Comparison of three Different Techniques of Epidural Catheter Fixation; Conventional Loop Fixation, Catheter Tunnelling and by Fixator Device to Prevent Epidural Catheter Migration – A Prospective Randomized Control Study

[1]Dr. R. Sandeep,[2]Dr. Balasubramanian,[3]Dr. Thirumurugan,[4]Dr. Dinesh Babu, [5]Dr. Suneeth P. Lazarus

[1] 3rd Year Postgraduate, Department of Anaesthesiology, Sri Manakula Vinayagar Medical College Hospital and Research Centre, PUDUCHERRY, India

[2] Professor, Department of Anaesthesiology, Sri Manakula Vinayagar Medical College Hospital and Research Centre, PUDUCHERRY, India

[3] Assistant Professor, Department of Anaesthesiology, Sri Manakula Vinayagar Medical College Hospital and Research Centre, PUDUCHERRY, India

[4] Professor, Department of Anaesthesiology, Sri Manakula Vinayagar Medical College Hospital and Research Centre, PUDUCHERRY, India

[5] Professor and Head, Department of Anaesthesiology, Sri Manakula Vinayagar Medical College Hospital and Research Centre, PUDUCHERRY, India

Abstract

Epidural anaesthesia technique can be used to provide both anaesthesia intraoperatively and analgesia in the postoperative period. The primary objective of the study was to compare the incidence of epidural catheter inward and outward migration in conventional catheter loop tape, Catheter tunnelling and fixator device to prevent epidural Catheter migration. Secondary Objective was to compare NRS score, incidence of analgesic failure, patients comfort during epidural catheter fixation and incidence of complications in all three groups.

Materials And Methods:

156 patients posted for Lower limb Orthopaedic Elective Surgeries requiring Epidural analgesia were randomized into three groups of fifty-two in each group (Group A, Group B and Group C). Group-A had epidural catheter fixed through conventional loop tape method, Group-B had epidural catheter fixed through subcutaneous tunnelling, Group-C had epidural catheter fixed through the fixator device. Epidural catheter migration, pain score using Numerical Rating scale (NRS), incidence of analgesic failure, patients' comfort during epidural catheter fixation and incidence of complications was assessed in all three groups.

Results:

Epidural catheter migration was significantly lesser in epidural catheter fixation devices group and tunnelling group compared to conventional loop fixation group. The incidence of analgesic failure was comparatively lesser in epidural catheter fixator devices group and subcutaneous tunnelling group when compared to conventional loop tape method. The NRS score was also significantly lower in epidural catheter fixation group and tunnelling group when compared to conventional loop fixation group. We observed higher comfort level of patients and less incidences of complications in epidural catheter fixation devices group.

Conclusion:

Epidural catheter migration was significantly reduced by subcutaneous tunnelling and epidural catheter fixation device when compared to the conventional loop tape approach in patients receiving lumbar epidural analgesia in the postoperative period. The epidural catheter fixator device is an easy, safe, and effective method which had better patient satisfaction scores and had reduced incidences of complications.

***Keywords*:** Epidural, Catheter, subcutaneous, analgesia

Introduction

Epidural anaesthesia technique provides anaesthesia intraoperatively and analgesia in the postoperative period.[1] For the management of the postoperative pain, it is the best and more superior when compared to parenteral analgesia. Maximum efficacy of postoperative epidural analgesia can be ensured by minimizing factors which are responsible for failure of epidural analgesia in the postoperative period.[2] There are chances of early termination of postoperative epidural analgesia due to epidural catheter migration which increases postoperative morbidity[3]. Gender, age, posture, mobility, body mass index (BMI), site, depth and length of epidural catheter, contact of dressing with fluids are the factors which causes migration of the epidural catheter. The epidural catheter fixation technique is the most practical and efficient method of preventing epidural catheter migration in the postoperative period. [4] Epidural catheter fixation through standard methods have been associated with greater than 50 % of the epidural catheter migration.[5] Subcutaneous tunnelling helps in preventing epidural catheter migration but has been associated with complications. Catheter fixation devices are newly introduced devices in securing epidural catheter for preventing epidural catheter migration.[6] [7] The purpose of this study was to compare the incidence of epidural catheter migration between three methods of securing epidural catheter conventional loop tape method, catheter subcutaneous tunnelling and catheter fixation devices, as there was very minimal research available which have shown significance.

