# Continuous epidural analgesia versus continuous femoral nerve block in management of post-operative pain in patients undergoing unilateral total knee arthroplasty: An open labelled randomized controlled trial

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## Abstract

**Introduction:** The most common concern associated with TKR is post-operative pain for both the patient and the surgeon. It is associated with multiple adverse physical and psychological consequences, which hinder postoperative mobilisation, increase the incidence of post-operative complications and the overall outcome. A number of modalities have been recommended of which regional techniques are preferred. Current study aims to compare post-operative management of pain in patients undergoing Total Knee arthroplasty (TKA) with epidural analgesia versus femoral nerve block.

**Material and methods:** Study was done in 100 patients posted for unilateral TKA. After obtaining written consent and ethical committee clearance patients were randomized in to two groups. Group "CEA"-8 mL 0.2% ropivacaine was given epidurally and Group "CFB"-bolus of 20 mL of 0.2% ropivacaine was given through femoral catheter.

Outcomes assessed were

- 1) Acute postoperative pain (during rest and movement).
- 2) Postoperative rescue analgesic consumption/rescue analgesia.
- 3) Quality of early postoperative rehabilitation (functional assessments).
- 4) Postoperative complications if any.

**Results:** There was no significant difference in Vas score during rest and activity in both the groups at 6 hrs,12, 24, 48 and 72 hours. There was no significant difference in both the groups with respect to rehabilitation indices and adverse events. Only 43.4% of patients belonging to group CFB, received rescue analgesia which was less when compared to patients in group CEA(57.6%) which was significant.

**Conclusion:** CFA have the advantage over CEA in terms of decreased need for rescue. analgesia with no neuraxial side effects.

**Keywords:** Continuous epidural analgesia, continuous femoral nerve block, post-operative pain, total knee arthroplasty

#### Introduction

Total Knee Replacement (TKR) helps relieve pain and restore motion in patients with severe knee Arthritis. Total TKRs being reported to registry increased from 1019 in 2006 to 27,000 in 2019. Majority of the patients (98.5%) were diagnosed with osteoarthritis knee <sup>[1]</sup>. TKR surgeries are now being increasingly performed in the younger age groups. The most common concern associated with TKR is post-operative pain for both the patient and the surgeon.

Post-operative pain is associated with multiple adverse physical and psychological consequences, which hinder postoperative mobilisation, increase the incidence of post-operative complications and potentially influence the overall outcome <sup>[2]</sup>. A number of modalities have been recommended for management of post-operative pain, including Administration of pre-emptive analgesics, continuous epidural infiltration, patient-controlled analgesia, peripheral nerve block: femoral nerve block, continuous intra-articular infusion and local intra-articular analgesic injection <sup>[3]</sup>.

Multimodal analgesia combining two or more of the above-mentioned modalities are recommended and found to be beneficial <sup>[4]</sup>. Of all these modalities, regional techniques are preferred over the others <sup>[5,6]</sup>.

Continuous Epidural analgesia (CEA) has the advantage of providing good analgesia and thus enabling early mobilisation and rehabilitation after TKA. Recently, femoral block is gaining popularity with the increasing use of ultrasound. Femoral Nerve Block (CFB) is found to be enough to provide adequate analgesia after knee surgeries and can be used as a good alternative to epidural block <sup>[7]</sup>. CFB is less likely to have complications seen with central neuraxial techniques and can be used as an alternative where epidural is contraindicated.

The current study aims to compare post-operative management of pain in patients with epidural analgesia versus femoral nerve block.

### **Materials and Methods**

A comparative study was conducted in a tertiary care teaching hospital, India after obtaining approval from Institutional Ethics Committee. Study was done in patients admitted in orthopaedic department for Total knee arthroplasty during February 2018 to December 2020.

Inclusion: Patients between the age range of 20-65 years, a diagnosis of knee osteoarthritis according to the criteria of the American College of Rheumatology <sup>[8]</sup>; an American Society of Anesthesiology (ASA) physical status of I-II <sup>[9]</sup>; no intra-articular treatment with any drug during the past 3 months; no history of prior knee surgery and of BMI less than 30 were included in the study.

Exclusion criteria: Patients with bleeding disorders, infection at the site of block, history of chronic analgesic usage, allergy to local anaesthetics, duration of surgery more than 150 minutes. Simultaneous or staged bilateral TKA or revision surgery, a known history of allergic reaction to any of the test agents, severe chronic medical diseases or chronic disabling diseases were excluded from the study.

