Accidental Epidural Catheter Removal Rates and Strength Required for Disconnection: a Retrospective Cohort and Experimental Study

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Abstract

Background: Epidural analgesia requires the use of epidural catheters, which are associated with certain risks such as accidental epidural catheter removal, including dislodgement and disconnection. Few studies have investigated accidental catheter removal rates and directly compared them among epidural connector types. This study aimed to examine the differences in accidental catheter removal rates associated with different catheter connector types and to experimentally determine the linear tensile strength required to induce disconnection in each connector type.

Methods: This retrospective cohort study included adult patients who underwent elective surgery and received patient-controlled epidural analgesia between December 2019 and August 2020. Patients were divided into groups according to the type of catheter connection used: standard (old group), new standard (new group), and new standard with taping (taping group). Furthermore, we prepared 60 sets of epidural catheters and connectors comprising 20 sets for each of the old, new, and taping groups, and used the digital tension meter to measure the maximum tensile strength required to induce disconnection. A multinomial logistic regression analysis was used to examine risk factors for disconnection. The experimental study groups were compared using one-way analysis of variance.

Results: The clinical study involved in 920 patients (360, 182, and 378 patients in the old, new, and taping group, respectively). Dislodgement rates were similar among the three groups. Disconnection was most likely to occur in the new group (5.5%) and least likely to occur in the taping group (0.3%) compared to the old group (1.9%). However, the new group was not a risk factor for disconnection. The experimental study identified tensile strengths of 12.41 N, 12.06 N, and 19.65 N in the old, new, and taping groups, respectively. Comparison tests showed a significant difference in the tensile strength required for disconnection between the new and taping groups but not between the new and old groups.

Conclusions: These findings suggest that taping the catheter connector connection may reduce the risk of disconnection, and thereby help improve patient outcomes. Further studies are required to clarify other parameters that may affect patient safety in this context.

Background

Epidural analgesia (EA) is effective and helps improve post-surgical morbidity and hospitalization outcomes [1–3]. EA is associated with the risk of complications and adverse events, such as accidental epidural catheter removal, including catheter dislodgement and disconnection, post-dural puncture headache, local anesthetic toxicity, and epidural abscess or hematoma formation [4]. Although accidental epidural catheter dislodgement and disconnection are minor complications, they could be associated with the catheter itself rather than patient- or staff-related factors.

Indeed, catheter-related accidental removal has been previously reported, following product design changes [5–10]. In 2016, the international standard ISO 80369-6 was published to help prevent neuraxial drug administration errors; the guideline recommended a non-Luer neuraxial connector design, which has

become the new standard [11]. Transition to the new standard began in October 2019 in Japan, and our hospital adopted the new standard in March 2020; subsequently, an increase in the rate of accidental catheter disconnection was noted. Consequently, we began taping the catheter connector connections, which appeared to reduce the number of accidental disconnections.

We hypothesized that catheter connector types are associated with accidental catheter removal rates. Therefore, this study aimed to examine the differences in accidental catheter removal rates associated with different catheter connector types and to experimentally investigate the linear tensile strength required to induce disconnection.

Methods

Study design and setting

The Institutional Review Board of the Seirei Hamamatsu General Hospital approved this single-center retrospective cohort study (approval number 3570) and waived the requirement for written informed consent. Study information was available on the hospital website, allowing participants the opportunity to opt-out; patients who did not opt-out were included in this study. The study site is an urban tertiary acute care and teaching hospital with 750 beds and a surgical load of 11,000 patients per year, among which approximately 7,000 patients are managed by the anesthesiology department. This manuscript adhered to the Strengthening the Reporting of Observational Studies in Epidemiology statement guidelines [12]. In addition, the experimental component of this study was performed in a designated area at the surgery center of our hospital.

Study population

All adult patients (aged ≥20 years) who received patient-controlled EA (PCEA) for postoperative analgesia in the general ward following elective abdominal, orthopedic, gynecologic, thoracic, urologic, or breast surgery between December 1, 2019, and August 31, 2020, were included in this study. The exclusion criteria for participation in the study were unplanned removal of the epidural catheter at the post-anesthesia care unit (PACU), reoperation required during PCEA administration, and incomplete data. The patients were divided into three groups according to the type of catheter connection used: patients for whom the old standard was used (December 1, 2019 to February 29, 2020; old group), those for whom the new standard was used (March 1, 2020, to April 19, 2020; new group), and those for whom the new standard with a taped catheter connector connection was used (April 20, 2020 to August 31, 2020; taping group).