Methodology

The study was carried at Sri Manakula Vinayagar Medical College and Hospital (SMVMCH) Kalitheerthalkuppam, Puducherry, after obtaining the approval from institutional ethics and research committee (EC/61/ 2022). The study was registered in Clinicals Trials Registry India. CTRI no CTRI/2023/01/048709. The study was a randomized controlled trail. period of study was from October 2022 to April 2024 after obtaining institutional Ethics Committee clearance The study was done on patients posted for Lower limb Orthopaedic Elective Surgeries requiring Epidural analgesia. All the patients satisfying the inclusion criteria in the period of study was equally divided into three groups and studied. **Inclusion Criteria included -** Patients underwent elective Epidural analgesia for Lower limb orthopaedic surgeries, Patients of ASA physical status 1 & 2, Patients of either sex and Age > 18 or <70 years.

Exclusion criteria: BMI > 40, allergy to the drugs that are tested or any other contraindications for epidural analgesia, Patients having local / systemic illness,Patients with Coagulation disorders, Patients who cannot lie down / non-co-operative / psychiatric illness, Patients' refusal for participation.

An initial sample population of 52 in each group, making a total of 156 was included in the study. Sample size for the present was calculated using the sample size formula. $n = f(\alpha/2, \beta) \times [p1 \times (100 - p1) + p2 \times (100 - p2)] / (p2 - p1)2$,where p1 and p2 are the percent 'success' in the control and experimental group respectively, and $f(\alpha, \beta) = [\Phi\text{-}1(\alpha) + \Phi\text{-}1(\beta)]2\Phi\text{-}$ 1 is the cumulative distribution function of a standardized normal deviate; for Binary difference/superiority clinical trial study design. [2]

Randomization was done by block randomization with block size of 15, by sequentially numbered, opaque, sealed envelope (SNOSE) with the help of external person not involved in study (epidemiology unit of community medicine department) this was done using random allocation software.

The Epidural catheter was fixed by conventional loop tape method, tunnelling or fixator device by an Anaesthesiologist who was not involved in study. He/she fixed the Epidural catheter according to the code received by the patient. While removing the epidural catheter the catheter position was observed by an Anaesthesiologist who was not involved in the study. The observer who recorded the data was not aware of the participants group. The participant did not know which group he/she is being allotted. Sequence was handed over to principal investigator in sealed envelope. Decoding was be done by the Statistician.

After obtaining informed consent, patients were shifted into the Operating Room. Under sterile aseptic measures at the Lumbar L2-L3 or L3-L4 intervertebral spaces, A median approach with loss of resistance to air technique was used to insert the epidural catheter (SIMS Portex® Ltd, Hythe, UK). Epidural catheter measuring 5cm was inserted into the epidural space. Epidural catheter was secured using methods designated for each group.[5]

Group (A): At the catheter insertion site, an epidural catheter loop was created, covered in sterile gauze, and then plastered with dynaplaster. After carefully pulling the remaining catheter section up to the right shoulder, the entire length was covered with dynaplaster

Group (B): the epidural catheter was subcutaneously tunnelled using a Tuohy 18G epidural needle, 1.5cm lateral to the midline. The epidural needle was used to create the tunnel 2-3cm long vertically in subcutaneous plane, moving from above to downward direction after infiltration with 2% lignocaine. Between the tunnel entry and the epidural puncture site, a little catheter loop was left. This loop was covered with a piece of sterile gauze under it. The remaining length of catheter was carefully drawn up to the right shoulder, and the entire length was covered with dynaplster

Group (C): had the epidural catheter threaded through the central opening of the fixator device (Smiths Medical LOCKIT Plus®), once it exits from the skin. The adhesive on the device sticks to the skin and clamp is closed over the catheter. The remaining portion of catheter was gently pulled up to the right shoulder, and the entire length was covered by dynaplaster.

The length of the epidural catheter that was inserted, the frequency of needle stick injuries, any unusual bleeding, and catheter breaking during fixation were the characteristics that were documented. The comfort level of the patient was assessed on a Likert scale ranging from -2 to +2.

