovassapian A. Use of the intubating LMA-FastrachTM in 254 patients with difficult-tomanage airways. Anesthesiology 2001;95:1175-81.
6. Sharma MU, Gombar S, Gombar KK, Singh B, Bhatia N. Endotracheal intubation through the intubating laryngeal mask airway (LMA-Fastrach™): A randomized study of LMA- Fastrach™ wire-reinforced silicone endotracheal tube versus conventional polyvinyl chloride tracheal tube. Indian J Anaesth 2013;57:19-24.
7. Seyed Siamdoust S, Rokhtabnak F, Djalali Motlagh S, Rahimzadeh P, Hassani V, Farnaghizad M. Comparison of the success rate of intubation between the LMA fastrach and AirQ-ILA methods in patients undergoing elective surgery during general anaesthesia. Anesth Pain Med 2018;8:e63424.
8. Sudheesh K, Chethana GM, Chaithali H, Nethra SS, Devikarani D, Shwetha G. A new second-generation supraglottic airway device (Ambu(®) AuraGain(•)) versus intubating laryngeal mask airway as conduits for blind intubation-A prospective, randomised trial. Indian J Anaesth 2019;63:558-64.
9. Schiewe R, Stoeck M, Gruenewald M, Hoecker J, Bein B. A comparison of blind intubation with the intubating laryngeal mask FASTRACH™ and the intubating laryngeal mask Ambu Aura-i™ a prospective randomised clinical trial. BMC Anesthesiol 2019;19:44.
10. Sarma R, Kumar R, Kumar NG, Agarwal M, Bhardwaj M, Ansari SA, *et al*. Comparative evaluation of intubating laryngeal mask airway (ILMA), I-gel and Ambu AuraGain for blind tracheal intubation in adults. J Anaesthesiol Clin Pharmacol 2022;38:130-6.
11. Darlong V, Chandrashish C, Chandralekha C, Mohan VK. Comparison of the performance of 'Intubating LMA'and 'Cobra PLA'as an aid to blind endotracheal tube insertion in patients scheduled for elective surgery under general anaesthesia. Acta Anaesthesiol Taiwan 2011;49:7-11.
12. Langeron O, Semjen F, Bourgain JL, Marsac A, Cros AM. Comparison of the intubating laryngeal mask airway with the fiberoptic intubation in anticipated difficult airway management. Anesthesiology 2001;94:968-72.
13. Kömür E, Bakan N, Tomruk ŞG, Karaören G, Doğan ZT. Comparison of the supraglottic airway devices classic, fastrach and supreme laryngeal mask airway: A prospective randomised clinical trial of efficacy, safety and complications. Turk J Anaesthesiol Reanim 2015;43:406-11.

How to cite this article: Arora HS, Mohan B, Badhan A, Kaur H. Ambu AuraGain Versus Intubating Laryngeal Mask Airway (Fastrach) as Conduits for Blind Intubation – A Prospective Randomized Study. Int J Sci Stud 2023;11(3):52-57.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

A Prospective Study of Evaluation of Temporal Bone Pathologies Using High-Resolution Computed Tomography in 50 Cases and its Correlation with Clinical Findings

Yashwanth Nagaraj[1], Rakesh Irappa Huddar[1], Ameet Mudda[2], Anagha Katte Madhusudana[3]

[1]Postgraduate, Department of Radiodiagnosis, Dr. B R Ambedkar Medical College and Hospital, Bengaluru, Karnataka, India, [2]Assistant Professor, Department of Radiodiagnosis, Dr. B R Ambedkar Medical College and Hospital, Bengaluru, Karnataka, India, [3]Postgraduate, Department of Oral and Maxillofacial Surgery, M R Ambedkar Dental College and Hospital, Bengaluru, Karnataka, India

Abstract

Background and Objectives: Ear disorders are a frequent clinical issue that people experience every day. Due to the incidence, complications, and recurrence of numerous temporal bone diseases, clinical examination alone is no longer sufficient in the modern world. Imaging is crucial to the management of these conditions and has a significant impact on the course of treatment. High-resolution computed tomography (HRCT) is a modified version of conventional CT and it offers a direct visual window into the temporal bone that reveals fine structural details. The present study aims to evaluate the normal variations, pathological processes such as infections, tumors, vascular lesions, trauma, congenital anomalies, complications from diseases, and their extent involving the temporal bone.

Materials and Methods: A prospective observational study was conducted at Dr B.R Ambedkar medical college on 50 cases presenting with symptoms and signs related to temporal bone pathology from January 1st, 2021 to July 1st, 2022. Patients were scanned in axial and coronal planes with 0.625–1.25 mm thin sections using sharp algorithm obtaining plain/non-contrast and contrast images. Results were tabulated using percentages.

Results: Among the 50 cases which were studied majority of the subjects were found in the age group 21–30 (12 cases). Infection was the most common pathology affecting the temporal bone. The ear pain, headache, tinnitus, Hearing loss, facial weakness and Vertigo are the most commonest symptoms observed. Left part 2 table and right part-2 and mastoid - HRCT findings table shows a significant approach for early screening of the patients. A total (n = 33) cases had complications from cholesteatoma. Amongst, the Facial canal erosion (10%); Malleus erosion (12%) and Stapes erosion (12%) is a common complications found in the above study. The current study will be serve as radiological navigation tool for the ENT specialist for operating the cases surgically.

Conclusion: For evaluating the temporal bone and its surrounding structures for its anatomy and pathologies, HRCT is superior to traditional investigational methods because it offers higher spatial resolution and greater soft tissue contrast. For a precise diagnosis to be made, a thorough clinical history and pertinent clinical examination are crucial.

Key words: Ear Disorders, High Resolution Computed Tomography (HRCT), Hearing Loss, Stapes Erosion, Temporal Bone

INTRODUCTION

The invention of high-resolution computed tomography (HRCT) changed temporal bone imaging in 1980.[1] Clinically, middle ear disease is a common clinical condition.[2] it serves as an extension of the upper respiratory tract and is vulnerable to bacterial and viral invasion through the Eustachian tube. The third most frequent reason for seeing an otorhinolaryngologist is for ear pathology, with inflammatory disorders of the middle ear being a popular justification for giving antibiotic prescriptions and performing surgery on kids and teenagers. In the past, a diagnosis was typically made solely by clinical examination. However, it was recommended that the current strategy for preventing and treating these disorders was insufficient

Access this article online

www.ijss-sn.com

Month of Submission : 04-2023
Month of Peer Review : 05-2023
Month of Acceptance : 06-2023
Month of Publishing : 06-2023

Corresponding Author: Dr. Yashwanth Nagaraj, Department of Radiodiagnosis, Dr. B R Ambedkar Medical College and Hospital, Bengaluru, Karnataka, India.

given the rise in the occurrence of infectious ear pathologies. Imaging is therefore crucial, especially in complex and recurrent illnesses where the results may have a major impact on the course of treatment.[3]

The complex anatomical structure known as the temporal bone contains the hearing and balance organs. Along with being close to the brain, it also contains vital veins and nerves. The temporal bone is in close contact with the brainstem, cerebellum, and temporal lobe of the brain. Imaging modalities such as plain radiographs, polytomography, angiography, and cisternography are used to evaluate temporal bone.[4] Radiograph has limitations due to complex architecture and overlap. A modification to standard CT is HRCT. A better understanding of the genesis, pathophysiology, and course of the disease is made possible by HRCT, which also allows for the early detection of problems.[5] HRCT accurately localizes primary temporal bone disease and identifies intracranial dissemination. A diagnosis of bone and air space problems is more accurate in HRCT. It provides a topographic image of the temporal bone and surrounding structures that is good.

Aims and Objectives

1. To study infections with in temporal bone and their complications
2. To study the congenital defects in the ear
3. To evaluate variations in the temporal bone anatomy in different pathologies.

MATERIALS AND METHODS

Source of Data

- Patients aged between 4 and 70 years with a complaint of temporal bone pathologies such as hearing loss, ear discharge, and tinnitus are referred from OPD/IPD of the ENT Department.

Study Design

- A Prospective study was done involving 50 patients with complaints regarding temporal bone pathologies such as hearing loss, ear discharge, tinnitus.

Study Period

- The study was done from January 1st, 2021, to July 1st, 2022.

Sample Size

The sample size was 50.

Place of Study

- Department of Radiodiagnosis, Dr B R Ambedkar medical college and Hospital, Bengaluru.

Ethical Clearance

Obtained.

Inclusion Criteria

1. Age: 4–70 years
2. Patient willing to give informed consent
3. The patient referred for HRCT Temporal bone from ENT Department
4. Patient with a history of trauma
5. Malignancies in the temporal bone.

Exclusion Criteria

1. Patient not willing to give informed consent
2. Pregnancy
3. Patients <4 years.

Methodology

This study assessing the efficacy of CT in the diagnosis of pathologies of temporal bone will be done on 50 cases. This study will be conducted between January 1st, 2021, and July 1st, 2022 in the Department of radiodiagnosis, Dr B R Ambedkar medical college, Bengaluru.

Selection of Patients

Patients having clinical features related to temporal bone pathology will be taken and referred for HRCT of the temporal bone.

All the patients will undergo detailed clinical examination in the ENT Department followed by HRCT temporal bone scanning in the Department of Radiodiagnosis. All the patients will be scanned with Toshiba activation 16.

Methods of Data Collection

Informed consent is taken from patients undergoing HRCT. The prospective study includes 50 patients with suspected pathologies in the temporal bone or the ear. Patients with a history of malignancies related to temporal bone were included. Then patients are scanned.

Statistical Analysis

Table 1 shows the disease-wise distribution of patients. As per the results, the common pathology observed was infection constituting 60% of cases (n = 30), followed by trauma (n = 11, 22%), Tumors (n = 5, 10%), congenital malformation (n = 2, 4%), and vascular lesions (n = 2, 4%).

Table 2 shows the gender-wise distribution of the patients. As per the results, the males were 30 (60%) and females were 20 (40%) with a sex ratio is 1:1.

Table 3 shows the age distribution, the mean age of the cases are 39.26 with SD 1.25 years, based on the mean and SD we categorized the age classes, the majority of

Table 1: Distribution of disease in patients

Diseases	No. of patients	Percentage
Infections	30	60
Tumours	5	10
Trauma	11	22
Congenital malformations	2	4
Vascular lesions	2	4

Table 2: Sex distribution

Gender	Number of patients	Percentage
Male	30	60
Female	20	40

Table 3: The age distribution

Age group	No.	%
<11–20	6	12
21–30	12	24
31–40	9	18
41–50	11	22
51–60	7	14
61–70	5	10
Total	50	100

the subjects were expressed the age 21–30 (12 cases) years followed by 31–40 years was 9 cases; 51–60 (7 cases) and least was <11–20 years 6 (12%).

The distribution of clinical diagnosis presented in Table 4, the results shows that majority of the cases were diagnosed B/L CSOM (11.54%) followed by left CSOM (5.77%) (Case 1); right squamous and mastoid temporal bone Fracture (7.69%); the two cases were diagnosed by left squamous temporal bone fracture (Case 2), left cholesteatoma, left EAC atresia were rest of each case were diagnosed by right glomus jugulo-tympanicum (Tumour) (Case 3), right vestibular schwannoma (Case 4), Right high riding jugular bulb, right otomastoiditis, right petrous ICA aneurysm. It was tested by Chi-square, the results were found to be significant $P < 0.01$.

Table 5 depicts that Descriptive statistics of HRCT Right part 1, the right external, middle, and inner ear were hypothetically tested using the logistic multivariate analysis, the results show that different components of the variables of the right ear and middle ear were found to be significant at 1% level of significance. In case of the inner ear, except lateral SCC and internal auditory were found to be significant, the rest of the variables were uncorrelated $P > 0.01$.

Table 6 depicts that descriptive statistics of HRCT findings (Left part-1, the left external, middle, and inner ear were hypothetically tested by using the logistic multivariate analysis, the results show that different components of

Table 4: Distribution of clinical diagnosis

Clinical diagnosis	No	%
B/L CSOM	6	11.54
B/L otomastoiditis	3	5.77
Left CSOM	4	7.69
Right squamous temporal bone fracture	4	7.69
Left otomastoiditis	3	5.77
Left squamous temporal bone fracture	3	5.77
Left cholesteatoma	4	7.69
Left EAC atresia	2	3.85
Left glomus jugulare paraganglioma (tumor)	1	1.92
Left mastoid temporal bone fracture	1	1.92
Left petrous temporal bone fracture	1	1.92
Right vestibular schwannoma (tumor)	3	5.77
Right cholesteatoma	4	7.69
Right glomus jugulo tympanicum (tumor)	1	1.92
Right high-riding jugular bulb	1	1.92
Right mastoid temporal bone fracture	1	1.92
Right otomastoiditis	3	5.77
Right petrous ICA aneurysm	1	1.92
Right squamous and mastoid temporal bone fracture	1	1.92
B/L cholesteatoma	1	1.92
Right CSOM	4	7.69
Total	50	100

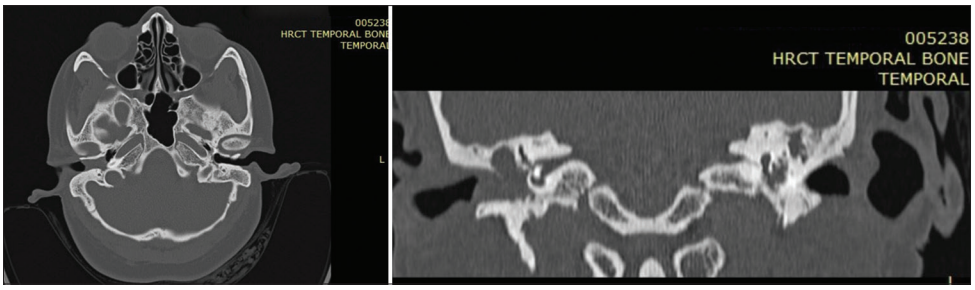
Table 5: Descriptive statistics of HRCT findings (Right part-1)

Particulars	Variables	Yes		No		*P*-value
		No	%	No	%	
Right external ear	Tympanic membrane thickening	19	38	31	62	<0.001
	Mass/collection	14	28	36	72	<0.001
	Scutum erosion	12	24	38	76	<0.001
Right middle ear	Prussaks space involvement	17	34	33	66	<0.001
	Opacification	22	44	28	56	<0.001
	Tegmen tympani erosion	4	8	46	92	<0.001
	Malleus Erosion	9	18	41	82	<0.001
	Incus erosion	11	22	39	78	<0.001
	Stapes erosion	10	20	40	80	<0.001
Right inner ear	Superior SCC	0	0	50	100	-
	Lateral SCC	2	4	48	96	<0.001
	Posterior SCC	0	0	50	100	-
	Cochlea andvestibule	0	0	50	100	-
	Internal Auditory canal	4	8	47	94	<0.001

Chi-square=10.85, *P*<0.01

the variables of the right ear and middle ear were found to be significant at 1% level of significance. In case of the inner ear, Lateral SCC was found to be significant, rest of the variables were uncorrelated $P > 0.01$.

Table 7 depicts the Descriptive statistics of HRCT findings (Right part-2), the right part mastoid and HRCT findings are hypothetically tested by using the logistic multivariate analysis, the results show that different all the components of the variables were found to be significant at 1% level of significance.



Case 1: A 50-year-old female patient presented with ear pain, ear discharge for 7 months and headache and hearing loss for 1 year. Axial and coronal image of HRCT temporal bone shows right middle opacification with ossicular erosion and sclerosis of right mastoid air cells. Mucosal thickening was seen in the left middle ear with sclerosis of left mastoid air cells

Table 6: Descriptive statistics of HRCT findings (Left part-1)

Particulars	Variables	Yes		No		*P*-value
		No	%	No	%	
Left external Ear	Tympanic membrane thickening	6	32	34	68	<0.001
	Mass/collection	10	20	40	80	<0.001
	Scutum Erosion	10	20	40	80	<0.001
Left middle ear	Prussaks space involvement	12	24	38	76	<0.001
	Opacification	17	34	33	66	<0.001
	Tegmen tympani erosion	1	2	49	98	>0.001
	Malleus erosion	3	6	47	94	<0.001
	Incus erosion	4	8	46	92	<0.001
	Stapes erosion	6	12	44	88	<0.001
Left inner ear	Superior SCC	0	0	50	100	-
	Lateral SCC	2	4	48	96	<0.001
	Posterior SCC	0	0	50	100	-
	Cochlea andvestibule	0	0	50	100	-
	Internal Auditory canal	0	0	50	100	-

Chi-square=4.61, *P*<0.01

Table 7: Descriptive statistics of HRCT findings (Right part-2)

Particulars	Variables	Yes		No		*P*-value
		No	%	No	%	
Mastoid	Opacified	28	56	22	44	<0.001
	Sclerosed	17	34	33	66	<0.001
	Abscess	1	2	49	98	>0.01
HRCT findings	Facial canal erosion	7	14	43	86	<0.001
	Jugular canal erosion	1	2	49	98	>0.01
	Sigmoid plate erosion	1	2	49	98	>0.01
	Fracture	6	12	44	88	>0.01
	Cholesteatoma	5	10	45	90	>0.01
	CSOM	15	30	35	70	<0.001

Chi-square=13.21, *P*<0.01

Table 8: Descriptive statistics of HRCT findings (Left part-2)

Particulars	Variables	Yes		No		*P*-value
		No	%	No	%	
Mastoid	Opacified	25	50	25	50	<0.001
	Sclerosed	17	34	33	66	<0.001
	Abscess	1	2	49	98	>0.01
HRCT findings	Facial canal Erosion	5	10	45	90	<0.001
	Jugular canal Erosion	0	0	50	100	>0.01
	Sigmoid plate erosion	1	2	49	98	>0.01
	Fracture	5	10	45	90	<0.001
	Cholesteatoma	5	10	45	90	<0.001
	CSOM	14	28	36	72	<0.001

Chi-square=9.68, *P*<0.01

Table 8 depicts that Descriptive statistics of HRCT findings (Left part-2), the left part mastoid, and HRCT findings are hypothetically tested using the logistic multivariate analysis, the results show that different all the components of the variables were found to be significant at 1% level of significance.

The complications of cholesteatoma (Case 5) were tested by the Chi-square test, as per the findings a total of 33 cases had complications from cholesteatoma. Among, the facial canal erosion (10%), malleus erosion (12%), and stapes erosion (12%) were found to be statistically significant $P < 0.01$ Table 9.

