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Analgesic Efficacy of Perineural Dexmedetomidine with Bupivacaine in Adductor Canal Block for Post Total Knee Arthroplasty: A Randomized Controlled Trial

Vachira Udompornmongkol[1], Pin Sriprajittichai[2], Nichanart Singrueang[1], Ponlawat Prangsri[1]
[1]*Department of Anesthesiology, Rajavithi Hospital,Thailand*
[2]*Department of Anesthesiology, Faculty of Medicine Chulalongkorn University, Bangkok, Thailand*

Background: Total knee arthroplasty (TKA) surgery is associated with severe postoperative pain. Currently, adductor canal block (ACB) is a widely used method to provide analgesia after TKA.

Objectives: The primary objective was to study the analgesic efficacy of perineural dexmedetomidine with bupivacaine in ACB in patients undergoing TKA, and the secondary objectives were to investigate the ambulation ability and the side effects.

Methods: Sixty patients aged 18-85 years, ASA status I-III underwent primary, unilateral TKA under spinal anesthesia. They were randomized into two groups; Group C received 20 mL of 0.25% bupivacaine and Group D received 20 mL of 0.25% bupivacaine plus 0.5 mcg/kg dexmedetomidine for ACB. The time to first rescue analgesia, 24-hour morphine consumption, postoperative pain score, quadriceps strength, the Timed Up and Go (TUG) test, patient satisfaction, and adverse outcomes were assessed.

Results: The patient demographic and intraoperative data were comparable in both groups. The median time to first rescue analgesia (group C: 196 [89, 363], group D: 184 [105, 267], and P-value = 0.112), 24-hour morphine consumption (group C: 6.5 [4, 10], group D: 9 [3.25, 14.50] and P-value = 0.245) and postoperative pain score at rest and on movement (P-value = 0.829 and 0.888, respectively) showed no significant differences between groups. There were no significant differences in TUG test, quadriceps strength, adverse events, and patient satisfaction between groups.

Conclusion: The addition dexmedetomidine to bupivacaine was not better than single-shot ACB regarding postoperative analgesia and ambulation ability following TKA.

Keywords: Adductor canal block, Bupivacaine, Dexmedetomidine, Total knee arthroplasty

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Total knee arthroplasty (TKA) surgery is associated with severe postoperative pain and adequate pain management is necessary for early postoperative mobilization and rehabilitation. Although good postoperative pain control may be achieved by continuous epidural anesthesia (CEA) or femoral nerve block (FNB), both methods have adverse effects such as muscle weakness, which may delay postoperative mobilization.[1]

Adductor canal block (ACB) has been recently introduced as a method capable of providing analgesia after TKA with mainly sensory blockade.[1-4] Randomized controlled trials have revealed that ACB provides at least equal analgesia as FNB, preserves quadriceps muscle strength better than FNB, and thus allowing for functional recovery within the first 24-hour post-TKA.[5-7] However, one important limitation of single-shot peripheral nerve block is the short duration of analgesia.

Correspondence to: Vachira Udompornmongkol, MD., E-mail: Vachirau@gmail.com
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Because the average duration of severe pain after TKA takes 2-3 days, a continuous ACB via catheter would seem to be a good choice. Unfortunately, perineural catheters may be technically difficult to insert, are prone to premature dislodgement, and may increase infection risk. There also were some case reports of local anesthetic-induced myotoxicity after continuous ACB.[8]

Various adjuvants have been used to enhance the duration and quality of local anesthesia. A randomized controlled trial showed that single-shot ACB with adjuvant was non-inferior to ACB catheter for TKA regarding opioid consumption.[9] Alpha-2 agonists, corticosteroids, morphine, and epinephrine have all been studied. Dexmedetomidine, a short-acting alpha-2 agonist, is commonly used to sedate patients in ICU. When combined with a local anesthetic, it enhances the duration of the local anesthetic block.[10] The effect of perineural dexmedetomidine is mainly peripheral, and it may exert its analgesic effects by maintaining the hyperpolarization of nerve fibers and blocking synaptic transmission.[10] In animal studies, dexmedetomidine as a perineural adjuvant was used safely in moderate doses and attenuated the bupivacaine-induced nerve injuries.[11-12] In human studies, dexmedetomidine as a perineural adjuvant act was used safely in some peripheral nerve blocks such as brachial plexus block[13], FNB[14] also ACB[15, 16] but the effects of the addition of dexmedetomidine to local anesthetics in ACB have not been well studied.