For sample size calculation, the study by Shanthanna H *et al.*, with average standard deviation 0.53 was considered to get a power of 80% and a confidence interval of 95% using the formula <sup>[7]</sup>:

$$n = (Z\alpha + Z\beta)^2 SD^2 \times 2/d^2$$

Where,  $Z\alpha=1.96$ ,  $Z\beta=0.84$ , SD=standard deviation, d=effect size 0.31. From this the samplesize (n) needed was found to be 45 in each group.

With non-response rate of 10% sample size was 50 in each group.

Hundred patients who were posted for unilateral TKA were selected by purposive sampling method. Patients were randomised and assigned to either of two groups.

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**Group "CEA":** 8 mL 0.2% ropivacaine was given epidurally. **Group "CFB":** Bolus of 20 mL of 0.2% ropivacaine was given through femoral catheter.

# Method of study

After obtaining written informed consent, Pre-anaesthetic check-up and routine investigations were done.

# Preoperatively

- Nil per oral status was confirmed.
- The procedure was explained and the patient was informed to communicate about perception of any pain or discomfort during the surgery which can be recorded using visual analogue scale.
- Patients were premedicated with tab diazepam 10 mg and tab ranitidine 150 mg orally.

# Procedure

Intra venous (IV) access was obtained using 18 gauge (G) IV cannula and Lactated Ringer's solution 500 ml was infused intravenously. In the operating room, monitoring procedures were started to record baseline ECG, PR, BP, RRand SpO<sub>2</sub> till the end of the surgery.

All patients were operated under general anaesthesia without any additional regional anaesthesia technique. TKA was performed through the traditional anterior medial parapatellar approach using a Scorpio non-restrictive geometry posterior- stabilised system (Stryker Howmedica Osteonics, NJ, USA) fixed with cement without patellar replacement. Duration of surgery and the total intraoperative blood loss, including the blood in the suction bottle (after deducting the lavage fluid)and the weights of gauze and sponges were recorded. A drain was clamped in place for the first 6 h postoperatively and removed on post-operative day (POD) 2. For patients in group CEA, 18 G epidural catheter was inserted at L2-3 interspace using 18 G Tuohy needle by loss of resistance technique to air. A test dose of 3 mL of 2% lignocaine with 1 in 2 lac adrenaline was given to rule out intravenous or intrathecal catheter placement. After the completion of surgery and before the analgesia of spinal wore off completely, patients in group CFB were given femoral block on the operated limb through an 18G catheter inserted under ultrasound guidance using in-plane approach and secured by tunnelling into subcutaneous tissue.

After surgery, CEA and CFB was commenced. Sensory block was assessed and confirmed using pinprick and cold sensation and continuous infusion of 0.2% ropivacaine at a rate of 5 mL per hour was given in both groups till 72 hours. Pain was assessed by horizontal visual analogue score (HVAS) at 6,12,24,48and 72 hours postoperatively and also on post-operative day 7 and 14 (POD) <sup>[10]</sup>. When HVAS > 4tramadol 50mg IV was given.

Rescue analgesics requirement during was assessed. Epidural or femoral catheters were periodically checked to rule out migration or infection at the site of insertion and were removed 72 hours post-surgery. Postoperative knee rehabilitation indices were measured by percentage of patients who were able to sit at the bedside and stand with help on the first POD1. On POD2 percentage of patients who were able to stand without help, use the walker, and transfer to chair with help was analysed. Percentage of patients who were able to transfer to a chair and do

walker mobilisation without help was looked for on POD3. Side-effects such as hypotension, dizziness, nausea, vomiting, urinary retention, respiratory depression were recorded.

**Data analysis:** Data collected in a structured questionnaire, entered and analysed using SPSS 22. Chi-square statistic and t test was used with P<0.05 as statistically significant.

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## Results

The mean age of the patients was 54.1 years. Majority of the patients were females (60%).Out of 100 patients 26% belong to ASA score I and 74% belong to ASA score II. Varus (79%) was the most common type of deformity in the patients. Out of 100 patients 69% of patients were either overweight or obese. Co-morbidities were present in 69% of patients (like hypertension, diabetes, thyroid and COPD). The patients in both the groups were similar with respect to age, gender, ASA classification, Type of deformity, BMI, Comorbidities, duration of surgery and estimated blood loss (table 1).