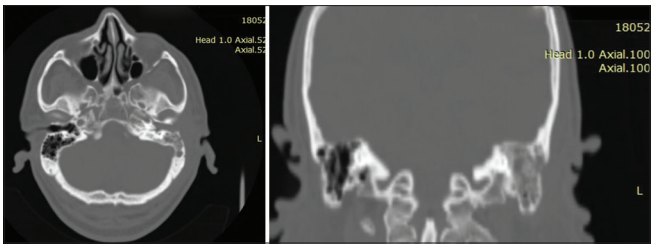
DISCUSSION

The temporal bone houses hearing and balancing organs. Radiography is challenging due to the complexity of the temporal bone. HRCT images have stronger contrast and improved spatial resolution. HRCT images have stronger contrast and improved spatial resolution. HRCT provides topographic viewing without superimposing. Pathology assessment of a disease allows for precise pathology assessment before surgical exploration. According to Jat *et al.*[6] in 2021, 50 patients with clinically suspected temporal bone symptoms underwent HRCT at Geetanjali Medical College and Hospital (Udaipur) between November 2017 and June 2019. By HRCT and Intra-op/Follow-up scans, CSOM and Cholesteatoma were the most frequently discovered diseases, followed by fractures, acoustic neuroma, Glomus tympanicum, and atretic EAC. When validated by intra-op/follow-up results, almost all lesions were appropriately diagnosed

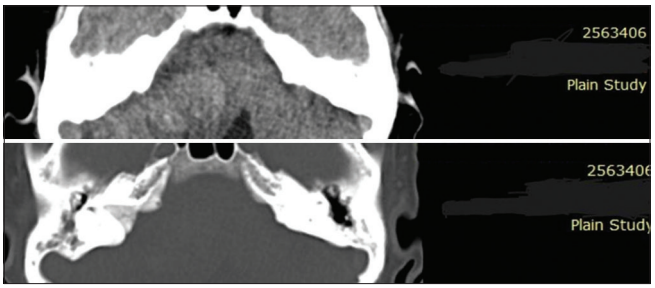
Table 9: Complications of cholesteatoma

Complication	No. of Patients	%
Abscesses	1	2
Facial canal erosion	5	10
Malleus erosion	6	12
Incus erosion	6	12
Stapes erosion	6	12
Tegmen erosion	3	6
Sigmoid plate erosion	2	4
Jugular bulb erosion	1	2
Semicircular canal erosion	3	6
	33	66

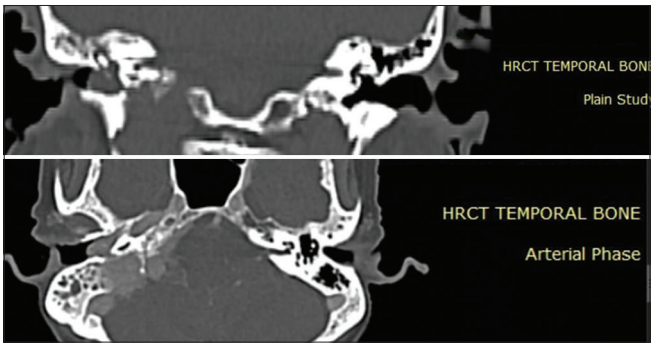
Chi-square=6.40, P<0.01



Case 2: A 60-year-old male patient presented with ear pain and ear discharge for 2 months. Axial and coronal image of HRCT temporal bone shows soft-tissue density lesion in the left middle ear with extension into the left external auditory canal. Opacification and sclerosis of left mastoid air cells noted

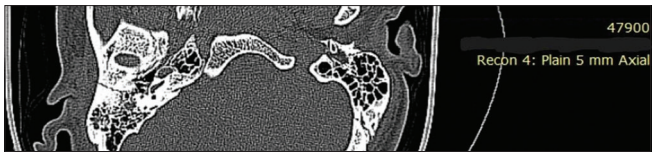


Case 3: A 45-year-old female patient presented with hearing loss and vertigo for 2 years. CT Axial and coronal section of the brain shows a fairly defined non-homogenous space-occupying mass lesion in the right cerebellopontine angle. The mass is extending into the right internal auditory canal/petrous temporal bone with the expansion of the right internal auditory canal. The mass effect is seen as compression of the right middle cerebellar peduncle /fourth ventricle



Case 4: A 67-year-old female patient presented with Tinnitus, hearing loss, and facial weakness for 5 years. Axial and coronal image of HRCT temporal bone shows a large irregular space occupying mass lesion in the right jugular foramen, right mastoid, and clivus on the right side. Mild destruction of petrous bone was seen. Mass is extending into the right middle ear and encases ossicles in the right middle ear. Mass is also extending into right CP angle.

by HRCT. In our study, the results, the males were 30 (60%) and females comprises 20(40%) with a sex ratio 1:1 the mean age of the cases is 39.26 with SD of 1.25 years, based on mean and SD. The Majority of the subjects expressed the age of 21–30 (12 cases) years followed by 31–40 years (9 cases); 51–60 (7 cases) and the least was <11–20 years 6 cases. A total of 84% of patients had experienced ear pain, 68% of patients had experienced ear discharge, headache presented (22%), tinnitus (12%), hearing loss (68%), and facial weakness and Vertigo (6%). HRCT produces images with higher contrast and spatial resolution. HRCT provides topographic visualization without artifacts. Pathology assessment of disease location, severity, and complications with HRCT is essential for surgical exploration. HRCT reveals the complex anatomy of the temporal bone, including ear ossicles, cochlea, and canals. The carotid canal, jugular fossa, major vessels, and nerves are depicted well on HRCT. This study evaluated the extent of chronic middle ear infections, temporal bone trauma, and neoplasms. Due to the ability to see temporal bone structures with great clarity, HRCT can be recommended not only in cases suspected with potential complications but also in all cases of temporal bone pathologies to know the extent of disease, inter-relationships of the tympano-mastoid compartment with adjacent neurovascular structures, varied pneumatization and the presence of anatomical variations, which should alert the clinician and guide in surgical approach and treatment plan.[7] In the present study, the clinical diagnosis were seen positive correlation, the resultsshow that the majority of the cases were diagnosed with B/L CSOM (11.54%) followed by left CSOM (5.77%); right squamous and mastoid temporal bone Fracture (7.69%); the two cases were diagnosed by left squamous temporal bone fracture, left cholesteatoma, Left EAC atresia were rest of eachcase were diagnosed by right glomus jugulo-tympanicum (Tumour), right high riding Jugular bulb, right otomastoiditis, right petrous ICA aneurysm. It was tested by Chi-square, the results were found to be significant $P < 0.01$. In HRCT - right external, middle and inner ear. The results shows that different components of the variables of the right ear and middle ear were found to be significant at 1% level of significance. In the case of inner ear, except lateral SCC and internal auditory were found to be significant, the rest of the variables were uncorrelated $P > 0.01$. In the case of left part-1, the external, middle and inner



Case 5: A 28-year-old male patient presented with ear pain, ear discharge, hearing loss, facial weakness, and swelling in the right temporal region for 1 day. Axial image of HRCT Temporal bone shows comminuted undisplaced fracture of mastoid part of the right temporal bone with fracture line extending till right middle ear with mild collection within and fracture line is seen extending into tympanic and squamous part of the right temporal bone.

ear results shows that different components of the variables of the right ear and middle ear were found to be significant at 1% level of significance. The inner ear and lateral SCC were found to be significant, rest of the variables were uncorrelated $P > 0.01$; (Right part-2), the right part Mastoid and HRCT findings are shows that all variables were found to be significant at 1% level of significance. A total ($n = 33$) cases had complications from cholesteatoma. Among, the facial canal erosion (10%); malleus erosion (12%) and Stapes erosion (12%) were found to be statistically significant $P < 0.01$. The maximum prevalence of temporal bone pathologies was found in 21–30 years and 31–40 years age groups (26%) each in our study. Temporal bone disease prevalence predominated in males (60%). The maximum prevalence of temporal bone pathologies was found in the right ear (46%), followed by the left ear (40%).

Maximum patients presented with hearing loss, otalgia, otorrhea, and headache.

CONCLUSION

HRCT is better than conventional modalities of investigations and provides high spatial resolution and better soft tissue contrast.

For the assessment of middle ear infections, clinical correlation is needed to evaluate the nature of middle ear soft tissue masses as cholesteatoma is mimicked by many other middle ear pathologies.

In these cases, HRCT,

- Is far advantageous in assessing the complications of infection.
- Lays down an anatomical road map for the surgeon preoperatively.
- Predicts certain normal variants of surgical significance pre-operatively.
- Identifies the hidden areas of the middle ear.
- A previously operated ear has an altered anatomy. The disease of such an ear has a different morphological pattern of involvement.

CT scan plays an important role,

- To comment regarding the extent of surgery and the general overall condition of the post-operative temporal bone including the internal auditory canal.
- The residual/recurrent diseases can be assessed.
- The Status of the inner ear can be established.
- Facial nerve anatomy can be clearly depicted.
- The relationship of the facial nerve to any surgical change or Cholesteatoma tissue can be best studied.
- The status of the ear ossicles or prostheses employed by the surgeon can be seen.

Neoplastic disease of the middle ear is best staged with HRCT. HRCT is not diagnostic of the pathological condition, hence the nature of the neoplastic process needs to be evaluated by a post-contrast scan.

The major functions of HRCT in the valuation of tumors of the temporal bone are summarized as follows –

- When tumors are present in the middle ear, HRCT serves to differentiate tumor from vascular anomalies and to determine the extent of deep involvement often obviating the need for angiography.

Where tumors are present by tinnitus or cranial nerve deficit without mass in the middle ear, HRCT serves to differentiate tumors from other benign and malignant lesions. When a lesion is large or appears atypical, angiography is of complementary value. Otherwise, unless embolization is contemplated, angiography is not always necessary.

By precisely defining intra-tympanic, mastoid, jugular wall, infra-labyrinthine, and petrous apical involvement as well as posterior, middle, and infratemporal fossa extension. HRCT provides essential information for planning the surgical approach.

REFERENCES

1. Parida S, Routray PN, Mohanty J, Pattanaik S. Role of HRCT in temporal bone diseases-a study of 100 cases. JK Sci 2018;20:34-8.
2. Anbarasu A, Chandrasekaran K, Balakrishnan S. Soft tissue attenuation in middle ear on HRCT: Pictorial review. Indian J Radiol Imaging 2012;22:298-304.
3. Thukral CL. Role of high resolution computed tomography in evaluation of pathologies of temporal bone. J Clin Diagn Res 2015;9:TC07-10.
4. Bagul M. High-resolution computed tomography study of temporal bone pathologies. Int J Sci Stud 2016;4:60-5.
5. Chidambaram PK, Rajkumar RV, Vinayagam S, Aiyappan SK, Karpagam B. High resolution CT imaging in pathologies of temporal bone. Int J Contemp Med Surg Radiol 2019;4:C11-7.

6. Kumar PR. A hospital based study of high resolution computed tomography and conventional radiography for evaluation of pathologies of temporal bone. Perspect Med Res 2020;8:18-23.
7. Jat HR, Daswani S, Sheldon M, Patel N. High resolution computed tomography in the evaluation of temporal bone pathology. Int J Med Biomed Stud 2021;5:180-9.

How to cite this article: Nagaraj Y, Huddar RI, Mudda A, Madhusudana AK. A Prospective Study of Evalution of Temporal Bone Pathologies Using High Resolution Computed Tomography in 50 Cases and its Correlation with Clinical Findings. Int J Sci Stud 2023;11(3):58-64.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Total Number of Root Canals Commonly Found During Endodontic Treatment of Primary Molars in North Indian Population - An *In Vivo* Study

Akansha Thapliyal[1], Sabreen Gujral[1], Shveta Sood[2], Naresh Sharma[3], Madhulika Srivastava[4]

[1]Postgraduate Student, Department of Pediatric and Preventive Dentistry, Manav Rachna Dental College, FDS, MRIIRS, Faridabad, Haryana, India, [2]Head, Department of Pediatric and Preventive Dentistry, Manav Rachna Dental College, FDS, MRIIRS, Faridabad, Haryana, India, [3]Professor, Department of Pediatric and Preventive Dentistry, Manav Rachna Dental College, FDS, MRIIRS, Faridabad, Haryana, India, [4]Reader, Department of Pediatric and Preventive Dentistry, Manav Rachna Dental College, FDS, MRIIRS, Faridabad, Haryana, India

Abstract

Introduction: Preserving primary teeth in the dental arch is a beneficial concept, thus it is advisable to employ endodontic therapy instead of extraction procedure wherever possible. To achieve and deliver successful endodontic therapy, the operator is required to have a comprehensive understanding of the anatomy of the tooth along with different variations that exist within the primary teeth. Even though CBCT remains the gold standard method for studies involving root canal morphologies, its limitations such as higher dose of radiation as well as procedural time and high cost makes its regular use in children difficult.

Purpose: The purpose of this study was to evaluate the total count of root canals found in primary maxillary and mandibular molars in the pediatric population of Delhi-NCR region (India) using routine radiographs during pulpectomy procedure, highlighting that conventional IOPA radiographs can be accurately utilized to determine the total number of root canals, as routine usage of CBCT in pediatric dental operatory is still in question. Majority of the studies that were carried out to determine root canal morphologies of primary teeth were performed on extracted teeth, but as the present study was done in-vivo, it got added to rationale behind using conventional radiographic technique for this study.

Method: 173 primary maxillary and mandibular molars were included and examined for the study. Data was collected and recorded from the operators who were performing pulpectomy in the department. The root canal orifices were clinically located according to the dentinal map and their number were determined following the clinical steps of access cavity preparation and de-roofing of the pulp chamber. The number of root canals were verified by placing number 15 or 20 endodontic files within the canals followed by taking routine IOPA radiographs.

Results: Out of 173 primary molars requiring pulpectomy, both 1st and 2nd primary maxillary molars were found to have 3 canals (mesiobuccal, distobuccal and palatal). 11% of 54 primary mandibular 1st molars had a single distal canal and 2 mesial canals, rest 89% had 2 canals in both mesial and distal roots. 100% of the primary mandibular 2nd molars had four root canals, two mesial and two distal.

Conclusion: IOPA radiography is still an effective and safe method that can be used in routine dental practice for endodontic procedures especially in pediatric patients.

Key words: Number of root canals, Primary molars, Intraoral periapical, Routine radiography, Root canal configuration

Access this article online

www.ijss-sn.com

Month of Submission : 04-2023
Month of Peer Review : 05-2023
Month of Acceptance : 06-2023
Month of Publishing : 06-2023

INTRODUCTION

Deep carious lesion being the leading cause for pulpal involvement in a tooth entails treatment for preservation of the tooth's integrity. Due to a narrower strip of mineralized tissue dividing the outer and inner tooth surfaces, increased bacterial penetration into the pulp can be observed in primary teeth when compared to permanent teeth.[1] Primary

Corresponding Author: Dr. Akansha Thapliyal, D-032, Westend Heights, DLF Phase-5, Gurugram - 122 009, Haryana, India.

teeth have a leading part in carrying out functions such as mastication, speech, and maintenance of adequate room for eruption of permanent dentition and consequently, and their pre-mature loss can adversely affect these roles.[2]

As preserving primary teeth in the dental arch is a beneficial concept, there is a routine demand for employment of endodontic therapy instead of extraction procedure.[3,4] Root canal therapy in primary teeth comprises pulp tissue removal, debriding and preparing, irrigating, and obturating the canals three dimensionally.[3] Through each of these stages, it is imperative that every step gets executed carefully for attaining overall success.[2] To achieve this, the operator is required to have a comprehensive understanding of the anatomy of the tooth along with different variations that exist within the primary teeth.[5]

The morphologic variations of root canals in primary teeth often produce complications in endodontic therapy.[6] When compared to permanent teeth, root canals of primary teeth present evident anatomical disparities in respect of size, shape, and internal and external morphology.[7] The presence of atypical internal geometry of the pulp cavity showing furcal and horizontal anastomosis makes endodontic therapy of primary teeth considerably challenging.[1] Mostly, a simpler root canal network is exhibited by primary teeth that have fully formed roots, featuring single canal per root. Though this system of simple canals may turn complex gradually in response to factors like secondary dentin formation that can change the number & size of the canals, and other factors like constriction of the canals as well as the beginning of physiologic root resorption.[3,8]

The literature accommodates various researches that have analyzed primary root canals including their morphologies in varied population groups utilizing different histologic and radiographic methods such as root sectioning, staining and clearing techniques, IOPA radiographs, cone beam computed tomography (CBCT), micro-computed tomography (micro-CT), and spiral computed tomography (SCT).[2,3,6,9,10]

Since their introduction, the non-invasive technologically advanced imaging methods such as CBCT and micro-CT have been extensively used for in-depth study of root canal networks.[3] Even though CBCT remains the gold-standard method for newer studies involving root canal morphologies, its limitations such as the cost of the device as well as the procedural cost, requirement of a trained staff, and specifically higher dose of radiation as well as procedural time make its regular use in children difficult.[5,11]

Although conventional radiographs provide only a 2D image which may lead to superimposition of the root canals, giving an inaccurate data, they are still used as the main diagnostic aid in routine practice for finding the size of carious lesion and analyzing canal morphology.[10] This is because they are more economical, readily available and provide much less exposure when compared to CBCT or spiral CT, therefore reducing the risk of radiation-induced carcinogenesis in children.[11,12]

Previous studies have observed an association of differences in root canal anatomies to racial and genetic factors.[5] Therefore, the aim of this *in vivo* study was to evaluate the total count of root canals found in primary maxillary and mandibular molars in the pediatric population of Delhi-National Capital Region (NCR) (India) using routine radiographs during pulpectomy procedure. Such a study can shed light on the commonly encountered root canals in primary molar teeth, which may increase the ease of providing superior quality treatment in the routine dental practice.

MATERIALS AND METHODS

All the children aged 3–9 years reporting to the outpatient department of Pediatric and Preventive dentistry at the FDS-Manav Rachna Dental College, MRIIRS, Faridabad, between January 2021 and January 2022 were analyzed according to the eligibility criteria for this study.

Inclusion Criteria

1. Children with good general health
2. Children requiring pulpectomy in primary maxillary or mandibular molars
3. Cooperative patients according to Frankl's behavior rating scale (scores 3 and 4).
4. Teeth with at least two-third roots remaining.

Exclusion Criteria

1. Teeth exhibiting ">Grade 1" mobility
2. Teeth with non-restorable coronal structure
3. Patients with special health-care needs.

173 primary maxillary and mandibular molars were included and examined for the study. Data were collected and recorded from the operators who were performing pulpectomy in the department.

The root canal orifices were clinically located according to the dentinal map and their number was determined following the clinical steps of access cavity preparation and de-roofing of the pulp chamber.

The number of root canals were verified by placing number 15 or 20 endodontic K files within the canals followed by taking IOPA radiographs and wherever required at different angulations using Sidexis XG (Sirona Dental Systems)

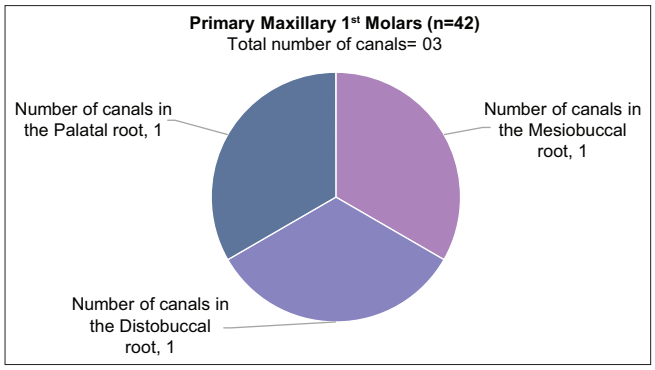


Figure 1: Number of maxillary 1st molars and frequency of the number of root canals found in them

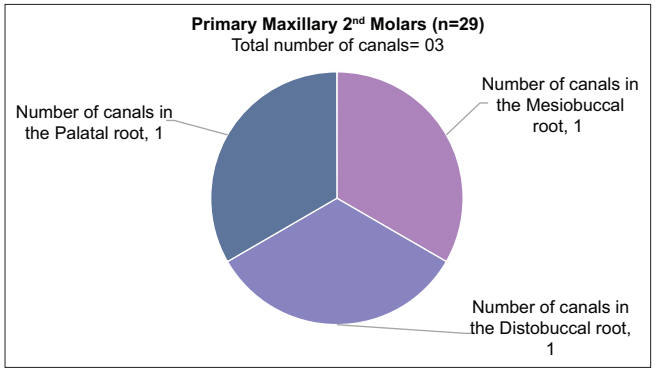


Figure 2: Number of maxillary 2st molars and frequency of the number of root canals found in them

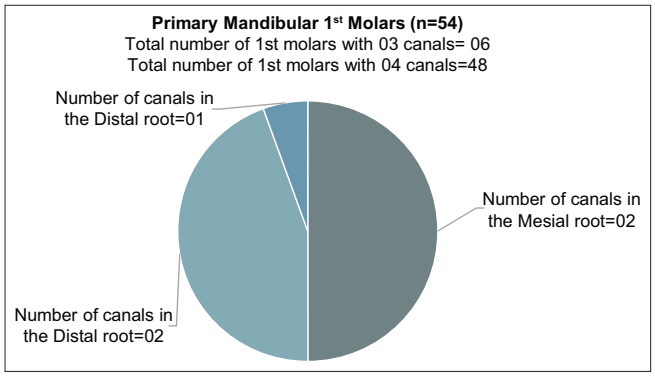


Figure 3: Number of mandibular 1st molars and frequency of the number of root canals found in them

software. The IOPAs were zoomed to obtain a magnified image for performing proper assessment of the root canals.

RESULTS AND DISCUSSION

A total of 173 primary molars were included in this study, out of which 71 molars were primary maxillary molars and 102 were mandibular molars.

Among the maxillary primary molars, 42 (59%) were 1st molars, all of which had 3 root canals. 29 (41%) were

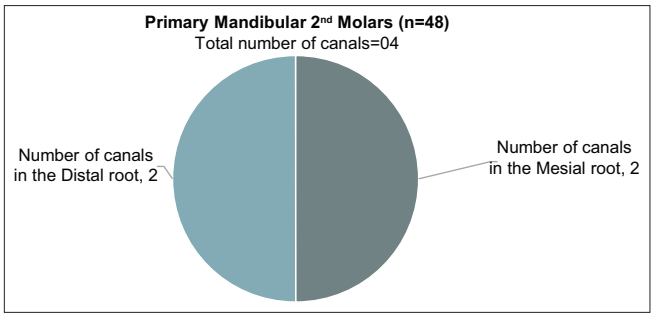


Figure 4: Number of mandibular 2nd molars and frequency of the number of root canals found in them

2nd molars with 100% of them having a total of 3 root canals [Figures 1 and 2].