Data collection and outcome variables

Data on the patients' demographic and clinical characteristics, including preoperative morbidities, operation type, intraoperative anesthesia information, postoperative morbidities, and accidental epidural catheter dislodgement and disconnection, were extracted from electronic medical records. The variables of interest included age, sex, height, weight, and body mass index (BMI). We included the American

Society of Anesthesiologists Physical Status (ASA-PS) grade and incidence of dementia among preoperative morbidities. Abdominal surgeries included upper gastrointestinal surgery, hepato-biliary-pancreatic surgery, and colorectal surgery; orthopedic surgery included lower limb orthopedic surgery. We identified the interspace level of epidural catheter placement from the intraoperative anesthesia information and based on this information divided the patients into the upper and middle thoracic vertebrae (Th3-7), lower thoracic vertebrae (Th8-12), and lumbar spine (L1-4) groups. We recorded the incidence of postoperative delirium (POD). Accidental epidural catheter removal was categorized as premature epidural catheter dislodgement and disconnection. Dislodgement was defined as accidental and unscheduled catheter removal from the catheter insertion site, and disconnection was defined as accidental and unscheduled catheter removal at the catheter connector connection site (Figure 1A). When the epidural catheter was removed for reasons other than dislodgement and disconnection, it was defined as a scheduled removal. The primary outcomes were the rates of accidental epidural catheter dislodgement and disconnection, categorized by the type of catheter connection. The secondary outcomes were risk factors associated for accidental epidural catheter disconnection.

Epidural catheter procedure

According to institutional standards, each anesthesiologist performed epidural puncture using a midline or paramedian approach in the lateral decubitus position and considered the interspace level of epidural catheter placement suitable for each type of surgery. Routinely, the distal end of the epidural catheter (Perifix^{TM} FX Catheter, B. Braun, Tochigi, Japan) was inserted 3–5 cm into the epidural space. The proximal end was connected to a connector (Perifix^{TM} Catheter Connector, B. Braun, Tochigi, Japan) and reinforced with the provided green cap. The connector was then connected to a bacterial filter (Perifix^{TM} Filter 0.2 μm, B. Braun, Tochigi, Japan). Subsequently, the catheter was covered at the insertion site with a transparent semipermeable sterile adhesive dressing (OPSITE^{TM} POST-OP, Smith+Nephew, Tuttlingen, Germany), and the rest of the catheter was secured from the dressing site to the shoulder using an elastic adhesive bandage (Silkytex^{TM} White No. 5, ALCARE, Tokyo, Japan) (Figure 2). Taping involved forming a loop around the epidural catheter and securing it to the connector and filter using surgical tape (NICHIBAN^{TM}<For hospitals>, NICHIBAN, Tokyo, Japan) (Figure 1B). All patients received a local bolus anesthetic dose or continuous infusion through the epidural catheter during surgery at the discretion of the anesthetist.

Postoperative epidural catheter management

At the end of surgery, the filter was connected to the infusion route of the 300-mL or 150-mL PCEA pump, which was aseptically conditioned with 100–300 mL of analgesics. Patients were transferred to the PACU, where their pain scores and levels of motor block were assessed by the nursing staff and the attending anesthesiologist. Motor impairment as a drug-associated adverse event was managed by a temporary reduction or discontinuation of the infusion. Epidural catheters suspected of being inserted into the spinal subarachnoid space were removed at once; these cases were excluded from analysis. In the absence of adverse events in the PACU, the patient was transferred to the general ward. The timing of

epidural catheter removal was determined by the attending physician and their team responsible for postoperative management in the general ward, including the administration of postoperative analgesia. When accidental epidural catheter removal was reported either by a nurse or patient, the physician on duty responded, as required, including removing the remaining catheter. In cases that lacked reports on accidental catheter removal in the medical records, we judged that the catheter was removed as scheduled.

Product preparation

We prepared 20 sets of standard connectors (Perifix™ Catheter Connector, B. Braun, Tochigi, Japan) and filters (Perifix™ Filter 0.2 μm, B. Braun, Tochigi, Japan), 40 sets of new standard connectors and filters, and 60 sets of epidural catheters (Perifix™ Catheter Connector, B. Braun, Tochigi, Japan) and the provided green caps. Moreover, 20 sets of the new standard connectors involved a loop formed around the epidural catheter that secured it to the connector and filter using surgical tape (NICHIBAN™<For hospitals>, NICHIBAN, Tokyo, Japan). One anesthesiologist (YI) assembled the 60 sets of epidural catheters, connectors, and filters as per standard clinical practice. The 60 sets were grouped and compared according to the catheter connector connection type into an old group, new group, and taping group. We also prepared a digital tension meter (Digital force gauge™ DS2-200N, IMADA, Aichi, Japan) to measure the tensile strength of the catheter and connector, and a hook linking the filter and tension meter.

Measuring methods

One clinical engineer (TK) secured the epidural catheter to the desk with 20 cm of elastic adhesive bandage (SilkytexTM White No. 5, ALCARE, Tokyo, Japan) (Figure 3). The epidural catheter was fixed 30 cm away from the connector and supported to remain in place. Another clinical engineer (MS) slowly and linearly pulled the tension meter connected to the epidural set at a constant velocity until disconnection was achieved. We measured the maximum tensile strength required to induce disconnection.

Statistical analyses

Continuous variables are presented as the mean with standard deviation (SD). Graphical methods were used to confirm the normal distribution of the variables. Comparisons among the groups were performed using the t-test for variables that were normally distributed. Categorical variables are reported as counts (%); comparisons among groups were performed using the chi-square test or Fisher exact test, as suitable. Residual analysis was used to compare the real and expected values, derived from the removal method.

