Original Article

A randomized, controlled trial of comparison of a continuous femoral nerve block (CFNB) and continuous epidural infusion (CEI) using 0.2% ropivacaine for postoperative analgesia and knee rehabilitation after total knee arthroplasty (TKA)

Harshil J. Gandhi, Lopa H. Trivedi, Deepshikha C. Tripathi, Deepika M. Dash, Amit M. Khare, Mayur U. Gupta

Department of Anaesthesiology, Government Medical College and Sir T. Hospital, Bhavnagar, Gujarat, India

Abstract

Background and Aims: Postoperative pain relief following total knee arthroplasty (TKA) is a major concern as it will help to achieve an effective functional outcome. The present study was conducted to compare continuous femoral nerve block (CFNB) and continuous epidural infusion (CEI) techniques using ropivacaine.

Material and Methods: Forty patients were randomly allocated into group F and group E to receive 0.2% ropivacaine through femoral catheter or epidural catheter respectively. An infusion was started @6 ml/h post-operatively when VAS was ≥4. The dose was titrated to keep VAS <4 (with minimum rate 2 ml/h and maximum rate 10 ml/h). If VAS ≥4 occurred despite maximum rate of infusion, a rescue analgesic was given. Primary objectives were to compare visual analogue score (VAS), rehabilitation indices, and rescue analgesic requirement. Secondary objectives were to assess patient and surgeon's satisfaction score, motor blockade, and complications if any.

Results: The mean VAS score, rehabilitation goals, rescue analgesic requirement, and patient's and surgeon's mean satisfaction scores were comparable in both the groups. Motor blockade was not seen and though the number of side effects were more in group E, they did not achieve statistical or clinical significance.

Conclusion: CFNB can be used as an alternative, effective postoperative analgesic technique for TKA.

Keywords: Continuous epidural infusion, continuous femoral nerve block, ropivacaine, visual analogue score

Introduction

Total knee arthroplasty (TKA) causes moderate-severe postoperative pain. Optimum postoperative analgesia will help to achieve an effective functional outcome. Multiple techniques have been tried for post-TKA pain control include intravenous patient-controlled analgesia (PCA), peripheral nerve blockade, and continuous epidural analgesia (CEA) techniques.[1]Continuous epidural analgesia remains a technique of choice for post operative analgesia.

Continuous peripheral nerve blockade using nerve locator or ultrasound guidance provides effective analgesia following TKA with fewer side effects. Till date, there are only a few studies which compare CFNB and CEA for the

Address for correspondence: Dr. Harshil J. Gandhi, Department of Anaesthesiology, Government Medical College and Sir T. Hospital, Bhavnagar - 364 001, Gujarat, India.
E-mail: Drharshilgandhi@gmail.com

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postoperative pain relief in TKA. Hence, we proposed to conduct present study to compare the two regional techniques using a relatively newer drug ropivacaine, s (-) enantiomer, known to have an excellent sensory effect.[2]

Material and Methods

After Institutional Review Board (IRB), approval (IRB No: 448/2014), and informed written consent from the patients, this prospective randomized clinical study was conducted in 40 adult patients in year 2013–2015. Sample size was calculated after assuming SD of 1, with permitted alpha error 0.05 and power of study 0.8. A minimum sample size of 17 was needed, hence a sample size of 20 patients in each group was chosen for the study. After thorough pre-anesthetic assessment and necessary investigations, patients aged 40 to 80 years, of either sex with American society of Anaesthesiologist (ASA) physical status I-III and BMI ≤30_kg/m^2 scheduled for primary TKA under subarachnoid blockade were included in the study. The patients with revision or infected TKA, peripheral neuropathy, allergy to local anesthetics, and contraindications of regional anesthesia (local site infection, coagulopathy, previous nerve injury, psychiatry illness, and uncooperative patients) were excluded from the study.