Out of 102 mandibular primary molars, 54 (53%) were 1st molars. 6 out of 54 mandibular 1st molars had only 1 canal in the distal root and 2 canals in the mesial root, rest 48 mandibular 1st molars had 2 canals each in mesial and distal roots [Figure 3].

48 (47%) out of 102 were mandibular 2nd molars, all of which had a total of 4 canals, 2 canals each in mesial and distal roots [Figure 4].

In pediatric patients, losing teeth due to caries brought about by substandard maintenance of oral hygiene, feeding, and dietary habits can affect a child's well-being profoundly since an early age.[9]

The chief objective of pulp treatment is to eradicate the etiological bacteria and create an uncontaminated environment within the tooth.[9] A root canal therapy's success depends on clinician's thorough grasp of the internal and external root canal morphology of the tooth. Treatment failures can mostly result from erroneous diagnosis of total number of root canals leading to improper debridement.[11] Complete knowledge of variations in root canal numbers and anatomy of primary molars can effectively reduce challenges faced by pediatric dentists while performing pulp therapies and increase effectiveness of the treatment.[1]

Various approaches have been employed to examine the root canal anatomy, including direct microscopic observation, macroscopic sectioning, packing inert material into the canal and then decalcifying it, filling of canals followed by clearing. Nonetheless, all these techniques result in loss of relation between the external structure and the pulp due to sample preparation procedures which is a significant limitation.[9]

In the present study, conventional IOPA radiographs have been utilized to determine the total number of root canals,

as routine usage of CBCT in pediatric dental operatory is still in question and its availability is still not widespread due to the cost.[13] CBCT contributes in more radiation exposure than the conventional techniques (effective radiation dose of CBCT and IOPA is 20–599 μSv and 5–35 μSv, respectively), which is a major issue in children, as due to their higher rate of tissue growth; they have a greater risk of receiving DNA damage.[13,14] It has been observed that a CBCT scan can have a 4 times higher average cancer risk for children younger than 12 for patients over 60 years.[15] In addition, majority of the studies that were carried out to determine root canal morphologies were performed on extracted teeth, but as the present study was done *in vivo*, it got added to rationale behind using conventional radiographic technique for this study.

The main restriction while employing conventional radiography for determining the root canal anatomy is overlapping of structures that result in concealment of the object of interest.[9] Attempt was made to overcome this limitation by taking radiographs from different angulations.

Several studies have reported that the root canal anatomy can differ in various races and ethnicities.[16] Such as studies performed in China by Wang *et al.* and Yang *et al.* have shown a higher prevalence of three-rooted primary mandibular second molar with varying root canal numbers in the population. The three-rooted variant has even been frequently observed through studies done by Ozcan *et al.*, in Turkey and Bagherian *et al.*, in Iran, but studies such as done by Katge and Wakpanjar have rarely reported such a variation in Indian population.[11] Thus, this study involved observing the total number of frequently encountered root canals in the pediatric population of Delhi-NCR region (India).

In the present study, both 1st and 2nd primary maxillary molars were found to have 3 canals (mesiobuccal, distobuccal, and palatal). Similar observations were mentioned in a short review done by Ramakrishnan *et al.*,[4] on the root canal configuration of primary maxillary molars where they found that 3 canals are the most common canal morphology in both the 1st and 2nd maxillary molars. Vijayakumar *et al.*[10] in their study found that 13 out of 15 primary maxillary 1st molars and 13 out of 15 primary maxillary 2nd molars had 3 canals. Study done by Katge and Wakpanjar[5] also reported that almost 90% of the maxillary 1st and 2nd primary molars had a total of 3 canals. Krishnamurthy *et al.*[1] reported that 80% of the primary maxillary second molars had a total of 3 canals, even with varying root anatomy.

In this study, 6 (11%) out of 54 primary mandibular 1st molars had a single distal canal and 2 mesial canals, rest 48 (89%) had 2 canals in both mesial and distal roots. In the study done by Gupta and Grewal,[6] on "root canal configuration of primary mandibular first molars", 100% of the teeth had 2 canals in mesial root, with 53.33% showing 2 canals in the distal root and 46.67% having only 1 root canal in the distal root. The result of the present study was not in agreement with Katge and Wakpanjar,[5] as they reported the presence of 2 root canals in the mesial root in 80% of the samples and 2 root canals in the distal root in 23% of the samples, therefore showing predominance of 1 root canal in the distal root.

Through the present study, it was seen that 100% of the primary mandibular 2nd molars had four root canals, two mesial and two distal. Similar results were found in the study performed by Aminabadi *et al.*,[7] which stated that 100% of the mesial roots and 100% of the distal roots had two canals in primary mandibular 2nd molars. Demiriz *et al.*[2] in their study mentioned that according to the previous studies done for evaluating the anatomy of primary mandibular 2nd molars, the most frequently reported root canal forms in primary mandibular 2nd molars were 2 canals in the mesial root and 2 canals in the distal root. Katge and Wakpanjar[5] in their study reported that mesial root had 2 canals in 100% sample teeth and 56.6% sample teeth had 2 canals in the distal root.

The dissimilarities in the number of root canals may be affected by differences in the ethnic groups making up the sample in various studies and also on the diagnostic aids used in those studies.[11]

CONCLUSION

Utilizing the results of the present study while keeping in mind, the limitations of the sample size, diagnostic aid used, and biases due to involvement of multiple operators, it can be concluded that majority of the primary maxillary molars had a total of 3 root canals and primary mandibular molars had a total of 4 root canals.

It can also be concluded that IOPA radiography is still an effective and safe method that can be used in routine dental practice for endodontic procedures, especially in pediatric patients, which goes in accordance with the AAPD guidelines which state that "intraoral imaging should be maintained as the standard diagnostic tool".[12]

AKNOWLEDGMENTS

None.

ETHICS STATEMENT

Approved.

REFERENCES

1. Krishnamurthy NH, Jose S, Thimmegowda U, Bhat PK. Evaluation of anatomical variations in root and canal morphology of primary maxillary second molars: A cone-beam computed tomography study. Int J Clin Pediatr Dent 2021;14:628-32.
2. Demiriz L, Bodrumlu EH, Icen M. Evaluation of root canal morphology of human primary mandibular second molars by using cone beam computed tomography. Niger J Clin Pract 2018;21:462-7.
3. Fumes AC, Sousa-Neto MD, Leoni GB, Versiani MA, da Silva LA, da Silva RA, *et al*. Root canal morphology of primary molars: A micro-computed tomography study. Eur Arch Paediatr Dent 2014;15:317-26.
4. Ramakrishnan M, Niveditha MS, Gurunathan D. A short review on the root canal configuration of primary maxillary molars. Bioinformation 2020;16:1033-6.
5. Katge F, Wakpanjar MM. Root canal morphology of primary molars by clearing technique: An *in vitro* study. J Indian Soc Pedod Prev Dent 2018;36:151-7.
6. Gupta D, Grewal N. Root canal configuration of deciduous mandibular first molars-an *in vitro* study. J Indian Soc Pedod Prev Dent 2005;23:134-7.
7. Aminabadi NA, Farahani RM, Gajan EB. Study of root canal accessibility in human primary molars. J Oral Sci 2008;50:69-74.
8. Chawla S, Goswami M, Sachdeva P, Walia V. Primary molars with extra root canals-a case series. J Dent Specialities 2016;4:55-60.
9. Lavanya S, Sujatha S. Detection of MB_2 canal in maxillary primary second molar using cone beam computerized tomography (CBCT)-an *in vitro* study. J Pharm Sci Res 2016;8:220-3.
10. Vijayakumar R, Selvakumar H, Swaminathan K, Thomas E, Ganesh R, Palanimuthu S. Root canal morphology of human primary maxillary molars in Indian population using spiral computed tomography scan: An *in vitro* study. SRM J Res Dent Sci 2013;4:139-42.
11. Mahesh R, Nivedhitha MS. Root canal morphology of primary mandibular second molar: A systematic review. Saudi Endod J 2020;10:1-6.
12. American Academy of Pediatric Dentistry. Prescribing Dental Radiographs for Infants, Children, Adolescents, and Individuals with Special Health Care Needs. The Reference Manual of Pediatric Dentistry. Chicago, Ill: American Academy of Pediatric Dentistry; 2021. p. 258-61. Available from: https://www.aapd.org/media/policies_guidelines/BP_radiographs.pdf [Last accessed on 2022 Jan 29].
13. Bhardwaj SS, Alghamdi S, Almulhim B, Alassaf A, Almalki A, Bhardwaj A, *et al*. CBCT in pediatric dentistry: Awareness and knowledge of its correct use in Saudi Arabia. Appl Sci 2022;12:335.
14. Farias A, Shetty NS, Rai S, Rao T. Medical imaging in oral implantology: Current status and practical recommendations. Res Rev J Dent Sci 2013;1:12-22.
15. Shetty SK, Madhur VK, Rajagopal S, Kumar MY. Radiation dose, risks and protection in CBCT-a literature review. Sch J Dent Sci 2021;8:288-91.
16. Sert S, Bayirli GS. Evaluation of the root canal configurations of the mandibular and maxillary permanent teeth by gender in the Turkish population. J Endod 2004;30:391-8.

How to cite this article: Thapliyal A, Gujral S, Sood S, Sharma N, Srivastava M. Total Number of Root Canals Commonly Found During Endodontic Treatment of Primary Molars in North Indian Population - An *In Vivo* Study. Int J Sci Stud 2023;11(3):65-69.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Comparative Evaluation of Changes in Salivary pH in Patients using Povidone Iodine Mouthwash versus Chlorhexidine Mouthwash during the Non-surgical Periodontal Therapy of Chronic Periodontitis Patients: A Randomized Clinical Study

Bhargavi Sheth[1], Poonam Rai[2]

[1]Post Graduate Student, Department of Periodontics and Oral Implantology, D Y Patil School of Dentistry, Navi Mumbai, Maharashtra, India, [2]Professor, Department of Periodontics and Oral Implantology, D Y Patil School of Dentistry, Navi Mumbai, Maharashtra, India

Abstract

Introduction: Saliva contains a variety of host defense factors. It influences calculus formation and periodontal disease. With a multitude of biomarkers and complexities in their determination, the salivary pH may be tried to be used as a quick chairside test.

Materials and Methods: The study was conducted in the outpatient department of the Department of Periodontics and Oral Implantology, DY Patil School of Dentistry, Navi Mumbai, Maharashtra, India. The study population consisted of 40 patients who were between 25 and 60 years in age.

Results: In the inter-group result interpretation, on comparing the means of the gingival index and plaque index, it was not statistically significant. Although when comparing the means of the salivary pH, between the two mouthwashes 2 weeks after its use, the difference in their pH values was statistically significant, where $P < 0.05$ as shown in Table 1, where Group A showed a better and more alkaline pH compared to Group B

Conclusion: Disease severity is strongly correlated to low pH values. Salivary pH is more acidic in periodontal disease conditions, compared to the periodontally healthy subjects where the salivary pH is more alkaline. The salivary pH was more acidic in the periodontitis group which had high gingival and plaque index values compared to periodontally healthy groups showing a positive correlation between pH and GI and PI

Key words: Chlorhexidine mouthwash, Chronic periodontitis patients, Disease progression, Non-surgical periodontal therapy, Periodontitis, Povidone iodine mouthwash, Salivary pH, Severity

INTRODUCTION

Chronic periodontitis is a destructive form of the periodontal disease, in which a long-standing inflammatory state of the supporting structures is seen. After its onset, the disease progresses with the loss of collagen fibers and attachment to the root surface, apical migration of the pocket epithelium, deepening of periodontal pockets, and the increase in alveolar bone resorption. Owing to the nature of this disease, the treatment needs to be quick and efficient, although if left untreated, the disease continues with progressive destruction of the alveolar bone, which in turn leads to increased tooth mobility followed by tooth loss.

Access this article online

www.ijss-sn.com

Month of Submission : 04-2023
Month of Peer Review : 05-2023
Month of Acceptance : 06-2023
Month of Publishing : 06-2023

Corresponding Author: Dr. Poonam Rai, Professor, Department of Periodontics and Oral Implantology, D Y Patil School of Dentistry, Navi Mumbai, Maharashtra, India.

Saliva is also known to be the mirror of the body. Not only is it used to monitor the general health but also the beginning of specific diseases. Biomarkers produced by both healthy individuals or by individuals affected by specific systemic diseases are sure-shot indicators that can be used to not only monitor the health status and disease onset but also the response to the treatment and its outcome. Since saliva plays an important role in the formation of the oral biofilm and host defence, secreted saliva may have a significant role in the establishment and progression of periodontal disease.

Salivary pH plays a very important role as a biochemical indicator in periodontal diseases. This parameter is defined as the degree of acidity or alkalinity of an aqueous solution. Since periodontal disease is characterized by the changes in the periodontium, such as inflammation, bleeding, bone loss, etc., it is feasible to believe this pathology modifies the properties of saliva including its pH. It is buffering action, facilitates it to maintain a neutral pH range (6.5–7.2) in the oral cavity, however, the salivary pH has been modified under the pathological conditions.

Due to these various reasons, it can be said that the salivary pH is altered in patients with periodontitis and returns to its normal range after periodontal treatment. Therefore measuring the pH of the saliva can serve as a complementary parameter for diagnosing and monitoring the periodontal health in patients with periodontal disease.[1]

Hence, this study is planned to comparatively evaluate the change in salivary pH in patients before and after the use of two mouthwashes, namely chlorhexidine 0.2% and povidone iodine 10% during the non-surgical therapy of chronic periodontitis patients.

MATERIALS AND METHODS

The study was conducted in the outpatient department of the Department of Periodontics and Oral Implantology, DY Patil School of Dentistry, Navi Mumbai, Maharashtra, India. The study population consisted of 40 patients who were between 25 and 60 years in age. They were divided into two groups:

- Group A - 20 participants who were given povidone iodine mouthwash
- Group B - 20 participants who were given chlorhexidine mouthwash.

The study inclusion criteria included subjects in the age group of 25–60 years, at least 20 teeth had to be in the oral cavity, bleeding on probing present, mild to moderate chronic periodontitis patients with pockets depth up to 5 mm, each quadrant having at least 2–3 sites with pocket depth up to 5 mm, no clear allergy to any of the components of the mouthwashes, subjects with periodontitis: Generalized chronic periodontitis diagnosed according to the AAP International Workshop for Classification of Periodontal Diseases, 1999.

The exclusion criteria involved patients under the age of 25 years, undergoing periodontal treatment in the past 6 months, with systemic diseases that could have influenced the therapy (patients with thyroid dysfunction, diabetes mellitus, cancer, osteoporosis, radiotherapy, and anticoagulant therapy), gingivitis patients, with mental or physical retardation that could have influenced the domestic oral hygiene, uncooperative patients, smokers, pregnant or lactating women, patients with salivary flow disorders such as xerostomia or pathology in salivary glands, subjects under medication that may affect salivary function or composition and uncooperative patients and those unwilling to sign the consent form.

The patients were explained in detail about the procedure and were made aware of the purpose of study. All the questions asked by the patients pertaining to the study were answered to the satisfaction of each patient to ensure co-operation.

The following clinical indices and parameters were recorded: Gingival index (Loe and Silness, 1963), plaque index (Turesky, Gilmore, Glickman modification of the Quigley Hein plaque index, 1970), and salivary pH.

After getting the written informed consent, all the subjects who participated in the study were subjected to measurement of clinical indices including Gingival Index and Plaque Index, followed by saliva sample collection from both groups. The first saliva sample was collected at baseline from both the groups after which non-surgical periodontal therapy was carried out on the same day (T0) for all the subjects in Group A and B. The patients were asked to use their respective mouthwash for 2 weeks and were then recalled (T1). The second saliva sample was collected from Group A and Group B 2 weeks after the first sample was collected, following which salivary pH assessment was carried out.

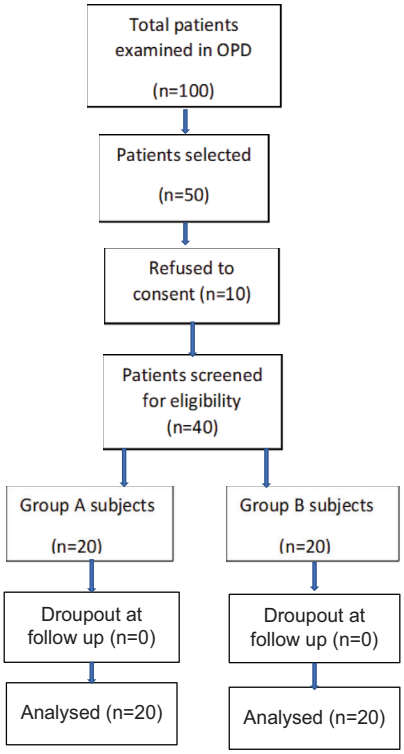
Saliva samples were obtained in the morning after an overnight fast, during which subjects were requested not to drink any beverages except water.

On the day of sample collection, subjects were given drinking water and were asked to rinse their mouth out well. 5 min after this oral rinse, the subject was asked to spit whole saliva. The participants were asked to refrain from talking and drop down the head and let the saliva run naturally to the front of the mouth. The subjects were also asked not to cough up mucus as saliva is collected. The subjects spit into the collection tube about once a minute for up to 10 min.

5 ml of saliva was collected in sterile 10 ml beaker. The saliva sample is collected between 9:00 am and 11:00 am following which the pH of saliva is immediately measured.

The table top pH meter Equiptronics, model EQ-610 manufactured by Equiptronic instruments was used for measuring the pH of saliva the device was standardized in pre-prepared buffer solutions of pH 4.01 and pH 9.18 to avoid any inaccuracies.

RESULTS



No subjects were lost during the 2-week follow-up, and all of them were included in the statistical analyses. No uneventful events were observed.

Table 1: Comparison of the mean difference (baseline – after 2 weeks) in terms of (mean [SD]) of plaque index values, gingival index values, and salivary pH level among both the groups using the unpaired *t*-test

Variables	Group	*n*	Mean	Standard deviation	*t* value	*P*-value
Plaque index	Group A	20	0.3200	0.19084	1.031	0.309
	Group B	20	0.3700	0.10311		
Gingival index	Group A	20	0.3100	0.19167	0.857	0.397
	Group B	20	0.3550	0.13563		
Salivary pH	Group A	20	0.1940	0.06901	2.915	0.006*
	Group B	20	0.1380	0.05116		

P<0.05 - Significant*, *P*<0.001 - Highly significant**. SD: Standard deviation

In the inter-group result interpretation, on comparing the means of the gingival index and plaque index, it was not statistically significant. Although when comparing the means of the salivary pH, between the two mouthwashes 2 weeks after its use, the difference in their pH values was statistically significant, where $P < 0.05$ as shown in Table 1, where Group A showed a better and more alkaline pH compared to Group B; hence, we can conclude that the use of povidone iodine mouthwash was more effective and changed the salivary pH to a more alkaline pH [Figures 1-3].

DISCUSSION

The pH of bodily fluids, namely blood and saliva, play a very important role in maintaining the health of an individual.[1] It is known that even a minor alteration as small as 0.1 in the salivary pH toward acidity which in turn increases the risk of caries. This is in accordance with an article by Pozhartiskaya *et al.* where it was concluded that changes in salivary pH are closely related to the caries resistance properties of saliva and greatly impact the clinical parameters such as probing pocket depth, clinical attachment level, gingival index and plaque index, along with the disease severity in chronic periodontitis patients. This could be attributed to the fact that a reduced salivary pH can increase the production of the reactive oxygen species, which in-turn leads to an increase in periodontal destruction.[2]

Moreover, Chlorhexidine mouthwash and Povidone iodine mouthwash are both widely used in dentistry, due to their excellent antimicrobial properties, Chlorhexidine mouthwash known to be a gold standard,[3] although very scarce studies have been carried out comparing the effect of these two mouthwashes on the salivary pH and their role in it's alteration.

Chronic periodontitis patients with pockets upto 5 mm were chosen, which was in accordance with studies carried out by Heitz and Lang in 2001 and by Pal *et al.* in 2021, who put forward the concept of critical probing depth of 5.4 mm, which means that a probing depth of above 5.5 mm, would benefit from additional surgical therapy, while sites with a shallower probing depth require only non-surgical therapy.

