Evaluation OfAnalgesic Effect of Femoral Nerve Block for Positioning Of Patient For Subarachnoid Block In Patients With Fracture Femur: A Randomized, Double Blind, Parallel Group, Comparative Study Between Ropivacaine And Bupivacaine

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Abstracts: Background: Ropivacaine is recently introduced in Indian market, need to evaluate further for its clinical profile. We evaluated the analgesic effect of Ropivacaine in comparision with Bupivacaine in femoral nerve block (FNB) for positioning of patient for subarachnoid block in patients with fracture femur. **Method:** Hundred patients of either sex, aged 18-80 years, American Society of Anaesthesiologist physical status I–III having femur fracture scheduled for surgery under subarachnoid block. The patients were randomly allocated into two groups of 50 patients each. Group R received Ropivacaine and Group B received Bupivacaine (20 ml, 0.5 %) in FNB guided by peripheral nerve locator. Patients were observed for onset and peak effect of sensory and analgesia, hemodynamic profile and complications if any. **Results:** The mean time for onset of sensory block and analgesia were comparable in both the groups ($p>0.05$). The peak of sensory block and subjective analgesia achieved earlier in group R ($p<0.001$), but objective analgesia score was comparable in both the groups ($p > 0.05$). Haemodynamics remain stable and no complications were noted except vascular puncture.
Conclusion: We conclude that FNB provides effective analgesia in patients with fracture femur for positioning of patient before subarachnoid block. We recommend the use of Ropivacaine as safer alternative to Bupivacaine in femoral nerve block, especially in compromised cardiovascular patients.

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Key Words: Analgesia, Bupivacaine, Femoral nerve block, Femur fracture, Ropivacaine.

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Introduction: Pain is an enigma to the whole mankind. Orthopaedics fractures are very painful. The definitive management of most fracture is operative intervention. Fractures of the femur are common, ranging from non-displaced to severe comminuted and almost always associated with significant soft-tissue injury. It causes severe pain to the patient while positioning for subarachnoid block, required for operative intervention.

Adequate pain relief before administrating subarachnoid block will increase patient's co-operation. Analgesia can be provided in form of systemic analgesics, local anaesthesia, or femoral nerve blocks (FNB).[1,2]FNB produces a more intense analgesia with fewer side effects than systemic opiates[3] and NSAIDs. Complications of FNB[4] are rare; damage to the nerve, haematoma by puncturing femoral artery with the needle, local anaesthesia toxicity etc.

Till date, Bupivacaine is the gold standard for nerve blocks due to its longer duration of action. Ropivavacaine, a newer local anaesthetic agent with greater selectivity for sensory blockade and has lower cardiovascular and neurological toxicity[5,6] seems to be an attractive choice. While searching through the literature, there are no studies available which compare Bupivacaine and Ropivacaine in FNB to provide analgesia for positioning in patients with fracture femur before subarachnoid block.

So, we decided to conduct prospective randomized, double blind study to compare Bupivacaine and Ropivacaine in FNB to provide analgesia before performing subarachnoid block in the sitting position in patients with shaft femur fracture, subtrochanteric femur fracture and supracondylar femur fracture.

Materials and Methods: After approval from institutional review board and informed written consent, this prospective, randomized, double blind, parallel group, comparative study was carried out in 100 patients of either sex, aged 18 - 80 years, American Society of Anaesthesiologist

physical status (ASAPS) I – III having femur fracture (shaft / subtrochanteric /supracondylar) scheduled for surgery under subarachnoid block. After thorough pre-anaesthetic evaluation and necessary investigations, patients with history of allergy to local anaesthetics, multiple fractures, pre-existing peripheral neuropathy, bleeding disorders, patient on anticoagulant therapy, psychiatric disorder, use of analgesics before 8 hours of subarachnoid block, local infections / inflammation and presence of a prosthetic femoral artery graft were excluded from study.

Patients were kept nil per oral 6-8 hours preoperatively. In the preanaesthetic preparation room, heart rate (HR), mean arterial pressure (MAP) and oxygen saturation (SpO_2) were recorded; intravenous line was secured (no.18 G) and infusion of Lactated Ringers solution was started. Patients were premedicated with Inj. Ranitidine 1 mg/kg body weight iv, Inj. Ondansetron 0.1 mg/kg body weight iv 10 minutes before performing FNB. All patients were explained 0-10 point visual analogue scale (VAS) on a sheet of paper where '0' labelled as 'no pain' and '10' as 'excruciating pain'.

