

Effectiveness of continuous femoral nerve block for pain relief after total knee arthroplasty: comparison with epidural patient-controlled analgesia and periarticular injection

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Abstract

Objective: To compare the clinical outcomes among three analgesic techniques, continuous femoral nerve block (CFNB), epidural patient-controlled analgesia (EPCA) and periarticular injection (PAI), in patients undergoing total knee arthroplasty (TKA).

Methods: This retrospective case–control study enrolled patients that underwent TKA. Visual analogue scale (VAS) pain scores, sleep disturbance, additional opioid consumption and incidence of opioid-related side-effects were assessed.

Results: A total of 120 patients were categorized into three groups: EPCA (group A, $n = 40$), PAI (group B, $n = 40$) and CFNB (group C, $n = 40$). Group C had significantly lower VAS pain scores than groups A and B at 8, 12 and 24 h after TKA. There were no significant differences in VAS pain scores among the three groups from 48 h after TKA. Sleep quality on the first day after surgery was significantly better in group C than in groups A and B. Additional opioid consumption was significantly lower in the group C than in the groups A and B. Group C showed a lower rate of opioid-related side-effects than groups A and B.

Conclusion: CFNB was a more effective additional analgesic technique than EPCA or PAI for acute postoperative pain control within 24 h of TKA.

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Keywords

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Introduction

Pain management after total knee arthroplasty (TKA) is a significant issue because many patients experience intolerable pain.^{1–5} Severe pain experienced during the early postoperative period impedes early rehabilitation by hampering the patient's ability to perform activities and may increase the risk of postoperative complications, including thromboembolic disease or nosocomial infections.^{1,2,5} Several techniques such as epidural patient-controlled analgesia (EPCA), periarticular injection (PAI) and femoral nerve block (FNB) have been developed and widely used to control initial pain after TKA.^{2–4,6} These techniques allow for early ambulation and physiotherapy initiation, which in turn expedite recovery, reduce length of hospital stay and lower postoperative complication risk.^{1,2}

Intravenous patient-controlled analgesia (IV-PCA) is used for effective pain relief. However, some patients experience several side-effects of opioid drugs, including nausea, vomiting, headache, dizziness and urinary retention.^{3,6} EPCA is widely used to manage postoperative pain because it has fewer side-effects than IV-PCA.^{7,8} Recently, interest in localized additional pain management methods, including FNB and PAI, has been increasing owing to their ability to ameliorate pain with few adverse effects.^{1,6} FNB is an effective technique, but it can damage quadriceps muscle power, which in turn delays ambulation and recovery.^{1,2} EPCA is an invasive procedure that restricts the mobility of patients until they completely recover motor power. PAI has several advantages including

simplicity of the technique and avoidance of motor blockade, but its analgesic efficacy is limited owing to its short duration of action.⁵

In terms of comparing EPCA, PAI and FNB, most studies have only included two of the techniques.^{3,6} To the best of our knowledge, no study has identified which of the three techniques is the most effective. The aim of this current study was to evaluate the effectiveness of pain management of the three techniques as well as their side-effects in patients undergoing primary TKA.

Patients and methods

Study population

This retrospective matched-pair case-control study enrolled consecutive patients that underwent primary TKA and received continuous femoral nerve block (CFNB) and the same number of consecutive patients that underwent primary TKA with EPCA and PAI according to the matching criteria between January 2014 and December 2019 in the Department of Orthopaedic Surgery, Inha University Hospital, Incheon, Republic of Korea. The patients were matched by age (± 5 years), sex, cause of TKA (primary osteoarthritis), body mass index (BMI; ± 2 kg/m²), Kellgren and Lawrence stage, preoperative pain score (± 1 visual analogue scale [VAS]) and tourniquet time (± 10 min). All of the patients underwent surgery by the same surgeon (M.K.K.). Patients were categorized into three groups: group A

(EPCA), group B (PAI) and group C (CFNB).

