Original Article

DOI: 10.7860/JCDR/2025/75906.20825

Effect of Epidural Volume Extension with 10 mL versus No Saline on Combined Spinal Epidural Anaesthesia for Elective Lower Limb Surgeries: A Randomised Controlled Study

Anaesthesia Section

UTKARSHINI KEDIA[1], VAIBHAVI SINGH[2]

ABSTRACT

Introduction: Combined Spinal Epidural Anaesthesia (CSEA) is a regional anaesthetic technique that offers flexibility in prolonging anaesthesia and improving postoperative analgesia compared to spinal anaesthesia.

Aim: To compare the effects of Epidural Volume Extension (EVE) with 0 mL and 10 mL of 0.9% normal saline on spinal anaesthesia in lower limb orthopaedic surgeries.

Materials and Methods: A randomised controlled study was conducted at Deen Dayal Upadhyay Hospital, Delhi, India on 72 American Society of Anaesthesiologists (ASA) I and II patients undergoing elective orthopaedic surgeries under CSEA. Patients were assigned to two groups: S0 with 0 mL and S10 with 10 mL of 0.9% normal saline on spinal anaesthesia using 12.5 mg (2.5 mL) of 0.5% hyperbaric bupivacaine in lower limb orthopaedic surgeries lasting less than three hours. Sensory block onset (pinprick method), motor block onset (Bromage scale), level of block, time to maximum sensory block, two-segment regression, and time to first epidural top-up were recorded. Haemodynamic parameters {Heart Rate (HR), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Mean Arterial Pressure (MAP), and SpO_2} were monitored preoperatively, intraoperatively and postoperatively. Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) version 21.1, with p-value <0.05 considered significant.

Results: Both groups, group S0 (N=36) and group S10 (N=36), were comparable in terms of age, gender, ASA grade and surgery duration. A significantly higher sensory block level was achieved in S10, (58.33% reached T4 vs. T8–T10 in S0 (p-value <0.001). Time to maximum sensory blockade was shorter in S10 (8.75±1.13 minutes vs. 10.17±3.85 minutes; p-value=0.042), while two-segment regression was longer (100.61±6.02 minutes vs. 76.72±7.66 minutes; p-value=0.001). Epidural top-ups were required in 83.33% of S0 patients vs. 16.67% in S10, with a longer mean time to top-up in S10 (147.5±4.97 minutes vs. 111.87±7.56 minutes; p-value <0.001). Haemodynamic parameters were similar across groups (p-value >0.05).

Conclusion: EVE with 10 mL of 0.9% normal saline enhances sensory block level, prolongs two-segment regression time and reduces the need for epidural top-ups in CSEA for lower limb surgeries. This technique maintains haemodynamic stability, making it a safe and effective modification of CSEA. Compared to no volume extension, EVE improves intraoperative conditions and enhances postoperative analgesia.

Keywords: Anaesthesia techniques, Haemodynamic parameters, Neuraxial anaesthesia, Orthopaedic surgery, Postoperative analgesia

INTRODUCTION

The use of neuraxial anesthaesia has gained popularity as it is considered to be a good choice in patients undergoing lower limb surgery [1]. The CESA was first described more than 35 years ago [2]. CSEA technique is a regional anaesthetic technique that has gained popularity as a preferred technique for caesarean sections and orthopaedic surgeries [3-5]. This approach allows for flexibility, as the operative procedure begins earlier whereas the epidural catheter allows anesthaesia to be extended as the spinal anesthaesia effect resolves and provides effective postoperative analgesia [6,7]. The EVE has been shown to provide a comparable sensory block to larger doses of intrathecal local anaesthetics (with no EVE) but with significantly faster motor recovery [8]. Various volumes of normal saline (5 mL, 7.5 mL, 10 mL, 15 mL and 20 mL) have been used for EVE technique; but there is no definitive consensus regarding the effective volume of normal saline for EVE on the sensory and motor block characteristics of spinal anesthaesia. Various studies on different type of surgeries with conventional and low doses of intrathecal drug have found different conclusions regarding these volumes [9-16].

The clinical advantages of EVE over other techniques in CSEA include better control over the extent and duration of the block, improved haemodynamic stability and faster recovery of motor function. EVE facilitates flexibility in anesthaesia management by using a lower dose of intrathecal local anaesthetic, which reduces potential side-effects such as hypotension and prolonged motor blockade [8]. The ability to fine-tune the anaesthetic effect makes EVE particularly useful in surgeries requiring precise sensory and motor control.

