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A NOVEL TECHNIQUE OF EPIDURAL CATHETER FIXATION AND COMPARISON BETWEEN THREE DIFFERENT APPROACHES

Anesthesiology

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ABSTRACT

Introduction: Numerous fixation devices have been designed to tether the catheter to the skin, including simple adhesive devices and more complex catheter clamps that adhere to the skin (Lockit ®, Portex, UK). Devices such as a balloon-tipped catheter (Patent No. US4973305) and a self- retaining catheter with wings that can be expanded outwards at the tip (Patent No. EP0931559) have not reached the market. It appears that the weak link in adhesive catheter fixation techniques is in the tethering of the adhesive to the skin.

Aim and objectives: Study was done to compare the traditional method of epidural catheter fixation, i.e, looping and tapping, used in our setup, with the newer techniques of fixation.

Material and Methods: 105 patients scheduled for elective abdominal (including gynaecological) surgeries, in whom epidural catheter fixation by looping and tapping in group of 35 patients, by subcutaneous tunnelling in another group, and by subcutaneous tunnelling with suturing and loping in group C, was placed for surgery and for postoperative analgesia for a minimum period of 24 hrs.

Results: The tunneling and looping technique showed more decrease in the incidence of dislodgement as compared to the simple looping and taping fixation (p=0.04). While the suturing and tunneling with looping technique showed no dislodgement.

KEYWORDS

Epidural Catheter With 18 G Tuohy Epidural Needle And Epidural Catheter, Synthetic Nonfilament, Non Absorbable Polyester Suture, Thorasic And Lumber Epidural.

Introduction:

In 1906, George Bernard Shaw wrote in The Doctor's Dilemma, "When doctors write or speak to the public about operations, they imply that chloroform has made surgery painless. People who have been operated upon know better." Surprisingly little progress was made in controlling postoperative pain, until a confluence of factors , like, the association between poor pain control and the risks of postoperative complications such as respiratory insufficiency and myocardial infarction, directed attention to the generally poor state of postoperative pain control[1]. Epidural analgesia has the ability to maintain continuous analgesia after placement of an epidural catheter, thus making it suitable for continuous post-operative pain relief[2] Epidural analgesia is achieved by placing a plastic catheter (polyurethane catheter or radio-opaque nylon catheter) into the epidural space and then injecting the titrated amounts of local anaesthetic and opioids into the epidural space, which is present inside the bony spinal canal, but just outside the duramater. In addition to gross body movements, changes in epidural pressure and cerebrospinal fluid oscillations contribute to displacement of epidural catheters. The epidural space is highly compartmentalized and complex structure, which may influence catheter placement. Dislodgement of epidural catheters may cause early termination of postoperative regional analgesia. Finally, it is speculated that catheter movement within the skin may potentially contribute to bacterial contamination[3]. Epidural catheter migration is a common problem that can inconvenience the anaesthetist and have potentially devastating consequences for the patient. Following insertion into the epidural space, the catheter can be simply taped with an adhesive dressing or tunnelled subcutaneously to reduce the incidence of migration. Numerous fixation devices have been designed to tether the catheter to the skin, including simple adhesive devices and more complex catheter clamps that adhere to the skin (Lockit®, Portex, UK). Devices such as a balloon-tipped catheter (Patent No. US4973305) and a self-retaining catheter with wings that can be expanded outwards at the tip (Patent No. EP0931559) have not reached the market. It appears that the weak link in adhesive catheter fixation techniques is in the tethering of the adhesive to the skin. In addition, unplanned catheter movement may be associated with rare, but clinically most relevant, complications such as spinal hematoma when occurring shortly after anticoagulant administration[4].Hazards of migration include inadvertent intravenous[5,6] or subarachnoid[7,8] injection and unilateral or failed block[9]. A fixation method with a low incidence of migration, and a means of predicting patients in whom migration is likely, are both desirable. In this study we demonstrate the impact of using maximum effort of catheter fixation by a combination of techniques each described as independently reducing dislodgement, i.e., a combination of subcutaneous tunneling, suturing, and looping.

Aim and Objectives:

To compare the Incidence of Epidural Catheter Dislodgement in the three Groups.To compare the Quality of Postoperative Analgesia in the three groups using Visual Analogue Scale.