In the oral cavity, the pH is maintained near neutrality by saliva, but studies have shown that patients with periodontal disease tend to have a more acidic pH, which is similar to the findings in this study. This can be due to the presence of bacteria such as *Porphyromonas gingivalis* which has its proteolytic activity at pH 5–5.5, which directly mediates vascular damage *in vivo* by degrading endothelial adhesion,

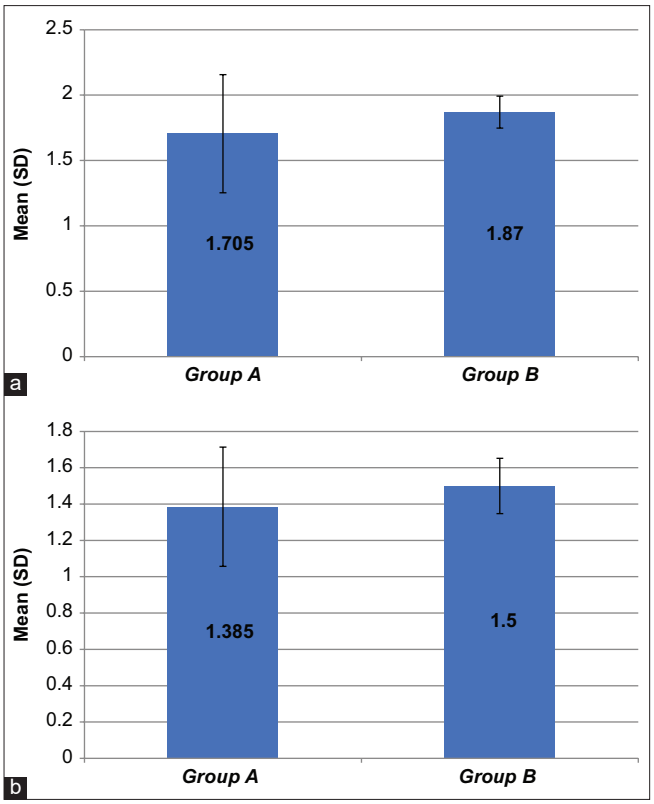


Figure 1: Comparison of plaque index values in terms of (mean [SD]) at different time intervals among both the groups using unpaired *t*-test. (a) Baseline, (b) after 2 weeks

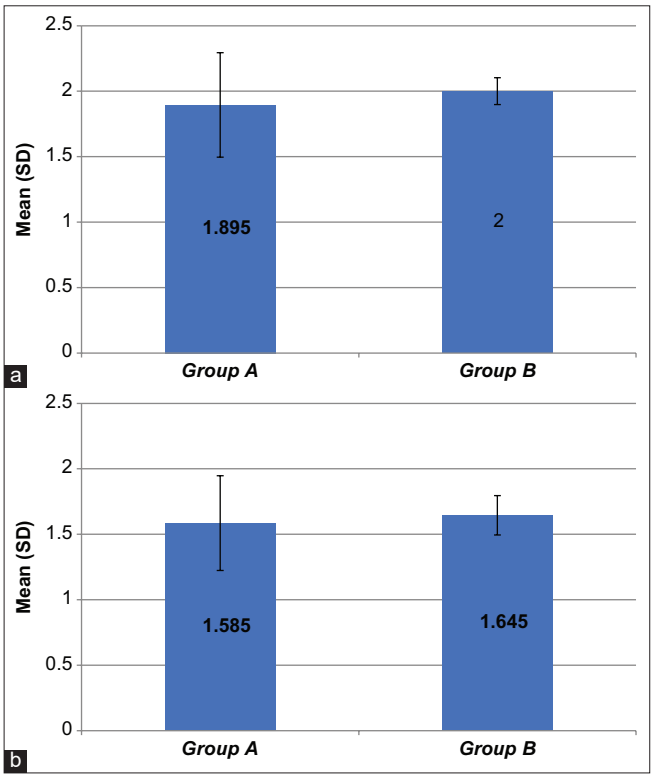


Figure 2: Comparison of gingival index values in terms of (mean [SD]) at different time intervals among both the groups using unpaired *t*-test. (a) Baseline, (b) after 2 weeks

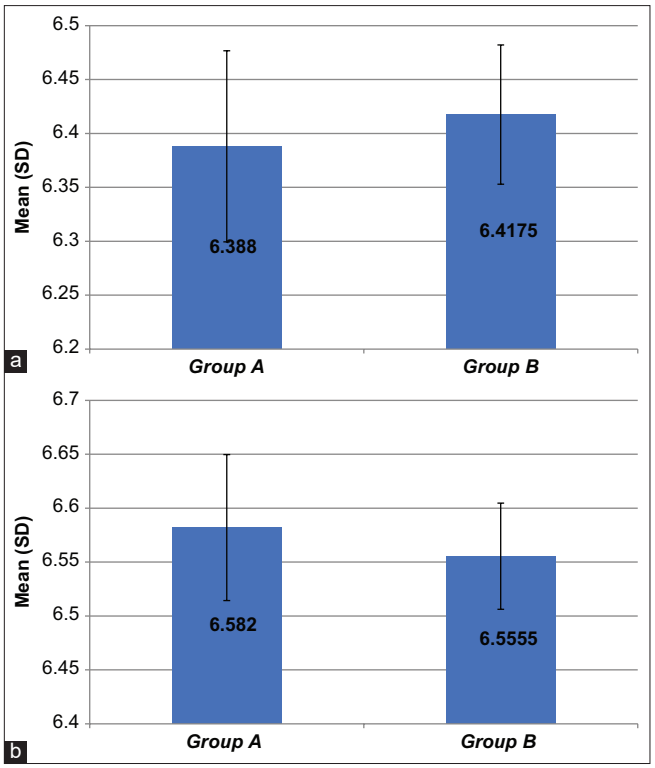


Figure 3: Comparison of Salivary pH values in terms of (mean [SD]) at different time intervals among both the groups using unpaired *t* test. (a) Baseline, (b) after 2 weeks

thus increasing vascular permeability and modulating leucocyte recruitment at the endothelial surface.[4] The local inflammation enhances cytokine and other inflammatory markers[5] which promotes the further destruction of periodontal tissue.

Saliva is used as a diagnostic fluid for a variety of reasons, namely- it meets the demands for being inexpensive, non-invasive and easy-to-use diagnostic tool.[1] As a clinical tool, saliva has many advantages over serum, including ease of collection, storing and shipping and it can be obtained at a low cost in sufficient quantities for analysis. For patients, the non-invasive collection techniques drastically reduces discomfort and anxiety making it easy to obtain repeated samples for monitoring over time. Also in diagnostic procedures, saliva is easier to handle because it does not clot, thus reducing the manipulations required.[1]

In the intergroup comparison there was a statistically significant difference ($P < 0.05$) seen in the salivary pH between the 2 groups after phase I therapy, where patients in Group A using Povidone iodine mouthwash showed a more favourable result, with a less acidic pH.

This is in accordance with a study conducted by Shin and Nam in 2018,[6] where as a result, the pH of saliva was elevated after CHX and PVI gargling, and a significant

increase was also shown in the comparison of the groups. The CFU of *S. mutans* decreased with gargling in the order of PVI and CHX. Based on this study, PVI caused the most effective change in the oral environment followed by CHX. This result is consistent with our study that gargling is an effective method for plaque control in the oral cavity as it increases the pH of saliva toward alkalinity in pre-operative patients.

This shows the direct relation between the presence of periodontal disease and the changes in salivary properties such as pH.

This gives enough reason to use saliva pH as a diagnostic tool in the prediction and follow-up of periodontal disease.

CONCLUSION

The following conclusions may be drawn from our study:

- Disease severity is strongly correlated to low pH values.
- Salivary pH is more acidic in periodontal disease conditions, compared to the periodontally healthy subjects where the salivary pH is more alkaline.
- The salivary pH was more acidic in the periodontitis group which had high gingival and plaque index values compared to periodontally healthy groups showing a positive correlation between pH and GI and PI.
- There is a definite improvement seen in the salivary pH after periodontal therapy bringing the pH of saliva towards a neutral pH.
- Even a minor variation as small as 0.1 in the pH of the saliva can greatly impact the pocket probing depth, clinical attachment level and disease severity, hence utmost care was taken to record the slightest change in pH.
- Mouthwashes play an important role in maintaining the oral hygiene and health of the oral cavity.
- Both povidone iodine 10% and Chlorhexidine 0.2% are equally effective in reducing the gingival index, plaque index, pocket-probing depth, and clinical attachment levels.
- Povidone iodine 10% when used as a mouthwash is more effective in raising the salivary pH, when compared to 0.2% Chlorhexidine mouthwash, thus making it a more efficient mouthwash in the treatment of chronic periodontitis.

Limitations

The present study includes the following limitations:

- Future studies with a larger number of participants are required.
- Subjects were re-evaluated 2 weeks after treatment; long-term follow-ups after treatment is necessary for better insights into salivary pH levels and disease severity.
- Our study results are entirely dependent on patient compliance and if they have strictly abided by the instructions given regarding the frequency of the use of the respective mouthwash.
- pH meter used in the present study is expensive compared to the use of pH strips for assessing saliva pH.
- As values of pH are extremely sensitive to the instrument used, if the pH meter is not cleaned regularly according to the manufacturer's instructions, it can lead to contamination of the saliva sample and can give altered results.

REFERENCES

1. Páez JO, de la Rosa LC, Banda JL. Salivary pH as an improvement parameter in patients with periodontitis. Cien Innov Salud 2020;e85:277-85.
2. Knaś M, Maciejczyk M, Waszkiel D, Zalewska A. Oxidative stress and salivary antioxidants. Dent Med Probl 2013;50:461-6.
3. Elzein R, Abdel-Sater F, Fakhreddine S, Hanna PA, Feghali R, Hamad H, *et al*. *In vivo* evaluation of the virucidal efficacy of chlorhexidine and povidone-iodine mouthwashes against salivary SARS-CoV-2. A randomized-controlled clinical trial. J Evid Based Dent Pract 2021;21:101584.
4. Farrugia C, Stafford GP, Potempa J, Wilkinson RN, Chen Y, Murdoch C, *et al*. Mechanisms of vascular damage by systemic dissemination of the oral pathogen *Porphyromonas gingivalis*. FEBS J 2021;288:1479-95.
5. Loos BG, Van Dyke TE. The role of inflammation and genetics in periodontal disease. Periodontol 2000 2020;83:26-39.
6. Shin AR, Nam SH. The effects of various mouthwashes on the oral environment change for oral health care. Biomed Res 2018;29:1724-9.

How to cite this article: Sheth B, Rai P. Comparative Evaluation of Changes in Salivary pH in Patients using Povidone Iodine Mouthwash versus Chlorhexidine Mouthwash during the Non-surgical Periodontal Therapy of Chronic Periodontitis Patients: A Randomized Clinical Study. Int J Sci Stud 2023;11(3):70-74.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Comparative Study of Dexmedetomidine, Clonidine, and Tramadol for Control of Post-operative Shivering after Surgery under Spinal Anesthesia

Joginder Pal Attri[1], Arshdeep Singh[2], Dipak Singh[3], Rajan Kumar[1]

[1]Professor, Department of Anaesthesia, Government Medical College, Amritsar, Punjab, India, [2]Senior Resident, Department of Anaesthesia, Government Medical College, Amritsar, Punjab, India, [3]Junior Resident, Department of Anaesthesia, Government Medical College, Amritsar, Punjab, India

Abstract

Background and Aims: Shivering is a common post-anesthetic occurrence defined as the involuntary repetitive activity of skeletal muscle. It is a common and distressing experience for many patients and occurs either during or immediately after the surgery. The incidence of shivering following spinal anesthesia is 30–60%. It is widely used as a safe anesthetic technique for both elective and emergency operations, including all open gynecology and obstetrics surgery and orthopedic surgery. The present study was carried out to compare the effects of tramadol, clonidine, and dexmedetomidine on post-operative shivering after spinal anesthesia.

Materials and Methods: This prospective randomized double-blind study was conducted in Guru Nanak Dev Hospital attached to Government Medical College, Amritsar, after taking written informed consent from patients in their vernacular language and approval from the Institutional Ethics Committee. This study was conducted on 90 patients, aged 18–60 years, American Society of Anesthesiologists Grade I and II, who were scheduled to undergo elective surgeries under spinal anesthesia and those who developed shivering were also included in the study. The patients were randomly divided into three groups, i.e., Group A, Group B, and Group C, receiving tramadaol, clonidine, and dexmedetomidine, respectively, for control of shivering. The incidence of control of shivering, along with the mean time taken to control shivering, was noted.

Results: The mean time taken to control shivering in Group C was 2.8 ± 0.12 min, Group A was 5.2 ± 0.41 min, and Group B was 6.14 ± 0.41 min. Group C takes the least time, whereas Group B takes more time to control shivering. The sedation achieved with dexmedetomidine was better than that achieved with clonidine and tramadol.

Conclusion: In conclusion, all drugs in this study effectively treated post-spinal shivering. However, the mean time taken by dexmedetomidine to control shivering was the least as compared to tramadol and clonidine.

Key words: Clonidine, Dexmedetomidine, Shivering, Tramadol

INTRODUCTION

Shivering is a common and distressing experience for many patients and occurs either during or immediately after the surgery. It is defined as an involuntary, repetitive activity of skeletal muscles. The incidence of shivering varies but is very high and it is approximately 40–50%.[1]

Access this article online

www.ijss-sn.com

Month of Submission : 04-2023
Month of Peer Review : 05-2023
Month of Acceptance : 06-2023
Month of Publishing : 06-2023

Spinal anesthesia is widely used as a safe anesthesia technique for both elective and emergency operations, including all open gynecology and obstetric surgery, orthopedic and plastic surgery of the lower limb and pelvis, and the majority of urological procedures.[2]

The main causes of shivering are heat loss, increased sympathetic tone, pain, and the systemic release of pyrogens. Shivering during surgery leads to an uncomfortable experience for the patient, which leads to an increase in oxygen consumption and carbon dioxide production by two- to three-fold. Shivering can also increase catecholamine production, lactic acidosis, intraocular pressure, and intracranial pressure.[3]

Corresponding Author: Dr. Rajan Kumar, Department of Anaesthesia, Government Medical College, Amritsar, Punjab, India.

Mild shivering increases oxygen consumption like that produced by light exercise, but severe shivering can increase oxygen consumption and metabolic rate by 100–600%. This can prove detrimental to patients with limited cardiac reserve. Shivering also creates difficulty in monitoring the patients, as most of the multiparameter monitors used for anesthesia show erroneous values.

Shivering is a physiological response to core heat production. The core body temperature is maintained within the range of 36.5°C–37.5°C, which is known as the thermo-neutral zone. Thermo-regulatory responses like vasoconstriction and shivering are activated when core body temperature falls below the normal range.[4] The spinal α motor neurons and their axons mediate the neurological mechanism of shivering, with their center at the preoptic nucleus of the anterior hypothalamus.[5]

After spinal anesthesia, shivering is more common than after general anesthesia, as the vasoconstriction effect after heat loss during surgery is lost when the patient is under spinal anesthesia due to sympathetic blockade.

MATERIALS AND METHODS

It was a prospective, randomized, double-blind study conducted in Guru Nanak Dev Hospital attached to Government Medical College, Amritsar, after taking written informed consent from patients in their vernacular language and approval from the Institutional Ethics Committee. This study was conducted on 90 patients, aged 18–60 years, American Society of Anesthesiologists (ASA) Grade I and II, who were scheduled to undergo elective surgeries under spinal anesthesia. Those who developed shivering were included in the study.

The patients who developed shivering under spinal anesthesia were randomly divided into three groups, with 30 patients in each group. Group A patients received tramadol 1 mg/kg intravenously, Group B received clonidine 1 μg/kg intravenously, and Group C received dexmedetomidine 0.5 μg/kg intravenously. The group allotment was decided by the computer-generated random envelope method. The first anesthesiologist opens the envelope, adds the study drug to 100 mL of normal saline, and hands it to the second anesthesiologist, who was blinded to the study drug. He administers the drug for over 10 min and monitors the patient.

A detailed preanesthesia checkup was done a day before the surgery. Details pertaining to the patient's clinical history, general physical examinations, and systemic examinations were taken. An assessment of the patient's airway was done. Patients were instructed to fast for 6–8 h for solids and 2 h for clear fluids before surgery.

On the day of surgery, all the vitals were recorded preoperatively. After shifting the patient, a multiparameter was attached to the patient, and continuous monitoring of pulse rate, blood pressure, respiratory rate, SpO_2, and axillary temperature was done. After venous cannulation, patients were preloaded with Ringer lactate solution. Under all aseptic conditions, the patient was asked to lie in the left lateral position. The back of the patient was painted with betadine and draped. Intervertebral space palpated. A 23G spinal needle was inserted into the L3–L4 space. 0.5% of 3.2 mL of heavy bupivacaine was injected into the subarachnoid space. The patient was immediately turned to a supine position. Oxygenation was started through a simple oxygen mask (5 l/min). Surgery was allowed to proceed under obtaining an adequate level of anesthesia.

The operating room temperature was maintained at 22°C for all the surgeries. No external warming devices were used, and fluids were administered at room temperature to all patients. The patients who developed shivering under spinal anesthesia were randomly divided into three groups, with 30 patients in each group. Group A patients received tramadol 1 mg/kg intravenously, Group B received clonidine 1 μg/kg intravenously, and Group C received dexmedetomidine 0.5 μg/kg intravenously.

The shivering intensity was graded on a scale of 1–4 as per Wrench.

- Grade 1: Patients having one or more of the following: piloerection, peripheral vasoconstriction, or peripheral cyanosis but without visible muscle activity
- Grade 2: Visible muscle activity confined to one muscle group
- Grade 3: Visible muscle activity in more than one muscle group
- Grade 4: Gross muscle activity involving the whole body. The patients were included in the study when they developed shivering with at least a grade of 2.

The hemodynamic monitoring was continued after the administration of the study drugs. The time taken to control shivering, recurrence, and adverse effects such as nausea, vomiting, dry mouth, and sedation score were observed. The sedation score proposed by Filos *et al.* was followed.

- Grade 1: Awake and alert patient
- Grade 2: Drowsy patient responding to verbal stimuli
- Grade 3: Drowsy but arousable to physical stimuli and
- Grade 4: Unarousable patient.

The monitoring was continued for 2 h after the administration of spinal anesthesia.

Statistical Analysis

After consulting with statisticians and monitoring the parameters of the study, i.e., blood pressure, oxygen saturation, respiratory rate, pulse rate, adverse effects of the study drugs, etc., the power of the study was increased to more than 85%. This study was conducted on 90 patients who were randomly divided into three groups, with 30 patients in each group. The data from the present study were systematically collected, compiled, and statistically analyzed to draw relevant conclusions.

Continuous data were presented as the mean with a standard deviation. Categorical data were expressed as percentages. Numerical variables were normally distributed and compared using the Chi-square test for non-parametric data and the *post-hoc* analysis of variance test for parametric data. The *P*-value was then determined to evaluate the level of significance.

The sample size was calculated keeping in mind at most 5% risk, a minimum of 85% power, and a 5% significance level (significant at the 95% confidence interval). Data were recorded in a Microsoft Excel spreadsheet and analyzed using the statistical Package for IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY, USA: IBM Corp., Chicago, Illinois, USA.

RESULTS

A total of 90 patients were studied and analyzed. The demographic parameters such as age, sex, BMI, ASA grade, and mean duration of surgery were comparable in both groups [Table 1].

The mean time for the onset of shivering in Group A was 23.2 ± 6.38 min, Group B was 24.66 ± 7.12 min, and Group C was 25.2 ± 6.96 min. The difference between the groups was statistically non-significant ($P > 0.05$) [Table 2].

The least time taken to control shivering by the drug was in Group C (2.8 ± 0.12 min), whereas Group A (5.2 ± 0.34 min) and Group B took more time (6.14 ± 0.41). The difference between groups A and B, B and C, A and C is statistically highly significant ($P < 0.001$) [Figure 1].

The sedation score was compared between Group A, Group B, and Group C. The difference between Group A and Group C was statistically significant, but the difference between Group A and Group B, Group B and Group C was found to be statistically nonsignificant [Figure 2].

The incidence of nausea and vomiting was observed in all three groups: Group A had 10 (33.33%) patients, Group B had 1 (3.33%) patient, and Group C had 1 (3.33%) patient.