Thus, this study's primary objective was to study the analgesic efficacy of perineural dexmedetomidine with bupivacaine in adductor canal block in patients undergoing TKA. Moreover, the secondary objectives were to investigate the ambulation ability and side effects.

Methods

This study was a randomized, triple-blinded controlled trial study. The study protocol was approved by the Institutional Review Board of Faculty of Medicine, Chulalongkorn University, and the Ethical Committee of Rajavithi hospital and registered in the Thai Clinical Trials Registry (TCTR20190124002). All subjects must give written informed consent to participate in the study.

All consecutive patients who had an age between 18-85 years, ASA physical status I-III and underwent primary, unilateral TKA under spinal anesthesia were eligible for inclusion. Patients who the nerve block or spinal block could not be performed, known allergy to any of the study drugs, on recent oral opioids in the last three months, pregnancy, cannot answer the study question or use the patient-controlled analgesia (PCA) device, coagulopathy, body mass index (BMI) of >35 kg/m^2, severe renal insufficiency, severe alcoholic disease or neuromuscular disease were excluded. By using computer-generated block randomization (block size 4) and opaque sealed envelopes, patients were randomly allocated to receive bupivacaine plus dexmedetomidine (group D) or bupivacaine plus normal saline (group C) in ACB. The staffs involved in clinical care, the patients, and assessors were not aware of the treatment assignment.

Preoperative care: All patients were trained to use the PCA device preoperatively and explained to rate pain score using numerical rating scale (NRS) both at rest and during movement. The preoperative NRS and demographic data also were recorded. The quadriceps motor strength and the timed up & go (TUG) test were also assessed by a blinded physiotherapist preoperatively. All patients did not receive any pre-emptive analgesic medication. Intravenous antibiotic and tranexamic acid (750 mg) were administered 30 minutes prior to surgery.

Anesthesia: Peripheral venous access was established, and standard ASA monitors (pulse oximeter, electrocardiogram, non-invasive blood pressure) were applied to all patients on their arrival in the anesthesia room. Pre-hydration with 500 mL intravenous crystalloid was given. Spinal anesthesia was performed with the patient in a lateral recumbent position. A 27-gauge needle was inserted at the L3-4 intervertebral space, and after ensuring that clear

cerebrospinal fluid was in free flow, 15 mg bupivacaine (3.0 mL of a 0.5% hyperbaric solution) was administered to achieve sensory block at or above the T10 dermatome. All patients did not receive any sedative medication.

Surgical care: The total knee replacements were performed in the standard manner in all patients. Before insertion of the prosthesis, the cocktail solution of 20 mL of 0.5% bupivacaine, 1 mg epinephrine, and 500 mg tranexamic acid was given as intra-articular infiltration.[17, 18] A pneumatic tourniquet used and a suction drain used was recorded.