Retrospective assessment of Overall Subjective Contentment with the procedure in the three groups *[using notes from 1 (Excellent) to 5 (insufficient)].*

To assess and compare the clinical signs of Infection or Inflammation at the Epidural catheter insertion and fixation site. (using classification recommended by *German Society of Anaesthesiologists).*

Material and Methods

The present study was undertaken in indoor patients admitted in N.S.C.B. Medical College & Hospital, Jabalpur over a period of one year.

Selection of Cases:

An informed written consent was taken from all the patients in the 3 groups after the approval of the Institutional Ethics committee. 105 patients of ASA class I-II , age between 18 to 65 years scheduled for elective abdominal (including gynaecological) surgeries, in whom epidural catheter was placed for surgery and for postoperative analgesia for a minimum period of 24 hrs were eligible for the study.

Criteria for Exclusion :

Patient refusal for epidural catheterization
Patient in whom regional anaesthesia is a contraindication;
Suffering from coagulopathy, blood dyscrasias and on anticoagulant therapy.
Skin sepsis and marked spinal deformity
Hypovolemia
Aortic and mitral stenosis

Patient with allergy to local anaesthetics Patient allergic to catheter material Any patient who were having active infections/ emergency cases

Design of Study : Prospective Randomised Study.
Group A- Patients in whom epidural catheter was fixed by looping and taping (the traditional method) - Our control group .

Group B- Patients in whom epidural catheter was fixed by subcutaneous tunneling with looping .

Group C- Patients in whom the epidural catheter was fixed by subcutaneous tunneling and suturing with looping.

Methodology :
After complete preoperative examination and proper premedication, patient was taken in the operation theatre. The patient was placed on the OT table in supine position. All the mandatory equipments (NIBP cuff, Pulse Oximetry probe, and ECG) were attached to the patient and baseline values of heart rate, BP, SPO_2 and respiratory rate were recorded. An i.v. line with an i.v. cannula (20G) were secured and preloading was done.A full aseptic technique was used to insert epidural catheter. The operator washed his/her hands and wore the mask, cap, sterile gown and sterile gloves. The tray contained company sterilized epidural needle (Tuohy 18 G) and epidural catheter with bacterial filters (PORTEX).In addition a 16 G i.v. cannula, a synthetic , monofilament , nonabsorbable polyester suture and adhesive tape were also required for the different fixation techniques in the three study groups.All catheter insertions were done in operation theatre with full aseptic precautions. Patient skin was prepared with 5% povidone iodine solution and rectified spirit and then covered with sterile drapes.The epidural catheter was then fixed in the following manners in the three different groups-

Group A :
Simple looping and taping ;the epidural catheter was formed into a circular loop at the skin exit site and then directed over the right shoulder, then, the loop was fixed with the help of adhesive tape, leaving the puncture site uncovered to facilitate assessment of the catheter position without movement likely induced by removal of the adhesive tape. Then, two sterile pieces of gauge were applied at the catheter puncture site and covered with adhesive tape.

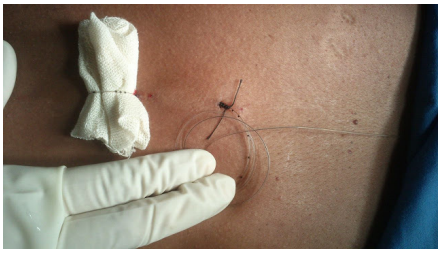
Group B –
After proper local skin infiltration with 2% lignocaine, the epidural catheter was subcutaneously tunneled (for 2.5 cms) using the tuohy needle ,along the paramedian groove , in order to facilitate passage of the catheter. Once the stylet was removed, the epidural catheter was threaded through the subcutaneous tunnel. The tuohy needle was then removed. Then, after making a small loop of the epidural catheter, after its exit from the tunnel, the catheter was directed over the right shoulder. The loop and the catheter puncture site were all secured using adhesive tape, as in Group A.

