Clinical Investigation

Comparative study of ultrasound-guided continuous femoral nerve blockade with continuous epidural analgesia for pain relief following total knee replacement

Address for correspondence:
Dr. Harsha Shanthanna, St Joseph's Healthcare's Charlton Campus, 50 Charlton Avenue East, Hamilton, Ontario L8N 4A6 Canada.
E-mail: harshamd@gmail.com

Harsha Shanthanna, Medha Huilgol[1], Vinay Kumar Manivackam[1], Amjad Maniar[1]
Department of Anesthesiology and Pain Medicine, McMaster University, Health Sciences Centre 2U1, Hamilton, Ontario, Canada, [1]Department of Anaesthesia, Critical Care and Pain, Columbia Asia Referral Hospital, Bangalore, Karnataka, India

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ABSTRACT

Background: Regional analgesia is widely used for total knee replacement surgeries (TKR) as it has lesser side-effects and better analgesic efficacy when compared with traditional oral analgesics. Peripheral nerve blockade has also been utilized, including continuous infusion techniques. With the use of ultrasound, the needle and catheter placement can be done accurately under real-time guidance. This may prove a more suitable approach compared with the epidural technique. **Aims:** Post-operative analgesia in TKR patients was compared between continuous epidural analgesia (CEA) and continuous femoral block (CFB) techniques. VAS scores and use of rescue analgesic were used as parameters. Secondary aims included comparison of rehabilitation scores and side-effects in the form hypotension, vomiting, itching and urinary retention. **Settings and Design:** Randomised, controlled, non-blinded study done in a tertiary care private hospital. **Methods:** Forty-two patients fulfilling the study criteria were randomised into the CEA and CFB groups. In total, four patients: three in the CFB group and one in the CEA group, were excluded because of catheter migration. **Statistical Analysis:** Mean VAS score at 6, 6–24, 24–48 and 48–72 h were considered. Significance was assessed at the 5% level. **Results and Conclusion:** VAS scores were significantly high (P=0.001) in the femoral group at 6 h, after which there was a declining trend, and scores were essentially similar from 24 h. Common side-effects were more common in the CEA group. Our study shows that CFB gives equivalent analgesia compared with CEA in TKR patients with clinically meaningful decrease in side-effects.

Key words: Continuous femoral catheter, ultrasound, total knee replacement, epidural, regional analgesia

INTRODUCTION

Total knee replacement (TKR) causes moderate to severe pain requiring effective analgesia. Apart from good pain relief and comfort, analgesia assists physiotherapy-rehabilitation, reduces the hospital stay and improves overall recovery.[1] Usually a multimodal regimen including non-steroidal anti-inflammatory drugs (NSAIDS), opioids and regional analgesia (RA) is used. NSAIDS, even in moderate doses, can cause side-effects, especially in the elderly population. Although potent analgesics, opioids are also associated with some serious adverse effects, which might limit their analgesic potential. Apart from effective analgesia, RA decreases the neuroendocrine stress response, central sensitization and muscle spasms that occur in response to painful stimuli in TKR patients.[2] Among the RA techniques, continuous epidural analgesia (CEA) has been the mainstay for a considerable period. There is substantial evidence showing reduced blood loss and fewer thromboembolic complications using neuraxial techniques in orthopaedic surgery.

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Compared with opioids, perineural analgesia provides significantly better pain relief and also decreases the side-effects.[3] Peripheral neural blockade (femoral +/- sciatic nerve, lumbar plexus) is also used, mostly by paraesthesia with or without nerve stimulation techniques. Ultrasound-guided needle and catheter placement is observed to be technically superior, with much accurate needle placement.[4] Being placed at peripheral locations probably increases the safety latitude of these techniques compared with the epidural technique. Although seemingly effective with comparatively less risk, there are not many head-to-head studies to compare the two techniques. In the following study, we compared the use of CEA against CFB for effective and safe post-operative analgesia for TKR patients in a randomized, non-blinded, two-arm parallel study.