The patients were randomized to two groups (Group F and Group E), 20 patients in each group by computer-generated random number sequence. The patients were kept nil by mouth 8 h before the surgery. All patients were given tablet alprazolam 0.5 mg on the night before surgery. In pre-anesthetic room, vital parameters such as heart rate (ECG), mean arterial blood pressure (NIBP), and peripheral oxygen saturation (pulse oximeter) were recorded, and 18G intravenous line was secured, and administered injection midazolam 1 mg intravenously before 30 min of surgery. In the operation theater, under all strict aseptic precautions in group F, femoral catheter (Contiplex D) was inserted and in group E, epidural catheter 18G (B Braun) was inserted.

In group F, the femoral catheter was inserted in femoral canal just below inguinal ligament using nerve locator (B Braun). Localization of femoral nerve was confirmed by quadriceps twitch at <0.5 mA using stimulation of 2 Hz; the catheter was passed 5 cm past the cannula.

In group E, epidural catheter 18G was inserted using 18G Tuohy epidural needle in left lateral position in L2-L3 intervertebral space. Epidural space was located by hanging drop method, and catheter was inserted 5 cm past the cannula. In all the patients after femoral or epidural catheter insertion, subarachnoid block was given in lateral position in L3-L4 intervertebral space using 25G spinal needle with 3 ml of 0.5% hyperbaric bupivacaine as a standard volume across all groups and also to achieve a dense sensory block to a level of T10.

Postoperative pain was assessed using visual analogue score (VAS). [VAS score: 0-no pain, 1 to 4-mild pain, 4 to 7-moderate pain, 8 to 10-severe pain, and 10-worst possible pain]. A continuous infusion of ropivacaine 0.2% was started at 6 ml/h when VAS was ≥4 (Maximum infusion rate was 10 ml/h and minimum infusion rate was 2ml/h). The infusion of ropivacaine was titrated at 1, 2, 4, 6, 8, 12, 24, 36, 48, and 72 h postoperatively depending on VAS score. The goal was to keep VAS <4. If any time VAS was ≥4, even if with maximum infusion rate, injection diclofenac sodium 1.5 mg/kg was given intravenously as a rescue analgesic.

All patients were also monitored for rehabilitation indices, satisfaction of the procedure, motor blockade, and complications if any (such as PONV, hypotension, giddiness, numbness/itching, and urinary retention). Surgeons were also asked about their response. Hypotension was defined as 30% reduction of BP from baseline.

Rehabilitation indices were assessed on post-operative day (POD) 1, 2, and 3. On the POD1, the patients were expected to be able to sit at the bedside and stand with help. On the POD2, they were expected to stand without help, able to walk using a walker and transfer to the chair with help. On the POD3, they were expected to transfer to a chair, walk, and mobilize without help.

Patients and surgeons were asked about their satisfaction to the procedure on POD1, POD2, and POD3 (Satisfaction scoring system: 1-poor, 2-good, and 3-excellent). Motor blockade was estimated_at 1, 2, 4, 6, 8, 12, 24, 36, 48, and 72 h intervals postoperatively using a modified Bromage scale (0-no blockade, 1-can flex knee, move foot but cannot raise leg, 2-can move foot only, and 3-cannot move foot or knee). Failure of the procedure was considered if hemorrhagic tap; CSF tap (in case of epidural) was seen, and there was accidental dislodgement of the catheter.

Results

In the present study, the demographic data of the patients in both the groups were comparable ($P > 0.05$) [Table 1].

The mean VAS pain scores at 1, 2, 4, 6, 8, 12, 24, 36, 48, and 72 h were comparable in both the groups, and difference was not significant statistically ($P > 0.05$) [Table 2].

On POD1, in group F, 60% patients and in group E, 70% patients were able to stand with help. On POD2, in group F, 75% and in group E, 60% patients were able to transfer himself to chair with help. On POD3, in group F, all patients and in group E, 95% patients were able to walk and mobilize without help. The differences in achieving rehabilitation goals among both groups were not significant statistically ($P > 0.05$) [Figure 1].

In group F, 6 patients (30%) required rescue analgesia in 1st 24 h, whereas in group E, 4 patients (20%) required rescue analgesia. After 24 h, no patients were required rescue analgesic in either group [Figure 2].