A multinomial logistic regression analysis was used to examine risk factors associated with accidental epidural catheter disconnection. Three groups (scheduled, dislodgement, and disconnection) were used as dependent variables, with the “scheduled” group acting as the reference group. A total of eight observation factors (age, sex, BMI, ASA-PS grade, interspace level, incidence of dementia, POD, and type of catheter connector) were used as independent variables. The adjusted odds ratios (ORs) and corresponding 95% confidence intervals (CIs) of each independent variable were calculated.

We conducted the experimental study and statistical analyses on the assumption that commonly manufactured products have a certain degree of normal distribution and uniformity because non-uniform products are generally removed during the manufacturing process; thus, we assumed that the data were normally distributed with homogeneous variance. The groups were compared using one-way analysis of variance (ANOVA). Dunnett's multiple comparisons test was performed as a post-hoc test, using new group as the control group. Based on previous studies [13, 14], the sample size was 20 tests per group.

Statistical analyses were performed using EZR version 1.54 (Saitama Medical Center, Jichi Medical University, Saitama, Japan) [15]. P-values <0.05 were considered statistically significant.

Results

Baseline characteristics of participants

In total, 953 patients received PCEA for postoperative analgesia; among them, 13 were excluded due to unplanned catheter removal and re-operation. Twenty additional patients were excluded owing to incomplete data on demographic characteristics. Finally, a total of 920 patients were included in this study, were allocated into either the old (n=360), new (n=182), or taping (n=378) group based on the type of catheter connection used (Figure 4). The patients' characteristics and perioperative findings are summarized in Table 1.

Table 1
Baseline characteristics of patients grouped by type of catheter connection.

	Old group	New group	Taping group	p-value
	(n = 360)	(n = 182)	(n = 378)	
Age (years)	56.1 (15.8)	56.6 (15.5)	64.1 (14.3)	< 0.001
Sex (male)	102 (28.3%)	49 (26.9%)	193 (51.1%)	< 0.001
Height (cm)	158.8 (8.4)	159.5 (7.6)	160.0 (9.0)	0.185
Weight (kg)	58.5 (11.8)	59.5 (12.4)	59.6 (12.2)	0.431
BMI (kg/m^2)	23.2 (3.9)	23.4 (4.0)	23.3 (4.0)	0.884
ASA-PS				
1	98 (27.2%)	40 (22.0%)	58 (15.3%)	< 0.001
2	216 (60.0%)	123 (67.6%)	256 (67.7%)	
3	46 (12.8%)	19 (10.4%)	64 (16.9%)	
Surgery type				
Abdominal	130 (36.1%)	62 (34.1%)	192 (50.8%)	< 0.001
Breast	2 (0.6%)	5 (2.7%)	5 (1.3%)	
Gynecology	144 (40.0%)	73 (40.1%)	36 (9.5%)	
Lower orthopedic	54 (15.0%)	20 (11.0%)	67 (17.7%)	
Thoracic	30 (8.3%)	12 (6.6%)	42 (11.1%)	
Urology	0 (0.0%)	10 (5.5%)	36 (9.5%)	
Interspace level				
A: Th3/4-Th7/8	36 (10.0%)	15 (8.2%)	48 (12.7%)	0.181
B: Th8/9-Th12/L1	267 (74.2%)	143 (78.6%)	261 (69.0%)	
C: L1/2-L4/5	57 (15.8%)	24 (13.2%)	69 (18.3%)	
Dementia	5 (1.4%)	1 (0.5%)	1 (0.3%)	0.188
POD	4 (1.1%)	4 (2.2%)	21 (5.6%)	0.002
Values are presented as means (SDs) or counts (%).				
Abbreviations: BMI: body mass index; ASA-PS: American Society of Anesthesiologists Physical Status; POD: postoperative delirium				

Rates of accidental epidural catheter dislodgement and disconnection

A total of 10 cases of accidental epidural catheter dislodgement were observed, at rates that were similar across the groups (1.7% vs. 0.5% vs. 0.8% for the old, new, and taping groups, respectively). A total of 18 cases of accidental epidural catheter disconnection were observed, and the rates were highest in the new group and lowest in the taping group (1.9% vs. 5.5% vs. 0.3% for the old, new, and taping groups, respectively) (Table 2).

Table 2
Rates of accidental epidural catheter removal by type of catheter connection.

Removal method	Old group	New group	Taping group
	(n = 360)	(n = 182)	(n = 378)
Scheduled			
Count	347 (96.4%)	171 (94.0%)	374 (98.9%)
Adjusted residual	-0.804	-2.631	2.927
Dislodgement			
Count	6 (1.7%)	1 (0.5%)	3 (0.8%)
Adjusted residual	1.360	-0.781	-0.717
Disconnection			
Count	7 (1.9%)	10 (5.5%)	1 (0.3%)
Adjusted residual	-0.021	3.848	-3.094
Values are presented as counts (%) or adjusted residuals.			
Residual analysis was based on the chi-square test.			
Adjusted residuals smaller than −2.58 or greater than 2.58 indicate a statistically significant difference at $p < 0.01$.			