The inclusion criteria were as follows: (i) received unilateral surgery; (ii) surgery undertaken by a single surgeon (M.K.K.). The exclusion criteria were as follows: (i) receipt of IV-PCA; (ii) receipt of simultaneous bilateral TKA; (iii) receipt of another surgery at the same time; (iv) contraindication to spinal anaesthesia (general anaesthesia); (v) allergy to local anaesthesia; (vi) local site infection; (vii) previous nerve injury; (viii) peripheral neuropathy; (ix) neuropathic pain; (x) history of stroke or major neurological deficit; (xi) psychiatric illness; (xii) abnormal liver, renal or cardiac function; (xiii) chronic kidney disease requiring dialysis; (xiv) morbid obesity (BMI >40 kg/m²); (xv) chronic use of opioids; (xvi) previous drug dependency; (xvii) inability to walk independently; (xviii) uncooperative patients.

The design and protocol of this study were reviewed and approved by the institutional review board of Inha University Hospital, Incheon, Republic of Korea (IRB no. INHAUH 2020-05-001) and an exemption from informed consent was obtained. The reporting of this study conformed to STROBE guidelines.⁹

Surgical procedures

All patients underwent TKA performed by the same surgeon (M.K.K.) and were subjected to the same procedures and postoperative management techniques. Under spinal anaesthesia, the patient was placed in the supine position, after applying a pneumatic tourniquet with the same pressure (350 mmHg). A standard mid-line skin incision was made with medial parapatellar approach. The same implant system (NexGen LPS® PS type; Zimmer Biomet, Warsaw, IN, USA) was adjusted with cement fixation (Optipac 80; Biomet Orthopaedics GmbH, Dietikon, Switzerland)

in all patients. Pain management and early postoperative rehabilitation protocols were similarly applied in all patients.

Premedication and spinal anaesthesia

Premedication was given to patients with a small volume of water as they departed for the operating room: (i) 37.5 mg tramadol hydrochloride/325 mg acetaminophen (Ultracet® tablet; Janssen Korea, Seoul, Republic of Korea); (ii) 2 mg polmacoxib (Acelex® tablet; CrystalGenomics, Seoul, Republic of Korea); (iii) 300 mg gabapentin (Neurontin® capsule; Jeil Pharm., Seoul, Republic of Korea). Standard monitoring (pulse oximeter, electrocardiography and non-invasive arterial pressure) was performed on all patients on their arrival to the anaesthetic room. After an intravenous (i.v.) preload with 500 ml of plasma solution, spinal anaesthesia was administered in the lateral position by inserting either a 25G or 27G spinal needle into the L2–L3 or L3–L4 intervertebral space. After confirming clear free flow of cerebrospinal fluid, 12.5 mg of racemic 0.5% bupivacaine was administered to achieve sensory block (to cold and pinprick) to the 10th thoracic dermatome or above.

Additional pain control procedure

For EPCA, after spinal anaesthesia, an epidural catheter was inserted approximately 4 cm in the direction of the head and then the patient was placed in the supine position. In the recovery room, when the sensory block height fell below T10, the patient received a continuous dose of total 100 ml of 0.75% ropivacaine 20 ml and 5 mg of 0.1% morphine sulphate with normal saline,¹⁰ after the administration of a 3-ml bolus dose of 0.1% ropivacaine with 1 ml 0.1% morphine sulphate via an epidural catheter as an initial loading dose.¹¹

An epidural pain control device was administered for 72 h at a rate of 2 ml/h.

For CFNB, the femoral nerve block was administered to the patient in the supine position. The pulse of the femoral artery was identified. Under ultrasonographic guidance, an 18G echogenic needle with stimulating catheter (E-Cath® Plus; Pajunk GmbH Medizintechnologie, Geisingen, Germany) was introduced 1 cm lateral to the femoral artery at the inguinal skin crease and advanced toward the cephalad at an angle of 45°–60° to the skin. Correct identification of the nerve was confirmed by the contraction of the quadriceps muscle using a nerve stimulator set between 0.2 and 0.5 mA (0.1 ms, 1 Hz). When appropriate muscle contractions were obtained between 0.2 mA and 0.5 mA, 25 ml of a local anaesthetic mixture containing 0.75% ropivacaine (5 ml) mixed with normal saline (20 ml) was slowly injected via a needle for each block after negative aspiration of blood. The catheter was then threaded with caution to maintain at all times the desired motor response. The threshold accepted for final catheter positioning was 0.8 mA of current intensity (0.1 ms width, 2 Hz). The catheter was then tunnelled for 5–7 cm under the skin to minimize dislodgement.¹² This was followed by a continuous infusion of 0.75% ropivacaine 60 ml mixed with normal saline 140 ml (0.225% ropivacaine, total 200 ml) at a rate of 3 ml/h. The catheter was maintained during 72 h and then removed.¹³