METHODS

After approval by the institutional ethical committee, all patients undergoing TKR and fulfilling the inclusion–exclusion criteria were approached. Exclusion factors included patient refusal, allergy to LA or other medications used in the study, coagulopathy, existing moderate to severe diabetic or other neuropathies and pre-existing severe pain conditions necessitating other analgesics, patients having bilateral TKR. For a primary outcome measure, VAS scores (0 no pain, 10 maximum pain) was used. Using an absolute reduction in the value of VAS by 2 units, a sample size of 40 patients was determined with 80% statistical power. After informed consent, patients were randomised into the CEA group or the CFB group using "random allocation software version 1.0.0" developed by the Department of Anesthesia, University of Medical Sciences-Isfahan, Iran. All patients in the CEA group had an epidural catheter inserted before spinal anaesthesia or general anaesthesia (GA); whereas in the CFB group, all femoral catheters were inserted after the surgery to lessen any impact on the operating list, with the availability of only one ultrasound machine. Epidural catheters were inserted through the L3-L4 interspace with loss of resistance to air technique using an 18 G Tuohy-epidural catheter set (B Braun Perifix epidural catheter set). Catheters were advanced until 4 cm within the epidural space. The differing timing in the introduction of catheters between the two groups creates a potential source of bias. However, care was taken to minimise any bias by inserting the femoral catheters and establishing analgesia before the patient was sensitised to post-operative pain. In cases having GA, femoral catheters were inserted and a bolus of LA mixture injected before extubation. In patients having spinal anaesthesia, femoral catheters were inserted and a similar bolus of LA mixture injected before the spinal analgesia wore off completely from the incision site. In all cases, the LA mixture injected was 12 mL bolus of 0.125% bupivacaine mixed with 2 mcg/mL fentanyl, which was similar to patients in the epidural group. Insertion of femoral catheters was done using continuous real-time US guidance under aseptic precautions using SonoSite-Micromaxx (SonoSite Inc., 21919 30th Drive SE, Bothell, WA 98021-3904, USA). The nerve was visualised in transverse view below the inguinal ligament; however, an in-plane approach with the Tuohy's 18 G epidural needle from the lateral aspect was used to position the needle just besides the nerve and a 18 G catheter (B Braun Perifix catheter set) was threaded in. (A small video of the same during insertion is presented in the online version of this paper.) All catheters were then tunnelled subcutaneously to bring them out laterally near the respective anterior superior iliac spine. In the CEA group, three out of 20 patients had GA and 17 had spinal anaesthesia. In the CFB group, six out of 22 patients had GA and 16 had spinal anaesthesia. In patients of GA, premedication was done using 1 mg of midazolam and 100 mcg of fentanyl. Induction was done using propofol 1% solution (1.5–2.5 mg/kg) with rocuronium (0.6 mg/kg) for muscle relaxation. Intra-operative analgesia was maintained with bolus doses of fentanyl 25 mcg to keep the heart rate and blood pressure within the range of 20% of the baseline measured pre-operatively. In all cases of GA, reversal was done with neostigmine (0.05 mg/kg) and glycopyrrolate (0.01 mg/kg) after confirming for at least three of the four (train of four) twitches with neuromuscular monitor. Similar to femoral catheters, all patients with epidural catheters were given a bolus of 12 mL of the same mixture before shifting to recovery. In recovery, level of blockade and analgesia was confirmed with testing for cold sensation and pin prick. In both groups, further doses were given and recorded to achieve satisfactory analgesia before shifting to the ward. Post-operative regimen for analgesia included continuous infiltration of a mixture of 0.125% bupivacaine with 2 mcg/mL of fentanyl, using the B Braun perfusor compact. The initial rate of infusion was set at 8 mL/h in both the groups, which was then titrated appropriate to patient's level of pain by the acute pain service (APS) personnel. The APS team would check on the patient twice each day. The change in rate was made after confirming no migration at the