The patients were randomly allocated into two groups by computer-generated random number sequence in 50 patients each.
Group R (n = 50): Patients received 20 ml, 0.5 % Ropivacaine in FNB.
Group B (n=50): Patients received 20 ml, 0.5 % Bupivacaine in FNB.

One member (other than principle investigator and co-principle investigator) filled up the drug as per the group assigned. Principle investigator performed the femoral nerve block responsible for monitoring of patient. Doctor who performed block was remained blinded to the content of the solution.

All patients were placed supine and FNB was performed under aseptic and antiseptic measures. The local site was prepared and 1- 2 ml of 2 % Inj. Lignocaine was given at needle insertion site. FNB was given with 22 G, 50 mm insulated needle using nerve locator (Stimuplex, B braun). The needle was introduced 1 cm lateral to the femoral artery and 1.5 cm below the inguinal ligament. When a current of 0.2-0.5 mA elicited quadriceps contraction and/or anterior displacement of patella, 20 ml of either Ropivacaine or Bupivacaine was injected as per assigned group, incrementally after a negative aspiration test.

Sensory block assessment (Table 1), subjective analgesia score using VAS scale (Figure 1) and objective analgesia score using Wong Baker Face Scale (Figure 2) were recorded at 0, 1, 3, 5, 10, 15, 20, 25, 30 minutes interval. Onset and peak effect of sensory block (Table 2) and analgesia were also noted. When pain scores ≤ 4, patient was shifted in operation theatre. Patient was given sitting position for subarachnoid block. If any patient in either group, reported pain scores > 4 during positioning, Inj. Fentanyl 0.5 mcg/kg iv every 5 min was supplemented until the pain scores≤ 4. However these patients were excluded from this study. Subarachnoid block was performed by 3rd year resident via midline approach at L_2-L_3 or L_3-L_4 level using 2-3 ml, 0.5% heavy Bupivacaine under supervision of consultant anaesthesiologist.

Table 1: Assessment Of Sensory Block*

Score	Clinical description
0	Sharp pains on pin prick
1	Touch sensation on pin prick
2	Not even touch sensation

*The sensory block was assessed with pin prick to 23 G hypodermic needle.

Table 2: Assessment Of Onset And Peak Of Sensory Block**

	Onset	Peak
Sensory block	Time duration from end of injection to dull response to pin prick.	Time duration from end of injection to no response to pin prick.

**Sensory block assessment was done over the antero-medial aspect of the thigh and knee, and the medial border of the leg and medial malleolus.

Figure 1: Subjective analgesia score (VAS-Visual Analogue Scale)

0----1----2----3----4----5----6----7----8----9----10
No Pain Moderate Pain Worst Pain

Figure 2: Objective analgesia score (Wong Baker Face Scale)

Any treatment required and complications if any, were recorded till 30 min after FNB. Pulse rate less than 60 was considered as bradycardia and treated with Inj. Atropine 0.6 mg iv. Blood pressure less than 90mmHg or 20% below the baseline considered hypotension and treated with intravenous fluid, colloid or Inj. Ephedrine 5 mg iv.

Statistical Analysis: Collected data were tabulated and analyzed using Graph Pad Prism online calculator. The mean values with standard deviation (SD) were calculated for all the parameters and comparison between the two groups was made using unpaired student's t-test. The difference between the two groups was said to be statistically significant if p value is < 0.05 and statistically highly significant if p value is < 0.0001, statistically non significant if p value is > 0.05.

Observation and Results: Figure 3 shows there was no statistically significant difference in mean time for onset of sensory block in both the groups (p >0.05). There was earlier peak of sensory block achieved in group R as compared to group B (p<0.0001). Table 3 shows demographic profile were comparable in both the groups (p >0.05).

Table 3: Demographic Profile of Both The Groups.

Demographic Profile	Group R Mean ± SD	Group B Mean ± SD	p value
Age (Years)	39.09 ± 18.85	39.28 ± 16.26	>0.05
Height (cm)	157.32 ± 4.44	157.3 ± 4.03	>0.05

Figure 4 shows there was no statistically significant difference in mean time for onset analgesia in both the groups (p>0.05). There was earlier peak of analgesia achieved in group R as compared to group B. (<0.0001)

Figure 3: Characteristics of sensory block in both the groups.