Parameters		Group CEA(n=50)	Group CFB (n=50)	Total (n=100)	P value
Age (mean ± SD)		53.2± 6.7	55±8.9	54.1±9.3	T test-1.1425/p- value0.2560
gender	Male	19	21	40	X <sup>2</sup> -0.1667/p-
gender	Female	31	29	60	value0.68
ASA	Score I	12	14	26	X <sup>2</sup> -0.2079/p-
Classification	Score II	38	36	74	value0.64818
	Varus	39	40	79	X <sup>2</sup> -2,4308/p-value 0.296585
Deformity	Valgus	4	7	11	
	No deformity	7	3	10	0.290383
BMI	Normal	13	18	31	X <sup>2</sup> -1.1688/p-0.27
	Overweight and obese	37	32	69	
Comorbidities	Present	33	36	69	X <sup>2</sup> -0.4208/p-value
	Absent	17	14	31	0.516
Duration of surgery (in minutes)		$90 \pm 17$	97±12	$93.5\pm18$	T test-1.3593/p- value0.1772
Estimated blood loss (in ml)		$345.2\pm56.1$	352 ± 66.1	349.1± 67.8	T test-0.5546/p- value0.5804

Table 1: Distribution	of patients	in Group C	EA versus	Group CFB
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Table 2: Visual analogue scale score for pain at rest in Group CEA versus Group CFB

<b>Baseline post-operative Time</b>	Group CEA (mean ± SD)	Group CFB (mean ± SD)	T test/p-value
6 hours	$4.92 \pm 1.02$	5.2±0.6	1.6731/0.0975
12 hours	$4.01{\pm}1.08$	$4.10 \pm 1.12$	0.4090/0.6834
24 hours	$3.98 \pm 1.25$	$3.85 \pm 1.23$	0.5242/0.6013
48 hours	1.56±0.72	1.62±0.3	0.5439/0.5877
72 hours	1.43±0.2	1.51±0.32	1.4991/0.1371
POD 7	$1.23 \pm 0.4$	1.02±0.2	3.3204/0.0013
POD 14	1.3±0.1	1.01±0.1	14.500/0.0001

The mean Visual analogue scale score for pain at rest was high initially and decreased with time. There was no significant difference in Vas score in both the groups at 6,12,24,48and 72 hours. In POD 7 and POD 14 VAS score was slightly low in Group CFB which was significant.

Table 3: Visual analogue scale score for pain during activity in Group CEA versus Group CFB

At Time in hours	Group CEA (mean ± SD)	Group CFB (mean ± SD)	T test/p-value
6 hours	$8.2\pm0.9$	$8.2 \pm 0.7$	0.00/0.1
12 hours	$7.6{\pm}1.08$	$7.3 \pm 0.8$	1.5783/0.1177
24 hours	$6.2 \pm 1.2$	6.1± 1.21	0.4149/0.6791
48 hours	5.21±0.76	5.11±0.4	0.4123/0.8233
72 hours	3.42±0.6	3.11±0.3	0.0015/3.2677
POD 7	2±0.3	1.9±0.2	1.9612/0.0527
POD 14	1.7±0.31	1.5±0.12	4.2544/0.0001

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The mean visual analogue scale score for pain during activity was high initially and decreased with time. There was no significant difference in Vas score during activity in both the groups at 6 hrs,12, 24, 48 and 72 hours. On POD 7 and POD 14 VAS score was slightly low in Group CFB which was significant. (table 3)

Rehabilitation indices		Group CEA (n=50)	Group CFB (n=50)	Total (n=100)	X <sup>2</sup> /P value
POD 1 sit at bed side and	Able to perform	27 (48.2%)	29 (51.8%)	56 (56%)	0.1623/0.687013
stand with help	Unable to perform	23(52.3%)	21(47.7%)	44(44%)	0.1023/0.08/013
POD 2 stand without help,	Able to perform	29(48.3%)	31 (51.7%)	60(60%)	
use walker and transfer to chair with help	Unable to perform	21(52.5%)	19 (47.5%)	40(40%)	0.1667/0.683091
POD 3 transfer to a chair	Able to perform	34 (51.5%)	32 (48.5%)	66 (66%)	
and use walker without help	Unable to perform	16(47%)	18(53%)	34(34%)	0.1783/0.672879

Table 4: Rehabilitation indices of Group CEA versus Group CFB

Rehabilitation indices were assessed on POD 1, POD2 and POD 3. They were assessed by checking whether the patients were able to perform activities like sit at bed side and stand with help, able to use walker and transfer to chair. There was no significant difference in both the groups with respect to rehabilitation indices. (table 4)

**Table 5:** Adverse events of patients in Group CEA versus CFB

Side effects	Group CEA (n=50)	Group CFB (n=50)	
Nausea/Vomiting	2 (4%)	6(12%)	
Pruritis	0(0%)	0(0%)	
Respiratory depression	1(2%)	0(0%)	
Urinary retention	2 (4%)	0(0%)	
Hypotension/ Dizziness	3(6%)	0(0%)	
Deep vein Thrombosis	2(4%)	1(2%)	
Incision complications	4(8%)	3 (6%)	

