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Original Article

Clinical Evaluation of Postoperative Pain Management: Continuous Epidural Analgesia (Cea) Vs. Continuous Femoral Nerve Blockade (CFNB)

Dr Mubashar ul Islam[1], Dr Jyoti[2]

[1]MD Anaesthesia, Asst Prof Department of Anaesthesiology, GMC Handwara, J & K.
[2]Assistant Professor Department of Anesthesiology Graphic Era Institute of Medical Sciences Dehradun, Uttarakhand

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Corresponding Author:

Dr Mubashar ul Islam
MD Anaesthesia, Asst Prof
Department of Anaesthesiology,
GMC Handwara, J & K.
Mail I'd:
mubasharislam87@gmail.com

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ABSTRACT

Background: Total knee replacement (TKR) is performed to reduce chronic pain and improve the functional state of patients suffering from degenerative disease like osteoarthritis.
Material & Methods: This is a prospective randomized study conducted at tertiary care hospital in Pune, over a period from November 2012 to July 2014. After obtaining approval from ethical clearance committee of the hospital, 60 patients (30 in each group) scheduled for elective total knee replacement were included in the study.
Result: There was no difference in the age between the two groups (P value 0.76). The mean ages of the groups were 70.6 ± 7.4 and 70.0 ± 6.8 for CEA and CFNB respectively. The difference of proportion of subjects observed between the study groups with respect to age was not statistically significant
Conclusion: This study shows that continuous infusion of bupivacaine for both continuous epidural analgesia (CEA) and continuous femoral nerve blockade (CFNB) provides an effective postoperative analgesia. The mean VAS scores remained within the mild pain range (<4) at any point of evaluation for 48 hours and the rescue analgesic consumption for first 24 hours was comparable in both the groups. Hemodynamic stability was maintained throughout the infusion in both the groups. Both the groups had similar incidence of complications (p>0.05). The patients in both the groups were able to ambulate on post operative day 1, with no difference in mean ambulation times in both the groups.

Keywords: Total Knee Replacement, Continuous Epidural Analgesia, Continuous Femoral Nerve Block, Postoperative Pain Management, Bupivacaine Infusion.

INTRODUCTION

Total knee replacement (TKR) is performed to reduce chronic pain and improve the functional state of patients suffering from degenerative disease like osteoarthritis.

Favourable patient outcome depends on surgical technique, postoperative analgesia, post operative rehabilitation and active mobilisation.[1] This requires input from different specialties, for which well coordinated clinical pathways on postoperative management have been shown to reduce hospital costs and improve quality of life of patients.

Although many hospitals have implemented clinical pathways to standardize the process of care, effectiveness of clinical pathways for TKR has not been reviewed critically.[2,3,4]They include conventional patient-controlled analgesia (PCA) and various neuraxial and peripheral nerve blocks.[5]

All the methods of pain management lead to sufficient analgesia, but they are not accompanied by an adequate reduction in endocrine stress response. Postoperative pain is only a secondary stressor and sufficient analgesia with subjective well-being does not prove a stress-free state.[6] Pain during the surgery and post-operative period has been major concern for the patient, surgeon and also the anesthesiologist. Perioperative pain is an impediment to recovery and various methods are

used to facilitate rapid return to normal functional activity. Post operative pain relief after total knee replacement is thus a major factor which requires attention. It is severe in 60% of patients and moderate in 30%.[7,8]

Optimal pain relief is must for physical therapy which leads early ambulation and rehabilitation of patients. Inadequate postoperative pain relief may result in harmful physiologic and psychological consequences that lead to significant morbidity. It has been seen that inadequately treated postoperative pain may lead to chronic pain.[9] Post-TKA pain directly impacts postoperative physiotherapy and mobilization which can result in stiffness and poor joint function. Post-TKA pain peaks up to 48 hours after surgery. Effective postoperative pain control is important, especially with the initiation of physiotherapy and early ambulation which hastens recovery and reduces hospital length of stay. The risk of postoperative complications, such as nosocomial infections and venous thromboembolism, has also been shown to decrease with early mobilization.[10]

