Original Article/*Özgün Araştırma*

doi: 10.54875/jarss.2023.59480

Comparison of Epidural Catheter Migration in Three Different Techniques of Catheter Fixation: A Prospective Randomised Study

Üç Farklı Kateter Sabitleme Tekniğinde Epidural Kateter Migrasyonunun Karşılaştırılması: Prospektif Randomize Bir Çalışma

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ABSTRACT

Objective: We hypothesized that subcutaneous tunnelling will be more efficacious in preventing epidural catheter migration in the postoperative period. To compare three different fixation techniques for migration of epidural catheter in the postoperative period.

Methods: Patients undergoing elective surgery with planned postoperative analgesia with lumbar epidural were included. They were divided into 3 groups based on catheter fixation – Group I: transparent adhesive dressing tape, Group II: fixator device (LockIt Plus®) and Group III: catheter subcutaneously tunnelled vertically. The catheter mark was noted during insertion and on removal at the end of second day. The primary outcome measure was epidural catheter migration; the secondary outcome measures were complications and patient satisfaction scores.

Results: Of the 170 patients recruited, 150 patients were included. The Likelihood Ratio (LR) of migration of group I in comparison to group II was 13.28 (p<0.001) while with group III was 7.06 (p=0.007). There was no significant difference between groups II and III (LR 1.12, p=0.29). The satisfaction scores were comparable among Groups II and III. There was no difference in complications among groups.

Conclusion: Epidural migration is significantly reduced by both tunnelling and Lockit plus® methods in comparison to a transparent adhesive dressing in patients on continuous lumbar epidural analgesia in the first two postoperative days. The subcutaneous tunnelling method is as safe in terms of migration as the LockIt plus® method of fixation.

Keywords: Catheter adverse effects, epidural analgesia, epidural catheter, postoperative pain

ÖZ

Amaç: Postoperatif dönemde epidural kateter migrasyonunu önlemede subkutan tünellemenin daha etkili olacağını varsaydık. Epidural kateter migrasyonu için üç farklı fiksasyon tekniğini karşılaştırdık.

Yöntem: Lomber epidural ile postoperatif analjezi planlanarak elektif cerrahi uygulanan hastalar dahil edildi. Kateter fiksasyonuna göre 3 gruba ayrıldı – Grup I: şeffaf yapışkan pansuman bandı, Grup II: fiksatör cihazı (LockIt Plus®) ve Grup III: dikey olarak subkutan tünel açılan kateter. Kateter işareti, yerleştirme sırasında ve ikinci günün sonunda çıkarıldığında not edildi. Birincil sonuç ölçütü epidural kateter migrasyonuydu; ikincil sonuç ölçütleri komplikasyonlar ve hasta memnuniyet skorlarıydı.

Bulgular: Çalışmaya, cerrahi uygulanan 170 hastadan 150'si dahil edildi. Grup I'in grup II'ye kıyasla Göç Olasılığı oranı (LR) 13.28 (p<0.001), grup III ile 7.06 (p=0.007) idi. Grup II ve III arasında anlamlı bir fark yoktu (LR 1,12, p=0,29). Memnuniyet puanları Grup II ve III arasında karşılaştırılabilirdi. Gruplar arasında komplikasyon açısından fark yoktu.

Sonuç: Epidural migrasyon, postoperatif ilk iki günde sürekli lomber epidural analjezi uygulanan hastalarda hem tünelleme hem de Lockit plus® yöntemleriyle transparan adeziv ile karşılaştırıldığında anlamlı olarak azaldı. Subkutan tünel açma yöntemi migrasyon açısından LockIt plus® sabitleme yöntemi kadar güvenli bulundu.

