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ORIGINAL RESEARCH

A Prospective, Randomized Study comparing the Efficacy and Safety of Adhesive Strip (Steri-Strips™) Fixation *vs* Subcutaneous Tunneling for securing Epidural Catheters in Pediatric Patients

[1]Ketan S Kulkarni, [2]Nandini M Dave, [3]Shriyam S Kulkarni, [4]Gita Nataraj, [5]Shivani Shinde
[6]Indrani Chincholi, [7]Madhu Garasia

ABSTRACT

Introduction: Effective epidural catheter fixation is a key aspect of postoperative pain management in pediatric patients. We conducted a prospective, randomized study comparing the efficacy and safety of adhesive strip (Steri-Strips™) *vs* subcutaneous tunneling for successful epidural catheter fixation.

Materials and methods: American Society of Anesthesiologists (ASA) grades I and II patients between the age group of 1 day and 12 years were included in the study. The parameters studied were inward and outward migration, and dislodgment of catheter. Erythema, induration, catheter snapping, catheter obstruction, total duration of epidural infusion, and catheter tip culture were also recorded. Feedback from the operator for ease of fixation technique was noted and reviewed.

Results: This study was performed in 64 patients posted for various abdominal, thoracic, and genital surgeries, requiring postoperative epidural analgesia. The epidural catheter was successfully placed in the first attempt in 61 patients. Outward migration was seen in six patients with Steri-Strips-taped catheters and in one patient with a tunneled catheter. Accidental removal was done in five patients with tunneled catheters and one patient with strip-taped catheter. Rescue analgesics were required in these patients. No inward migration of catheter was seen in both the groups. Bleeding from tunneling site was seen in five patients.

Conclusion: In comparison with a tunneling technique for epidural catheter fixation, a simple method of applying Steri-Strips™ to epidural catheters significantly reduces the incidence of accidental removal.

Keywords: Epidural catheter fixation, Pediatric patients, Steri-Strip, Subcutaneous tunneling.

[1]Senior Registrar, [2]Additional Professor, [3]Ex-Clinical Associate [4]Professor, [5]Assistant Professor, [6]Professor and Head, [7]Professor and Ex-Head

[1,2]Department of Anesthesia, Seth Gordhandas Sunderdas Medical College, Mumbai, Maharashtra, India

[3]Sir H. N. Reliance foundation Hospital, Girgaon, Mumbai Maharashtra, India

[4-7]Department of Microbiology, Seth Gordhandas Sunderdas Medical College, Mumbai, Maharashtra, India

Corresponding Author: Ketan S Kulkarni, Senior Registrar Department of Anesthesia, Seth Gordhandas Sunderdas Medical College, Mumbai, Maharashtra, India, Phone: +919890450064 e-mail: ketan29.5@gmail.com

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INTRODUCTION

Displacement of epidural catheters and subsequent inadequate analgesia is a significant problem in patients undergoing any major abdominal and thoracic surgery, even in adults. Children invariably have the habit of changing postures and thus they are more prone for catheter displacement. Moreover, physiotherapy, diagnostic scanning, and many other interventions increase the chances of epidural catheter dislodgement in the immediate postoperative period. Dislodgement of catheter jeopardizes postoperative pain relief. Catheter fixation is thus an important aspect of postoperative pain management. To prevent epidural catheter migration/dislodgement, secure fixation is essential. Several fixation methods (a strip of adhesive foam transfixed with a suture,[1] Niko Epi-Fix device, Tegaderm dressing alone or with additional filter shoulder fixation,[2] Lockit device,[3] and subcutaneous tunneling of catheter[4]) have been studied for their efficacy and safety. But all these studies have been conducted in adults. Epidural fixation devices available in the market are made up of polyvinyl chloride and quite bulky for a child, which can be uncomfortable and may cause injury. Evidence is lacking regarding the optimum method for epidural catheter fixation in pediatric patients. We conducted a prospective, randomized study comparing the efficacy and safety of adhesive strip, Steri-Strips™ (3M, St. Paul, Minnesota) fixation *vs* subcutaneous tunneling of the epidural catheter for securing lumbar and thoracic epidural catheters in pediatric patients undergoing thoracic and abdominal surgeries.

MATERIALS AND METHODS

Approval from the institutional ethics committee for this study was obtained. Patients between the age group of 1 day and 12 years and belonging to ASA grades I and II were included in the study from January 2016 to August 2017. Written informed consent was obtained from either parents or legal guardian. Patients with significant spinal deformities, preexisting neurological disabilities, and on anticoagulation medications were excluded.

