Decreasing the Leakage of Continuous Femoral Nerve Catheter Fixation Using 2-octyl Cyanoacrylate Glue (Demabond®): A Randomized Controlled Trial Study

Vanlapa Arnuntasupakul
Mahidol University Faculty of Medicine Ramathibodi Hospital
Lisa Sangkum
Mahidol University Faculty of Medicine Ramathibodi Hospital https://orcid.org/0000-0002-4638-0198
Rungrawan Buachai
Mahidol University Faculty of Medicine Ramathibodi Hospital
Theerawat Chalacheewa (drtheerawat@gmail.com)

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Abstract

Background: Continuous peripheral nerve catheters (CPNCs) have been used for postoperative pain relief. The common problem with CPNCs is pericatheter leakage that can compromise the sterile dressing, un-necessitating frequent dressing that may increase the risk of dislodgement and perineural catheter colonization or infections. Adhesive glue is useful for fixing peripheral nerve catheter as well as prevent leakage around the puncture site. This study aimed to evaluate the incidence of pericatheter leakage by using fixation with 2-octyl cyanoacrylate glue (Demabond®) compared to sterile strip.

Methods: Thirty patients undergoing unilateral total knee arthroplasty and received continuous femoral nerve block were randomized to perineural catheter fixation with 2-octyl cyanoacrylate glue or sterile strip. The primary outcome was the incidence of pericatheter leakage. Secondary outcomes included frequent of catheter migration, difficulty of catheter removal, pain score and patient satisfaction.

Results: The incidence of pericatheter leakage at 48 hours was 0% versus 100% in the intervention and control group. The incidence of displacement at 24 and 48 hours was 6.7% versus 93.3% and 6.7% versus 100%, respectively ($P < 0.001$). There was no difference in numeric rating scale, difficulty of catheter removal as well as satisfaction scores between groups.

Conclusion: Catheter fixation with 2-octylcyanoacrylate reduced the incidence of pericatheter leakage as well as catheter displacement over 48 hours compare to sterile strip.

Background

Continuous peripheral nerve catheters (CPNCs) have been used for sustained postoperative pain relief with opioid sparing effect, improved rehabilitation and patient well being (1–3). The challenging to maintain CPNC function is to secure in the correct position especially in the freely mobile sites, such as the neck and limb region. Moreover, the technique should prevent pericatheter leakage that may increase risk of dislodgement, colonization and infection (4). Several methods to secure catheters have been studied, such as suturing, cutaneous suture (5) and retrograde subcutaneous tunneling (6). However, accidental dislodgment and pericatheter leakage are still a frequent problem.

In our institute, we mainly place catheters using the catheter-through-needle method. As it helps us to confirm the tip position after the surgery by using nerve stimulator. Since the needle is larger than the catheter size, thereby, pericatheter leakage is a significant problem in our patient. Having a simple, non-invasive, reliable method for catheter fixation and preventing dislodgment would be beneficial. Previous studies (7–10) showed that adhesive glue was an effective method for peripheral nerve catheter fixation; however, leakage around the pericatheter was only their secondary outcome. Therefore, we conduct a single-center, randomized controlled study to evaluate the incidence of pericatheter leakage by using sterile stripe or 2-ocylcyanoacrylate (Dermabond®) in femoral catheter. We hypothesized that fixing the continuous femoral nerve catheter with 2-ocylcyanoacrylate (Dermabond®) would reduce the incidence

of pericatheter leakage within 48 hours. The secondary outcomes were catheter migration, numeric rating scale score (NRS), difficulty of catheter removal, and patient satisfaction with analgesia.

Methods

Study participants

After receiving approval by the Ramathibodi hospital research ethics board. This trial was registered on Thai clinical trial registry: TCTR20200228002, registered 24 February 2020- Retrospectively registered, http://www.clinicaltrials.in.th/index.php?tp=regtrials&menu=trialsearch&smenu=lsresult&task=search&task2=ls. Written informed consent was obtained from all participants. We enrolled 30 adult patients aged 40–80 years, with American Society of Anesthesiologists physical status I-IV who were scheduled to undergo total knee arthroplasty (TKA). We excluded patients who refused to participate in the study, those with localized infection at the inguinal area of the operated leg and patient who contraindicate to femoral nerve block or allergy to local anesthetic drug/ adhesive glue.