Anahtar sözcükler: Kateter yan etkileri, epidural analjezi, epidural kateter, postoperatif ağrı

INTRODUCTION

The causes of failure of epidural analgesia even after successful placement of the catheter in the epidural space include epidural catheter dislodgement (1–3), failed analgesic levels, catheter blockage and use of inadequate concentrations or doses of local anaesthetics (4). Migration of epidural catheters may cause early termination of postoperative regional

Received/Geliş tarihi : 16.03.2023
Accepted/Kabul tarihi : 23.06.2023
Publication date : 31.07.2023

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Cite as: Viburajah V, Selvaraj V, E J SK, Kalyan S. Comparison of epidural catheter migration in three different techniques of catheter fixation: A prospective randomised study. JARSS 2023;31(3):203-209.

analgesia or intravascular or intrathecal delivery of drugs leading to increased postoperative morbidity in patients. Migration of catheters can also result in epidural hematoma and therefore neurologic complications in patients on perioperative deep vein thrombosis prophylaxis. The factors affecting the migration of epidural catheter are the patient's Body Mass Index (BMI), size of the needle used, depth of catheter insertion, site of epidural, duration of usage, gender, age, patient positioning, movement of the spine and contact of the dressing with fluids (5,6). Catheter migration is mainly affected by the type of fixation method (5). Secure fixation of the catheters can result in lesser complications, better postoperative analgesia, and high patient satisfaction (7). The incidence of catheter migration has varied from 0% to 7.3% in the obstetric population and 5-12% in the non-obstetric population (5,8,9). The epidural catheters are fixed by various techniques including standard dressing over a loop, transparent adhesive dressing over a loop, various methods of subcutaneous tunnelling, Epi-Fix™ (ConvaTec Limited, Deeside, UK), LockIt Plus® (Smiths Medical International Limited, Ashford, UK) and Tegaderm™ (3MHealthcare, St. Paul, MN, USA). We conducted a prospective, randomized study comparing the incidence of epidural catheter migration of more than one centimeter between the three methods of securing the epidural catheter namely looped epidural catheter under a transparent adhesive dressing, subcutaneous tunnelling of the epidural catheter and LockIt Plus® for securing the epidural catheter in surgical patients in the postoperative period. We hypothesized that subcutaneous tunnelling will be more efficacious in preventing epidural catheter migration in the postoperative period.

MATERIAL and METHODS

After obtaining Institutional Ethics Committee approval (REF/2021/01/040156) of the protocol and registration of the trial in the clinical trial registry – India (CTRI/2021/01/030758) and obtaining written informed consent, participants were included in the study. Adult, non-obstetric patients posted for surgeries under regional anaesthesia, with a lumbar epidural catheter, with no contraindication to receive a neuraxial block were included in the study. Patients who had pre-existing neurological disabilities, significant spinal deformities, expressed refusal at any point of the study and who were unable to understand, express and communicate visual analogue scores were excluded.

They were randomised and assigned into one of the three groups, based on a computer-generated random number, by an anaesthesiologist who is blinded about the study protocol and concealed by the sealed envelope technique. The epidural catheter was inserted using 'Epidural minipack' kit (SIMS Portex® Ltd, Hythe, UK), in sitting position at L2-3 or L3-4 spaces in all the patients. After identifying the epidural space by loss of resistance to air and to 0.9% saline, a 16G Portex® epidural catheter was inserted, leaving 6 cm within the space. The epidural catheter fixation was done as described below.

Group I (n=50) A loop of epidural catheter was formed at the catheter insertion site and fixed with transparent adhesive dressing tape.

Group II (n=50) had the epidural catheter threaded through the central eyelet of the fixator device LockIt Plus® (Smiths Medical International Limited, Ashford, UK), after its exit from the skin. The adhesive on the device sticks to the skin and the clamp is closed over the catheter. The catheter was gently pulled up to the right shoulder, and the entire length was covered by a transparent adhesive dressing (Figure 1).

Group III (n=50) had the epidural catheter subcutaneously tunnelled vertically using a Tuohy 18 G epidural needle 1.5 cm lateral to the midline. The epidural needle was used to create the tunnel 2 to 3 cm long in the subcutaneous plane, moving from above downward after local infiltration, with its lower end at the same horizontal level as the epidural puncture site. The catheter was gently lined up to the right shoulder, and the entire length was covered by a transparent adhesive dressing (Figure 1).