Local Infiltration At The Site Of Tunneling

Subcutaneous Tunneling

Tunneling Followed By Looping

GROUP B : STEPS OF SUBCUTANEOUS TUNNELING
Group C–A subcutaneous tunnel was created as stated above. And the distal part of the subcutaneous tunnel was sutured to the skin using a synthetic, monofilament, nonabsorbable polyester suture, taking sufficient precaution, as to avoid damage or kinking in the Epidural catheter. Adhesive tape was applied, leaving the puncture site uncovered as in the other two groups, followed by further use of sterile gauge pieces and adhesive tape to secure the catheter at its exit site from the skin.



Group C:subcutaneous Tunneling With Suturing And Looping

The distance between epidural tip and skin surface was recorded in each patient.

All catheters were tested for inadvertent intravascular or subarachnoid placement using test dose (containing 1ml of 1:10,000 Adr. + 3ml 2% Lidocaine). The operations were performed under epidural anaesthesia alone or combined with spinal anaesthesia or general anaesthesia as required.

Postoperative followup :
The anaesthesiologist visited each patient 6 hourly for first 12 hours and then, daily, i.e., 24 hourly thereafter, upto 3days. Pain intensity (using Visual Analogue Scale, VAS score), use of *Rescue Analgesic* (if any) and signs of catheter related complications were assessed during follow-up visits, along with the assessment of the following study endpoints.

Study Endpoints :Epidural Catheter Dislodgement.
The distance between catheter tip and the skin were recorded a second time at the time of catheter removal and were compared to the preoperative value directly after catheter insertion. Absolute values for catheter length were determined in millimeters using a ruler. Significant outward movement was defined as >2.5 cm from the position at insertion. For inwards movement >1 cm was defined as significant ***(as per Burstal's definition of catheter dislodgement).***
Quality of Postoperative Analgesia. Postoperative analgesia was assessed, using VAS ***(Visual Analogue Scale)*** score.

Overall Patient Satisfaction. At the time of epidural catheter removal, overall subjective contentment with the procedure was assessed retrospectively, using notes from *1(Excellent) to 5 (Insufficient).*

Clinical signs of Inflammation/Infection.
Statistical Analysis: All the records were rechecked for their completeness and consistencies. Illogical entries were resolved before analysis. Non numeric entries were coded numerically into nominal/ordinal distribution before analysis. Categorical variables were summarized in frequency and percent distribution and Chi-square or Fishers exact test was performed as appropriate. Continuous variables were analyzed using mean±sd or median with inter quartile range as appropriate. Mean difference between two independent groups and two observation on same subject were analyzed by using independent t-test and paired t-test respectively after normalized the distribution otherwise non-parametric test was applied. For testing the null hypothesis, 0.05 Alpha and 95% confidence limit was applied.

Material Required :
1. Epidural trolley with 18G Tuohy epidural needle and epidural catheter (PORTEX).
2. 2ml and 5 ml Disposable Syringes.
3. 5% Povidone iodine and Rectified spirit.
4. Sponge holding forceps and Gauge pieces.
5. Test dose (1 ml 1:10,000 Adr. + 3ml 2% Lidocaine).
6. Injection Bupivacaine (.5% plane) of Astra Zenca.
7. 16 G i/v cannula.

8. Synthetic ,monofilament, nonabsorbable polyester suture.
9. Adhesive tape.
10. Emergency drugs/intubation kit.
11. Resuscitation kit.
12. *Rescue Analgesia*- i.v. 1000 mg Paracetamol (100ml) [In case analgesia could not be provided by means of Epidural catheter].

Epidural Trolley(with Its Contents)

Observations and Result

The observations are as follows-

Table No. – 1 Agewise Distribution Of The Studied Population

AGE GROUPS (in years)	Group A	Group B	Group C	Total
<20 yrs	0	2	0	2 (1.90%)
21-30 yrs	5	5	5	15(14.29%)
31-40 yrs	15	11	16	42 (40%)
41-50 yrs	10	12	11	33 (31.42%)
51-60 yrs	4	5	0	9 (8.57%)
>60 yrs	1	0	3	4 (3.81%)
				105
MEAN + S.D.	40.51 +10.55	40.6 + 11.30	40.34 +10.04	

Significance: A Vs B p=1.0, A Vs C p=1.0, B Vs C p=1.
There was no statistically significant difference (p>0.05).So the groups were comparable.