skin entry site and adequate level of sensory blockade by testing for cold (ice) and also pin prick. This was similarly done in both the groups. The rate was reduced only in cases where it continued to provide optimum pain relief with improving physiotherapy. Any such change in the rate was noted and considered for that hour. The average rate of infusion was calculated as the mean for the day. All patients in both groups had oral proxyvon (paracetamol + dextropropoxyphene hydrochloride) three-times a day, given as a part of multimodal analgesia. Primary outcome measures were: (1) VAS scores (0–10) for pain and (2) the use of rescue analgesic in the form of IV tramadol 50 mg bolus. VAS scores at rest were recorded each hour for the first 6 h and every 2 h after that. For the sake of statistical analysis, mean VAS score measured over the first 6, 6–24, 24–48 and 48–72 h were considered. The first 6 h were considered as the intensity of pain is supposed to be highest during this time period and often necessitates increasing titration of analgesics. Secondary outcome measures included (A) rehabilitation-physiotherapy scores in the form of flexion, extension and range of motion, (B) side-effects in the form of nausea-vomiting, hypotension, difficulty in passing urine requiring catheterisation and itching and (C) patient satisfaction score. A rescue analgesic was administered whenever requested for by the patient. The time and the quantity of tramadol used were also noted. Rehabilitation in the form of passive and active knee movements was initiated from post-operative Day 1. The rehabilitation team member would note the active knee flexion and extension scores measured by a goniometer and record them. Catheters were observed for catheter migration, infection and were taken out at the end of 72 h in all patients. In Total, four patients: three in the CFB group and one in the CEA group, were excluded as catheters had to be taken out within 24 h due to migration outwards. A patient satisfaction score, on a scale of 1–10 (1 – least satisfied and 10 – most satisfied), was recorded before the patient was discharged from the hospital. In both groups, dalteparin sodium at a dose of 10,000 IU was given at least 12 h before the catheter insertion. The post-operative single daily dose was given only after 8 h, and then continued.

Statistical analysis

The statistical softwares, namely statistical analysis system (SAS) 9.2, statistical package for social sciences (SPSS) 15.0, Stata (Data Analysis and Statistical Software) 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver.2.11.1, were used for the analysis of the data. Descriptive statistical analysis was carried out. Results on continuous measurements are presented as mean ± SD and results on categorical measurements are presented as number (%). Significance was assessed at the 5% level of significance. Student's t test (two-tailed, independent) was used to find out the significance of study parameters on a continuous scale between two groups on metric parameters; Mann Whitney U test was used to find the significance between the two groups for parameters on the non-interval scale. Chi-square/ Fisher exact test was used to find the significance of study parameters on a categorical scale.

RESULTS

Catheters were easily inserted in all patients. The analysis of patient demographics showed that both groups were nearly matched with respect to age and gender [Table 1].

As shown in [Figure 1], VAS scores were significantly high (P=0.001) in the femoral group at 6 h, after which there was a declining trend and scores were essentially similar from 24 h. The use of rescue analgesic was also higher in the femoral group; eight patients required a bolus of tramadol 50 mg, with only one patient requiring 100 mg, compared with four patients in the epidural group. This difference was not statistically significant. After the first 6 h, use of rescue analgesic was nearly the same in both the groups. The mean rate of infusion was 8.5 mL/h in the femoral group and 7.5 mL/h in the epidural group. Neither the dose nor the rate were considered for analysis as they may be affected by the level of catheter infusion and the proximity of the catheter tip to the nerve.

