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Developing a device model for a safe and effective method in catheter fixation: An experimental study

Kateter sabitlemesinde güvenli ve etkin bir yöntem için cihaz modeli geliştirilmesi: Deneysel bir çalışma

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ABSTRACT

Aim: Current permanent catheter fixation techniques may lead to epidural catheter dislodgement or extrusion, resulting in risks such as catheter migration, inadequate analgesia, and unintended spinal block. This study aimed to compare a newly developed fixation device with the conventional suture method used for epidural catheter fixation.

Materials and Methods: The Epilock® device, developed at Ege University Technopark CND ARGE, was manufactured using Polylactic Acid Thermoplastic Polymer (PLA+) material via a 3D printer. After obtaining ethical approval, 10 Sprague Dawley rats (5 males, 5 females) were anesthetized and randomly allocated into two groups. In the Control Group (n=5), epidural catheters were fixed 11 cm beneath the skin with silk sutures (20 knots). In the Experimental Group (n=5), catheters were secured using the Epilock® device. Fixation time was recorded, and the rats were monitored for catheter stability and infection for 7 days.

Results: In the Control Group (n=5), the mean catheter fixation time was 258 ±250 seconds, while in the Experimental Group (n=5) it was 175 ±150 seconds. The Epilock® device significantly reduced fixation time compared the Control Group (p=0.032). Catheters remained significantly longer in place in the Experimental Group on the first day (p=0.048), whereas no significant difference was found on the second day (p=1.000).

Conclusion: The Epilock® device provided a shorter procedure time and improved initial catheter retention compared with conventional suturing. These findings suggest it may enhance patient comfort, especially for those with positioning difficulties, and has the potential to be a valuable option in routine practice with further development and larger studies.

Keywords: epidural catheter, catheher fixation, catheter adverse effects

ÖZ

Amaç: *Günümüzde kullanılan kalıcı kateter sabitleme yöntemleri epidural kateterin yer değiştirmesine veya dışarı çıkmasına neden olabilmektedir. Bu durum, kateter göçü, yetersiz analjezi ve istenmeyen spinal blok gibi riskler taşır. Bu deneysel çalışmada, tarafımızca geliştirilen yeni bir sabitleme cihazı ile epidural kateter sabitlemesinde kullanılan geleneksel sütür yöntemi karşılaştırılmıştır.*

Gereç ve Yöntem: *Ege Üniversitesi Teknopark CND ARGE tarafından geliştirilen Epilock® cihazının prototipi, Polilaktik Asit Termoplastik Polimer (PLA+) kullanılarak üç boyutlu yazıcıda üretilmiştir.*

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Etik kurul onayı sonrasında, 10 Sprague Dawley sıçanı (5 dişi, 5 erkek) anestezi altında rastgele iki gruba ayrılmıştır. Kontrol grubunda (n=5) epidural kateterler, ipek sütürlerle (20 düğüm) derinin 11 cm altına sabitlenmiştir. Deney grubunda (n=5) ise kateterler Epilock® cihazı ile sabitlenmiştir. Kateter sabitleme süresi kaydedilmiş, kateter stabilitesi ve enfeksiyon açısından sıçanlar 7 gün boyunca izlenmiştir.

Bulgular: *Kontrol grubunda ortalama kateter sabitleme süresi 258 ± 250 saniye iken, deney grubunda 175 ± 150 saniye bulunmuştur. Epilock® cihazının kateter sabitleme süresini istatistiksel olarak anlamlı şekilde azalttığı gösterilmiştir (p=0,032). Kateter kalış süreleri karşılaştırıldığında, deney grubunda kateterler ilk günde anlamlı derecede daha uzun süre yerinde kalmıştır (p=0,048). Ancak ikinci günde anlamlı fark saptanmamıştır (p=1,000).*

Sonuç: *Epilock® cihazı, geleneksel sütür yöntemine kıyasla daha kısa işlem süresi ve daha iyi erken dönem kateter retansiyonu sağlamıştır. Bu bulgular, özellikle pozisyon vermede zorluk yaşayan hastalarda konforun artırılmasına katkı sağlayabilir. Güvenli ve pratik bir alternatif olarak öne çıkan cihazın, gerekli geliştirmeler ve geniş kapsamlı klinik çalışmalarla rutin kullanımda önemli bir seçenek olabileceği düşünülmektedir.*

Anahtar Sözcükler: *Epidural kateter, kateter tespiti, kateter komplikasyonu*

INTRODUCTION

Permanent catheterization through epidural and nerve block techniques is a widely used and effective method for postoperative pain management, labor analgesia, and chronic pain treatment. One of the main factors limiting its success is catheter displacement or complete dislodgement (1).