Table 1: Demographic parameters

Parameter	Group A (*n*=30)	Group B (*n*=30)	Group C (*n*=30)	*P* (NS)
Mean age (years)	40.03±10.29	38.86±12.22	39.46±9.12	>0.05
Sex				
Male	16	14	19	0.426
Female	14	16	11	
ASA grade				
I	21	21	24	>0.05
II	9	9	6	

P>0.05=NS. NS: Non-significant, ASA: American Society of Anesthesiologists, *n*: Number of patients

Table 2: Time of onset of shivering (min)

Time of onset of shivering (min)	Mean±SD		
	Group A	Group B	Group C
Mean time of onset of shivering	23.2±6.38	24.66±7.12	25.2±6.96
P			
Group A versus B		0.425	
Group B versus C		0.742	
Group A versus C		0.250	

SD: Standard deviation

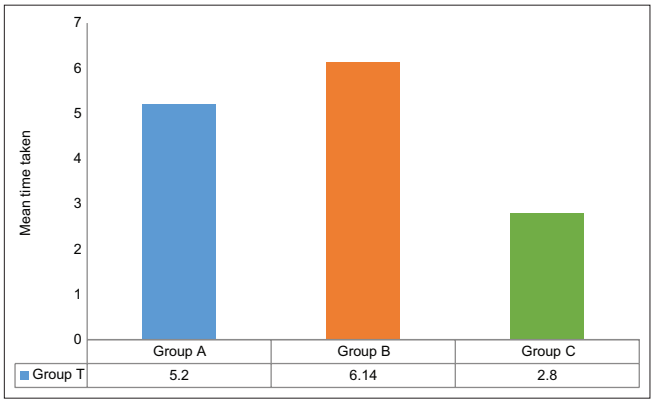


Figure 1: Mean time taken to control shivering

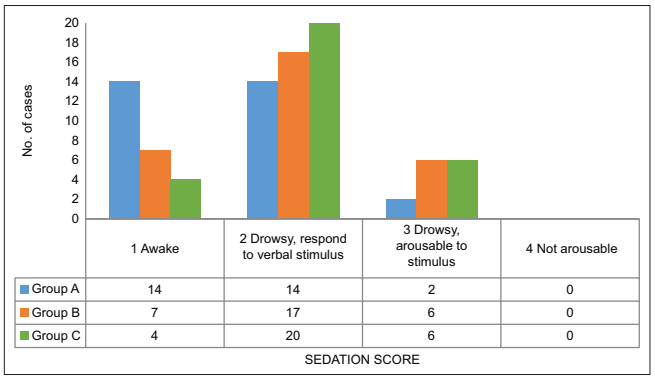


Figure 2: Sedation score

The difference between groups A and B and groups A and C is statistically highly significant, but the difference between groups B and C is statistically non-significant [Figure 3].

Complications such as bradycardia and hypotension were noted in each group. In our study, hypotension was observed in 11 patients (36.67%) in Group C, 8 patients (26.67%) in Group B, and 5 (16.67%) patients in Group A. Hence, the difference between these groups was statistically non-significant ($P > 0.05$). In our study, bradycardia was observed in all three groups. Group C has 6 (20%) patients, Group B has 3 patients (10 patients), and Group A has 2 (6.67%) patients. Hence, the difference between these groups was statistically non-significant [Table 3].

DISCUSSION

The study was carried out to compare the efficacy of tramadol, clonidine, and dexmedetomidine to control shivering in patients undergoing surgery under spinal anesthesia.

In the present study, the mean time taken by the drug to control of shivering. Group C was 2.8 ± 0.12 min, Group A was 5.20 ± 0.34 min, whereas Group B was, i.e., 6.14 ± 0.41 min. Group C takes the least time, whereas Group B takes more time to control shivering. The difference between Group A and B, Group B and C, and Group A and C is statistically highly significant ($P < 0.001$).

A similar study was conducted by Kundra *et al.* in 2017 to compare the efficacy of dexmedetomidine and tramadol on post-spinal anesthesia shivering. They concluded that the time to the cessation of shivering was significantly less with dexmedetomidine (2.9 ± 0.23 min) than with tramadol (4.6 ± 0.40 min) ($P < 0.001$). The difference between the groups was statistically highly significant.[6]

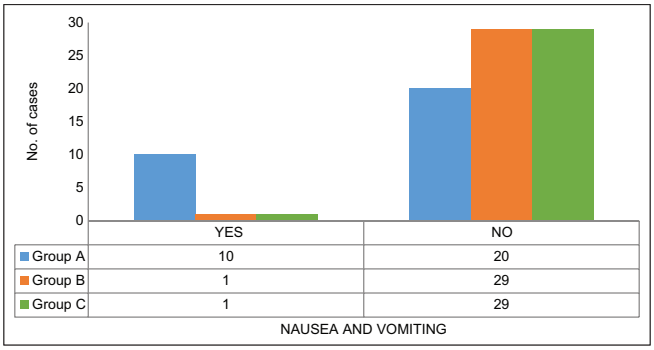


Figure 3: Incidence of nausea and vomiting

Table 3: Complications

Parameter	Group A (*n*=30)	Group B (*n*=30)	Group C (*n*=30)	*P* (NS)
Bradycardia	2	3	6	>0.05
Hypotension	5	8	11	0.426

NS: Non-significant

A similar comparative study was done by Verma *et al.* in 2018 to evaluate dexmedetomidine and tramadol for attenuation of post-spinal anesthesia shivering. They concluded that the time taken for cessation of shivering of significantly less with dexmedetomidine 2.95 ± 1.18 min than in tramadol 7.15 ± 1.77 min ($P < 0.05$). The difference between these groups was statistically significant.[7]

In our study, sedation scores were compared between Group A, Group B, and Group C. The difference between Group A and Group C was statistically significant, but the difference between Group A and Group B, Group B and Group C was statistically non-significant.

A similar study was done by Ramesh *et al.* in 2019 on a clinical comparative study between intravenous dexmedetomidine and tramadol for the control of post-spinal anesthesia shivering. They concluded that patients on dexmedetomidine were more sedated than those on tramadol ($P < 0.001$). The difference between these groups was statistically highly significant.[8]

A similar study was done by Wang *et al.* in 2020 on intravenous dexmedetomidine versus tramadol for the treatment of shivering after spinal anesthesia (randomized controlled trial). They concluded that patients on dexmedetomidine had a higher incidence of sedation than tramadol ($P = 0.005$). The difference between groups was statistically significant.[9]

In our study, bradycardia and hypotension were compared between Group A, Group B, and Group C. The difference between Group A and Group C, Group A and Group B, and Group B and Group C were statistically non-significant. However, the incidence of bradycardia and hypotension was more with dexmedetomidine as compared to tramadol and clonidine.

A similar study was done by Verma *et al.* in 2018 to compare dexmedetomidine and tramadol for attenuation of post-spinal anesthesia shivering. They concluded that hypotension was observed in three cases of tramadol compared to dexmedetomidine. Hence, the difference between these groups was statistically non-significant ($P = 0.24$).[7]

CONCLUSION

In conclusion, all drugs in this study, namely tramadol (1 mg/kg IV), clonidine (1 μg/kg IV), and dexmedetomidine (0.5 μg/kg IV) effectively treated post-spinal shivering. However, the mean time taken by dexmedetomidine to control of shivering was the least, i.e., 2.8 min, as compared to other drugs, and the recurrence rate is also less with dexmedetomidine.

There was no statistically significant difference in hemodynamic changes in all three groups.

REFERENCES

1. De Witte J, Sessler DI. Perioperative shivering: Physiology and pharmacology. Anesthesiology 2002;96:467-84.
2. Ozaki M, Kurz A, Sessler DI, Lenhardt R, Schroeder M, Moayeri A, *et al.* Thermoregulatory thresholds during epidural and spinal anesthesia. Anesthesiology 1994;81:282-8.
3. Katyal S, Tewari A. Shivering: Anaesthetic considerations. J Anaesth Clin Pharmacol 2002;18:363-76.
4. Henneman E. Organization of the motoneuron pool: The size principle. In: Mountcastle VB, editor. Medical Physiology. 14th ed. St Louis: CV Mosby; 1980. p. 718-41.
5. Alfonsi P. Postanaesthetic shivering: Epidemiology, pathophysiology, and approaches to prevention and management. Drugs 2001;61:2193-205.
6. Kundra TS, Kuthiala G, Shrivastava A, Kaur P. A comparative study on the efficacy of dexmedetomidine and tramadol on post-spinal anesthesia shivering. Saudi J Anaesth 2017;11:2-8.
7. Verma A, Bhandari D, Dhande P, Jain S, Tidke S. Comparative evaluation of dexmedetomidine and tramadol for attenuation of post-spinal anaesthesia shivering. J Clin Diagn Res 2018;12:78-80.
8. Ramesh K, Bhushanam KN, Sharma BA, Kumar SS. A clinical comparative study between intra venous dexmedetomidine and tramadol for control of post spinal anesthesia shivering. J Dent Med Sci 2019;18:26-31.
9. Wang J, Wang Z, Liu J, Wang N. Intravenous dexmedetomidine versus tramadol for treatment of shivering after spinal anesthesia: A meta-analysis of randomized controlled trials. BMC Anesthesiol 2020;20:104.

How to cite this article: Attri JP, Singh A, Singh D, Kumar R. Comparative Study of Dexmedetomidine, Clonidine, and Tramadol for Control of Post-operative Shivering after Surgery under Spinal Anesthesia. Int J Sci Stud 2023;11(3):75-79.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Neurotoxic Effects of Aspirin on the Developing Mouse Cerebellum: Implications for Human Health

Shubhangi Yadav

Assistant Professor, Department of Anatomy, All India Institute of Medical Sciences, Raebareli, Uttar Pradesh, India

Abstract

Introduction: Aspirin is a non-steroidal anti-inflammatory drug (NSAID). Pregnant women often seek relief from common discomforts such as headaches, fever, and arthritis by easily purchasing it over-the-counter. NSAIDs are commonly used during pregnancy, especially for managing chronic conditions such as inflammatory bowel disease, rheumatoid arthritis, and spondyloarthropathy. In addition, aspirin may be prescribed for obstetrical complications such as preterm labor and polyhydramnios. However, before prescribing long-term aspirin therapy, health-care professionals carefully evaluate the benefits against the potential complications associated with its use. Despite the extensive use of aspirin during pregnancy, there is limited literature available on its potentially harmful effects on fetal development. Therefore, the present study aims to address this knowledge gap by investigating the teratogenicity of aspirin.

Materials and Methods: Pregnant Swiss albino mice were divided into two groups of 151 mice each: control and treated. Aspirin was given to the treated group at a dose of 100 mg/kg body weight from the 3rd to the 5th day of gestation. The control group received an equivalent amount of tap water. The mouse from each group was sacrificed on the 19th day of gestation. After fixation in a 10% neutral formalin solution, the brains of the fetuses were dissected, photographed, and further processed for histological observations.

Results: On histological observation of the brain, the cerebellum of the treated fetuses showed many pathological changes.

Conclusion: Aspirin, although widely used, may cause toxicity and teratogenicity. Clinicians, therefore, need to be cautious and judicious when prescribing aspirin to pregnant women, being aware of its potential embryo-fetal toxicity.

Key words: Cerebellum, Neurotoxicity, Teratogenicity

INTRODUCTION

Aspirin, is non-steroidal anti-inflammatory drug (NSAID) that is widely used to alleviate pain, reduce fever, and provide anti-inflammatory benefits.[1] It is frequently utilized by pregnant women, particularly during the initial stages of pregnancy. While NSAIDs are typically prescribed for chronic conditions such as inflammatory bowel disease, rheumatoid arthritis, and spondyloarthropathy during pregnancy, aspirin also finds application in managing obstetric complications such as preterm labor and polyhydramnios. Surprisingly, it was only recognized for its preventive effects against heart attacks and ischemic strokes in the past 25 years, despite being used for over a century. The incidence of first-trimester exposure to aspirin can be attributed to women being unaware of their pregnancy. Studies conducted in Canada, Denmark, and Sweden reported a prevalence of early NSAID exposure during pregnancy of 2.9%, 3%, and 3.4%, respectively.[2-4] Aspirin is readily available over-the-counter, making it easily accessible without a prescription. The recommended safe dosage of aspirin ranges from 75 mg to 4 g per day. Its antithrombotic properties stem from the inhibition of the cyclooxygenase enzyme, which affects platelet function and reduces thromboembolic potential but may also lead to prolonged bleeding and bleeding complications.

Several studies have highlighted the vulnerability of the developing brain to various environmental insults, including exposure to medications during critical periods of gestation.[5-7] The cerebellum, a vital structure in the brain

Access this article online

www.ijss-sn.com

Month of Submission : 04-2023
Month of Peer Review : 05-2023
Month of Acceptance : 06-2023
Month of Publishing : 06-2023

Corresponding Author: Dr. Shubhangi Yadav, Department of Anatomy, All India Institute of Medical Sciences, Raebareli Campus, Raebareli - 229 405, Uttar Pradesh, India.

responsible for motor coordination and cognitive functions, undergoes dynamic development during the embryonic and early postnatal stages. Disruptions in cerebellar development can lead to long-lasting impairments in motor control and cognitive abilities.

The aim of this study is to investigate the potentially toxic effects of aspirin on the cerebellum of developing mice. We hypothesize that aspirin exposure during critical periods of cerebellar development may disrupt normal cellular processes, leading to structural and functional abnormalities in this brain region.

MATERIALS AND METHODS

Female Swiss albino mice weighing 20–25 g with an average age of 80–100 days were used in this study following approval from the institutional ethical committee. The mice were obtained from the Department of Anatomy, IMS, and BHU Varanasi Animal House.

Pregnant mice were divided into two groups as follows: Group 1: The control group administered an equivalent amount of tap water. Group 2: Treatment group orally administered aspirin at a dose of 100 mg/kg of body weight from day 3 to day 5 of gestation.

Each group consisted of 151 mice. Aspirin tablets (100 mg) from Reckitt Benckiser, Delhi, were used for the treatment. Prior to administration, one tablet was dissolved in 10 ml of tap water. The dosage of the drug was adjusted based on the body weight of the mice to achieve a proportionate dose of 100 mg/kg for the treated group. The drug was administered to the mice through oral gavage.

On the 19th day of gestation, mice from each group were euthanized using deep ether anesthesia. A uterotomy was performed to collect the fetuses. The general appearance and presence of gross malformations in the collected fetuses were documented through photography. Subsequently, the fetuses were preserved in a 10% neutral formalin solution for 7 days. After fixation, the fetal brains were dissected, photographed, and further processed for histological observations.

RESULTS

The control cerebellum shows well-defined three layers: the outer molecular, middle Purkinje, and inner granular layers [Figure 1]. In the treated cerebellum, there is thinning as well as loss of cohesion in the cells inside the molecular layer. The spaces between the different layers are also increased. The cellularity in each layer is also reduced considerably. The disappearance of cells and the cohesion of smaller vacuolated spaces give rise to the spongiform appearance of the treated cerebellar cortex [Figures 2 and 3].

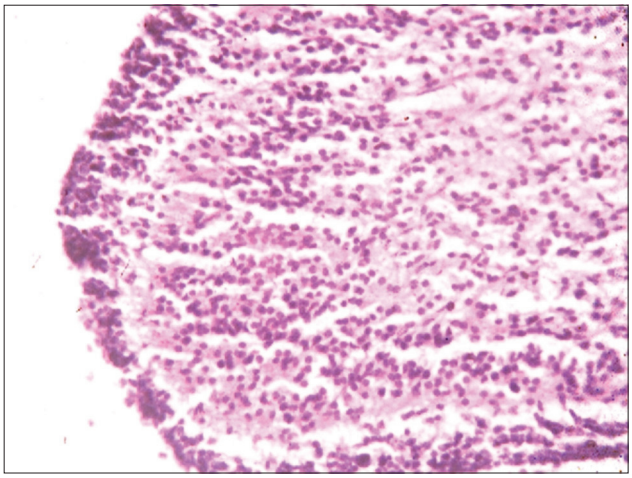


Figure 1: Photomicrograph showing control cerebellum (H and E, ×100)

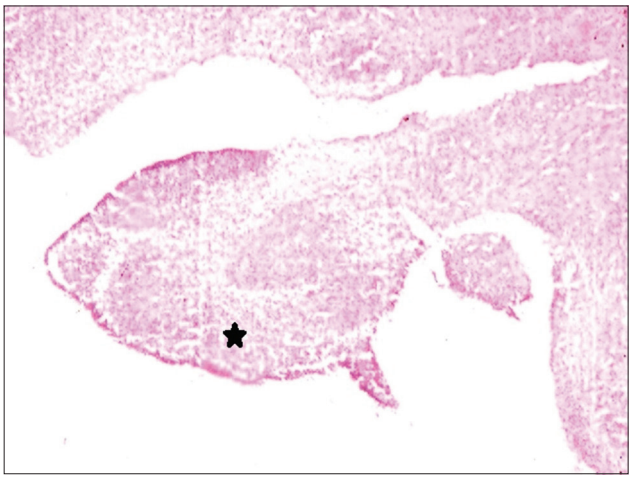


Figure 2: Photomicrograph showing treated Cerebellum (H and E, ×100). Showing reduced cellular density (★)

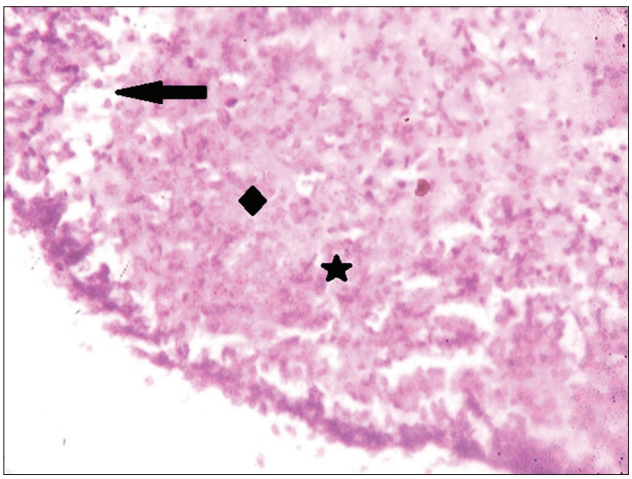


Figure 3: Photomicrograph showing treated cerebellum (H and E, ×400). Showing emptry spaces (→), degeneration of cells (★), paucity of cells (♦)

DISCUSSION

This study investigated the neurotoxic effects of aspirin on developing embryos. The findings of our study revealed significant evidence supporting the neurotoxic properties of aspirin during embryonic development.

The present study identified an increased incidence of apoptotic cell death in the brains of embryos exposed to aspirin. This suggests that aspirin may induce neurotoxicity by triggering apoptotic pathways, leading to the loss of developing neurons.

The observed neurotoxic effects of aspirin on the developing embryo align with previous studies that have reported similar findings.

In a study conducted by Sheppard *et al.*,[8] the focus was on investigating the negative effects of salicylate, the active component of aspirin, on various aspects of neurological health, such as hearing loss, neurotoxicity, tinnitus, and neuropathophysiology. The researchers discovered that the harmful effects of acetylsalicylate were primarily attributed to the inhibition of serotonin-mediated GABA inhibition, which plays a crucial role in maintaining precise frequency tuning in the auditory system.

Deng *et al.*[9] explored the impact of salicylate, including high doses of aspirin, on spiral ganglion neurons. Their findings indicated that elevated levels of salicylate induced an apoptotic response in these neurons, leading to cell death. Furthermore, it was observed that salicylate increased the production of superoxide radicals in spiral ganglion cells, suggesting a potential mechanism underlying the death of cochlear spiral ganglion neurons.

A recent meta-analysis[10] provided further evidence regarding the risks associated with maternal prenatal exposure to NSAIDs, including aspirin. The analysis indicated an increased risk of cerebral palsy and cognitive-behavioral disorders in offspring when mothers were exposed to NSAIDs or non-opioid painkillers during pregnancy. The interference with neurulation, the early process of brain development, was proposed as a potential mechanism contributing to the elevated risk.

Petersen *et al.*[11] conducted a study involving mother–child pairs from large cohorts in Denmark and Norway. Their findings revealed a significant association between aspirin use during pregnancy and a higher risk of bilateral spastic cerebral palsy in children.

In addition, on-going research by Landman *et al.*[12] aims to assess the long-term effects of antenatal exposure to low-dose aspirin compared to a placebo. The study focuses on evaluating survival rates, neurodevelopmental outcomes, behavioral patterns, and general health in children at the age of four. The primary focus is on identifying potential delays in neurodevelopment and the presence of behavioral problems, providing further insight into the possible neurotoxic effects of aspirin.

Collectively, these studies, along with our own findings, reinforce the notion of the neurotoxicity associated with aspirin exposure, shedding light on potential mechanisms and supporting the need for caution and further investigation when considering the use of aspirin during pregnancy.

CONCLUSION

The timing of aspirin administration during pregnancy plays a crucial role in influencing fetal development. Research has shown that when aspirin is given during early gestation, it is associated with an increased risk of miscarriage and congenital anomalies. Conversely, when administered during the third trimester of gestation, it has been linked to renal and vascular effects, including the closure of the ductus arteriosus and persistent pulmonary hypertension in newborns. It has been established that NSAIDs, including aspirin, can cross the placenta and reach the fetal circulation.

The primary pharmacological effect of aspirin on the developing fetus is believed to be through the inhibition of prostaglandin synthesis. This mechanism may contribute to the observed adverse effects on fetal development.