For the PAI, an injection solution containing a total volume of 100 ml of 0.2% ropivacaine, 1 ml of ketorolac (30 mg/ml) and 0.5 ml of epinephrine (1 mg/ml). This solution was injected into the rest of the capsule, the cut quadriceps tendon, the patellar ligament and soft tissues surrounding the joint, and the subcutaneous tissues after suturing the incision made during medial parapatellar arthrotomy.¹²

Clinical assessment

For each group, four clinical assessments were compared for evaluating the effects. The effect of each technique on postoperative pain relief was estimated at rest and after 4, 8, 12, 24, 48 and 72 h using a VAS score (0–10 cm, where 0 indicates no pain and 10 indicates extreme pain).

The quality of sleep subjectively experienced by the patients on the first day after surgery was investigated using a questionnaire (Table 1). The patients were surveyed on the day after surgery. The score ranged from 0 to 10, where 0 point indicated no sleep disturbance; 1–3 points, mild sleep disturbance; 4–6 points, moderate sleep disturbance; and 7–10 points, severe sleep disturbance.

Consumption of additional opioids in each group was checked and calculated by converting to a corresponding dose of morphine as described below. The incidence of opioid side-effects, such as nausea/vomiting, dizziness, headache, constipation and sedation, was recorded for the first 72 h after surgery.

Consumption of additional opioids

To supplement the three analgesic regimens, 50 mg/ml tramadol hydrochloride (Tridol injection 50 mg; Yuhan, Seoul, Republic of Korea) i.v. was used for controlling pain when pain at rest exceeded 5 on the VAS. A pethidine hydrochloride (25 mg/0.5 ml; Hana Pethidine HCL Injection 25 mg; Hana Pharm Co., Seoul, Republic of Korea) i.v. injection was used for treating severe pain (>7 on the VAS). Consumption of additional opioids was converted to an equivalent dose of oral morphine using the guidelines published by the National Drug and Alcohol Research Center.¹⁴

Table 1. A questionnaire for evaluating sleep quality on the first day after surgery in a study that investigated the effectiveness of pain management using epidural patient-controlled analgesia, periarticular injection or continuous femoral nerve block in patients that underwent total knee arthroplasty.

Questionnaire		
Questions		Score
Did you sleep well on the first night after the surgery compared with usual?	Very well	0
	Well	1
	Not really	2
	No	3
Have the analgesics helped you sleep well?	Very effective	0
	Effective	1
	Little effective	2
	Ineffective	3
How many additional analgesics did you take to fall asleep?	Three +	4
	Three	3
	Two	2
	One	1
	None	0
Total score ^a		10

^a0 point, no sleep disturbance; 1–3 points, mild sleep disturbance; 4–6 points, moderate sleep disturbance; 7–10 points, severe sleep disturbance.

Statistical analyses

All statistical analyses were performed using IBM SPSS Statistics for Windows, Version 25.0 (IBM Corp., Armonk, NY, USA). Continuous data are presented as mean \pm SD and categorical data as *n* of patients (%). A repeated measures analysis of variance (ANOVA) test was undertaken to analyse the change in VAS pain score over different time-points. Continuous data were analysed using a one-way ANOVA test and categorical data were analysed using Pearson's χ^2 -test. A Scheffe's *post-hoc* test was used to assess any statistical significance between the time-points and between the groups at a defined time. A *P*-value <0.05 was considered statistically significant.

Results

The patient selection and matching process is presented in Figure 1. Of 564 patients

that underwent TKA, 374 patients were included in the study after applying the exclusion criteria. Of the 374 patients, 40 patients underwent CFNB (group C); and 40 patients that underwent EPCA (group A) or PAI (group B) were selected according to the matching criteria. Age, sex, surgical side, BMI and tourniquet time of the patients before surgery are presented in Table 2. Among the three groups, there were no significant differences in these variables.