The transparent film permitted regular inspection of the epidural catheter. The study parameters observed are the inter-vertebral space at which the epidural was sited, the distance between the skin and the epidural space (cm), the catheter mark at the skin level (measured with a measurement scale calculated from the nearest visible marking on the catheter in centimetre). The catheter mark on the skin was also noted after 48 hours from the time of insertion. The epidural catheters are removed 48 hours after insertion. The catheter insertion site was assessed for any soakage, bleeding and erythema every 24 hours without disturbing the catheter. The primary outcome measure was epidural catheter migration; the secondary outcome measures were postoperative analgesia, presence of soakage, erythema, pain at the site of injection and patient satisfaction scores.

The anaesthesiologist placing the epidural catheter initiated an acute pain service enrolment form containing patient demographic data, details of epidural catheter placement including the vertebral level of the catheter placement, depth of the epidural space, and catheter mark at the catheter insertion site in all the groups. The catheter mark was also noted before catheter removal and the difference between the two values was calculated as the catheter migration. Inward migrations and outward migrations of 1 cm or more were considered as significant. All patients received 0.125% bupivacaine with 1 μg mL^{-1} of fentanyl as a continuous post-

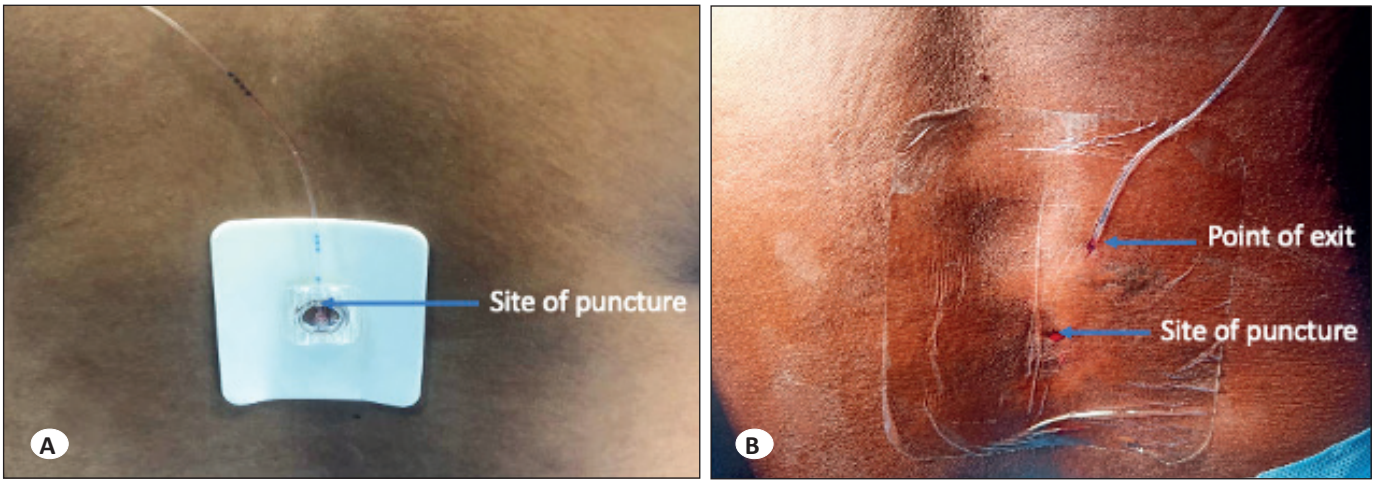

Figure 1. Epidural catheter fixation techniques. Catheter fixation by **A)** Fixator device (Locklt Plus®) **B)** Subcutaneous Tunnelling.

