Original Article

Improving Epidural Catheter Fixation using Benzoin Tincture with Transparent Film Dressing for Postoperative Pain Control: A Randomized Controlled Trial

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Objective: To evaluate the incidences of the peeling-off of transparent dressings and the migration of epidural catheters after the application of benzoin tincture.

Materials and Methods: This double-blinded, randomized controlled trial was performed on 552 patients receiving continuous epidural analgesia after abdominal and thoracic surgeries at Siriraj Hospital. Patients were equally allocated into 2 groups. In "Group B", patients were painted before the placement of dressings with benzoin tincture on the skin and the epidural catheters; the tincture was provided in ready-to-use packs produced by the Division of Pharmacy, Siriraj Hospital. In "Group T", patients were not painted. Photos were taken upon completion of the dressings, at the finish of operations, and once daily until the dressings were removed. The dressings were assessed by two independent researchers who did not know the patient groups.

Results: A total of 523 patients were analyzed. The incidences of the whole sheet peeling off, and the consequential need for redressing as the catheters were no longer secured, were 71 (27.8%) in Group T and 47 (17.5%) in Group B ($p = 0.005$). This gave the number needed to benefit of 9.7, 95% confidence interval [CI] 5.75 to 31.92; absolute risk reduction 0.10, 95% CI 0.03 to 0.17; relative risk 0.55, 95% CI 0.39 to 0.77; and relative risk reduction 0.4505, 95% CI 0.22-0.6. The overall migration of the catheters was significantly less in the benzoin tincture group.

Conclusions: Applying benzoin tincture on the skin and epidural catheters before placing transparent film dressings significantly reduced the incidences of dressing peeling off and migration of the epidural catheter on the second postoperative day.

Keywords: Benzoin tincture, Transparent film dressing, Epidural catheter, Epidural catheter migration, Continuous epidural analgesia, Postoperative analgesia

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Continuous epidural analgesia [CEA] using epidural catheters is an effective method of providing postoperative analgesia for abdominal surgery[1,2]. Inadequate analgesia after CEA leads to patient suffering and increased postoperative complications[3]. The enhanced recovery after surgery [ERAS] protocol with adequate analgesia has proven beneficial for patients after surgery[4]. Multimodal analgesia and early ambulation are the gold standard in the ERAS protocol with the use of CEA.

Catheter dislodgement or secondary migration of an epidural catheter after correct placement are the leading causes of failed and premature termination of CEA[5]. The method of catheter fixation plays a very important role in preventing these problems. Attempts to minimize the migration or dislodgement of epidural catheters in early mobilized patients have been reported; they include the tunneling and suturing of catheters,

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and the use of special fixation devices[6-9]. Tunneling led to a significantly decreased inward catheter migration in the study done by Bougher et al[6]. Burstal et al[7] found that subcutaneous tunneling prevented clinically significant inward and outward movement of epidural catheters. Tunneling is not a standard practice at Siriraj Hospital because of the risk of catheter transection and kinking of the catheter under the tunnel. Suturing of the epidural catheter has similarly been associated with less migration, but at the cost of increased inflammation at the puncture site and difficulties at removal time[10]. The fixation devices for epidural catheter are now commercially released as products like LockIt Plus (Smiths Medical International Limited, Ashford, UK), StatLock (C.R. Bard, Inc., Covington, GA, USA) and Epi–Fix (ConvaTec Limited, Deeside, UK). Some of those devices significantly reduce both migration and the incidence of analgesic failure; however, they may cause catheter kinking, which leads to complete occlusion and hence the need for reinsertion of the catheter.

Tegaderm (3M Healthcare, St. Paul, MN, USA) is a transparent film dressing with ease of application and ready availability. The transparency of this dressing makes possible observations of the position of the catheter as well as inspections for infection at the insertion site. The incidence of migration of the catheter after applying the transparent film dressing is 28%[11].