Given the growing use of low-dose aspirin as a prophylactic measure during pregnancy, it is essential to gather more long-term data to determine any potential harm and assess possible benefits in the future. Physicians need to be cautious and judicious when prescribing aspirin to pregnant women, being aware of its potential embryo-fetal toxicity. Close monitoring and individualized risk–benefit assessments are necessary to ensure the safety and well-being of both the mother and the developing fetus.

ACKNOWLEDGMENT

The author acknowledges the support of the technical and laboratory staff of the institute.

REFERENCES

1. Paul AD, Chauhan CK. Study of usage pattern of nonsteroidal anti-inflammatory drugs (NSAIDs) among different practice categories in Indian clinical setting. Eur J Clin Pharmacol 2005;60:889-92.

2. Ofori B, Oraichi D, Blais L, Rey E, Bérard A. Risk of congenital anomalies in pregnant users of non-steroidal anti-inflammatory drugs: A nested case-control study. Birth Defects Res B Dev Reprod Toxicol 2006;77:268-79.
3. Olesen C, Steffensen FH, Nielsen GL, de Jong-van den Berg L, Olsen J, Sørensen HT. Drug use in first pregnancy and lactation: A population-based survey among Danish women. The EUROMAP group. Eur J Clin Pharmacol 1999;55:139-44.
4. Ericson A, Källén BA. Nonsteroidal anti-inflammatory drugs in early pregnancy. Reprod Toxicol 2001;15:371-5.
5. David A, Pancharatna K. Developmental anomalies induced by a non-selective COX inhibitor (ibuprofen) in zebrafish (*Danio rerio*). Environ Toxicol Pharmacol 2009;27:390-5.
6. Gamarra JS Jr., Godoi AF, de Vasconcelos EC, de Souza KM, de Oliveira CM. Environmental risk assessment (ERA) of diclofenac and ibuprofen: A public health perspective. Chemosphere 2015;120:462-9.
7. Ji K, Liu X, Lee S, Kang S, Kho Y, Giesy JP, *et al.* Effects of non-steroidal anti-inflammatory drugs on hormones and genes of the hypothalamic-pituitary-gonad axis, and reproduction of zebrafish. J Hazard Mater 2013;254-255:242-51.
8. Sheppard A, Hayes SH, Chen GD, Ralli M, Salvi R. Review of salicylate-induced hearing loss, neurotoxicity, tinnitus and neuropathophysiology. Acta Otorhinolaryngol Ital 2014;34:79-93.
9. Deng L, Ding D, Su J, Manohar S, Salvi R. Salicylate selectively kills cochlear spiral ganglion neurons by paradoxically up-regulating superoxide. Neurotox Res 2013;24:307-19.
10. Moungmaithong S, Leung BW, Sahota DS, Wang CC, Leung TY, Poon LC. Assessment of embryo morphology following perinatal exposure to aspirin, ibuprofen and paracetamol using whole embryo culture system. J Matern Fetal Neonatal Med 2022;35:8786-93.
11. Petersen TG, Liew Z, Andersen AN, Andersen GL, Andersen PK, Martinussen T, *et al.* Use of paracetamol, ibuprofen or aspirin in pregnancy and risk of cerebral palsy in the child. Int J Epidemiol 2018;47:121-30.
12. Landman AJ, van Limburg Stirum EV, van 't Hooft J, Leemhuis AG, Finken MJ, van Baar AL, *et al.* Long-term outcomes following antenatal exposure to low-dose aspirin: Study protocol for the 4-year follow-up of the APRIL randomised controlled trial. BMJ Open 2022;12:e060632.

How to cite this article: Yadav S. Neurotoxic Effects of Aspirin on the Developing Mouse Cerebellum: Implications for Human Health. Int J Sci Stud 2023;11(3):80-83.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Efficacy of Lateral Internal Sphincterotomy in Patients Undergoing Milligan - Morgan Hemorrhoidectomy

K Prashanth[1], Sushrith Urs[2], P Hamsa Priya[2], M Amar[2]

[1]Assistant Professor, Department of General Surgery, Dr. B. R. Ambedkar Medical College, Bengaluru, Karnataka, India, [2]Post Graduate, Department of General Surgery, Dr. B. R. Ambedkar Medical College, Bengaluru, Karnataka, India

Abstract

Background and Objectives: Hemorrhoids are the most common anorectal disorder and usually present with painless bleeding per rectum. Treatment of grade 3 and 4 hemorrhoids usually involves various surgical methods, from open hemorrhoidectomy to modern laser surgery. However, the open excisional technique, i.e., Milligan–Morgan hemorrhoidectomy still remains one of the best methods of treatment. But it is associated with significant postoperative pain, which is attributed to spasm of the internal sphincter, which leads to other complications and delays discharge. So, combining lateral internal sphincterotomy with hemorrhoidectomy was proposed and practiced in various studies. The study was aimed at identifying the efficacy of lateral internal sphincterotomy in reducing post hemorrhoidectomy pain and associated complications after Milligan–Morgan hemorrhoidectomy.

Materials and Methods: A prospective observational study was conducted at Dr. B. R. Ambedkar Medical College and Hospital, Bengaluru, between January 2021 and June 2022, which involved 120 patients undergoing surgery for hemorrhoidal disease. They were divided into 2 groups of 60 each, one with patients undergoing Milligan–Morgan hemorrhoidectomy and the other with patients undergoing lateral internal sphincterotomy. Postoperative details were collected, tabulated, and analyzed using statistical tools.

Results: Among the study groups, patients undergoing lateral internal sphincterotomy with Milligan–Morgan hemorrhoidectomy were reported to have significantly less postoperative pain compared to patients undergoing only Milligan–Morgan hemorrhoidectomy. Furthermore, postoperative urinary retention, duration of hospital stay, and time to return to work were less with the sphincterotomy group. However, fecal incontinence was seen in 1 patient in the lateral internal sphincterotomy group, though not statistically significant.

Conclusion: Lateral internal sphincterotomy is a well-effective method that can be combined with Milligan–Morgan hemorrhoidectomy to reduce postoperative complications.

Key words: Excisional hemorrhoidectomy, Hemorrhoidectomy, Hemorrhoids, Lateral Internal sphincterotomy, Post hemorrhoidectomy pain

INTRODUCTION

Hemorrhoids are the most common and distressing pathology of the anal canal, which refers to the downward displacement of dilated vascular submucosal anal cushions, commonly located at the 3, 7, and 11 o'clock positions of the anal canal. Per rectal bleeding, mucosal discharge, prolapse, pruritus ani, and pain at rest and during defecation are the common presentations of hemorrhoids, and if not treated, may develop complications.[1-3]

Various treatment options for hemorrhoidal disease are in practice, which include the most commonly practiced Milligan-Morgan technique, the Ferguson technique, stapled hemorrhoidectomy, Barron's banding, injection sclerosant therapy, cryosurgery, infrared coagulation, LASER therapy, the technique using a harmonic scalpel or ligasure, and Doppler-guided hemorrhoidal artery ligation.[4] All the techniques of hemorrhoidectomy are known to cause significant postoperative pain, and no single surgical technique has been proven to significantly reduce the pain.[5]

Access this article online

www.ijss-sn.com

Month of Submission : 04-2023
Month of Peer Review : 05-2023
Month of Acceptance : 06-2023
Month of Publishing : 06-2023

Corresponding Author: Dr. Amar M, Post Graduate, Department of General Surgery, Dr B R Ambedkar Medical College, Bengaluru, Karnataka, India.

Surgical open hemorrhoidectomy involving Milligan-Morgan technique is the treatment method of choice for grade 3 and grade 4 hemorrhoids. However, Milligan-Morgan hemorrhoidectomy is considered a painful operation.[6] The exact cause of post hemorrhoidectomy pain has not yet been completely defined, but it is assumed to be due to spasm of the internal sphincter, (which gets exposed during hemorrhoidectomy), anal packing, urinary retention, and wound edema.[7]

Numerous invasive and noninvasive methods are used in the management of posthemorrhoidectomy pain, which includes lateral internal sphincterotomy, Lord's dilatation, perianal application of nitroglycerine ointment,[8] calcium channel blocker, or local anesthetics[10], and the use of metronidazole.[9] Furthermore, various studies have compared different surgical techniques, like open versus the semi-closed hemorrhoidectomy[11] or the use of diathermy versus the use of scissors for closed hemorrhoidectomy,[12] trying to identify methods to reduce postoperative pain.

Postoperative pain is associated with significant morbidities like retention of urine, prolonged need for parenteral analgesics, prolonged hospital stay, cost of treatment, and delay in resuming work.

Lateral internal sphincterotomy, along with Milligan-Morgan hemorrhoidectomy, is a method employed to reduce spasm and anal canal pressure, with a subsequent reduction in pain and other hemorrhoidectomy related complications.[7,13-15] However, it is still a matter of debate among surgeons whether to use sphincterotomies for reducing postoperative pain due to the associated catastrophic complication, i.e., fecal incontinence associated with it.[15,16]

Hence, the present study was aimed at comparing efficiency of Milligan–Morgan hemorrhoidectomy alone and Milligan–Morgan hemorrhoidectomy with lateral internal sphincterotomy in reducing postoperative pain and other hemorrhoidectomy related complications.

Objectives of the Study

To compare the efficiency of combining lateral internal sphincterotomy with Milligan – Morgan hemorrhoidectomy with respect to postoperative pain, urinary retention, postoperative hospital stay, fecal incontinence, and resuming work.

MATERIALS AND METHODS

A prospective observational study was conducted between January 2021 and June 2022 in patients undergoing open surgical treatment for grade 3 and 4 hemorrhoids in all surgical units of the Department of General Surgery, Dr. B. R. Ambedkar Medical College, Bengaluru, which includes a total of 120 patients. Patients were divided into 2 groups of 60 patients: Group A, including patients undergoing Milligan–Morgan hemorrhoidectomy and Group B, including patients undergoing Milligan–Morgan hemorrhoidectomy with lateral internal sphincterotomy.

Inclusion Criteria

- Age >18 years
- Both males and females
- Diagnosis of grade 3 or 4 hemorrhoids
- Patient willing to give informed consent.

Exclusion Criteria

- Age <18 years
- Patient not willing to give informed consent
- Recurrent hemorrhoids
- Associated fistula or fissure
- Malignancy
- Cirrhosis and portal hypertension
- Pregnancy.

Patients who were diagnosed with grade 3 and 4 hemorrhoids by clinical examination and underwent hemorrhoidectomy under spinal anesthesia were included in the study. Patients were observed and data collected using a proforma. Parameters noted during the postoperative period were:

1. Pain at the surgical site, assessed using the Visual Analog Scale at 12 h, 24 h, 48 h and at 7 days after surgery
2. Urinary retention
3. Fecal incontinence is assessed using Wexner's scoring system
4. Duration of postoperative hospitalization
5. Return to work.

The data were tabulated using Microsoft Excel and analyzed using SPSS software Version 17 Manufacturer: IBM/ USA. The results were obtained and compared with previous data obtained through a review of the literature.

RESULTS

- In the study, the patients aged between 21 and 75 years were in the study with a mean age of 45.32 years and a median age of 45.50 years, and the majority of the patients were between 31 and 60 years. However, distribution according to age was similar in both groups. Among the study participants, 90 were males and 30 were females, with a similar distribution in both groups

Age parameters	
Mean (years)	45.32
Median	45.50
Minimum (years)	21
Maximum (years)	75

Age distribution among patients			
Age (years)	**Group A**	**Group B**	**Total**
21–30	10	4	14
31–40	12	18	30
41–50	24	16	40
51–60	10	16	26
61–70	4	12	8
71–80	0	2	2
Total	60	60	120

Gender distribution among patients			
Gender	**Group A**	**Group B**	**Total**
Male	48	42	90
Female	12	18	30
Total	60	60	*n*=120

- Posthemorrhoidectomy pain was significantly higher among the patients who had undergone only hemorrhoidectomy (Group A and Graph 1) when compared to those who had undergone lateral internal sphincterotomy with hemorrhoidectomy (Group B and Graph 2), signifying the role of lateral internal sphincterotomy in reducing postoperative pain
- Postoperative urinary retention was seen in 12 patients in Group A and 2 patients in Group B, signifying a reduction in urinary retention after lateral internal sphincterotomy, which has reduced postoperative pain

Distribution of urinary retention among patients		
Group	**Yes**	**No**
Group A	12	48
Group B	2	58
Total	14	106

- Duration of hospital stay was significantly high among Group A (mean hospital stay= 3.60 days) compared to Group B (mean hospital stay = 2.60 days)

Mean duration of hospital stay			
Group	**Mean**	**SD**	**SEM**
Group A	3.60	0.894	0.163
Group B	2.60	0.675	0.123

SD: Standard deviation, SEM: Standard error of the mean

- One patient in Group B who has undergone lateral internal sphincterotomy has developed fecal incontinence, and none in Group A has developed fecal incontinence

Mean of incontinence score			
Group	**Mean**	**SD**	**SEM**
Group A	0.0	0.000	0.000
Group B	0.10	0.407	0.074

SD: Standard deviation, SEM: Standard error of the mean

- The mean duration to return to work was longer in Group A (17.43 days) compared to Group B (10.23 days).

Mean duration to return to work in days			
Group	**Mean**	**SD**	**SEM**
Group A	17.43	6.388	1.166
Group B	10.23	2.431	0.444

SD: Standard deviation, SEM: Standard error of mean

DISCUSSION

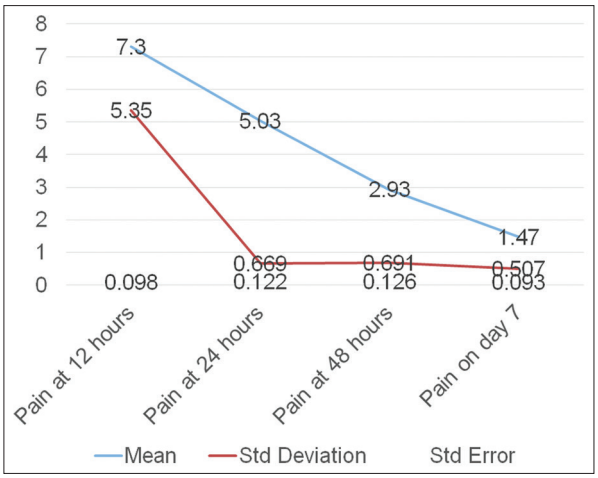
In the present study, postoperative pain, urinary retention, duration of hospitalization, and duration of return to work were found to be less when hemorrhoidectomy was combined with lateral internal sphincterotomy rather than only hemorrhoidectomy without sphincterotomy. However, anal incontinence was seen in one case with a sphincterotomy. The results were consistent with the studies done by Selvarajan,[17] Taha,[3] Hosseini *et al.,*[18] Das *et al.*[19] and Vijayaraghavalu *et al.*[20]

A meta-analysis conducted by Wang *et al.*[21] studied 10 randomized controlled trials involving 1560 patients and concluded that lateral internal sphincterotomy significantly reduces posthemorrhoidectomy pain, and reduces patients' postoperative analgesic needs, and also reduces the incidence of anal stenosis but increases the incidence of fecal incontinence. Notaras[22] in 1971 advocated lateral internal sphincterotomy instead of anal dilatation. DiBella and Esteinne[7] in 1990 found that lateral internal sphincterotomy reduces postoperative pain by reducing the tone of the internal sphincter.

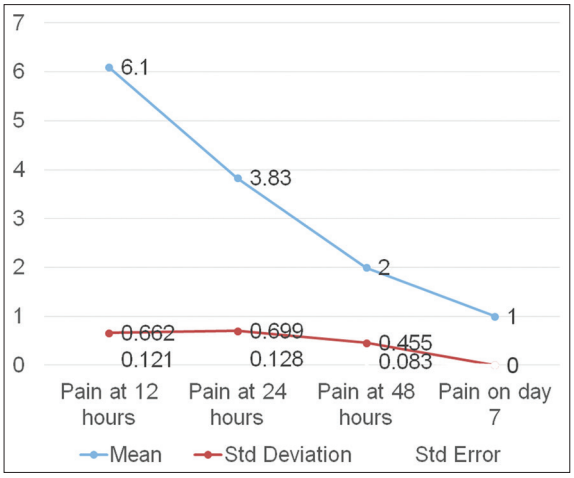
Kamruzzaman *et al.*[23] found that open hemorrhoidectomy with lateral internal sphincterotomy reported less post hemorrhoidectomy pain as compared to hemorrhoidectomy alone, which was consistent with our study results. They concluded that lateral internal sphincterotomy combined with hemorrhoidectomy is a more suitable procedure than lateral internal sphincterotomy alone.

Diana *et al.*[24] found that patients undergoing lateral internal sphincterotomy have less pain only on the first postoperative day but not in the medium- and long-term follow-up.

Raza[25] found that most patients who underwent open hemorrhoidectomy with lateral internal sphincterotomy



Graph 1: Visual analog scale for postoperative pain in Group A



Graph 2: Visual analog scale for postoperative pain in Group B

were totally pain-free at the end of the study when compared to patients who underwent hemorrhoidectomy alone.

According to Abedidost *et al.*[26] report, reduction in posthemorrhoidectomy pain with lateral internal sphincterotomy has a significant relationship between the two groups on the 1st, 2nd, and 5th postoperative days.

In contrast, Mathai *et al.*,[27] Chen *et al.*[15] and William *et al.*[16] reported that there was no added advantage in reducing postoperative pain scores, and they concluded that it was unnecessary to add lateral internal sphincterotomy to routine hemorrhoidectomy which has an added risk of fecal incontinence.

CONCLUSION

The results of our study show that Milligan–Morgan hemorrhoidectomy with lateral internal sphincterotomy is better in terms of reducing posthemorrhoidectomy pain, urinary retention, the need for urinary catheterization, reducing the duration of hospital stay, and an early return to work. Hence, Milligan–Morgan hemorrhoidectomy combined with lateral internal sphincterotomy can be used as a regular technique to reduce postoperative complications and maximize patient satisfaction.