Epidural analgesia has been popular over recent decades as there is evidence for reduced blood loss and fewer thromboembolic complications using neuraxial techniques in orthopaedic surgery. A recent systematic review comparing lumbar epidural blockade with systemic opioid analgesia reported better dynamic pain scores in the epidural group but no difference in the incidence of side effects overall. But patients who received epidurals had more frequent hypotension, urinary retention, and pruritis whereas systemic opioids caused more sedation. More importantly, there is evidence that patients undergoing TKR are at increased risk of serious neurological complications as a result of epidural blockade. This is most likely related to degenerative spinal changes and anticoagulant therapy. One alternative regional anaesthesia technique is peripheral nerve blockade (PNB) of major nerves supplying the lower limb.[11]

PNB may provide effective unilateral analgesia with a lower incidence of opioid-related and autonomic side-effects, less motor block, and fewer serious neurological complications. Continuous PNB techniques also appear to provide pain relief superior to systemic opioid analgesia but with a lower incidence of side-effects. Advances in nerve localization such as ultrasound imaging and continuous catheter technology have also helped to increase interest in PNB for lower limb surgery. This study is designed to compare the analgesia provided by continuous lumbar epidural technique versus continuous femoral nerve block technique following total knee replacement and complications following two techniques.

AIM AND OBJECTIVES

Aim

Comparison of continuous lumbar epidural analgesia (CEA) versus continuous femoral nerve block (CFNB) for pain relief following total knee replacement (TKR).

Objectives

- To determine differences in the quality of analgesia provided by the two techniques.
- To study the post-op complications and ambulation following surgery in two techniques.

MATERIAL AND METHODS

This is a prospective randomized study conducted at tertiary care hospital in Pune, over a period from November 2012 to July 2014. After obtaining approval from ethical clearance committee of the hospital, 60 patients (30 in each group) scheduled for elective total knee replacement were included in the study.

Inclusion Criteria

- ASA physical status I and II.
- The patients scheduled for elective Total Knee Replacement.

Exclusion Criteria

- Patient refusal or inability to give written informed consent.
- Infection at site of injection.
- Hypersensitivity to study drugs.
- Patients with altered coagulation parameters or on anticoagulants.
- Patients with spinal abnormalities.
- Contraindications to CFNB like infection at site of injection or previous femoro-popliteal surgery.

Study Protocol & Grouping

The selection of patients was carried out randomly by draw of lots technique and were divided into 2 groups of 30 each:

- Group A: Continuous epidural analgesia (CEA).
- Group B: Continuous femoral nerve blockade (CFNB) of the operative limb.

After explaining the procedures of spinal anaesthesia, CEA/CFNB to the patients, a written consent was obtained. Pre-anesthetic examination included general examination, systemic examination of cardio vascular system, respiratory system,

central nervous system and examination of spine. Routine investigations like complete blood count, hemoglobin, coagulation profile, electrocardiogram, chest X-ray PA view, X-ray of the affected knee joint were carried out before taking up the patient for surgery. Patients were premedicated with alprazolam 0.25 mg orally the night before and in the morning of surgery. All patients were kept nil orally for 8 hours before surgery.

Patients were counseled about the intensity of pain normally associated with the surgery and pain relief that could be achieved with the technique employed. The use of visual analog scale (VAS) was described at a pre-operative visit. VAS was made using a scale with numbers ranging from 0-10 and shown to the patient. The intensity of pain gradually increased from 0 to 10 which were pointed out by the patient on the scale. The effectiveness of analgesia was measured by the Visual Analog Pain Score (0-no pain and 10-worst pain) at 0, 1, 6, 12, 18, 24, 30, 36, 42, and 48 hours post operatively starting from onset of infusion.