Table No. – 2 Gender Wise Distribution Of The Studied Population

Group	Male	Female	Total
A	14	21	35
B	13	22	35
C	13	22	35

Chi square=0.08, p=0.96
There was no statistically significant difference (p>0.05).So the groups were comparable.

Table No. – 3 Weightwise Distribution Of Cases According To Study Group

	GROUP A	GROUP B	GROUP C
MEAN + S.D.	49.51 + 6.66	49.83 + 7.92	49.8 + 6.84

A Vs B p=1.0, A Vs C p=1.0, B Vs C p
There was no statistically significant difference (p>0.05).So the groups were comparable

Table No.-4 Epidural catheter dislodgement in the studied groups

	Group A (n=35)	Group B (n=35)	Group C (n=35)
Outward Migration (> 2.5cms)	9	4	0
Inward Migration (>1cms)	3	0	0
OR (95% CI)	3.69(0.80-22.95)		
Kruskal-Wallis Test*	Chi Square= 6.132; P<0.05		

*Comparison of Dislodgement between the groups A, B & C (Table 4)

- Dislodgement seen in Group A- 12/35 (34.3%; 95% CI 19.1-52.2)
- Dislodgement seen in Group B- 4/35 (11.4%; 95% CI 3.2-26.7)
- Dislodgement seen in Group C- None
- A Vs B: Odds Ratio (95% CI): 4.04 (1.03-19.08); p=0.04
- Tunneling and looping (Group B) decreased the incidence of catheter dislodgement from 12/35 (Group A ; simple looping and taping) to 4/35 (Tunneling and looping) significantly (p=0.04).
- No significant dislodgement observed in Group C.
- Of all the dislodgements, outward migration (13/105) was found to be more common than inward migration (3/105)[OR=3.69].
- No complications occured by tunneling of the catheters.
- Particularly, no episode of subcutaneous hematoma, bleeding, or occlusion of the catheter lumen by sutures was noticed.

Table No. –5 Distribution Of Insignificant Outward Dislodgements

Outward Migrations	<0.5cms	0.5-2.0cms	2.0-2.5cms
Group A	7 (43.75%)	6 (37.5%)	3 (18.75%)
Group B	21 (75%)	4 (14.29%)	3 (10.71%)
Group C	29 (87.88%)	3 (9.09%)	1 (3.03%)
PERCENTAGE	74.0%	16.8%	9.1%

Chi square = 11.22, p value = 0.24

- In group A, 43.75% of the insignificant dislodgements were within a range of 0.5cm , 37.5% in the range of 0.5-2cm and 18.75% in the range of 2-2.5cm.
- In group B, 75% of the insignificant dislodgements were within a range of 0.5cm, 14.29% in the range of 0.5-2cm and 10.71% in the range of 2-2.5cm.
- In group C, 87.88% of the insignificant dislodgements were within a range of 0.5cm, 9.09% in the range of 0.5-2cm and 3.03% in the range of 2-2.5cm.

Table No. – 6 Distribution Of Insignificant Inward Dislodgement

Inward Migrations	<0.5 cm	0.5-1 cm
Group A	6 (85.7%)	1 (14.29%)
Group B	3 (100%)	0
Group C	2 (100%)	0
PERCENTAGE	91.67%	8.33%

Chi square = 0.78, p value = 0.68

- In group A , 85.7% of the insignificant inward dislodgements were within a range of 0.5cm and 14.29% in the range of 0.5-1cm.
- In group B , 100% of the insignificant inward dislodgements were within a range of 0.5cm and none in the range of 0.5-1cm.
- In group C , 100% of the insignificant inward dislodgements were within a range of 0.5cm and none in the range of 0.5-1cm.

Table No. –7 Median Vas Score At Different Time Intervals

MEDIAN VAS SCORES	Group A	Group B	Group C
6 hrs	2	0	1
12 hrs	2	1	1
24 hrs	3	2	2
48 hrs	3	2	2
72 hrs	4	3	3
MEDIAN SCORE(25th-75th percentile)	3 (2-4)	2 (1-3)	2 (1-3)
z-value	5.79	0.01	Reference
p-value	<0.0001	0.92	-

- Analgesic quality was found to be better in group B and C, however this was found to be statistically insignificant.