Randomization and blinding

Our research coordinator who was not involve in the study performed computer-generated simple 1:1 ratio to 2-octyl cyanoacrylate glue (Demabond®) (Dermabond group) or normal practice fixation (Control group). Allocation of patients to each group was concealed in a sealed envelope. The anesthesiologist who performed femoral nerve block open the envelope just before the time of block performance. All other research outcome assessor and caregiver were blinded to group allocation. Patient blinding was maintained by standardizing the perceptible elements of block between both groups: position, ultrasound probe placement, needle insertion site, use of nerve stimulation, and local anesthetic injection volume. Our study was adhered to CONSORT guideline.

Femoral nerve block performance

For patients undergoing unilateral TKA, femoral sheath catheters were inserted pre-operatively using a nerve stimulator. A Stimulong® continuous nerve block set 18-gauge 50 mm Tuohy needle and 20-gauge catheter). After sterile preparation and draping of the femoral area on the operative side, stimulation at 2 Hz and 1.5 mA was applied after the needle was felt to have gone through two fascial planes, 1.5 cm lateral to the femoral artery. When quadriceps contraction was detected, the current was decreased, and the needle position was optimized for evident contraction at a current output of 0.2–0.5 mA. The Stimulong® catheter was attached to the nerve stimulator and the catheter slowly thread until a depth of 3–5 cm from the needle tip while maintaining quadriceps contraction at a current ≤ 0.5 mA. The catheter was repositioned as necessary to sustain continuous quadriceps contraction at a current ≤ 0.5 mA. The needle was withdrawn, and the patients were divided into the following 2 groups: Dermabond group; catheter is sealed with 2-octyl cyanoacrylate liquid adhesive (Dermabond®), and the area is covered with

transparent dressing (Tegaderm™) (Fig. 1). Control group; catheter is secured with sterile strip to secure the catheter, and the area is covered with transparent dressing (Tegaderm™) (Fig. 1).

The patients were then transferred to the operating room for spinal anesthesia. We perform spinal anesthesia using a 27-gauge quicke needle with a solution of isobaric Marcaine 10–15 mg at the second to the fourth lumbar level. No local anesthetics were given through the femoral catheter during surgery. In the recovery room, the patients were given a 15-mL bolus of bupivacaine 0.125% injected through the femoral catheter. The femoral catheter was then infused with bupivacaine 0.08% at 5 mL/h. Every patient received acetaminophen 100 mg (every 6 hours) and naproxen 250 mg (every 8 hours) for 3 days. If patient had postoperative pain score more than 4, morphine 3 mg were administered as rescue analgesia.

Outcomes

The primary outcome was the leakage at the catheter site, classified as Mild; fluid was around the catheter, < 1 cm from the insertion site Moderate; fluid was around the catheter, > 1 cm from the insertion site but still in the transparent dressing (Tegaderm™). Severe; fluid out of the transparent dressing (Tegaderm™)

The secondary outcomes, which included catheter migration, difficulty of catheter removal, and patient satisfaction, were assessed by the acute pain service nurse at postanesthetic care unit (PACU), 24 h and 48 h postoperative period.

Statistical Methodology

Demographic characteristics of the subjects in each randomized controlled study were analyzed. Continuous variables are reported using mean and standard deviation values or median and range values. Categorical variables are presented using counts and percentages and tested using Chi-Square or Fisher exact test, as appropriate. Continuous variables were tested for normality with the Shapiro-Wilk test. T test or Mann-Whitney test were used for group comparisons as appropriate. P-value < 0.05 implied statistical significance. The statistical software SPSS 20.0 for Windows was used for data analyses.

The sample size was calculated assuming a catheter leakage rate of 50% with standard fixation techniques based on previous literature (9) and institutional pilot data to have at least 80% power to see a clinically relevant reduction to zero percentage with a 2-sided type I error rate of 0.05. A sample size of 11 subjects in each arm of each group was considered adequate. Additional 4 subjects per groups were recruited to prevent loss of power because of early withdrawal or protocol violations. Thus, 15 subjects per group was the derived sample size.