Benzoin tincture solution is commonly used as a topical adhesive agent to prevent the peeling-off of the adhesive dressing. The antimicrobial properties of benzoin tincture make it suitable for application close to the epidural puncture site. The overall aim of this study was to identify whether benzoin tincture, when applied correctly, is associated with reductions in the peeling-off of the transparent film dressing and in epidural catheter migration at different epidural insertion sites for postoperative analgesia.

Materials and Methods

After approval by the Siriraj Institutional Review Board, Faculty of Medicine Siriraj Hospital (Si. 373/2014) and the obtaining of written informed consents from subjects, this prospective, double-blinded, randomized controlled trial was conducted at Siriraj Hospital, Bangkok, Thailand.

The inclusion criteria were patients aged >18 years old undergoing elective upper or lower abdominal or thoracic surgeries, with plans for postoperative CEA. Patients with a history of allergy to cosmetics, benzoin tincture and transparent adhesive dressings were excluded.

Participants were randomly allocated into two groups; Group T received Tegaderm dressings, while Group B received a benzoin tincture application before the Tegaderm dressings. The device allocations were made according to instructions placed in identical, opaque, sealed envelopes. The envelopes were prepared in a 1: 1 ratio of potential group allocations before random assortment and block randomization. No more than one envelope was permitted to be selected per patient, and the operator used the device specified in the envelope. After the device assignments, the operators were not amenable to blinding, but no disclosures were made to the assessors regarding the group allocations.

The benzoin tincture pads used in the present study were prepared by the Division of Pharmacy, Siriraj Hospital. We tested the preparation for ease of use and for adequacy of application to the area covered by the transparent film dressing and along the catheter track to the shoulder. After trying to soak a swab stick, a piece of cotton, and pads of gauze of different sizes, we found that 2x2 in^2 gauze containing 1.5 mL of benzoin tincture in the sealed laminated aluminum sterile package was best for the purpose.

Before the study commenced, the research team instructed the consultant anesthesiologists involved in the study in the correct method of applying the benzoin tincture and the transparent film dressings. Either the consultant anesthesiologist or a trainee in the assigned operating room of the enrolled case was responsible for the epidural catheter insertion. In the event that the catheter was inserted by a trainee, the consultant anesthesiologist would apply the study materials in the manner that had been taught. The epidural catheter was inserted using the loss of resistance to air technique and standard equipment, with the patient in a lateral position. Upon location of the epidural space, the catheter was inserted, leaving 4 cm within the space. According to the group allocation, one of the following two kinds of dressing was then applied to the skin. Group T had the epidural catheter secured using 12x10 cm^2 Tegaderm adhered over the J loop of the catheter formed at the puncture site, and then a 5-cm width of Fixomull adhesive tape (BSN Medical, Luxembourg City, Luxembourg) was applied, starting from 2 cm below the upper edge of the Tegaderm and along the rest of the catheter to the same side of the shoulder. With the use of the tincture pad, Group B had benzoin tincture applied to the skin close to the

puncture site, and on to the area that would be covered by the 12x10 cm^2 Tegaderm, as well as the epidural catheter under the dressing, and to the area just beyond the dressing to the small area above. Then, the Fixomull adhesive tape was applied to the shoulder in the same manner as for Group T. The patients were asked to straighten and relax their backs before the dressing applications. The analgesics administered via the epidural catheter were ordered by the acute pain service team.

Photographs of the transparent film dressings were taken at the following time points: when the dressing was complete (T0), the end of the operation (T1), and once daily (T2, T3, T4, …) until the epidural catheter was removed. If a dressing had to be removed due to the premature termination of the CEA as a failed block, or to reposition the catheter due to a unilateral block, the patient was withdrawn from the study.