Risk factors associated with accidental epidural catheter disconnection

The results of multinomial logistic regression analysis show that there was a statistically significant association between catheter disconnection and age, BMI, ASA-PS2, ASA-PS3, dementia, and the taping group but not with the old group (Table 3).

Table 3
Risk factors associated with accidental epidural catheter disconnection by removal method.

Disconnection vs. Scheduled			
	OR	95% CI	p-value
Age (years)	1.07	1.01–1.12	0.011
Sex			
Female	1	Ref	
Male	1.09	0.338–3.05	0.873
BMI (kg/m^2)	1.18	1.04–1.34	0.011
ASA-PS			
1	1	Ref	
2	2.41E5	3.74E4–1.56E6	0.000
3	2.29E6	2.51E4–2.08E6	0.000
Interspace level			
A: Th3/4-Th7/8	1	Ref	
B: Th8/9-Th12/L1	0.997	0.205–4.65	0.475
C: L1/2-L4/5	0.472	0.059–3.80	0.994
Dementia	0.001	1.28E-3–1.29E-3	0.000
POD	5.13	0.762–34.5	0.093
Group			
New	1	Ref	
Old	0.391	0.139–1.10	0.074
Taping	0.025	0.003–0.206	< 0.001
Values are presented as odds ratios or 95% confidence intervals.			
Abbreviations: OR: odds ratio; CI: confidence interval; BMI: body mass index; ASA-PS: American Society of Anesthesiologists Physical Status; POD: postoperative delirium			

Experimental study results

The mean (SD) tensile strength was calculated for each group; there was a significant difference among the groups in the tensile strength required for disconnection ($p < 0.01$).

The highest tensile strength values were recorded for the taping group, with a mean value of 19.65 (3.19) N. The corresponding values for the old and new groups were 12.41 (1.16) N and 12.06 (1.40) N, respectively (Figure 5).

Dunnett's multiple comparison test revealed a significant difference in the tensile strength recorded for the new and taping groups (mean difference =7.59, $p < 0.01$); the tensile strength values recorded for the new and old groups were comparable (mean difference = 0.35, $p < 0.823$).

Discussion

This was a retrospective cohort study examining the differences in accidental catheter removal rates associated with different catheter connector types. Overall, 28 of 920 (3.0%) patients experienced accidental epidural catheter removal; among them, dislodgement and disconnection occurred in 10 of 920 (1.09%) and in 18 of 920 (1.96%) patients, respectively. In addition, the experimental study revealed that greater tensile strength was required for disconnection in the taping group than in the other groups.

The lack of significant difference in dislodgement rates among the groups may be accounted for by the fact that the back-fixation method remained the same despite the change in the design standards of the catheter connector.

Accidental epidural catheter dislodgement may result in inadequate analgesia, leading to the occurrence of complications or extension of the hospital stay. Therefore, various methods of reducing the risk of dislodgement have been proposed, which include the standard use of steri-strips and clear adhesive dressing, as well as the Lockit design [16], attaching the catheter to the skin with dressing and a single suture [17], and using a tunneling technique [18]. We empirically combined the transparent semipermeable sterile adhesive dressing and elastic adhesive bandage to strengthen the fixation of the epidural catheter; fixing the catheter to the skin with transparent adhesive dressing may help prevent it from slipping.

Previous studies have reported dislodgement rates in the range of 1.2–5.1% [4, 19, 20]. The present rates were comparable with or lower than those previously reported, suggesting that this approach may be beneficial.

In contrast, accidental epidural catheter disconnection from its connector may result in patient harm, including not only inadequate analgesia but also increased risk of bacterial contamination [21]; therefore, disconnection should be prevented. Although product manufacturers have the responsibility to pursue design solutions that minimize the risk of such events [10], healthcare workers should supplement these efforts to ensure patient safety.

Previous studies have reported disconnection rates in the range of 1.7–2.3% [4, 19, 20]; these rates were comparable with the rate in this study’s old group, which was 1.9%. In the clinical study, there was a significant difference in disconnection rates among the groups; specifically, these rates were highest in

the new group and lowest in the taping group. In multinomial logistic regression analysis, however, the new group was not a risk factor for disconnection compared with the old group. In addition, there was no significant difference in tensile strength required for disconnection between the new and old groups in the experimental study. The differences in removal rates between the new and old groups may be influenced by older age, a high BMI, the ASA-PS grade, and dementia.

A similar taping method has been previously introduced to protect the junction between the catheter and filter from the effect of any force [22]; however, we found this method ineffective in our setting and thus developed an alternative approach that involves taping in two places with a loop. Findings from both the clinical and experimental studies suggest that taping the catheter connector connection in two places with a loop may reduce the risk of disconnection.