Results

After screening and randomization, there were 30 patients included and final analysis. The CONSORT flow diagram is shown in Fig. 3. In both group, there was no significant difference in the sex, age, body mass index (BMI), and ASA physical status of the subjects in the two groups (Table 1). The incidence of

pericatheter leakage at 48 hours was 0% in dermabond group and 100% in control group. The incidence of catheter displacement was lower in dermabond group compare to control group (At 24 hours: 6.7% versus 73.3%, P < 0.001, 48 hours: 6.7% versus 93.3%). There were no different in 24 and 48-hours numerical rating scale (NRS) between group (24 hours NRS 2 (0–7) versus 2 (0–8), P = 0.54), 48-hours NRS 2 (0–7) versus 2 (0–7), P = 0.81) as well as satisfaction score (Satisfaction score: Dermabond vs. control group: 9.13 ± 1.13 vs 9.07 ± 1.28, P = 0.881) (Table 2). In both group, there was no incidence of dislodgement as well as difficulty of catheter removal.

Table 1
Patient's demographic data

	Dermabond group (15)	Control group (15)	P-value
Male/Female, n	0/15	3/12	0.224
Age (y), mean ± SD	68.2 ± 7.5	66.33 ± 6.77	0.48
BMI ($kg.m^{-2}$), mean ± SD	25.99 ± 3.67	27.41 ± 3.26	0.272
ASA I/II/III, n	0/8/7	1/8/6	>0.999
Data are represented as median (minimum-maximum) or as indicated in the table.			

Table 2
Catheter and subject related outcomes for Dermabond compared with control group

	Dermabond group	Control group	P-value
Leakage, n (%)			
24 h after operation	**0 (0%)**	**14 (93.33%)**	**< 0.001***
Mild	-	2 (13.33%)	
Moderate	-	2 (13.33%)	
Severe	-	10 (66.67%)	
48 h after operation	**0 (0%)**	**15 (100%)**	**< 0.001***
Mild	-	2 (13.33%)	
Moderate	-	1 (6.67%)	
Severe	-	12 (80%)	
Displacement, n (%)			
24 h after operation	1 (6.67%)	11 (73.33%)	< 0.001*
48 h after operation	1 (6.67%)	14 (93.33%)	< 0.001*
NRS			
24 h after operation	2 (0–7)	2 (0–8)	0.539
48 h after operation	2 (0–7)	2 (0–7)	0.806
Satisfaction score, mean ± SD	9.13 ± 1.13	9.07 ± 1.28	0.881

Discussion

This prospective randomized trial study reveals a significant improvement of pericatheter leakage by using 2-octylcyanoacrylate (Dermabond®) fixation compare with sterile strip. It also prevents the occurrence of catheter displacement and dressing changes frequency while maintain high quality pain control and satisfaction score.

Two -octylcyanoacrylate (Dermabond®) is a liquid monomer that spontaneously polymerizes in the presence of moisture to create a waterproof bond with the surrounding epidermis. Several studies have compared this surgical adhesive against suture for the closure of lacerations in both trauma and elective surgery. Therefore, many studies have been evaluated efficacy of dermabond on CPNCs. Gurnaney et al. reported the incidence of pericatheter leakage before and after introduce dermabond as a catheter fixation protocol. They found that the incidence of catheter leakage reduced from 3.87–0.56% (11). David B et al. conducted a study compared fixation continuous interscalene catheter with Dermabond® and

Mastisol. They reported the incidence of pericatheter leakage in continuous interscalene perineural catheter, as the secondary outcome, comparing Dermabond and Mastisol. They found that the incidence of leakage at 48 hours was 0% in the Dermabond group and 50% in the Mastisol group.