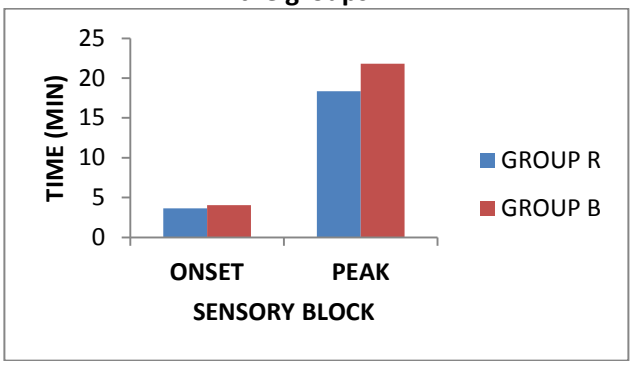


Figure 4: Characteristics of subjective analgesia score using VAS in both the groups.

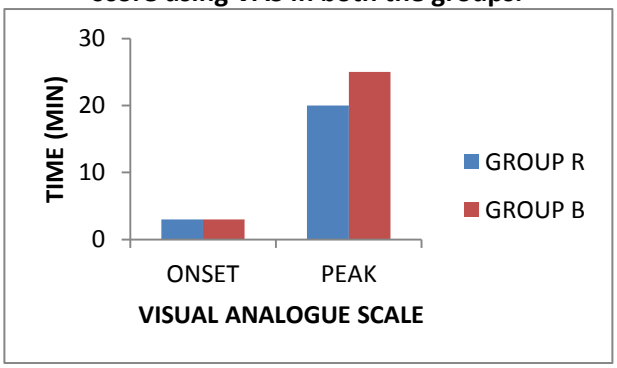


Figure 5: Characteristics of objective analgesia score using Wong Baker Face Scale in both the groups.

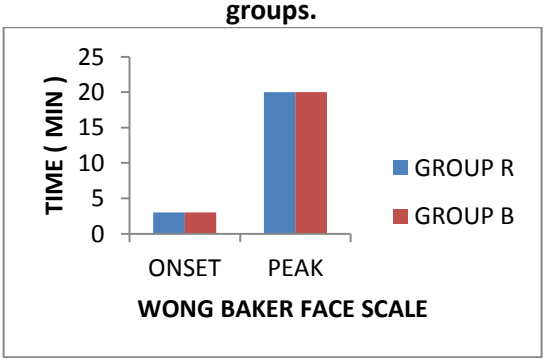
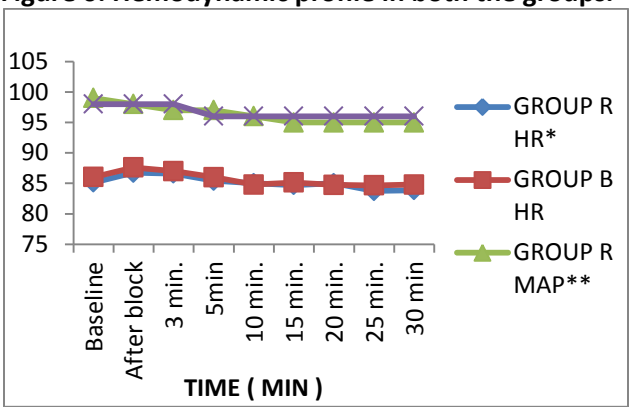


Figure 5 shows there was no statistically significant difference in mean time of onset and peak effect of analgesia in both the groups (p>0.05).

Figure 6 shows the changes in heart rate and mean blood pressure were comparable in both the groups (p>0.05).

No major complications were found except accidental vascular puncture while giving the block (group R: 4 %, group B: 2%).

Figure 6: Hemodynamic profile in both the groups.



* HR- Heart Rate (per min), **MAP- Mean Arterial Pressure (mmHg)

Discussion: Annual incidence of midshaft femur fractures is approximately 10 per 100,000 per year.[7] Peak incidence occurs among young, decreasing after 20 years, then again increase in those over 75 years.[8] Majority of femur fractures occur in proximal third. The neck of femur is most frequently fractured because it is the narrowest and weakest part of the bone.[9]

A study[2] suggest that underused technique of FNB is simple, effective and cheap method of analgesia if used in emergency department. Another study[10] shows that FNB effectively decreases pain, anxiety, and heart rate after femoral trauma. A study[11] also suggest that it is effective in relieving pain and muscle spasm cause by fractured bone and help for positioning during conduct of regional anaesthesia, even when patients' legs are placed in traction.