To the best of our knowledge, this is the first study examining accidental catheter removal rates and connection strength of epidural catheter connectors since the use of epidural connectors and filters has become the international standard. Several previous studies have investigated accidental removal rates of epidural catheters [4, 19, 20, 23, 24]; however, few clinical studies have directly compared epidural connector designs. Doyle et al. [13] compared the connection strength of epidural catheter connectors using increment weight as a surrogate measure of linear force. Richardson et al. [14] compared the connection strength using dynamic linear force testing under controlled laboratory conditions. In contrast, we investigated the connection strength of epidural catheter connectors, including that which is compliant with the international standard published in 2016, using linear tensile strength to induce disconnection. The present findings provide evidence that may help improve patient safety.

Limitations

This study has some limitations. First, this was a retrospective study, and there may be multiple known and unknown confounders, including the timing of ambulation, patient mobilization, context of accidental epidural catheter removal, and failure to record the outcome, all of which may have affected the present findings. Nevertheless, the present findings remain meaningful, as randomized controlled trials are impractical in this context. Furthermore, the included groups were heterogenous owing to the differences in the timing and type of surgery. In April 2021, the Japanese government issued a state of emergency owing to the coronavirus disease pandemic, which resulted in the postponement of many elective surgeries [25]. Second, the epidural set used at our hospital was one of many types available. Although B Braun only manufactures one type of filter and connector, three types of epidural catheters are available. Furthermore, the present findings may not be generalized to catheters from other manufacturers. However, they may provide clinical guidance on preventing accidental epidural catheter removal, as the type of epidural catheter does not affect the back-fixation method. Finally, we could not perform laboratory-based testing under formal conditions, controlling for temperature, pressure, and humidity. However, the present experiment was conducted under conditions representative of those encountered in surgical practice. Furthermore, although the clinical engineer involved in the experiment pulled the tension meter connected to the epidural set at a constant velocity, it remains unclear whether

the force applied was indeed constant. Finally, although the taping method may not have been applied uniformly in all cases, any variability is representative of clinical practice.

Conclusions

This study showed that taping the catheter connector connection in two places with a loop increased the tensile strength required for disconnection and reduced the risk of disconnection in PCEA. A lower disconnection rate may help improve patient outcomes. The present findings may help improve patient safety. Further studies are required to clarify other parameters that may affect patient safety in this context.

Abbreviations

EA: epidural analgesia, PCEA: patient-controlled epidural analgesia, PACU: post-anesthesia care unit, BMI: body mass index, ASA-PS: American Society of Anesthesiologists Physical Status, POD: postoperative delirium; OR: odds ratio, CI: confidence interval

Declarations

Ethics approval and consent to participate

The Institutional Review Board of the Seirei Hamamatsu General Hospital approved this single-center retrospective cohort study (approval number 3570) and waived the requirement for written informed consent. Study information was available on the hospital website, allowing participants the opportunity to opt-out; patients who did not opt-out were included in this study.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Not applicable.

Authors' contributions

YI was the main author of this manuscript. YI, TK, and MS contributed to the conception and design of the study, survey creation, and acquisition of data. YI and HY contributed to the analysis and interpretation of data. HM and YT supervised manuscript drafting and provided critical feedback. All authors read and approved the final manuscript.