Experimental protocol: A nurse who was not involved in the study opened an opaque sealed envelope that decided whether the patient was to receive 20 mL of 0.25% bupivacaine plus 0.5 mcg/kg dexmedetomidine[15] or 20 mL of 0.25% bupivacaine plus 1 mL normal saline and prepared that perineural medication. The ACB was performed postoperatively at the postanesthesia care unit (PACU) by an experienced anesthesiologist who was blinded to the addition of a perineural adjuvant. After sterile preparation and draping, the 8-cm, 22-gauge needle (SonoTap-PAJUNK® USA) was inserted in-plane from the lateral side at the mid-thigh level in the supine position[19] and advanced through the sartorius muscle and fascia. ACB was performed under real-time ultrasound guidance, using an ultrasound machine (ALOKA CO., LTD, TOKYO, JAPAN) with a high-frequency linear ultrasound probe and the adductor canal, with the superficial femoral artery and vein within, was identified. Once the needle tip was located in the adductor canal, 1-2 mL of normal saline was injected to confirm the position of the needle then the perineural medication (20 mL of 0.25% bupivacaine plus 0.5 mcg/kg dexmedetomidine or 20 mL of 0.25% bupivacaine plus 1 mL normal saline) was injected anterior to the artery and deep under the sartorius muscle.

Postoperative care: The patient was observed at least 60 minutes in the PACU. Heart rate (HR), non-invasivearterial blood pressure (NIBP), and SpO_2 were monitored continuously for the first hour after the ACB, and then 6-hourly for the next 24 hours. If hypotension (defined as mean arterial pressure <80% basal value) occurred, the patient was treated with 6 mg ephedrine intravenously and 250 ml intravenous crystalloid in 10 minutes. If bradycardia (HR <60 bpm) occurred, the patient was treated with 0.6 mg atropine intravenously. If desaturation (SpO_2 <90%) occurred, the patient was treated with oxygen cannula 3 LPM. Nausea and vomiting score (3-point descriptive verbal scale, 0=no, 1=nausea, 2=retching or vomiting) was also assessed at 6, 12, 18, and 24 hours postoperatively, and the highest score during the period was recorded. If the symptom was persisted more than 15 minutes, or the patient requested, 4 mg ondansetron intravenous was given. Sedation score was assessed using Ramsey score (<u>If awake</u>: 1=anxious, agitated, restless, 2=cooperative, oriented, tranquil, 3=responsive to commands only, <u>If asleep:</u> 4=brisk response to light glabellar tap or loud auditory stimulus, 5=sluggish response to light glabellar tap or loud auditory stimulus and 6=no response to light glabellar tap or loud auditory stimulus) at 6, 12, 18, and 24 hours postoperatively, and the highest score during the period was recorded. If excessive sedation occurred (Ramsay score >4), the oxygen cannula 3 LPM was given, and the patient was closely observed. A blinded physiotherapist assessed the quadriceps strength and the TUG test at 48 hours after the ACB. A blind team member also assessed patient satisfaction at 48 hours after the ACB.

Postoperative pain management: At PACU, the patients were connected with the PCA devices, allowing them to control pain. The PCA device contained 100 mL of morphine 1 mg/mL with the setting of morphine bolus dose 1 mL, no background infusion, lockout interval 6 minutes, and 1 hour-limit 10 mg. Time to first rescue dose and morphine consumption in 24 hours were recorded. If no contraindication, two tabs of 500 mg paracetamol oral were taken q 4-6 hours in all patients. NRS pain score was also assessed at rest and on movement immediately after the ACB, and then 6-hourly

for the next 24 hours, and the score was recorded.

If postoperative delirium or postoperative cognitive dysfunction occurred, the outcomes that could not be collected were considered as the missing data.

Sample size calculation and statistical analysis

The comparison of the first rescue analgesic duration was the primary determinant of the sample size. The sample size was calculated based on the assumption that the addition of dexmedetomidine would increase the duration of analgesia 120 minutes, level of significance as 0.05, power as 80% and common standard deviation based on the previous study as 156.6720, assuming equal group sizes. The Sample size per group was calculated as 27. Therefore, a total of 60 cases were enrolled to cover for 10% dropouts.

All statistical analyses were performed using SPSS v22 (SPSS, Inc., Chicago, IL, USA). Continuous data were were tested the distribution using the Shapiro-Wilk test, and presented as mean and standard deviation for normally distributed data, and as median and interquartile range (Q_1 and Q_3) for non-normally distributed data. Categorical data were presented as frequency and percentage.