Key studies highlight that EVE can achieve a sensory block comparable to larger doses of intrathecal local anaesthetic, but with the added advantage of faster motor recovery. For instance, EVE has been shown to optimise the balance between effective anesthaesia and patient recovery time, which is crucial in orthopaedic lower limb surgeries where early mobilisation is beneficial [6-8]. Furthermore, EVE reduces the need for higher doses of intrathecal local anaesthetic, minimising drug-related side-effects and complications [9].

The choice of 10 mL and 0 mL volumes of normal saline in this study addresses critical gaps in the literature regarding the optimal volume for EVE. While volumes ranging from 5 mL to 20 mL have been explored in various studies [9-16], there is no consensus on the most effective volume for achieving the desired sensory and motor block characteristics. Using 10 mL of saline allows for evaluation of its impact on sensory block height, time to achieve maximum block and two-segment regression, compared to no EVE (0 mL).

The inclusion of 0 mL as a control provides a baseline to assess the specific contributions of volume expansion to the efficacy of spinal anesthaesia. This approach bridges the gap between clinical practice and research, offering insights into the practical utility of EVE in lower limb surgeries. Additionally, by focusing on 10 mL, the study evaluates a mid-range volume that may strike a balance between achieving an adequate block and minimising adverse effects, thereby addressing the variability in conclusions drawn from previous research [9-16]. This focused comparison could help establish evidence-based guidelines for EVE volume selection in orthopaedic surgeries.

With this background, the present study was designed to compare the effects of varying volumes of normal saline (0 mL and 10 mL) used for EVE on the maximum sensory block. Additionally, the study aimed to evaluate the two-segment regression time (in minutes), onset times for sensory and motor blocks (in minutes), haemodynamic parameters, and the duration until the first epidural top-up in patients undergoing elective orthopaedic lower limb surgeries under CSEA.

MATERIALS AND METHODS

This double-blind, randomised controlled study was conducted over six months, from March 2021 to September 2021, Deen Dayal Upadhyay Hospital, Delhi, India. Ethical approval was granted by the institutional ethical and scientific committee (approval number: IEC-DDUH/upn62/2021-03-23/62/v1), and written informed consent was obtained from all participants before their inclusion in the study.

Inclusion criteria: Patients aged between 18 and 60 years, with an ASA physical status of I or II, and scheduled for elective lower limb orthopaedic surgeries were included in the study.

Exclusion criteria: Patients with known allergies to the study drugs, spine deformities or degenerative spine disorders, cognitive impairment or communication difficulties, contraindications to neuraxial blockade such as coagulopathy or local infections, or major systemic illnesses like hepatic or renal dysfunction, cardiovascular disorders, or Chronic Obstructive Pulmonary Disease (COPD) were excluded from the study.

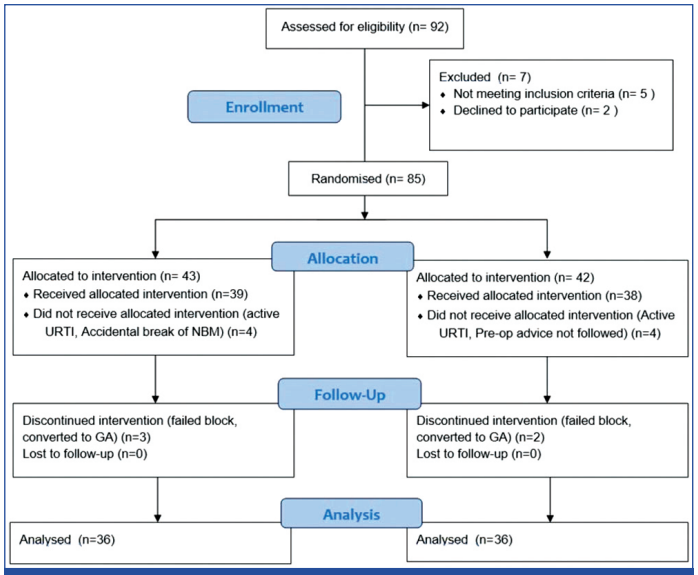
Sample size calculation: The sample size was calculated based on the findings of a previous study by Bhandari RS et al,. [11]. In that study, the mean time to achieve maximum sensory block was 9.83±1.72 minutes in the EVE group and 12.33±1.83 minutes in the combined spinal-epidural group. Using these values, a sample size of 36 patients per group was calculated, with a power of 95%, a significance level of 5%, a confidence interval of 95%, and a 6% non inclusion rate, using WinPepi Version 11.65 software.