All patients were equally satisfied and difference was not significant statistically ($P > 0.05$) [Figure 3]. Surgeons were equally satisfied with both the procedures. ($P > 0.05$) [Figure 4].

Side effects were more with the CEI group. In group F, 2 patients and in group E, 4 patients had PONV, however, the difference was not significant statistically. ($P > 0.05$) In group E, 3 patients had hypotension and 2 patients had itching.

There was no motor blockade seen in either group. Two patients were already excluded from the study (In one patient, there was accidental dislodgement of the femoral catheter and in one patient epidural catheter converted in-to subarachnoid catheter).

Statistical methods

Statistical analysis was done by graph pad instat 3.0 software. A P value ≤ 0.05 is considered significant. Values on continuous measurements are presented as mean ± standard deviation, and values on categorical measurement are presented as number (%). Intergroup comparison was done using the unpaired student t test for quantitative data and Chi-square test for qualitative data.

Table 1: Demographic profile of patients

Demographic profile	Group F	Group E	*P*
Age (years) (Mean±SD)	57.65±6.82	59.10±8.30	0.52
Gender (M/F)	4/16	5/15	>0.75
Weight (kg) (Mean±SD)	65.40±7.29	64.80±8.71	>0.99

Table 2: Mean VAS score of the patients

Vas score	Group F (mean±SD)	Group E (mean±SD)	*P*
1 h	0.95±0.83	0.85±0.93	0.64
2 h	1.58±1.46	1.75±1.02	0.99
4 h	1.45±1.00	1.30±0.92	0.49
6 h	1.30±1.30	1.55±1.20	0.41
8 h	0.65±0.87	0.85±0.88	0.43
12 h	0.45±0.83	0.65±0.75	0.25
24 h	0.20±0.70	0.15±0.37	0.82
36 h	0.20±0.62	0.10±0.31	0.97
48 h	0.1±0.31	0.00±0.00	0.00
72 h	0.1±0.31	0.00±0.00	0.00

Discussion

TKA is associated with postoperative pain, which is moderate in 30% and severe in 60% of patients.[2] Hence, the main focus is to provide postoperative analgesia during initial 48–72 h thereby allowing early ambulation and rehabilitation. Till date, epidural analgesia remains the "gold standard," but it has rare and sometimes serious postoperative neurological and cardiovascular complications such as epidural hematoma (0.5 per 10,000), abscess formation (<0.3 per 10,000), and cardiac arrest (1 per 10,000).[3]

Peripheral nerve blocks provide intense site-specific analgesia, has lower side effects compared to epidural technique, and can be given in case of epidural failure.

While comparing analgesic efficacy, in the present study, VAS score was comparable in both the groups. The result was

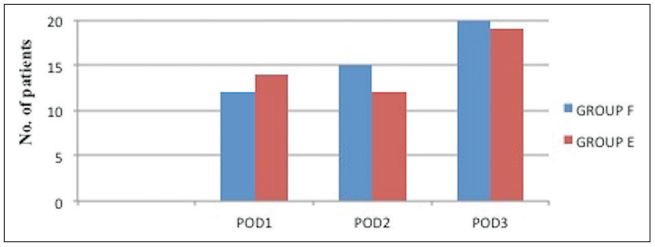

Figure 1: All rehabilitation goals achievements in both the groups. POD - Post Operative Day, POD1-Post Operative Day, POD2- Post Operative Day2, POD3- Post Operative Day 3