Even after successful placement of the catheter in the epidural space, causes of epidural analgesia failure include epidural catheter dislodgement. This leads to premature termination of analgesia and reduced treatment effectiveness. Catheter migration can also cause serious complications like hematoma, especially in patients receiving anticoagulant therapy (2,3). Furthermore, catheter mobility and loosening at the insertion site increase the risk of local infection (4,5).

The factors affecting the migration of epidural catheters 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. Catheter migration is mainly affected by the type of fixation method (6,7). Secure fixation of the catheters can result in fewer complications, better postoperative analgesia, and high patient satisfaction (8).

Current fixation methods include creating loops with standard dressings, transparent adhesive dressings, subcutaneous tunneling, and commercially available devices such as Epi-Fix™ (ConvaTec Limited, Deeside, UK), LockIt Plus® (Smiths Medical International Limited, Ashford, UK), and Tegaderm™ (3M Healthcare, St. Paul, MN, USA). Nevertheless, none of these fully meet the criteria for an ideal fixation method—reliability, non-invasiveness, low cost, patient comfort, and long-term stability (9).

In this paper, we aimed to compare the new fixation method (Epilock®), with the conventional suture method used for epidural catheter fixation.

MATERIALS and METHODS

This experimental study was conducted by CND R&D, operating within Ege University Technopark. Approval for the study was obtained from the Ege University Local Ethics Committee for Animal Experiments (Approval no: 2025-025 and Date:25.06.2025).

The Epilock® device was designed to address the disadvantages of current fixation methods. It contains an internal channel that allows the catheter to pass through without kinking and a rounded tip to protect the skin exit site. The device also includes a groove that enables fixation to the skin with a simple suture. Its flat structure conforms to the curvature of the back, enhancing patient comfort. The prototype was manufactured using Polylactic Acid Thermoplastic Polymer (PLA+) with a Bambu Lab X1-Carbon Combo 3D printer (Figure-1).

Ten Sprague Dawley rats (5 males, 5 females, 250–350 g) were included in the study. Anesthesia was induced with intramuscular ketamine (50 mg/kg) and xylazine (4 mg/kg). Subjects were randomized into two groups by a blinded anesthesiologist using a computer-generated sequence and sealed envelopes. The same

anesthesiologist performed all procedures: In the Control group (n=5), the epidural catheter was placed subcutaneously and fixed to the skin with simple silk suture (20 knots) so that it remained 11 cm under the skin (Figure-2).

In the Experimental group (n=5), the epidural catheter was placed subcutaneously and fixed to the skin with silk suture using the Epilock® epidural catheter fixator apparatus so that it remained 11 cm under the skin (Figure-3).

Catheter fixation time was recorded. Rats were monitored daily for 7 days for catheter/device stability and infection. In our study, catheters were not removed by the researchers. It was anticipated that they would spontaneously dislodge during follow-up.

Statistical Analysis

Experimental data were analyzed using IBM SPSS Statistics for macOS, version 30.0 (IBM Corp., Armonk, NY, USA). Descriptive values for categorical data were presented as frequency and percentage. Categorical variables were compared using Chi-Square or Fisher's Exact Test. A p-value <0.05 was considered statistically significant.

RESULTS

The mean catheter fixation time was 258 ± 250 seconds in the control group and 175 ± 150 seconds in the experimental group. Fixation time was significantly shorter with the Epilock® device (p=0.032).

Catheter status distribution is shown in Table-1 and Figure-4. All rats in the control group were observed to have their catheters removed within the first 24 hours. On the first day, one catheter was observed to have dislodged in the experimental group; on the second day, four catheters were observed to have dislodged; and on the third day, all catheters were observed to have dislodged. Catheter retention was significantly higher in the experimental group on day 1 (p=0.048), but no significant difference was observed on day 2 (p=1.000).

One device was removed together with the catheter on day 1, two devices were removed on day 3, and two devices remained in place for 7 days despite catheter removal. No local infection occurred in either group.