A total of 85 patients were enrolled, while 72 patients were analysed.

Study Procedure

The study employed a double-blind (Researcher and Patient) design to minimise bias. Patients were randomly allocated to one of two groups using a computer-generated random number table [Table/Fig-1]. Allocation concealment was ensured using sequentially numbered, opaque, sealed envelopes, which were opened only after the participant's details were recorded. In group S0, no saline was administered via the epidural catheter, while in group S10, 10 mL of sterile, preservative-free 0.9% normal saline was injected through the epidural catheter immediately after the patient was positioned supine.

Standard procedures for preanesthaesia evaluation, operation theatre preparation and administration of CSEA were followed. Intrathecal hyperbaric bupivacaine 0.5 mL (4 cc) was used in all patients. Sensory block assessments were conducted every minute until a T10 level was achieved, with a maximum cut-off time of 10 minutes.



[Table/Fig-1]: Consort diagram.

Parameters studied included the maximum sensory level achieved, the time to reach maximum sensory block, two-segment regression, and the onset time of sensory and motor blocks. Haemodynamic variables, including SBP, DBP, and HR, were recorded at baseline, immediately after spinal anesthaesia, every five minutes for the first 30 minutes, every 10 minutes for the subsequent hour, and every 30 minutes until the end of the surgery. Pain levels were assessed using the Visual Analog Scale (VAS), which ranged from 0 to 10, where 0 indicated no pain while 10 represented very severe pain and epidural top-ups with 0.5% bupivacaine were administered when VAS scores reached or exceeded 4. Adverse events such as hypotension, defined as a decrease in SBP >30% from baseline, and bradycardia, defined as a decrease in HR >30% from baseline, were treated appropriately.

STATISTICAL ANALYSIS

Data were recorded and analysed using Microsoft Excel and SPSS Version 21.1. Normally distributed continuous variables were compared using Analysis of Variance (ANOVA). Nominal categorical data were analysed using the Chi-squared test or Fisher's exact test, as appropriate. Non normally distributed continuous variables were analysed using the Kruskal-Wallis test, with subsequent comparisons conducted using the unpaired t-test. For all analyses, a p-value <0.05 was considered statistically significant.

RESULTS

Ninety-two patients were assessed for enrollment, 85 were randomly assigned into two groups, and 72 were analysed. The demographic characteristics of the subjects in both groups, including age, gender distribution, ASA grades, and duration of surgery, were comparable, as no statistically significant difference was observed between the groups for any of these parameters (p-value >0.05, Chi-square test for categorical variables and unpaired t-test for continuous variables), indicating effective randomisation [Table/Fig-2].

Parameter	Group S0 (n=36)	Group S10 (n=36)	p-value
Age (years)	42.8±10.2	43.5±11.1	0.764
Gender (M/F)	20/16	18/18	0.582
ASA grade I/II	22/14	24/12	0.638
Duration of surgery (min)	115.6±23.5	116.8±24.2	0.894

[Table/Fig-2]: Demographic and clinical characteristics of patients in Group S0 and Group S10.
Chi-square test for categorical variables and unpaired t-test for continuous variables, indicating effective randomisation

While the onset of sensory and motor blocks was similar between the groups, group S10 achieved a faster maximum sensory

blockade and demonstrated a significantly prolonged two-segment regression time [Table/Fig-3].

Parameter	Group S0 (N=36)	Group S10 (N=36)	p-value
Onset of sensory block (min)	2.38±0.49	2.27±0.45	0.588
Onset of motor block (min)	3.15±0.55	3.08±0.50	0.642
Time to maximum sensory block (min)	10.17±3.85	8.75±1.13	0.042*
Two-segment regression time (min)	76.72±7.66	100.61±6.02	0.001*

[Table/Fig-3]: Distribution of cases as per the duration of onset of both sensory and motor, time to achieve maximum sensory level and the time needed for two segment regression (ANOVA).
Group S0: No normal saline administered for EVE; Group S10: 10 mL of normal saline administered for EVE; *Statistically significant

The level of maximum sensory block achieved was significantly higher in group S10, with 58.33% achieving T4 level compared to T8-T10 in group S0 (p-value <0.001) [Table/Fig-4].