This prospective randomized trial systematically followed perineural catheter leakage in continuous femoral nerve block that is lower extremities block over 48 hours after total knee arthroplasty. These resulted reveals that Dermabond was significantly more effective in preventing perineural catheter leakage than the conventional method using sterile strip. Moreover, the use of Dermabond involved reduced pericatheter bleeding from the puncture site. There was no difficulty in catheter removal, suggesting that despite a waterproof bond with the epidermis, Dermabond does not increase the difficulty of catheter removal at the time of planned discontinuation. Although the cost of Dermabond is more than that of the sterile strip at our hospital, the indirect costs of failed CPNBs from the effect they might have on the clinical outcomes and nursing care. In this study, we found no leakage in the Dermabond group; thus, there was no need to change the dressing and meant less nursing care. Thus, if Dermabond is used for ambulatory patients, they can take care of themselves very well.

Our study has certain limitations. There are several perineural catheter systems available in the market today, and these results may not be universally applicable to all types of peripheral nerve block catheters.

Conclusion

Fixation catheter with 2-octylcyanoacrylate (Dermabond®) reduced the incidence of pericatheter leakage as well as catheter displacement over 48 hours in a continuous femoral block when compared to sterile strip.

Abbreviations

BMI: Body mass index

CPNCs: Continuous peripheral nerve catheters (CPNCs)

NRS: Numeric rating scale score

PACU: Post anesthetic care unit

TKA: Total knee arthroplasty

Declarations

Ethics approval and consent to participate

Written informed consent was obtained from all participants. The study was approved by the Ramathibodi hospital research ethics board. This trial was registered on Thai clinical trial registry:

TCTR20200228002, registered 24 February 2020- Retrospectively registered, http://www.clinicaltrials.in.th/index.php?tp=regtrials&menu=trialsearch&smenu=lsresult&task=search&task2=ls.

Consent for publication:

Not applicable

Availability of data and materials:

The datasets during and/or analyzed during the current study 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

Conceptualization: T.C., V.A.; Methodology: L.S., T.C.; Formal analysis and investigation: T.C., L.S., R.B.; Writing - original draft preparation: T.W., V.A., L.S.; Writing - review and editing: T.W.