operative epidural infusion with an elastomeric pump (Royal Fornia Medical Equipment Co Ltd). All patients were followed up by the acute pain service resident twice daily in the post-operative period until the epidural catheter was removed. During the first 72 h when epidural analgesia was delivered, pain scores were noted every 4 h. A visual analogue scale (VAS) of ≥ 4 was treated with rescue analgesic tramadol 50 mg intravenous. Epidural analgesia was discontinued in cases of inadequate analgesia, with outward migrations exceeding 2 cm and alternative analgesia methods was provided. Each patient was also assessed daily for catheter migration, catheter dressing, analgesia adequacy, and catheter insertion site inflammation (defined as an area of erythema and induration >5 mm around the skin exit site and/or visible pus). The satisfaction scores were noted on a 5-point scale with 1 denoting the least satisfaction and 5 indicating high satisfaction.

Statistical Analysis

The sample size calculation was based on epidural migration values reported in a previous study by Gautam et al (6) with an incidence of 36% migration in the group with adhesive dressing and an incidence of 4-17% in the tunnelling group. A sample size of 45 was obtained with a 95% confidence level. An additional 10% was included to enrol a total of 50 patients in each group to address attrition. Demographic data and skin-to-space were compared by one-way analysis of variance (ANOVA). The catheter migration incidence was analysed with chi-square tests and effect size by Cramers V. Chi-square test and Likelihood Ratio was used to compare migration between groups. Ordinal data of rescue analgesics and satisfaction scores were analysed by the contingency table. JASP (JASP Team (2022). JASP (Version 0.16.3) [Computer software] was used to perform the statistical analyses. A two-sided p-value of < 0.05 was considered significant.

RESULTS

A total of 170 patients were recruited in the preoperative period for participation in the study of which 150 patients were included (Figure 2). There was no loss of follow-up or attrition among the 150 patients. There was no significant difference in age ($p = 0.63$; Mean ± Standard Deviation (SD) of 50.64 ± 14.87, 52.52 ± 17.22 and 49.64 ± 13.41 respectively in groups I, II and III), sex ($p=0.33$) and BMI ($p=0.45$). The skin-to-space distance had a non-normal distribution and a $p=0.23$ among the groups (median value, median absolute deviation – Group I: 4,0; Group II: 4,0.5; Group III: 3.5,0.5). The incidence of catheter migration was maximum in Group I as compared to that of other groups (Table 1). The Likelihood Ratio (p) of migration of Group I in comparison to Group II was 13.28 ($p<0.001$) while with group III was 7.06 ($p=0.007$). There was no significant difference between Groups II and III (LR 1.12, $p=0.29$). There was a significant difference in the length at removal among the groups ($p=0.006$) (Figure 3). Group I had a significant difference in length at removal in comparison to the other groups, while there was no difference between Groups II and III (Table 2). There was no difference in the number of position changes in the postoperative period ($p=0.11$). The median value, median absolute deviation for the satisfaction scores were 4, 0 in Group I; 4,1 in Group II and 5,0 in Group III. There was a significant difference in satisfaction scores between Group I and the other groups ($p<0.001$). The scores were compared between the groups (Table III). There was no clinical difference in the VAS scores. There was no significant difference in soakage, erythema, or pain among the groups (p of 0.28, 0.47 and 0.15 respectively).

DISCUSSION

This prospective randomised study aimed to compare the migration of lumbar epidural catheters in different methods

Table I. Epidural Catheter Migration Characteristics among the Groups (Number of Patients)

Migration	Group I	Group II	Group III	p	Cramers V
Yes (n)	17	3	6	< 0.001*	0.32
No (n)	33	47	44		

*p<0.05 is significant.