After surgery, patient was shifted to postoperative ward. Patients was assessed for NRS score every 2nd hourly in Postoperative period, when NRS score >4, Epidural analgesia was activated. All patients received 8ml of 0.125% bupivacaine with 50 mcg/kg of Morphine Q12th hourly. After epidural analgesia activation patients pain assessment was done with NRS score second hourly for the 1st six hours, then every sixth hourly for remaining 72 hours. While removal of the epidural catheter, which occurred 72 hours after initiating the epidural analgesia inward and outward movement of epidural catheter, erythema, induration at catheter insertion site were seen and noted in the Performa. After 72 hours once the epidural analgesia was discontinued patients were prescribed with alternative parenteral analgesia. When patients had an NRS score >4 during the 1st 72 hours of epidural analgesia epidural catheter insertion site was assessed for migration of epidural catheter. If epidural catheter had outward migration exceeding 2cm, epidural analgesia was discontinued due to inadequate analgesia. which was followed by administration of alternative parenteral analgesia and same was recorded in the Performa.[8]

Statistical analysis:

Data entry was conducted using Epi Info software version 7.2.1.0, with subsequent analysis performed using Statistical Package for the Social Sciences (SPSS) version 24.0. Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. Categorical variables underwent chi-square tests, while continuous variables were subjected to one-way ANOVA with Bonferroni correction for multiple comparisons. A significance level of $P < 0.05$ was considered statistically significant.

Table 1: Sociodemographic characteristics of the study participants across the three study groups (N=156)

Characteristics	Group-A (N = 52), n(%)	Group-B (N = 52), n(%)	Group-C (N = 5), n(%)	P value
Age Mean ±SD	41.17 (12.18)	41.59 (13.22)	39.98 (13.240	0.513
Gender				
Men	43 (82.69)	35 (67.31)	43 (82.69)	0.728
Women	9 (17.31)	17 (67.31)	9 (17.31)	
Weight Mean ±SD	70.17 (16.92)	66.80 (16.05)	64.79 (15.69)	0.816
BMI	25.88 (5.26)	24.89 (5.52)	24.17 (5.38)	0.415

Mean ±SD				
ASA				
ASA Category - 1	27 (51.92)	30 (57.69)	28 (53.84)	0.454
ASA Category - 2	25(48.07)	22 (42.30)	24 (46.15)	

FIG 1: CONSORT flow diagram showing the number of participants at each stage of the study