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Not applicable

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Figures

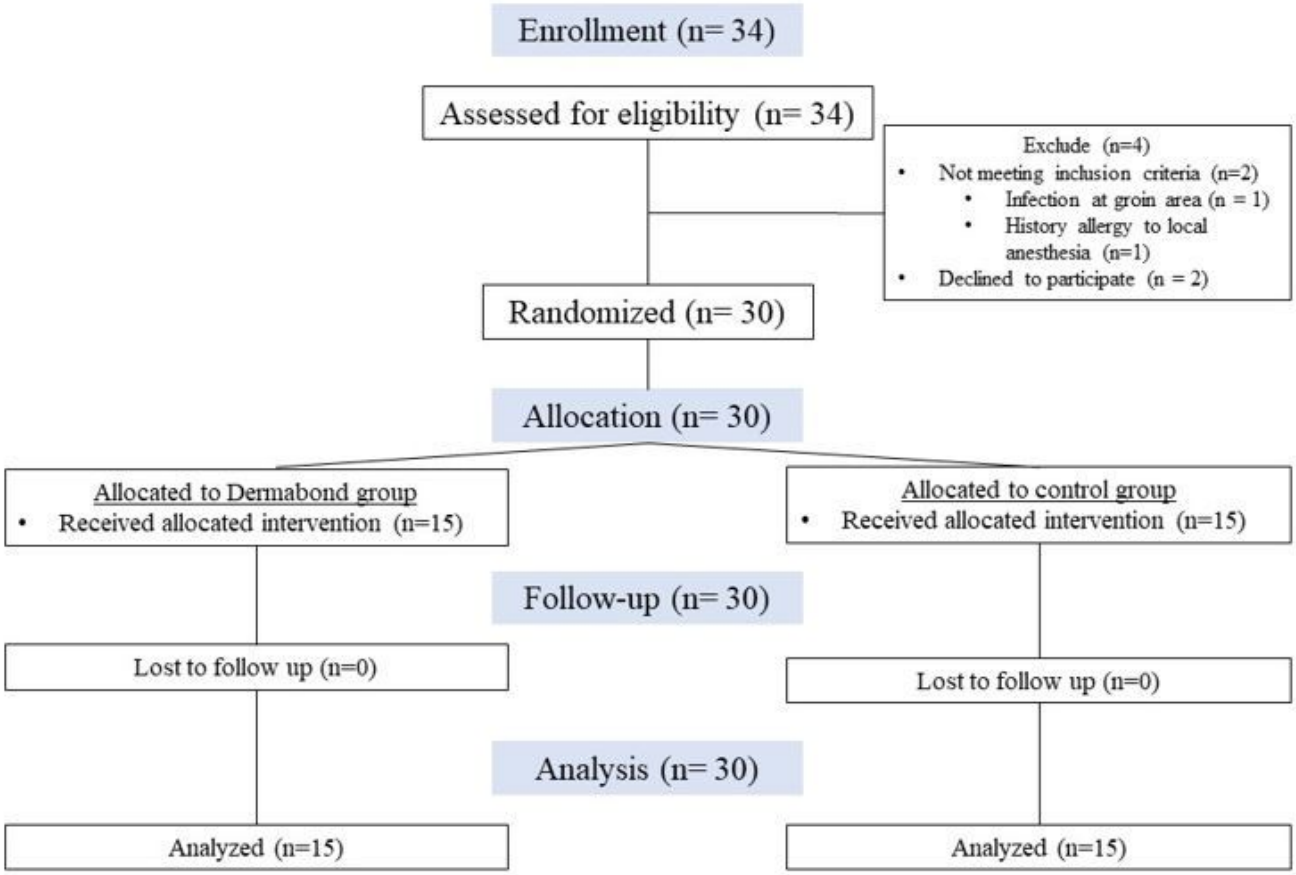

Figure 1

CONSORT flow diagram

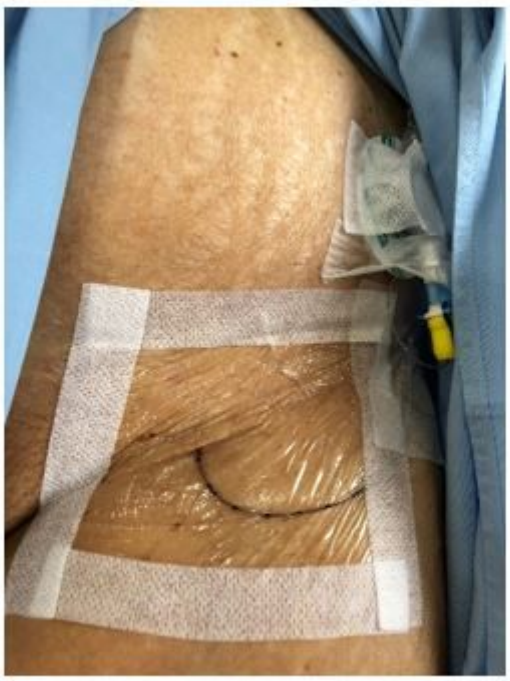

Figure 2

Catheter fixation with Dermabond®

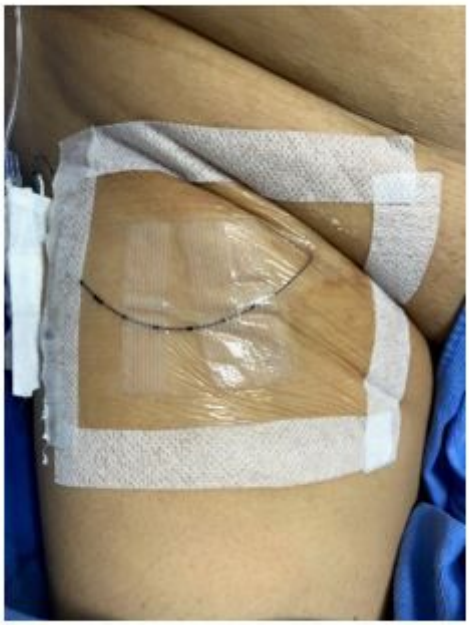

Figure 3

Catheter fixation with sterile strip

Supplementary Files

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- CONSORT2010Checklist3.doc