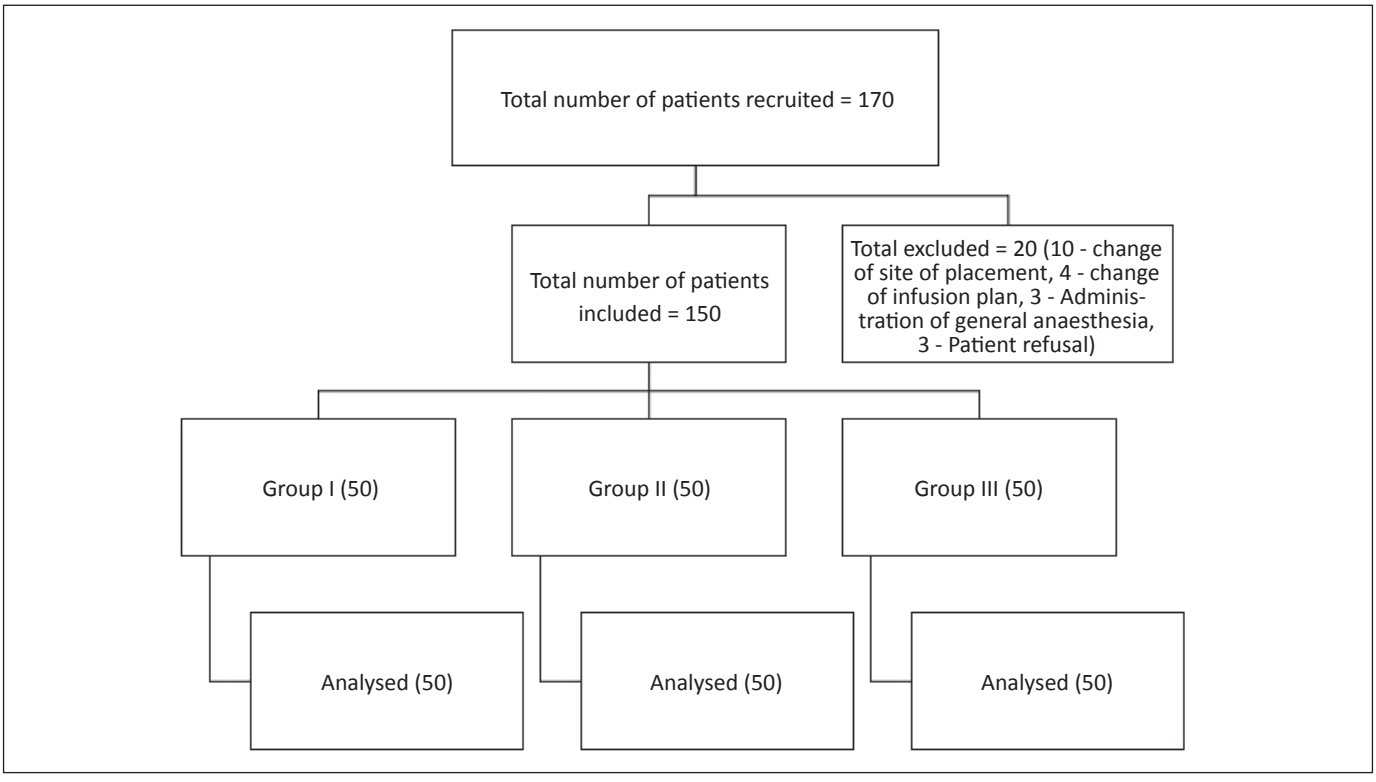

Figure 2. Consort flow diagram.