Level of sensory block	Group S0	Group S10	p-value
T10	6 (16.67%)	0	<0.001*
T8	30 (83.33%)	0	<0.001*
T6	0	15 (41.67%)	<0.001*
T4	0	21 (58.33%)	<0.001*

[Table/Fig-4]: Comparison of sensory block levels between group S0 and group S10.
*Statistically significant; Chi-square test

Epidural top-up was administered with bupivacaine when VAS scores reached or exceeded 4. Group S10 required significantly fewer epidural top-ups and had a longer duration before the first top-up compared to Group S0 [Table/Fig-5].

Parameter	Group S0 (N=36)	Group S10 (N=36)	p-value
Patients requiring top-up	30 (83.33%)	6 (16.67%)	<0.001*
Time to top-up (Min)	111.87±7.56	147.5±4.97	<0.001*

[Table/Fig-5]: Comparison of epidural top ups between group S0 and group S10.
*Statistically significant; Statistical analysis was performed using the Chi-square test for categorical variables and unpaired t-test for continuous variables

The incidence of haemodynamic complications was similar between the groups, with around 13.88% of participants developing hypotension, while 8.33% developed bradycardia in S10 group, affirming the safety of the EVE technique [Table/Fig-6].

Parameter	Group S0 (N=36)	Group S10 (N=36)	p-value
Hypotension	4 (11.11%)	5 (13.88%)	0.724
Bradycardia	2 (5.55%)	3 (8.33%)	0.645

[Table/Fig-6]: Comparison of haemodynamic complications between group S0 and group S10.
Statistical analysis was conducted using the Chi-square test

DISCUSSION

The EVE technique is a modification of CSEA in which the onset and level of block obtained by subarachnoid block are increased by a small volume of saline [12]. Present study demonstrated that EVE with 10 mL of 0.9% normal saline in CSEA resulted in a significantly higher maximum sensory block level, prolonged two-segment regression time, and reduced the need for epidural top-ups compared to no EVE. These findings suggest that EVE enhances the efficacy of spinal anesthaesia without compromising haemodynamic stability. Present study results align with prior studies and contribute to the growing evidence supporting the benefits of EVE in orthopaedic lower limb surgeries.

The maximum sensory block level was significantly higher in the EVE group (S10), with 58.33% of patients achieving a T4 level compared to T8-T10 in the non-EVE group (S0). This was consistent with studies by Salman C et al., and Bhandari RS et al., which reported that EVE facilitated higher sensory block levels, improving intraoperative conditions [9,11]. Similarly, Kohli AV et al., found that larger volumes of normal saline (10-15 mL) resulted in a greater cephalad spread of sensory blockade in lower abdominal surgeries, supporting present study findings [17]. However, Doganci N et al., suggested a ceiling effect beyond a certain volume, indicating that larger saline volumes may not always proportionally enhance sensory spread [13].

The two-segment regression time was significantly prolonged in the S10 group (100.61±6.02 minutes vs. 76.72±7.66 minutes in S0). This aligns with the study by Singh S et al., which found that EVE with 10 mL normal saline extended sensory blockade duration [14]. Similarly, Preethi HN and Ravishankar BM reported that 7.5 mL of saline led to a significant prolongation of two-segment regression [15]. In contrast, Tyagi A et al., noted that while EVE extended the blockade, higher volumes (15-20 mL) did not further prolong the effect, suggesting an optimal range for efficacy [16].

The time to achieve maximum sensory blockade was significantly shorter in the EVE group (8.75±1.13 minutes vs. 10.17±3.85 minutes in S0). Present study findings align with studies by McNaught AF and Stocks GM as well as Jain G et al., who reported that EVE accelerates the onset of sensory blockade by facilitating cephalad spread of intrathecal local anaesthetic [3,4]. Additionally, a comparative study by Elgebaly MT et al., on hip surgeries highlighted that EVE with 10 mL of saline significantly reduced the time to maximum block compared to lower volumes, reinforcing present study results [18]. However, Hakim KYK, suggested that while EVE reduces onset time, the effect is less pronounced with higher saline volumes beyond 10 mL [19].