Analysis of side-effects showed that all the four common side-effects were twice as common in the epidural group than in the femoral study group [Figure 2]. Only one patient in the femoral group had urinary retention when compared with four in the

Table 1: Patient demographics

	Epidural		Femoral	
	No	%	No	%
Age in years				
51-60	6	31.6	5	26.3
61-70	12	63.2	12	63.2
>70	1	5.3	2	10.5
Total	19	100	19	100
Mean±SD	63.58±5.04		63.53±4.96	
Gender				
Male	11	57.9	10	52.6
Female	8	42.1	9	47.4
Total	19	100	19	100

epidural group. The differences were not statistically significant. Four patients of the epidural group showed hypotension-systolic less than 90 mmHg. There were no infectious complications observed in either group. Rehabilitation scores were nearly the same in both the groups, as shown in Table 2. Patient satisfaction score was measured on a scale of 1–10. Patients in the epidural group were slightly more satisfied, with a mean±SD score of 8.11±1.05, when compared with the femoral group, 7.53±0.91.

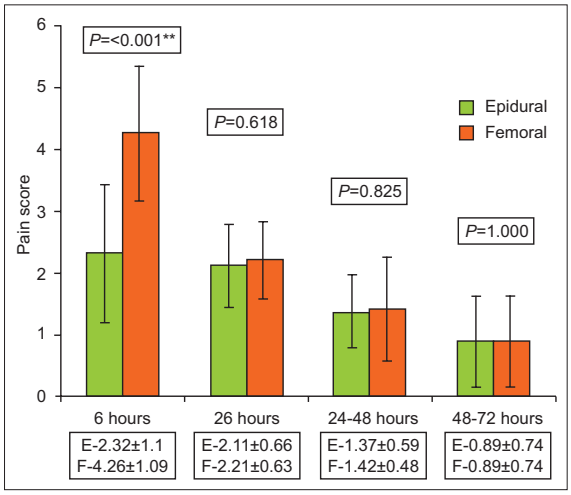

Figure 1: Graphical representation of post-operative pain scores; all values are mean+SD. *P* value obtained by Student's t test shows a highly significant difference at 6 h

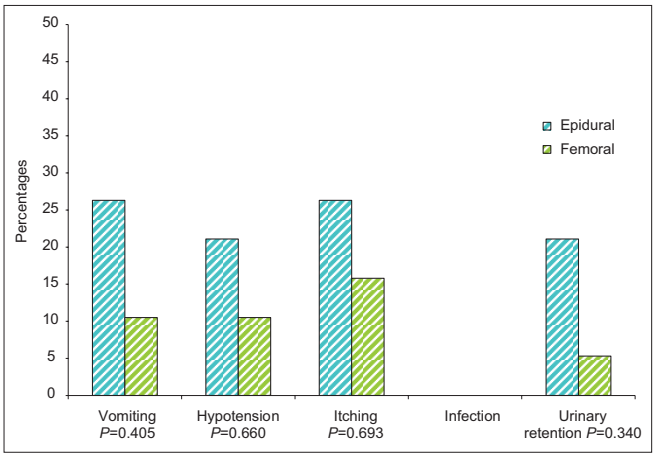

Figure 2: Graphical representation of the side-effects observed; depicted as % values

Table 2: Comparison of rehabilitation scores; results are median±Sd; *P* value is obtained by Mann Whitney U test

Rehab score	Epidural	Femoral	*P* value
Flexion			
1st post-op day	81.84±7.85	81.32±6.83	0.733
2nd post-op day	85.00±5.00	84.47±5.75	0.908
Extension			
1st post-op day	22.89±5.35	24.21±5.34	0.488
2nd post-op day	18.42±4.43	19.74±4.85	0.385
ROM			
1st post-op day	58.88±6.20	57.37±6.54	0.544
2nd post-op day	67.10±5.08	64.47±5.24	0.154