The mean VAS pain scores of the three groups at 4, 8, 12, 24, 48 and 72 h after TKA are presented in Table 3. Among the three groups overall, significant differences in the mean VAS pain scores were observed at 8, 12 and 24 h ($P < 0.001$ for all comparisons), whereas there were no significant differences at 4, 48 and 72 h. Group C (CFNB) had significantly better pain scores than groups A (EPCA) and B

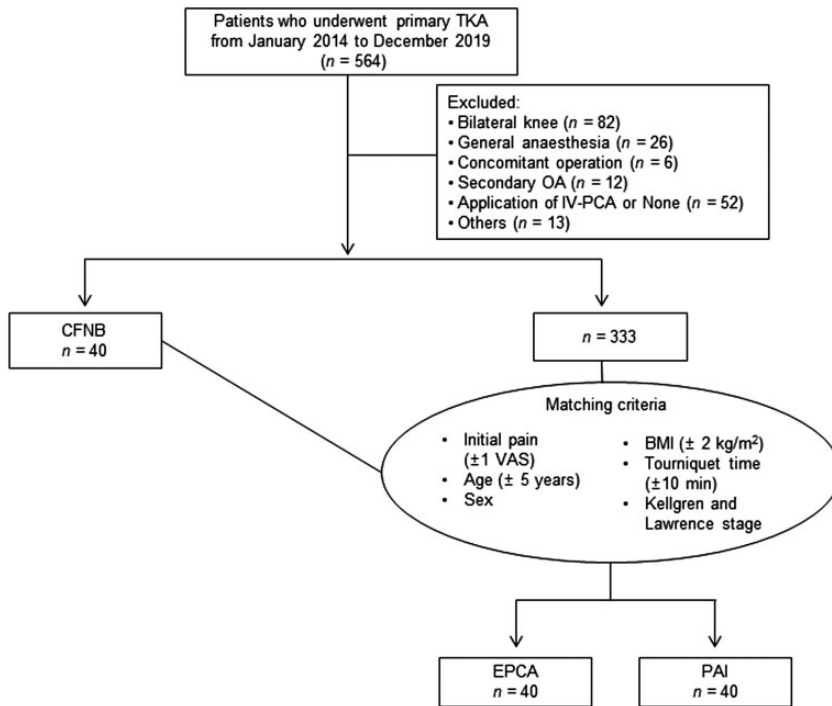


Figure 1. Flowchart of patient selection for a study that investigated the effectiveness of pain management using epidural patient-controlled analgesia (EPCA), periarticular injection (PAI) or continuous femoral nerve block (CFNB) in patients that underwent total knee arthroplasty (TKA). OA, osteoarthritis; IV-PCA, intravenous-patient-controlled analgesia; BMI, body mass index; VAS, visual analogue scale.

(PAI) at 8, 12 and 24 h ($P < 0.001$ for all comparisons). Group B (PAI) had a better mean VAS pain score than group A (EPCA) at 8 h ($P = 0.016$) and 12 h ($P = 0.047$), but both groups had similar pain scores at other times.

The sleep quality scores showed that 11 of 40 patients (27.5%) in group A (EPCA), 13 of 40 patients (32.5%) in group B (PAI) and 22 of 40 patients (55.0%) in group C (CFNB) had no sleep disturbance (Table 4). Sleep quality during the first postoperative night was significantly better in group C (CFNB) than in groups A (EPCA) and B (PAI) ($P = 0.028$). A total of 33 of 40 patients (82.5%) in group C (CFNB) reported a sleep disturbance of either 'none' or 'mild' grade. There were no

significant differences between groups A (EPCA) and B (PAI) in terms of sleep disturbance.