Patients included in the study were randomized by sealed envelope method to allocate to one of the two study groups. Cards with group S or T written were kept in the sealed envelopes, and randomly one card was chosen for each patient.

Depending upon the surgery, epidural catheter placement either in thoracic or in lumbar region using midline or paramedian approach was performed under general anesthesia in lateral position. Loss of resistance to air or saline was used to identify the epidural space depending on operator's preference. Appropriate position of epidural catheter was determined by "meniscus sign" and by giving test dose. A 3 cm length of the epidural catheter was placed in the epidural space and fixed by either of the techniques mentioned.

Group S had the epidural catheter fixed by using Steri-Strips™. A small loop of catheter was left between the epidural puncture site and adhesive strips. Group T had the epidural catheter subcutaneously tunneled. The Tuohy epidural needle was used to create the tunnel 2 to 3 cm long in subcutaneous plane, moving in from cranial to caudal direction approximately 1 cm lateral to the midline, with its lower end at the same horizontal level as the epidural puncture site. A small loop of catheter was left between the epidural puncture site and the tunnel entry.

A small loop was placed in both the groups to reduce drag on the catheter. Following this, in both groups the catheter was covered with a transparent dressing, Tegaderm® (3M, St. Paul, Minnesota), and was pulled up to the right shoulder. The entire length was covered by dressing, Micropore® (3M, St. Paul, Minnesota). Feedback from the operator for ease of fixation technique on a scale of 1 to 5 was obtained after fixation of the catheter (1: Extremely easy; 2: easy; 3: okay; 4: difficult; 5: extremely difficult).

All catheters were flushed with 0.75 mL of saline to rule out catheter kink postfixation. Immediately after surgical procedure, patient was placed in lateral position again and epidural dressing was checked and changed if required. Also the mark of fixation at skin and migration if any was noted. Patient was extubated thereafter. Finally before shifting the patient out of the operating room, epidural catheter was checked to rule out obstruction if any. For postoperative pain relief a bolus of injection bupivacaine 0.125% 0.75 mL/kg was given. Either continuous infusion [injection bupivacaine (0.0625%) 0.25 mg/kg/hr] or intermittent boluses [injection bupivacaine (0.0625%) 0.2 mL/kg] was used depending upon the choice of concerned anesthesia consultant. Catheter was kept *in situ* as long as it was required for postoperative pain relief.

Patients were assessed daily for postoperative pain relief. At which time, till the day of catheter removal erythema, induration, induration, inward and outward migration of the catheter were noted. The duration for which catheter was *in situ*, catheter snapping, dislodgment, and obstruction of catheter was also recorded.

Migration of more than 1 cm was considered as significant enough to report. If the entire length of the catheter had become displaced so that the tip was visible at the skin, the catheter was classified as dislodged. Pain scores were noted every 6 hourly. An age-appropriate scale was used to assess pain relief and Injection Paracetamol 15 mg/kg every 8 hourly was used as a part of multimodal analgesia regimen as standard of care. Injection morphine 0.2 mg intravenously was used as rescue analgesic. Once catheter was removed, its distal 5 cm portion was cut with sterile scissors and transported in a sterile tube for immediate culture. In the lab, using a sterile forceps, the catheter was removed from the tube and was placed on a 5% sheep blood agar plate. The tip was rolled, back and forth, on the entire surface of the agar, pressing firmly on the agar surface without breaking the medium. Incubation of the plates was done at 35°C in CO_2 incubator. Readings from the plates were taken at 24 and 48 hours. If growth was detected, counting of isolated colonies was done. A count of >15 colony-forming units (CFU) was considered as significant and actual number was also recorded. A count of <15 CFU was considered significant in case of *Staphylococcus aureus, Streptococcus pyogenes,* Enterobacteriaceae, and *Pseudomonas aeruginosa*. Antimicrobial sensitivity testing was done for all significant isolates.

These evaluations were performed by an independent observer. The technique of fixation was not revealed to the coinvestigator involved in the statistical analysis of the data.

Data were expressed as mean with standard deviation for continuous variables. Categorical variables were expressed as numbers. The statistical analysis was performed using Statistical Package for the Social Sciences (SPSS Inc., Illinois, Chicago, version 17.0). Independent samples t-test was applied to continuous variables. The categorical variables, such as gender, Likert score, bleeding, and outward migration were analyzed by chi-square test; $p < 0.05$ was considered as statistically significant.

To represent monthly patient population of 70 (2–3 per day) when confidence level was set at 95% and confidence interval at 5%, the sample size was calculated to be 59 patients, so we included 60 patients (30 in each group) (www.surveysystem.com).