ROM - Range of motion

DISCUSSION

Our study demonstrates that "CFB provides equivalent analgesia compared to CEA after TKR, except for the initial 6 hrs, during which time it was significantly inferior". Our study also demonstrates that the common side-effects are more common with the epidural group compared with the femoral group. Earlier studies comparing the two techniques show results consistent with the present study.[5-7] In one of the largest studies, Barrington *et al.* showed equivalent analgesia between the two techniques.[5] Even the metaanalysis by Fowler *et al.* is in agreement with our finding, except for the first 6 h.[2] The use of tramadol as a rescue analgesic mirrored the difference showed by VAS scores; however, this was not significant. Earlier studies using other opioids have shown similar results.[6-8] The decreased efficacy of CFB compared with CEA in the first 6 h may be related to the sciatic nerve component for knee innervation, which was not blocked in the femoral group. Our observation showed that patients with CFB complained of pain in their calf. Anatomically, the knee joint derives its nerve supply predominantly from the femoral nerve; however, there seems to be an important component from the sciatic nerve that manifests as pain related to calf and leg.[9] Earlier studies are inconclusive regarding the necessity of sciatic blockade. The metaanalysis by Fowler *et al.* indicated no difference in pain scores between CEA and peripheral nerve blocks (PNB), even when analysed separately, with or without sciatic block. In a study by Ben-David *et al.*, 83% of the patients did not derive comparable analgesia with CFB alone and required addition of continuous sciatic infusion.[9] Weber *et al.* reported that 67% of the patients who had a femoral block required sciatic block post-operatively.[10] In fact, there are nearly an equal number of studies arguing sufficient[6,7] and insufficient blockade[10-13] with femoral blockade alone. Pham-Dang and others found similar results with increased pain scores in the first 36 h.[14] However, the continuous blockade of sciatic nerve has certain drawbacks, and the relative safety advantage of PNB when compared to epidural will only narrow.[15] The rehabilitation scores were similar in both groups at all times, as observed in other studies.[2,7,8] However, the "unilateral blockade" achieved by CFB encourages early mobilisation apart from passive and

active mobilisation of the operated limb. This was also observed by Barrington *et al*.[5] The incidence of common side-effects observed with CEA was lower in the CFB group by more than half. Although a statistical difference could not be achieved, probably because of the number of subjects, it was clinically meaningful and perhaps the most evident difference, given the equivalent analgesia and rehabilitation achieved with both techniques. Patients having TKR are mostly beyond 50 years, and many suffer from cardiovascular disease requiring anticoagulant medications. CFB does not necessitate withholding of these medications as rigorously as needed for CEA, which means lesser risk of altering the physiological profile. Another deviation from the consensus opinion was the performance of PNB on anaesthetised patients in our study. Catheters are mostly inserted pre-operatively as a routine practice. However, femoral catheters were inserted post-operatively to lessen any impact on the operating list. Despite the theoretical concern of nerve injury, there are no prospective randomised controlled studies that compare the relative risks of PNB performed on anaesthetised against conscious patients. In general, there is insufficient published data to lend support to either argument.[16,17] In fact, an earlier audit done by the American Society for Regional Anesthesia had shown that the practice is common in adults and children.[18] In an extensive survey, Stats *et al.* analysed 1065 PNB with patients being followed-up for 12 months prospectively. Forty-five percent of those blocks were performed under GA. Thirteen patients showed neurological complications, of which only two were done under anaesthesia.[19] Sawyer quotes a background incidence of one nerve palsy in 1000 (0.1%) with GA alone.[20] Considering that ultrasound (US) was not used in most of the earlier studies of PNB, it is difficult to compare the techniques where real-time US guidance was used. However, we agree with the general consensus that PNB done in conscious patients possibly provides an additional level of safety. In our study, the "patient satisfaction score" indicated slightly better scores with CEA. This was not significant.

CONCLUSION

Our study demonstrates that continuous femoral blockade using US guidance provides equivalent analgesia with a lower incidence of common side-effects when compared with continuous epidural analgesia. It is also associated with decreased exposure to potentially significant neuraxial complications. The inferior analgesia in the initial period may be helped by a single-shot sciatic blockade.

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