For between-group comparisons, the Student's t-test was used to test the difference of normal-distributed data and the non-parametric test was used to test in non-normal distributed data. Chi-square test was used to compare the for proportions between groups. Kaplan-Meier survival analysis with logrank test was used for comparisons of time to first rescue dose. Generalized estimating equation analysis (ordinal logistic) is used for the between-group comparisons of NRS pain score at rest and on movement over time. Intention to treat analysis is used for all outcomes, and p-value<0.05 was considered to indicate a statistically significant difference.

Results

Patient recruitment and flow through the protocol are described in the consolidated standards of reporting trials (CONSORT) diagram. (Figure 1) Two patients were excluded from the study due to not meeting the inclusion criteria and declination to participate. Therefore, 60 patients were randomized into two groups. (30 in group C and 30 in group D). In the perioperative period, two patients in group C were excluded from the study due to protocol violation where the patients did not receive the intraarticular cocktail solution, and two patients in group D were excluded from the study due to disagreement to continue and protocol violation where the patient did not receive the intraarticular cocktail solution. Finally, 28 patients in group C and 28 patients in group D were able for data analysis.

There were no differences between the group in demographic data including age, gender, BMI, ASA, preoperative pain score, and intraoperative data including duration of anesthesia, duration of surgery, baseline HR, baseline MAP, intraoperative fluid, intraoperative blood loss, tourniquet used, and drain used. (Table 1)