The quality of the analgesia depends on the fracture site[12], excellent relief can be obtained for midshaft fractures, good relief for lower third fractures, and partial relief for upper third fractures but fracture of the femoral neck would be unlikely to be effective, considering the innervations of this area of the bone.

Subarachnoid block is routinely used for definitive treatment of femur fracture at our institution. Even a slight movement and sitting position to perform a subarachnoid blockade results in overriding of the fracture ends and is extremely painful, almost always requires analgesics[11] may be in form of peripheral nerve block or systemic analgesics. As the patients of femur fractures are elderly, it is better to avoid systemic analgesics which are having more complications compared to peripheral nerve block.

Salvatore Sia et al[3] compared femoral nerve block and intravenous Fentanyl for analgesia before performing subarachnoid block in the sitting position in patients with femoral shaft fracture. He concluded FNB is more advantageous than iv Fentanyl to facilitate the sitting position for subarachnoid block in patients undergoing surgery for femoral shaft fractures.However, Arissilamaroonet al[13] were unable to demonstrate a benefit of FNB over iv Fentanyl for patient positioning before subarachnoid block.

The techniques like ultrasound guided nerve blocks and nerve locator assisted blocks offer the advantage of being more objective as the nerves can be identified more accurately and avoid possible injury to the nerve and surrounding structures. A peripheral nerve locator is relatively simple to use while ultrasonography needs availability, experience and expertise in the field. We used peripheral nerve locator (Stimuplex, B braun) in our study.[14]

Ropivacaine and Levobupivacaine were developed[15] to avoid the Bupivacaine related toxicities. The clinical safety profile of Ropivacaine seems to be more favourable than that of Levobupivacaine.

Present study shows, sensory onset time was comparable in both groups ($p>0.05$). Similar results were also found in other studies.[16]The peak of sensory block was achieved earlier in group R compared to group B ($p<0.001$), similar to results of Bertini Let al[17]. Onset of analgesia (VAS and Wong Baker Face Scale) was comparable in both the groups ($p>0.05$). Peak of analgesia was achieved earlier in group R using VAS ($p<0.001$) but was comparable using Wong Baker Face Scale ($p>0.05$). The reason for earlier sensory peak and analgesic peak may be vasoactivity of the Ropivacaine which is responsible for increase in speed with which local anaesthetic molecules penetrate into peripheral nerves as compared with Bupivacaine. The subjective analgesia score (VAS) and objective analgesia score (Wong Baker Face

Scale) were not corresponding to each other may be due to operative stress on the patient not allowing facial expressions to change.

In this study, the haemodynamic profiles (heart rate, MAP, SpO_2) in either of the groups were stable and remained comparable to baseline and to each other group ($p>0.05$). Other authors also found stable haemodynamic profile[18]. No other major complications were found except accidental vascular puncture while giving the block (group R: 4 %, group B: 2%). These findings were similar to other studies[4].

The limitations of this study were (1) the ultrasonography could be used for more accuracy, (2) the procedure of FNB is considered time consuming, but to lessen its impact on surgical work, the FNB was given in preanaesthetic preparation room, (3) motor effects were not evaluated to avoid painful stimuli and possible further displacement of fractures.

With earlier sensory and analgesia peak in Ropivacaine group, the position for subarachnoid block can be given earlier than Bupivacaine group. Ropivacaine is a promising newer local anaesthetic drug to be used in femoral nerve block for the positioning for subarachnoid block in patients of fracture femur.

Conclusion: To conclude, femoral nerve block is simple, effective and cheap method to provide analgesia in patients with fracture femur for positioning of patient before subarachnoid block. Ropivacaine has similar onset of sensory and analgesia but earlier peak of sensory and analgesia allow us to position the patients earlier compared to Bupivacaine. Both the drugs have stable hemodynamic profile without any adverse effects or complication. We recommend the use of Ropivacaine as safer alternative to Bupivacaine in femoral nerve blocks, especially in compromised cardiovascular patients.

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