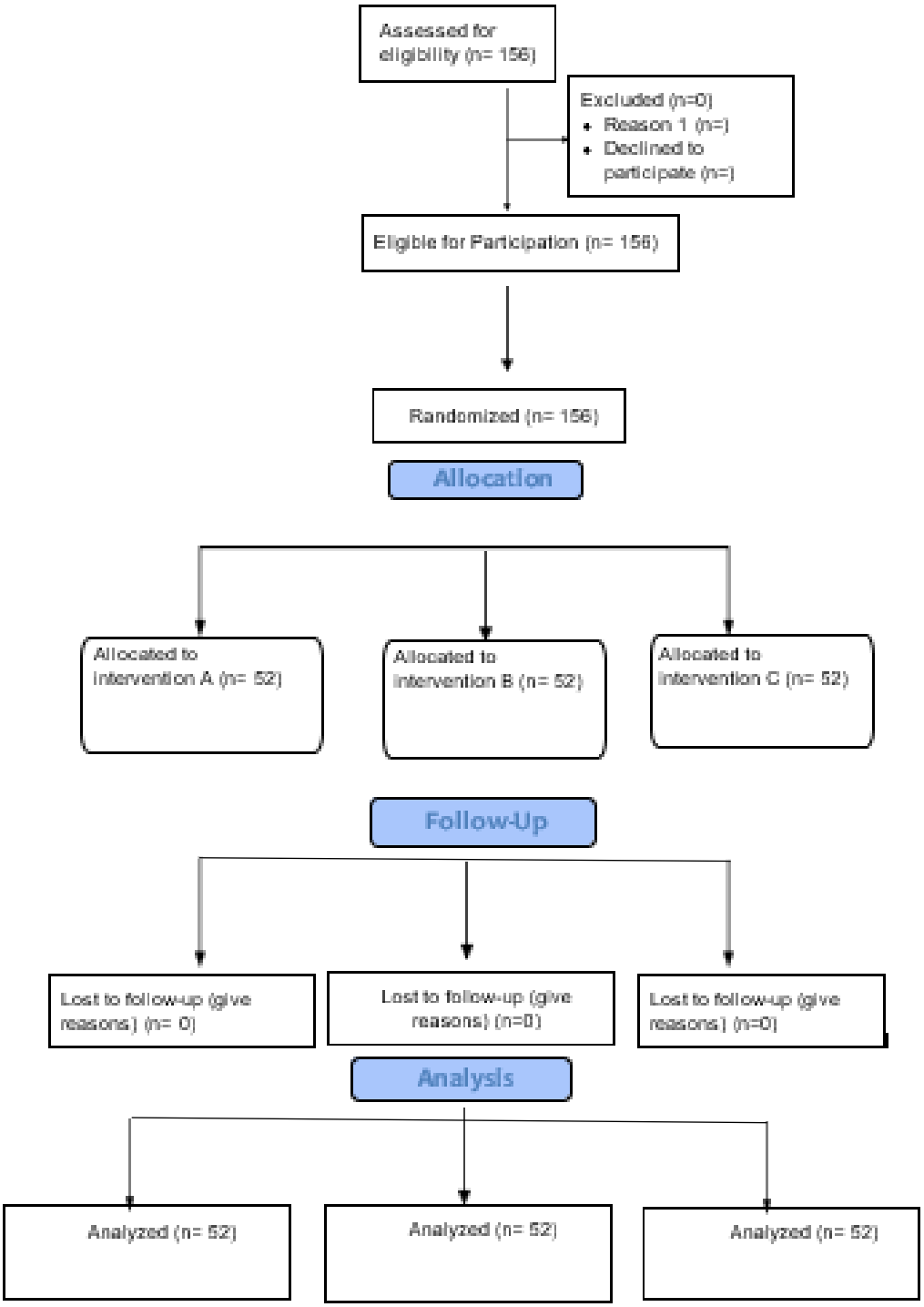


Table 2. Incidence of Outcome Measures

Outcome measure incidence	**Group A (N=52) n(%)**	**Group B (N=52) n(%))**	**Group C (N=52) n(%)**
Catheter migration	16 (30)	3 (5.7)	2 (3.8)
P value		0.001	<0.001
Inward migration	2 (3.8)	0	0
Outward migration	14 (26.9)	3 (5.7)	2 (3.8)
P value		0.003	<0.001
Failure of analgesia	14 (26.9)	3 (5.7)	2 (3.8)
P value		0.003	<0.001