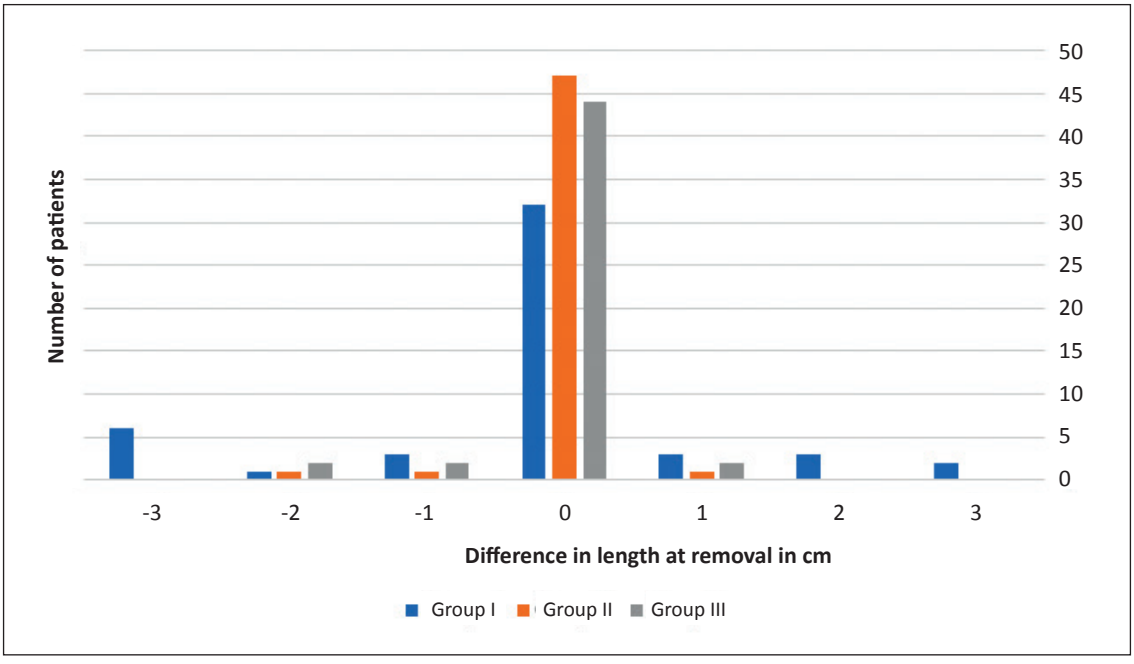

Figure 3. Difference in length at removal of the epidural catheter.

Table II. Comparison of Difference in Length at Removal of the Epidural Catheter among the Groups

Difference in Length	χ^2	p
Group II vs III	1.1	0.78
Group I vs III	13.63	0.03*
Group I vs II	15.85	0.01*

*p<0.05 is significant.

Table III. Comparison of Satisfaction Scores at the Time of Epidural Catheter Removal Among the Groups

Satisfaction Score	Group I (n)	Group II (n)	Group III (n)	Kendall Tau-b
2	3	5	1	p<0.001
3	4	1	1	
4	38	20	16	
5	5	24	32	

*p<0.05 is significant.

of fixation of the catheter after its placement in patients coming for non-obstetric surgeries. We found that the incidence of significant migration of epidural catheter happens more with the traditional technique of fixing the catheter with an adhesive tape over a loop compared to the subcutaneous tunnelling method and LockIt Plus®. The incidence rate of catheter migration was similar in subcutaneous tunnelling to that of LockIt Plus®.

More than 40 years back, an article by Duffy, described the problem of epidural migration and suggested adherent dressing to overcome the problem (10). This self-adhesive transparent dressing was the most common method of securing an epidural catheter in clinical practice. Migration of the catheter can result in inadequate analgesia, intrathecal or intravascular deposition of the drug, neuropathic pain, or neurological complications. Migration has been described as the most common reason for the termination of epidural infusion (11). Catheters when sufficiently threaded into the epidural space may provide a tissue frictional hold which may technically prevent migration of the catheter after fixation. But, when catheters are threaded beyond the recommended 5-7 cm may lead to a change in direction or knotting of the catheter and the ensuing complications (12). Various definitions have been used for migrations (6,9,13,14), with variations for inward and outward migrations. It has been shown by a previous study that catheter migration of less than 1 cm was unlikely to be associated with complications due to catheter migration as described above (8). Hence, we considered migration of more than 1 cm as the significant length of migration of the epidural catheter in this study.