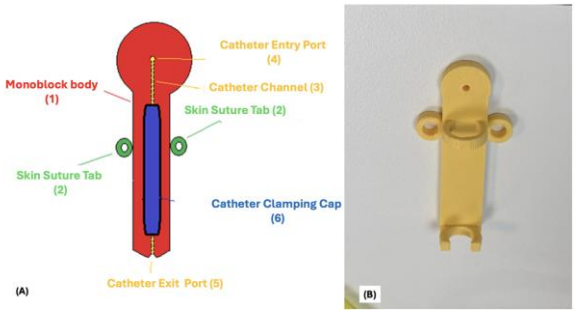

Figure -1.(A) Schematic Drawing of The Device (B) Epilock® device (via a 3D printer)

Figure-2. Control Group-Epidural Catheter Fixation

Figure-3. Study Group-Fixation Using the Epilock® Device

Table-1. Evaluation of Follow-up Times for Experimental and Control Groups

Catheter	Control (n=5) n (%)	Experimental (n=5) n (%)	p
1st day follow up			**0.048***
Catheter dislodged	**5 (100)**	**1 (20)**	
Catheter nondislodged	**0 (0)**	**4 (80)**	
2nd day follow up			1.000
Catheter dislodged	5 (100)	4 (80)	
Catheter nondislodged	0 (0)	1 (20)	
3rd day follow up			NA
Catheter dislodged	5 (100)	5 (100)	
Catheter nondislodged	0 (0)	0 (0)	

NA: not applicable, *p<0.05

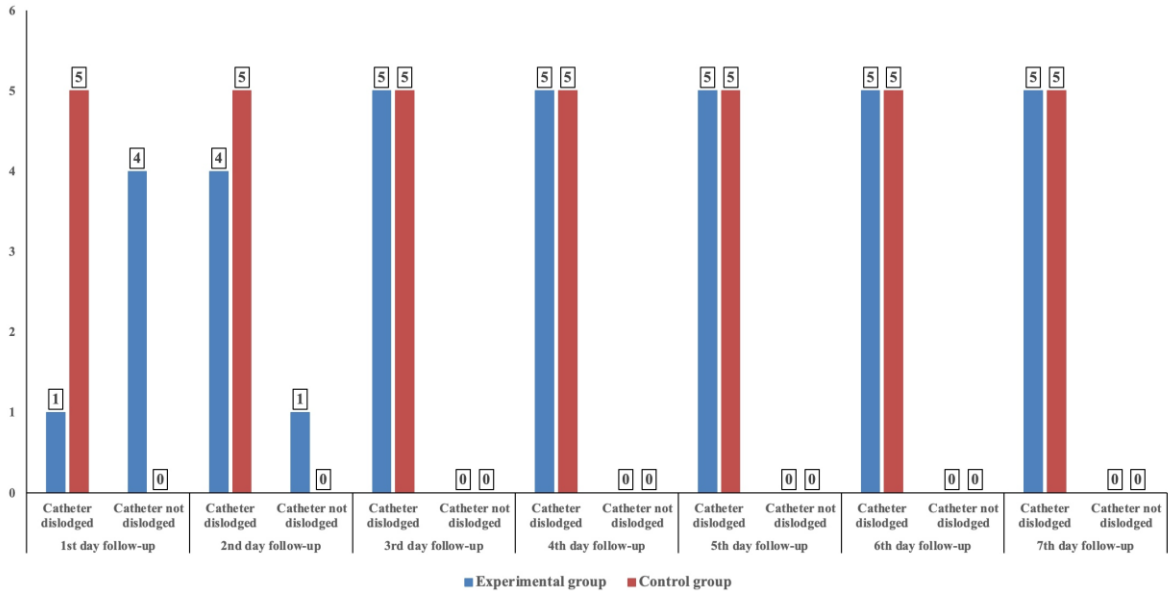

Figure-4. Comparison of groups according to the fixation status of catheters in daily follow-up

DISCUSSION

Epidural analgesia is widely used for postoperative pain management and provides high patient satisfaction (10). However, catheter migration, dislodgement, or complete removal is a significant problem that limits the success of analgesia. This complication can lead not only to a loss of pain control but also to serious adverse events, such as intravascular injection, subdural block, or spinal block (9). Therefore, secure fixation is essential for both safety and effectiveness.