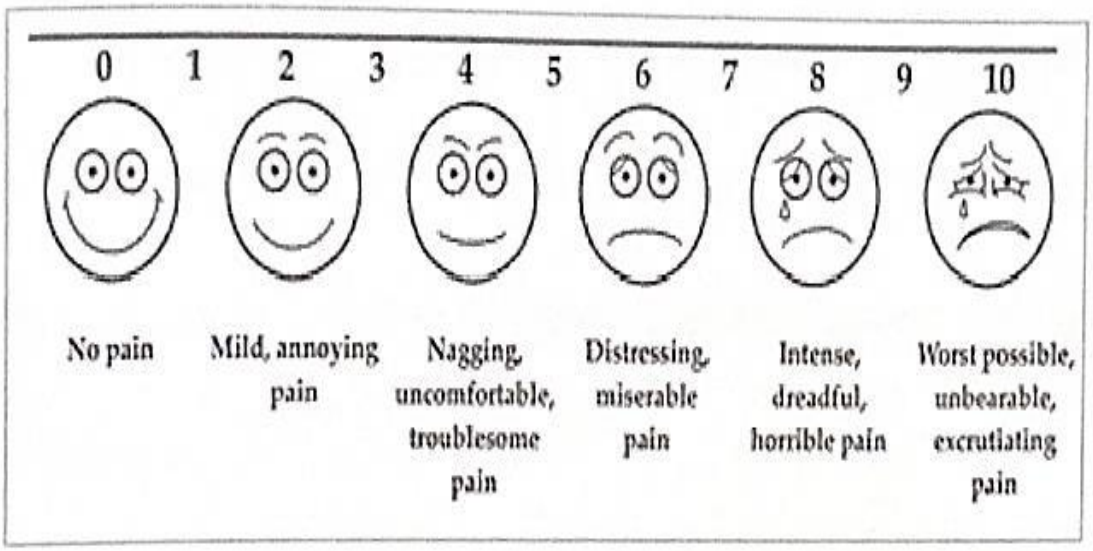


Figure 4: Visual Analogue Pain Scale Diagram

Inj Paracetamol 15 mg/kg IV 8 hourly was given to patients of both the groups. The rescue analgesia in the form of Inj Tramadol 50 mg IV was given if the patient complained of pain (this point corresponded to poor analgesia on the scale). Total dose of rescue analgesics administered to the patient was noted.

Technique of Anesthesia

After shifting the patients to the operation theatre, intravenous access was secured with 16/18 gauge cannula. The following equipments needed for the performance of the block procedure were kept ready: Spinal set, epidural set & femoral nerve blockade set along with nerve stimulator, contiplex B-Braun continuous nerve blockade set and an elastomeric infusion pump. All resuscitative equipments and emergency drugs were kept ready at hand. Anesthesia machine and circuits were checked and kept ready. Contiplex B-Braun continuous nerve blockade set consist of a cannula over short bevel needle, an accompanying catheter, with an integrated wire for nerve stimulation and connection tubing for concurrent aspiration and injection.

The primary anaesthetic technique was spinal anaesthesia in both groups using 15 to 17.5 mg of 0.5% bupivacaine (Heavy). In epidural group, a multi-orifice epidural catheter was secured before giving spinal anaesthesia using loss of resistance to air technique. Epidural space was identified at L2/L3 or L3/L4 intervertebral space, with the patient in sitting position, using an 18G Tuohy needle. A 20G catheter was secured at a length of 8-10 cm. A test dose of 2% lignocaine with adrenaline was given. Catheter was secured using sterile dressing. A bolus of 10ml of 0.125% bupivacaine was given as a bolus in the post operative period before the start of the continuous infusion.

The continuous femoral nerve block was established before spinal anaesthesia under aseptic precautions, with the patient in supine position and the ipsilateral limb kept slightly abducted. Anatomical landmark was marked for the point of needle insertion, 1cm below the inguinal ligament and 1cm lateral to the femoral artery pulsation. The contiplex continuous nerve block set was flushed and connected to the nerve stimulator. Cutaneous anesthesia was established by raising the skin wheal with 2% lignocaine. The needle was advanced at 45 degree angle to the skin in a cephalad direction to elicit a patellar twitch. The position of the needle was considered correct when the contractions were elicited at 0.5 mA. A 20 gauge catheter was inserted and advanced 2 cm beyond the needle tip. Then the catheter was flushed with saline, secured in place and fixed with a transparent adhesive plaster.