Two authors, O.P. and V.S., who were blinded to the patients' groupings, reviewed the photos of each patient and graded the following: the length of the catheter at the skin (to the nearest 0.5 cm); the pattern and area of the peeling-off of the edge of the transparent film dressing (grades 1 to 4); the pattern and area of bleeding (grades 1 to 4); the pattern and area of oozing serum (grades 1 to 4); and the pattern and area of the air located under the transparent film dressing (grades 1 to 4). The grading criteria are shown in the appendices. The yellowish color of the benzoin tincture was difficult to see in the photos, making blinding to the assessors possible. All photos were reviewed by the two authors to ensure consistency in the gradings; whenever the gradings differed, a consensus was reached.

The criteria for the termination of the study protocol for each patient were the premature changing of the Tegaderm; the requirement for the application of additional adhesive tape due to a large area of peeling leaving the epidural catheter no longer secured; the displacement of an epidural catheter that caused the epidural analgesia to fail; and the appropriate time to remove the catheter (which was determined by the acute pain service team). The patients' characteristics, time, dislodgement of the catheter, distance migrated by the catheter, and reasons for changing the initial Tegaderm (namely, bleeding, the oozing of serum, locular air, and peeling-off of the edge) were recorded.

Statistical analysis

The sample size was calculated using data extracted from the acute pain service of Siriraj Hospital. The incidence of peeling-off of transparent film dressings was 20.6%. A calculation for a 50% reduction in the incidence of peeling-off, with a probability level of 0.05 and a power of 0.80, yielded a sample size of 251 patients for each of the two study groups. We enrolled 552 patients (*i.e.*, 10% extra) to allow for dropouts and failed blocks.

The Kolmogorov Smirnov test was used to verify the normal distribution of the continuous variables; those variables were expressed as mean $\pm$ standard deviation. Statistical analysis was done using SPSS Statistics for Windows, version 18.0 (SPSS Inc., Chicago, Ill., USA). The distributed continuous variables were compared using Student's unpaired t-test. Categorical variables were expressed as numbers and percentages, and comparisons between groups were made using the Chi-square or Fisher's exact test, as appropriate. All analyses were two-tailed, and $p<0.05$ was considered statistically significant. The intention-to-treat analysis was used to calculate number needed to benefit [NNB], absolute risk reduction [ARR], relative risk [RR] and relative risk reduction [RRR].

Results

A total of 552 patients were recruited, of whom 523 were subsequently included in the analyses during the period from August 2014 to January 2017 (Figure 1). There were no significant differences between the groups with respect to age, body weight, body mass index or the operative site (Table 1). The incidences of catheter dislodgement were 3.9% and 5.2% for Groups T and B, respectively. Seventy-one patients (27.8%) in Group T and 47 (17.5%) in Group B needed their dressings changed because of an epidural catheter that was no longer secured; the difference was statistically significant ($p = 0.005$). The number of patients who needed a dressing change and the reasons for those changes (which, in the case of some patients, was more than one) are at Table 2. The incidences of bleeding, oozing serum and air being located under the dressing, and the extent of the peeling-off of the dressings, all of which were great enough to make the epidural catheter no longer secured, were significantly lower for Group B than Group T. The incidences of inward and outward catheter migrations of >1 cm at the end of the operations were significantly different ($p = 0.024$) between the groups, with 30.1% and 21.4% for Groups T and B, respectively (Table 3).

The distributions of the percentage of epidural catheter migrations from the original position to the

end of the operation (T0-T1 time) and to second postoperative day (T0-T3 time) for the two groups were not significantly different (Figure 2 and 4). Group B had a significantly lower percentage of catheter migration on the first postoperative day (T0-T2 time), as shown in Figure 3 (p = 0.020). The proportion of transparent film dressings that were still in a good condition at the appropriate time for the epidural catheter removal was significantly higher in Group B than in Group T (72% and 58.4%, respectively; p = 0.001).

The number of patients who had no catheter displacement by the end of the operation was significantly higher in Group B than in Group T (Table 3). There were no complications; no incidents of subarachnoid or intravenous catheter insertions; and no reports of patient discomfort, redness of the skin or itching related to the dressing used in either of the groups.