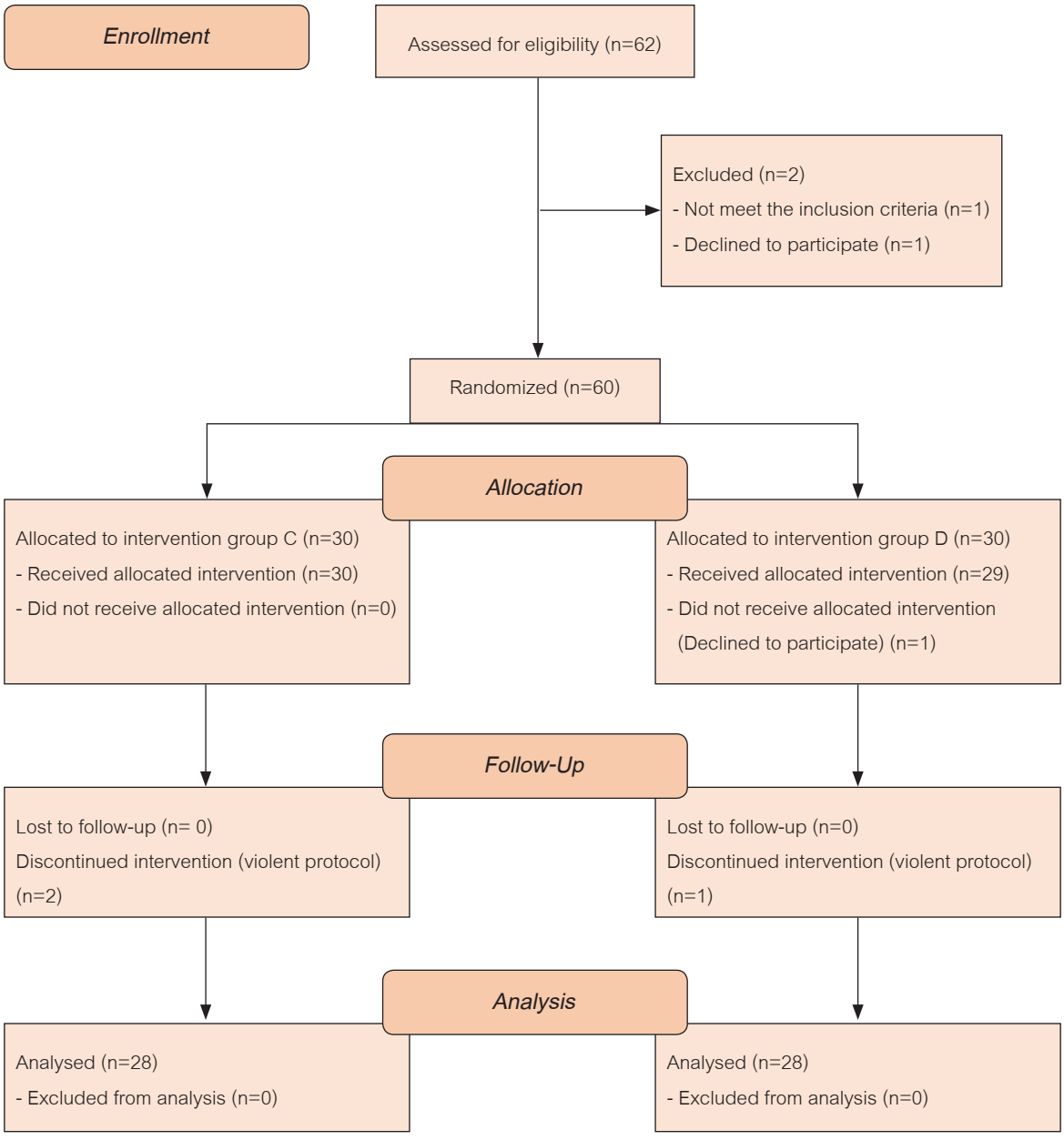

Figure 1 The Consolidated Standards of Reporting Trials (CONSORT) diagram

Table 1 Patient demographics and intraoperative data

	Group C (N=28)	Group D (N=28)	P-value
Demographic data			
Age (year)	69.11 ± 6.57	69.46 ± 6.60	0.840
Gender			0.716
M	5 (17.86)	4 (14.29)	
F	23 (82.14)	24 (85.71)	
BMI (kg/m^2)	27.36 ± 4.36	26.71 ± 3.24	0.527
ASA physical status			0.951
I	1 (3.57)	1 (3.57)	
II	20 (71.43)	21 (75.00)	
III	7 (25.00)	6 (21.43)	
Preoperative pain score			
At rest	0 (0, 0)	0 (0, 0)	0.927
On movement	6.5 (4, 8)	6 (5, 8)	0.589
Intraoperative data			
Duration of anesthesia (min)	110 (100, 133.75)	110 (101.25, 130)	0.980
Duration of surgery (min)	75 (70, 85)	80 (70, 83.75)	0.574
Baseline HR (beat.min^{-1})	74.36 ± 11.88	75.96 ± 15.44	0.664
Baseline MAP (mmHg)	107.93 ± 16.43	108.36 ± 15.88	0.921
Intraoperative fluid (mL)	1200 (1000, 1500)	1100 (1000, 1300)	0.231
Intraoperative blood loss (mL)	100 (20, 187.5)	100 (30, 200)	0.882
Tourniquet			0.567
Yes	10 (35.71)	8 (28.57)	
No	18 (64.29)	20 (71.43)	
Drain			1.000
Yes	17 (60.71)	17 (60.71)	
No	11 (39.29)	11 (39.29)	

Values are expressed as mean ± SD, median (Q_1, Q_3) or number of patients (%)

The Kaplan-Meier survival curve was shown in Figure 2. Two patients in group C did not equest any additional morphine in 24 hours. The median time to first rescue dose of morphine was not different between both groups (group C: 196 [89, 363], group D: 184 [105, 267], and P-value=0.112). Postoperative morphine consumption in 24 hours was not different between both groups (group C: 6.5 [4, 10], group D: 9 [3.25, 14.50] and P-value=0.245) and postoperative pain score assessed in the form of NRS (1-10) at rest and on movement also showed no significant differences at all points of follow up between groups (P-value=0.829 and 0.888, respectively). (Table 2)