Postoperative Monitoring & Protocols
Intraoperatively no anesthetic agent was given through the epidural catheter or femoral catheter. Patients were monitored with ECG, non invasive blood pressure, and pulse oximeter. Fluid management was left to the anaesthetist's discretion. In all patients thigh tourniquet was used with a pressure of less than 350mmHg and the tourniquet was released within 120 minutes.

In recovery, CEA group received an infusion of 0.125% bupivacaine started at a rate of 5 ml/hr through an elastomeric infuser (Baxter Infuser, capacity of 250ml) and in recovery patients with CFNB received a femoral infusion of bupivacaine 0.25% commenced at 2.5 ml/hr with an elastomeric infusion pump/ electronic infusion pump, which continued for 48 hours postoperatively. Infusion was discontinued if the catheter was blocked or if any leak was noticed through the catheter site. Infusion was terminated at 48 hours and catheter was removed 12 hours after the last dose of anticoagulants (if any) in both the groups.

The daily postoperative check-up also included the neurological examination of the operated limb for clinical features of nerve dysfunction (e.g., Paresthesia, pain, or weakness). Sensory level to pin prick, visual analogue pain score, motor blockade time to first ambulation, hemodynamic parameters including heart rate and NIBP were recorded. Ambulation time was recorded when the patient would walk on the ground with support. Motor blockade assessment, though difficult because of the knee brace, was done with Bromage scale (Gd I = Free movement of legs and feet, Gd II = Just able to flex knees with free movement of feet, Gd III = Unable to flex knees, but with free movement of feet, Gd IV = Unable to move legs or feet).

The side effects due to administration of infusion drugs and rescue analgesics were noted down during post-operative periods. Nausea, vomiting, shivering, pruritis, respiratory depression (Respiratory Rate < 10), hypotension, hematoma at the site of injection, drowsiness, euphoria or dysphoria and urinary retention were observed. Urinary retention was defined as inability of the patient to void urine, causing discomfort to the patient supplemented with the clinical examination for confirmation of distended bladder. Hypotension was defined as decrease in systolic blood pressure more than 20% of baseline.

STATISTICAL ANALYSIS
Chi-square test has been used to test the significance of homogeneity of sex distribution, complications, comorbidities, rescue analgesia and motor blockade. Student-t test has been used to find the significance of mean difference of analgesia (VAS scores), ambulation and to test the homogeneity of samples on age and weight. ANOVA was used to find the variance of VAS over the duration of 48 hrs within each group. Changes in variables within each group were analyzed with multiple paired t-tests. A p value ≤ 0.05 is considered significant. Values are presented as mean ± standard deviation.

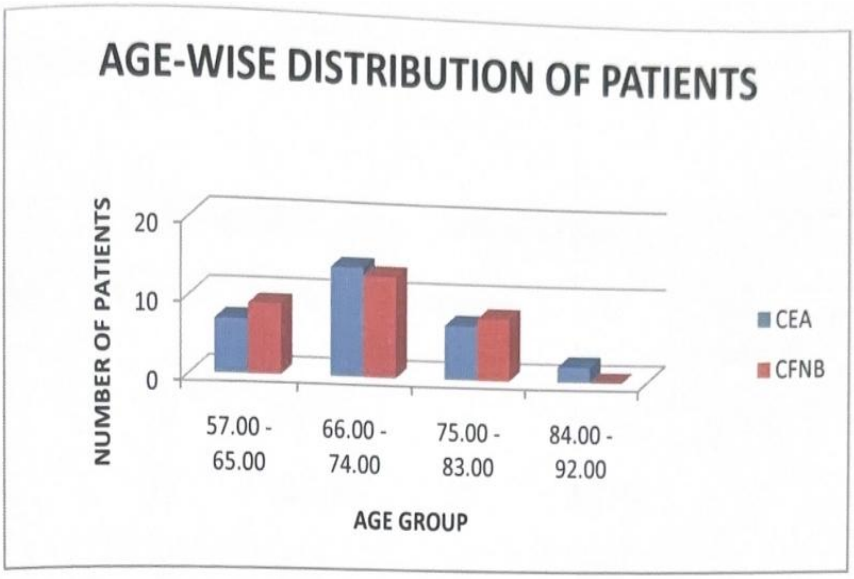
Statistical Software: The statistical software namely SPSS 17.0 was used for the analysis of the data. Microsoft Word and Excel have been used to generate the graphs, tables and charts.