In our study, 80% of catheters in the Experimental Group remained in place on the first day, compared with 0% in the Control Group. This finding suggests that the Epilock® device offers

superior mechanical stability compared with conventional suturing. Migration rates reported in the literature vary between 5% and 50% depending on patient population and fixation technique (7,8,11,12). While the reported incidence of catheter migration in literature ranges from 5% to 50%, the fact that 80% of catheters in the experimental group—fixed with the Epilock® device—remained in place on day one demonstrates that the device enhances mechanical stability and is more reliable than existing methods. This result is important not only for maintaining effective analgesia but also for improving patient comfort and clinical workflow by reducing the need for repeated catheter placements. Moreover, the statistically significant reduction in catheter fixation time highlights the practical applicability of the device, particularly in high-volume clinical settings.

Numerous fixation methods have been suggested in the literature to avoid these complications. Approximately 40 years ago, Duffy defined the problem of epidural migration and proposed adhesive dressings to reduce this problem (13). Today, transparent self-adhesive dressings are the most widely used method due to their simplicity and low cost. However, catheter migration can lead to inadequate analgesia, intrathecal or intravascular drug administration, neuropathic pain, or neurological complications (14). For this reason, several alternative fixation methods have been proposed.

The subcutaneous tunneling method is one of them. Various tunneling approaches (Pavy, Molnar, Murray) have been described, but each carries potential risks such as catheter transection, needlestick injury. Although tunneling can improve catheter stability, its clinical use is limited due to its invasive nature, additional procedure time, and potential infection risk (1,11). Similarly, clamping devices such as Lockit® have been found to be effective in providing stability, but their routine use has been limited due to reasons such as cost, difficulty of access, and skin irritation. Furthermore, some reports have indicated that the clamp may disrupt the integrity of the dressing, increasing the risk of infection (15). In a prospective randomized study comparing these methods, tunneling and the Locklt plus® methods were found to significantly reduce epidural migration in the first two postoperative days compared to transparent adhesive dressings. This study states that subcutaneous tunneling is as safe as the Locklt plus® fixation method in terms of migration (16).

In our study, catheters were not removed by the researchers. It was anticipated that they would spontaneously dislodge during follow-up. The catheters were observed to be dislodged in all rats in the control group by the end of the first day. In the experimental group, one rat's catheter was dislodged on the first day, and four rats' catheters were dislodged on the second day. By the third day, all rats' catheters were dislodged. While a statistically significant relationship between catheter statuses in the experimental and control groups was observed on the first day (p=0.048), no significant relationship was seen on the second day (p=1.000).

A meta-analysis of 11 studies evaluated the efficacy of the tunneling technique for epidural catheter fixation on catheter migration and infection, compared to conventional fixation techniques. It emphasized that the tunneling technique reduces inward migration compared to conventional methods but found no evidence that it reduces outward migration or infection risk. This suggests that the full benefits of catheter fixation methods are not yet completely understood, and that each method has its own specific advantages and disadvantages (4).

The absence of infection in our study is a noteworthy finding. This may be due to the biocompatibility of the PLA+ material used and aseptic working conditions. However, the literature reports that the rates of epidural catheter-related infections vary between 0.8% and 5.5% (2–4). Due to the small sample size (n=10) and the short follow-up period of our study, the generalizability of this finding is limited. Therefore, there is a need for longer-term studies with larger sample sizes.

This study has several limitations**.** The small number of animals reduces statistical power. The use of an animal model (rats) prevents direct extrapolation of results to human anatomy. In addition, catheter retention was evaluated only for 72 hours, which limits long-term conclusions. Technical issues specific to the animal model—such as gnawing of the device tips—are unlikely in human practice but suggest that the device's material strength should be further improved.

Future research should include biomechanical durability tests, evaluation of alternative materials, and studies in larger animal models. Before human clinical use, issues such as sterilization

methods, cost-effectiveness, and impact on patient comfort must also be investigated.

CONCLUSION

Epilock® significantly reduced catheter fixation time and improved short-term catheter retention compared with conventional suturing methods. As a safe, practical, and low-cost alternative, it shows promise for routine clinical use, pending further refinement and validation in larger experimental and clinical studies.

Conflicts of interest: The authors declared no conflict of interest.

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