Epidural top-ups were required in 83.33% of S0 patients versus only 16.67% in S10, with a significantly longer mean time to top-up in S10 (147.5±4.97 minutes vs. 111.87±7.56 minutes; p<0.001). Similar trends were observed in studies by Bedi V et al., and Naaz S et al., which found that EVE delays the requirement for additional anaesthetic doses [20,21]. This suggests that EVE contributes to prolonged analgesia, reducing the need for repeated dosing. The safety of EVE was also reinforced by present study findings, as haemodynamic parameters remained comparable between groups, consistent with previous studies by Tyagi A et al., and Hakim KYK [16,19].

Overall, present study supports the use of 10 mL of 0.9% saline for EVE in CSEA, demonstrating its effectiveness in enhancing sensory blockade and reducing anaesthetic requirements without increasing adverse effects. The findings are consistent with multiple studies confirming that EVE is a valuable technique in optimising neuraxial anesthaesia for lower limb surgeries. Present study addresses a critical gap in the literature by specifically evaluating the impact of 10 mL of EVE, a volume that strikes a balance between efficacy and safety, and provides practical insights for clinical practice. Study's prospective, randomised, double-blind design minimises bias and enhances the reliability of the findings. Additionally, the use of clearly defined inclusion and exclusion criteria ensures the homogeneity of the study population, thereby allowing for robust comparisons between the groups. Moreover, comprehensive monitoring of sensory, motor and haemodynamic parameters adds to the depth of the analysis, reinforcing the validity of the conclusions. Future research should explore variations in saline volume and patient-specific factors to further refine its clinical application.

Limitation(s)

Patients aged between 18 to 60 years were included, in present study. The geriatric age group, who are more vulnerable to local anesthaesia used in neuraxial blockwere not included in present study [1,8]. The follow-up period was short, and patient was not followed beyond the postoperative period. The use of ultrasound for confirmation of the epidural space during application of epidural block was not available for present study. A total of 36 patients were

included in each group while the study was adequately powered, a larger multicentre study could further validate the study's findings and enhance generalisability.

CONCLUSION(S)

The EVE with 10 mL of 0.9% normal saline significantly enhances the sensory block level, prolongs two-segment regression time, and reduces the need for epidural top-ups in CSEA for lower limb surgeries. The technique does not compromise haemodynamic stability, making it a safe and effective modification of CSEA. Compared to no volume extension, EVE improves intraoperative conditions and postoperative analgesia.