One patient in group C and one patient in group D could not be assessed for postoperative quadriceps motor strength and TUG test. Therefore, 27 patients in group C and 27 patients in group D were able to ambulate ability data analysis, as shown in Table 3. There were no significant differences in TUG test between both groups at preoperative (group C: 21.21 [17.08, 39.99], group D: 24.19 [17.36, 32.10] and P-value=0.849) and at 48-hour postoperative (group C: 70.19 [59.66, 98.61], group D: 81.89 [49.12, 118.75] and P-value=0.966). When compared to the preoperative evaluation, both groups had significantly extended time of postoperative TUG test. The preoperative and

48-hour postoperative quadriceps strength were also similar between groups (group C: 16.68 [13.61, 21.54], group D:19.15 [14.58, 20.56] and P-value=0.647; group C: 12.83 [9.46, 16.56], group D: 12.86 [8.08, 17.12] and P-value=0.441, respectively).

The incidences and treatments of adverse events, including hypotension, bradycardia, nausea and vomiting, excessive sedation, and desaturation, showed no statistical differences between groups. The patient satisfaction rates of group C and group D also showed no statistical differences (group C: 2 [2, 2], group D: 2 [1.25, 2], and P-value=0.754) and no patient in both groups was dissatisfied the postoperative pain control. (Table 4)

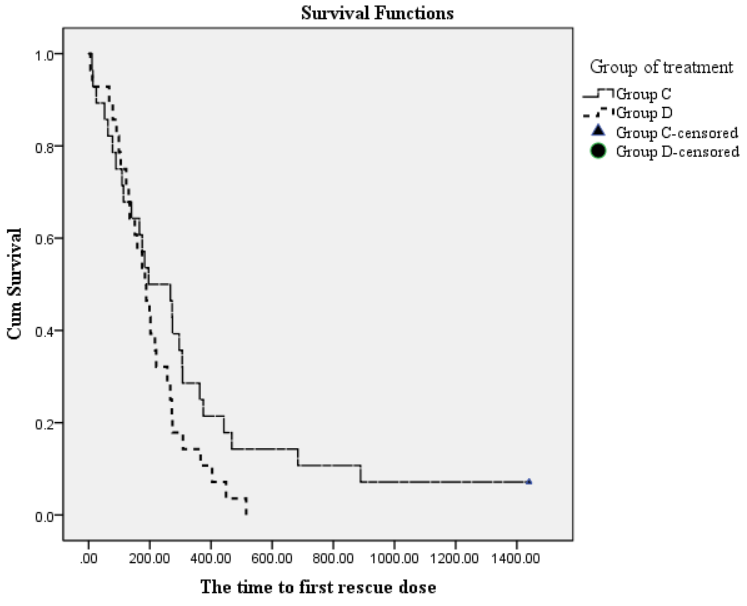

Figure 2 The time to first rescue dose

Table 2 Postoperative pain outcomes

	Group C (N=28)	Group D (N=28)	P-value
Morphine consumption in 24 h (mg)	6.5 (4, 10)	9 (3.25, 14.50)	0.245
NRS at rest			0.829
after ACB	0 (0, 0)	0 (0, 0)	
at 6 h	2 (0, 3)	3 (1, 5)	
at 12 h	2 (0, 4)	2 (0.25, 4)	
at 18 h	2 (0, 3.75)	1 (0, 2)	
at 24 h	0.50 (0, 2.75)	0.50 (0, 2)	
NRS during movement			0.888
after ACB	0 (0, 0)	0 (0, 0)	
at 6 h	3 (2.25, 5)	5 (3, 6.75)	
at 12 h	3.50 (2, 7)	3.50 (3, 5)	
at 18 h	3.50 (2, 5)	3 (2, 5)	
at 24 h	3 (1, 4.75)	3 (2.25, 4.75)	

Values are expressed as median (Q_1, Q_3)