An intention-to-treat analysis was performed. It can be extrapolated that the application of benzoin tincture before applying the dressing with the transparent film in 10 patients would result in one incident less of peeling-off of the dressing than would be expected in the absence of benzoin tincture (NNB = 9.7 [5.75, 31.92], with an ARR of 10.30% [0.03, 0.17], and an RR of 0.55 [0.39, 0.77]). The application of benzoin tincture could prevent the peeling-off of the dressing for 45% of the patients (RRR 45.05% [0.22, 0.61]).

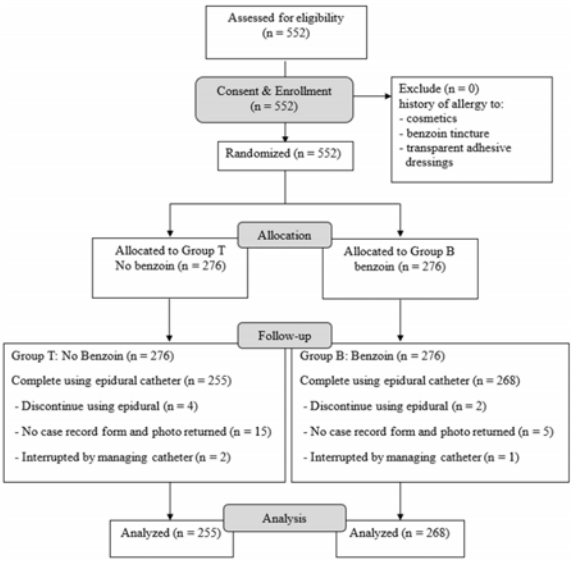

Figure 1. CONSORT Flow diagram.

Discussion

The ERAS pathways reduce the delay until full recovery after major abdominal surgery by attenuating the surgical stress and maintaining postoperative physiological functions. The implementation of the ERAS pathways has been shown to impact positively in reducing the rate of postoperative morbidity, and in turn, the length of stay in hospital and the related costs[12]. Compared with parenteral opioids, an epidural blockade has been shown to provide better a postoperative static and dynamic analgesia for the first 72 h[13]. An epidural catheter dislodgement is the most hazardous problem encountered by a pain management team as this event has a lasting impact on a patient's pain optimization

Table 1. Demographic data

Characteristics	Group T	Group B	p-value
Age (year)	60.4±13.2	58.3±14.0	0.450
ASA physical status-I: II: III	21:178:53 (8.3:70.6:21.0)	40:168:59 (15: 62.9: 22.1)	0.264
Ward-general: private	114:139 (45.1:54.9)	113:152 (42.6:57.4)	0.579
Body weight (kg)	58.9±12.3	59.7±12.8	0.461
Height (cm)	158.3±8.6	158.6±7.5	0.684
Body mass index (kg/m^2)	23.6±4.7	23.9±4.8	0.461
Operation site			0.477
Upper abdomen	90 (35.7)	104 (39.7)	
Lower abdomen	83 (32.9)	83 (31.7)	
Upper and lower abdomen	56 (22.2)	46 (17.6)	
Chest	23 (9.1)	29 (11.1)	

The data are presented as mean ± standard deviation or n (%, proportion)

Table 2. Reasons for changing the Tegaderm dressings

	Group T	Group B	*p*-value
Bleeding at the catheter site	16 (6.3)	5 (1.9)	0.010*
Oozing under the dressing	7 (2.7)	7 (2.6)	0.925
Air under the dressing	25 (9.8)	14 (5.2)	0.046*
Peeling at the edge of the dressing	41 (16.1)	24 (9.0)	0.014*
Epidural catheter migrated out through the skin	10 (3.9)	14 (5.2)	0.477

The data are presented as n (%, proportion)
* $p<0.05$ indicates statistical significance

Table 3. Number of cases with no catheter displacement

	Group T	Group B	*p*-value
At the end of the operation	174 (69.9)	206 (78.6)	0.024*
At 1st operative day	83 (37.1)	109 (43.8)	0.137
At 2nd postoperative day	61 (34.7)	78 (38.6)	0.426