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Figures

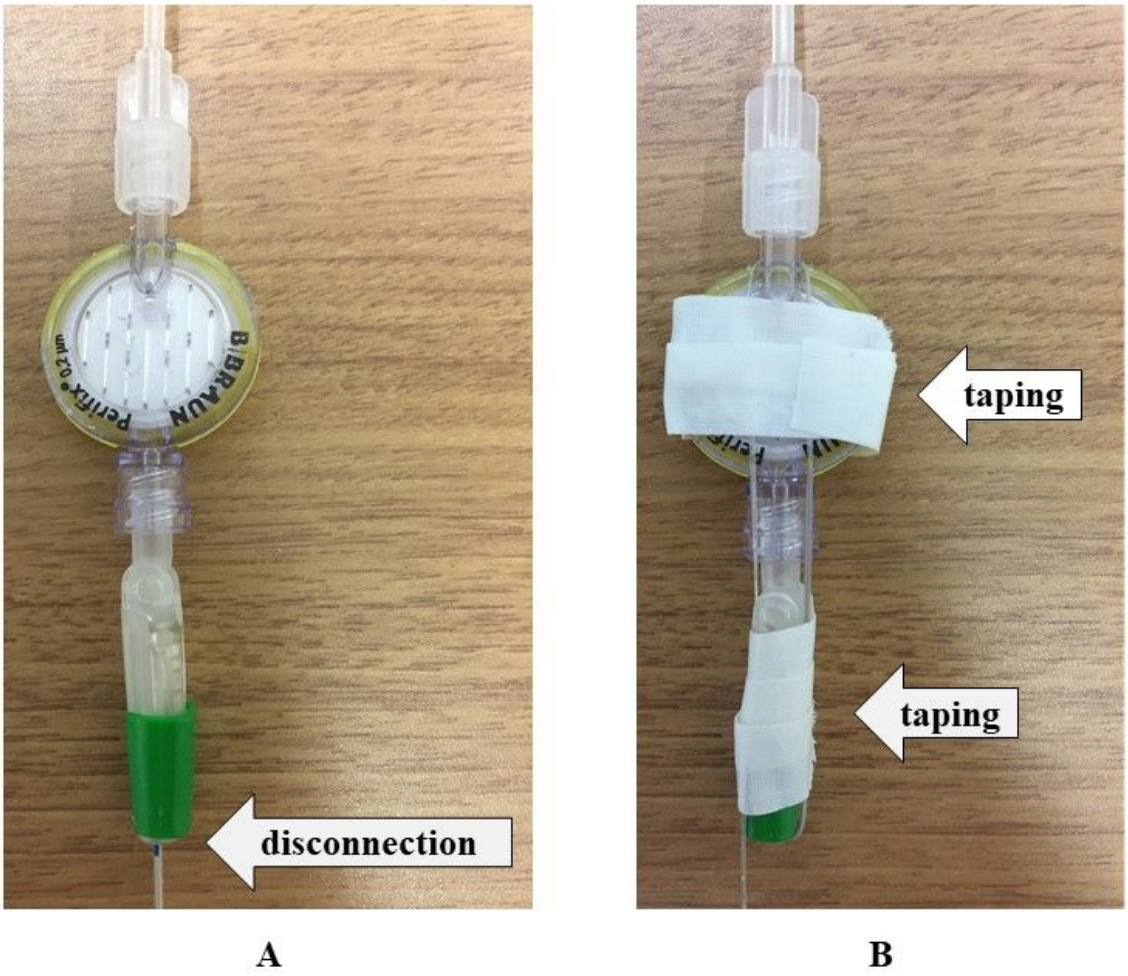

Figure 1

Type of catheter removal and epidural catheter connection. Disconnection was defined as catheter removal at the catheter connector connection site (A), and taping involved a loop around the epidural catheter that was secured to the connector and filter in two places using surgical tape (B).