REFERENCES

1. Quraishy SM, Idris F, Sultan N. Outpatient treatment of hemorrhoids with electronic coagulator initial experience with 103 patients. Med Spectr 1999;21:20-2.
2. Suchdev S, Ghayassuddin M, Younus SM, Mirani AJ, Ghias N, Qazi A, *et al.* Calcium channel blockers for pain relief after haemorrhoidectomy; a randomized controlled trial from Karachi, Pakistan. Pak J Surg 2014;30:187-92.
3. Taha SA. Routine internal sphincterotomy with hemorrhoidectomy for third and fourth degree hemorrhoids greatly improves the outcome. IJGE 2003;4:48-51.
4. Allen-Mersh TG, Mann CV. Open haemorrhoidectomy (St Mark's ligation/excision method). In: Fielding LP, Goldberg SM, Rob C, editors. Rob and Smith's Operative Surgery: Surgery of the Colon, Rectum & Anus. 5th ed. Oxford: Butterworth-Heinemann; 1993. p. 789-96.
5. Kanellos I, Zacharakis E, Christoforidis E, Angelopoulos S, Kanellos D, Pramateftakis MG, *et al.* Usefulness of lateral internal sphincterotomy in reducing postoperative pain after open hemorrhoidectomy. World J Surg 2005;29:464-8.
6. Khubchandani IT. Internal sphincterotomy with hemorrhoidectomy does not relieve pain: A prospective, randomized study. Dis Colon Rectum 2002;45:1452-7.
7. DiBella F, Esteinne G: Indications for internal medioposterior with anoplasty of lateral sphincterotomy during hemorrhoidectomy: Our experience. Minerva Chir 1990;45:361-3.
8. Wasvary HJ, Hain J, Mosed-Vogel M, Bendick P, Barkel DC, Klein SN. Randomized, prospective, double-blind, placebo-controlled trial of effect of nitroglycerin ointment on pain after hemorrhoidectomy. Dis Colon Rectum 2001;44:1069-73.
9. Balfour L, Stojkovic SG, Botterill ID, Burke DA, Finan PJ, Sagar PM. A randomized, double-blind trial of the effect of metronidazole on pain after closed hemorrhoidectomy. Dis Colon Rectum 2002;45:1186-90.
10. Vinson-Bonnet B, Coltat JC, Fingerhut A, Bonnet F. Local infiltration with ropivacaine improves immediate postoperative pain control after hemorrhoidal surgery. Dis Colon Rectum 2002;45:104-8.
11. Mikuni N, Oya M, Komatsu J, Yamana T. A prospective randomized comparison between an open hemorrhoidectomy and a semi-closed (semi-open) hemorrhoidectomy. Surg Today 2002;32:40-7.
12. Ibrahim S, Tsang C, Lee YL, Eu KW, Seow-Choen F. Prospective, randomized trial comparing pain and complications between diathermy and scissors for closed hemorrhoidectomy. Dis Colon Rectum 1998;41:1418-20.
13. Mortensen PE, Olsen J, Pedersen IK, Christiansen J. A randomized study on hemorrhoidectomy combined with anal dilatation. Dis Colon Rectum 1987;30:755-7.
14. Eisenhammer S. Internal anal sphincterotomy plus free dilatation versus anal stretch with special criticism of the anal stretch procedure for hemorrhoids: The recommended modern approach to hemorrhoid treatment. Dis Colon Rectum 1974;17:493-522.
15. Chen WS, Leu SY, Wang FM. The roles of hemorrhoidectomy and lateral internal sphincterotomy in the treatment of hemorrhoids – Clinical and manometric study. Zhonghua Yi Xue Za Zhi (Taipei) 1989;43:255-60.
16. William A, Zbar A, Kmiot W. Anorectal investigation. In: A Companion to Specialist Surgical Practice Colorectal Surgery. 2nd ed. Philadelphia: W.B. Saunders; 2001.
17. Selvarajan R. Efficacy of haemorrhoidectomy versus haemorrhoidectomy with internal sphincterotomy in treatment of haemorrhoids: A retrospective randomized controlled trial study. Int Surg J 2021;8:839-43.
18. Hosseini SV, Sharifi K, Ahmadfard A, Mosallaei M, Pourahmad S,

Bolandparvaz S. Role of internal sphincterotomy in the treatment of hemorrhoids: A randomized clinical trial. Arch Iran Med 2007;10:504-8.
19. Das DK, Choudhury UC, Lim ZS. Effectiveness of internal sphincterotomy in reducing post open hemorrhoidectomy pain: A randomized comparative clinical study. Int J Collaborat Res Intern Med Public Health 2013;5:398-406.
20. Vijayaraghavalu S, Prasad RG, Rajkumar S. The role of lateral internal sphincterotomy in haemorrhoidectomy: A study in a tertiary care center. Cureus 2021;13:e15630.
21. Wang WG, Lu WZ, Yang CM, Yu KQ, He HB. Effect of lateral internal sphincterotomy in patients undergoing excisional hemorrhoidectomy. Medicine (Baltimore) 2018;97:e11820.
22. Notaras MJ. The treatment ofanal fissure by lateral subcutneous internal sphincterotomy – A technique and results. Br J Surg 1971;58:96-100.
23. Kamruzzaman M, Rashid MH, Kabir N, Rahman MM, Khan MM. A comparative study between open hemorrhoidectomy with lateral internal sphincterotomy and hemorrhoidectomy without lateral internal sphincterotomy. Int Organ Sci Res 2018;17:57-60.
24. Diana G, Guercio G, Cudia B, Ricotta C. Internal sphincterotomy reduces postoperative pain after Milligan Morgan haemorrhoidectomy. BMC Surg 2009;9:16.
25. Raza MW. Haemorrhoidectomy with and without lateral internal sphinterotomy. J Rawalpindi Med Coll 2013;17:189-91.
26. Abedidost S, Poya M, Shafe SM. The effect of internal sphincterotomy on post hemorrhoidectomy pain. Arak Med Univ J 2011;14:58-63.
27. Mathai V, Ong BC, Ho YH. Randomized controlled trial of lateral internal sphincterotomy with haemorrhoidectomy. Br J Surg 1996;83:380-2.

How to cite this article: Prashanth K, Urs S, Priya PH, Amar M. Efficacy of Lateral Internal Sphincterotomy in Patients Undergoing Milligan - Morgan Hemorrhoidectomy. Int J Sci Stud 2023;11(3):84-88.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

A Comprehensive Study of Covid Associated Mucormycosis at Our Institution

K M Elango[1], K Praveen Kumar[2], S Kumaresan[3], T Shabarish[4], K Jaivignesh[4]

[1]Associate Professor, Department of ENT, Government Vellore Medical College, Vellore, Tamil Nadu, India, [2]Assistant Professor, Department of ENT, Government Vellore Medical College, Vellore, Tamil Nadu, India, [3]Professor, Department of ENT, Government Vellore Medical College, Vellore, Tamil Nadu, India, [4]2nd Year PG Student, Department of ENT, Government Vellore Medical College, Vellore, Tamil Nadu, India

Abstract

Introduction: The incidence of opportunistic fungal infections, especially Mucormycosis, was very high during the second wave of the COVID-19 pandemic. Overall, the morbidity and mortality due to COVID-associated mucormycosis (CAM) were very high, especially in India and other high-bearing countries. Various coexisting factors had led to a high incidence of CAM.

Aim: The aim of the study is to analyze various epidemiological factors, risk factors, diagnosis, surgical management, morbidity, and mortality of CAM that occurred during the second wave of COVID-19 at our institution.

Methods of Study: All patients confirmed to have CAM by various laboratory, clinical, radiological, and histopathological methods were studied and analyzed at our institution using the data available during the study period.

Results: A total of 54 patients, who had CAM were studied. 24 patients were female, and 30 patients were male. The mean age for females was 47.83, and the mean age for males was 54.33. Diabetes and previous steroid usage were the most common risk factors associated with 16 patients had previous steroid therapy; 3 patients were HIV +ve; and the mortality rate was 5.6% among CAM patients.

Conclusion: CAM had a multifactorial etiology. Based on the site of involvement, rhinoorbital mucormycosis was the most common. Disseminated and pulmonary Mucormycosis were the least common. Most of the patients were confirmed by clinical, radiological, and histopathological methods, and most of the patients had medical treatment with injections of amphotericin or posaconazole, followed by tablets of posaconazole. Most of the patients underwent surgical debridement for clearance.

Key words: COVID-19 associated mucormycosis, COVID-19, Diabetics, Mucormycosis epidemiology mucormycosis

INTRODUCTION

For some years, fungal rhinosinusitis has become increasingly recognized, but classification and treatment are still under debate.

1. Mucormycosis is a term to describe an acute, typically opportunistic mycotic infection caused by organisms that belong to the family *Mucorales,* class Zygomycetes (Phycomycetes). The broad term phycomycosis is a group of infections caused by Rhizopus, Absidia, and Mucor.
2. Mucormycosis belongs to the classification of acute invasive or acute fulminant Sinusitis with rapidly progressive tissue invasive and vascular invasive features, especially in immunocompromised individuals.
3. COVID-19 Pandemic produced decreased CD4 and CD8 counts and decreased granulocytic and phagocytic activities for opportunistic fungal infections like Mucormycosis, which is usually inhaled as spores from soil and produces fulminant infections.

Based on the site of involvement Mucormycosis may be: (1) Rhino mucormycosis; (2) Rhino orbital; (3) Rhino Orbito cerebral; (4) Rhino cerebral; (5) Cutaneous mucormycosis; (6) Pulmonary mucormycosis; or (7) Disseminated mucormycosis.

Access this article online

www.ijss-sn.com

Month of Submission : 04-2023
Month of Peer Review : 05-2023
Month of Acceptance : 06-2023
Month of Publishing : 06-2023

Corresponding Author: Dr. K M Elango, Department of ENT, Government Vellore Medical College, Vellore, Tamil Nadu, India.

Aim of Study

The aim of the study was as follows:

1. To study the clinical and epidemiological profile of COVID-associated mucormycosis (CAM) presented to our institution during the study period
2. To study the risk factors associated with CAM during the study period
3. To study various findings (clinical, radiological, and laboratory) associated with CAM
4. To study the treatment details, morbidity, and mortality.

Study Type

This is a retrospective, observational, hospital-based study.

Study Period

June 01st, 2021–November 31st, 2021.

MATERIALS AND METHODS

Based on the data available in the institution for the period from June 01st, 2021 to November 31st, 2021, all COVID-associated mucor mycosis patients were studied with respect to age, gender, sight, etiology, and treatment-related morbidity and mortality. The following evaluation was done on patients with CAM.

1. Epidemiological patients
2. Complete case history
3. Analysis of risk factors and previous treatment history
4. Exact site and grade of disease
5. Treatment history
6. Morbidity and mortality.

Inclusion Criteria

1. All CAM patients of all ages and genders were included.
2. All CAM patients positive for COVID-19 within a 3-month period were included.
3. All CAM patients tested positive for mucormycosis by clinical, radiological, laboratory, and histopathological methods were included.
4. All CAM patients preexisting risk factors and other comorbidities were included.

Exclusion Criteria

1. Patients negative for mucormycosis were excluded
2. Patients with COVID positivity tested after 3 months were excluded
3. Patients who tested positive for other fungal infections were excluded.

Statistical Methods

The mean (SD) and percentage of frequency were used. Continuous and categorical variables were analyzed. The chi-square test was used to assess the difference between categorical variables. $P < 0.05$ is considered as statistical significance.

RESULTS

Out of 54 patients, 24 were females and 30 were males. The mean age of presentation for males was 47.83. The mean age of presentation for females was 54.33.

Table 1: Gender Distribution of CAM

Sex	No of cases	percentage
Male	30	55.56
Female	24	44.44
Total	54	100

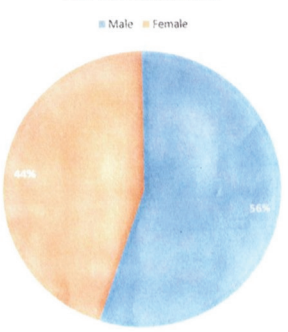
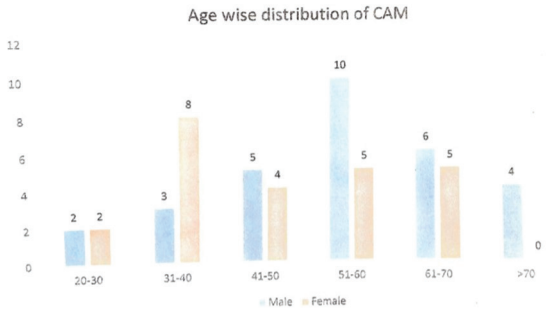


Table 2: Age wise distribution of CAM

Age in Years	Male	Female	Total
20-30	2	2	4
31-40	3	8	11
41-50	5	4	9
51-60	10	5	15
61-70	6	5	11
>70	4	0	4
Total	30	24	54



The Most Common Site of CAM

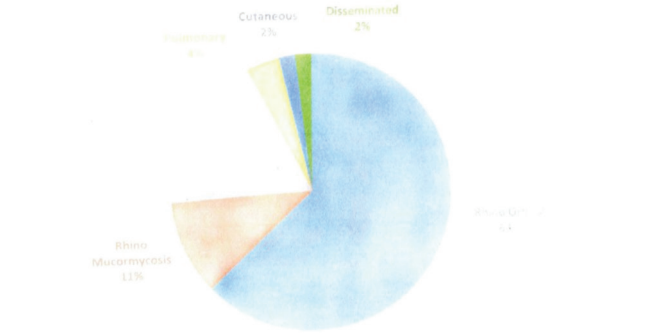
During this study, several sites of presentation occurred: rhino, rhino orbital, rhino orbital cerebral, rhino cerebral, and pulmonary mucormycosis. Cutaneous Mucormycosis, visceral of disseminated Mucormycosis. In our study, Rhino Orbital Mucormycosis was the most common.

Clinical Presentation of CAM

Patients with CAM presented with various signs and symptoms; many of them had nasal congestion, rhinorrhoea, fever of varying degrees, facial and orbito-facial swelling, periorbital edema, chemosis, ophthalmoplegia, proptosis, decreasing vision to complete visual loss, erythema, cranial nerve involvement, altered consciousness, etc. The most

Table 3: Site of involvement of CAM

Site	Number	%
Rhino Orbital	34	62.96
Rhino Mucormycosis	6	11.11
Rhino Orbitocerebral	10	18.51
Pulmonary	2	3.72
Cutaneous	1	1.85
Disseminated	1	1.85



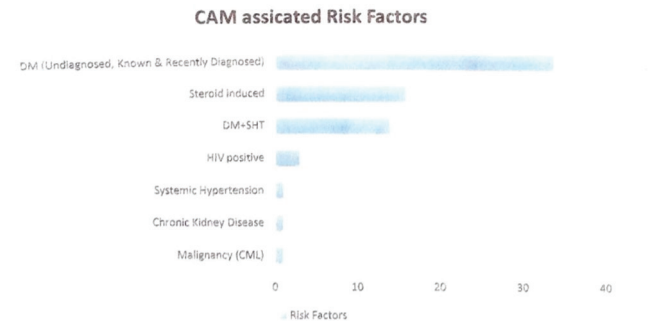
common symptoms were facial swelling, pain, and a fever of varying degrees.

On examination, the most common finding was edematous nasal mucosa with discoloration (pale to black necrotic material). Commonly in the middle meatus and adjoining middle inferior turbinate, risk factors and etiological factors.

Most of the patients, up to 80%, had pre-existing type 2 diabetes mellitus or newly diagnosed (undiagnosed) type 2 DM. Up to 29.6% of the patients had received steroid treatment for COVID-19 previously. Up to 20% of patents had other comorbidities such as uncontrolled hypertension, HIV positivity on dialysis for renal failure, or other malignancies.

Table 4: CAM associated Risk Factors

Risk Factors	No	%
DM (Undiagnosed, Known & Recently Diagnosed)	34	62.96
Steroid induced	16	29.62
DM+SHT	14	25.92
HIV positive	3	5.56
Systemic Hypertension	1	1.85
Chronic Kidney Disease	1	1.85
Malignancy (CML)	1	1.85



Methods for Diagnosis

Various methods were followed for the identification of the case, such as clinical evaluation, radiological presentation, laboratory investigation, and histopathological diagnosis.

All patients suspected of CAM had a nasal smear for identification of mucor frozen sections and a biopsy of suspected material for histopathological and radiological evaluation.

The final diagnosis was made by examination under the microscope for fungal hyphae for mucormucosis in 100% of patients.

Treatment Done for CAM Patients

Various treatment modalities were followed in various centers. In our institution, after confirmation of CAM, the patient was treated with injection amphotericin 0.7–1 mg/kg body weight with a test dose of 1 mg in 5% dextrose on the first day of therapy.

The majority of the patients' diagnosed positive for CAM underwent complete surgical endoscopic debridement, and five patients underwent partial maxillectomy for recurrent, residual, and extensive mucormycosis. None of the patients had orbital exenteration; one patient had a craniotomy for intracranial mucormycosis.

Table 5: Treatment Given for CAM patients

Early Endoscopic Surgical Debridement	34	62.96
Retro orbital Injection of Amphotericine	12	22.22
Surgical Debridement with partial maxillectomy	5	9.23
Craniotomy with Neurosurgical Management	2	3.70
Orbital Extraction	0	0

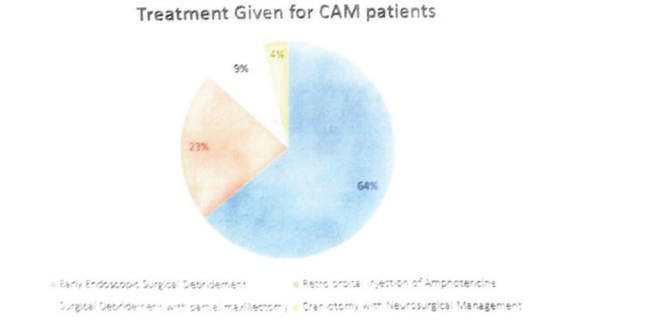
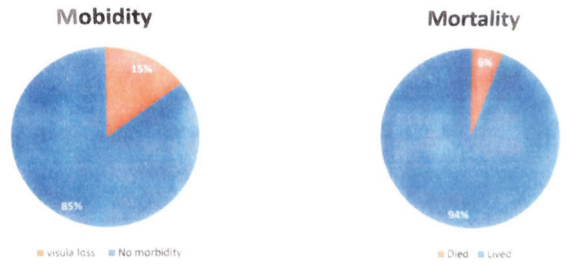


Table 6: Morbidity and Mortality of CAM

	Number	Percentage
Total number of patients who lost their visual morbidity	8	14.8%
Total number of patients who lost their lives	3	5.56%



DISCUSSION

Mucormycosis fungi have Mucoid predilection for vascular invasion of large and small arteries and veins causing thrombosis, is necrosis of tissues, or black intranasal eschar, is the pathognomonic finding in acute fulminant fungal rhinosinusitis when mucor is the predominant fungal organism.[3] In our study, ademallow nasal mucosa with pale or blackish discoloration in the middle meatus and adjoining middle and inferior tubercles was the commonest finding.

Mucormycosis is acute filament fungal rhinosinusitis that occurs especially in immunocompromised status (1. AIDS, hematological disorders, type 1 diabetes, uncontrolled diabetes dh, long-standing steroids, immunosuppressive therapy, and malignancy) (2. Presumably, hyperglycemia, acidosis, and immunosuppression enhance tissue and vascular invasion and fungal growth) (3. Mucor has an active carotene reductasa system that it thorws on with increased glucose acidic pH.[4] In our study, uncontrolled diabetes (type 2) and newly or undispensed dh with treatment of steroid for COVID-19 were also common etiological factors.

*Mucormycetes are confirmed by the presence of large, irregularly shaped, non-septal hyphae that branch at right angles of 6–50 μm in hyphae size.[3]

In our study, we also confirmed CAN by microscopic examination and confirmed the presence of Mucor hyphae.

A commoner LT finding was Nodular Mucosal thickening of paranasal sinuses without air fluid level with spotty destruction of bony walls in our study. Another commoner finding was involvement of the orbit and cranium.

*Amphotericin-B remains the drug of choice for systemic treatment of most acute fungal rhinosinusitis.[1,2]

In our institution, we also gave systemic amphotericin-B with careful monitoring of Renal function. For patients with altered liver and renal function, we gave systemic liposomal amphotericin at a dose of 2.5 mg/l orally and injection posaconazole for 3 weeks, followed by tablet posaconazole for 3–6 months.

Control of primary disorders is very important, even with early diagnosis. Even with early surgical debridement and complete medical treatment, fatalities of 25–100% have been repeated. In our institution, out of 54 patients, deaths were reported, and mortality% of 5.568 patients had complete loss of vision with morbidity % of 14.8%.[5-12]

CONCLUSION

At the end of our study, our institute was closed for a period of 6 months during the peak of COVID-associated Muconmycotis through mates was more commonly involved; uncontrolled diabetes and previous steroid treatment were the most commonly involved; unwanted diabetes and previous steroid treatment were the most common etiological and risk factors. Rhino-orbital mucormycosis was the commonest. The most common clinical findings were Nasal congestion, facial and orbital facial swelling, and pain. The most common diagnostic method was the demonstration of fungal hyphae by Microscopy, all on par with other institutions. Early diagnosis, early medical treatment, and surgical debridement were done for all patients. The morbidity rate was slightly lower in our institution when compared with other institutions. The age, gender, diagnostic criteria, clinical findings, etiological risk factors, morbidity, and mortality were well defined in the study.

REFERENCES

1. Watkinson JC, Clarke RW, editors. Scott-Brown's Otorhinolaryngology and Head and Neck Surgery: 3 Volume Set. Florida: CRC Press; 2018.
2. Gumashta J, Gumashta R. COVID19 associated mucormycosis: Is GRP78 a possible link? J Infect Public Health 2021;14:1351-7.
3. Kennedy DW. Diseases of Sinus: Diagnosis and Management. Hamilton: BC Decker Inc.; 2001. p. 179-94.
4. Baker RD. Mucormycosis; a new disease. J Am Med Assoc 1957;163:805-8.
5. Skiada A, Pavleas I, Drogari-Apiranthitou M. Epidemiology and diagnosis of mucormycosis: An update. J Fungi (Basel) 2020;6:265.
6. Prakash H, Chakrabarti A. Global epidemiology of mucormycosis. J Fungi (Basel) 2019;5:26.
7. Jeony W, Keighley C, Wolfe R, Lee WL, Slavin MA, Kong DC, *et al*. The epidemiology and clinical manifestations mucormycosis: A systematic review and meta-analysis of case reports. Clin Microbial Infect 2019;25:26-34.
8. Lionakis MS, Kontoyiannis DP. Glucocorticoids and invasive fungal infection. Lancet 2003;362:1828-38.
9. Deutsch PG, Whittaker J, Prasad S. Invasive and non-invasive fungal rhinosinusitis-a review and update of the evidence. Medicina (Kaunas) 2019;55:319.
10. Maartens G, Wood MJ. The clinical presentation and diagnosis of invasive fungal infections. J Antimicrob Chemother 1991;28 suppl A:13-22.
11. Mehta S, Pandey A. Rhino-orbital mucormycosis associated with COVID-19. Cureus 2020;12:e10726.
12. Mishra N, Mutya VS, Thomas A, Rai G, Reddy B, Mohanan AA, *et al*. A case series of invasive mucormycosis in patients with COVID-19 infection. Int J Otorhinolaryngeal Head Neck Surg 2021;7:867-70.