The data are presented as n (%, proportion)
* $p<0.05$ indicates statistical significance

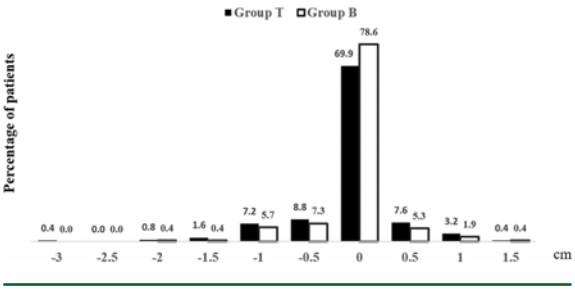

Figure 2. Percentage of patients with catheter migration during the period from T0 to T1 Minus numbers are the inward movement in cm, and plus numbers are the outward movement in cm (to the nearest of 0.5 cm; $p = 0.300$).

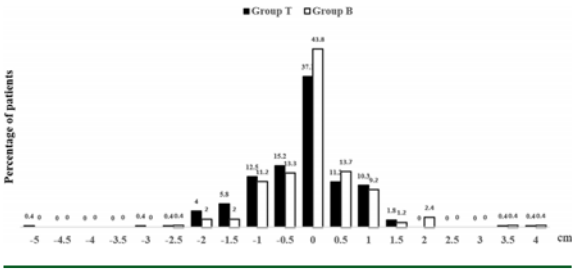

Figure 3. Percentage of patients with catheter displacement during the period from T0 (time that dressing was finished) to T2 (the first postoperative day). Minus numbers are the inward movement in cm, and plus numbers are the outward movement in cm (to the nearest 0.5 cm; $p = 0.020$).

and overall recovery, and it may result in increased patient morbidity. The present study had catheter dislodgement rates of 3.9% (Group T) and 5.2% (Group B). These were lower than the rate (21%) found in another study, which also showed that tunneling can reduce the incidence of dislodging from 21% to 3%[14]. By comparison, the application of the benzoin tincture did not reduce the incidence of catheter dislodgement in the present study.

The lowest possible occurrence of epidural catheter migration is very important for effective postoperative CEA in patients who ambulate early. Migration of epidural catheters occurs as an inevitable consequence of patient factors: movement and activity while the catheter is in situ. To prevent the migration of catheters in patients who mobilize early, the tunneling and suturing of catheters, and the use of special fixation devices, have been investigated[10,11]. The application of benzoin tincture in the present study did not significantly reduce the overall inward or outward migration of the catheter on the first postoperative day, but migration on the second postoperative day (T0–T3 time) was significantly less than in the control group. The proportion of transparent film dressings

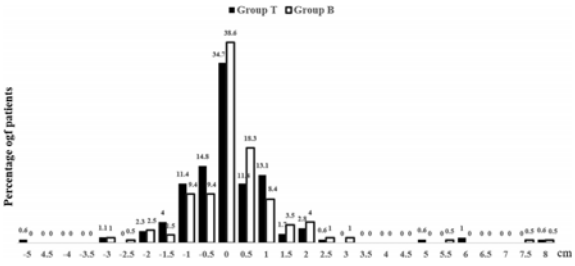

Figure 4. Percentage of patients with catheter displacement during the period from T0 (time finish the dressing) to T3 (second postoperative day). Minus numbers are the inward movement in cm, and plus numbers are the outward movement in cm (to the nearest 0.5 cm; p = 0.087).

that were still in good condition at the appropriate time for epidural catheter removal was significantly higher in the benzoin tincture group than in the group using the transparent film dressing alone (72% vs. 58.4%, respectively; $p = 0.001$).

The presence of perspiration, the leakage of blood, or the oozing of serum around a catheter insertion site can cause a transparent film dressing to lose adherence between the skin and the catheter. In the present study, the incidences of bleeding, oozing serum and locular air under the dressing, and the peeling-off of the edge of the dressing which would make the catheter no longer secured, were significantly lower in the benzoin tincture group.