Table 3 Ambulation ability outcomes

	Group C (N=27)	Group D (N=27)	P-value
Quadriceps strength (torque)			
Preoperative	16.68 (13.61, 21.54)	19.15 (14.58, 20.56)	0.647
Postoperative at 48 h	12.83 (9.46, 16.56)	12.86 (8.08, 17.12)	0.441
TUG test (min)			
Preoperative	21.21 (17.08, 39.99)	24.19 (17.36, 32.10)	0.849
Postoperative at 48 h	70.19 (59.66, 98.61)	81.89 (49.12, 118.75)	0.966

Values are expressed as median (Q_1, Q_3)

Table 4 Adverse events, treatments and patient satisfaction

	Group C (N=28)	Group D (N=28)	P-value
Hypotension	1 (3.70)	0 (0)	1.000
Received ephedrine	1 (3.70)	0 (0)	1.000
Bradycardia	0 (0)	0 (0)	N/A
Received atropine	0 (0)	0 (0)	N/A
Nausea and vomiting score			
During 0 - 6 h	0 (0, 0)	0 (0, 0)	0.322
During 6 - 12 h	0 (0, 0)	0 (0, 0)	0.317
During 12 - 18 h	0 (0, 0)	0 (0, 0)	0.585
During 18 - 24 h	0 (0, 0)	0 (0, 0)	0.317
Received ondansetron	1 (3.70)	4 (14.82)	0.352
Excessive sedation	0 (0)	0 (0)	N/A
Desaturation	0 (0)	0 (0)	N/A
Patient satisfaction score	2 (2, 2)	2 (1.25, 2)	0.754

Values are expressed as number of patients (%) and median (Q_1, Q_3)

Discussion

Adductor canal block (ACB), an alternative form of a peripheral nerve block (PNB), is almost a pure sensory nerve block that has been recently introduced as a method capable of providing analgesia with preserving quadriceps muscle strength after TKA.[1-4] Various perineural adjuvants have been studied with the aim of enhancing the duration and the quality of local anesthesia in single-shot ACB.[9]

Dexmedetomidine, a short-acting alpha-2 agonist, enhances the duration of local anesthetic block when combined with local anesthetics.[10, 21] The effect of perineural dexmedetomidine is mainly peripheral and it may exert its analgesic effects by maintaining hyperpolarization of nerve fibers and blocking synaptic transmission.[10]

The study of Kang Z et al. found that the application of dexmedetomidine caused some neurotoxicity in a dose-dependent manner and low dose dexmedetomidine is neuroprotective and suppresses both inflammatory response and neuronal death in neonate rats.[11] The present study used the low-dose of dexmedetomidine (0.5 mcg/kg), the low dose of clinical use, for adding to 0.25% bupivacaine 20 mL because we concerned that most of our participants were elderly patients.[22]

The present study's findings did not support our hypothesis that single-shot ACB with perineural 0.5 mcg/kg dexmedetomidine plus 0.25% bupivacaine 20 mL (group D) is better than single-shot ACB with 0.25% bupivacaine 20 mL (group C) in term of postoperative analgesia following TKA. The median time to first rescue dose of morphine, 24-hr morphine consumption and postoperative pain score at rest and on movement were not different between groups.

The study of Kampitak W et al. reported that combining local infiltrate analgesia (LIA) to single-dose ACB with 0.5% levobupivacaine 20 mL had a significantly longer time for 1st rescue dose (491 min vs 143 min, P-value=0.04).[20] The present study which also combined LIA to single-shot ACB had shorter the median time to first rescue dose (group C: 196 min). Compared to the study of Kampitak W et al., the present study used a mixture of 0.5% bupivacaine 20 mL, epinephrine 1 mg and tranexamic acid 500 mg, while the study of Kampitak W et al. used a mixture of 0.5% levobupivacaine 20 mL, morphine 5 mg, adrenaline 0.3 mg in saline solution in a total volume of 100 mL. In addition, our study used different concentration and type of local anesthetics for ACB (group C: ACB with 0.25% bupivacaine 20 mL) and used only oral paracetamol, not NSAIDs additional to PCA morphine. These things may the cause of the shorter median time to first rescue dose in our study.