RESULTS AND DATA TABLES
Demographic Profile Analysis: Any p-value < 0.05 is defined as statistically significant.

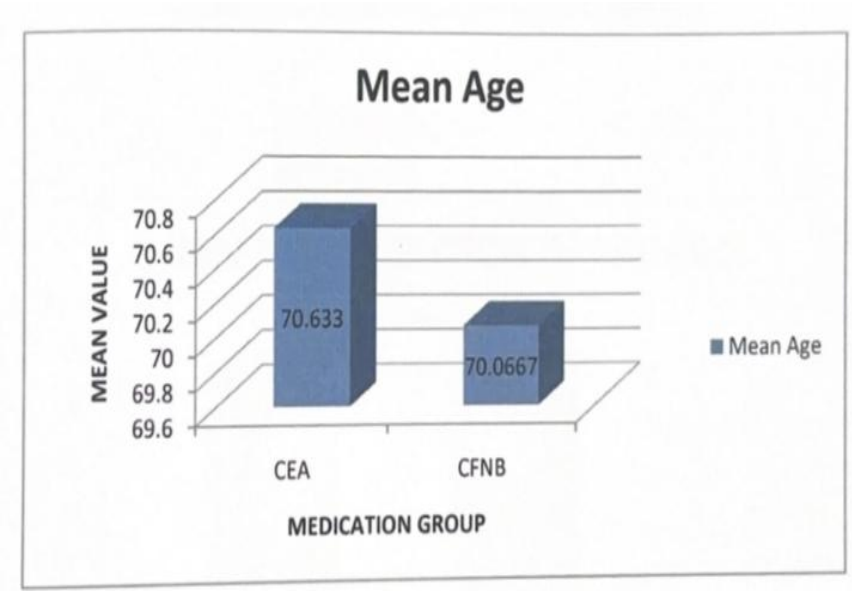
Table 2: Showing The Age Of Patients Under Study

Age group(years)	CEA (Number)	CEA %	CFNB (Number)	CFNB %	P-VALUE
57.00 - 65.00	7	23.3	9	30.0	P=0.760
66.00 - 74.00	14	46.7	13	43.3	
75.00 - 83.00	7	23.3	8	26.7	
84.00 - 92.00	2	6.7	0	0.0	
Total	**30**	**100**	**30**	**100**	

Mean ± SD: CEA = 70.633 ± 7.4115 | CFNB = 70.067 ± 6.893



(Figure 5: Graph Showing Age Distribution — Synthesized Presentation)