After reviewing nearly 2,000 photos of every patient in this study, two authors (V.S. and O.P.) concluded that there are two mechanisms for air to become loculated under a transparent film dressing. Firstly, any blood or oozing serum present during the application of the transparent film dressing was prone to leak out via the catheter track, leaving space for the loculation of air under the dressing. Secondly, pockets of air may become caught under the transparent film dressing as a result of incorrect operator technique during the dressing's application.

The incidence of catheter migration in other studies[6,14] where the epidural catheter had been fixed by transparent film dressing was found to range between 36% and 56%. The definition for catheter migration differs between studies[15]. In the present study, we accepted a migration of <1 cm. This is because migration is an inevitable event among ambulating patients, and any movements of <1 cm would not lead to failed analgesia because we had left 4 cm of the catheter within the epidural space in every patient. We defined a significant catheter migration as being an inward or outward movement of >1 cm. The application of benzoin tincture in the present study reduced the incidence of migrations after the operations from 30.1% to 21.4%.

Bougher et al[6] conducted a prospective randomized study to determine the effect of tunneling on catheter migration in 82 patients receiving postoperative epidural analgesia. Those authors demonstrated a greater than 20% reduction in the incidence of inward catheter migration, and more tunneled catheters (62%) remained within 0.5 cm of their original position than the conventional dressings that used Opsite dressings (Smith & Nephew, London, UK) alone (38%). However, tunneling increases the risk of needle stick injuries to the operator and can cause local inflammation of the skin[14]. In comparison, no patient in the present study had redness of the skin or itching related to the dressings used in either group.

In the present study, it can be extrapolated that applying benzoin tincture before the application of transparent film dressings in 10 patients would result in 1 incident less of peeling-off of the dressing that would otherwise be expected in the absence of benzoin tincture (The intention-to-treat analysis had an NNB of 9.7 and an ARR of 10.3%). The application of benzoin tincture could prevent the peeling-off of the catheter for 45% of the patients.

Limitations

The present study had several limitations. One is that a confounding factor, namely, the movements of patients after the operation, was not monitored. Patient-position changes cause transparent dressings to lose adherence between the skin and the catheters. The authors also could not show the effects of BMI on the migration of the catheters because very few patients in this study had a BMI of more than 35 kg/m^2. Neither ambient air or air-conditioned could be demonstrated as having an effect. Moreover, the quality of the photos was operator dependent. Even though we tried to solve this problem by having two assessors, some photos were blurred, so there was consequently a need to reach a consensus.

Conclusion

Applying benzoin tincture before a transparent film dressing did not reduce the incidence of catheter dislodgements, but did significantly reduce

the incidence of premature changes of the transparent film dressings from 27.8% to 17.5%. Applying benzoin tincture before the transparent film dressing in 10 patients would result in one incident less of peeling-off of the dressing that would otherwise be expected in the absence of benzoin tincture.

What is already known on this topic?

Migration of an epidural catheter after correct placement is one of the leading causes of failed and premature termination of CEA. To minimize the migration of catheters in early mobilized patients, the tunneling and suturing of catheters plus the use of special fixation devices have been investigated.

What this study adds?

Applying benzoin tincture can reduce the incidences of premature changing of the transparent film dressings and catheter migrations, especially on the first postoperative day.

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Trial registration

Thai Clinical Trial Registry as TCTR20140903005.

Potential conflicts of interest

The authors declare no conflict of interest.

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Appendix 1. Grading criteria for the transparent dressings

Grading criteria	Grading for all criteria
1) Peeling-off of the edge of transparent dressing	1 = none
2) Under the transparent dressing	2 = diameter <20 mm and 1 position only
Pattern and area of bleeding	3 = diameter either ≥20 mm, or <20 mm with >1 position
Pattern and area of oozed serum	4 = dislodgement of epidural catheter
Pattern and area of air	