The previous study investigating the factors affecting the migration of epidural catheters has shown that weight, BMI, epidural space length, change in positions, epidural pressure and CSF oscillations can affect the migration of the catheter (4,8,15). Some of the factors that determine a successful epidural catheter placement includes position of placement, site of insertion, technique used to identify the space and the equipment which were standardised in both the groups in our study (4). Our study showed a higher percentage of migration (34%) with adhesive taping similar to the previous studies (14). Catheter migration has been attributed to nearly one-third of failed epidurals (16). The likelihood of migration with adhesive taping was more when compared with the fixator device and with tunnelling in our study. We have in addition analysed the quantity of migration in each group. This was maximum in the group with adhesive taping alone, with no difference between the other two groups. This shows equal efficacy of both tunnelling and LockIt Plus® in preventing migration in contrast to a previous study (9). This could be due to the difference in surgical procedures in the groups in the study by Sharma and colleagues.

LockIt Plus® has a plastic clamp which when closed can hold the catheter. Though blood and fluid can get collected in the resultant dead space, fixation is not affected as the fixator device is attached to the skin separately by its adhesive surface (7). A previous study showed that inward migration was not different when compared with dressing, while outward migration was significantly less in the LockIt Plus® group (7). Another study has shown a significant movement in 12% of patients while using this device (17).

Tunnelling of the catheter has produced mixed results in previous studies (9,13,18–20). Burstal and colleagues observed a reduction in both inward and outward movement, with an incidence of 4% inward movement and 10% outward movement (13). Our study was comparable with a total displaced catheter incidence of 12%. Bougher and colleagues stated that outward movement was not reduced with tunnelling (19). In 2016, Sharma and colleagues compared tunnelling to fixation devices such as LockIt® and found that tunnelling did not outperform them (9). Tunnelling has been described to reduce the risk of contamination and infection at the catheter site (21,22). Tunnelled catheters are described as effective and safe in paediatric and obese patients (18). Complexity of the tunnelling procedure, local inflammation, and the risk of snapping of the catheter should be weighed against the cost-effectiveness of the procedure. Our study did not find a significant difference in complication rates among the groups.

The other method used to prevent failure was to insert catheters deeper into the epidural space (minimum of 5 cm rather than 4 cm) with a decrease of 43% in dislodgement rate

(3). But insertion of more than 6 cm can result in migration outside the epidural space and coiling. Epidural dislodgement and disconnection due to the securing of the drug port connector have been studied. A higher tensile strength was required to disconnect the catheter if taping was done at the connector site, when measured using a digital tension meter (23). There was no difference which was noted in dislodgement rates in the study.

We found a higher satisfaction in the LockIt Plus® and the tunnelling group, with no difference between them, differing from the previous study (9). The satisfaction with epidural has been attributed to multiple factors like effective analgesia, type of surgery, site of epidural and ambulation (11). The mapping of the hypoesthesic area may not correspond to the pain intensity and therefore efficacy of the epidural (24). There was no difference in complication rates observed in our study in contrast to the previous study (9).

The limitations of our study include the conduct of the study at a single centre, thereby not measuring various human factors and latent problems causing dislodgement. We included all non-obstetric surgeries done under lumbar epidural. Standardisation of surgery could have guided us in finding the cause of dislodgement as sweating and soiling at the site differs with procedures.

CONCLUSION

Epidural migration is significantly reduced by both tunnelling and LockIt Plus® methods in comparison to transparent adhesive in patients on continuous lumbar epidural analgesia in the first two postoperative days. There was no difference between the tunnelling and the fixator device regarding migration, satisfaction scores and complications.

AUTHOR CONTRIBUTIONS

Conception or design of the work: VV, SK
Data collection: VV, SK
Data analysis and interpretation: SKEJ
Drafting the article: SKEJ
Critical revision of the article: VV, VS, SKEJ
Other (study supervision, fundings, materials, etc: VS, SKEJ
The author (VV, VS, SKEJ, SK) reviewed the results and approved the final version of the manuscript.

Acknowledgements: None

Declaration of interests: VV, VS, SKEJ and SK have no interests to declare.

Conflict of interest: No conflict of interest declared.

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