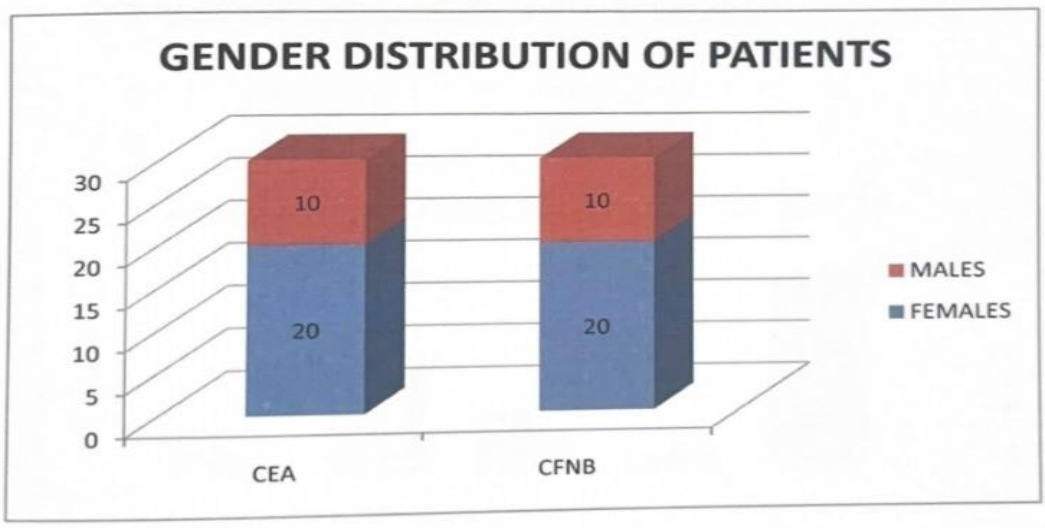


(Figure 6: Graph Showing Mean Age Of The Groups — Synthesized Presentation)

There was no difference in the age between the two groups (P value 0.76). The mean ages of the groups were 70.6 ± 7.4 and 70.0 ± 6.8 for CEA and CFNB respectively. The difference of proportion of subjects observed between the study groups with respect to age was not statistically significant.

Table 3: Gender Distribution Of Patients

Gender	Group CEA (No.)	Group CEA %	Group CFNB (No.)	Group CFNB %	p-value
Male	10	33.3%	10	33.3%	0.784 (Chi-sq 0.075)
Female	20	66.7%	20	66.7%	
Total	**30**	**100%**	**30**	**100%**	

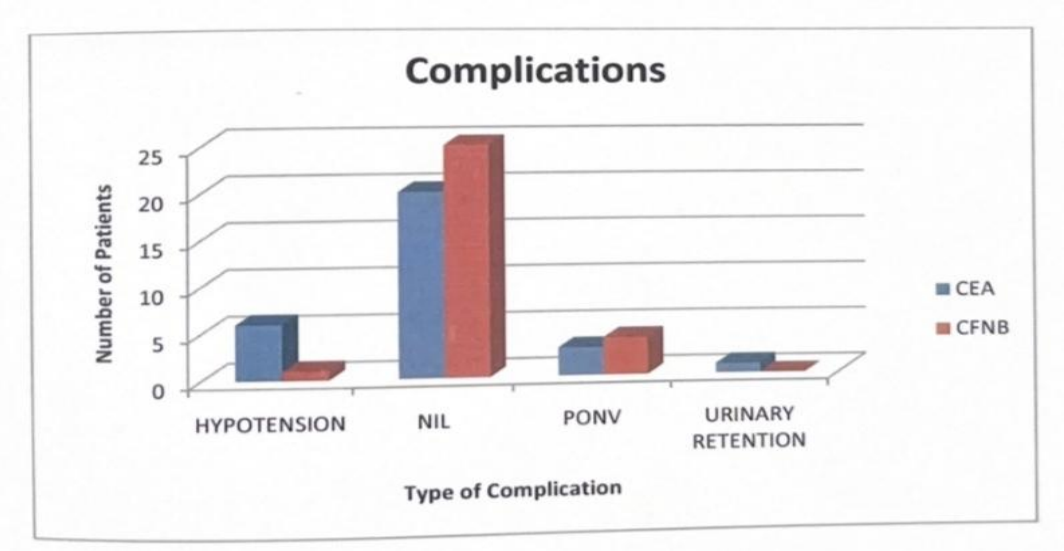


(Figure 7: Graph Showing Gender Distribution — Synthesized Presentation)

60 patients of either sex had participated in the study. Both groups had predominantly female patients with 66.7% in each group and statistically insignificant (p=0.784). Gender distribution was comparable in both the groups.