The additional analgesic requirements are presented in Figure 2. The cumulative mean \pm SD opioid consumption (converted to an equivalent dose of oral morphine) at 72 h was as follows: 67.4 ± 19.2 mg in group A (EPCA), 62.9 ± 14.3 mg in group B (PAI) and 33.4 ± 17.5 mg in group C (CFNB). The cumulative opioid consumption was significantly lower in the group C (CFNB) compared with groups A (EPCA) and B (PAI) ($P < 0.001$ for both comparisons). There were no significant differences between groups A (EPCA) and B (PAI). In each group, opioid consumption between 24 h and 48 h ($24 \text{ h} < t \leq 48 \text{ h}$) was significantly

Table 2. Preoperative demographic and clinical characteristics of patients ($n = 120$) included in a study that investigated the effectiveness of pain management using epidural patient-controlled analgesia (EPCA), periarticular injection (PAI) or continuous femoral nerve block (CFNB) following total knee arthroplasty.

Characteristics	Group		
	EPCA $n = 40$	PAI $n = 40$	CFNB $n = 40$
Age, years	70.8 ± 7.8	69.4 ± 6.5	70.9 ± 5.3
Sex			
Female	30 (75.0%)	30 (75.0%)	30 (75.0%)
Male	10 (25.0%)	10 (25.0%)	10 (25.0%)
Side			
Right	22 (55.0%)	25 (62.5%)	23 (57.5%)
Left	18 (45.0%)	15 (37.5%)	17 (42.5%)
Body mass index, kg/m ²	26.7 ± 3.8	26.4 ± 2.8	26.6 ± 3.3
Tourniquet time, min	92.3 ± 9.5	93.7 ± 8.1	95.0 ± 9.5

Data presented as mean ± SD or n of patients (%).

No significant between-group differences ($P \geq 0.05$); continuous data were compared using one-way analysis of variance; categorical data were compared using Pearson's χ^2 -test.

Table 3. Visual analogue scale (VAS) pain scores during the 72 h after total knee arthroplasty in patients ($n = 120$) included in a study that investigated the effectiveness of pain management using epidural patient-controlled analgesia (EPCA), periarticular injection (PAI) or continuous femoral nerve block (CFNB).

Postoperative time-point	Group			Statistical analyses ^a			
	EPCA $n = 40$	PAI $n = 40$	CFNB $n = 40$	Overall significance	EPCA versus PAI	EPCA versus CFNB	PAI versus CFNB
4 h	2.57 ± 1.36	2.29 ± 0.46	2.11 ± 0.53	NS	NS	NS	NS
8 h	4.86 ± 1.70	3.94 ± 1.08	2.29 ± 0.89	$P < 0.001$	$P = 0.016$	$P < 0.001$	$P < 0.001$
12 h	6.86 ± 2.22	5.83 ± 1.58	2.91 ± 1.07	$P < 0.001$	$P = 0.047$	$P < 0.001$	$P < 0.001$
24 h	5.09 ± 1.42	4.97 ± 1.15	3.09 ± 0.98	$P < 0.001$	NS	$P < 0.001$	$P < 0.001$
48 h	3.60 ± 1.09	3.71 ± 1.02	3.46 ± 1.12	NS	NS	NS	NS
72 h	2.91 ± 1.12	3.26 ± 0.89	3.11 ± 0.83	NS	NS	NS	NS

Data presented as mean ± SD.

^aContinuous data were compared using one-way analysis of variance followed by Scheffe's post-hoc analysis; NS, no significant difference ($P \geq 0.05$).

higher than that between 0 and 24 h ($t \leq 24$ h) or between 48 and 72 h ($48 \text{ h} < t \leq 72 \text{ h}$) ($P < 0.001$ for all comparisons).

Groups A (EPCA), B (PAI) and C (CFNB) had 14 of 40 patients (35.0%), 12 of 40 patients (30.0%) and eight of 40 patients (20.0%) with probable

side-effects of opioid use, respectively. There were no significant differences among the three groups. The most frequent side-effects in all patients were postoperative nausea and vomiting (PONV) (15 of 34 patients; 44.1%), dizziness/headache (nine of 34 patients; 26.5%), constipation

Table 4. Adverse events and sleep disturbance after total knee arthroplasty in patients ($n = 120$) included in a study that investigated the effectiveness of pain management using epidural patient-controlled analgesia (EPCA), periarticular injection (PAI) or continuous femoral nerve block (CFNB).