Figure 2: Comparison of Numerical Rating Scale score between three groups

NRS score comparison between three groups **(N=156)**

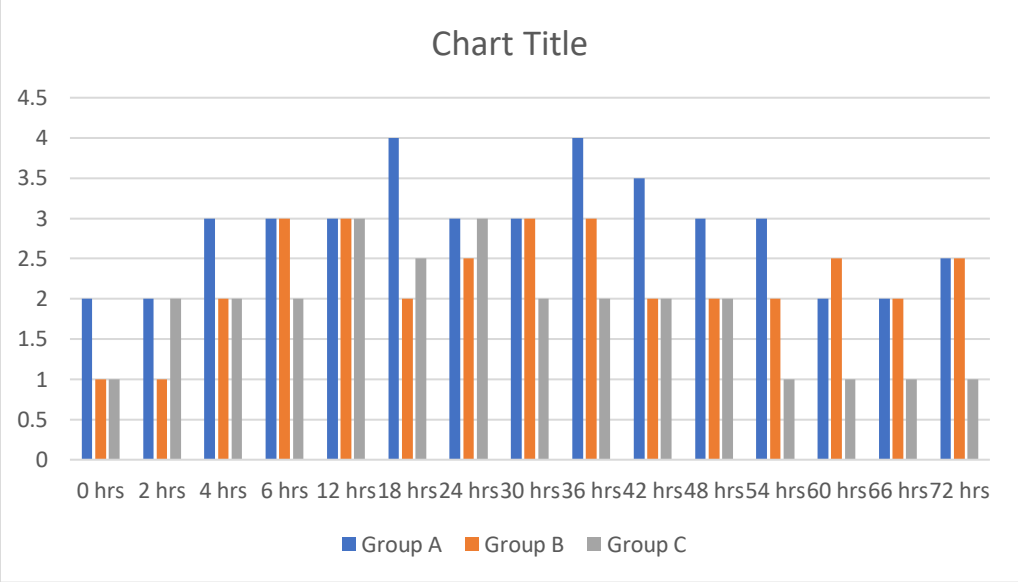


Figure 3 Epidural Catheter Migration

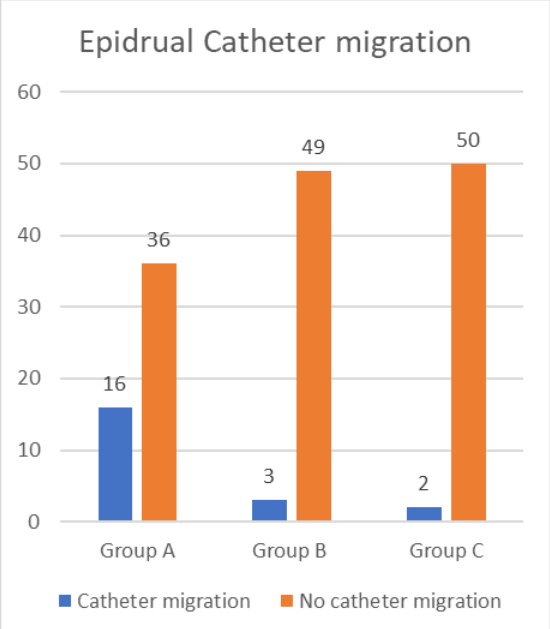


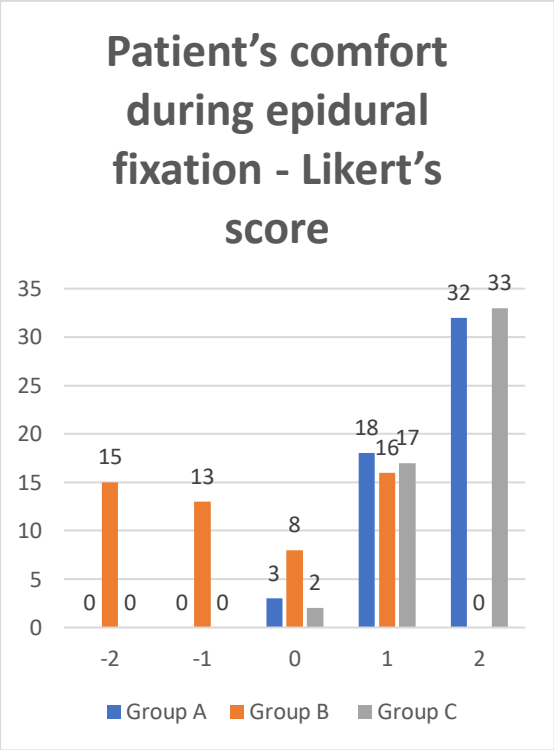
Table 3 Patient's comfort during epidural fixation - Likert's score

(N=156)

Likert scale, patient's perspective	**-2** (totally unacceptable)	−1 (unacceptable)	0 (indecisive and neutral)	+1 (acceptable)	+2 (completely acceptable)	**P value**
Group A	0	0	3 (6)	18 -36	29 -58	

Group B	15 -29.4	13(25.4)	7 - 13.7	16 (31.3)	0	<0.001
Group C	0	0	2 (3.8)	17 (32.6)	33(63.4)	

Figure 4 patients comfort during epidural fixation – Likert's score



Discussion

The prospective randomized study aimed to compare the migration of lumbar epidural catheter in different methods of fixation after its placement in patients requiring postoperative analgesia for lower limb orthopaedic surgeries.[9] Epidural catheter migration is a critical issue leading to analgesic failure and other associated complications. our study found that the catheter Fixation device group had the lowest incidence of catheter migration (3.8%) compared to the tunnelling method group (5.7%) and conventional loop tape method group (30%). [10][11]Our study findings highlight the necessity of using advanced fixation devices to enhance the reliability of epidural analgesia By minimizing catheter migration, these devices help to achieve consistent pain relief, reduce the risk of complications, and improve overall patient outcomes[12]