Table 5: Showing Comparison Of The Complications

Complications	CEA Freq	CEA %	CFNB Freq	CFNB %	Chi-squared	p-value
HYPOTENSION	6	20.0	1	3.3	2.286	P = .1306
PONV	3	10.0	4	13.3	0	P = 1.0000
URINARY RETENTION	1	3.3	NIL	NIL	-	Cannot Be Calculated
Total	**30**	**100.0**	**30**	**100**	**5.270**	**0.153**



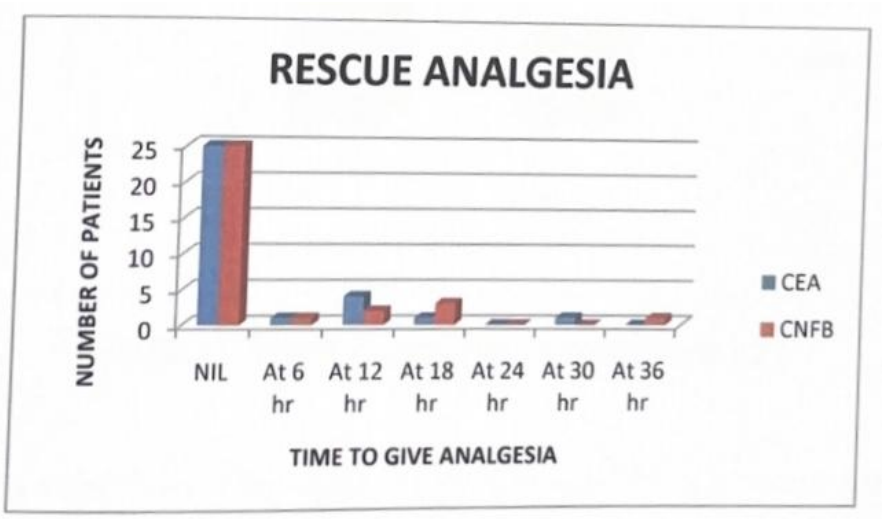
(Figure 10: Graph Showing Comparison Of The Complications — Synthesized Presentation)

10 patients in group A had complications while 5 patients in group B. There was lower incidence of complications in group B, although this difference was statistically insignificant (0.153). Complications noticed in the patients were hypotension, PONV, and urinary retention.

There was a higher incidence of hypotension in group A, 6 patients (20%) than in group B, 1 patient (3%) which was statistically insignificant (p=0.1306). 3 patients in group A had PONV and in 4 patients in group B. It was statistically insignificant (p= 1.000). Urinary retention was seen in only 1 patient in group A and none in group B. Although the difference in rate of complication was not statistically significant but the difference was clinically significant.

Table 7: Showing Comparison Of Rescue Analgesia At Different Times

Rescue Analgesia	CEA	CNFB	Chi-Square	Significance Level
NIL	25	25	3.667	P = 0.5983
at 6 hr	1	1		
at 12 hr	4	2		
at 18 hr	1	3		
at 24 hr	0	0		
at 30 hr	1	0		
at 36 hr	0	1		

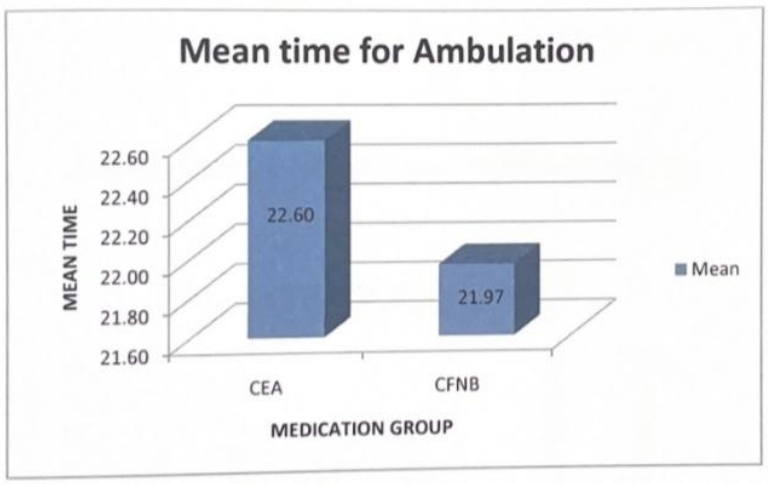


(Figure 12: Graph Showing Comparison Of Rescue Analgesia — Synthesized Presentation)