	Group		
	EPCA $n = 40$	PAI $n = 40$	CFNB $n = 40$
Adverse events			
Overall	14 (35.0%)	12 (30.0%)	8 (20.0%)
Nausea/vomiting	7 (50.0%)	5 (41.7%)	3 (37.5%)
Dizziness/headache	4 (28.6%)	3 (25.0%)	2 (25.0%)
Constipation	1 (7.1%)	2 (16.7%)	2 (25.0%)
Urinary retention	2 (14.3%)	2 (16.7%)	1 (12.5%)
Sleep disturbance^a			
None (0)	11 (27.5%)	13 (32.5%)	22 (55.0%)
Mild (1–3)	7 (17.5%)	8 (20.0%)	11 (27.5%)
Moderate (4–6)	11 (27.5%)	11 (27.5%)	5 (12.5%)
Severe (7–10)	11 (27.5%)	8 (20.0%)	2 (5.0%)

Data presented as n of patients (%).

^a $P = 0.028$ for sleep disturbance; Pearson's χ^2 -test.

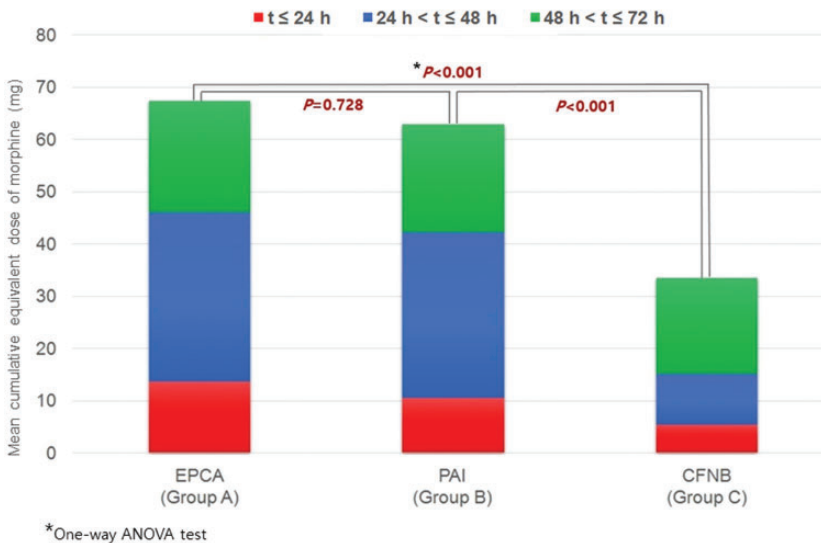


Figure 2. Consumption of opioids at 72 h after total knee arthroplasty for patients ($n = 120$) included in a study that investigated the effectiveness of pain management using epidural patient-controlled analgesia (EPCA), periarticular injection (PAI) or continuous femoral nerve block (CFNB). All opioids were converted to an equivalent dose of oral morphine (mg). Mean cumulative equivalent doses were compared using one-way analysis of variance. The colour version of this figure is available at: <http://imr.sagepub.com>.

(five of 34 patients; 14.7%) and urinary retention (five of 34 patients; 14.7%) (Table 4). There were no significant differences among patients in the three groups in terms of the adverse events that they experienced.

Discussion

The most important finding of this current study was that CFNB was associated with significantly lower pain scores compared with EPCA or PAI at 8, 12 and 24 h after TKA surgery. Moreover, CFNB could reduce additional opioid consumption at 72 h after TKA surgery and reduce the incidence of PONV.

Postoperative pain after TKA is a significant concern to patients and surgeons and appropriate pain management is essential for early mobilization and functional recovery.^{15,16} The conventional analgesia approaches after TKA include IV-PCA or EPCA.¹⁶ However, the use of systemic opioids is associated with side-effects such as nausea, vomiting, pruritus and sedation.^{7,17} These adverse effects may compromise early rehabilitation after TKA.¹ Recently, local anaesthetics such as FNB and/or PAI have been introduced as alternative strategies for managing pain in the early phase after TKA.³ This current study evaluated the efficacy of PAI or CFNB in controlling pain without complications compared with conventional EPCA.