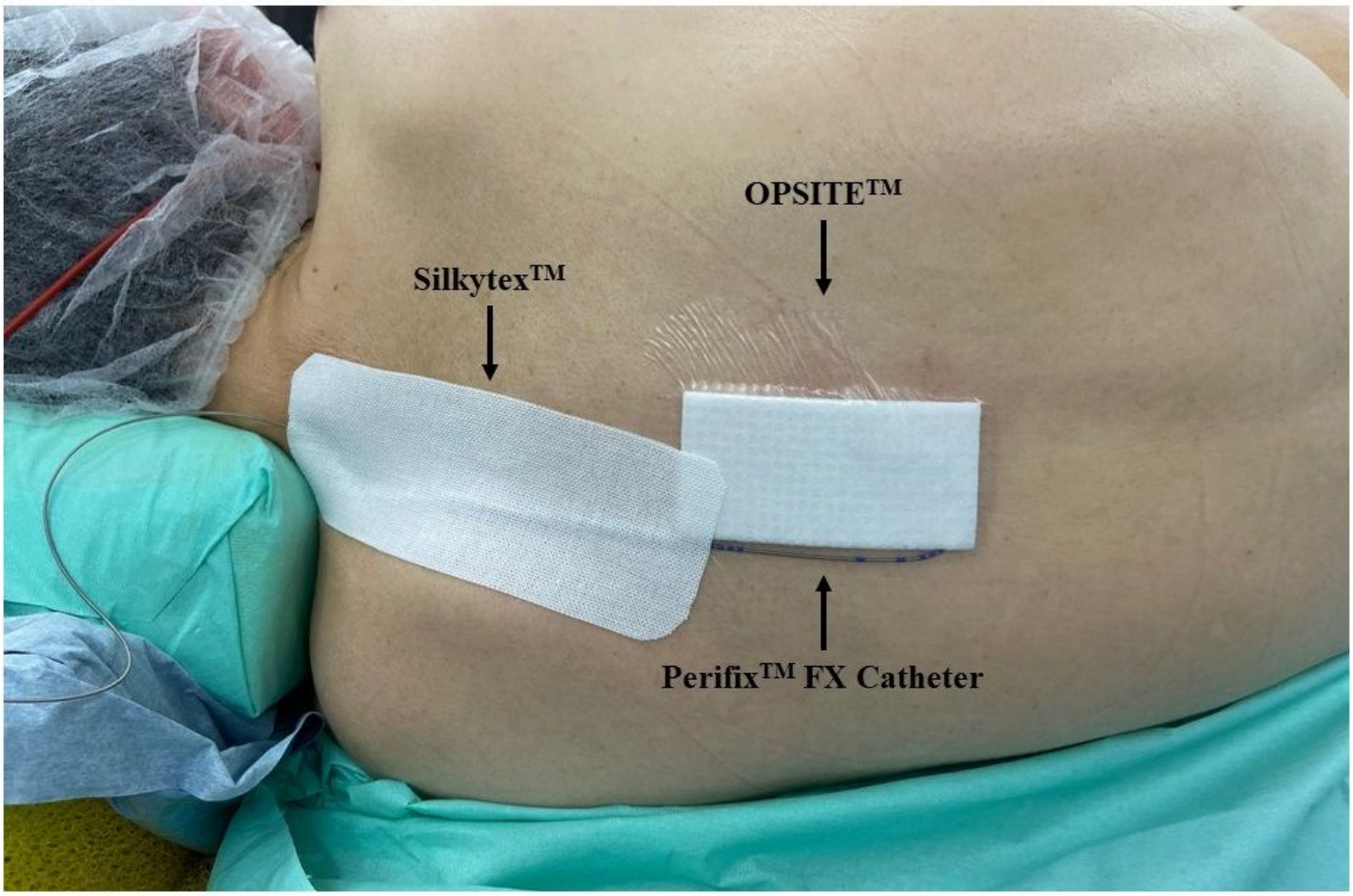

Figure 2

Back-fixation method. The epidural catheter was covered at the insertion site with a transparent semipermeable sterile adhesive dressing, and the rest of the catheter was secured from the dressing site to the shoulder using an elastic adhesive bandage.

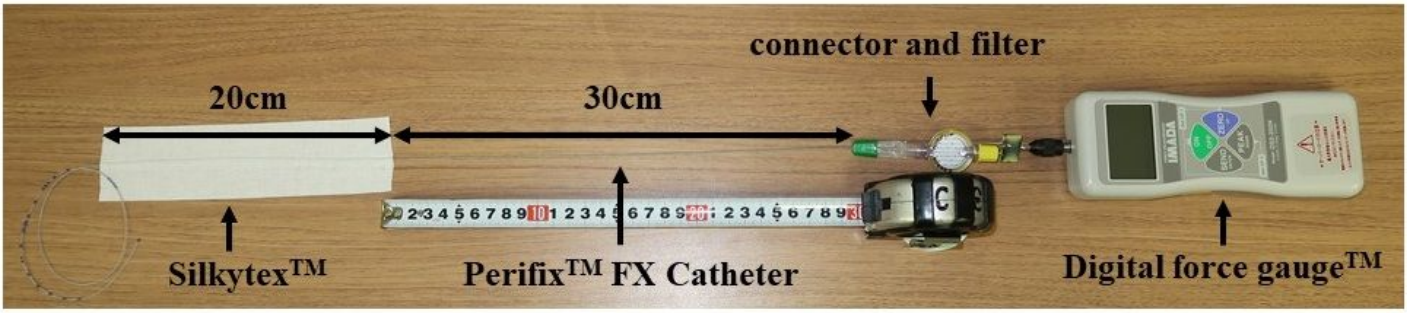

Figure 3

Measurement conditions. The epidural catheter was secured to the desk with a 20 cm elastic adhesive bandage and fixed 30 cm away from the connector.