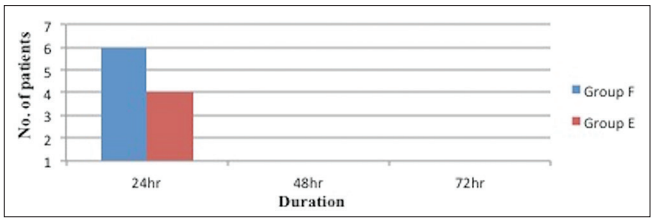

Figure 2: Rescue analgesic requirement in each group

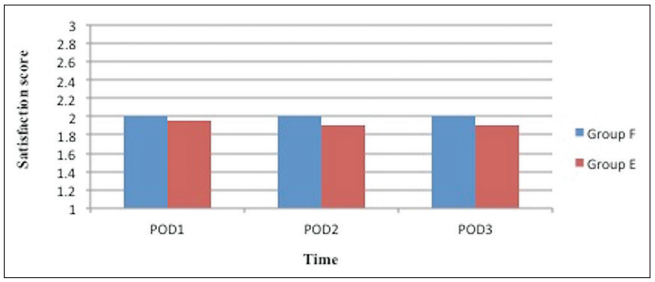

Figure 3: Patient's mean satisfaction score comparison. POD - Post operative day, POD1- Post Operative Day1, POD2- Post Operative Day2, POD3- Post Operative Day3

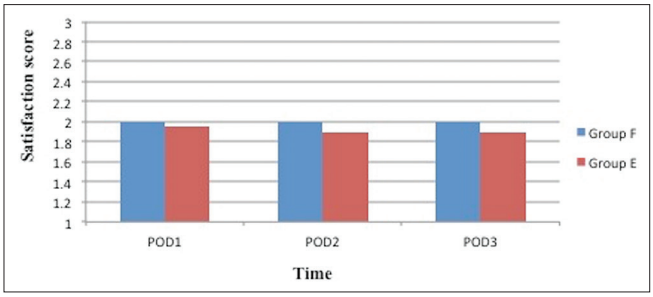

Figure 4: Surgeon's mean satisfaction score comparison. POD - Post Operative Day, POD1- Post Operative Day1, POD2- Post Operative Day2, POD3- Post Operative Day3

comparable with the results of the study done by Barrington *et al.*[4] who observed equivalent analgesia between CFNB and CEA groups after TKA. However, he used 0.2% bupivacaine for femoral infusion and 0.2% ropivacaine with 4 mcg/ml fentanyl for epidural infusion. The meta-analysis done by Fowler *et al.*[5] showed equivalent analgesia in both CFNB and CEA group. In the study done by Capdevilla X *et al.*[6] showed no significant difference in VAS scores between both the groups using continuous epidural and continuous femoral infusion with 1% lignocaine, 0.03 mg/ml morphine, and 2_mcg/ml clonidine at the rate of 0.1 ml/kg/h. In the study done by Patchara Sundarathiti N *et al.*[7] patients received a continuous infusion of 0.125% levo-bupivacaine at 8 ml/h in CFNB group, whereas continuous infusion of 0.125% levo-bupivacaine with morphine 0.0125 mg/ml was used in the epidural group. They found that there were no significant differences in the VAS scores for the first hour and at postoperative 12–72 h between the two groups. At postoperative 6–12 h, the VAS scores were significantly greater in the CFNB compared with the CEA, mainly due to inability of femoral approach to block sciatic and obturator component.

The motor blockade was assessed with the modified Bromage scale at different intervals, and there was no motor blockade seen in either group in the present study due to motor sparing effect of ropivacaine. In contrast to the present study, a study done by Patchara Sundarathiti N *et al.*[7] have found more intense blockade with CFNB than CEA group. A study done by Mulroy MF *et al.*[8] found more intense motor blockade in CFNB group, which could be ascribed to use of bupivacaine in their studies.

Rehabilitation of a patient after TKA plays a vital role in surgical outcome. The goal of physical therapy during the early post-operative phase (0–3 days) is to decrease swelling, increase range of motion, enhance muscle control, and strength in the involved lower extremity and maximize patient's mobility with a goal of functional independence. In our institute, postoperative physical exercise is done in the form of quadriceps muscle strengthening, resistive ankle, and foot movements with sustained leg rising as soon as possible. In the present study, achievements of goals were comparable in both the groups ($P > 0.05$).

Conclusion

CFNB and CEA both provide satisfactory and comparable analgesia, rehabilitation, and patient's as well as surgeon's satisfaction. Side effects such as PONV, hypotension, and itching are more in CEA than in CFNB group, however shall need a larger sample size in future studies to delineate clinical and statistical differences among these groups.

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Conflicts of interest

There are no conflicts of interest.

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