Pain management efficacy, was measured through the Numerical Rating Scale (NRS). In our study we found that epidural catheter migration happened as early as first four hours in the post operative period which we were able to detect using NRS score.[13] Pain score became statistically significant after first fourth hour between the three groups which showed clinical correlation between epidural catheter migration and increase in pain scores. There was a clinically significant difference in pain score between the conventional loop tape method when compared to other two epidural catheter fixation methods, but there was no significant difference in pain scores between tunnelling and fixator device group during the postoperative period indicating pain scores were similar as catheter remains in position and had not migrated. Our study's findings imply that the primary function of the epidural catheter—delivering analgesia— is affected by the type of epidural catheter fixation technique.[14] Our study findings emphasize that As long as the catheter remains functional and is in the correct position, patients cannot expect consistent pain. highlighting importance of choosing fixation methods that enhance catheter stability & enhancing the analgesic effectiveness. [15][16]

Patient comfort, assessed using the Likert scale, was highest with the catheter fixator device group. Approximately 94% of patients in this group reported high satisfaction levels, indicating that the method was well-received and considered comfortable by most of the participants. In stark contrast, only around 40% of patients using the tunnelling method reported acceptable levels of comfort, with a significant portion finding the technique unacceptable. This substantial difference highlights the importance of the fixation method in patient experience and comfort. [17] This study supports the conclusion that devices designed for ease of use and minimal invasiveness can significantly enhance patient satisfaction. [18] The higher comfort levels associated with the catheter Fixation devices attributed to its design, which minimizes skin irritation and discomfort while ensuring the catheter remains securely in place. This approach not only reduces the risk of catheter-related complications but also enhances overall patient experience by providing a stable and comfortable

fixation method. Consequently, the catheter Fixation devices is recommended as a preferred option for epidural catheter fixation due to its ability to maximize patient comfort and satisfaction.[19]In our study, patients who underwent the tunnelling method experienced higher rates of these complications compared to those using other fixation methods.[20]Less invasive methods, like the catheter Fixation devices, which showed lower rates of inflammation and erythema, might be preferable as they reduce the likelihood of skin complications while still providing adequate fixation.[21]higher complication rates associated with the tunnelling method underscore the importance of selecting fixation techniques that minimize invasive procedures to enhance patient outcomes.

The Limitations of our study are, first, we did not use transparent dressing to cover the epidural catheter, we were able to identify catheter migration only when there was sudden change in NRS pain score. But pain being a multifactorial factor varies from patient to patient, time to ambulation, mobilization there by it could not detect catheter migration earlier. The study was conducted at a single centre, thereby not measuring various human factors and latent problems causing dislodgement.[22]

Conclusion

Epidural catheter migration is significantly reduced by subcutaneous tunnelling and epidural catheter fixation device when compared to the conventional loop tape approach in patients receiving lumbar epidural analgesia in the postoperative period. The epidural catheter fixator device is an easy, safe and effective method which had better patient satisfaction scores and had reduced incidences of complications.