Out of 50 patients 14 (28%) patients in Group CEA had side effects where as on 10 patients (20%) in group CFB has side effects. (table 5)

Parameters	In POD 1,2,3	Group CEA (n=50)	Group CFB (n=50)	Total (n=100)	X <sup>2</sup> /P value
Deserve analogois measived	Received	38(57.6%)	28(43.4%)	66(66%)	4.4563/0.034772
Rescue analgesia received	Not received	12(35.3%)	22(64.7%)	34(34%)	
A duance events	Reported	14(58.3%)	10(41.7%)	24(24%)	0.8772/0.348972
Adverse events	Not reported	36(47.4%)	40(52.6%)	76(76%)	0.8772/0.348972

Only 43.4% of patients belonging to group CFB, received rescue analgesia which was less when compared to patients in group CEA(57.6%) which was significant. Adverse events were more reported in patients belonging to CEA (58.3%) when compared to patients in Group CFB (41.7%) which was not significant. (table 6)

## Discussion

Severe postoperative pain has been associated with serious complications including ischemic cardiac events and myocardiac insufficiency that result from increased stress on the cardiovascular system <sup>[11]</sup>. In addition, immobilization caused by pain may increase the risk

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of decreased pulmonary function, gastrointestinal complications, such as ileus, and thrombus formation that are related to surgical stress<sup>[12]</sup>.

Hence analgesic technique and the immediate and remote postoperative outcome and success of surgery are always interrelated. Epidural group had significantly elevated incidence of urinary retention, dysesthesiaand arterial hypotension <sup>[13]</sup>. Singelyn*et al.* showed 4 times less incidence of secondary effects with a femoral catheter compared to an epidural one <sup>[14]</sup> and Chelly *et al.* showed more cardiovascular stability and less nausea and vomiting with Peripheral nerve blocks<sup>[15]</sup>. The current study compared continuous epidural analgesia over continuous femoral nerve block in post-operative pain management.

The patients in both groups are comparable in the current study with respect to age, gender, BMI, ASA physical status score, type of deformity, co-morbidities and duration of surgery which was similar to study by T G Anupama *etal*. where patients in both the groups were similar with respect to age, gender, ASA physical status score, duration of surgery and weight. Mean age of patients in current study was slightly higher than patients mean age in study by T G Anupama *etal*. <sup>[16]</sup>

In the current study there was no significant difference between two groups with respect to VAS score during rest and activity till 72 hours which was similar to study by T G Anupama *etal.*,NRS scores for 6, 12, 24, 48 and 72 hours were mostly in the mild or moderate range and were similar in both epidural and CFNB groups<sup>[16]</sup>. On POD 7 and POD 14 VAS score at rest and during activity was slightly low in Group CFB which was significant in the current study.

In the current study Only 43.4% of patients belonging to group CFB, received rescue analgesia which was less when compared to patients in group CEA(57.6%) which was statistically significant. The finding was similar to study by Ganapathy as well as Capdevilla where a modified 3-in-1 Winnie continuous femoral block with local anesthetic, compared to continuous epidural showed a lower quantity of opioid required to control pain at rest and during passive mobilization <sup>[17,13]</sup>.

In the current study There was no significant difference in both the groups with respect to rehabilitation indices. Ganapathy as well as Capdevilla reported a better articular mobility in the immediate postoperative period in CFB group compared to CEA group <sup>[17,13]</sup>.

Our study is similar to Fowler's meta-analysis which included systematic review of all randomized trials comparing epidural analgesia with peripheral PNB for TKA. In which 464 patients were evaluated for morphine consumption, epidural and PNB side effects, and the patient satisfaction in both the groups<sup>[18]</sup>. The study reported thatno significant difference in pain VAS scores between epidural and PNB for the first 24 hours; better patient satisfaction in CFB group also suggested the addition of sciatic nerve block improves the quality of analgesia by reducing posterior knee and calf pain, corresponding to the area innervated by the sciatic nerve <sup>[21-25]</sup>.

Though adverse events reported in CEA in the current group was slightly higher it was not significant, similar to study by T G Anupama *et al.* and Gandhi H J *et al.* <sup>[26]</sup>.

# Conclusions

CFB is as effective as CEA in post-operative pain management in patients undergoing total knee arthroplasty with no significant difference in rehabilitation indices in either of the groups. CFB have the advantage over CEA in terms of decreased need for rescue analgesia with no neuraxial side effects.

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