Table No. – 8 Mean Satisfaction Score Among The Three Groups

	GROUP A	GROUP B	GROUP C
MEAN SATISFACTION SCORE	2.09 + 0.6	1.97 + 0.78	2.26 + 0.70
t-test	1.09	1.61	Reference
p-value	0.28	0.11	-

Overall Satisfaction Score :[1-Excellent,2-very good,3-good,4-Not good,5-Insufficient.

No statistically significant difference was seen between the groups.

Table No.-9 Number of cases showing clinical signs of infection/inflammation

All patients recieved systemic antibiotic medications as single shot surgical prophylaxis that was repeated once in patients with duration of surgery >6 hours.

	Group A	Group B	Group C
Mild	0	2	2
Moderate	0	0	0
Severe	0	0	0

- Mild signs of inflammation were noted in 4 cases (2 each in group B and C).
- Only redness and swelling was observed in the above cases. No pressure pain at catheter insertion, or tunneling site was noted .
- No patient showed moderate or severe infection. No antibiotics were required to be given for EC related infections.

Discussion

The present study was conducted to study the Epidural catheter dislodgement by various methods of fixation, during the post-operative period of analgesia. Along with these, other concerns were assessment of postoperative analgesia, signs of infection/ inflammation and patient satisfaction with the procedure. In present study incidence of epidural catheter dislodgement was 15.2% (16/105). **Timur and Sellmann et al** reported a dislocation rate of 37 percent. **Bishton et al** in their study on epidural catheter migration found a catheter migration rate of 36%[10]. While catheter dislodgement rate was 28% in the study conducted by **Burstal et al**[11].The rationale behind this study is that the multiorifice epidural catheters used in the study have the most proximal orifice located 14 mm from catheter tip. If epidurals were inserted 30 mm, a dislodgement of 25 mm would consecutively lead more or less to procedural failure. As most of the orifice bearing part of the catheter would be out of the epidural space. Thus we chose to define outwards movement of >2.5 cm as significant, as described by Burstal et al.[11]

In addition, these authors found that more tunnelled catheters (62%) remained within 0.5 cm of their original position compared to conventional dressing with Opsite dressing alone (38%). Similar observations have been found in the present study. The incidence of catheter migration in other studies[10,12] where the epidural catheter were fixed by conventional methods was found to range between 36 and 56%. Therefore, it appears that subcutaneous tunneling is beneficial in reducing clinically significant movement of epidural catheters inserted for postoperative analgesia[13].The tunneling and looping technique showed more decrease in the incidence of dislodgement as compared to the simple looping and taping fixation (p=0.04). While the suturing and tunneling with looping technique showed no dislodgement.There were no instances of subarachnoid catheter migration in the present study ,as might be expected for an event with a prevalence of 0.1%-0.2%[14,15].

We also observed that epidural catheters fixed as described, were more likely to move outwards than inwards. Similar observations have been made in previous studies by **Bishton et al**[10] and **Burstal et al**[11].In the present study, inward migration was seen only in three cases which were fixed by the conventional technique, which shows that tunneling techniques have a very significant impact on reduction of inward migration of the EC.

Summary And Conclusion

Managing very severe pain is important and not always easy. Epidural analgesia has been associated with physiological benefits that may attenuate the detrimental perioperative effects of surgery and lead to improvement in patient outcome apart from providing pain relief it also helps in attenuation of stress response.

Epidural catheter dislodgement has been noted as one of the important causes responsible for early termination of regional analgesia.

This study was conducted to evaluate and compare three different methods of Epidural catheter fixation for catheter dislodgement and quality of postoperative analgesia in various abdominal surgeries.

Tunneling with suturing (method C) and tunneling with looping (method B) reduced average extent and incidence of clinically relevant Epidural catheter dislodgement in Epidurals (more than the conventional method A). Method C showed better results than method B. However tunneling techniques were associated with mild signs of inflammation in two cases in each group. Patient satisfaction score was statistically insignificant between the groups.

Thus, the Tunneling with suturing and looping proved to be the most effective method of securing epidural catheters, as per the finding of this study. The Tunneling techniques proved to be better than looping and taping where maximum dislodgement was seen. Hence, we suggest that epidural catheters should be fixed using tunneling techniques to minimize their rate of dislodgement .

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