How to cite this article: Elango KM, Kumar KP, Kumaresan S, Shabarish T, Jaivignesh K. A Comprehensive Study of Covid Associated Mucormycosis at Our Institution. Int J Sci Stud 2023;11(3):89-92.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Pneumoperitoneum by Veress Needle versus Hasson Technique in Laparoscopic Surgeries – A Prospective Interventional Study

S K Mohammad Wasim[1], R Lakshmana[2], Neethish K Paul[3], Sethu Raman[3]

[1]Junior Resident, Department of General Surgery, SRM Medical College and Research Institute, Chennai, Tamil Nadu, India, [2]Professor, Department of General Surgery, SRM Medical College and Research Institute, Chennai, Tamil Nadu, India, [3]Assistant, Department of General Surgery, SRM Medical College and Research Institute, Chennai, Tamilnadu, India

Abstract

Background: Laparoscopy faces challenges in accessing the abdominal cavity, with high complications, and techniques include the Veress needle, Hasson procedure, and incisions over the abdominal wall. The study aims to compare the peritoneal access with the Veress needle and Hasson technique in laparoscopic surgeries regarding complications and outcomes.

Materials and Methods: This prospective interventional study was conducted in the Department of General Surgery of SRM Medical College Hospital and Research Center for 18 months–January 2021–July 2022. One hundred patients, 50 undergoing laparoscopic surgery for the abovementioned disease, received open-access procedures, and 50 underwent closed procedures. Access time – 3–6 min; pain, duration, Gas leak, extraperitoneal insufflations, visceral injury, vascular injury, and port site infection were noted.

Results: Most patients were reported as male in both groups (V: 58%; B: 56%), and most patients belonged to the age group of 31–40 years (V: 38%; H: 42%). No significant difference in gender, age group, diagnosis, procedure, complications, or pain at discharge between groups. (V) group patients showed a higher mean time for primary trocar (6.82 min), and (H) group patients were observed with a mean time of 4.22 min with a significant effect ($P < 0.0001$). The average access time was found to be higher in the (V) group of patients (5.98 min) than (H) group patients (4.34 min), with a significant effect ($P < 0.0001$).

Conclusion: Compared to the Hasson technique, the Veress needle method creates pneumoperitoneum faster, while the Hasson technique had higher gas leakage.

Key words: Abdominal incision, Hasson, Laparoscopy, Pneumoperitoneum, Surgery, Veress

INTRODUCTION

Laparoscopy is a technique used to examine the organs and tissues inside the abdominal cavity.[1] The abdominal cavity (pneumoperitoneum) is sufficiently distended, and the abdominal contents are seen using a lighted telescope. Laparoscopic surgery was once referred to as minimally invasive surgery. Still, the phrase was switched to minimum access surgery since it is an invasive treatment with the same risks of significant problems as traditional open surgery.[2] Because the abdominal incision is replaced with extremely tiny incisions just large enough to insert a trocar (5–10 mm in diameter), Let's assume that this procedure causes the patient the smallest possible stress. That means less time spent resting and recovering from surgery, less time spent in pain management, and a quicker time to full activity and work capacity. It offers several benefits for individuals, the healthcare system, and society. Primary abdominal access is the most challenging aspect of laparoscopic surgery since it is often performed blindly and is linked with vascular and visceral damage.[3]

The first incision into the abdominal cavity is a common injury site during laparoscopy.[4] Because most laparoscopic injuries occur during verses and trocar insertion, laparoscopic

Access this article online

www.ijss-sn.com

Month of Submission : 04-2023
Month of Peer Review : 05-2023
Month of Acceptance : 06-2023
Month of Publishing : 06-2023

Corresponding Author: Dr. S K Mohammad Wasim, Department of General Surgery, SRM Medical College and Research Institute, Chennai, Tamil Nadu, India.

surgeons are mainly concerned with minimising first-entry complications. Although laparoscopy complications are uncommon, they may be severe and life-threatening. A 3.6% mortality incidence is related to laparoscopy-induced intestinal damage.[5] Injuries to the intestines, main abdominal vessels, bladder, and anterior abdominal wall vessels are life-threatening. If there is a delay in diagnosing or reporting visceral injuries, the morbidity will grow and may lead to death. Post-operative infection, subcutaneous emphysema, and extraperitoneal insufflation are less significant problems that may develop.[5]

A recent literature assessment found the likelihood of immediate access problems at advanced laparoscopic tertiary centers to be 0.1%. It implies that, despite technological and clinical advancements, main access difficulties were reduced but were not eradicated. Open laparoscopy, in which the trocar connected to a gas inlet is inserted through the incision into the abdomen cavity and then inflated (the "secure approach") (Hasson technique, direct trocar insertion), and pneumoperitoneum can be created during laparoscopy using a variety of various methods. The Veress (closed) needle technique is the prevalent technique. However, complications might arise when a needle is blindly inserted. This method has the potential to cause visceral and vascular damage. Avoiding the risks of blindly inserting a trocar and verses needle, Hasson created the idea of open laparoscopy in 1971.[6] The entrance consists mainly of mini-laparotomy. The incision is sufficiently long to provide dissection, incise of the fascia, and direct access to the peritoneal cavity.[6]

There is no apparent agreement about the preferred route of peritoneal cavity entrance. Some experts think that the Hasson open approach is preferable to the traditional closed entrance technique, arguing that it is less dangerous, prevents gas embolisms, and substantially minimizes the risk of vascular and intestinal damage associated with immediate access. However, various research has shown contradictory results, and no consensus exists.[7] As a result, the purpose of the study is to compare two approaches for accessing the abdominal cavity and "creating a pneumoperitoneum during laparoscopy." The study aims to compare the peritoneal access with the Veress needle and Hasson technique in laparoscopic surgeries regarding complications and outcomes.

MATERIALS AND METHODS

This prospective interventional study was conducted in the Department of General Surgery of SRM Medical College Hospital and Research Center for 18 months–January 2021–July 2022.

Inclusion Criteria

Adults of both sexes, aged 18 and older, with acute or chronic abdominal disorders such as cholelithiasis, calculus cholecystitis, appendicitis, and umbilical hernia conditions requiring biopsies and without comorbidities were included in the study.

Exclusion Criteria

Persons younger than 18 and patients who underwent previous abdominal surgeries, suspected adhesions, and situations requiring converting to open procedures were excluded from the study.

One hundred patients, 50 undergoing laparoscopic surgery for the abovementioned disease, received open-access procedures, and 50 underwent closed procedures.

Comparison of data collected from the Veress needle and Hasson technique under the following variables: Access time – 3–6 min, pain, duration, Gas leak, extraperitoneal insufflations, visceral injury, vascular injury, and port site infection were noted [Figures 1 and 2]. A structured proforma was used to collect relevant information for each selected patient.

Statistical Analysis

The data's average, standard deviation, frequency, and percentage were all shown. The *t*-test for independent samples was used to make comparisons between continuous variables. In addition, we compared categorical variables using the Pearson Chi-square test. $P < 0.05$ was judged statistically significant for a two-tailed test. The study was conducted with IBM's Statistical Package for the Social Sciences version 21.0. (IBM-SPSS Science Inc., Chicago, IL).

RESULTS

Most patients were reported as male in both groups (V: 58%; B: 56%), whereas females were reported as 42% in group (V) and 44% in a group (H). Most patients belonged to the age group of 31–40 years in both groups (V: 38%; H: 42%), followed by the age group of 41–50 years (V: 28%; (H): 28%). However, a minimum of patients were observed in the age group of more than 61 years in both groups (V: 6%; (H): 2%) [Table 1].

Of all patients in the (V) group, the majority of patients underwent Paraumbilical hernia 14 (28%), followed by cholelithiasis 10 (20%). In contrast, in the (H) group, most of the patients were found with cholelithiasis 13 (26%), followed by Paraumbilical hernia 11 (26%) of all patients [Table 1].

The procedure followed for surgery in both groups of patients was also recorded during the study. In the (V)

group, LAP appendicectomy was performed on most patients, 19 (38%), followed by LAP cholecystectomy and LAP IPOM in 14 (28%). In the (H) group, LAP appendicectomy was performed on most patients [Table 2].

Of 50 patients in the CL group, bowel injury was observed in a maximum of patients 5 (10%), followed by loss of space 3 (4%), whereas, in the (H) group, port site leakage was observed in the majority of patients 5 (10%).

The extent of pain experienced 24 h after the surgery was also noted during the study asking the patient severity that they are experiencing orally. Severe pain was observed by the majority of patients in (V) group 26 (52%), whereas, in the (H) group, majority of patients experienced moderate pain 28 (56%). Most group (V) patients, 29 (58%), experienced mild pain during discharge, whereas the majority of (H) group patients, 28 (56%) found with no pain [Table 2].

(V) group patients showed a higher mean time for primary trocar (6.82), whereas (H) group patients observed a mean time of 4.22. The average access time was found to be higher in the (V) group of patients (5.98) than in the (H) group of patients (4.34). There was no significant difference in the average duration of stay in both groups of patients (V: 4.66; (H): 4.76) [Table 3].

Table 1: Comparison of gender, age, and diagnosis between groups

Variables	Veress (V) group (%)	Hasson (H) group (%)	*P*-value
Gender			
Female	21 (42)	22 (44)	0.84
Male	29 (58)	28 (56)	
Age group			
<30	8 (16)	10 (20)	0.787
31–40	19 (38)	21 (42)	
41–50	14 (28)	14 (28)	
51–60	6 (12)	4 (8)	
>61	3 (6)	1 (2)	
Diagnosis			
Acute appendicitis	7 (14)	9 (18)	0.919
Acute chronic appendicitis	3 (6)	2 (4)	
Calculus cholecystitis	4 (8)	2 (4)	
Cholelithiasis	10 (20)	13 (26)	
Paraumbilical hernia	14 (28)	11 (22)	
Sub acute appendicitis	9 (18)	9 (18)	
TB abdomen	3 (6)	4 (8)	

Table 2: Comparison of procedures, complications, and pain between groups

Variables	Group		*P*-value
	Veress (%)	Hasson (%)	
Procedure			
D lap with biopsy	3 (6)	4 (8)	0.905
Lap appendicectomy	19 (38)	20 (40)	
Lap cholecystectomy	14 (28)	15 (30)	
Lap IPOM	14 (28)	11 (22)	
Complication			
Bowel injury	5 (10)	1 (2)	0.062
Entry on the wrong plane	2 (4)	0	
Extraperitoneal insufflation	2 (4)	0	
Loss of space	3 (6)	1 (2)	
Omental injury	2 (4)	0	
Port site leakage	2 (4)	5 (10)	
Nil	34 (68)	43 (86)	
Pain			
Moderate	21 (42)	28 (56)	0.371
Severe	26 (52)	20 (40)	
Very severe	3 (6)	2 (4)	
Pain at discharge			
Mild pain	29 (58)	22 (44)	0.161
No pain	21 (42)	28 (56)	

DISCUSSION

Pneumoperitoneum formation and trocar entry, which account for more than half of laparoscopic operation challenges, happen before surgery. Although the incidence of visceral and vascular damage from either procedure is unknown, fewer than 1% of patients have morbidity from having a pneumoperitoneum created and the initial trocar inserted. Hence, in our study, we compared the two methods side by side to see which was better for laparoscopic surgeries.[1-4]

In the present study, most patients were reported as male in both groups (V: 58%; B: 56%), whereas females were reported as 42% in the group (V) and 44% in group (H). Furthermore, most patients belong to the age group of 31–40 years in both groups (V: 38%; (H): 42%), followed by the age group of 41–50 years (V: 28%; (H): 28%). However, a minimum of patients was observed in age groups of more than 61 years in both groups (V: 6%; (H): 2%). These findings in the present study are from earlier reported studies.[8]

In our study, in the (V) group, the maximum number of patients diagnosed with paraumbilical hernia was 14 (28%), followed by cholelithiasis 10 (20%), whereas, in the (H) group, majority of patients observed with cholelithiasis 13 (26%), followed by paraumbilical hernia 11 (26%) of all patients. In their research, Bonjer *et al.* found a similar.[9]

Table 3. Primary trocar, access time, and duration of stay between groups

Variables	Group		*P*-value
	Veress	Hasson	
Time taken for primary trocar	6.82 0.85	4.22 0.86	<0.0001
Access time	5.98 2.25	4.34 1.73	<0.0001
Duration of stay	4.66 2.17	4.76 0.96	0.767

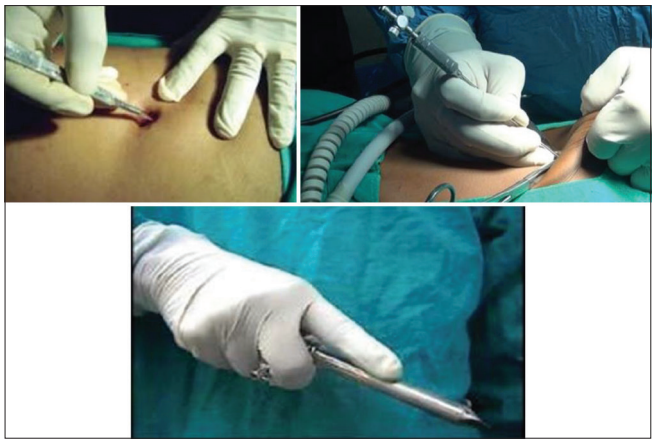


Figure 1: Veress needle technique

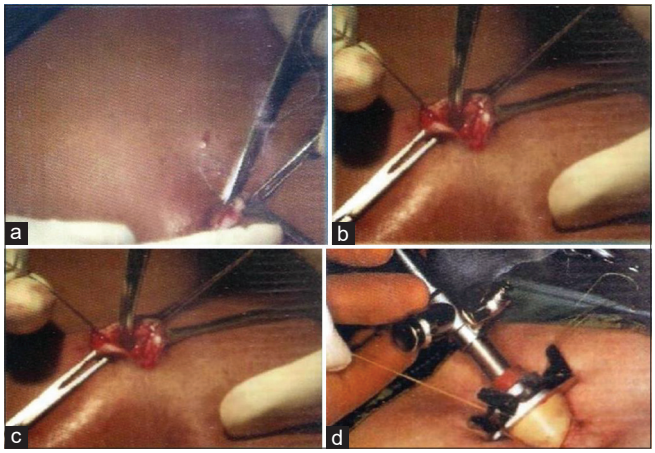


Figure 2: Hasson technique (a) a transverse incision around 2.5 cm is made supra (or) infraumbilically (or) transumbilical, (b) dissection of subcutaneous tissue is proceeded up to the rectus sheath, (c) the peritoneal breach is expanded with the artery forceps, and (d) the Hasson cannula is passed through the above incision, into the peritoneal cavity

In our study, in the (V) group, LAP appendicectomy was carried out on most patients, 19 (38%), followed by LAP cholecystectomy and LAP IPOM in 14 (28%). Whereas, in the (H) group, LAP appendicectomy was performed on most patients. Zaman *et al.* reported a laparoscopic cholecystectomy procedure in a maximum number of patients (85%) in both open and closed groups.[10]

In our study, of all patients in the (V) group, bowel injury complication was observed in a maximum of patients 5 (10%) followed by loss of space 3 (4%). In contrast, in the (H) group, port site leakage was observed in most patients 5 (10%). Juneja *et al.*, in their study, reported port site wound infection in most patients in both (V) and (H) group patients.[15] However, Taye *et al.*, in their investigation, reported difficulty in primary complications in most of the patients of the (V) group (1.73%) and leakage of gas (1.8%) in the (H) group of patients.[11]

In our study, most patients in the (V) group reported severe pain 26 (52%), whereas, in the (H) group, most patients experienced moderate pain 28 (56%) during the surgery. At the time of discharge, it was found that most of the group (V) patients, 29 (58%), experienced mild pain, whereas most of the (H) group patients, 28 (56%), had no pain. These findings in the present study are similar to earlier reported studies.[12]

In our study, (V) group patients showed a higher mean time for primary trocar (6.82 min). In contrast, (H) group patients were observed with a mean time of 4.22 min with a significant effect ($P < 0.0001$). The results of our investigation are consistent with studies by Peitgen *et al.* and Cogliandolo *et al.*, which demonstrate that the open approach is quicker than the closed technique and has a comparable frequency of problems.[13,14]

In our study, the average access time was found to be higher in the (V) group of patients (5.98 min) than (H) group patients (4.34 min), with a significant effect ($P < 0.0001$). Juneja *et al.* also reported a similar finding in their investigation, where there was a significant effect ($P < 0.03$) in access time between the V (2.83 min) and (H) (2.52 min) group of patients.[15]

In our study, duration of hospital stay after the surgery, there was no difference in the average duration of stay in both groups of patients (V: 4.66 days; (H): 4.76 days). Zaman *et al.*, in their study, also reported similar findings, where there was an insignificant difference in the average duration of stay in V (49.71 days) and (H) (45.1 days) group patients.[11]

Limitations of the study

There are some limitations of the study, such as the fact that the study data contained a small number of patients and it is a single-centered study and was collected during the covid pandemic; hence, the number of elective cases and cases opted for laparoscopy where minimal number and included in the study.

CONCLUSION

The incidence of these characteristics did not change significantly between the two approaches, making the open technique, also known as Hasson's technique, and the closed technique, also known as Veress' technique, nearly equal in terms of the degree of pain experienced during and after surgery and complications. However, compared to the Hasson approach, the "Veress needle method created pneumoperitoneum faster," and the Hasson technique had higher gas leakage. Therefore, more definitive information

is needed for multi-centric research with a systematic review, a high sample size, and meta-analyses.

REFERENCES

1. Agha R, Muir G. Does laparoscopic surgery spell the end of the open surgeon? J R Soc Med 2010;96:544-6.
2. Ajao OG. Abdominal incisions in general surgery: A review. Ann Ib Postgrad Med 2007;5:59-63.
3. Chotai NR, Choksi BB, Damor S, Bhedi A. Intraperitoneal access by closed method (veress needle) versus open (Hasson's) method in laparoscopic surgery to create pneumoperitoneum. Int Surg J 2017;4:2786-90.
4. Hasson HM. A modified instrument and method for laparoscopy. Am J Obstet Gynecol 1971;110:886-7.
5. Elbiss HM, Abu-Zidan FM. Bowel injury following gynecological laparoscopic surgery. Afr Health Sci 2017;17:1237-45.
6. Schafer M, Lauper M, Krahenbuhl L. Trocar and Veress needle injuries during laparoscopy. Surg Endosc 2001;15:275-80.
7. Vellinga TT, De Alwis S, Suzuki Y, Einarsson JI. Laparoscopic entry: The modified Alwis method and more. Rev Obstet Gynecol 2009;2:193-8.
8. Hamayun M, Saba N, Bilal M, Mehsud N. Compare open versus closed pneumoperitoneum in laparoscopic surgery. Gomal J Med Sci 2015;13:115-7.
9. Bonjer HJ, Hazebroek EJ, Kazemier G, Giuffrida MC, Meijer WS, Lange JF. Open versus closed establishment of pneumoperitoneum in laparoscopic surgery. Br J Surg 1997;84:599-602.
10. Zaman M, Singal S, Singal R, Shah A, Sandhu KS, Singh B, *et al*. Comparison of open and closed entry techniques for the creation of pneumoperitoneum in laparoscopic surgery in terms of time consumption, entry-related complications and failure of technique. World J Laparosc Surg 2010;8:69-71.
11. Taye MK, Fazal SA, Pegu D, Saikia D. Open versus closed laparoscopy: Yet an unresolved controversy. J Clin Diagn Res 2016;10:QC04-7.
12. Bathla V, Thekdi P, Koradia P, Jhala D, Gadhvi U. Comparative study of modified open technique and closed technique for primary trocar insertion in laparoscopic surgery. Int J Res Med Sci 2016:160-4.
13. Peitgen K, Nimtz K, Hellinger A, Walz MK. Open approach or Veress needle in laparoscopic interventions? Results of a prospective randomised controlled study. Chirurg 1997;68:910-3.
14. Cogliandolo A, Manganaro T, Saitta FP, Micali B. Blind versus open approach to laparoscopic cholecystectomy: A randomized study. Surg Laparosc Endosc 1998;8:353-5.
15. Juneja I, Bhatt J, Vaishnani B. Open versus closed method of establishing pneumoperitoneum for laparoscopic surgery. Int J Res Med 2016;5:9-13.

How to cite this article: Wasim SKM, Lakshmana R, Paul NK, Raman S. Pneumoperitoneum by Veress Needle versus Hasson Technique in Laparoscopic Surgeries – A Prospective Interventional Study. Int J Sci Stud 2023;11(3):93-97.

Source of Support: Nil, **Conflicts of Interest:** None declared.