RESULTS

This study was performed in 64 patients posted for various abdominal, thoracic, and genital surgeries, requiring postoperative epidural analgesia. The epidural catheter was successfully placed in the first attempt in 61 patients. Two patients from tunneling and one from Steri-Strips group required more than two attempts and hence were excluded from the final analysis.

The two groups were comparable with respect to age, gender, catheter *in situ* days, thoracic, abdominal, and genital surgeries (Table 1).

The surgeries performed were decortication procedures, laparotomies, genitoplasty, hepatoportojejunostomy, ureteric reimplantation, pyeloplasty, splenectomy, and choledocalcyst removal. None of our patients received low-molecular-weight heparin prophylaxis preoperatively or postoperatively.

Table 2 represents the comparative statistics of Likert score for operator comfort in performing epidural fixation.

Table 1: The demographics of the patients enrolled for the study

Parameters	*S group (mean ± SD)*	*T group (mean ± SD)*	*p-value*
Age (months)	52.27 ± 41.76	60.66 ± 48.95	0.23
Weight in kg	13.63 ± 7.43	15.27 ± 9.22	0.22
Gender (male/female)	19/11	14/16	0.19
Site (thoracic/lumbar)	(20/10)	(22/8)	0.57
Duration (in days)	4.2 ± 1.03	4.33 ± 1.73	0.26
Infusion/boluses	27/3	27/3	1

SD: Standard deviation

Migration and accidental removal of catheter incidence is listed in Table 3. Bleeding from the site of tunneling was seen on postoperative day 1 in five patients in tunneling group. Epidural dressing was changed in all of these patients. There was no bleeding episode postoperative day 2 and onward. Complications are listed in Table 4. Out of the six accidentally removed catheter patients, one patient received patient-controlled analgesia and rest of them received nurse-controlled analgesia. Apart from these six patients, none of the other patients required rescue analgesic, even the patients with outwardly migrated catheter.

DISCUSSION

An effective epidural analgesia requires secure catheter fixation technique(s) and vigilant intra- and postoperative care of the catheter insertion site. Accidental dislodgement or migration of epidural catheter results in inadequate analgesia. With an increased requirement of intravenous analgesics, delayed recovery, and prolonged hospital stay, the technique of catheter fixation should be robust, and preferably be uncomplicated and operator friendly.

The epidural catheter was kept 3 cm in the space as per our institutional policy and migration of more than 1 cm was reported as significant. Burstal et al[5] described outward movement of >2.5 cm and inward movement of >1 cm as significant. They concluded that the epidural catheters are more likely to move outward than inward. In their study, out of the 60 migrated catheters only 17 catheters migrated inside by more than 1 cm. Similar findings were also observed by Bishton et al.[6] Our study also showed similar results with no epidural catheter migrating inward.

In our study, the incidence of migration was more in the Steri-Strips group as compared with the tunneling group. Similar findings were observed by Burstal et al[5]

Table 2: Operator's comfort for epidural fixation technique—Likert's score

	1: Extremely easy	*2: Easy*	*3: OK*	*4: Difficult*	*5: Extremely difficult*	*p-value*
S group	30	0	0	0	0	–
T group	16	4	6	2	2	

Table 3: Incidence of migration and accidental removal of epidural catheter

Parameters	*S group*	*T group*	*p-value*
Inward migration	0	0	
Outward migration	6	1	0.02 (two-tailed mid-p exact test)
Accidental removal	1	5	0.054 (two-tailed mid-p exact test)

Table 4: Incidence of complications

Parameters	*S group*	*T group*	
Bleeding from the site of tunneling	0	5	$p < 0.05$ (two-tailed mid-p exact test)
Catheter snapping	0	0	
Catheter obstruction	0	0	
Erythema	0	0	
Catheter tip culture positive	0	0	
Rescue analgesic	1	5	0.054 (two-tailed mid-p exact test)

and they concluded that tunneling when compared with Steri-Strips decreases the incidence of migration but does not abolish it. In our study, even though the migration was more than 1 cm it was less than 2 cm in either of the groups. Thus, the catheter migration did not affect the quality of analgesia in either of the groups. We believe that the catheter length was adequately in the epidural space despite migrating >1 cm. No requirement of rescue analgesia in any of these patients validated this opinion. Bishton et al[6] observed a 100% correlation between catheter migration (≥25 mm) and failed epidural block.

Low incidence of inward migration of catheters reported by Bougher et al,[4] Mourisse et al,[7] and Burstal et al[5] could possibly be due to higher volume of epidural drug infusion and/or boluses. We did not observe any inward catheter migration in our study. We believe that low-dose requirement of pediatric patients and less frequent dosing (8 hourly) might have contributed to this.