Regarding the addition of perineural dexmedetomidine, unlike our study, Goyal R et al. demonstrated that addition of dexmedetomidine 0.25 mcg/kg and 0.5 mcg/kg to 10 mL of 0.75% ropivacaine (dilute to 20 mL per side) can provide longer duration of analgesia, lesser tramadol consumption and lesser pain on movement than 10 mL of 0.75% ropivacaine alone (dilute to 20 mL per side) in dose-dependent manner in ACB after simultaneous bilateral TKA.[15] The present study used the same dose of dexmedetomidine (0.5 mcg/kg) but we did not find any benefit concerning postoperative analgesia. Compared to the study of Goyal R et al., our study combined LIA to single-shot ACB and used oral paracetamol as a basic regimen. These things may lead to obscure analgesic effect of low dose of perineural dexmedetomidine.

Although ACB is almost a pure sensory nerve block, it still affects the motor function of vastus medialis muscle. So, we chose the low concentration as 0.25% of bupivacaine that was widely used in the previous study. The range of volume of local anesthetics used in the previous study for adequate spreading in the adductor canal was about 15-30 mL, so our study used volume 20 mL of 0.25% bupivacaine.[20]

Even if patients with adductor canal blocks may have greater preservation of quadriceps strength compared to patients with femoral nerve blocks, the study of Jaeger et al. reported that the median quadriceps strength of patients receiving adductor canal catheter was 52% of baseline.[23] Moreover decreased quadriceps strength after TKA can be expected even when a block is not performed at all.[24] Our study found that the median 48-hour postoperative quadriceps strength was 83.67% and 78.72% of preoperative baseline in group C and group D, respectively. Compared to the study of Jaeger et al., the present study performed a single-shot ACB, not a continuous ACB via catheter.

In the study of Goyal R et al., the addition of dexmedetomidine to local anesthetics resulted in the patients walked more steps but comparable quadriceps strength.[15] The present study also found no differences in preoperative and 48-hour postoperative quadriceps strength and TUG test between groups. The TUG test, unlike the stepped walk, is the time used to walk in the same distance. The median 48-hour postoperative TUG test (group C: 70.19 [59.66, 98.61], group D: 81.89 [49.12, 118.75]) was longer than preoperative baseline (group C: 21.21 [17.08, 39.99], group D: 24.19 [17.36, 32.10]) in both groups. These may due to decreased quadriceps strength and the use of walking aids in early postoperative period. However, there were high rates of patient satisfaction with low adverse event rates in both groups.

All ACB were performed by anesthesiologists with considerable experience in ultrasound-guided

peripheral nerve block. However, the success of the block was not determined after the bolus injection because the ACB was performed immediately postoperatively that spinal anesthesia was still not wear-off in most patients. Although every outcome measurement can be assessed except postoperative quadriceps strength and TUG test in 2 patients (1 in group C and 1 in group D) due to surgical conditions, the present study did not assess the cognitive function that can affect the clinical judgment in elderly patients. These may be considered as limitations of the study.

To our knowledge, the present study is the first study that evaluates the analgesic efficacy of dexmedetomidine as the perineural adjuvant with bupivacaine for the ACB following TKA. Further studies with a higher total dose of dexmedetomidine may be required to establish the efficacy of ACB with dexmedetomidine as the perineural adjuvant after TKA.

Conclusions

The addition of 0.5 mcg/kg dexmedetomidine to 20 mL of 0.25% bupivacaine is not better than single shot ACB with 20 mL of 0.25% bupivacaine regarding postoperative analgesia and ambulation ability following TKA. Although there were high rates of patient satisfaction with low rate of adverse event in both groups.

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