References

1. Gautam, S., Agarwal, A., Das, P., Khuba, S., & Kumar, S. (2020). Prevention of epidural catheter migration: a comparative evaluation of two tunnelling techniques. Korean Journal of Anaesthesiology, 74, 59 - 64.
2. Tadokoro T, Kakinohana M, Navarro M, Goya M, Odo Y. The effectiveness of applying soft tissue bonding adhesive composed of 2-ethyl cyanoacrylate to epidural catheter fixations using film dressings: an open-label, randomized, parallel-group comparative study. Anesthesia & Analgesia. 2019 Jul 1;129(1):149-54.
3. Su J, Soliz JM, Hancher-Hodges S, Popat KU. Factors associated with complete outward migration of postoperative epidural analgesia catheters placed for oncologic surgery: A 10-year single-center retrospective study. Journal of clinical anesthesia. 2020 Nov;66:109955.
4. McLeod GA, Davies HT, Munnoch N, Bannister J, MacRae W. Postoperative pain relief using thoracic epidural analgesia: outstanding success and disappointing failures. Anaesthesia. 2001 Jan;56(1):75-81.
5. Bishton IM, Martin PH, Vernon JM, Liu WH. Factors influencing epidural catheter migration. Anaesthesia. 1992 Jul;47(7):610-2.
6. Sharma A, Parasa SK, Tejvath K, Ramachandran G. Epidural catheter fixation. A comparison of subcutaneous tunneling versus device fixation techniq
7. Holladay J, Sage K. Epidural Catheter. 2023 Jun 5. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan–. PMID: 32644541.
8. Chestnut DH, Owen CL, Bates JN, Ostman LG, Choi WW, Geiger MW. Continuous infusion epidural analgesia during labor: a randomized, double-blind comparison of 0.0625% bupivacaine/ 0.0002% fentanyl versus 0.125% bupivacaine. Anesthesiology. 1988;68(5):754–759. doi:10.1097/00000542-198805000-00013.
9. Kulkarni N, Savant P, Patravale V. Application of loop tape in pediatric patients: A comparative study. J Pediatr Surg. 2017;52(8):1234-1238.
10. Sellmann T, Hoffmann F, Wappler F, Sakka SG. Reduced dislodgment and bacterial contamination using tunneling with a loop: A randomized controlled trial. Ann Surg. 2014;259(3):528-534.
11. Tripathi M, Pandey M. Efficacy of tunneling with a loop in pediatric patients: A comparative analysis. J Clin Pediatr Surg. 2000;35(6):789-794.

12. Viburajah V, Selvaraj V, EJ SK, Kalyan S. Comparison of Epidural Catheter Migration in Three Different Techniques of Catheter Fixation: A Prospective Randomised Study. Journal of Anesthesia/Anestezi Dergisi (JARSS). 2023 Jul 1;31(3).

13. Wheatley, R., Schug, S., & Watson, D. (2001). Safety and efficacy of postoperative epidural analgesia. British Journal of Anaesthesia, 87(1), 47-61.

14. Chadwick VL, Jones M, Poulton B, Fleming BG. Epidural catheter migration: a comparison of tunnelling against a new technique of catheter fixation. Anaesthesia and intensive care. 2003 Oct;31(5):518-22.

15.. Abukhudair HY, Farhoud EN, Abufarah KM, Obaid AT, Yousef OA, Aloqoul AM. Tunneling does not prevent dislodgment of epidural catheters: a randomized trial. Anesthesia Essays and Researches. 2018 Oct 1;12(4):930-6.

16. Burstal R, Wegener F, Hayes C, Lantry G. Subcutaneous tunnelling of epidural catheters for postoperative analgesia to prevent accidental dislodgement: a randomized controlled trial. Anaesthesia and intensive care. 1998 Apr;26(2):147-51.

17. Jose R, Greenlin L, Isac D, Yadav B, Joselyn AS. Epidural catheter migration in non-obstetric adult surgical patients: A prospective, observational, cohort study. Indian Journal of Anaesthesia. 2023 Jun 1;67(6):509-14.

18. Hamilton CL, Riley ET, Cohen SE. Changes in the position of epidural catheters associated with patient movement. The Journal of the American Society of Anesthesiologists. 1997 Apr 1;86(4):778-84.

19. Hermanides J, Hollmann MW, Stevens MF, Lirk P. Failed epidural: causes and management. British journal of anaesthesia. 2012 Aug 1;109(2):144-54.

20. Jørgensen H, Fomsgaard JS, Dirks J, Wetterslev J, Andreasson B, Dahl JB. Effect of epidural bupivacaine vs combined epidural bupivacaine and morphine on gastrointestinal function and pain after major gynaecological surgery. British journal of anaesthesia. 2001 Nov 1;87(5):727-32.

21. Clark MX, O'Hare K, Gorringe J, Oh T. The effect of the Lockit epidural catheter clamp on epidural migration: a controlled trial: apparatus. Anaesthesia. 2001 Sep;56(9):865-70.

22. Chow L, Wahba R, Hong A, Walker A. Epidural catheter migration during labor: a comparison between standard and Epi-Guard fixation. Int J Obstet Anesth. 2011 Oct;20(4):366-7. doi: 10.1016/j.ijoa.2011.07.002. Epub 2011 Sep 9. PMID: 21907566.