Accidental removal of catheter occurred in six patients in our study. The incidence was higher in the tunneled group. All of these patients in tunneled group had bleeding, the entire length of the catheter had become displaced, and the tip was visible at the skin with bleeding under the transparent dressing at the time of postoperative visit on day 1. A catheter in Steri-Strips group came out during application of abdominal binder. Rescue analgesics were administered to these patients guided by age-appropriate pain scale.

Tripathi and Pandey[8] found a dislocation rate of 3% in tunneled catheters compared with 21% in control group. In control group, catheter was nearly covered with transparent dressing without any addition fixation technique. Bougher et al[4] reported one catheter dislodgement from the epidural space in the nontunneled group where a transparent adhesive spray was used to fix the catheter before covering it with a transparent dressing. The definitions of catheter migration and catheter removal merge and are not differentiated clearly in the relevant studies.

Sharma et al[9] reported tunneled site bleeding in nine patients who were on preoperative low-molecular-weight heparin for deep vein thrombosis prophylaxis. Bleeding from the tunneling site was observed in five patients in our study. Delicate and higher vascularity of tissues in pediatric patients and the technique for creating tunnels with 2 to 3 cm dissection by needle could have led to tissue trauma and bleeding.

The study by Sharma et al[9] showed that the patients were less comfortable and less receptive toward tunneling procedure. A Likert's scoring was done by them to assess patient satisfaction which showed many dislikes for tunneling. Our study did not reveal such patient experience as all the patients were induced under general anesthesia while the catheter insertion was done. Instead, we recorded the operator satisfaction with the technique of catheter fixation. The level of ease was more in the group where epidural fixation was done using Steri-Strips as compared with the tunneling group.

Limited data on catheter breakage are available in pediatric patients. Lenox et al[10] reported a case of caudal catheter sequestration in a 23-month-old child and recommended that the broken fragment should be surgically removed in children, considering that it has the potential to cause neurological damage secondary to infection, fibrosis, migration, or direct mechanical neural irritation. A total of 15 studies reporting 30 cases of breakage of epidural catheters were reviewed by Hobaika[11] who recommended the length of catheter that should be placed in the epidural space and the indications of surgical retrieval in the event of catheter breakage. We did not encounter any case of catheter breakage fortunately. Our practice of daily postoperative checking and dressing change at catheter site whenever needed averted any event of catheter fracture.

Catheter obstruction has been reported in three patients due to improper fixation and kinking of catheter.[9] Our study did not report any case of catheter obstruction. Regular monitoring of catheter site in the postoperative period was done to rule out any kinking in the catheters. Catheter flushing with 0.75 mL of saline in immediate postoperative period and each time before administrating a drug bolus during postoperative visits aided in maintaining catheter patency.

Tripathi and Pandey[8] reported a high incidence (29%) of local inflammation at the site of tunneling. Sellmann et al[12] reported that three patients had signs of local infection (2.5%). In their study, a total of 22 catheters were found to be colonized by pathogens out of which 14 catheters were taped and 8 were tunneled. Bubeck et al[13] reported a reduced colonization caudal catheters in children if tunneled. No evidence of erythema or bacterial contamination of catheter tip was encountered in our study. We believe that following standard aseptic and antiseptic precautions while performing the procedure and guarded handling of catheter were the key factors.

There are some limitations to our study. Anesthetic operators recording catheter migration were not blinded for catheter fixation technique as it was impossible to hide the Steri-Strips application or tunneling of catheter and expose the marking of the catheter at skin to note the catheter migration. Also we did not compare other commercially available devices and suturing technique for fixation of the catheter. We did not include these commercially available products as they are not available in pediatric sizes and catheter removal could have become

more difficult after suturing especially in uncooperative pediatric patients.

CONCLUSION

In comparison with a tunneling technique for epidural catheter fixation, a simple method of applying Steri-Strips™ to epidural catheters significantly reduces the incidence of accidental removal. Though outward migration is significantly more in catheters fixed with Steri-Strips™, it does not reflect into inadequate analgesia when compared with tunneling technique. Tunneling as well as Steri-Strips™ application technique for epidural fixation does not cause inward migration of the catheters in pediatric patients. An operator-friendly technique with no additional needle pricks, lesser incidence of dressing soakage, and accidental removal of catheter is more appropriate. Application of Steri-Strips™ was found to be more efficacious than subcutaneous tunneling for epidural catheter fixation in our study.

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