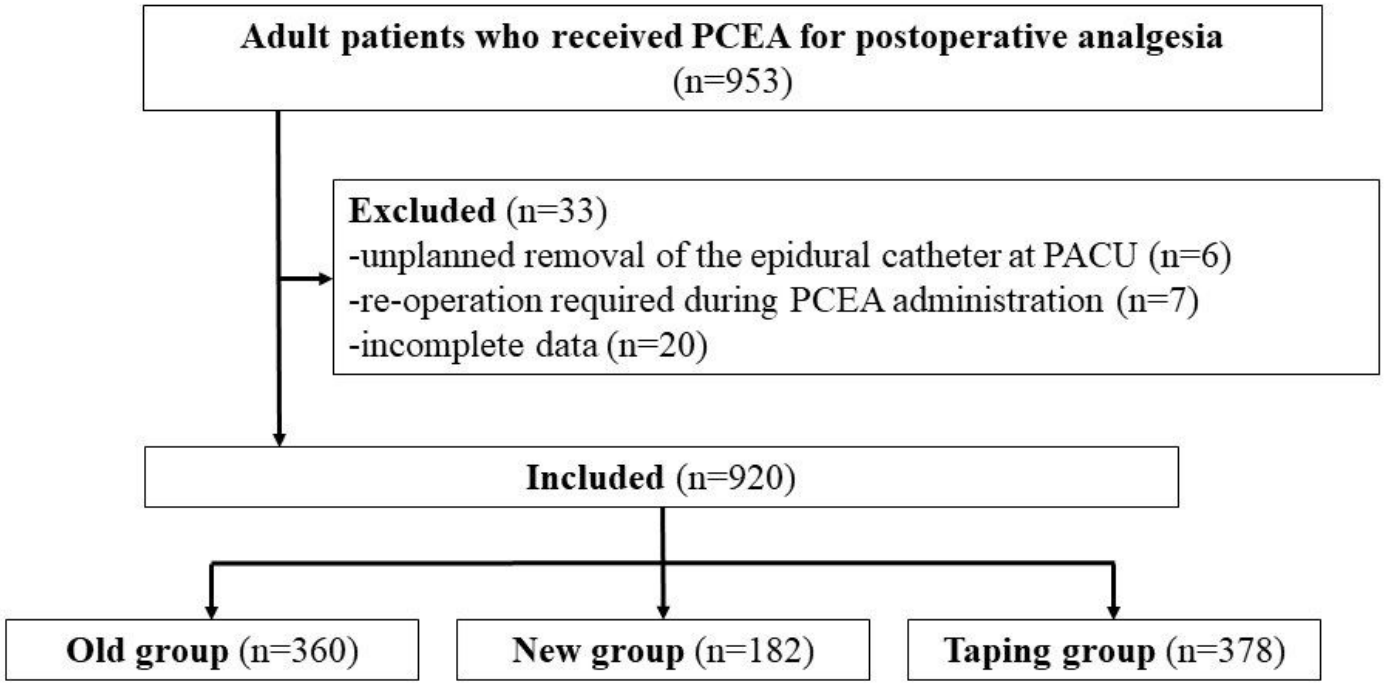

Figure 4

Flowchart of the study.

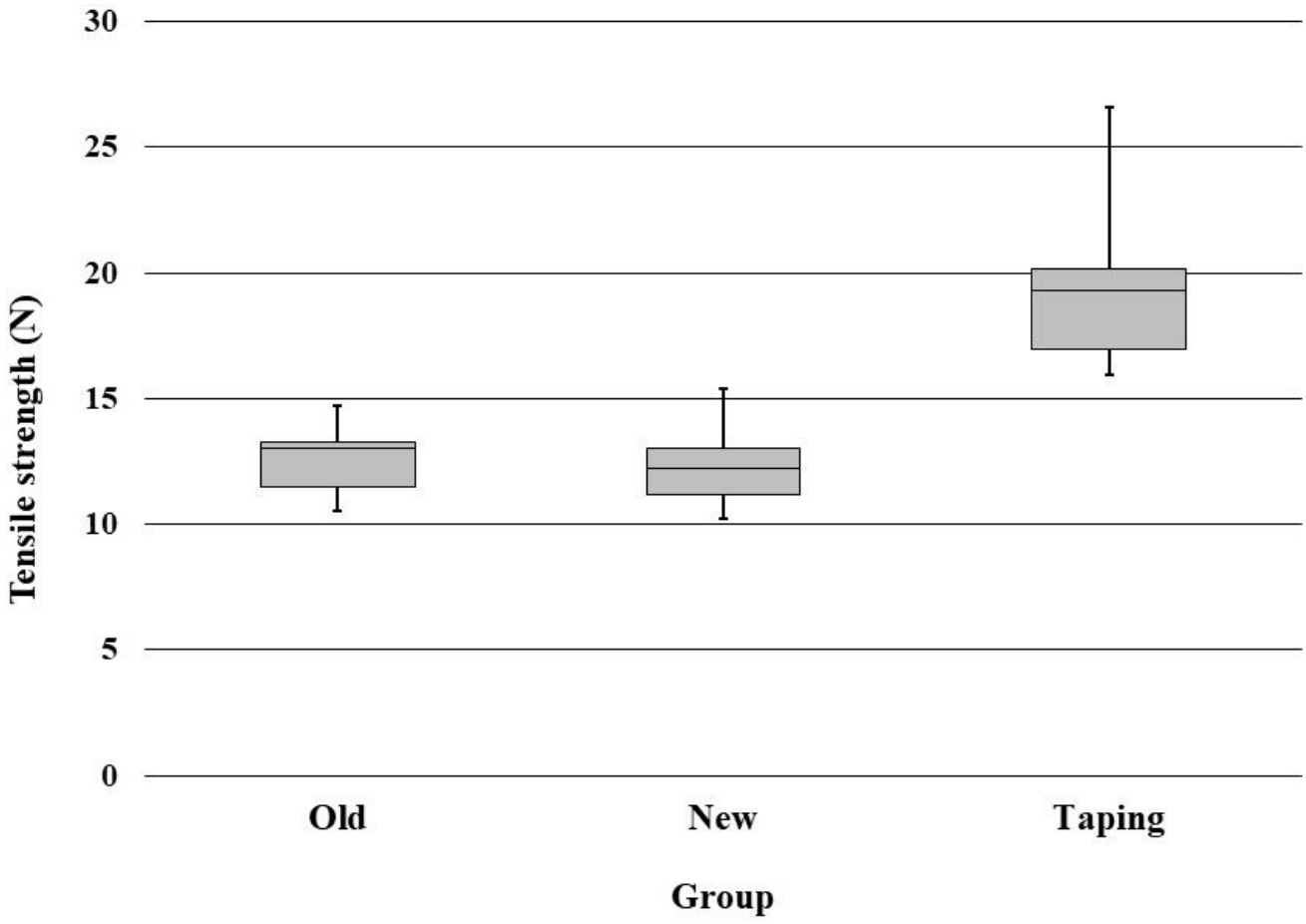

Figure 5

Box plot of tensile strength values.