25 patients in each group did not require rescue analgesia. 5 patients in each group received rescue analgesia at different times either once or more than once. There was no statistical difference between the two groups regarding consumption of rescue analgesia (p= 0.598).

Table 8: Showing Mean Ambulation Time

Metric	GROUP	N	Mean	Std. Deviation	Std. Error Mean	t-Value	p-value
Ambulated after time in Hours	CEA	30	22.6000	2.69866	.49271	0.976	0.333
	CFNB	30	21.9667	2.31164	.42205		



(Figure 13: Graph showing mean ambulation time — Synthesized Presentation)

The mean time of ambulation in group A was 22.6 ± 2.7 hours and group B was 21.9 ± 2.3 hours. There was statistically no significant difference in both the groups (p=0.333).

SUMMARY AND CONCLUSION

The randomized clinical study was performed to compare continuous femoral nerve blockade (CFNB) and continuous epidural analgesia (CEA) for post operative pain relief, requirement of number of rescue analgesic doses, incidence of side effects, ambulation times and hemodynamic monitoring in patients undergoing TKR.

This study was conducted in 60 ASA grade A and B patients, scheduled to undergo TKR under spinal anesthesia. After random allocation, patients of group A (n=30) received CEA while the patients of group B (n=30) received CFNB.

Post operatively both the groups received continuous infusion of Inj bupivacaine 48 hrs. Data on pain scores, requirement of rescue analgesics, hemodynamic stability and side effects were noted at 0, 1, 6, 12, 18, 24, 30, 36, 42, and 48 hrs.

Both the groups (CFNB/CEA) were comparable for age, sex, weight, and comorbidities with no statistical difference. There were no statistically significant hemodynamic changes observed in both the groups. The median VAS scores remained within the mild pain range (<4) within the groups and between the groups for 48 hrs, suggesting equivalent efficacy of analgesia in both the techniques. The number of rescue analgesic requirement in the groups over first 24 hrs was insignificant.

Incidence of postoperative side effects was comparable in both the groups. The common side effects included – hypotension, PONV and urinary retention.

Thus, we found that both:

- CFNB and CEA provide effective postoperative analgesia with similar pain scores, equal consumption of rescue analgesic agents and hemodynamic stability.
- There side effect are comparable in both the groups.
- The ambulation time was comparable in both the groups.

CONCLUSION

This study shows that continuous infusion of bupivacaine for both continuous epidural analgesia (CEA) and continuous femoral nerve blockade (CFNB) provides an effective postoperative analgesia. The mean VAS scores remained within the mild pain range (<4) at any point of evaluation for 48 hours and the rescue analgesic consumption for first 24 hours was comparable in both the groups. Hemodynamic stability was maintained throughout the infusion in both the groups. Both the groups had similar incidence of complications (p>0.05). The patients in both the groups were able to ambulate on post operative day 1, with no difference in mean ambulation times in both the groups.

Hence we conclude that CFNB can also be considered as an effective regional component of a multimodal analgesic strategy after knee surgery. CFNB is preferable for those who present challenges regarding epidural catheter placement like previous lumbar spine surgery and vertebral anomalies.

Presently there is insufficient data to provide firm recommendations for all aspects of continuous femoral nerve blockade analgesia. Future work is needed to determine which surgical procedures gain benefit, what optimal solutions should be used and optimal means of delivery for each application. Further trials are needed to show advantages other than improved analgesia and decreased side effects to justify their continued use.

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