Periarticular injection is reported to have good efficacy in controlling pain and few side-effects, as well as is being cost effective and easy to use.¹⁸ The rationale for using an analgesic cocktail is that pharmaceutical synergy produces more effective analgesia.^{18,19} However, studies to determine the drug combinations that play the most important role in improving postoperative

pain control are lacking.²⁰ Many studies on PAI have revealed good results for various medications and combinations including ropivacaine, ketorolac and epinephrine.^{18–23} All of these combinations reportedly showed good efficacy toward pain control with only a few complications.²⁰ This current study used a combination of ropivacaine, ketorolac and epinephrine. Epinephrine prolongs the action of local agents by facilitating contraction of the smooth muscles that line the arterioles to potentially minimize intra-articular bleeding and prolong the time the agents would act locally.²⁴ The component ketorolac not only acts as an anti-inflammatory analgesic but also possesses synergistic activity when administered along with other oral nonsteroidal anti-inflammatory drugs.¹⁸ The current results demonstrated that the pain reduction mediated by PAI was significantly better than that mediated by EPCA at 8 h and 12 h after TKA surgery. However, the pain reduction brought about by PAI could not be prolonged beyond 12 h and was not superior to that mediated by CFNB.

Femoral nerve block has been introduced as an effective method for postoperative pain control after TKA.^{1,2,25,26} Several studies have demonstrated that the addition of FNB in TKA provides the patients with a higher quality of postoperative pain control and improves patient satisfaction with fewer side-effects during the early postoperative period.^{1,2,25–27} FNB can be applied as a single-shot FNB (SSFNB) or as a continuous block using a catheter and an infusion pump (CFNB). CFNB has the advantage of permitting analgesic delivery for a longer postoperative duration as opposed to SSFNB.^{26,27} Previous studies have shown that the duration of SSFNB-mediated analgesic effect is typically 12–24 h, whereas severe pain does not considerably fade for

48–72 h after TKA.²⁷ CFNB has the advantage of permitting analgesic delivery for a longer postoperative duration than SSFNB.²⁶ In consideration of this pain duration, the current study used CFNB and the results showed that compared with EPCA or PAI, the pain relief mediated by CFNB was significantly greater at 24 h after TKA; but after 48 h, the extent of pain relief was not significantly different between the three pain management methods.

Femoral nerve block has more efficient analgesic outcomes, although quadriceps femoris weakness following FNB is a significant concern.^{1,2,25,28,29} It is important because it can lead not only to delays in rehabilitation but also falls or fracture events.^{1,29} Although quadriceps muscle weakness after FNB is generally observed for approximately 3–6 months, several studies have demonstrated that there is no difference in clinical recovery.^{1,29} The power of the quadriceps femoris muscle was not measured in the current study, but there were no falls or fracture events with regard to motor block of the quadriceps muscle and no incidence of neurological dysfunctions that could not be treated by rehabilitation.

This study had several limitations. First, the study had an inherent limitation of not being a randomized, prospective study but rather a retrospective study. However, a matched-pair case–control study design was used for matching variables in order to improve the reliability of the results. Secondly, substantial variance in self-reported pain scores may routinely arise among patients despite imparting education on rating the pain score and having an understanding of the value of using aggregate scores. Thirdly, the concentrations and doses of ropivacaine in CFNB and EPCA were different and this could have affected the results. Because of differences in typical concentrations and doses between central

anaesthesia and peripheral anaesthesia, it was not possible to match the exact drug concentrations between the two groups. Finally, the effect of CFNB or PAI may be technique-dependent, which could affect the clinical results. However, the injection regimen was identical and was performed by the same surgeon or anaesthesiologist, which minimized the potential for confounding effects on anaesthetic technique.

In conclusion, CFNB was a more effective additional analgesic technique than EPCA or PAI for achieving acute postoperative pain control within 24 h of TKA surgery. CFNB had a significant positive impact on sleep quality on the first day after surgery and reduced opioid consumption compared with EPCA or PAI.

Author contributions

Myung Ku Kim, Dong Jin Ryu, Dae Gyu Kwon and Yoon Sang Jeon designed the study. Sang Hyun Ko and Yoon Joong Hwang performed the data collection and participated in manuscript preparation. Sang Hyun Ko performed the statistical analysis. Myung Ku Kim performed the surgeries. All authors have read and approved the final manuscript.

Declaration of conflicting interest

The authors declare that there are no conflicts of interest.

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