REFERENCES

[1] Covert CR, Fox GS. Anaesthesia for hip surgery in the elderly. Can J Anaesth. 1989;36(3):311-19.
[2] Brownridge P. Epidural and subarachnoid analgesia for elective caesarean section. Anaesthesia. 1981;36(1):70-70.
[3] McNaught AF, Stocks GM. Epidural volume extension and low-dose sequential combined spinal-epidural blockade: Two ways to reduce spinal dose requirement for caesarean section. Int J Obstet Anesth. 2007;16(4):346-53.
[4] Jain G, Singh DK, Bansal P, Ahmed B, Dhama SS. Comparison of low doses of intrathecal bupivacaine in combined spinal epidural anaesthesia with epidural volume extension for caesarean delivery. Anesth Essays Res. 2012;6(1):47-52.
[5] Sudhakaran S, Ashwini S. A prospective study evaluating the effectiveness of epidural volume extension with normal saline in combined spinal epidural anaesthesia for lower limb orthopaedic surgeries using low dose intrathecal hyperbaric bupivacaine. Int Arch Integr Med. 2017;4(2):52-60.
[6] Coates MB, Mumtaz MH, Daz M, Kuz M. Combined subarachnoid and epidural techniques. Anaesthesia. 1982;37(1):89-90.
[7] Loubert DC, O'Brien PJ, Fernando R, Walton N, Philip S, Addei T, et al. Epidural volume extension in combined spinal epidural anaesthesia for elective caesarean section: A randomised controlled trial. Anaesthesia. 2011;66(5):341-47.
[8] Brown DL. Spinal, epidural, and caudal anesthesia. Gropper MA, Cohen NH, Eriksson LI, Fleisher LA, Leslie K, Wiener-Kronish JP, editors. In: Miller's Anesthesia. 9th ed. Philadelphia, PA: Churchill Livingstone/Elsevier; 2019.
[9] Salman C, Kayacan N, Ertuğrul F, Bigat Z, Karsl B. Combined spinal-epidural anesthesia with epidural volume extension causes a higher level of block than single-shot spinal anesthesia. Braz J Anesthesiol. 2013;63(2):267-72.
[10] Tyagi A, Kumar S, Salhotra R, Sethi AK. Minimum effective volume of normal saline for epidural volume extension. J Anaesthesiol Clin Pharmacol. 2014;30(2):228.
[11] Bhandari RS, Bhatia R, Agrawal S. Epidural volume extension with saline in combined spinal-epidural anesthesia for hip surgeries using low dose of intrathecal hyperbaric bupivacaine. Anesth Essays Res. 2018;12(1):145.
[12] Beale N, Evans B, Plaat F, Columb MO, Lyons G, Stocks GM. Effect of epidural volume extension on dose requirement of intrathecal hyperbaric bupivacaine at Caesarean section. Br J Anaesth. 2005;95(4):500-03.
[13] Doganci N, Apan A, Tekin O, Kaymak C. Epidural volume expansion: Is there a ceiling effect. Minerva Anestesiol. 2010;76(4):334-39.
[14] Singh S, Vijayalakshmi BC, Kattishettar D. A prospective randomised comparative study between 10 mL and 15 mL of normal saline for epidural volume expansion on 10 mg of 0.5% hyperbaric bupivacaine spinal anesthesia for elective infraumbilical surgeries in adult patients. Indian J Anaesth. 2019;15:224-28.
[15] Preethi HN, Ravishankar BM. Effect of epidural volume extension with 7.5 mL of normal saline on sensory block for caesarean section. Int J Med Anesthesiol. 2020;3(1):32-34.
[16] Tyagi A, Sharma CS, Kumar S, Sharma DK, Jain AK, Sethi AK. Epidural volume extension: A review. Anaesth Intensive Care. 2012;40(4):604-13.
[17] Kohli AV, Bhat K, Wakhloo R, Gulati S. Comparison of different volumes of normal saline for epidural volume extension in combined spinal epidural anesthesia for lower abdominal surgeries. JK Sci. 2019;21(3):95-101.
[18] Elgebaly MT, Yousef AA, Abd El Hafez AA, El Mawy MG. The value of epidural volume extension in hip surgeries using combined spinal epidural anesthesia. Tanta Med J. 2022;50(2):110-16.
[19] Hakim KYK. Comparative study between sequential combined spinal epidural anesthesia versus epidural volume extension in lower limb surgery. Ain-Shams J Anesthesiol. 2020;12(1):4.
[20] Bedi V, Debbarma S, Sharma S, Navaria R, Jhawer A, Choudhary S. Evaluation of impact of epidural volume extension on the quality of spinal anaesthesia in patients undergoing proximal femoral nailing surgeries – Randomised controlled study. Anaesthesiol Intensive Ther. 2023;55(5):366-71.
[21] Naaz S, Shukla U, Gupta R, Ozair E, Asghar A. A randomized controlled trial on epidural volume extension in combined spinal epidural anesthesia for lower limb surgeries using intrathecal ropivacaine in older adults. Bali J Anesthesiol. 2020;4(Suppl 2):S44-S49.

PARTICULARS OF CONTRIBUTORS:
1. Assistant Professor, Department of Anaesthesia, Dr. D. Y. Patil Medical College, Hospital and Research Centre, Dr. D. Y. Patil Vidyapeeth (Deemed to be University), Pune, Maharashtra, India.
2. Junior Resident, Department of Anaesthesia, Dr. D. Y. Patil Medical College, Hospital and Research Centre, Dr. D. Y. Patil Vidyapeeth (Deemed to be University), Pune, Maharashtra, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Vaibhavi Singh,
Junior Resident, Department of Anaesthesia, Dr. D. Y. Patil Medical College, Hospital and Research Centre, Dr. D. Y. Patil Vidyapeeth (Deemed to be University),
Sant Tukaram Nagar, Pimpri Colony, Pimpri, Chinchwad,
Pune-411018, Maharashtra, India.
E-mail: baibhavis19@gmail.com

PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Oct 01, 2024
- Manual Googling: Mar 04, 2025
- iThenticate Software: Mar 06, 2025 (13%)

ETYMOLOGY: Author Origin

EMENDATIONS: 7

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Sep 29, 2024**
Date of Peer Review: **Jan 08, 2025**
Date of Acceptance: **Mar 08, 2025**
Date of Publishing: **Apr 01, 2025**